INSTRUCTIONS FOR AUTHORS

Thank you for your interest in *Stem Cell Investigation* (SCI; sci.amegroups.com; ISSN 2313-0792). To ensure fast peer review and publication, please follow the instructions to prepare your manuscript. We are looking forward to your submission.

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1. ABOUT THE JOURNAL

The *Stem Cell Investigation* (SCI; ISSN 2313-0792) is a free access, peer-reviewed journal covering basic, translational, and clinical research on all aspects of stem cells. It publishes original research articles and reviews on embryonic stem cells, induced pluripotent stem cells, adult tissue-specific stem/progenitor cells, cancer stem-like cells, stem cell niche, stem cell technology, stem cell-based drug discovery, and regenerative medicine.

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Online ISSN 2313-0792
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2. REVIEW PROCESS

Manuscripts are assigned to an Associate Editor or the Editor-in-Chief who solicits reviewers (typically, two external reviews are sought). The reviewers' evaluations and Associate 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 four weeks of decision; major revisions within three months. 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 Associate 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 recommend preferred reviewers by providing the Editor-in-Chief with the names, addresses and email addresses of up to three suitably qualified individuals of international standing but 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. Where 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 author and reader. If extensive alterations are required, the manuscript will be returned to the author for revision.

FAST TRACT FOR PREVIOUSLY SUBMITTED MANUSCRIPTS

It is common that manuscripts reporting provocative scientific findings are turned down by high impact journals for failing to meet their "rigid" requirement. These manuscripts can be submitted to the journal in their original formats and get reviewed. The authors are encouraged to submit the comments from their previous submissions to accelerate the reviewing process. Accepted manuscripts will be sent back to the authors for reformatting before publication.

3. MANUSCRIPT CATEGORIES

(1) RESEARCH ARTICLES
(2) INVITED REVIEWS
(3) IMAGE REPORTS
(4) RAPID COMMUNICATIONS
(5) SHORT REPORTS
(6) RESEARCH HIGHLIGHTS
(7) OPINION
(8) PERSPECTIVES
(9) COMMENTARIES
(10) EDITORIALS
(11) CLINICAL GUIDELINES
(12) METHODOLOGY
(13) LETTERS TO THE EDITOR
(14) CASE REPORTS

(1) RESEARCH ARTICLE

Full-length reports of original research in either basic or clinical science.

Note: Research articles should entail a section describing the contribution each author made to the manuscript. See section "Authors' Contribution" for details. Meta-analysis will be categorized into this type.

(2) INVITED REVIEW

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.

Note: Systematic review/meta-analysis article should entail a section describing the contribution each author made to the manuscript. See section "Author Contributions" for details.

(3) IMAGE REPORT

Image Report is intended for publication of a necessarily self-explanatory photograph, diagram, plot, or video clip that depicts original clinical or experimental data with unusual and/or novel observations through static or video images. Each submission must contain a single, high-resolution figure (TIFF format, minimum 300 dpi), or a video clip and a description of no more than 300 words. For clinical images, all identifiable personal information must be absent. All other policies governing submissions to the Journal apply to this article type.

(4) RAPID COMMUNICATION

Rapid Communication is a brief, definitive report of highly significant and timely findings in the field. Authors should indicate the submission as such, and if on preliminary inspection the editor believes the paper is of a nature to warrant this category, the paper will receive very rapid review and, if acceptable, will be published within an average of 8 weeks from receipt.

(5) SHORT REPORT

Manuscripts reporting original observations that do not warrant publication as a full research article will be considered for the short report. These submissions will undergo full peer review.

(6) RESEARCH HIGHLIGHT

Research Highlights are 'digest' of the best/most interesting research papers that are in-press or lately published in the field of stem cells. They are usually solicited by editors and written by experts in specific areas.

(7) OPINION

Opinion piece is an article type specially created for researchers to interact and debate. Opinions are supposed to be more profound than commentary articles. The authors may go beyond science to healthcare policy, ethics, or society. Opinion pieces should be written in an open, free and non-technical style. They can be written with authority, color, vivacity and personal voice.

(8) PERSPECTIVE

Compared with reviews of a scientific topic, perspective articles can be more personal, forward-looking or speculative. Most of Perspectives will be solicited by the editors; however, we also welcome timely, unsolicited Perspectives. Proposals for perspectives may be submitted; however, in this case authors should send an outline of the proposed article prior to submission.

(9) COMMENTARY

Commentary articles comment on articles that are published in SCI or other journals which the authors strongly agree with, have something to add to, or have their contradictory view on.

(10) EDITORIAL

Proposals for Editorials may be submitted; however, in this case authors should only send an outline of the proposed paper for initial consideration.

(11) CLINICAL GUIDELINE

Guidelines need to be the product of a large group of individuals who are recognized 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.

(12) METHODOLOGY

Methodology articles should present a new experimental or computational 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.

(13) LETTERS TO THE EDITOR

Letters must offer perspective to content published in SCI. A Letter must reference the original source, and a Response to a Letter must reference the Letter in the first few paragraphs. Letters can use an arbitrary title, but a Response must cite the title of the Letter: e.g., Response to [title of Letter]. This ensures that readers can track the line of discussion.

(14) CASE REPORT

New observations of diseases, clinical findings or novel/unique treatment outcomes relevant to practitioners in Stem Cell. The text should be arranged as follows: Introduction, Case Presentation, Discussion.

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.

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.

4. STRUCTURE OF THE MANUSCRIPT

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

In keeping with the latest guidelines of the International Committee of Medical Journal Editors, each author's contribution to the paper is to be quantified. The title should be short, informative and contain the major key words so that readers and in particular online users will discover the article easily in online search. Do not use abbreviations in the title.

ABSTRACT AND KEYWORDS

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. 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 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.

MAIN 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 have those clear sections; they can be written in several sections with their own headings according to the topic.

AUTHOR CONTRIBUTIONS

This section is only required for original articles and review articles. 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 "Acknowledgments" 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.

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 chairperson 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, 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 ab-breviated in the style used in PubMed. Authors are responsible for the accuracy of the references. The format of reference sees as follow.

1) Journal article

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

2) 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.

e.g.: Furuya R, Takahashi R, Furuya S, et al. Is urethritis accompanied by seminal vesicu-litis? Int J Urol. DOI: 10.1111/j.1442-2042.2009.02314.x

3) Book

e.g.: Ernstoff M. Urologic Cancer. Blackwell Science, Boston, 1997.

4) 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. 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/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 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.

Videos: SCI 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://sci.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 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).

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. HUMAN AND ANIMAL RIGHTS, INFORMED CONSENT

When reporting experiments on human subjects, authors should indicate whether the procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national). If doubt exists whether the research was

conducted in accordance with the ethical standards, the authors must explain the rationale for their approach, and demonstrate that the institutional review body explicitly approved the doubtful aspects of the study. When reporting experiments on animals, authors should be asked to indicate whether the institutional and national guide for the care and use of laboratory animals was followed.

Editors should protect the confidentiality of individual information (e.g. that obtained through the doctor–patient relationship). It is therefore almost always necessary to obtain written informed consent from patients described in case reports and for photographs of patients. 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).

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 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).

10. RANDOMIZED CONTROLLED TRIALS

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

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