

Guidelines on Ethical Conduct and Publication of Health Research

The General Directorate of Research and Studies (GDRS)
MOH, KSA Responsibilities / Duties and Recommendation

These concise guidelines set out key issues related to research and publication ethics of papers submitted for publication as well as the duties, responsibilities and recommendations of the General Directorate for Research and Studies (GDRS) in this regard. They are intended as a reference for MOH authors and Institutional Review Boards (IRBs), along with health journal's reviewers, editors and publishers as well.

Background to the Development of the Guidelines:

The guidelines are needed to provide authors with clear and easily accessible information on the important issues to ensure that their papers are ethically compliant. GDRS endeavours to maintain the highest ethical standards for the published health research articles. The Directorate 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).

Adherence to ethical standards for the conduct and reporting of research is not only a moral imperative but it also improves the research quality. All research journals, have encountered cases of suspected violation 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. In some cases, the authors were unaware of or unfamiliar with key ethical aspects of research conduct and manuscript publication.

Allegations Against an Author:

An allegation of ethical misconduct can have a severe impact on a researcher's career, so it's always important to fully investigate it. There are several recommended steps to be followed:

- Notify the publisher.
- Consult the relevant Local Institutional Review Board (IRB).
- Ensure giving the author the opportunity to respond.
- Discuss the findings with the publisher – depending on the severity of the case, you may need to involve the author's institution, employer, or funder.
- Keep records of all written communication.
- Maintain confidentiality.
- Refer / elevate the matter to MOH Central Institutional Review Board (CIRB).
- Remain neutral – it's important not be influenced by third parties.
- Act with integrity and if the situation has arisen through a lack of knowledge on the author's part, educate them.



Ethical Publishing:

- Authorship of the paper: Authorship should be limited to those who have made a significant contribution to the conception, design, execution, or interpretation of the reported study.
- Originality and plagiarism: The authors should ensure that they have written entirely original works, and if the authors have used the work and /or words of others that should be appropriately cited or quoted.
- Data access and retention: Authors may be asked to provide the raw data in connection with a paper for editorial review, and should be prepared to provide public access to such data.
- Multiple, redundant or concurrent publication: An author should not in general publish manuscripts describing essentially the same research in more than one journal or primary publication. However, Elsevier does not view the following uses of a work as prior publication: publication in the form of an abstract; publication as an academic thesis; publication as an electronic preprint.
- Acknowledgement of sources: Proper acknowledgment of the work of others must always be given.
- Disclosure and conflicts of interest: All submissions must include disclosure of all relationships that could be viewed as a potential conflict of interest.
- Fundamental errors in published works: When an author discovers a significant error or inaccuracy in his/her own published work, it is the author's obligation to promptly notify the journal editor or publisher and cooperate with the editor to retract or correct the paper.
- Reporting standards: Authors of reports of original research should present an accurate account of the work performed as well as an objective discussion of its significance.
- Hazards and human or animal subjects: Statements of compliance are required if the work involves chemicals, procedures or equipment that have any unusual hazards inherent in their use, or if it involves the use of animal or human subjects.
- Use of patient images or case details: Studies on patients or volunteers require IRB approval and informed consent, which should be documented in the paper.

Authors' Responsibilities:

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

Ethical Approval:

The author of medical research involving human subjects should comply with ethical principles according to the World Medical Association's Declaration of Helsinki and CIOMS. For research involving humans, every research article must include a declaration that before carrying out its field work, the study had obtained ethical clearance from an institutional review board. The relevant documentation of ethical approval may be required. 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 must be provided indicating the reasons it was not required.

GDRS has the right to retract (withdraw) the published manuscript when the author of health research affiliated to MOH did not comply with ethical principles such as: The author of the research article did not obtain ethical approval from the concerned institutional review board (IRB) prior to carrying out the fieldwork.

Informed Consent:

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, if there is a reasonable justification or where agreeable by the relevant IRB. Where participants were unable to give such consent, alternative consent might be acceptable, however proxy consent always requires ethical approval. Authors may be asked to provide copies of detailed informed consent form, including explanatory information provided to participants.

Signing GDRS, MOH "Data Share Agreement" before Conducting the Study:

GDRS has the right to retract (withdraw) the published manuscript when the author of health research affiliated to MOH did not comply with ethical principles such as: The author of health research did not sign "Data share agreement" before conducting the study.

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. Along with ensuring the respect of the participants and their communities.

Competing Interests:

The authors should 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. The paper will not be rejected due to declared competing interest but, if considered relevant, it may be included in the published paper.

Funding:

The authors are required to state all sources of study funding.

Clinical Trials Registration:

Registration of clinical trials in The Saudi Clinical Trials Registry (SCTR) before undertaking the trial is a necessary condition for publication (more information can be obtained by visiting the web links: <https://sctr.sfda.gov.sa/Home.aspx?lang=en> & <https://sctr.sfda.gov.sa/Guidance.aspx?lang=ar>)

Authorship:

According to the ICMJE Recommendations on authorship credits, 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.

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:

The submitted papers should be original and not published, accepted for publication or currently under consideration for publication elsewhere. The authors are required to affirm this and disclose any papers that overlap with the submitted paper. This applies to paper(s) published in other languages. 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 for publication. Such abstracts should not exceed 0.. words.

Scientific Misconduct:

Allegations or evidence of scientific misconduct should be taken seriously. Examples of scientific misconduct include:

1. **Violation of ethical research standards:** failure to adhere to standards for research involving humans and animals.
2. **Fabrication and falsification of data and abuse of accepted research practices:** making up data, intentionally altering data, and manipulating experiments/analysis to obtain desired results.

GDRS has the right to retract (withdraw) the published manuscript when there is a proven evidence that the author of health research affiliated to MOH has practiced scientific misconduct such as; fabrication, falsification of data and abuse of accepted research practices.

3. **Plagiarism:** using the published language, ideas of others without proper 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 placed within inverted commas.
4. **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.
5. **Improprieties of authorship:** this refers to improperly assigning authorship credit either by inclusion ("guest" authorship) or exclusion ("ghost" authorship).
6. Any misconduct in the conduct of research, and preparation or submission of the manuscript is considered unacceptable for publication.

Response to Possible Scientific Misconduct:

The suspected misconduct in research publication or professional behavior should be taken seriously. Any cause of concern will be investigated on a case-by-case basis and seek resolution. GDRS will follow the guidelines and recommendations of recognized bodies including COPE, the ICMJE, and WAME.

In most cases, GDRS will endeavor to resolve the issue in the first instance by a discussion with the author(s), stakeholders, and through the local IRB. However, if concerns remain, the case may be reported the King City Ethics Oversight Office Abdulaziz for Science and Technology.

Submitted papers found to be in violation of publication ethics will be rejected. Even if an article will be rejected for other scientific reasons, if it is considered unethical, GDRS has the right to take further action.

In the case of an already published paper, unethical behavior may result in the request for retraction of the paper. Authors found to have infringed ethical standards will be kept on record and may be prohibited from submission for obtaining IRB in the future.

Duties of the Publisher:

- 1. Guardianship of the scholarly record:** The publisher should support maintaining the integrity of the scholarly record. The publisher should establish, adopt and seriously apply policies and procedures to support editors, reviewers and authors in performing their ethical duties under the relevant guidelines. Furthermore, working with other publishers to set standards for best practices on ethical matters, errors and retractions.
- 2. Safeguard editorial independence:** The publisher must ensure that advertising, reprint or other commercial revenue have no influence on editorial decisions.
- 3. Collaborate to set industry best practice:** The publisher should promote best practice by offering editors membership of the Committee on Publication Ethics (COPE) and providing editors with Crossref Similarity Check reports for all submissions to editorial systems.
- 4. Provide editors with technical, procedural & legal support:** The publisher must support editors in communicating other journals and /or publishers and to provide specialized legal review and counsel if necessary.
- 5. Educate researchers on publishing ethics:** The publisher ought to provide extensive education and advice on publishing ethics standards, particularly for early career researchers.

Duties of Editors:

1. Publication decisions

The editor of a learned journal is solely and independently responsible for deciding which of the articles submitted to the journal should be published.

2. Peer Review

The editor shall ensure that the peer review process is fair, unbiased, and timely.

3. Fair Play

The editor should evaluate manuscripts for their intellectual content without regard to race, gender, sexual orientation, religious belief, ethnic origin, citizenship, or political philosophy of the authors.

4. Journal Metrics

The editor must not attempt to influence the journal's ranking by artificially increasing any journal metric.

5. Confidentiality

The editor must protect the confidentiality of all material submitted to the journal and all communications with reviewers, unless otherwise agreed with the relevant authors and reviewers.

6. Declaration of Competing Interests

Any potential editorial conflicts of interest should be declared to the publisher in writing prior to the appointment of the editor, and then updated if and when new conflicts arise.

7. Vigilance over the Published Record

The editor should work to safeguard the integrity of the published record by reviewing and assessing reported or suspected misconduct (research, publication, reviewer and editorial), in conjunction with the publisher (or society).

Duties of Reviewers:

- 1. Contribution to Editorial Decisions:** Peer review assists the editor in making editorial decisions and through the editorial communications with the author may also assist the author in improving the paper. In addition to the specific ethics-related duties. Reviewers are asked generally to treat authors and their work as they would like to be treated themselves. Any selected referee who feels unqualified to review the research reported in a manuscript should notify the editor and decline to participate in the review process.
- 2. Confidentiality:** Any manuscripts received for review must be treated as confidential documents. Reviewers must not share the review or information about the paper with any one or contact the authors directly without permission from the editor. Unpublished materials disclosed in a submitted manuscript must not be used in a reviewer's own research without the express written consent of the author.

3. **Alertness to Ethical Issues:** A reviewer should be alert to potential ethical issues in the paper and should bring these to the attention of the editor, including any substantial similarity or overlap between the manuscript under consideration and any other published paper of which the reviewer has personal knowledge. Any statement that an observation, derivation, or argument had been previously reported should be accompanied by the relevant citation.
4. **Standards of Objectivity & Competing Interests:** Reviews should be conducted objectively. Reviewers should be aware of any personal bias when reviewing a paper. Referees should express their views clearly with supporting arguments. Reviewers should consult the Editor before agreeing to review a paper where they have potential conflicts of interest resulting from competitive, collaborative, or other relationships or connections with any of the authors, companies, or institutions connected to the papers. If a reviewer suggests that an author includes citations to the reviewer's work, this must be for scientific reasons and not with the intention of increasing the reviewer's citation count.

Authors Have a Right to Appeal Editorial Decisions:

1. Journals should consider establishing and publishing a mechanism for authors to appeal editorial decisions.
2. Editors should allow appeals to override earlier decisions following appropriate reconsideration of the editorial process and decision making (for example, additional factual input by the authors, revisions, extra material in the manuscript, or appeals about conflicts of interest and concerns about biased peer review).
3. Editors should mediate all exchanges between authors and peer reviewers during the peer-review process. Editors may seek comments from additional peer reviewers to help them make their final decision.
4. Journals should state in their guidelines that the editor's decision following an appeal is final.
5. Journals should consider establishing a mechanism for authors and others to comment on aspects of the journal's editorial management.

GDRS, MOH Recommendation:

- GDRS recommends MOH researchers to publish their manuscripts in the most prestigious journals within the subject area, which occupy the first or the second quartiles, Q1 & Q2 respectively. As ranking journals is an essential tool for investigating the level of influence and impact of a journal on the international research community.
- GDRS warns research authors from ‘predatory publishers’. They are individuals or companies that use the open access financial system to defraud authors and readers by promising reputable publishing platforms but delivering nothing. They frequently have imaginary editorial boards, do not operate any peer review or quality control and behave unethically. They also undermine the scholarly information and publishing environment with a deluge of poor quality, unchecked and invalidated articles often published on temporary sites, thus losing long-term visibility and access to the articles and the scholarly record as well.

Key Resources:

- [1] Journal EM. EMHJ Guidelines on Ethical Conduct and Publication of Health Research. East Mediterr J 2016;Vol. 22.
- [2] Publishing E. Publishing ethics guidelines. Publ Emerald 2021. <https://www.emeraldgrouppublishing.com/our-services/journal-editors/publishing-ethics-guidelines>.
- [3] Elsevier. Ethical publishing Policies & guidelines Copyright. Elsevier 2021. <https://www.elsevier.com/authors/policies-and-guidelines>.
- [4] Elsevier. Ethical publishing Policies & guidelines. Elsevier 2021. <https://www.elsevier.com/about/policies/publishing-ethics>.
- [5] SAUDI CLINICAL TRIALS REGISTRY-SCTR. SAUDI CLINICAL TRIALS REGISTRY GUIDANCE. SCTR 2021. <https://sctr.sfda.gov.sa/Guidance.aspx?lang=ar>.
- [6] Editors. WA of M. Recommendations on Publication Ethics Policies for Medical Journals. World Assoc Med Ed 2021. <https://wame.org/recommendations-on-publication-ethics-policies-for-medical-journals>.
- [7] ASSOCIATION WM. World Medical Association's Declaration of Helsinki. WORLD Med Assoc 2021. <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>.
- [8] SCIENCES CFIOOM. COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES. Counc Int Organ Med Sci 2021. <https://cioms.ch/>.
- [9] publicationethics.org. Promoting integrity in scholarly research and its publication. COPE 2021. <https://publicationethics.org/>.
- [10] Editors I committee of medical J. Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals. Ed Int Comm Med J 2021. <http://www.icmje.org/recommendations/>.
- [11] Wiley. Best Practice Guidelines on Research Integrity and Publishing Ethics,. Wiley 2021. <https://authorservices.wiley.com/ethics-guidelines/index.html>.
- [12] Beall J. Best practices for scholarly authors in the age of predatory journals. Ann R Coll Surg Engl 2016;98. <https://doi.org/10.1308/rcsann.2016.0056>.