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# Therapeutic Innovation & Regulatory Science

## Manuscript Submission Guidelines and Information

Submit a Manuscript at: <http://mc.manuscriptcentral.com/tirs>

*Therapeutic Innovation & Regulatory Science (TIRS)* is the official scientific journal of DIA that strives to advance medical product discovery, development, regulation, and use through the publication of peer-reviewed original and review articles, commentaries, and letters to the editor across the spectrum of converting biomedical science into practical solutions to advance human health.

The 8 focus areas of the journal are as follows:

- Biostatistics
- Clinical Trials
- Product Development and Innovation
- Global Perspectives
- Policy
- Regulatory Science
- Product Safety
- Special Populations

We welcome your Original Research submissions on any of the above subjects or related topics, as well as Reviews, Analytical Reports, Meeting Reports, or Commentaries (see “Other Types of Submissions” below). Please read and follow the instructions outlined below. Use the [manuscript submission checklist](http://www.sagepub.com/upm-data/78363_TIRS_submission_checklist) ([http://www.sagepub.com/upm-data/78363\\_TIRS\\_submission\\_checklist.docx](http://www.sagepub.com/upm-data/78363_TIRS_submission_checklist.docx)) to ensure all submission requirements have been met. Failure to follow these instructions may delay manuscript processing. Authors may expect an average of 31 days from submission to first decision. Please contact the editorial office with any questions:

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### 1. Editorial Policy

**Prior Publication.** Manuscripts are accepted for consideration with the understanding that they have not been published elsewhere and are not concurrently under review elsewhere. Papers that have been presented at scientific meetings are accepted for consideration, as well as original papers developed from student and professional posters presented at conferences and

meetings. Please disclose the conference or meeting where the information was first presented.

**Authorship.** The journal adheres to the guidelines for authorship as established by the International Committee of Medical Journal Editors (ICMJE) (<http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>). Authorship credit is extended to individuals who met all 3 requirements: substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; drafting the information product or revising it critically for important intellectual content; and final approval of the version to be published. All persons designated as authors should qualify for authorship, and all those who qualify should be listed. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content. Others who contribute through acquisition of funding, general supervision of researchers/authors, or review and approval of an information product, by themselves, do not qualify for authorship but should be acknowledged appropriately. Contributors may be asked to confirm authorship as defined by ICMJE guidelines. Any changes to the author line subsequent to manuscript acceptance will be reviewed by the editor.

**Ghostwriting and Guest Authorship.** Ghostwriting occurs when the author of an article does not reveal contributions of other authors as coauthors to the publication nor does the contributors are listed in the acknowledgement. The use of a medical/technical writer is not prohibited per se, but if the writer qualifies for authorship, it must be assigned, otherwise, the writer should be acknowledged for his or her assistance. Guest authorship occurs when the author contribution does not meet the 3 criteria set above and the person is listed as an author. The journal does not tolerate ghostwriting or guest authorship, as both situations suggest the lack of scientific integrity and honesty.

**Ethics, Privacy Guidelines.** SAGE is committed to upholding the integrity of the academic record. We encourage authors to refer to the Committee on Publication Ethics' [International Standards for Authors](#) and view the Publication Ethics page on the [SAGE Author Gateway](#). 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) and with the Helsinki Declaration of 1964, as revised, or current local regulatory requirements, whichever affords more protection. If doubt exists whether the research was conducted in accordance with the Helsinki Declaration, the authors must explain the rationale for their approach, and demonstrate that the institutional review body explicitly approved 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.

**Informed Consent.** Patients have a right to privacy that should not be infringed without informed consent. Identifying information, including patients' names, initials, or hospital numbers, should not be published in written descriptions, photographs, and pedigrees unless the information is essential for scientific purposes and the patient (or parent or guardian) gives written informed consent for publication. Informed consent for this purpose requires that a patient who is identifiable be shown the manuscript to be published. Authors should identify Individuals who provide writing assistance and disclose the funding source for this assistance.

Identifying details should be omitted if they are not essential. Complete anonymity is difficult to achieve, however, and informed consent should be obtained if there is any doubt. For example, masking the eye region in photographs of patients is inadequate protection of anonymity. If identifying characteristics are altered to protect anonymity, such as in genetic pedigrees, authors should provide assurance that alterations do not distort scientific meaning, and editors should so note. When informed consent has been obtained it should be indicated in the published article.

## 2. Additional Guidelines for Manuscript Preparation

**Abbreviations and Units of Measurement.** Terms appearing frequently within a paper may be abbreviated but should be spelled out at first citation, with the abbreviation following in parentheses. Units of measurement should be in accord with the Système International (SI). Acronyms and abbreviations should be spelled out in the article title and abstract.

**Clinical Trials.** *TIRS* conforms to the [ICMJE requirement](#) that clinical trials are registered in a WHO-approved public trials registry at or before the time of first patient enrolment as a condition of consideration for publication. The trial registry name and URL, and registration number must be included at the end of the abstract.

**Drug and Dosage Selection.** If applicable, authors are expected to make every effort to ensure the accuracy of the information in an article, particularly with regard to drug selection and dose.

However, appropriate information sources should be consulted, especially for new or unfamiliar drugs or procedures. It is the responsibility of every practitioner to evaluate the appropriateness of a particular opinion in the context of actual clinical situations and with due consideration to new developments.

**Permissions.** If a figure or table has been previously published, a credit line should be included, and authors must obtain a letter of permission from the copyright holder. A copy of each permission letter must be submitted with the manuscript.

**Conflicts of Interest and Financial Support.** For each submitted manuscript, all authors are required to complete the ICMJE Conflict of Interest Form (<http://www.icmje.org/conflicts-of-interest/>) and return it to the corresponding author. The corresponding author should gather all authors' forms for upload to the submission site at the time of article submission, as well as list all conflicts of interest in a single paragraph on the manuscript title page. If the paper has only one author, it is that author's responsibility to complete and upload the ICMJE form at time of submission as well as list all conflicts of interest on the manuscript title page. In addition, any sources of financial support received (eg, grants, sponsorships) should be listed in a funding statement on the article title page.

Conflict of interest and funding statements will appear in the published article.

**Reporting Guidelines.** The relevant [EQUATOR Network](#) reporting guidelines should be followed depending on the type of study. For example, all randomized controlled trials submitted for publication should include a completed [Consolidated Standards of Reporting Trials \(CONSORT\)](#) flow chart as a cited figure, and a completed CONSORT checklist as a supplementary file. Other resources can be found at [NLM's Research Reporting Guidelines and Initiatives](#).

## 3. Manuscript Format and Organization

**Acceptable File Types.** Manuscript files should be submitted in Microsoft Word format. Pages should be 8.5 × 11 inches in size, with 1-inch margins on all sides; double space the text using 12-point font size throughout. The page number should appear on each page. Submissions should be written in clear, understandable, grammatically correct American English. Authors who wish to use an **English language editing service** can find more information at the end of these instructions.

As part of our commitment to ensuring an ethical, transparent and fair peer review process SAGE has become a supporting member of [ORCID, the Open Researcher and Contributor ID](#). ORCID provides a persistent digital identifier that distinguishes researchers from every other researcher and, through integration in key research workflows such as

manuscript and grant submission, supports automated linkages between researchers and their professional activities ensuring that their work is recognized. The collection of ORCID iDs from corresponding authors is now part of the submission process of this journal. If you already have an ORCID iD you will be asked to associate that to your submission during the online submission process. If you do not already have an ORCID iD please follow this [link](#) to create one.

### Original Research Manuscript Submissions

**Style.** Manuscripts, including references, are to be prepared according to the *AMA Manual of Style*, 11th ed. (AMA).

**Length.** In most cases, we recommend that submissions of regular manuscripts not exceed 5000 words, including tables, figures, and references. However, in certain cases (eg, comprehensive review papers), a higher limit may be appropriate. Please contact the Editorial Office with any questions regarding manuscript length.

**Manuscript Title Page.** The manuscript title page should be uploaded separately and should include: (1) the article type and article title; (2) the full name(s) of each author, including academic degrees, listed in order of appearance; (3) each author's affiliated institution (eg, department or section, institution, city, and state or country); (4) the name and address, including email address, of the author to whom correspondence is to be sent; (5) acknowledgment of individuals who were of direct help in the preparation of the study; (6) the name, date, and location of conference or workshop at which paper was presented, if any; (7) any potential conflicts with respect to the research authorship, and/or publication of the study (or indicate no conflicts of interest); and (8) any financial support received (or indicate no financial support).

**Manuscript file.** The manuscript should include the title of the article, followed by an abstract that is 150 to 250 words long. For original research papers and clinical trials, the abstract should be structured into 4 sections, with headings as follows: (1) *Background* (provide the study objective); (2) *Methods* (describe the study design and methods used); (3) *Results* (summarize the most important results of your study); and (4) *Conclusions* (state the answer to your original study objective). For other types of submissions (Reviews, Analytical Reports, Meeting Reports, Commentaries) the abstract should be unstructured. Following the abstract, list 5-6 keywords for indexing. To aid in searchability, words in the title should not be used. For further guidance on search engine optimizing, go to the [Journal Author Gateway](#) on the publisher's website (<http://www.uk.sagepub.com/journalgateway/findArticle.htm>).

**Text.** Papers should be organized as follows: Introduction, Materials and Methods (for experimental papers) or Patients and Methods (for clinical papers), Results, Discussion, and

Conclusions. Other descriptive headings and subheadings may be used, if appropriate. The methods, apparatus (including names of manufacturers for any products used or cited), and procedures should be identified in sufficient detail to allow other investigators to reproduce the results. References should be given for all discussions of previous studies and for all nonstandard methods used. Trade names may appear in parentheses and should be capitalized. Patients' identification, names, initials, or hospital numbers should not be used.

**Statement on Human and Animal Rights.** All studies involving human subjects must include a statement in the Methods section that the study has been approved by the appropriate institutional review board (IRB) and/or national research ethics committee. Include the full name of the reviewing entity. Studies involving experiments on animals must include a statement indicating that the international, national, and/or institutional guidelines for the care and use of animals have been followed, and that the study has been approved by a research ethics committee.

**Acknowledgements.** All contributors who do not meet the criteria for authorship should be listed in an Acknowledgements section. Examples of those who might be acknowledged include a person who provided purely technical help, or a department chair who provided only general support.

**References.** Type references double-spaced and number them consecutively in the order in which they are first mentioned in the text (not alphabetically). List up to 6 authors; for references with more than 6 authors list the first 3 followed by "et al." References should conform to AMA style; see sample listings below. Authors are responsible for the accuracy and completeness of the references. Sample reference listings are below.

#### Journal article:

1. Rainier S, Thomas KD, Tokarz D, Herr KA, Garland L. Assessment and measurement of pain in older adults: review and recommendations. *Arch Intern Med*. 2005;164:171-179.
2. Canetta SM, Kimball PT 3rd, Busch R, et al. Colesevelam hydrochloride-ezetimibe combination lipid-lowering therapy in diabetics with a history of statin intolerance. *Endocr Pract*. 2010;6:267-278.

#### Journal article, publish-ahead-of-print:

3. Van der hoek L, Pyrc K, Jebbink MF, et al. Identification of a new human coronavirus [published online March 21, 2009]. *Nat Med*. doi:10.1038.nm1024.

#### Book:

4. Dobkin BH, Lipman AG, Jacox AK, et al. *The Clinical Science of Neurologic Rehabilitation: Principles and Practice*. New York, NY: Oxford University Press; 2003.

*Chapter in a book:*

- Barnes JJ, Cohen R, Cardoo EJ. Microcosms in aquatic ecosystem research. In: Hemingway E, ed. *Pollution and Aquatic Ecosystems*. Springfield, VA: National Technical Information Service; 1986:24-39.

“Unpublished observations” and “personal communications” should be inserted in parentheses in the text. For references that are currently in press, include author, title, and name of journal, followed by “(in press).”

**Tables and Figures.** Number each table and figure consecutively as it should appear in the article. Include in-text callouts for each to ensure accurate placement. Submit each figure in a separate file. See below for further details. **Note: There is a charge to print figures in color (\$800 for the first page, \$200 for each additional page). Color reproduction online is free of charge, and figures submitted in color will appear as submitted in the online issue.**

**Tables:** Tables should be submitted in an editable format; Microsoft Word or Excel tables are preferred. Number each table in order as it should appear in text, and include a brief title. Add footnotes if needed at the bottom of the table. All tables will be reformatted and typeset in the journal’s table style.

**Figures and Artwork:** Submit images at or slightly larger than the final publication size (3.5 to 7 inches wide [9-18 cm]), with text sizes proportional to the image. Remove unneeded white space around images. Line-based artwork such as graphs and charts should be submitted in the format they were originally created (eg, Word, Excel, or PowerPoint file); for line art that is scanned, resolution should be at least 300 dots per inch (dpi). Photos and halftone images should be submitted as TIFF, EPS, PSD, or JPEG files at minimum 300-dpi resolution.

**Supplementary Online Material.** Supplementary material in the form of text, figures, tables, and/or videos offer the author additional possibilities to publish supporting material in the form of high-resolution images, background datasets, video/animation sequences, sound clips, etc. A URL for the supplementary material will be added to an article, and a link will be provided in the online version.

Acceptable video file types are QuickTime (\*.mov), MPEG Movie (\*.mpeg), and Microsoft AVI Video (\*.avi); acceptable audio files include Windows Media Player (\*.wma) and MP3 (\*.mp3).

Submit all other supplementary material as final PDF(s) together with the article. Please provide a concise and descriptive caption for each file. Place an “S” before supplementary table and figure numbers (eg, Table S1).

**Survey Data.** If your paper includes and draws conclusions from survey data, your response rate should be 50% or greater. Survey research that does not include response rates or includes response rates of less than 50%, will not be considered for publication.

**Other Types of Submissions**

**Review of Literature.** Reviews of literature will be considered a comprehensive, significant, critical, and analytical review that include essential information on a well-delineated subject. Reviews must synthesize and critically evaluate available data rather than simply describing the findings. Review papers should make every effort to stay within 5000 words, although longer papers will be considered based on topic.

**Analytical Reports.** Analytical reports are designed to highlight significant technical/methodologic advances that are of value and interest to the broad readership of the journal. These may, for example, include outcomes of working groups exploring new methodologies across the spectrum of drug development, evaluation, regulation, and communication. These are definitive reports of findings of high impact, significance, and timeliness and import to not only the *TIRS* readership but all those involved in the medical product development process. Analytical reports are subject to the same peer-review rigor as research articles and follow similar author instructions. The Editor-in-Chief and editorial board members reserve the right to edit title, abstract, and précis for articles that are accepted to improve their clarity, brevity, and quality.

**Expert Commentaries.** Expert commentaries will be written by acknowledged authorities in their fields (often by invitation, although all such experts are encouraged to submit manuscripts in this category). The goal of this category is to allow the author more freedom than is usually available to express personal insights, views on the likely development of his/her field of study, and perspectives that may influence this development to the benefit of patients. These papers are also subject to the peer-review process. Recommended length for Expert Commentaries is 1500 words.

**Letters to the Editor.** Letters may address articles published in the Journal, or provide thoughts and insights on a specific topic not directly related to a specific publication in the Journal. In the first case, they should be no longer than 500 words of text (excluding name, affiliation, and references), and may have up to 5 references. The author(s) of the original article will be given the opportunity to reply to letters in a response of similar length. To keep discussion timely, letters should be received relatively soon after the publication of the original article. In the second case, letters should address a topic of timely interest and be no longer than 1000 words. As with all other submissions, publication decisions by the Editor are final.

#### 4. Submission, Peer-Review, and Production and Publication Process

**Submission.** Manuscripts are to be submitted online at <http://mc.manuscriptcentral.com/tirs>, and authors will be required to set up an account in the SAGE Track system powered by ScholarOne. Authors will be guided stepwise through the creation and uploading of all manuscript files. All correspondence, including notification of the Editor's decision and requests for revision, will take place via email.

**Peer Review.** *TIRS* operates a conventional single-blind reviewing policy in which the reviewer's name is always concealed from the submitting author. Upon submission of a manuscript to the *TIRS Scholar One* site, the following steps are taken to ensure a thorough and detailed peer-review of each author's manuscript by experts in the paper's interest area.

Authors are responsible for all statements made in their work, including changes made by the copy editor and authorized by the corresponding author after review of typeset page proofs. While every effort is made by the Publisher and Editorial Board to see that no inaccurate or misleading data, opinion, or statement appears in this journal, they wish to make it clear that the data and opinions appearing in the articles and advertisements herein are solely the responsibility of the contributor or advertiser concerned. Accordingly, the Publisher, the Editorial Board and Editor and their respective employees, officers, and agents accept no responsibility whatsoever for the consequences of any such inaccurate or misleading data, opinion, or statement.

If a reviewer suspects that a submitted paper is a duplicate publication, fraudulent, plagiarized or has other concerns about the integrity of the data or the paper, this will immediately be reported to the Editor. A decision regarding the publication of the paper will be made by the Editor, in consultation with the Managing Editor. All decisions made by the Editor are final.

1. After online submission, manuscripts are reviewed for the following:
  - Formatting
  - Submission completeness, ie, that all necessary and cited components are included in usable formats (eg, figures, tables, references, supplementary online materials)
  - English proficiency
  - Survey standards
  - General appropriateness to journal's scope
  - Response to reviewer comments (revised manuscripts only)
2. The manuscript is then:
  - Rejected if the topic is outside the scope of *TIRS*, does not meet survey standards, is poor science, or if the manuscript contains poor formatting or is written in poor English.
    - o If the manuscript is rejected outright for poor formatting or poor English, we invite resubmission if the necessary steps are taken to improve the paper.

- Sent to Statistics Associate Editor for reviewer selection if the paper's methodology is based on statistics.
  - Sent for peer review to at least two (2) reviewers, based on areas of expertise. Reviewers are asked to comment on the following:
    - o Original Manuscripts
      - Are the standard components of a research paper presented clearly (abstract, introduction, methods, results, discussion)?
      - Does the abstract clearly reflect the key points of the article?
      - Is the research hypothesis clearly stated in the introduction?
      - Is the methodology sound and clearly explained?
      - Is the research question answered in the results?
      - Are the conclusions justified? Are the results convincing?
      - Are the strengths and weaknesses of the research summarized in the discussion?
      - Is the appropriate literature cited and summarized throughout?
      - The novelty of the work and the significance to the field.
    - o Review Articles and Analytical Reports
      - Does the abstract clearly reflect the key points of the article? Is the main argument clearly stated in the introduction?
      - Is the literature appropriately cited and does it improve the arguments or discussion posed in the article?
      - Is the article thought-provoking and/or controversial?
3. The Editor-in-Chief will make a decision following:
    - The receipt of two (2) independent peer reviews for new submissions.
    - The receipt of necessary additional input from an Associate Editor or original reviewers on revised manuscripts if the topic is outside his area of expertise or if major revisions were required.

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All accepted manuscripts are published on the TIRS website at <http://tirs.sagepub.com> in the “Online First” section. Online First articles are considered fully published and citable. Unless otherwise notified, the manuscript will also appear in a print issue of the journal. The exact timing of the print publication is at the discretion of the Editor-in-Chief.

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