Therapeutic Innovation & Regulatory Science Manuscript Submission Guidelines and Information

Manuscripts for *Therapeutic Innovation & Regulatory Science* 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.

Upon acceptance of an article, authors will be asked to complete a Journal Contributor's Publishing Agreement. An email will be sent to the corresponding author confirming acceptance of the manuscript together with a link to the online agreement. Please review the document for necessary signatures in the case of work-for-hire and government-submitted manuscripts.

Please read and follow the instructions outlined below. Failure to follow these instructions may delay manuscript processing. Please contact the editorial office with any questions:

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I. 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.

Ethics, Privacy Guidelines. 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.

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. Guidelines for Manuscript Preparation

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

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

Drug and Dosage Selection. The 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.

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Financial Support and Conflicts of Interest. All papers must indicate the affiliation of each author and include a statement for each author whether they have any financial arrangement or connection with the sponsor of the study or the organization that provided support for the work. Any conflict of interest and funding information should appear on the title page of the submitted manuscript. In addition, authors of accepted papers will be required to fill out a conflict of interest form. Statements of funding sources and conflicts of interest will be published in the final article.

Editor's Note. These instructions for manuscript preparation assume that certain resources are available to the author. Although compliance with these instructions will increase the probability of publication in the Journal, authors should not be discouraged from submitting manuscripts that do not completely comply with these instructions. If an author feels his/her manuscript is worthy of publication in the Journal, he/she should do as much as possible to comply, then submit it to the Editor. If the Editor and Editorial Board agree on its desirability for publication, the editorial office will assist in satisfying the Publisher's manuscript preparation requirements.

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 bottom of these instructions.

Regular Manuscript Submissions

Length. In most cases, submissions of regular manuscripts should not exceed 5000 words, including tables, figures, and references. However, in certain cases (eg, comprehensive review papers), a higher limit may be appropriate. Authors are encouraged to contact the Editor via the editorial office if they feel that a higher limit would serve the best interests of readers.

Title Page. Page 1 should include: a) the title of the article; b) the full name(s) of the author(s) with degree(s); c) affiliations (eg, job title, department, institution, city, and state or country where the work was done), indicating which authors are associated with which affiliations; d) acknowledgments of grant support and of individuals who were of direct help in the preparation of the study; e) name, date, and location of DIA Workshop at which paper was presented, if appropriate; and f) the name and address, including email address, of the author to whom correspondence is to be sent.

Abstract and Keywords. Page 2 should include the title of the article, followed by the abstract, which should be about 150 words. The abstract should summarize the main points of the article, the purpose of the study, basic procedures followed, main findings, and principal conclusions. Following the abstract, list 5-6 keywords for indexing.

Text. Papers should be organized as follows: Introduction, Materials and Methods (for experimental papers), Results, Discussion, and Conclusions. Other descriptive headings and subheadings may be used, if appropriate. The methods, apparatus (including manufacturer's name and address), 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.

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:

- 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.
- 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 ahead of print March 21, 2009]. *Nat Med.* doi:10:1038.nm1024.

Book:

 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 Ecosys*tems. 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. Place each table and 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.

<u>Tables</u>: Tables should be submitted in an editable format and not as images; 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 and credit lines if needed at the bottom of the table. All tables will be reformatted and typeset in the journal's table style.

<u>Figures and Artwork</u>: 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 Power-Point file); for line art that is scanned, resolution should be 1000 dots per inch (dpi). Photos and halftone images should be submitted as TIFF, EPS, PSD, or JPEG files at minimum 300-dpi resolution.

Supplementary Data. Supplementary online data 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 supplementary material in electronic format 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).

Other Types of Submissions

Rapid Communications. The goal of this type of submission, which will be peer-reviewed, is to facilitate the opportunity to publish empirical research findings in a rapid manner: both review of submissions and publication of accepted manuscripts will be expedited. Manuscripts should not exceed 1750 words. Additionally, 2-3 figures and/or tables and up to 5 references are permitted. Since articles appearing in this category will be peer-reviewed publications, they should be regarded as the single report of the original data presented: more detailed and lengthy versions will not be considered. However, this vehicle may be ideal in certain circumstances, such as concise reports of preliminary data from pilot studies, and reports of empirical data validating a new measurement methodology against the currently accepted gold standard.

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 or her field of study, and perspectives that may influence this development to the benefit of patients.

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. Peer-Review and Production Process

Manuscripts are examined by the Editor and by 2 additional reviewers. We request that authors submit up to three (3) suggested reviewers for their paper, to ensure that the manuscript is reviewed by someone with expertise in the subject matter, and to expedite the process and facilitate timely review. Decisions of the Editor are final. All material accepted for

publication is subject to copyediting. Authors will receive page proofs before publication, and should answer all queries and carefully check all editorial changes at this point. Authors are responsible for the scientific content of their articles.

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 for DIA. All decisions by the Editor are final.

5. English Language Editing Services

Authors who would like to refine the use of English in their manuscripts might consider utilizing the services of SPi, a non-affiliated company that offers Professional Editing Services to authors of journal articles in the areas of science, technology, medicine or the social sciences. SPi specializes in editing and correcting English-language manuscripts written by authors with a primary language other than English. Visit www.prof-editing.com for more information about SPi's Professional Editing Services, pricing, and turnaround times, or to obtain a free quote or submit a manuscript for language polishing. Please be aware that SAGE has no affiliation with SPi and makes no endorsement of the company. An author's use of SPi's services in no way guarantees that his or her submission will ultimately be accepted. Any arrangement an author enters into will be exclusively between the author and SPi, and any costs incurred are the sole responsibility of the author.