

EMHJ Guidelines on Ethical Conduct and Publication of Health Research

Published on the following pages are the EMHJ Guidelines on Ethical Conduct and Publication of Health Research. They are also available on the EMHJ webpage. These Guidelines set out key issues related to research and publication ethics and EMHJ's expectations of papers submitted for possible publication. They are intended as a reference for both authors and reviewers.

Background to the development of the Guidelines

Adherence to ethical standards for the conduct and reporting of research is not only a moral imperative but it also results in better and more meaningful research.

As with all research journals, EMHJ has encountered cases of suspected infringement of ethical research conduct and publication, including lack of ethical clearance and/or informed consent of participants when needed and instances of plagiarism and duplicate publication. Our experience in addressing such incidents suggested that in some cases the authors were genuinely unaware of or unfamiliar with key ethical aspects of research conduct and publication, for example what constitutes plagiarism, why duplicate publication is unacceptable. While we provide brief information in the EMHJ authors' guidelines and links to relevant sites and publications, we have had no explicit or detailed guidelines on research and publication ethics and EMHJ's position on these issues and response to cases of suspected ethical misconduct.

It was considered that such guidelines were needed to make EMHJ's position known and transparent and to provide authors with clear and easily accessible information on the important ethical issues to help ensure that their papers were ethically compliant. Therefore review and endorsement of draft guidelines on ethical conduct and publication of health research was included in the agenda of the Expanded EMHJ Editorial Meeting in June 2015.

In preparation for the meeting, and based on key resources and documents from leading institutions and associations for research and publication ethics, guidelines were drafted and revised inhouse in April and May 2015. These were shared with the Editorial Board members and other invited participants of the Expanded Board meeting before the meeting and their comments invited. All participants provided their observations and these were compiled for review at the meeting. In follow-up and in line with the discussions and observations made at the meeting, the guidelines were further revised and finalized.

EMHJ would like to thank all the Board Members and participants of the Expanded EMHJ Editorial Meeting for their valuable contribution to the preparation of these Guidelines.

EMHJ Guidelines on Ethical Conduct and Publication of Health Research

EMHJ endeavours to maintain the highest ethical standards for the articles it publishes. In order to do so, the Journal follows established international standards and guidelines on the conduct and publication of health research including: World Medical Association's Declaration of Helsinki; the *Council for International Organizations of Medical Sciences* (CIOMS); the Committee on Publication Ethics (COPE); the International Committee of Medical Journal Editors (ICMJE); and the World Association of Medical Editors (WAME).

These guidelines explain the EMHJ's position on specific ethical aspects of the conduct and reporting of research. They provide authors with guidance on the ethical standards they are expected to conform to in their papers submitted for consideration for publication, and outline EMHJ's procedures if standards are breached.

Authors' responsibilities

Papers submitted for consideration for publication to the EMHJ should comply with the Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly work in Medical Journals of the ICMJE.

Ethical approval

EMHJ expects authors to adhere to the Ethical Principles for Medical Research Involving Human Subjects laid down in the World Medical Association's Declaration of Helsinki and CIOMS. For research involving humans, every research article submitted to EMHJ must include a declaration that before carrying out its field work, the study had obtained ethical clearance from a recognized body in the country, for example from institutional review boards or research ethics committees. Ethical clearance from non-national bodies might be acceptable if there is a valid justification (e.g. lack of any national or local ethics committee). EMHJ may require to see the relevant documentation of ethical approval. Research involving animals will also be expected to follow the related standards of ethical research. If ethical clearance was not considered to be required, a statement to that effect must be provided indicating the reasons it was not required. In any case, the authors are expected to follow all requirements of ethical conduct of research, reporting of the findings and preparation of the manuscript.

Informed consent

EMHJ requires, where appropriate, a statement from the authors that all persons who participated in research had given their voluntary, informed written consent. Verbal consent might be acceptable, however, if there is a reasonable justification or where sanctioned by the body providing the ethical approval. Where participants were unable to give such consent, surrogate consent might be acceptable (e.g. from a parent), however surrogate consent always requires ethical approval. Authors may be asked to provide copies of detailed informed consent form, including explanatory information provided to participants.

Participant confidentiality and respect

Manuscripts should be prepared to preserve participants' confidentiality. Authors are expected to obtain an individual's explicit consent for the use of any personal or medical information that may make the participant identifiable. Authors are expected to ensure the dignity and respect of the participants and their communities in the manuscript.

Competing interests

EMHJ requires authors to provide details of any competing interests. A competing interest may occur when the author(s) personal, family or institutional interests (e.g. sources of funds, earnings, relationships, etc.) might be affected by the research, its findings or publication of the manuscript. EMHJ will not reject a paper solely on the basis of a declared competing interest but will take this into consideration when assessing a paper and, if considered relevant, it may be included in the published paper.

Funding

EMHJ requires authors to state all sources of funding for the study.

Clinical trials registration

EMHJ requires registration of clinical trials in a public trials registry before undertaking the trial as a condition of consideration for publication (more information can be obtained by visiting the web link: http://www.who.int/ictrp/trial_reg/en/).

Authorship

EMHJ follows the ICMJE Recommendations on authorship credits, which aim to ensure that all and only those who have made material contribution to the research are named as authors. These require that all four of the following criteria be met to be considered an author:

- substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- drafting the work or revising it critically for important intellectual content; AND
- final approval of the version to be published; AND
- agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Every person who meets all four criteria should be identified as an author. Those who meet some but not all of these criteria should be included in an acknowledgement. It should be noted that data collection, laboratory testing, data management, acquisition of funds, provision of support for the study, etc. do not qualify (on their own) for being included in the list of authorship.

Previous publication

EMHJ expects papers submitted to be original and not published, accepted for publication or currently under consideration for publication elsewhere. EMHJ requires authors to affirm this and disclose any papers that overlap with the submitted paper. This applies to paper(s) published in other languages, although translation may occasionally be considered with the agreement of the other journal. Oral presentation of study findings at a conference or publication of an abstract only in conference proceedings does not normally prohibit submission of the full paper to the EMHJ. Such abstracts should not exceed 500 words.

Scientific misconduct

EMHJ takes any allegation or evidence of scientific misconduct seriously. Examples of scientific misconduct include:

Violation of ethical research standards: failing to adhere to standards for research involving humans and animals.

Fabrication and falsification of data and abuse of accepted research practices: making up data, deliberately suppressing and/or altering data, and manipulating experiments/analysis to obtain desired results.

Plagiarism: using the published language, ideas of others without appropriate acknowledgment of their source and representing them as one's own. When referring to the published ideas/opinions of others full referencing is expected. Brief quoted statements could be acceptable, if good justification is provided and they are placed within inverted commas.

Duplicate publication: this refers to publication of a paper by at least some of the same authors that overlaps substantially with another one already published, without clear reference to the previous publication. Duplicate publication is considered unethical in particular for original research because it can lead to double-counting of data and inappropriate weighting of the results of a single study.

Improprieties of authorship: this refers to improperly assigning authorship credit either by inclusion ("guest" authorship) or exclusion ("ghost" authorship).

Any misconduct in the conduct of research, and preparation or submission of the manuscript is considered unacceptable for publication in the EMHJ.

EMHJ's response to possible scientific misconduct

EMHJ takes seriously any suspected misconduct in research, publication or professional behaviour. EMHJ will investigate, in confidence, any cause of concern on a case-by-case basis and seek resolution.

EMHJ will follow the guidelines and recommendations of recognized bodies including COPE, the ICMJE, and the World Association of Medical Editors (WAME). EMHJ may seek advice from internal or external sources of advice if needed.

In most cases, EMHJ will endeavour to resolve the issue in the first instance by discussion with the author(s). However if concerns remain, the case may be reported to the appropriate authorities, including supervisors/employers, and relevant professional body(ies).

Submitted papers found to be in breach of publication ethics will be rejected. Even if an article would be rejected for other scientific reasons, if it is considered unethical, EMHJ may nonetheless take further action. In the case of an already published

paper, unethical behaviour may result in retraction of the paper. Authors found to have infringed ethical standards will be kept on record and may be banned from publishing in EMHJ in the future.

EMHJ responsibilities

EMHJ upholds the authors' right to fair, objective and ethical handling of their papers. EMHJ follows the WAME recommendations on best practices for Peer Review Selection. EMHJ operates a double blind peer review system and endeavours to ensure that neither the authors nor the reviewers are aware of the each other's identities. Editors and reviewers are required to declare any conflicts of interests and to maintain the confidentiality of the manuscript under review. Reviewers may not refer the manuscript to a colleague without the permission of the Editor nor make use of any part of it before publication.

Authors may appeal decisions on their papers if they believe there is good case for making an appeal. Appeals will be carefully considered.

Key resources

1. World Medical Association's Declaration of Helsinki (<http://www.wma.net/en/30publications/10policies/b3/>)
2. Council for International Organizations of Medical Sciences (<http://www.cioms.ch/>)
3. International Ethical Guidelines for Biomedical Research Involving Human Subjects (http://www.cioms.ch/publications/layout_guide2002.pdf)
4. International Guidelines for Ethical Review of Epidemiological Studies (<http://www.ufrgs.br/bioetica/cioms2008.pdf>)
5. Committee on Publication Ethics (<http://publicationethics.org/>)
6. International Committee of Medical Journal Editors (<http://www.icmje.org/>)
7. Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly work in Medical Journals of the International Committee of Medical Journal Editors (<http://www.icmje.org/icmje-recommendations.pdf>)
8. World Association of Medical Editors. Recommendations on Publication Ethics Policies for Medical Journals (<http://www.wame.org/about/recommendations-on-publication-ethics-policie>)

Additional publications and resources

WHO

1. Ethical issues in patient safety research: interpreting existing guidance (2013) (http://apps.who.int/iris/bitstream/10665/85371/1/9789241505475_eng.pdf)
2. Standards and operational guidance for ethics review of health-related research with human participants (2011) (http://apps.who.int/iris/bitstream/10665/44783/1/9789241502948_eng.pdf?ua=1&ua=1)
3. Quality practices in basic biomedical research (QPBR) training manual (2010) (http://apps.who.int/iris/bitstream/10665/44293/1/9789241599207_eng.pdf?ua=1 and http://apps.who.int/iris/bitstream/10665/44293/2/9789241599214_eng.pdf)
4. Casebook on ethical issues in international health research (2009) (http://apps.who.int/iris/bitstream/10665/44118/4/9789241547727_eng.pdf?ua=1 and http://apps.who.int/iris/bitstream/10665/44118/17/9789290219576_ara.pdf)
5. Research ethics committees: basic concepts for capacity-building (2009) (http://apps.who.int/iris/bitstream/10665/44108/1/9789241598002_eng.pdf?ua=1)
6. Marshall PA. Ethical challenges in study design and informed consent for health research in resource-poor settings. UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases http://apps.who.int/iris/bitstream/10665/43622/1/9789241563383_eng.pdf?ua=1)
7. WHO ethical and safety recommendations for researching, documenting and monitoring sexual violence in emergencies (2007) (http://apps.who.int/iris/bitstream/10665/43709/1/9789241595681_eng.pdf and http://apps.who.int/iris/bitstream/10665/43709/2/9789241595681_ara.pdf)

8. Scientific working group on life science research and global health security: report of the first meeting, Geneva, Switzerland, 16-18 October 2006 (2007) (http://apps.who.int/iris/bitstream/10665/80111/1/WHO_CDS_EPR_2007.4_eng.pdf)
9. Handbook: quality practices in basic biomedical research 2006 (http://apps.who.int/iris/bitstream/10665/43512/1/9241594454_eng.pdf)
10. A practical guide for health researchers (2004) (<http://applications.emro.who.int/dsaf/dsa237.pdf>)
11. Manual for editors of health science journals (2009) (<http://applications.emro.who.int/dsaf/dsa1034.pdf>)
12. Regulation of privacy and data protection in the use of electronic health information. An international perspective and reference source on regulation and legal issues related to person-identifiable health databases. Pan American Health Organization (2001).

Further WHO publications related to the ethics of specific issues can be found at: <http://www.who.int/ethics/publications/year/en/>

Other

1. Council of Science Editors. White Paper on Publication Ethics (<http://www.councilscienceeditors.org/resource-library/editorial-policies/white-paper-on-publication-ethics/>)
2. The Office of Research Integrity (<http://ori.hhs.gov/about-ori>)
3. National Institutes of Health. Office of Clinical Research and Bioethics Policy (<http://osp.od.nih.gov/office-clinical-research-and-bioethics-policy>)
4. Ethics and Research Guidance. Medical Research Council, UK (<http://www.mrc.ac.uk/research/research-policy-ethics/>)
5. Equator Network (Enhancing the QUAlity and Transparency Of health Research). Research ethics, publication ethics and good practice guidelines (<http://www.equator-network.org/library/research-ethics-publication-ethics-and-good-practice-guidelines/#etguid>)
6. Miguel Roig. Avoiding plagiarism, self-plagiarism, and other questionable writing practices: A guide to ethical writing (2006) (<http://www.cse.msu.edu/~alexliu/plagiarism.pdf>)
7. Danis M, Largent E, Grady C, Wendler D, Chandros Hull S, Shah S, et al. Research ethics consultation: a casebook. OUP; 2012.