ACE ANNALS OF CANCER EPIDEMIOLOGY
HELPS HUMAN APPLY EPIDEMIOLOGICAL STUDIES TO FIGHT AGAINST CANCERS

Instructions to Authors

Thank you for your interest in Annals of Cancer Epidemiology (ACE). 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.

TABLE OF CONTENT

1. ABOUT THE JOURNAL

Annals of Cancer Epidemiology (ACE) is an international, peer-reviewed, open-access journal with the goal to help human apply epidemiological studies to fight against cancers by providing an open-access platform and user-friendly facilities to worldwide cancer researchers, clinicians, scientists and policy makers, and shape an effective communication and collaboration amongst them.

The scope of Annals of Cancer Epidemiology includes but not limited to the following aspects: cancer statistics, descriptive epidemiology, studies of affecting factors for diseases, prevention, evaluation of interventions, screening, early detection, precise diagnosis, methodological issues and theory, etc.

All submissions and review processes of ACE are conducted electronically to expedite the reviews and publication process. ACE will spare no effort to minimize the duration of review and publication processes whilst maintaining the highest standards of each, and will maintain innovative efforts to meet readers' need.

The editors and an international advisory group of scientists and clinician-scientists as well as other experts will hold ACE articles to the high-quality standards. ACE welcomes submissions of Original Research (full length and short reports), Review Articles and Editorials to published research.

Journal Abbreviation: Ann Cancer Epidemiol

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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: Originality and clinical impact are essential

for acceptance of Original Articles. Such an article is to present original basic science or clinical research findings by the authors in the field of cancer epidemiology. Systematic review with meta-analysis in ACE is addressed as original article. The abstract should contain the following subheadings: Background, Methods, Results and Conclusions. Original articles should entail a section describing the contribution of each author to the manuscript as well as Statement of Ethics Approval. See section "AUTHORS' CONTRIBUTION" and section "STATEMENT OF ETHICS APPROVAL" for details.

(2) REVIEW ARTICLE

Word limit: 6,000 words maximum including abstract but excluding references, tables and figures.
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(3) BRIEF REPORT

Word limit: 2,500 words including abstract but excluding references, tables and figures.
Abstract: 250 words, unstructured (no sub-headers).
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Figures/tables: 8 maximum.
Description: Manuscripts containing pertinent and interesting observations concerning cancer epidemiology 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.

(4) DESCRIPTIVE BRIEF REPORT FROM REGIONAL AND LOCAL REGISTRIES

Descriptive Brief Reports from Regional and Local Registries provides a forum for authors to report patterns of cancer obtained from regional or local cancer registries with limited resources. This section of ACE provides authors with the opportunity to carefully describe their data collection methods and cancer patterns observed.
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Abstract: 250 words, unstructured (no sub-headers).
References: 35 maximum.
Figures/tables: 8 maximum.

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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.

(6) EDITORIAL COMMENTARY

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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.

(7) CORRESPONDENCE

Word limit: 1000 words maximum excluding references, tables and figures.
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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.

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Figures/tables: no maximum, but 8 figures should be sufficient.
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(9) CLINICAL GUIDELINE
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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 (it is recommended that figures, tables and videos are provided in separate files).

TITLE PAGE
The title page should include

- 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. (abbreviations is not allowed)
- The full names of the authors and the addresses of the institutions at which the work was carried out (in English).
- The full postal and email address, plus facsimile and telephone numbers, of the corresponding author.
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ABSTRACT AND KEYWORDS
The abstracts must adhere to the specifications under the section Manuscript Categories. The abstract of an original article, review article, systematic review and meta-analysis, should be structured into four paragraphs with sub-headers of background, methods, results and conclusions. The abstracts for all the other manuscript types should be unstructured. The abstract should not contain any abbreviations or acronyms, as well as citations of reference, figures or tables. And general statements (e.g. "the significance of the results is discussed") should be avoided. Following the Abstract, 3-5 keywords should be given.

TEXT
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If an article describes any procedure, technology or apparatus that is new, has not been used in the indication described, or is being used for a purpose for which it was not originally intended, it is the responsibility of the authors to ensure that all ethical committee, institutional review board, and/or governing body approval has been properly obtained. Such approval must be explicitly stated in the

main text.

The text should be keyed double-spaced throughout. A clearly readable font should be used (e.g. Arial, Calibri, Times New Roman, Verdana). Font size should be 10 or 12. Pages should be numbered. Language should be English. Spelling can be British or American, but consistent throughout. Any abbreviations should be defined on first usage in the text. Terms that are mentioned less than 3 or 4 times in the text should not be abbreviated.

AUTHOR CONTRIBUTIONS

This section is only required for original article, review article, systematic review and meta-analysis article. It describes the contribution each author made to the 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. Authors should meet conditions 1, 2, and 3. 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:

(I) Conception and design:

(II) Administrative support:

(III) Provision of study materials or patients:

(IV) Collection and assembly of data:

(V) Data analysis and interpretation:

(VI) Manuscript writing: All authors

(VII) Final approval of manuscript: All authors

Note: 1. VI and VII of all authors are obligatory while the rest information are case based; 2. Contributions section is not required when there is only one author.

ACKNOWLEDGMENTS

Textual material that names the parties which the author wishes to thank or recognize for their assistance in, for example, producing the work, funding the work, inspiring the work, or assisting in the research on which the work is based.

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ACE policy requires that all authors of all manuscripts sign a statement revealing: 1) Any financial interest in or arrangement with a company whose product was used in a study or is referred to in an article, 2) Any financial interest in or arrangement with a competing company, 3) Any other financial connections, direct or indirect, or other situations that might raise the question of bias in the work reported or the conclusions, implications or opinions stated including pertinent commercial, governmental, private or other sources of funding for the individual author(s) or for the affiliated department(s) or organization(s), personal relationships, or direct academic competition. Statements related to study design, such as providers of the drugs used in the study should be indicated in the Methods section of the article, and other financial interests which are not directly related to carrying out the study should be stated in the Acknowledgements.

FOOTNOTE

a. Conflicts of Interest: See section "Conflict 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, authors should also indicate "Financial Disclose" section as "None".
c. Ethical statement: the authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. Please note that the above statement must be included in the footnote of the article as part of the Ethical Statement.

REFERENCES

A list of references to the literature should be arranged sequentially following appearance in the text. Personal communications, and unpublished data should not be included in the list of references, but can be mentioned in the text.

The Vancouver system of referencing should be used (examples are given below). 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.

• 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.

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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

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

• 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.

• Online publications
e.g., Hraska V, Photiadis J, Poruban R, Asfour B. Ross-Konno operation in children . Multimed Man Cardiothorac Surg doi: 10.1510/mmcts.2008.003160.
or
e.g., Thurber JS, Deb SJ, Collazo LR. Ascending-to-descending aortic bypass for coarctation of the aorta. CTSNet [published 12 May 2008, accessed 30 November 2011]. Available from: http://www.ctsnet.org/sections/clinicalresources/adultcardiac/

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 Table should be on a separate page; tables must be typed and editable in tabular form that is convenient for copyediting and typesetting; and they should not be inserted as images.
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.

FIGURES
All illustrations (line drawings and photographs) are classified as figures. Figures should be numbered consecutively in the order of reference in the text. Figures should be provided separately. 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 page column (82 mm), intermediate (118 mm) or the full text width (173mm).
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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.

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(keep the bit rate as high as possible), MPEG(MPEG video fle), flash video (flv.), DVD video format, etc. 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://ace.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 number 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 captilize 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 Collegiate Dictionary.

Units: All measurements must be given in SI or SIderived 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.

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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.

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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 predetermined 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.

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

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- 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:

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- 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.

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- 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. STATEMENT OF ETHICS APPROVAL

Statement of Ethics Approval: We require every research article submitted to include a statement that the study obtained ethics approval (or a statement that it was not required and why), including the name of the ethics committee(s) or institutional review board(s), the number/ ID of the approval(s), and a statement that participants gave informed consent before taking part. The statement should be described in the method section.

* When concerning 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). Furthermore, authors also need to confirm that the patient has given their consent for the publication. The editorial office may request copies of the informed consent documentation at any time. We recommend the following wording used for the consent section as: "Written informed consent was obtained from the patient for publication of this article and any accompanying images. A copy of the written consent is available for review by the Editors-in-Chief of this journal."

* When concerning 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.

8. 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 could 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)

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10. AUTHORS' RESPONSIBILITY AND POLICIES ON CONFLICT OF INTEREST

(1) Authors' responsibility

We ask all authors to confirm that: 1) they have not previously published or have not submitted the same manuscript elsewhere, 2) they took a significant part in the work and approved the final version of the manuscript, 3) they have complied with ethical standards, 4) they agree AME publishing company, to get a license to publish the accepted article when the manuscript is accepted, and 5) they have obtained all necessary permissions to publish any figures or tables in the manuscript.

(2) 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). 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.

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

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- 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
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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.".

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11. 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).

12. RANDOMIZED CONTOLLED TRIALS

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GENERAL

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