

UNIFORM REQUIREMENTS

FOR MANUSCRIPTS SUBMITTED TO BIOMEDICAL
JOURNALS:

WRITING AND EDITING FOR BIOMEDICAL JOURNALS

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TRAINING SESSION ON INTRODUCTORY BIOETHICS: RESEARCH ETHICS
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ABOUT THE UR

- The Vancouver Group (1978)
- The International Committee of Medical Journal Editors (ICMJE)
- Most recent version of UR - 2004

POTENTIAL USERS

- “...to help authors and editors in their mutual task of creating and distributing accurate, clear, easily accessible reports of biomedical studies.”
- Other stake holders -- peer reviewers, publishers, the media, patients and their families, general readers.

AUTHORSHIP AND CONTRIBUTORSHIP

- “An ‘author’ is generally considered to be someone who has made substantive intellectual contributions to a published study...”
- Requirement for disclosure of contributorship and guarantorship

WHO IS THE AUTHOR?

- Substantial contribution to conception and design, or acquisition of data, or analysis and interpretation of data
- drafting the article or revising it critically for important intellectual content
- final approval of the version to be published

MULTI-CENTER GROUP

- In case of large, multi-center group, individuals who are directly responsible for the manuscript should be identified.
- These should meet the authorship criteria.
- Corresponding author should supply the names of the team and the group name.

AUTHORSHIP

- “Acquisition of funding, collection of data, or general supervision of the research group, alone, does not justify authorship.”
- “All persons designated as authors should qualify for authorship, and all those who qualify should be listed.”

AUTHORSHIP

- “Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.”

GUARANTOR

- “the person who takes the responsibility for the integrity of the work as a whole, from inception to published article, and publish that information.”

ACKNOWLEDGMENTS

- “All contributors who do not meet the criteria for authorship should be listed in an acknowledgments section.”
- Persons who provide technical help, typists, librarians, lab assistants, department chairs, etc.

SCIENTIFIC MISCONDUCT

- Fabrication
- Falsification
- Plagiarism
- Misrepresentation of authorship
- Unreasonable delaying review or publication for personal gain

PLAGIARISM

- Taking words or ideas from another article and present them as if they were one's own.
- Paraphrasing without citation is a case of plagiarism
- Why plagiarism is not allowable

THE ROLE OF THE EDITOR

- “The editor of a journal is the person responsible for its entire content.”
- Difference between owner and editor of a journal.
- Example -- Journal of the Medical Association of Thailand

EDITORIAL FREEDOM

- “The concept of editorial freedom should be resolutely defended by editors even to the extent of their placing their positions at stake.”
- Important role of the Editorial Advisory Board.

EDITORIAL FREEDOM

- “...editors-in-chief should have full authority over the editorial content of their journal.”
- “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.”

EDITORIAL FREEDOM

- “Editors should be free to express critical but responsible views about all aspects of medicine without fear of retribution, even if these views might conflict with the commercial goals of the publisher.”

EDITORIAL FREEDOM

- “Editors and editors’ organizations have the obligation to support the concept of editorial freedom and to draw major transgressions of such freedom to the attention of the international medical, academic, and lay communities.”

PEER REVIEW

- Essential part of scholarly endeavor and scientific process
- “critical assessment of manuscripts submitted to journals by experts who are not part of the editorial staff.”
- Policies regarding reviewing.

CONFLICTS OF INTEREST

- Conflicts of interest can undermine the credibility of the work and of the journal.
- “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...”

CONFLICT OF INTEREST

- Example --
 - Publication of an article reporting effectiveness of a certain drug when the journal is sponsored by the manufacturer.
 - Reviewers have a personal relationship with authors and are influenced by it.

CONFLICT OF INTEREST

- “All participants in the peer review and publication process must disclose all relationships that could be viewed as presenting a potential conflict of interest.”

INDIVIDUAL AUTHOR'S COMMITMENTS

- Authors should reveal any potential conflict of interests that could bias their work.
- Conflict of Interest Notification Page

PROJECT SUPPORT

- **Academic integrity**
- “Authors should describe the role of the study sponsor, if any, in study design; in the collection, analysis, and interpretation of data; in the writing of the report; and in the decision to submit the report for publication.”

EDITORS, REVIEWERS OR JOURNAL STAFF

- Editors should avoid peer reviewers who have potential conflicts of interests with the author.
- “Reviewers must disclose to editors any conflicts of interest that could bias their opinions of the manuscript, and they should disqualify themselves from reviewing specific manuscripts if they believe it to be appropriate.

EDITORS, REVIEWERS OR JOURNAL STAFF

- “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 involvement in any of the issues they might judge.”

PRIVACY AND CONFIDENTIALITY

- Patients have a right to privacy that should not be infringed without informed consent.
- Informed consent should be obtained if there is any doubt -- the rule is to protect the privacy of the patient or the research subject.

INFORMED CONSENT

- The fact that informed consent has been obtained from the research participants should be explicitly mentioned in the text of the article.

AUTHORS AND REVIEWERS

- Editors should protect the confidentiality of the author, and likewise they should also respect the confidentiality of the reviewers.
- Privileged communication -- manuscripts are private property of the author.

PROTECTION OF HUMAN SUBJECTS AND ANIMALS

- Authors should tell that their work conforms to the guidelines which are generally accepted.
- Helsinki Declaration
- The same goes for research on animals.

PUBLISHING AND EDITORIAL ISSUES

- Corrections and Retractions
 - ‘Scientific fraud’ -- if this is detected, then the journal must print a retraction.
 - The first author in the retracted article should be the one who writes the retraction.

COPYRIGHT

- In most cases, the author will be asked to transfer the copyright to the publisher of the journal.
- But there are now more 'open access' journals, mostly in electronic form.

DUPLICATE SUBMISSION

- Most journals will not consider articles that have simultaneously been submitted to other journals.
- Possibility of same pool of reviewers, or publishing the same article, disagreements as to copyright, etc.

REDUNDANT PUBLICATION

- Articles that are substantially the same as another, previous one.
- Author should tell editors of any redundant publications.
- 'Pre-prints' -- circulation of 'first drafts'

OBLIGATION TO REGISTER CLINICAL TRIALS

- Starting July 1, 2005, manuscripts submitted to ICMJE journals will be required to be registered in publicly accessible databases.

REASONS FOR REGISTRATION

- “By suppressing negative findings and exaggerating positive ones, by downplaying harms and talking up benefits, healthcare decisions are based on incomplete data and ultimately harm the patients” (Abbasi K, BMJ 2004; 329:637-638)

REGISTRATION SITE

- www.clinicaltrials.gov
- Other sites are allowable, if they satisfy all the criteria.

BMJ'S CRITERIA FOR A SUITABLE REGISTRY

- Free to access, searchable, and identifies trials with a unique number
- Registration is free or has minimal cost
- Registered information is validated
- Registered entry includes details to identify the trial and investigator and includes the status of the trial
- The research question, methodology, intervention, funding, and sponsorship must all be disclosed.

ขอบคุณครับ!