### Special Article

# Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication Updated April 2010

## Publication Ethics: Sponsorship, Authorship, and Accountability International Committee of Medical Journal Editors

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#### I. STATEMENT OF PURPOSE

#### I. A. About the Uniform Requirements

A small group of editors of general medical journals met informally in Vancouver, British Columbia, in 1978 to establish guidelines for the format of manuscripts sub-mitted to their journals. This group became known as the Vancouver Group. Its requirements for manuscripts, in-cluding formats for bibliographic references developed by the National Library of

Medicine (NLM), were first pub-lished in 1979. The Vancouver Group expanded and evolved into the International Committee of Medical Jour-nal Editors (ICMJE), which meets annually. The ICMJE has gradually broadened its concerns to include ethical principles related to publication in biomedical journals.

The ICJME has produced multiple editions of the Uniform Requirements for Manuscripts Submitted to Bio-medical Journals. Over the years, issues have arisen that go beyond manuscript preparation, resulting in development of a number of Separate Statements on editorial policy. The entire Uniform Requirements document was revised in 1997; sections were updated in May 1999 and May 2000. In May 2001, the ICMJE revised the sections related to potential conflict of interest. In 2003, the committee revised and reorganized the entire document and incorporated the Separate Statements into the text. The committee prepared this revision in 2010.

The total content of the Uniform Requirements for Manuscripts Submitted to Biomedical Journals may be re-produced for educational, not-for-profit purposes without regard for copyright; the committee encourages distribution of the material.

Journals that agree to use the Uniform Requirements are encouraged to state in their Instructions to Authors that their requirements are in accordance with the Uni-form Requirements and to cite this version. Journals that wish to be listed on www.ICMJE.org as a publication that follows the Uniform Requirements should contact the ICMJE secretariat office.

The ICMJE is a small working group of general medical journals, not an open-membership organization. Occa-sionally, the ICMJE will invite a new member or guest when the committee feels that the journal or organization will provide a new perspective. Open membership organi-zations for editors and others in biomedical publication include the World Association of Medical Editors www

.WAME.org, the Council of Science Editors (www .councilscienceeditors.org/), and the European Association of Science Editors (www.ease.org. uk).

#### I. B. Potential Users of the Uniform Requirements

The ICMJE created the Uniform Requirements primarily to help authors and editors in their mutual task of creating and distributing accurate, clear, easily accessible reports of biomedical studies. The initial sections address the ethical principles related to the process of evaluating, improving, and publishing manuscripts in biomedical jour-

nals and the relationships among editors and authors, peer reviewers, and the media. The latter sections address the more technical aspects of preparing and submitting manu-scripts. The ICMJE believes that the entire document is relevant to the concerns of both authors and editors.

The Uniform Requirements can provide many other stakeholders—peer reviewers, publishers, the media, pa-tients and their families, and general readers—with useful insights into the biomedical authoring and editing process.

#### I. C. How to Use the Uniform Requirements

The Uniform Requirements state the ethical principles in the conduct and reporting of research and provide rec-ommendations relating to specific elements of editing and writing. These recommendations are based largely on the shared experience of a moderate number of editors and authors, collected over many years, rather than on the re-sults of methodical, planned investigation that aspires to be "evidence-based." Wherever possible, recommendations are accompanied by a rationale that justifies them; as such, the document serves an educational purpose.

Authors will find it helpful to follow the recommendations in this document whenever possible because, as described in the explanations, doing so improves the qual-ity and clarity of reporting in manuscripts submitted to any journal, as well as the ease of editing. At the same time, every journal has editorial requirements uniquely suited to its purposes. Authors therefore need to become familiar with the Instructions to Authors specific to the journal they have chosen for their manuscript—for example, the topics suitable for that journal, and the types of papers that may be submitted (for example, original articles, reviews, or case reports)—and should follow those instructions.

### II. ETHICAL CONSIDERATIONS IN THE CONDUCT AND REPORTING OF RESEARCH

#### II A. Authorship and Contributorship

#### II. A. 1. Byline Authors

An "author" is generally considered to be someone who has made substantive intellectual contributions

to a published study, and biomedical authorship continues to have important academic, social, and financial implications

(1). An author must take responsibility for at least one com-ponent of the work, should be able to identify who is respon-sible for each other component, and should ideally be confident in their co-authors' ability and integrity. In the past, readers were rarely provided with information about contributions to studies from persons listed as authors and in Acknowl-edgments (2). Some journals now request and publish information about the contributions of each person named as having participated in a submitted study, at least for orig-inal research. Editors are strongly encouraged to develop and implement a contributorship policy, as well as a policy on identifying who is responsible for the integrity of the work as a whole.

While contributorship and guarantorship policies obviously remove much of the ambiguity surrounding contri-butions, they leave unresolved the question of the quantity and quality of contribution that qualify for authorship. The ICJME has recommended the following criteria for authorship; these criteria are still appropriate for journals that distinguish authors from other contributors.

- Authorship credit should be based on 1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be pub-lished. Authors should meet conditions 1, 2, and 3.
- When a large, multicenter group has conducted the work, the group should identify the individuals who accept direct responsibility for the manuscript (3). These individuals should fully meet the criteria for authorship/ contributorship defined above, and editors will ask these individuals to complete journal-specific author and conflict-of-interest disclosure forms. When submitting a manuscript authored by a group, the corresponding author should clearly indicate the preferred citation and identify all individual authors as well as the group name. Journals generally list other members of the group in the Acknowl-edgments. The NLM indexes the group name and the names of individuals the group has identified as being di-

rectly responsible for the manuscript; it also lists the names of collaborators if they are listed in Acknowledgments.

- Acquisition of funding, collection of data, or general supervision of the research group alone does not con-stitute authorship.
- All persons designated as authors should qualify for authorship, and all those who qualify should be listed.
- Each author should have participated sufficiently in the work to take public responsibility for appropriate por-tions of the content.

Some journals now also request that one or more authors, referred to as "guarantors," be identified as the per-sons who take responsibility for the integrity of the work as a whole, from inception to published article, and publish that information.

Increasingly, authorship of multicenter trials is attributed to a group. All members of the group who are named as authors should fully meet the above criteria for author-ship/contributorship.

The group should jointly make decisions about contributors/authors before submitting the manuscript for publication. The corresponding author/guarantor should be prepared to explain the presence and order of these individuals. It is not the role of editors to make authorship/ contributorship decisions or to arbitrate conflicts related to authorship.

#### II. A. 2. Contributors Listed in Acknowledgments

All contributors who do not meet the criteria for authorship should be listed in an acknowledgments section. Examples of those who might be acknowledged include a person who provided purely technical help, writing assis-tance, or a department chairperson who provided only gen-eral support. Editors should ask corresponding authors to declare whether they had assistance with study design, data collection, data analysis, or manuscript preparation. If such assistance was available, the authors should disclose the identity of the individuals who provided this assistance and the entity that supported it in the published article. Finan-cial and material support should also be acknowledged.

Groups of persons who have contributed materially to the paper but whose contributions do not justify authorship may be listed under such headings as "clinical inves-tigators" or "participating investigators," and their function or contribution should be described—for example, "served as scientific advisors," "critically reviewed the study pro-posal," "collected data," or "provided and cared for study patients." Because readers may infer their endorsement of the data and conclusions, these persons must give written permission to be acknowledged.

#### II. B. Editorship

#### II. B. 1. The Role of the Editor

The editor of a journal is the person responsible for its entire content. Owners and editors of medical journals have a common endeavor—publication of a reliable, read-able journal produced with due respect for the stated aims of the journal and for costs. Owners and editors, however, have different functions. Owners have the right to appoint and dismiss editors and to make important business deci-sions in which editors should be involved to the fullest extent possible. Editors must have full authority for deter-mining the editorial content of the journal. The concept of editorial freedom should be resolutely defended by editors even to the extent of their placing their positions at stake. To secure this freedom in practice, the editor should have direct access to the highest level of ownership, not to a delegated manager.

Editors of medical journals should have a contract that clearly states their rights and duties, the general terms of the appointment, and the mechanisms for resolving conflict.

An independent editorial advisory board may be useful in helping the editor establish and maintain editorial policy.

#### II. B. 2. Editorial Freedom

The ICMJE adopts the World Association of Medical Editors' definition of editorial freedom. According to this definition, editorial freedom, or independence, is the con-cept that editors-in-chief have full authority over the edi-torial content of their journal and the timing of publica-tion of that content. Journal owners should not interfere in the evaluation, selection, or editing of individual articles either directly or by creating an environment that strongly influences decisions. Journal owners should not require ed-itors to publish supplements as part of their contractual agreements. Editors should base decisions on the validity of the work and its importance to the journal's readers, not on the commercial success of the journal. Editors should be free to express critical but responsible views

about all as-pects of medicine without fear of retribution, even if these views conflict with the commercial goals of the publisher. Editors and editors' organizations are obligated to support the concept of editorial freedom and to draw major trans-gressions of such freedom to the attention of the interna-tional medical, academic, and lay communities.

#### II. C. Peer Review

Unbiased, independent, critical assessment is an intrinsic part of all scholarly work, including the scientific process. Peer review is the critical assessment of manu-scripts submitted to journals by experts who are not part of the editorial staff. Peer review can therefore be viewed as an important extension of the scientific process. Although its actual value has been little studied and is widely debated (4), peer review helps editors decide which manuscripts are suitable for their journals and helps authors and editors to improve the quality of reporting. A peer-reviewed journal submits most of its published research articles for outside review. The number and kinds of manuscripts sent for review, the number of reviewers, the reviewing procedures, and the use made of the reviewers' opinions may vary. In the interests of transparency, each journal should publicly disclose its policies and average turn-around times in its Instructions to Authors.

#### II. D. Conflicts of Interest

Public trust in the peer-review process and the credibility of published articles depends in part on how well conflict of interest is handled during writing, peer review, and editorial decision making. Conflict of interest exists when an author (or the author's institution), reviewer, or editor has financial or personal relationships that inappro-priately influence (bias) his or her actions (such relation-ships are also known as dual commitments, competing in-terests, or competing loyalties). These relationships vary from being negligible to having great potential for influ-encing judgment. Not all relationships represent true conflict of interest. On the other hand, the potential for conflict of interest can exist regardless of whether an individual believes that the relationship affects his or her scientific judgment. Financial relationships (such as employment, consultancies, stock ownership, honoraria, and paid expert testimony) are the most easily identifiable conflicts of in-terest and the most likely to undermine the credibility of the journal, the authors, and of science itself. How-ever, conflicts can occur for other reasons, such as personal

relationships, academic competition, and intellectual passion.

All participants in the peer-review and publication process must disclose all relationships that could be viewed as potential conflicts of interest. Disclosure of such rela-tionships is also important in connection with editorials and review articles, because it can be more difficult to de-tect bias in these types of publications than in reports of original research. Editors may use information disclosed in conflict-of-interest and financial-interest statements as a basis for editorial decisions. Editors should publish this information if they believe it is important in judging the manuscript.

### II. D. 1. Potential Conflicts of Interest Related to Individual Authors' Commitments

When authors submit a manuscript, whether an article or a letter, they are responsible for disclosing all financial and personal relationships that might bias their work. To prevent ambiguity, authors must state explicitly whether potential conflicts do or do not exist. Authors should do so in the manuscript on a conflict-of-interest notification page that follows the title page, providing additional detail, if necessary, in a cover letter that accompanies the manuscript. (See Section IV. A. 3. Conflict-of-Interest Disclosure.)

The ICMJE developed a uniform disclosure form that ICMJE member journals piloted in 2009. The second ver-sion of the form is now available, as is an accompanying Glossary. Other journals are welcome to adopt this form.

Authors should identify individuals who provide writing or other assistance and disclose the funding source for this assistance.

Investigators must disclose potential conflicts to study participants and should state in the manuscript whether they have done so.

Editors also need to decide whether to publish information disclosed by authors about potential conflicts. If doubt exists, it is best to err on the side of publication.

### II. D. 2. Potential Conflicts of Interest Related to Project Support

Increasingly, individual studies receive funding from commercial firms, private foundations, and government. The conditions of this funding have the potential to bias and otherwise discredit the research.

Scientists have an ethical obligation to submit creditable research results for publication. Researchers should not enter into agreements that interfere with

their access to all of the data and their ability to analyze them indepen-dently, and to prepare and publish manuscripts. Authors should describe the role of the study sponsor, if any, in study design; collection, analysis, and interpretation of data; writing the report; and the decision to submit the report for publication. If the supporting source had no such involvement, the authors should so state. Biases potentially introduced when sponsors are directly involved in research are analogous to methodological biases. Some journals, therefore, choose to include information in the Methods section about the sponsor's involvement.

Editors may request that authors of a study funded by an agency with a proprietary or financial interest in the outcome sign a statement, such as "I had full access to all of the data in this study and I take complete responsibility for the integrity of the data and the accuracy of the data analysis." Editors should be encouraged to review copies of the protocol and/or contracts associated with project specific studies before accepting such studies for publication. Editors may request a statistical analysis of all data by an independent biostatistician. Editors may choose not to consider an article if a sponsor has asserted control over the authors' right to publish.

#### II. D. 3. Potential Conflicts of Interest Related to Commitments of Editors, Journal Staff, or Reviewers

Editors should avoid selecting external peer reviewers with obvious potential conflicts of interest - for example, those who work in the same department or institution as any of the authors. Authors often provide editors with the names of persons they feel should not be asked to review a manuscript because of potential, usually professional, con-flicts of interest. When possible, authors should be asked to explain or justify their concerns; that information is important to editors in deciding whether to honor such requests.

Reviewers must disclose to editors any conflicts of interest that could bias their opinions of the manuscript, and they should recuse themselves from reviewing specific manuscripts if the potential for bias exists. As in the case of authors, silence on the part of reviewers concerning poten-tial conflicts may mean either that conflicts exist and the reviewer has failed to disclose them or conflicts do not exist. Reviewers must therefore also be asked to state explicitly whether conflicts do or do not exist. Reviewers must

not use knowledge of the work, before its publication, to further their own interests.

Editors who make final decisions about manuscripts must have no personal, professional, or financial involve-ment in any of the issues they might judge. Other mem-bers of the editorial staff, if they participate in editorial decisions, must provide editors with a current description of their financial interests (as they might relate to editorial judgments) and recuse themselves from any decisions in which a conflict of interest exists. Editorial staff must not use information gained through working with manuscripts for private gain. Editors should publish regular disclosure statements about potential conflicts of interests related to the commitments of journal staff.

#### II. E. Privacy and Confidentiality

#### II. E. 1. Patients and Study Participants

Patients have a right to privacy that should not be violated without informed consent. Identifying information, including names, initials, or hospital numbers, should not be published in written descriptions, photographs, or pedigrees unless the information is essential for scientific purposes and the patient (or parent or guardian) gives written informed consent for publication. Informed consent for this purpose requires that an identifiable patient be shown the manuscript to be published. Authors should disclose to these patients whether any potential identifiable material might be available via the Internet as well as in print after publication. Patient consent should be written and archived with the journal, the authors, or both, as dictated by local regulations or laws. Applicable laws vary from locale to locale, and journals should establish their own policies with legal guidance. Since a journal that ar-chives the consent will be aware of patient identity, some journals may decide that patient confidentiality is better guarded by having the author archive the consent and in-stead providing the journal with a written statement that attests that they have received and archived written patient consent.

Nonessential identifying details should be omitted. Informed consent should be obtained if there is any doubt that anonymity can be maintained. For example, masking the eye region in photographs of patients is inadequate protection of anonymity. If identifying characteristics are altered to protect anonymity, such as in genetic pedigrees, authors should provide assurance, and editors should so note, that such alterations do not distort scientific meaning.

The requirement for informed consent should be included in the journal's Instructions for Authors. When informed consent has been obtained, it should be indicated in the published article.

#### II. E. 2. Authors and Reviewers

Manuscripts must be reviewed with due respect for authors' confidentiality. In submitting their manuscripts for review, authors entrust editors with the results of their scientific work and creative effort, on which their reputation and career may depend. Authors' rights may be vio-lated by disclosure of the confidential details during review of their manuscript. Reviewers also have rights to confidentiality, which must be respected by the editor. Confidenti-ality may have to be breached if dishonesty or fraud is alleged but otherwise must be honored.

Editors must not disclose information about manuscripts (including their receipt, content, status in the reviewing process, criticism by reviewers, or ultimate fate) to anyone other than the authors and reviewers. This includes requests to use the materials for legal proceedings.

Editors must make clear to their reviewers that manuscripts sent for review are privileged communications and are the private property of the authors. Therefore, review-ers and members of the editorial staff must respect the authors' rights by not publicly discussing the authors' work or appropriating their ideas before the manuscript is published. Reviewers must not be allowed to make copies of the manuscript for their files and must be prohibited from sharing it with others, except with the editor's permission. Reviewers should return or destroy copies of manuscripts after submitting reviews. Editors should not keep copies of rejected manuscripts.

Reviewer comments should not be published or otherwise publicized without permission of the reviewer, author, and editor.

Opinions differ on whether reviewers should remain anonymous. Authors should consult the Information for Authors of the journal to which they have chosen to submit a manuscript to determine whether reviews are anonymous. When comments are not signed, the reviewers' identity must not be revealed to the author or anyone else without the reviewers' permission.

Some journals publish reviewers' comments with the manuscript. No such procedure should be adopted

without the consent of the authors and reviewers. However, reviewers' comments should be sent to other persons reviewing the same manuscript, which helps reviewers learn from the review process. Reviewers also may be notified of the editor's decision to accept or reject a manuscript.

### II. F. Protection of Human Subjects and Animals in Research

When reporting experiments on human subjects, authors should indicate whether the procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008 (5). If doubt exists whether the research was conducted in accordance with the Helsinki Declaration, the authors must explain the rationale for their approach and demonstrate that the institutional re-view body explicitly approved the doubtful aspects of the study. When reporting experiments on animals, authors should indicate whether the institutional and national guide for the care and use of laboratory animals was followed.

# III. PUBLISHING AND EDITORIAL ISSUES RELATED TO PUBLICATION IN BIOMEDICAL JOURNALS

#### III. A. Obligation to Publish Negative Studies

Editors should seriously consider for publication any carefully done study of an important question, relevant to their readers, whether the results for the primary or any additional outcome are statistically significant. Failure to submit or publish findings because of lack of statistical significance is an important cause of publication bias.

### III. B. Corrections, Retractions, and "Expressions of Concern"

Editors must assume initially that authors are reporting work based on honest observations. Nevertheless, two types of difficulty may arise.

First, errors may be noted in published articles that require the publication of a correction or erratum on part of the work. The corrections should appear on a numbered page, be listed in the Table of Contents, include the complete original citation, and link to the original article and vice versa if online. It is conceivable that an error could be so serious as to vitiate the entire body of the work, but this is unlikely and should be addressed by editors and authors on an individual

basis. Such an error should not be con-fused with inadequacies exposed by the emergence of new scientific information in the normal course of research. The latter requires no corrections or withdrawals.

The second type of difficulty is scientific fraud. If substantial doubt arises about the honesty or integrity of work, either submitted or published, it is the editor's responsibility to ensure that the question is appropriately pursued, usually by the authors' sponsoring institution. Ordinarily, it is not the responsibility of the editor to conduct a full investigation or to make a determination that responsi-bility lies with the institution where the work was done or with the funding agency. The editor should be promptly informed of the final decision, and if a fraudulent paper has been published, the journal must print a retraction. If this method of investigation does not result in a satisfactory conclusion, the editor may choose to conduct his or her own investigation. As an alternative to retraction, the editor may choose to publish an expression of concern about aspects of the conduct or integrity of the work.

The retraction or expression of concern, so labeled, should appear on a numbered page in a prominent section of the print journal as well as in the online version, be listed in the Table of Contents page, and include in its heading the title of the original article. It should not simply be a letter to the editor. Ideally, the first author of the retraction should be the same as that of the article, although under certain circumstances the editor may accept retractions by other responsible persons. The text of the retraction should explain why the article is being retracted and include a complete citation reference to that article.

The validity of previous work by the author of a fraudulent paper cannot be assumed. Editors may ask the author's institution to assure them of the validity of earlier work published in their journals or to retract it. If this is not done, editors may choose to publish an announcement expressing concern that the validity of previously published work is uncertain.

Editors who have questions related to editorial or scientific misconduct may find it useful to consult the excel-lent flow charts that the Committee on Publication Ethics (COPE) has developed (http://www.publicationethics.org.uk). COPE, which was formed in 1997, is a forum in which editors of peerreviewed journals can discuss issues related to the integrity of the scientific record; it supports and

encourages editors to report, catalogue, and instigate investigations into ethical problems in the publication process. COPE's major objective is to provide a sounding board for editors struggling with how best to deal with possible breaches in research and publication ethics.

#### III. D. Overlapping Publications

#### III. D. 1. Duplicate Submission

Most biomedical journals will not consider manuscripts that are simultaneously being considered by other journals. Among the principal considerations that have led to this policy are: 1) the potential for disagreement when two (or more) journals claim the right to publish a manu-script that has been submitted simultaneously to more than one; and 2) the possibility that two or more journals will unknowingly and unnecessarily undertake the work of peer review, edit the same manuscript, and publish the same article.

However, editors of different journals may decide to simultaneously or jointly publish an article if they believe that doing so would be in the best interest of public health.

#### III. D. 2. Redundant Publication

Redundant (or duplicate) publication is publication of a paper that overlaps substantially with one already published in print or electronic media.

Readers of primary source periodicals, whether print or electronic, deserve to be able to trust that what they are reading is original unless there is a clear statement that the author and editor are intentionally republishing an article. The bases of this position are international copyright laws, ethical conduct, and cost-effective use of resources. Duplicate publication of original research is particularly problematic because it can result in inadvertent double-counting or inappropriate weighting of the results of a single study, which distorts the available evidence.

Most journals do not wish to receive papers on work that has already been reported in large part in a published article or is contained in another paper that has been submitted or accepted for publication elsewhere, in print or in electronic media. This policy does not preclude the journal from considering a paper that has been rejected by another journal, or a complete report that follows publication of a preliminary report, such as an abstract or poster displayed at a professional meeting. It also does not prevent journals from considering a paper that has been presented at

a scientific meeting but was not published in full, or that is being considered for publication in a proceedings or similar format. Brief press reports of scheduled meetings are not usually regarded as breaches of this rule, but they may be if additional data or copies of tables and figures amplify such reports. The ICMJE does not consider results posted in clinical trial registries as previous publication if the re-sults are presented in the same, ICMJE-accepted registry in which initial registration of trial methods occurred and if the results are posted in the form of a brief structured abstract or table. The ICMJE also believes that the results registry should either cite full publications of the results when available or include a statement that indicates that the results have not yet been published in a peer-reviewed journal.

When submitting a paper, the author must always make a complete statement to the editor about all submissions and previous reports (including meeting presentations and posting of results in registries) that might be regarded as redundant or duplicate publication. The author must alert the editor if the manuscript includes subjects about which the authors have published a previous report or have submitted a related report to another publication. Any such report must be referred to and referenced in the new paper. Copies of such material should be included with the submitted manuscript to help the editor decide how to handle the matter.

If redundant or duplicate publication is attempted or occurs without such notification, authors should expect ed-itorial action to be taken. At the least, prompt rejection of the submitted manuscript should be expected. If the editor was not aware of the violations and the article has already been published, then a notice of redundant or duplicate publication will probably be published with or without the author's explanation or approval.

Preliminary reporting to public media, governmental agencies, or manufacturers of scientific information de-scribed in a paper or a letter to the editor that has been accepted but not yet published violates the policies of many journals. Such reporting may be warranted when the paper or letter describes major therapeutic advances or public health hazards, such as serious adverse effects of drugs, vaccines, other biological products, medicinal de-vices, or reportable diseases. This reporting should not jeopardize publication, but should be discussed with and agreed upon by the editor in advance.

#### III. D. 3. Acceptable Secondary Publication

Certain types of articles, such as guidelines produced by governmental agencies and professional organizations, may need to reach the widest possible audience. In such instances, editors sometimes deliberately publish material that is also being published in other journals, with the agreement of the authors and the editors of those journals. Secondary publication for various other reasons, in the same or another language, especially in other countries, is justifiable and can be beneficial provided that the following conditions are met.

- The authors have received approval from the editors of both journals (the editor concerned with secondary pub-lication must have a photocopy, reprint, or manuscript of the primary version).
- The priority of the primary publication is respected by a publication interval of at least 1 week (unless specifi-cally negotiated otherwise by both editors).
- 3. The paper for secondary publication is intended for a different group of readers; an abbreviated version could be sufficient.
- 4. The secondary version faithfully reflects the data and interpretations of the primary version.
- 5. The footnote on the title page of the secondary version informs readers, peers, and documenting agencies that the paper has been published in whole or in part and states the primary reference. A suitable footnote might read: "This article is based on a study first reported in the [title of journal, with full reference]."

Permission for such secondary publication should be free of charge.

- 6. The title of the secondary publication should indicate that it is a secondary publication (complete republication, abridged republication, complete translation, or abridged translation) of a primary publication. Of note, the NLM does not consider translations to be "republications" and does not cite or index translations when the original article was published in a journal that is indexed in MEDLINE.
- 7. Editors of journals that simultaneously publish in multiple languages should understand that NLM indexes the primary language version. When the full text of an article appears in more than one language in a journal issue (such as Canadian journals with the article in both English and French), both languages are indicated in the MED-

LINE citation (for example, Mercer K. The relentless challenge in health care. Healthc Manage Forum. 2008 Summer; 21(2):4-5. English, French. No abstract available. PMID:18795553.)

#### III. D. 4. Competing Manuscripts Based on the Same Study

Publication of manuscripts to air the disputes of coinvestigators may waste journal space and confuse readers. On the other hand, if editors knowingly publish a manu-script written by only some of a collaborating team, they could be denying the rest of the team their legitimate co-authorship rights and journal readers access to legitimate differences of opinion about the interpretation of a study.

Two kinds of competing submissions are considered: submissions by coworkers who disagree on the analysis and interpretation of their study, and submissions by coworkers who disagree on what the facts are and which data should be reported.

Setting aside the unresolved question of ownership of the data, the following general observations may help edi-tors and others address such problems.

#### III. D. 4. a. Differences in Analysis or Interpretation

If the dispute centers on the analysis or interpretation of data, the authors should submit a manuscript that clearly presents both versions. The difference of opinion should be explained in a cover letter. The normal process of peer and editorial review may help the authors to resolve their disagreement regarding analysis or interpretation.

If the dispute cannot be resolved and the study merits publication, both versions should be published. Options include publishing two papers on the same study, or a single paper with two analyses or interpretations. In such cases, it would be appropriate for the editor to publish a statement outlining the disagreement and the journal's involvement in attempts to resolve it.

### III. D. 4. b. Differences in Reported Methods or Results

If the dispute centers on differing opinions of what was actually done or observed during the study, the journal editor should refuse publication until the disagreement is resolved. Peer review cannot be expected to resolve such problems. If there are allegations of dishonesty or fraud, editors should inform the appropriate authorities; authors should be notified of an editor's intention to report a sus-picion of research misconduct.

### III. D. 5. Competing Manuscripts Based on the Same Database

Editors sometimes receive manuscripts from separate research groups that have analyzed the same data set (for example, from a public database). The manuscripts may differ in their analytic methods, conclusions, or both. Each manuscript should be considered separately. If interpreta-tion of the data is very similar, it is reasonable but not mandatory for editors to give preference to the manuscript that was received first. However, editorial consideration of multiple submissions may be justified under these circum-stances, and there may even be a good reason to publish more than one manuscript because different analytical ap-proaches may be complementary and equally valid.

#### III. E. Correspondence

The corresponding author/guarantor has primary responsibility for correspondence with the journal, but the ICMJE recommends that editors send a copy of any cor-respondence to all listed authors.

Biomedical journals should provide the readership with a mechanism for submitting comments, questions, or criticisms about published articles, as well as brief reports and commentary unrelated to previously published articles. This probably but not necessarily takes the form of a correspondence section or column. The authors of articles discussed in correspondence should be given an opportunity to respond, preferably in the same issue in which the original correspondence appears. Authors of correspon-dence should be asked to declare any competing or conflicting interests.

Published correspondence may be edited for length, grammatical correctness, and journal style. Alternatively, editors may choose to publish unedited correspondence, for example in rapid-response sections on the Internet. The journal should declare its editorial practices in this regard. Authors should approve editorial changes that alter the substance or tone of a letter or response. In all instances, editors must make an effort to screen discourteous, inaccurate, or libelous statements and should not allow ad hominem arguments intended to discredit opinions or findings.

Although editors have the prerogative to reject correspondence that is irrelevant, uninteresting, or lacking cogency, they have a responsibility to allow a range of opinions to be expressed. The correspondence column should not be used merely to promote the journal's or the editors' point of view.

In the interests of fairness and to keep correspondence within manageable proportions, journals may want to set time limits for responding to published material and for debate on a given topic. Journals should also decide whether they would notify authors when correspondence bearing on their published work is going to appear in stan-dard or rapidresponse sections. Journals should also set policy with regard to the archiving of unedited correspondence that appears online. These policies should be published both in print and electronic versions of the journal.

### III. F. Supplements, Theme Issues, and Special Series

Supplements are collections of papers that deal with related issues or topics, are published as a separate issue of the journal or as part of a regular issue, and are usually funded by sources other than the journal's publisher. There is evidence that supplement content can be of lower quality than the content of the parent journal (6). Because funding sources can bias the content of supplements through the choice of topics and viewpoints, journals should consider adopting the following principles. These same principles apply to theme issues or special series that have external funding and/or guest editors.

- The journal editor must be given and take full responsibility for the policies, practices, and content of supplements, including complete control of the decision to select authors, peer reviewers, and content for the supplement. Editing by the funding organization should not be permitted.
- The journal editor must retain the authority to send supplement manuscripts for external peer review and to reject manuscripts submitted for the supplement. These conditions should be made known to authors and external supplement editors before beginning editorial work on the supplement.
- 3. The journal editor must approve the appointment of any external editor of the supplement and take responsibility for the work of the external editor.
- 4. The source of the idea for the supplement, sources of funding for the research, publication, and products of the funding source that are considered in the supplement should be clearly stated and prominently located in the supplement, preferably on each page. Whenever possible, supplements should be funded by more than one sponsor.

- 5. Advertising in supplements should follow the same policies as those of the rest of the journal.
- 6. Journal editors must enable readers to distinguish readily between ordinary editorial pages and supplement pages.
- Journal editors and supplement editors must not accept personal favors or remuneration from sponsors of supplements.
- 8. Secondary publication in supplements (republication of papers published elsewhere) should be clearly identified by the citation of the original paper. Supplements should avoid redundant or duplicate publication. Supplements should not republish research results, but republication of guidelines or other material in the public interest might be appropriate.
- The principles of authorship and disclosure of potential conflicts of interest discussed elsewhere in this document should be applied to supplements.

#### III. G. Electronic Publishing

Most biomedical journals are now published in electronic as well as print versions, and some are published only in electronic form. Because electronic publishing (which includes the Internet) is the same as publishing in print, in the interests of clarity and consistency the recom-mendations of this document should be applied to electronically published medical and health information.

The nature of electronic publication requires some special considerations, both within and beyond this docu-ment. At a minimum, Web sites should indicate the following: names, appropriate credentials, affiliations, and relevant conflicts of interest of editors, authors, and contributors; documentation and attribution of references and sources for all content; information about copyright; disclosure of site ownership; and disclosure of sponsorship, advertising, and commercial funding.

Linking from one health or medical Internet site to another may be perceived as an implicit recommendation of the quality of the second site. Journals thus should exercise caution in linking to other sites; when users are link-ing to another site, it may be helpful to provide an explicit statement that they are leaving the journal's site. Links to other sites posted as a result of financial considerations should be clearly indicated as such. All dates of content posting and updating should be indicated. In electronic

layout as in print, advertising and promotional messages should not be juxtaposed with editorial content, and commercial content should be clearly identified as such.

Electronic publication is in flux. Editors should develop, make available to authors, and implement policies on issues unique to electronic publishing. These issues include archiving, error correction, version control, choice of the electronic or print version of the journal as the journal of record, and publication of ancillary material.

Under no circumstances should a journal remove an article from its Web site or archive. If a correction or re-traction becomes necessary, the explanation must be labeled appropriately and communicated as soon as possible on a citable page in a subsequent issue of the journal.

Preservation of electronic articles in a permanent archive is essential for the historical record. Access to the archive should be immediate and controlled by a third party, such as a library, instead of the publisher. Deposi-tion in multiple archives is encouraged.

#### III. H. Advertising

Most medical journals carry advertising, which generates income for their publishers, but advertising must not be allowed to influence editorial decisions. Journals should have formal, explicit, written policies for advertising in both print and electronic versions; Web site advertising policy should parallel that for the printed journals. Editors must have full and final authority for approving advertise-ments and enforcing advertising policy.

When possible, editors should make use of the judgments of independent bodies for reviewing advertising. Readers should be able to distinguish readily between ad-vertising and editorial material. The juxtaposition of edi-torial and advertising material on the same products or subjects should be avoided. Interspersing advertising pages within articles interrupts the flow of editorial content and should be discouraged. Advertising should not be sold on the condition that it will appear in the same issue as a particular article.

Journals should not be dominated by advertising, but editors should be careful about publishing advertisements from only one or two advertisers, as readers may perceive that these advertisers have influenced the editor.

Journals should not carry advertisements for products that have proved to be seriously harmful to health-for example, tobacco. Editors should ensure that existing reg-ulatory or industry standards for advertisements specific to their country are enforced, or develop their own standards. The interests of organizations or agencies should not control classified and other nondisplay advertising, except where required by law. Finally, editors should consider all criticisms of advertisements for publication.

#### III. I. Medical Journals and the General Media

The public's interest in news of medical research has led the popular media to compete vigorously for information about research. Researchers and institutions some times encourage reporting research in the nonmedical media before full publication in a scientific journal by holding a press conference or giving interviews.

The public is entitled to important medical information within a reasonable amount of time, and editors have a responsibility to facilitate the process. Biomedical journals are published primarily for their readers, but the general public has a legitimate interest in their content: An appropriate balance between these considerations should guide the journal's interaction with the media. Doctors in practice need to have reports available in full detail before they can advise their patients about the reports' conclusions. Moreover, media reports of scientific research before the work has been peerreviewed and fully vetted may lead to dissemination of inaccurate or premature conclusions.

An embargo system has been established in some countries to prevent publication of stories in the general media before publication of the original research in the journal. The embargo creates a "level playing field," which most reporters appreciate since it minimizes the pressure on them to publish stories they have not had time to prepare carefully. Consistency in the timing of public release of biomedical information is also important in minimizing economic chaos, since some articles contain information that has great potential to influence financial markets. On the other hand, the embargo system has been challenged as being self-serving of journals' interests and an impediment to rapid dissemination of scientific information.

Editors may find the following recommendations useful as they seek to establish policies on these issues.

- Editors can foster the orderly transmission of medical information from researchers, through peerreviewed journals, to the public. This can be accomplished by an agreement with authors that they will not publicize their work while their manuscript is under consideration or awaiting publication and an agreement with the media that they will not release stories before publication of the orig-inal research in the journal, in return for which the journal will cooperate with them in preparing accurate stories.
- Editors need to keep in mind that an embargo system works on the honor system; no formal enforcement or policing mechanism exists. The decision of a significant number of media outlets or biomedical journals not to respect the embargo system would lead to its rapid dissolution.
- Very little medical research has such clear and urgently important clinical implications for the public's health that the news must be released before full publication in a journal. However, if such exceptional circum-stances occur, the appropriate authorities responsible for public health should decide whether to disseminate infor-mation to physicians and the media in advance and should be responsible for this decision. If the author and the appropriate authorities wish to have a manuscript considered by a particular journal, the editor should be consulted before any public release. If editors acknowledge the need for immediate release, they should waive their policies limiting prepublication publicity.
- Policies designed to limit prepublication publicity should not apply to accounts in the media of presentations at scientific meetings or to the abstracts from these meetings (see Redundant Publication). Researchers who present their work at a scientific meeting should feel free to discuss their presentations with reporters, but they should be discouraged from offering more detail about their study than was presented in the talk.
- When an article is soon to be published, editors should help the media prepare accurate reports by providing news releases, answering questions, supplying advance copies of the journal, or referring reporters to the appropriate experts. This assistance should be contingent on the media's

- cooperation in timing the release of a story to coincide with publication of the article.
- Editors, authors, and the media should apply the abovestated principles to material released early in electronic versions of journals.

#### JJJ. J. Obligation to Register Clinical Trials

The ICMJE believes that it is important to foster a comprehensive, publicly available database of clinical trials. The ICMJE defines a clinical trial as any research project that prospectively assigns human subjects to intervention or concurrent comparison or control groups to study the cause and effect relationship between a medical intervention and a health outcome. Medical interventions include drugs, surgical procedures, devices, behavioral treatments, process of care changes, and the like.

The ICMJE member journals will require, as a condition of consideration for publication in their journals, reg-istration in a public trials registry. The details of this policy are contained in a series of editorials (see Editorials, under Frequently Asked Questions). The ICMJE encourages ed-itors of other biomedical journals to adopt similar policy.

The ICMJE does not advocate one particular registry, but its member journals will require authors to register their trial in a registry that meets several criteria. The registry must be accessible to the public at no charge. It must be open to all prospective registrants and managed by a not for profit organization. There must be a mechanism to ensure the validity of the registration data, and the registry should be electronically searchable. Trial registration with missing fields or fields that contain uninformative terminology is inadequate.

It is important to note that the ICMJE requires registration of trial methodology but does not require registration of trial results; it recognizes the potential problems that could arise from the posting of research results that have not been subjected to an independent peer review process. However, the ICMJE understands that the U.S. Food and Drug Administration Amendments Act of 2007 (FDAAA) does require researchers to register results. The ICMJE will not consider results to be previous publication if they are posted in the same primary clinical trial registry as the initial registration and if the results are posted in the tabular form dictated by the FDAAA. Researchers should be aware that editors of journals that follow the ICMJE recommendations

may consider more detailed description of trial results and results published in registries other than the primary registry (in the case of FDAAA, ClinicalTrials.gov) to be prior publication. The ICMJE anticipates that the climate for results registration will change dramatically over coming years and the ICMJE may need to amend these recommendations as additional agencies institute other mandates related to results registration.

The ICMJE recommends that journals publish the trial registration number at the end of the abstract. The ICMJE also recommends that, whenever a registration number is available, authors list this number the first time they use a trial acronym to refer to either the trial they are reporting or to other trials that they mention in the manuscript.

### IV. MANUSCRIPT PREPARATION AND SUBMISSION

### IV. A. Preparing a Manuscript for Submission to a Biomedical Journal

Editors and reviewers spend many hours reading manuscripts, and therefore appreciate receiving manuscripts that are easy to read and edit. Much of the information in a journal's Instructions to Authors is designed to accomplish that goal in ways that meet each journal's particular editorial needs. The following information provides guidance in preparing manuscripts for any journal.

#### IV. A. 1. a. General Principles

The text of observational and experimental articles is usually (but not necessarily) divided into the following sections: Introduction, Methods, Results, and Discussion. This so-called "IMRAD" structure is not an arbitrary publication format but rather a direct reflection of the process of scientific discovery. Long articles may need subheadings within some sections (especially Results and Discussion) to clarify their content. Other types of articles, such as case reports, reviews, and editorials, probably need to be for-matted differently.

Electronic formats have created opportunities for adding details or whole sections, layering information, crosslinking or extracting portions of articles, and the like only in the electronic version. Authors need to work closely with editors in developing or using such new publication formats and should submit supplementary electronic material for peer review.

Double-spacing all portions of the manuscript-including the title page, abstract, text, acknowledgments, ref-erences, individual tables, and legendsand generous mar-gins make it possible for editors and reviewers to edit the text line by line and add comments and queries directly on the paper copy. If manuscripts are submitted electronically, the files should be double-spaced to facilitate printing for reviewing and editing.

Authors should number all of the pages of the manuscript consecutively, beginning with the title page, to facilitate the editorial process.

### IV. A. 1. b. Reporting Guidelines for Specific Study Designs

Research reports frequently omit important information. Reporting guidelines have been developed for a number of study designs that some journals may ask authors to follow. Authors should consult the Information for Authors of the journal they have chosen.

The general requirements listed in the next section relate to reporting essential elements for all study designs. Authors are encouraged also to consult reporting guidelines relevant to their specific research design. A good source of reporting guidelines is the EQUATOR Network (http://www.equator-network.org/home/).

#### IV. A .2. Title Page

The title page should have the following information:

- Article title. Concise titles are easier to read than long, convoluted ones. Titles that are too short may, however, lack important information, such as study design (which is particularly important in identifying randomized, controlled trials). Authors should include all information in the title that will make electronic retrieval of the article both sensitive and specific.
- 2. Authors' names and institutional affiliations. Some journals publish each author's highest academic degree(s), while others do not.
- 3. The name of the department(s) and institution(s) to which the work should be attributed.
- 4. Disclaimers, if any.
- 5. Contact information for corresponding authors. The name, mailing address, telephone and fax numbers, and e-mail address of the author responsible for correspon-dence about the manuscript (the "corresponding author;" this author may or may not be the "guarantor" for the integrity of the study). The corresponding author

should indicate clearly whether his or her e-mail address can be published.

- The name and address of the author to whom requests for reprints should be addressed or a statement that reprints are not available from the authors.
- 7. Source(s) of support in the form of grants, equipment, drugs, or all of these.
- 8. A running head. Some journals request a short run-ning head or footline, usually no more than 40 characters (including letters and spaces) at the foot of the title page. Running heads are published in most journals, but are also sometimes used within the editorial office for filing and locating manuscripts.
- 9. Word counts. A word count for the text only (excluding abstract, acknowledgments, figure legends, and references) allows editors and reviewers to assess whether the information contained in the paper warrants the amount of space devoted to it, and whether the submitted manuscript fits within the journal's word limits. A separate word count for the Abstract is useful for the same reason.
- 10. The number of figures and tables. It is difficult for editorial staff and reviewers to determine whether the figures and tables that should have accompanied a manuscript were actually included unless the numbers of figures and tables are noted on the title page.

#### IV. A. 3. Conflict-of-Interest Notification Page

To prevent potential conflicts of interest from being overlooked or misplaced, this information needs to be part of the manuscript. The ICMJE has developed a uniform disclosure form for use by ICMJE member journals (http://www.icmje.org/coi\_disclosure.pdf). Other journals are welcome to adopt this form. Individual journals may differ in where they include this information, and some journals do not send information on conflicts of interest to reviewers. (See Section II. D. Conflicts of Interest.

#### IV. A. 4. Abstract

Structured abstracts are preferred for original research and systematic reviews. The abstract should provide the context or background for the study and should state the study's purpose, basic procedures (selection of study sub-jects or laboratory animals, observational and analytical methods), main findings (giving specific

effect sizes and their statistical significance, if possible), principal conclu-sions, and funding sources. It should emphasize new and important aspects of the study or observations. Articles on clinical trials should contain abstracts that include the items that the CONSORT group has identified as essential (http://www.consort-statement.org/? f 1190).

Because abstracts are the only substantive portion of the article indexed in many electronic databases, and the only portion many readers read, authors need to be careful that they accurately reflect the content of the article. Unfortunately, the information contained in many abstracts differs from that in the text (7). The format required for structured abstracts differs from journal to journal, and some journals use more than one format; authors need to prepare their abstracts in the format specified by the journal they have chosen.

The ICMJE recommends that journals publish the trial registration number at the end of the abstract. The ICMJE also recommends that, whenever a registration number is available, authors list that number the first time they use a trial acronym to refer to either the trial they are reporting or to other trials that they mention in the manuscript.

#### IV. A. 5. Introduction

Provide a context or background for the study (that is, the nature of the problem and its significance). State the specific purpose or research objective of, or hypothesis tested by, the study or observation; the research objective is often more sharply focused when stated as a question. Both the main and secondary objectives should be clear, and any prespecified subgroup analyses should be described. Pro-vide only directly pertinent references, and do not include data or conclusions from the work being reported.

#### IV. A. 6. Methods

The Methods section should include only information that was available at the time the plan or protocol for the study was being written; all information obtained during the study belongs in the Results section.

### IV. A. 6. a. Selection and Description of Participants

Describe your selection of the observational or experimental participants (patients or laboratory animals, including controls) clearly, including eligibility and exclusion criteria and a description of the source population. Because the relevance of such variables as age and sex to the object of research is not always clear, authors should explain their use when they are

included in a study report-for example, authors should explain why only participants of certain ages were included or why women were excluded. The guiding principle should be clarity about how and why a study was done in a particular way. When authors use such variables as race or ethnicity, they should define how they measured these variables and justify their relevance.

#### IV. A. 6. b. Technical Information

Identify the methods, apparatus (give the manufacturer's name and address in parentheses), and procedures in sufficient detail to allow others to reproduce the results. Give references to established methods, including statistical methods (see below); provide references and brief descriptions for methods that have been published but are not well known; describe new or substantially modified methods, give the reasons for using them, and evaluate their limitations. Identify precisely all drugs and chemicals used, including generic name(s), dose(s), and route(s) of administration.

Authors submitting review manuscripts should include a section describing the methods used for locating, select-ing, extracting, and synthesizing data. These methods should also be summarized in the abstract.

#### IV. A. 6. c. Statistics

Describe statistical methods with enough detail to en-able a knowledgeable reader with access to the original data to verify the reported results. When possible, quantify findings and present them with appropriate indicators of measurement error or uncertainty (such as confidence intervals). Avoid relying solely on statistical hypothesis testing, such as *P* values, which fail to convey important information about effect size. References for the design of the study and statistical methods should be to standard works when possible (with pages stated). Define statistical terms, abbreviations, and most symbols. Specify the computer software used.

#### IV. A. 7. Results

Present your results in logical sequence in the text, tables, and illustrations, giving the main or most important findings first. Do not repeat all the data in the tables or illustrations in the text; emphasize or summarize only the most important observations. Extra or supplementary materials and technical detail can be placed in an appendix where they will be accessible but will not interrupt the flow of the text, or they can be published solely in the electronic version of the journal.

When data are summarized in the Results section, give numeric results not only as derivatives (for example, percentages) but also as the absolute numbers from which the derivatives were calculated, and specify the statistical meth-ods used to analyze them. Restrict tables and figures to those needed to explain the argument of the paper and to assess supporting data. Use graphs as an alternative to ta-bles with many entries; do not duplicate data in graphs and tables. Avoid nontechnical uses of technical terms in statis-tics, such as "random" (which implies a randomizing device), "normal," "significant," "correlations," and "sample." Where scientifically appropriate, analyses of the data by such variables as age and sex should be included.

#### IV. A. 8. Discussion

Emphasize the new and important aspects of the study and the conclusions that follow from them in the context of the totality of the best available evidence. Do not repeat in detail data or other information given in the Introduction or the Results section. For experimental studies, it is useful to begin the discussion by briefly summarizing the main findings, then explore possible mechanisms or explanations for these findings, compare and contrast the results with other relevant studies, state the limitations of the study, and explore the implications of the findings for fu-ture research and for clinical practice.

Link the conclusions with the goals of the study but avoid unqualified statements and conclusions not adequately supported by the data. In particular, avoid making statements on economic benefits and costs unless the manuscript includes the appropriate economic data and analyses. Avoid claiming priority or alluding to work that has not been completed. State new hypotheses when war-ranted, but label them clearly as such.

#### IV. A. 9. References

### IV. A. 9. a. General Considerations Related to References

Although references to review articles can be an efficient way to guide readers to a body of literature, review articles do not always reflect original work accurately. Readers should therefore be provided with direct references to original research sources whenever possible. On the other hand, extensive lists of references to original work on a topic can use

excessive space on the printed page. Small numbers of references to key original papers often serve as well as more exhaustive lists, particularly since references can now be added to the electronic version of published papers, and since electronic literature searching allows readers to retrieve published literature efficiently.

Avoid using abstracts as references. References to papers accepted but not yet published should be designated as "in press" or "forthcoming"; authors should obtain written permission to cite such papers as well as verification that they have been accepted for publication. Information from manuscripts submitted but not accepted should be cited in the text as "unpublished observations" with written permission from the source.

Avoid citing a "personal communication" unless it provides essential information not available from a public source, in which case the name of the person and date of communication should be cited in parentheses in the text. For scientific articles, obtain written permission and confirmation of accuracy from the source of a personal communication.

Some but not all journals check the accuracy of all reference citations; thus, citation errors sometimes appear in the published version of articles. To minimize such errors, references should be verified using either an electronic bibliographic source, such as PubMed or print copies from original sources. Authors are responsible for checking that none of the references cite retracted articles except in the context of referring to the retraction. For articles published in journals indexed in MEDLINE, the ICMJE considers PubMed the authoritative source for information about retractions. Authors can identify retracted articles in MEDLINE by using the following search term, where pt in square brackets stands for publication type: Retracted publication [pt] in PubMed.

#### IV. A. 9. b. Reference Style and Format

The Uniform Requirements style for references is based largely on an American National Standards Institute style adapted by the NLM for its databases. Authors should consult NLM's Citing Medicine for information on its recommended formats for a variety of reference types. Authors may also consult sample references, a list of examples extracted from or based on Citing Medicine for easy use by the ICMJE audience; these sample references are maintained by NLM.

References should be numbered consecutively in the order in which they are first mentioned in the text. Identify references in text, tables, and legends by Arabic numerals in parentheses. References cited only in tables or figure legends should be numbered in accordance with the se-quence established by the first identification in the text of the particular table or figure. The titles of journals should be abbreviated according to the style used in the list of

Journals Indexed for MEDLINE, posted by the NLM on the Library's Web site. Journals vary on whether they ask authors to cite electronic references within parentheses in the text or in numbered references following the text. Authors should consult with the journal to which they plan to submit their work.

#### IV. A. 10. Tables

Tables capture information concisely and display it efficiently; they also provide information at any desired level of detail and precision. Including data in tables rather than text frequently makes it possible to reduce the length of the text.

Type or print each table with doublespacing on a separate sheet of paper. Number tables consecutively in the order of their first citation in the text and supply a brief title for each. Do not use internal horizontal or vertical lines. Give each column a short or an abbreviated heading. Authors should place explanatory matter in footnotes, not in the heading. Explain all nonstandard abbreviations in footnotes, and use the following symbols, in sequence:

Identify statistical measures of variations, such as standard deviation and standard error of the mean.

Be sure that each table is cited in the text.

If you use data from another published or unpublished source, obtain permission and acknowledge that source fully.

Additional tables containing backup data too extensive to publish in print may be appropriate for publication in the electronic version of the journal, deposited with an archival service, or made available to readers directly by the authors. An appropriate statement should be added to the text to inform readers that this additional information is available and where it is located. Submit such tables for consideration with the paper so that they will be available to the peer reviewers.

#### IV. A. 11. Illustrations (Figures)

Figures should be either professionally drawn and photographed, or submitted as photographic quality digital

prints. In addition to requiring a version of the figures suitable for printing, some journals now ask authors for electronic files of figures in a format (for example, JPEG or GIF) that will produce high-quality images in the Web version of the journal; authors should review the images of such files on a computer screen before submitting them to be sure they meet their own quality standards.

For x-ray films, scans, and other diagnostic images, as well as pictures of pathology specimens or photomicrographs, send sharp, glossy, black-and-white or color pho-tographic prints, usually 127 f 173 mm (5 f 7 inches). Although some journals redraw figures, many do not. Letters, numbers, and symbols on figures should therefore be clear and consistent throughout, and large enough to remain legible when the figure is reduced for publication. Figures should be made as self-explanatory as possible, since many will be used directly in slide presentations. Titles and detailed explanations belong in the legends not on the illustrations themselves.

Photomicrographs should have internal scale markers. Symbols, arrows, or letters used in photomicrographs should contrast with the background.

Photographs of potentially identifiable people must be accompanied by written permission to use the photograph.

Figures should be numbered consecutively according to the order in which they have been cited in the text. If a figure has been published previously, acknowledge the original source and submit written permission from the copyright holder to reproduce the figure. Permission is required irrespective of authorship or publisher except for documents in the public domain.

For illustrations in color, ascertain whether the journal requires color negatives, positive transparencies, or color prints. Accompanying drawings marked to indicate the region to be reproduced might be useful to the editor. Some journals publish illustrations in color only if the author pays the additional cost.

Authors should consult the journal about requirements for figures submitted in electronic formats.

#### IV. A. 12. Legends for Illustrations (Figures)

Type or print out legends for illustrations using double spacing, starting on a separate page, with Arabic numerals corresponding to the illustrations. When symbols, arrows, numbers, or letters are used to identify parts of the illustrations, identify and explain

each one clearly in the legend. Explain the internal scale and identify the method of staining in photomicrographs.

#### IV. A. 13. Units of Measurement

Measurements of length, height, weight, and volume should be reported in metric units (meter, kilogram, or liter) or their decimal multiples.

Temperatures should be in degrees Celsius. Blood pressures should be in millimeters of mercury, unless other units are specifically required by the journal.

Journals vary in the units they use for reporting hematologic, clinical chemistry, and other measurements. Authors must consult the Information for Authors of the particular journal and should report laboratory information in both local and International System of Units (SI). Editors may request that authors add alternative or non-SI units, since SI units are not universally used. Drug concentrations may be reported in either SI or mass units, but the alternative should be provided in parentheses where appropriate.

#### IV. A. 14. Abbreviations and Symbols

Use only standard abbreviations; use of nonstandard abbreviations can be confusing to readers. Avoid abbreviations in the title of the manuscript. The spelled out abbreviation followed by the abbreviation in parenthesis should be used on first mention unless the abbreviation is a standard unit of measurement.

#### IV. B. Sending the Manuscript to the Journal

An increasing number of journals now accept electronic submission of manuscripts, whether on disk, as an e-mail attachment, or by downloading directly onto the journal's Web site. Electronic submission saves time and money and allows the manuscript to be handled in electronic form throughout the editorial process (for example, when it is sent out for review). For specific instructions on electronic submission, authors should consult the journal's Instructions for Authors.

If a paper version of the manuscript is submitted, send the required number of copies of the manuscript and figures; they are all needed for peer review and editing, and the editorial office staff cannot be expected to make the required copies.

Manuscripts must be accompanied by a cover letter, which should include the following information.

- A full statement to the editor about all submissions and previous reports that might be regarded as redundant publication of the same or very similar work. Any such work should be referred to specifically and referenced in the new paper. Copies of such material should be included with the submitted paper to help the editor address the situation.
- A statement of financial or other relationships that might lead to a conflict of interest, if that information is not included in the manuscript itself or in an authors' form.
- A statement that the manuscript has been read and approved by all the authors, that the requirements for authorship as stated earlier in this document have been met, and that each author believes that the manuscript represents honest work if that information is not provided in another form (see below).
- The name, address, and telephone number of the corresponding author, who is responsible for communicating with the other authors about revisions and final approval of the proofs, if that information is not included in the manuscript itself.

The letter should give any additional information that may be helpful to the editor, such as the type or format of article in the particular journal that the manuscript represents. If the manuscript has been submitted previously to another journal, it is helpful to include the previous editor's and reviewers' comments with the submitted manuscript, along with the authors' responses to those com-ments. Editors encourage authors to submit these previous communications. Doing so may expedite the review process.

Many journals now provide a presubmission checklist to help the author ensure that all the components of the submission have been included. Some journals now also require that authors complete checklists for reports of cer-tain study types (for example, the CONSORT checklist for reports of randomized, controlled trials). Authors should look to see if the journal uses such checklists, and send them with the manuscript if they are requested.

Letters of permission to reproduce previously published material, use previously published illustrations, report information about identifiable persons, or to acknowledge people for their contributions must accompany the manuscript.

#### **V. REFERENCES**

- A. References Cited in This Document
- Davidoff F, for the CSE Task Force on Authorship. Who's the author? Problems with biomedical authorship, and some possible solutions. Science Editor. 2000;23: 111-9.
- Yank V, Rennie D. Disclosure of researcher contributions: a study of original research articles in *The Lancet*. Ann Intern Med. 1999;130:661-70.
- 3. Flanagin A, Fontanarosa PB, DeAngelis CD. Authorship for research groups. JAMA. 2002;288:3166-8.
- 4. Godlee F, Jefferson T. Peer Review in Health Sciences. London: BMJ Books; 1999.
- 5. http://www.wma.net/e/policy/b3.htm (accessed June 26, 2009).
- Rochon PA, Gurwitz JH, Cheung CM, Hayes JA, Chalmers TC. Evaluating the quality of articles published in journal supplements compared with the quality of those published in the parent journal. JAMA. 1994;272:108-13.
- 7. Pitkin RM, Branagan MA, Burmeister LF. Accuracy of data in abstracts of published research articles. JAMA. 1999;281:1110-1.
- B. Other Sources of Information Related to Biomedical Journals World Association of Medical Editors (WAME) Council of Science Editors (CSE)

European Association of Science Editors (EASE) Cochrane Collaboration

Committee on Publication Ethics (COPE) EQUATOR NETWORK http://www.equator-network.org

### VI. ABOUT THE INTERNATIONAL COMMITTEE OF MEDICAL JOURNAL EDITORS

The ICMJE is a group of general medical journal editors whose participants meet annually and fund their work on the Uniform Requirements for Manuscripts. The

ICMJE invites comments on this document and sugges-tions for agenda items.

# VII. AUTHORS OF THE UNIFORM REQUIREMENTS FOR MANUSCRIPTS SUBMITTED TO BIOMEDICAL JOURNALS

The ICMJE participating journals and organizations and their representatives who approved the revised

Uni-form Requirements for Manuscripts in April 2010 include

Annals of Internal Medicine, British Medical Journal, Cana-dian Medical Association Journal, China Medical Journal, Croatian Medical Journal, Journal of the American Medical Association, Nederlands Tijdschrift voor Geneeskunde (The Dutch Medical Journal), New England Journal of Medicine, New Zealand Medical Journal, The Lancet, The Medical Journal of Australia, Revista Me´dica de Chile, Tidsskrift for Den Norske Lægeforening (The Journal of the Norwegian Medical Association), Ugeskrift for Laeger (Journal of the Danish Medical Association), the U.S. NLM, and the World Association of Medical Editors.

### VIII. USE, DISTRIBUTION, AND TRANSLATION OF THE UNIFORM REQUIREMENTS

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organizations provide the ICMJE secretariat with the citation for that reprint or translation so that the ICMJE can keep a record of such versions of the document.

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Before sending an inquiry, please consult Frequently Asked Questions at www.icmje.org, as this section of the Web site provides answers to the most commonly asked questions.

Inquiries about the Uniform Requirements should be sent to the ICMJE Secretariat office by using the "Contact ICMJE" link on the home page of www.icmje.org. Please do not direct inquiries about individual studies, individual journal styles, or individual journal policies to the ICMJE secretariat office. The ICMJE does not archive individual journal contact information. Manuscripts intended for submission to a journal must be sent directly to the jour-nal, not to the ICMJE.

#### references according to the . . .

#### **VANCOUVER STYLE**

The Vancouver Style, or Uniform Requirements Style, is based on an ANSI standard adapted by the National Library of Medicine (NLM) for databases such as Medline. It was developed in Vancouver in 1978 by editors of medical journals who now meet annually as the International Committee of Medical Journal Editors (ICMJE). Over 500 medical journals (including BMJ, CMAJ, & JAMA) use this style.

#### In the text:

- PReferences are numbered consecutively in the order they are first mentioned. Place each reference number in parentheses, throughout the text, tables, and legends. If the same reference is used again, re-use the original number. (See number 3 in the example below.)
- Direct quotes are to be used very sparingly. If a direct quote is necessary, place quotation marks around the quote and number the reference as usual. (See number 6 in the example below.)
- Tables are numbered consecutively. Supply a
  brief title for each table and give each column a
  short heading. Be sure that the table is mentioned
  in the text. If the data is taken from another
  source, include the source in the list of references
  at the end of the paper. Place explanatory matter

in a note, not in the heading. For notes use the following symbols in this sequence: \*, +, \*\*, ++, etc

- Internet sources may, in time, be deleted, changed, or moved, so it is a good idea to keep a hard copy for your records. Also, take care to critically evaluate the reliability of the information.
- Personal communication used as a reference should be avoided, unless it provides essential information not available from a public source. Do not number this type of reference; instead cite the name of the person and date of communication in parentheses in the text. Use this method to cite a conversation or to cite notes taken by a student in class. (See the example below).

#### On the references page:

- The last page of your paper is entitled REFERENCES. No footnotes or bibliography are used.
- Numbering: List all references in order by number, not alphabetically. Each reference is listed once only, since the same number is used throughout the paper.
- Authors: List each author's last name and initials; full first names are not included. List all authors, but if the number exceeds six, give the first six followed by "et al." (see example 1 on next page). For books with chapters written by individual authors, list the authors of the chapter first, then the chapter title, followed by "ln:", the editors' names, and the book title (see example 6).
- Book titles, chapter titles: Capitalize the first letter of the first word in the title. The rest of the title is in lower-case, with the exception of proper names (see example 5). Do not underline the title; do not use italics.
- Journal citations: List the abbreviated journal title\*, period, year, semi-colon, volume, issue number in parentheses\*\*, colon, page range, and a period.

For example, Brain Res. 2002;935(1-2):40-6.

- \* To find the abbreviation go to PubMed Medline's Journals Database, (http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=journals), and search by journal title. If the title is not found, abbreviate according to the style used in Medline.
- \*\* The issue number may be omitted if the journal is paginated continuously through the volume.
- Pages: For journals, the entire page range of an article is given, not the specific page on which

the information was found. For books, no page numbers are given, with two exceptions: the page number of a dictionary entry is included (see example 7), as well as the page range of a chapter with its own author (see example 6).

**Examples:** The next page is an example of a reference page. For more examples, please consult:

- PE/1475/INT/2006 REF Uniform Requirements for Manuscripts Submitted to Biomedical Journals
- http://www.icmje.org/ Writing and Editing for Biomedical Publication: International Committee of Medical Journal Editors website
- http://www.nlm.nih.gov/bsd/ uniform\_requirements.html Sample References for Uniform Requirements for Manuscripts Submitted to Biomedical Journals
- http://www.ncbi.nlm.nih.gov/books/ bv.fcgi?rid=citmed Citing Medicine – sample references

#### **REFERENCES**

Journal article, personal author(s):

 Rose ME, Huerbin MB, Melick J, Marion DW, Palmer AM, Schiding JK, et al. Regulation of interstitial excitatory amino acid concentrations after cortical contusion injury. Brain Res. 2002;935(1-2):40-6.

Journal article, organization as author:

 Diabetes Prevention Program Research Group. Hypertension, insulin, and proinsulin in participants with impaired glucose tolerance. Hypertension. 2002;40(5):679-86.

Book, personal author(s):

 Murray PR, Rosenthal KS, Kobayashi GS, Pfaller MA. Medical microbiology. 4th ed. St. Louis: Mosby; 2002.

Book, organization as author and publisher:

 Royal Adelaide Hospital; University of Adelaide, Department of Clinical Nursing. Compendium of nursing research and practice development, 1999-2000. Adelaide (Australia): Adelaide University; 2001.

#### Book, editor(s):

 Berkow R, Fletcher AJ, editors. The Merck manual of diagnosis and therapy. 16<sup>th</sup> ed. Rahway (NJ): Merck Research Laboratories; 1992.

#### Chapter in a book:

6. Meltzer PS, Kallioniemi A, Trent JM. Chromosome alterations in human solid tumors.

In: Vogelstein B, Kinzler KW, editors. The genetic basis of human cancer. New York: McGraw-Hill; 2002. p. 93-113.

#### Dictionary entry:

7. Dorland's illustrated medical dictionary. 29th ed. Philadelphia: W.B. Saunders; 2000. Filamin; p. 675.

#### **Newspaper article:**

8. Tynan T. Medical improvements lower homicide rate: study sees drop in assault rate. The Washington Post. 2002 Aug 12;Sect. A:2 (col. 4).

#### Legal material:

 Regulated Health Professions Act, 1991, Stat. Of Ontario, 1991 Ch.18, as amended by 1993, Ch.37: office consolidation. Toronto: Queen's Printer for Ontario; 1994.

#### CD-ROM:

 Anderson SC, Poulsen KB. Anderson's electronic atlas of hematology [CD-ROM]. Philadelphia: Lippincott Williams & Wilkins; 2002.

#### Journal article on the Internet:

 Abood S. Quality improvement initiative in nursing homes: the ANA acts in an advisory role. Am J Nurs [serial on the Internet]. 2002 Jun [cited 2002 Aug 12];102(6):[about 3 p.]. Available from: http://www.nursingworld.org/AJN/2002/june/ Wawatch.htm.

#### **Book on the Internet**

12. Foley KM, Gelband H, editors. Improving palliative care for cancer [monograph on the Internet]. Washington: National Academy Press; 2001 [cited 2002 Jul 9]. Available from: http:// www.nap.edu/books/0309074029/html/.

#### **Encyclopedia on the Internet**

 A.D.A.M. medical encyclopedia [Internet]. Atlanta: A.D.A.M., Inc.; c2005 [cited 2007 Mar 26]. Available from: http://www.nlm.nih.gov/medlineplus/encyclopedia.html.

#### Internet homepage/website:

14. Canadian Cancer Society [homepage on the Internet]. Toronto: The Society; 2006 [updated 2006 May 12; cited 2006 Oct 17]. Available from: http://www.cancer.ca/.

#### Part of an Internet homepage/website

15. American Medical Association [homepage on the Internet]. Chicago: The Association; c1995-2002 [updated 2001 Aug 23; cited 2002 Aug 12]. AMA Office of Group Practice Liaison; [about 2 screens]. Available from: http://www.ama-assn.org/ama/pub/category/1736.html.

Note: Italicized headings are for the purposes of this handout only; they do not normally appear on a reference page.

#### Avoiding Plagiarism: Why Use References?

Plagiarism is taking, using, and submitting the thoughts, writings, etc., of another person as one's own. Often students are uncertain when to acknowledge sources, or when to assume that a concept or theory belongs to the domain of general knowledge. If in doubt, include a reference. Types of concepts that require a reference include: discoveries, theories, controversies and opinions. Don't forget to acknowledge the source of illustrations, charts, and tables of data. For more information and specific examples, consult "How Not to Plagiarize" www.utoronto.ca/writing/plagsep.html.

#### There are several reasons for including a reference:

- it is ethical to credit others for their contributions to your writing;
- it may be a legal obligation in the case of copyright;
- to protect you in the case of questionable allegations;
- to reflect your prior reading effort;
- to show the sequence of events involved in the resolution of a scientific problem, as part of your argument.

**Paraphrases**: It is often necessary to reduce a concept or theory into a few sentences. While the words may be your own, the concepts or theories are not; and you must give credit to your sources. The use of paraphrasing, rather than direct quotes, is often preferred because it helps with creating flow in building logical arguments.

Quotations: Direct quotations are to be used very sparingly. The chief drawback is that the text becomes choppy and difficult to read. Using the author's own words in a direct quote is usually justified for only the following reasons:

- credibility, an argument gains credibility by quoting a known authority;
- power, an argument gains power by the skillful weaving-in of knowledge into the text;
- eloquence, an argument gains eloquence by using a direct quote that illuminates the concept.