

Uniform Requirements for Manuscripts Submitted to Biomedical Journals, ICMJE

홍 성 태

의편협 기획평가위원장
대한의학회 간행위원장,
Editor, JKMS



Uniform Requirements, 2010

**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**



Foundation of Uniform Requirements

- First meeting for guidelines at [Vancouver](#) in 1978
- First published in 1979
- Basic structure of a manuscript
- Standard uniform for ICMJE journals
- Recommended by NLM, AMA
- Revised 1997, 1999, 2000, 2001, 2003, 2006, 2008, 2010
- Encourage to use this document
- Closed members



Contents of Uniform Requirements

- I. Statement of Purpose**
- II. Ethical Considerations in the Conduct and Reporting of Research**
- III. Publishing and Editorial Issues Related to Publication in Biomedical Journals**
- IV. Manuscript Preparation and Submission**
- V. References**
- VI. About the International Committee of Medical Journal Editors**
- VII. Authors of the Uniform Requirements**
- VIII. Use, Distribution, and Translation of the Uniform Requirements**
- IX. Inquiries**



Contents of Uniform Requirements

I. Statement of Purpose

A. About the Uniform Requirements

B. Potential Users of the Uniform Requirements

C. How to Use the Uniform Requirements



Contents of Uniform Requirements

II. Ethical Considerations in the Conduct and Reporting of Research

A. Authorship and Contributorship

1. Byline Authors
2. Contributors Listed in Acknowledgments

B. Editorship

1. The Role of the Editor
2. Editorial Freedom

C. Peer Review



Contents of Uniform Requirements

D. Conflicts of Interest

1. Potential Conflicts of Interest Related to Individual Authors' Commitments
2. Potential Conflicts of Interest Related to Project Support
3. Potential Conflicts of Interest Related to Commitments of Editors, Journal Staff, or Reviewers

E. Privacy and Confidentiality

1. Patients and Study Participants
2. Authors and Reviewers

F. Protection of Human Subjects and Animals in Research



Contents of Uniform Requirements

III. Publishing and Editorial Issues Related to Publication in Biomedical Journals

- A. Obligation to Publish Negative Studies
- B. Corrections, Retractions, and “Expressions of Concern”
- C. Copyright
- D. Overlapping Publications
 - 1. Duplicate Submission
 - 2. Redundant Publication
 - 3. Acceptable Secondary Publication



Contents of Uniform Requirements

- 4. Competing Manuscripts Based on the Same Study
 - a. Differences in Analysis or Interpretation
 - b. Differences in Reported Methods or Results
- 5. Competing Manuscripts Based on the Same Database
- E. Correspondence
- F. Supplements, Theme Issues, and Special Series
- G. Electronic Publishing
- H. Advertising
- I. Medical Journals and the General Media
- J. Obligation to Register Clinical Trials



Contents of Uniform Requirements

IV. Manuscript Preparation and Submission

A. Preparing a Manuscript for Submission to Biomedical Journals

1. a. General Principles

b. Reporting Guidelines for Specific Study Designs

2. Title Page

3. Conflict-of-Interest Notification Page

4. Abstract and Key Words

5. Introduction



Contents of Uniform Requirements

6. Methods

- a. Selection and Description of Participants
- b. Technical Information
- c. Statistics

7. Results

8. Discussion

9. References

- a. General Considerations Related to References
- b. Reference Style and Format



Contents of Uniform Requirements

10. Tables

11. Illustrations (Figures)

12. Legends for Illustrations (Figures)

13. Units of Measurement

14. Abbreviations and Symbols

B. Sending the Manuscript to the Journal



Contents of Uniform Requirements

V. References

A. Print References Cited in this Document

B. Other Sources of Information Related to
Biomedical Journals

VI. About the International Committee of Medical Journal Editors

VII. Authors of the Uniform Requirements

VIII. Use, Distribution, and Translation of the Uniform Requirements

IX. Inquiries



Statement of Purpose

- About the Uniform
- Potential users
- How to use the Uniform



Ethical Considerations in the Conduct and Reporting of Research: Authorship 1

- Byline Authors: An “author” is generally considered to be someone who has made substantive intellectual contributions to a published study.
- *An author must take responsibility for at least one component of the work, should be able to identify who is responsible for each other component, and should ideally be confident in their co-authors’ ability and integrity.*



Ethical Considerations in the Conduct and Reporting of Research: Authorship 2

- 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 published.
- Authors should meet conditions 1, 2, and 3.



Ethical Considerations in the Conduct and Reporting of Research: Authorship 3

- **Contributorship**: Acquisition of funding, collection of data, or general supervision of the research group alone does not constitute authorship. All contributors who do not meet the criteria for authorship should be listed in an acknowledgments section.
- 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 portions of the content.



Ethical Considerations in the Conduct and Reporting of Research: Authorship 4

- Guarantors: persons who take responsibility for the integrity of the work as a whole, from inception to published article, and publish that information.
- Some journals request one or more authors as “gaurantors”.



Role of the Editor

- The editor of a journal is the **person responsible for its entire content**. Editors must have full authority for determining the editorial content of the journal.
- Owners have the right to appoint and dismiss editors and to make important business decisions in which editors should be involved to the fullest extent possible.



Editorial Freedom

- **Editorial freedom**, or independence, is the concept that editors-in-chief have full authority over the editorial content of their journal and the timing of publication of that content.
- 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.



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 manuscripts submitted to journals by experts who are not part of the editorial staff.
- Each journal should publicly disclose its policies and average turn-around times in its Instructions to Authors.



Conflicts of Interest

- Conflict of interest exists when an author (or the author's institution), reviewer, or editor has financial or personal relationships that inappropriately influence (bias) his or her actions (such relationships are also known as dual commitments, competing interests, or competing loyalties).
- All participants in the peer-review and publication process must disclose all relationships that could be viewed as potential conflicts of interest.



Conflicts of Interest

- Editors may use information disclosed in conflict-of-interest (COI) 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.
- Potential COI related to Authors' commitments
- Potential COI related to Project support
- Potential COI related to commitments of Editors, Journal Staff, or Reviewers



Privacy

- Patients have a right to **privacy** that should not be violated without informed consent.
- Nonessential identifying details should be omitted. **Informed consent** should be obtained if there is any doubt that anonymity can be maintained.
- The requirement for informed consent should be included in the journal's Instructions for Authors.



Confidentiality

- 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.
- Confidentiality may have to be breached if **dishonesty or fraud** is alleged but otherwise must be honored.
- Reviewers must not be allowed to make copies of the manuscript and must be prohibited from sharing it with others, except with the editor's permission.



Protection of Subjects

- 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.
- When reporting experiments on animals, authors should indicate whether the institutional and national guide for the care and use of laboratory animals was followed.



Publishing and Editorial Issues

- Obligation to publish negative studies
- **Corrections**: 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.
- **Scientific fraud**: If substantial doubt arises, the responsibility lies with the institution where the work was done or with the funding agency.



Publishing and Editorial Issues: Retraction

- 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.
- **Notice of concern**: alternative to retraction
- The retraction or expression of concern, so labeled, should appear on a numbered page in a prominent section, be listed in the Table of Contents page, and include in its heading the title of the original article.



Publishing and Editorial Issues: Copyright

- Transfer copyright to the journal in most journals.
- Some “open-access” journals do not require copyright transfer.
- Various copyright status by article in a given journal



Overlapping Publications 1

- Multiple submission
- **Redundant publication**: publication of a paper that overlaps substantially with one already published
- 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.



Overlapping Publications 2

- 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.
- **Any such report must be referred to and referenced in the new paper.** Copies of such material should be included with the submitted manuscript.



Acceptable Secondary Publication 1

1. The authors have received **approval** from the editors of both **journals**.
2. The priority of the primary publication is respected by a publication interval of at least 1 week.
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**.



Acceptable Secondary Publication 2

“This article is based on a study first reported in the [title of journal, with full reference].”

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.
7. Editors of journals that simultaneously publish in multiple languages should understand that NLM **indexes the primary language version**.



Competing Manuscripts Based on the Same Study

- Submissions by coworkers who disagree on the analysis and interpretation of their study: the authors should submit a manuscript that clearly presents both versions. If the dispute cannot be resolved and the study merits publication, both versions should be published.
- Submissions by coworkers who disagree on what the facts are and which data should be reported: the journal editor should refuse publication until the disagreement is resolved.



Competing Manuscripts Based on the Same Database

- The manuscripts may differ in their analytic methods, conclusions, or both. Each manuscript should be considered separately.



Correspondence

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



Supplements and Special Series

- 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.
 1. The journal editor must be given and take full responsibility for the policies, practices, and content of supplements.
 2. Authority to send external peer review
 3. Appointment of external editor
 4. Statement of source of idea for the supplement
 5. Advertising in the same policies
 6. Differentiate pages in supplements
 7. Do not accept any favor
 8. Secondary publication in the same principle
 9. Authorship and conflict of interest: same



Electronic Publication

- Common and popular, increasing by both publication
- Alternative to print publication
- 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.



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.
- Editors must have full and final authority for approving advertisements and enforcing advertising policy.



General Media

- Researchers and institutions sometimes 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.
- Embargo system: prevent publication of stories in the general media before publication



Obligation to Register Clinical Trials

- Clinical trial: 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.
- ICMJE member journals will require, as a condition of consideration for publication in their journals, registration in a public trials registry.
- The ICMJE recommends that journals publish the trial registration number at the end of the abstract



IV. Manuscript Preparation and Submission

- The manuscript should be prepared according to journals' Instructions to Authors.
- Text: IMRAD Structure for originals. Introduction, Methods, Results, and Discussion
- Subheadings
- Different format for case reports, reviews, and editorials
- Adding details in electronic formats
- Double spacing in title page, abstract, text, references, acknowledgements, figure legends
- Paging consecutively beginning with the title page



Title Page

- Article Title
- Authors' names and institutional affiliations
- The name of the department(s) and institution(s)
- Disclaimers, if any
- Contact information for corresponding authors
- The name and address of the author to whom requests for reprints should be addressed
- Source(s) of support in the form of grants
- A running head
- Word counts, number of figures and tables



Conflict-of-Interest Notification Page

- Uniform disclosure form: available for member journals at http://www.icmje.org/coi_disclosure.pdf



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 subjects or laboratory animals, observational and analytical methods), main findings (giving specific effect sizes and their statistical significance, if possible), principal conclusions, and funding sources.



Introduction

- A **brief background**, references to the most pertinent papers general enough to inform readers, and the relevant findings of others should be included. The specific question that the authors' particular investigation studied should also be stated.



Methods

- The Methods section should include only information that was available at the time the plan or protocol for the study was being written.
- 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.
- 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.
- Describe statistical methods with enough detail.



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.
- Avoid nontechnical uses of technical terms in statistics, such as “random” (which implies a randomizing device), “normal,” “significant,” “correlations,” and “sample.”



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.
- Link the conclusions with the goals of the study but avoid unqualified statements and conclusions not adequately supported by the data.



References

- Small numbers of references to key original papers often serve as well as more exhaustive lists.
- Cite preferably electronic version of published papers.
- Avoid using abstracts as references.
- References to papers accepted but not yet published should be designated as “in press” or “forthcoming”.
- 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”.
- Check the accuracy of all reference citations to minimize errors



Tables

- Tables capture information concisely and display it efficiently.
- Type or print each table with double-spacing 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: use the following symbols, in sequence *, †, ‡, §, ¶, **, ††, ‡‡, §§, , ¶¶.
- If you use data from another published or unpublished source, obtain permission and acknowledge that source fully.



Illustrations

- Figures should be either professionally drawn and photographed, or submitted as photographic-quality digital prints.
- Some journals ask authors for electronic files of figures in a format (JPEG or GIF).
- Letters, numbers, and symbols should be clear consistent.
- Figures should be self-explanatory as possible.
- Figures should be numbered consecutively according to the order in which they have been cited in the text.



Legends for Illustrations

Units of Measurement

- Type legends for illustrations using double spacing, starting on a separate page, with Arabic numerals corresponding to them.
- When symbols, arrows, numbers, or letters are used to identify parts of illustrations, identify and explain each one clearly.
- Measurements of length, height, weight, and volume should be reported in metric units (meter, kilogram, or liter).
- Temperature should be in degrees Celsius.
- Authors must consult the Information for Authors of the journal and should report laboratory information in both local and International System of Units (SI).



Abbreviations and Symbols

- Use only standard abbreviations.
- Avoid abbreviations in the title.
- The spelled-out abbreviation followed by the abbreviation in parenthesis should be used on first mention.



Sending the Manuscript to the Journal

- Most journals accept electronic submission.
- Paper version submission: required copies of the manuscript and figures
- Cover letter must accompany manuscripts with statements
 - All submissions and previous reports that might be regarded as redundant publication
 - Financial or other relationships that might lead to a conflict of interest
 - Reading and approval by all the authors, proper authorship, and the manuscript represents honest work.
- Name, address, and telephone number of the corresponding author
- The letter should give any additional helpful information.
- Encourage previous submission and review comments.
- Provide presubmission checklist



Cover Letter

- Brief introduction to the paper
- Declare originality of data, not duplicate publication even in part, not multiple submission
- Declare no more publication if accepted
- Disclosure of “conflict of interest”
- Authorship declaration



Others for the Uniform Requirements

- References
- About the International Committee of Medical Journal Editors
- Authors of the Uniform Requirements for Manuscripts Submitted to Biomedical Journals
- Use, Distribution, and Translation of the Uniform Requirements
- Inquiries



Open Discussion 1

1. 35명 치료 환자의 5-10년간 경과를 보고한 원저 논문 접수. 심사 중에 동일 저자가 41명 동일 질병 환자의 치료 1년간 추적 결과를 발표한 논문을 발견하였다.
2. 편집인에게 학회 원로 회원이 2010년도 모든 접수된 원고의 목록(논문제목, 저자명)의 정보공개를 요구하였다.



Open Discussion 2

3. 이미 발표된 논문의 저자명이 잘못되었다면
서 저자의 일부를 교체하고 순서를 조정하
는 요청을 받았다.
4. 논문 한 편에 공동일저자와 공동책임저자의
인쇄를 요청받았다.
5. 편집인의 게재거부 결정에 저자가 강하게
반발하면서 승복하지 않는다.

