INSTRUCTION FOR AUTHORS

Thank you for your interest in Translational Gastroenterology and Hepatology (TGH). Please consult the following instructions to help you prepare your manuscript, and feel free to contact us with any questions. To ensure fast peer review and publication, manuscripts that do not adhere to the following instructions will be returned to the corresponding author for technical revision before undergoing peer review. We are looking forward to your submission.

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1. ABOUT THE JOURNAL

Translational Gastroenterology and Hepatology (Transl Gastroenterol Hepatol; TGH; Online ISSN 2415-1289) is an open-access, peer-reviewed online journal that focuses on cutting-edge findings in the field of translational research in gastroenterology and hepatology and provides current and practical information on diagnosis, prevention and clinical investigations of gastrointestinal, pancreas, gallbladder and hepatic diseases. Specific areas of interest include, but not limited to, multimodality therapy, biomarkers, imaging, biology, pathology, and technical advances related to gastrointestinal and hepatic diseases. Contributions pertinent to gastroenterology and hepatology are also included from related fields such as nutrition, surgery, public health, human genetics, basic sciences, education, sociology, and nursing.

TGH is indexed by PubMed/PubMed Central, Scopus and Emerging Sources Citation Index (ESCI).

Editor-in-Chief: Jia-fu Ji, MD, FACS

Journal Abbreviation: Transl Gastroenterol Hepatol

Publisher: AME Publishing Company

2. MANUSCRIPT CATEGORIES

(1) ORIGINAL ARTICLE

Word limit: 5,000 words maximum including abstract but excluding references, tables and figures.

Abstract: 450 words maximum, with sub-headers (background, methods, results and conclusions).

References: no maximum.

Figures/tables: no maximum, but 8 figures should be sufficient.

Description: Full-length reports of current research in either basic or clinical science. The meta-analysis in TGH are addressed as original article. Original article should entail a section describing the contribution of each author made to the manuscript. See section "Author contributions" for details.

(2) REVIEW ARTICLE

Word limit: 6,000 words maximum including abstract but excluding references, tables and figures.

Abstract: 450 words maximum, unstructured (no use of sub-headers).
References: no maximum.
Figures/tables: minimum 1 figure or table.

Description: Reviews are comprehensive analyses of specific topics. They are submitted upon invitation by the Editors. Proposals for reviews may be submitted; however, in this case authors should only send an outline of the proposed paper for initial consideration. Both solicited and unsolicited review articles will undergo peer review prior to acceptance. Review article should entail a section describing the contribution of each author made to the manuscript. See section "Author contributions" for details.

(3) CORRESPONDENCE

Word limit: 1000 words maximum excluding references, tables and figures.
Abstract: not required for this manuscript type.
References: 10 maximum.
Figures/tables: Only 1 table or figure.
Description: Correspondence on content published in the Journal or on other topics of interest to our readers is welcomed. The journal might invite replies from the authors of the original publication, or pass on letters to these authors. Correspondence is also referred to as Letter to the Editor.

(4) EDITORIAL

Word Limit: 2,500 words maximum excluding references, tables and figures.
Abstract: not required for this manuscript type.
References: 25 maximum.
Figures/Tables: 2 maximum.
Description: Editorial is written by recognized leader(s) in the field. It is generally solicited by the (Deputy) Editor(s)-in-Chief.

(5) EDITORIAL COMMENTARY

Word Limit: 2,500 words maximum excluding references, tables and figures.
Abstract: not required for this manuscript type.
References: 25 maximum.
Figures/Tables: 2 maximum.
Description: The Editors will invite an expert in the field to discuss a paper or report or event within the past few months or so, or in the near future and provide a commentary on the importance of each accepted paper to outline its strengths and weaknesses. It should set the problems addressed by the paper/report/event in the wider context of the field.

(6) CASE REPORT

Word limit: 2,500 words maximum excluding references, tables and figures.
Abstract: 300 words maximum, unstructured (no use of sub-headers).
References: 20 maximum.
Figures/tables: 8 maximum.
Description: New observations of diseases, clinical findings or novel/unique treatment outcomes relevant to practitioners in cardiology. The text should be arranged as follows: Introduction, Case Report, Discussion. Only cases of exceptional interest and novelty are considered. For manuscripts that do not qualify, Editors may ask authors to shorten manuscripts and rewrite as Letters to the Editor.

(7) MEETING REPORT

Word limit: 4,000 words maximum including abstract but excluding references, tables and figures.
Abstract: 350 words maximum, unstructured (no use of sub-headers).
References: no maximum.
Figures/tables: no maximum, but 8 figures should be sufficient.
Description: Brief reports of symposia and conferences in cardiovascular research. Reports must be submitted within 2 months of the meeting date in order to maintain their timeliness. Only those Meeting Reports dealing with topics of interest to the readership and that contain novel information and insights from the meeting are accepted for publication. A Meeting Report should be a thoughtful, critical commentary which shows an appreciation of the connections among the various presentations and reveals the consensus, if any, which emerged at the meeting. Before submitting a full Meeting Report, authors should only send an outline of the proposed paper for initial consideration.

(8) TECHNICAL NOTE

Word limit: 2,500 words including abstract but excluding references, tables and figures.
Abstract: 250 words maximum, unstructured (no use of sub-headers).
References: 35 maximum.
Figures/tables: 10 maximum.
Description: Technical notes articles should present a new experimental or improved method, test or procedure. The method described may either be completely new, or may offer a better version of an existing method. The article must describe a demonstrable advance on what is currently available. The method needs to have been well tested and ideally, but not necessarily, used in a way that proves its value.

(9) BRIEF REPORT

Word limit: 2,500 words including abstract but excluding
references, tables and figures.
Abstract: 250 words, unstructured (no use of sub-headers).
References: 35 maximum.
Figures<tables: 8 maximum.
Description: Manuscripts containing pertinent and interesting observations concerning cardiovascular research and reports on new observations or studies that do not warrant publication as a full research article will be considered for the Brief Reports. These submissions will undergo full peer review.

(10) CLINICAL GUIDELINE

Word limit: 6,000 words maximum including abstract but excluding references, tables and figures.
Abstract: 450 words maximum, unstructured (no use of sub-headers).
References: no maximum.
Figures<tables: minimum 1 figure or table.
Description: Guidelines need to be the product of a large group of individuals who are recognised authorities in their field. Guidelines will be written by a working party to include a steering committee (usually at least 4 members) and other authors representing a wide range of those with special relevant expertise as well as those whose everyday practice will be influenced by the guidelines.

3. STRUCTURE OF THE MANUSCRIPT

The length of manuscripts must adhere to the specifications under the section Manuscript Categories.

Manuscripts should be presented in the following order: (i) title page, (ii) abstract and key words, (iii) text, (iv) acknowledgments, (v) footnote, (vi) references, (vii) supplementary material, (viii) figure legends, (ix) tables (each table complete with title and footnotes) and (x) figures.

TITLE PAGE

The title page should contain (i) the title of the paper. 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. (ii) the full names of the authors and (iii) the addresses of the institutions at which the work was carried out together with (iv) the full postal and email address, plus facsimile and telephone numbers, of the author to whom correspondence about the manuscript should be sent. The present address of any author, if different from that where the work was carried out, should be supplied in a footnote. A short running title (less than 60 characters) should also be provided.

In keeping with the latest guidelines of the International Committee of Medical Journal Editors, for the systematic review/meta-analysis, original article and review article, the information of author contribution is needed.

ABSTRACT AND KEYWORDS

The length of abstracts must adhere to the word count specifications under the section Manuscript Categories. The abstract should state the main problem, methods, results and conclusions. Do not use reference, table or figure in the abstract. It must be factual and comprehensive. The structured abstract should state the background, methods, results, and conclusions. The use of abbreviations and acronyms should be limited and general statements (e.g. “the significance of the results is discussed”) should be avoided. The abstract of a systematic review/meta-analysis, original article and review article should be structured into four paragraphs with sub-headers of background, methods, results and conclusions. The abstracts for all other manuscript types should be unstructured.

Three to five key words should be supplied below the abstract, in alphabetical order, and should be taken from those recommended by the US National Library of Medicine’s Medical Subject Headings (MeSH) browser list at: http://www.nlm.nih.gov/mesh/meshhome.html.

TEXT

Authors must use the following sub-headers to divide the sections of their Original Article manuscript: Introduction, Methods, Results, Discussion, Acknowledgment, Footnote, References, and when relevant, Supplementary Material. Plus, authors should follow the same structures in systematic review and meta-analysis. However, review, commentary and others do not have those clear sections, they can be written in several sections with their own headers according to the topic.

AUTHOR CONTRIBUTIONS

This section is only required for systematic review/meta-analysis, original and review article. It describes the contribution of each author made to be manuscript. 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. 4) Agreement to be accountable for all aspects of the work in ensuring that questions that related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. Author should meet conditions 1, 2, 3, and 4, and all who meet the four criteria should be indentified as authors. Those who do not meet all four criteria should be acknowledged (see section
“Acknowledgement”). Please note that acquisition of funding, collection of data, language editing or general supervision of the research group alone does not constitute authorship.

The “Author Contributions” section should be completed as follow:

1. Conception and design:
2. Administrative support:
3. Provision of study material or patients:
4. Collection and assembly of data:
5. Data analysis and interpretation:
6. Manuscript writing: All authors.
7. Final approval of manuscript: All authors.

Note: 1. Manuscript writing part and Final approval of manuscript part are required to be included while other parts are based on actual applicability; 2. Contribution is not required when there is only one author.

ACKNOWLEDGMENTS

a. 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 or language editing assistance, or a department chairman who provided only general support. Financial and material support should also be acknowledged.
b. Funding: Details of all funding sources for the work in question should be included in the Acknowledgment section.
The following rules should be followed:
The sentence should begin: “This work supported by...”
The full official funding agency name should be given, i.e. “National Institutes of Health”, not “NIH” (full RIN-approved list of UK funding agencies);
Grant numbers should be given in brackets as follows: “[grant number XXX]”. Multiple grant numbers should be separated by a comma as follows: “[grant numbers XXX, YYY]”;
Agencies should be separated by a semi-colon (plus “and” before the last funding agency).
Where individuals need to be specified for certain sources of funding the following text should be added after the relevant agency or grant number “to [author initials]”; An example is given here: “This work was supported by the National Institutes of Health [AA123456 to C.S., BB765432 to M.H.]; and the Alcohol & Education Research Council [h6ygr667789]”.
c. When there is nobody or funding to be acknowledged, please describe as “None”.

FOOTNOTE

a. Conflicts of Interest: See section “Conflicts of Interest” for details.
b. Financial Disclose: Some variables, such as “measures of income inequality and degree of financial openness, are not included in our study because of the limited availability of good quality data across countries over the sample period”. When there is no financial disclose, this section should be removed.

REFERENCES

In the text, references should be cited using Arabic numerals in round brackets in which they appear consecutively [e.g., “cancer-related mortality (19)”; “heart failure (29,30)’’]. If cited in tables or figure legends, number according to the first identification of the table or figure in the text.

In the reference list, cite the names of all authors when there are three or fewer; when three or more, list the first three followed by et al. Do not use ibid. or op cit. Reference to unpublished data and personal communications should not appear in the list but should be cited in the text only (e.g. Smith A, 2000, unpublished data). All citations mentioned in the text, tables or figures must be listed in the reference list. Names of journals should be abbreviated in the style used in Pubmed. Authors are responsible for the accuracy of the references.

The format of reference sees as follow.

❖ Journal article


❖ Online article not yet published in an issue

An online article that has not yet been published in an issue (therefore has no volume, issue or page numbers) can be cited by its Digital Object Identifier (DOI). The DOI will remain valid and allow an article to be tracked even after its allocation to an issue.

❖ Book

❖ Chapter in a Book
e.g.: Gilchrist RK. Further commentary: Continent stroma. In: King LR, Stone AR, Webster GD (eds). Bladder Reconstruction and Continent Urinary Diversion. Year Book Medical, Chicago, 1987; 204-5.

TABLES

Tables should be self-contained and complement, but not duplicate information contained in the text. All tables should
be numbered consecutively in the order of reference in the text. Each column must carry an appropriate heading and, if measurements are given, the units should be given in the column heading. Column headings should be brief, with units of measurement in parentheses; all abbreviations must be defined in footnotes. Footnote symbols: †, ‡, §, ¶, should be used (in that order) and *, **, *** should be reserved for P-values. Statistical measures such as SD or SEM should be identified in the headings.

If tables have been reproduced from another source, a letter/permission from the copyright holder (usually the Publisher), stating authorization to reproduce the material, must be submitted as supplemental materials during paper submission. Plus, when a manuscript is accepted for publication, please provide us with the tables in tabular form which is convenient for copyediting and typesetting.

FIGURES

All illustrations (line drawings and photographs) are classified as figures. Figures should be numbered consecutively in the order of reference in the text. Magnifications should be indicated using a scale bar on the illustration. If figures have been reproduced from another source, a letter/permission from the copyright holder (usually the Publisher), stating authorization to reproduce the material, must be submitted as supplemental materials.

Size Figures should be sized to fit within the column (82 mm), intermediate (118 mm) or the full text width (173 mm).

Resolution Figures must be supplied as high resolution saved as .eps or .tif. Halftone figures 300 dpi (dots per inch), Color figures 300 dpi saved as CMYK, figures containing text 400 dpi, Line figures 1,000 dpi.

Color figures Files should be set up as CMYK (cyan, magenta, yellow, black) and not as RGB (red, green, blue) so that colors as they appear on screen will be a closer representation of how they will print in the Journal.

Line figures Must be sharp, black and white graphs or diagrams, drawn professionally or with a computer graphics package.

Text sizing in figures Lettering must be included and should be sized to be no larger than the journal text or 8 point (Should be readable after reduction – avoid large type or thick lines). Line width between 0.5 and 1 point.

Figure legends Type figure legends on a separate page. Legends should be concise but comprehensive – the figure and its legend must be understandable without reference to the text. Include definitions of any symbols used and define/explain all abbreviations and units of measurement.

VIDEO

TGH will accept digital files in mp4, flash video (flv.), MPEG(MPEG video file), DVD video format, mov., avi., and mwv. formats or video on CD/DVD. Contributors are asked to be succinct, and the Editor-in-chief reserves the rights to require shorter video duration if necessary. Video files can be submitted with a manuscript online: http://tgh.amegroups.com/pages/view/submit-multimedia-files.

Duration: Video files should be limited to 20 minutes.

Quality: Please set the video aspect ratio as 4:3 or 16:9 (widescreen). The original video should be of high quality. The resolution is no less than 1280*720, the frame rate no less than 24 frames per second and the bit rate no lower than 5Mbps.

Text in video: All the text notes, explanations or descriptions, etc. in the video must be in English. And the logo or watermark of hospital should not be stick on the screen. Plus, the information of patients should be erased from the video.

Video legends: Legends for the video files should be provided. The video files should be numbered consecutively in the order of reference in the text.

APPENDIX

The supplementary appendix should be paginated, with a table of contents, followed by the list of investigators (if there is one), text (such as methods), figures, tables, and then references. The supplementary appendix should not be included in the article’s reference list.

The appendix must be submitted in a Word file. The appendix will not be edited for style. It will be presented online as additional information provided by the authors.

The published article will contain a statement that supplementary material exists online and will provide the reader with a URL and link. To reference the supplementary appendix in the text of the article, refer to it as in the following example:

“Many more regressions were run than can be included in the article. The interested reader can find them in a supplementary appendix online”.

EQUATIONS

Equations should be numbered sequentially with Arabic numerals; these should be ranged right in parentheses. All variables should appear in italics. Use the simplest possible form for all mathematical symbols.

4. STYLE OF THE MANUSCRIPT

Manuscripts must follow the style of the Vancouver agreement detailed in the International Committee of Medical Journal Editors’ revised ‘Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for
Biomedical Publication’, as presented at: http://www.ICMJE.org/.

Author name Each author’s given name should be followed by family name.
Capitalize each letter of the Family name. A hyphen could be used in Family name according to the rule in Author region
Capitalize the first letter of those words/ syllables that they hope to be abbreviated in their given name, otherwise, DO NOT capitalize the first letter and use a hyphen to connect it with its anterior word.

Spelling The Journal uses US spelling and authors should therefore follow the latest edition of the Merriam–Webster’s Colloquiate Dictionary.

Units All measurements must be given in SI or SI- derived units. For more information about SI units, please go to the Bureau International des Poids et Mesures (BIPM) website at: http://www.bipm.fr.

Abbreviations Must be used sparingly – only where they ease the reader’s task by reducing repetition of long, technical terms. Initially use the word in full, followed by the abbreviation in parentheses. Thereafter use the abbreviation only.

Trade names Drugs should be referred to by their generic names. If proprietary drugs have been used in the study, refer to these by their generic name, mentioning the proprietary name, and the name and location of the manufacturer, in parentheses.

5. REVIEW PROCESS

Manuscripts are assigned sequentially to Science Editors. An Science Editor solicits reviewers (typically, two external reviews are sought). The reviewers’ evaluations and Science Editor’s comments are compiled by the Editor-in-Chief for disposition and transmittal to the authors. A decision is made usually within four weeks of the receipt of the manuscript.

The Editor-in-Chief will advise authors whether a manuscript is accepted, should be revised or is rejected. Minor revisions are expected to be returned within two weeks of decision; major revisions within three weeks. Manuscripts not revised within these time periods are subject to withdrawal from consideration for publication unless the authors can provide extenuating circumstances.

A number of manuscripts will have to be rejected on the grounds of priority and available space. A manuscript may be returned to the authors without outside review if the Editor-in-Chief and Science Editor find it inappropriate for publication in the Journal. Similarly, the Editors may expedite the review process for manuscripts felt to be of high priority in order to reach a rapid decision. Such ‘fast-track decisions’ will normally occur within one week of receipt of the manuscript.

Authors may provide the Editor-in-Chief with the names, addresses and email addresses of up to three suitably qualified individuals of international standing who would be competent to referee the work, although the Editor-in-Chief will not be bound by any such nomination. Likewise, authors may advise of any individual who for any reason, such as potential conflict of interest, might be inappropriate to act as a referee, again without binding the Editor-in-Chief.

The Editor-in-Chief’s decision is final. If, however, authors dispute a decision and can document good reasons why a manuscript should be reconsidered, a rebuttal process exists. In the first place, authors should write to the Editor-in-Chief.

All journals Manuscripts should be written in a clear, concise, direct style so that they are intelligible to the professional reader who is not a specialist in the particular field. When contributions are judged as acceptable for publication, the Editor and the Publisher reserve the right to modify manuscripts to eliminate ambiguity and repetition and improve communication between authors and readers. If extensive alterations are required, the manuscript will be returned to the author for revision.

6. ETHICAL CONSIDERATIONS

Authors must state that the protocol for the research project has been approved by a suitably constituted Ethics Committee of the institution within which the work was undertaken and that it conforms to the provisions of in accordance with the Helsinki Declaration as revised in 2013, available at: http://www.wma.net/en/30publications/10policies/b3/%20index.html. The journal retains the right to reject any manuscript on the basis of unethical conduct of either human or animal studies. All investigations on human subjects must include a statement that the subject gave informed consent. Patient anonymity should be preserved. Photographs need to be cropped sufficiently to prevent human subjects being recognized (or an eye bar should be used).

◆ For studies in the following categories:
Randomized controlled trials or other intervention research: This category includes any study that carries out medical intervention(s) on patients or healthy individuals.
Case-control study: A case-control study is designed to retrospectively analyze the exposure to the risk factor of interest in subjects with known outcomes (with or without disease; dead or alive; or, with or without other pre-determined endpoints).
Prospective cohort study: In a prospective cohort study, patients with known exposure to a risk factor are followed and then the outcomes (with or without disease; or, dead or alive) were identified.
Cross-sectional studies: Cross-sectional studies are performed to investigate the occurrence of a specific disease or the status quo of a clinical condition.
Basic or translational medical research using human specimens:
• Authors must state whether their studies had been approved by an institutional review board (IRB) (if yes, please provide
the number of approval document). For a multi-center study, IRB approval must be obtained from each center.

- The authors must state whether all the subjects had signed the informed consent forms. For subjects under 18 years of age or those with limited capacity for civil conduct, the authors must state whether their caregivers had signed the informed consent forms.
- Also, the authors should state whether the study outcomes will affect the future management of the patients.

◆ For other categories:

**Retrospective and ambispective cohort studies:** In these studies, the patients’ exposure to risk factor(s) were retrospectively identified, followed by the retrospective follow-up of the patients to determine the relationship between the future or current endpoints (with or without disease; or, dead or alive) and the exposure.

- For studies in this category, authors must state whether their study had been approved by an institutional review board (IRB) (if yes, please provide the number of approval document). For a multi-center study, IRB approval must be obtained from each center.
- Also, the authors should state whether the study outcomes will affect the future management of the patients.
- The authors must state whether all the subjects had signed the informed consent forms before enrollment. For subjects under 18 years of age or those with limited capacity for civil conduct, the informed consent forms could be signed by their family members or caregivers. For studies on patient data retrieved from hospital medical record system or social insurance systems, an informed consent form is not required; however, the authors still need to declare whether the patient’s personal data have been secured.

**Systematic review and meta-analysis, review, opinion, hypothesis, and editorial**

- No statement on medical ethics is required.

**Case report and visualized surgery:**

- No statement on medical ethics is required. However, in cases of involving new and controversial treatments, approval from IRC might be required.
- Informed consent must be obtained from the subjects or their caregivers.

**Diagnostic accuracy tests:** These studies are performed to evaluate the efficiency of a specific index test in disease diagnosis.

- For studies in this category, authors must state whether their study had been approved by an institutional review board (IRB) (if yes, please provide the number of approval document). For a multi-center study, IRB approval must be obtained from each center.
- Also, the authors should state whether the study outcomes will affect the future management of the patients.
- If the study has a prospective design: the authors must state whether all the subjects had signed the informed consent forms before enrollment. For subjects under 18 years of age or those with limited capacity for civil conduct, the authors must state whether their caregivers had signed the informed consent forms. However, for retrospective studies based on a hospital medical record system, no informed consent is required.

**Nested case-control study:** In a nested case-control study, the patients were followed up after the biological samples are obtained from the subjects, and then a subset of patients are chosen for the analysis.

If the study has a prospective design:

- Authors must state whether their study had been approved by an institutional review board (IRB) (if yes, please provide the number of approval document). For a multi-center study, IRB approval must be obtained from each center.
- Also, the authors should state whether the study outcomes will affect the future management of the patients.
- The authors must state whether all the subjects have signed the informed consent forms before they enter the study, no matter whether they enter the final analysis. For subjects under 18 years of age or those with limited capacity for civil conduct, the authors must state whether their caregivers had signed the informed consent forms.

If the study is based on a previously available specimen bank, the authors must:

- State whether the specimen bank had been approved by the IRB upon its establishment;
- State whether all the subjects had signed the informed consent forms during the establishment of the bank (attached with the numbers of approval documents).

**Post hoc analysis:** In a post hoc analysis, the authors re-examines the currently available data from different perspectives.

- The authors need to state whether the previous studies had been approved by the local medical ethics committee(s)
- Also, it is important to state whether all the subjects had signed the informed consent forms in the previous studies.

For more information on statement of ethics, please feel free to consult our editorial staff.

7. 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 is required for Case report, original/research articles and visualized surgery. The statement should be included in the footnote.

It may be possible to publish without explicit consent if the report is important to public health (or is in some other way important); consent would be unusually burdensome to obtain; and a reasonable individual would be unlikely to object to publication (all three conditions must be met).

8. POLICIES ON CONFLICT OF INTEREST

Our journal complies with the International Committee of Medical Journal Editors’ uniform requirements on Conflict of Interest statement.

Conflict of Interest exists when an author (or the author’s institution), reviewer, or editor has financial or personal relationships with other persons or organizations that inappropriately influence (bias) his or her actions. The existence of such relationships does not necessarily represent true conflict of interest. The potential for conflict of interest can exist whether or not an individual believes that the relationship affects their judgment. Financial relationships (such as employment, consultancies, stock ownership, honoraria, paid expert testimony, patents) are the most easily identifiable conflicts of interest and the most likely to undermine the credibility of the journal, the authors, and of science itself (http://www.icmje.org/index.html). Conflict of interest would be included in the FOOTNOTE section.

(1) Participants

All participants in the peer-review and publication process—not only authors but also peer reviewers, editors, and editorial board members of journals—must consider their conflicts of interest when fulfilling their roles in the process of article review and publication and must disclose all relationships that could be viewed as potential conflicts of interest.

a. Authors

When authors submit a manuscript of any type or format they are responsible for disclosing all financial and personal relationships that might bias or be seen to bias their work.

b. Peer Reviewers

Reviewers should be asked at the time they are asked to critique a manuscript if they have conflicts of interest that could complicate their review. Reviewers must disclose to editors any conflicts of interest that could bias their opinions of the manuscript, and should recuse themselves from reviewing specific manuscripts if the potential for bias exists. Reviewers must not use knowledge of the work they’re reviewing before its publication to further their own interests.

c. Editors and Journal Staff

Editors who make final decisions about manuscripts should recuse themselves from editorial decisions if they have conflicts of interest or relationships that pose potential conflicts related to articles under consideration. Other editorial staff members who participate in editorial decisions must provide editors with a current description of their financial interests or other conflicts (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. Guest editors should follow these same procedures.

(2) Reporting Conflicts of Interest

Articles should be published with statements or supporting documents, declaring:

❖ Authors’ conflicts of interest; and
❖ Sources of support for the work, including sponsor names along with explanations of the role of those sources if any in study design; collection, analysis, and interpretation of data; writing of the report; the decision to submit the report for publication; or a statement declaring that the supporting source had no such involvement; and
❖ Whether the authors had access to the study data, with an explanation of the nature and extent of access, including whether access is on-going.

To support the above statements, editors may request that authors of a study sponsored by a funder 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.”

If there is conflict of interest for the authors, authors must state conflict of interest based on the actual condition; if there is no conflict of interest, state conflict interest section as the following format: “The author has no conflicts of interest to declare.” or “The authors have no conflicts of interest to declare.”

9. CLINICAL TRIALS REGISTRY

We require, as a condition of consideration for publication, registration in a public trials registry. Trials must register at or before the onset of patient enrollment. This policy applies to any clinical trial starting enrollment after January 1, 2006. For trials
that began enrollment before this date, we require registration by April 1, 2006, before considering the trial for publication. We define a clinical trial as any research project that prospectively assigns human subjects to intervention or comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome. Studies designed for other purposes, such as to study pharmacokinetics or major toxicity (e.g., phase I trials) are exempt.

We do not advocate one particular registry, but registration must be with a registry that meets the following minimum criteria: (1) accessible to the public at no charge; (2) searchable by standard, electronic (Internet-based) methods; (3) open to all prospective registrants free of charge or at minimal cost; (4) validates registered information; (5) identifies trials with a unique number; and (6) includes information on the investigator(s), research question or hypothesis, methodology, intervention and comparisons, eligibility criteria, primary and secondary outcomes measured, date of registration, anticipated or actual start date, anticipated or actual date of last follow-up, target number of subjects, status (anticipated, ongoing or closed) and funding source(s).

Registries that currently meet these criteria include: (1) the registry sponsored by the United States National Library of Medicine (www.clinicaltrials.gov); (2) the International Standard Randomized Controlled Trial Number Registry (http://www.controlled-trials.com); (3) the Australian Clinical Trials Registry (http://www.actr.org.au); (4) the Chinese Clinical Trials Register (http://www.chictr.org); and (5) the Clinical Trials Registry - India (http://www.ctri.in).

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