

Editorial

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Accountability and Transparency in Medical Publishing: Position and Policies of Le Jacq on Authorship, Acknowledgments, Conflicts of Interest, and Secondary and Redundant Publication

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This article reviews Le Jacq's position and policies for the consideration of papers for publication within its scientific journals. Le Jacq encourages ethical behavior in the reporting of clinical information and trial results and provides practical guidance to authors and updates current practices, as needed. These policies were developed to offer our journal editors, editorial boards, peer reviewers, authors, and academic society partners a foundation for implementing ethical publication practices.

Le Jacq strongly believes in the consistent application of its policies to any and all manuscripts submitted to its journals for consideration irrespective of the funding sources which may include governmental groups, academic medical centers, nonprofit research organizations, or the biotech, device, or pharmaceutical industries.

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2. Acknowledgment and Disclosure Standards

- 2.1 In addition to authorship requirements, Le Jacq believes that transparency and disclosure of the contributions of all parties involved in the research, preparation, and submission of a manuscript are critical to maintaining credibility with the readership of our publications. Contributors who do not meet the ICMJE authorship criteria or otherwise cannot be included due to the 12-author limitation should be included in an Acknowledgment statement within the manuscript. Acknowledgment statements not only include the name of the contributor but also their specific contribution to the subject matter of the submitted manuscript. Therefore, the Acknowledgment statement

should, as applicable, present our readers with the following:

- 2.2 The funding source of the research.
- 2.3 Explicit acknowledgment of any contributions made by anyone other than an author named in the byline.
- 2.4 The name of the organization funding professional medical writer support.

2.5 Sample Acknowledgments and Disclosures

- 2.5.1 “Drs A, B, and C designed and conducted the study, including patient recruitment, data collection, and data analysis. Dr A prepared the manuscript draft with important intellectual input from Drs B and C. All authors approved the final manuscript. [Company] provided funding for the study and statistical support in analyzing the data with input from Drs A, B, and C and also provided funding for editorial support. Drs A, B, and C had complete access to the study data. We would like to thank Dr D for her editorial support during preparation of this manuscript.”
- 2.5.2 “The authors acknowledge the efforts of [medical writer] for assistance in preparing this review article, revising the text based on intellectual input from the authors, and styling the paper for journal submission. Editorial support was funded by [company], and Dr A received an honorarium for time and effort spent preparing this article.”
- 2.6 Please visit www.blackwellpublishing.com/publicationethics for further examples.

3. Conflict of Interest

- 3.1 Le Jacq requires that the corresponding author provide a statement about conflicts of interests related to the products or services covered within the submitted manuscript. These statements should provide information about the financial remuneration (eg, employment, stock or patent ownership, consultancy, or speaker’s fees) relevant to the

area of research or discussion contained within the submitted manuscript. Conflict of interest disclosures should be detailed in the Acknowledgement/Disclosure statement. ² The minimum amount of conflict of interest information will be published within the article to provide context and transparency for our readers, including but not limited to a statement if an author indicates no conflict of interest.

3.2 Sample Disclosure of Conflict of Interest

- 3.2.1 “[Name] has received fees for serving as a speaker, a consultant, and an advisory board member for [company] and has received research funding from [organization]. [Name] is an employee of [organization] and owns stock and shares in [company]. [Name] owns patent [patent identification and brief description].”

4. Secondary Publication

- 4.1 In many instances, more than one publication is developed from a given clinical trial, in part due to the enormous amount of data generated from large-scale trials. The sheer magnitude of data provides the opportunity to explore and answer additional valid clinical questions beyond the primary results, or the limited number of journal pages. Although some investigators have expressed the importance of disseminating all relevant data from one study in just one publication, in reality, most journals cannot support the number of pages that would be required to achieve such publication.
- 4.2 Because previously published material is protected under copyright law, Le Jacq condemns duplicate publication practices; however, we do recognize secondary publication and proper referencing of source material as a justifiable and beneficial practice for communicating clinical trial information. Additional analysis and publication of these data can be beneficial to

different groups of readers, such as clinicians, researchers, and family practitioners. In addition, subgroup analyses on different patient populations (by age, race, ethnicity) can provide important information and insights that may or may not have been communicated through the primary publication. These exploratory analyses, if performed appropriately and cautiously interpreted, can provide additional insights in understanding the results of a given trial, the treatment used, and the patient population studied. When submitting a secondary publication paper (which is considered derivative of a study for which a primary paper has already been published) consider the following guidelines:

- 4.2.1 The secondary nature of the publication must be clearly indicated in the title and text.
- 4.2.2 The corresponding author must cite the primary publication. In some cases, an editor may request a copy of the primary publication for reference.
- 4.2.3 Secondary publication can and should be abbreviated from the primary publication. ²
- 4.2.4 A notation should be included, either within the cover letter or within the footnotes of the submission, that informs us, peer reviewers, editors, and readers that the data contained have been published in whole or in part and accurately cites the corresponding primary publication.
- 4.2.5 The secondary publication should consistently reflect the data and interpretations reported in the primary publication.

5. Redundant Publication: Clinical Trial Registration and Clinical Results Postings

- 5.1 Since 2005, most medical journals have required clinical trials be registered on a publicly accessible Web site, most notably, www.clinicaltrials.gov, ⁴ before considering a manuscript for publication. Le Jacq requires that trials be registered on the public registry before publication, as outlined in the ICMJE policy. ¹ For an editor to consider an

unregistered trial manuscript for publication, a brief explanation should be included in the cover letter explaining why the trial has not been registered at the time of the submission.

- 5.2 In 2002, the Pharmaceutical Research and Manufacturers Association of America (PhRMA) published the Principles of Conduct on Clinical Trials and Communication of Clinical Trial Results,⁵ indicating that companies would pursue publication of both positive and negative results of clinical trials. Subsequently, PhRMA launched a clinical study results database (www.clinicalstudyresults.org) to provide a centralized repository for confirmatory study results in a standardized format and presentation.
- 5.3 Le Jacq will consider for publication only work that has not been previously published.³
- 5.4 Le Jacq does not consider the following as prior publication:
 - 5.4.1 Presentation of data in an abstract or poster at a scientific meeting.
 - 5.4.2 Presentation of results at an investigator meeting.
 - 5.4.3 Posting results to a publicly accessible results database (data without interpretation or discussion).

Again, Le Jacq believes in maintaining the highest standards in ethical publishing and will pursue any identified misconduct by any party. The policies outlined here are not meant to be comprehensive with regard to the entire publication process. Please refer to Information for Authors on our Web site (www.lejacq.com/PDF_Info/IFAuthors/IFA.pdf) for further detail.

Strong editorial policies and processes are implemented to foster a sustainable and credible publishing model. Ethical publication practices are needed to provide a framework for all parties involved, and Le Jacq trusts that participants in the publishing process respect and will adhere to the policies contained herein.

References

- 1** International Committee of Medical Journal Editors. Uniform requirements for manuscripts submitted to biomedical journals. *N Engl J Med.* 1997;336:309–316.
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- 3** Graf C, Wager E, Bowman A, et al. Best Practice Guidelines on Publication Ethics: a publisher's perspective. *Int J Clin Pract Suppl.* 2007;(152):1–26.
- 4** ClinicalTrials.gov Web site. <http://www.clinicaltrials.gov>. Accessed July 2, 2007.
- 5** Pharmaceutical Research and Manufacturers of America. Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results. <http://www.phrma.org/files/Clinical%20Trials.pdf>. Accessed May 24, 2007

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