

INSTRUCTIONS FOR AUTHORS

Thank you for your interest in the *mHealth* (online ISSN 2306-9740). Please consult the 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

The *mHealth* (online ISSN 2306-9740) journal is an open access, peer-reviewed online journal, published by AME publishing company.

The new journal publishes articles that describe new findings in the field of using of mobile technologies to improve public health, particularly regarding underserved populations; health research, training, and education applications; and delivery systems around the world.

The aim of the Journal is to provide a forum for the dissemination of mobile technologies, which have the potential to transform global health care on many fronts, from research and diagnostics to training and preventative interventions. The Journal features a distinguished editorial board, which brings together a team of highly experienced specialists from such diverse fields as medical research, software design, clinical health care, hardware manufacture and network transmission. The Journal hopes to spur development and deployment of innovative, practical, affordable and effective solutions to health challenges in underserved and resource-poor populations.

The entire submission and review process are managed

through OJS system, an electronic system, which provides an efficient way and ensures a rapid turnaround of papers submitted for publication.

Editor-in-Chief: Dr. Steven Tucker, MD, FACP, FAMS

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2. REVIEW PROCESS

Manuscripts are assigned to Associate Editors who solicits reviewers. The reviewers' evaluations and Associate Editor's comments are compiled by the Editor-in-Chief for disposition and transmittal to the authors. The Editor-in-Chief will advise authors whether a manuscript is accepted, should be revised or is rejected. Manuscripts not revised within the allotted time are subject to withdrawal from consideration for publication unless the authors can provide extenuating circumstances.

Authors may provide the Editor-in-Chief with the names, addresses and email addresses of up to at least one suitably qualified individuals of international standing who

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would be competent to referee the work (no conflict of interest), although the Editor-in-Chief will not be bound by any such nomination.

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.

3. MANUSCRIPT CATEGORIES

Original Article

Word limit: 5,000 words maximum excluding the title page, abstract, references, figures, figure legends, and tables.

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: Original scientific report of clinical research.

Original article should normally be in the format of Introduction, Methods, Results, Discussion and Conclusion.

It should entail a section describing the contribution of each author made to the manuscript. See section "Author contributions" for details.

Review Article

Word limit: 5,000 words maximum excluding the title page, abstract, references, figures, figure legends, and tables.

Abstract: 450 words maximum, unstructured (no use of sub-headers).

References: no maximum.

Description: Review articles are comprehensive analyses of specific topics. It should entail a section describing the contribution of each author made to the manuscript. See section "Author contributions" for details.

Systematic Review and Meta-analysis

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

Abstract: Structured. 450 words maximum.

References: No maximum.

Figures/tables: No maximum.

Description: A comprehensive, scholarly, balanced, systematic review of evidence-based literature including all findings; these are not opinion submissions. Submissions should be state-of-the-art science confined mostly to the best available evidence.

All meta-analyses of randomized trials must adhere to the guidelines outlined in the PRISMA statement, designed to improve manuscript quality. Authors must include a suitable PRISMA flow chart in their submission.

mHealth will consider for publication Cochrane review articles that have been substantially shortened and rewritten for a audience, but such submissions must state

this on the title page of the manuscript, and copies of the original article must be sent to the Editorial Office for consideration. You must also apply for permission from the Cochrane Library – further information on how to do this is available in the Cochrane Manual. Submissions must relate to important clinical subjects and be accompanied by author analysis leading to conclusions.

The abstract should contain the following subheadings: Background, Methods, Results and Conclusions. Systematic Reviews and Meta-analysis articles should entail a section describing the contribution of each author to the manuscript. See section "Authors' Contribution" for details.

Viewpoint

Word limit: 1200 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: Viewpoints may address virtually any important topic in medicine, public health, research, ethics, health policy, or health law and generally are not linked to a specific article. Viewpoints should be well focused, scholarly, and clearly presented and must have no more than 3 authors.

Books & Arts

Word limit: 2,000 words maximum.

Abstract: Not required for this manuscript type.

Description: This section publishes reviews of books, as well as art pieces, performances etc.; the section also accepts comment pieces on trends in these matters. For reviews of books, authors should provide the book information (e.g. Health Attitude: Unraveling and Solving the Complexities of Healthcare by John R. Patrick. 322pp. Attitude LLC, Palm Coast, FL, 2015. ISBN: 069235736X).

World Report

Word limit: 1,000-2,500 words.

Abstract: Not required for this manuscript type.

Description: This section covers news about science, medicine, policy issues, and people related to mobile health. Most of the writers of World Report articles are professional journalists, but an important event in your country that might be of wider interest can be brought to the attention of our World Report editors.

Meet the Professional

Interviews about Professionals in the field of mobile health. This column is often commissioned by the editorial office.

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.

Perspective

Word limit: 3000 words maximum including abstract but excluding references, tables and figures.

Abstract: 300 words maximum, unstructured (no use of sub-headers)

References: No maximum.

Figures/tables: minimum 1 figure or table

Description: Perspective articles can be more subjective, forward-looking or speculative. A paper presenting controversial positions or papers of the same topic advocating opposite opinions will be published as Perspectives. Most perspective articles will be solicited by the editors. However, we also welcome timely, unsolicited perspective articles.

Commentary

Word limit: 1,500 words maximum excluding references, tables and figures.

Abstract: Not required for this manuscript type.

References: 20 maximum, including the article discussed.

Figures/tables: 2 maximum.

Description: Commentary, upon Editor's invitation, discusses a paper or report or event within the past few months or so, or in the near future. It should set the problems addressed by the paper/report/event in the wider context of the field. Proposals for Commentary may be submitted; however, in this case authors should only send an outline of the proposed paper for initial consideration.

Letters to the Editor

Letters usually offer perspective to content published in *mHealth*, which must be cited as first reference. Letters of any matter of interest to readers of *mHealth* are also published. The text is limited to 1500 words excluding the references, figure legends. No abstracts are required.

Letter in Reply

Replies by authors should not exceed 500 words of text and 6 references. They should have no more than 3 authors.

Case Report

Word limit: 2,500 words maximum excluding abstract, references, tables and figures.

Abstract: 300 words maximum, unstructured (no use of sub-headers)

References: No maximum. Figures/tables: No maximum.

Description: Case report should describe novel use of mobile technology in the health field. Examples may include introduction of interesting or significant devices, Apps etc., an institution or consortium's experience with mobile technology in medicine, patient use of mobile technology in managing their own health and use of mobile technology in clinical experiment.

Information that can be linked to the patients' identification must be carefully masked. If the case report includes a patient's information, the authors should provide a statement at the end of the main text to confirm that the patient has given their consent for the Case reports to be published. The editorial office may request copies of the informed consent documentation at any time. We recommend the following wording is used for the consent section: "Written informed consent was obtained from the patient for publication of this Case report and any accompanying images. A copy of the written consent is available for review by the Editor-in-Chief of this journal."

If the patient has died, then consent for publication must be sought from the next of kin of the patient. If the patient is a minor, or unable to provide consent, then consent must be sought from the parents or legal guardians of the patient. In these cases, the statement in the 'Consent' section of the manuscript should be amended accordingly.

4. 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) disclosure;
- (vi) references;
- (vii) supplementary material;
- (viii) figure legends;
- (ix) tables (each table complete with title and footnotes);
- (x) figures. Footnotes to the text are not allowed and any such material should be incorporated into the text as parenthetical matter.

Title Page

The title page should contain

- (i) the title of the manuscript.
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 corresponding author. The present address of any author, if different from that where the work was carried out, should be supplied in a footnote.
- (v) a short running title (less than 60 characters)

In keeping with the latest guidelines of the International Committee of Medical Journal Editors, for the original article and review article, the information of author contribution is needed (See section “Author’s Contribution” for details).

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 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 an original article should be structured into four paragraphs with sub-headers: background, methods, results and conclusions. The abstracts for other manuscript types should be unstructured.

Three to five key words should be supplied below the abstract. Use terms from the medical subject headings (MeSH) list of Index Medicus.

Text

Authors must use the following subheadings to divide the sections of their Original Article manuscript: Introduction, Methods, Results, Discussion, Acknowledgment, Disclosure, References, and when relevant, Supplementary Material.

However, review, perspective, opinion and commentary articles do not require these specifically outlined sections, and they can be written in several sections with their own headings, as suitable.

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 identified as authors. Those

who do not meet all four criteria should be acknowledged (see section “Acknowledgements” for details). 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.

Acknowledgements

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 RINapproved 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 [hfygr667789]”.

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 Disclosure: 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 disclosure, 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, the Vancouver system of referencing should be used (examples are given below). 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.

• Journal article

1. Gibas Z, Prout DF Jr, Pontes JR. Chromosome changes in germ cell tumours of the testis. *Cancer Genet Cytogenet* 1986; 19: 254-52.

• 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.

1. Furuya R, Takahashi R, Furuya S, et al. Is urethritis accompanied by seminal vesiculitis? *Int J Urol*. DOI: 10.1111/j.1442-2042.2009.02314.x

• Book

2. Ernststoff M. *Urologic Cancer*. Blackwell Science, Boston, 1997.

• Chapter in a Book

3. 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.

• Electronic material

e.g.: Fasquel J, Chabre G, Zanne P, *et al.* A role-based component architecture for computer assisted interventions: illustration for electromagnetic tracking and robotized motion rejection in flexible endoscopy. *MIDAS Journal*,

Systems and Architectures for Computer Assisted Interventions 2009, Available online: <http://www.midasjournal.org/browse/publication/648>.

Tables

Tables should be self-contained and complement, but not duplicate, information contained in the text. Number tables consecutively in the text in Arabic numerals. Type tables on a separate page with the legend above. Legends should be concise but comprehensive – the table, legend and footnotes must be understandable without reference to the text. Vertical lines should not be used to separate columns. 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 from the copyright holder (usually the Publisher), stating authorization to reproduce the material, must be attached to the covering letter.

Figures

All illustrations (line drawings and photographs) are classified as figures. Figures should be cited in consecutive order in the text. Magnifications should be indicated using a scale bar on the illustration. If figures have been reproduced from another source, a letter from the copyright holder (usually the Publisher), stating authorization to reproduce the material, must be attached to the covering letter.

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 or RGB, figures containing text 400 dpi, Line figures 1,000 dpi.

Color figures

Files can be set up as CMYK (cyan, magenta, yellow, black) or as RGB (red, green, blue), but CMYK colors are better represented in printing.

Line figures

The line 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

mHealth will accept digital files in mp4, flash video (flv.), MPEG(MPEG video file), DVD video format, mov., avi., and mwm. 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://mhealth.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.

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.

Supporting information

Supporting Information is provided by the authors to support the content of an article but they are not integral to that article. They are hosted via a link on Synergy but do not appear in the print version of the article. Supporting Information must be submitted together with the article for review; they should not be added at a later stage. They can be in the form of tables, figures, appendices and even video footage. Reference to Supporting Information in the main body of the article is allowed. However, it should be noted that excessive reference to a piece of Supporting Information may indicate that it would be better suited as a proper reference or fully included figure/table. The materials will be published as they are supplied and will not be checked or typeset in any way. All Supporting Information files should come with a legend, listed at the end of the main article. Each figure and table file should not

be larger than 5MB, although video files may be larger.

5. 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 authors must state whether their caregivers had signed the informed consent forms. For deceased patients or those who had lost 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.

6. 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).

7. POLICIES ON CONFLICTS 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>).

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."

8. 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 1 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>).

9. RANDOMIZED CONTROLLED TRIALS

Reporting of randomized controlled trials should follow the guidelines of The CONSORT Statement: <http://www.consort-statement.org>.

10. COPYRIGHT

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