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Ethical and Legal Guidance in Biomedical Publishing :

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Ethical and Legal Guidance in Biomedical Publishing*

The *AMA Manual of Style*, Tenth Edition

Stacy L. Christiansen, MA

Editor's Note: As stated by Stacy Christiansen, the "AMA Manual of Style, tenth edition" is deserving of the praise that it is "the bible" of how to create and edit scientific publications. As such, we recommend that it be read and frequently referred to by all who write, review, and edit scientific information. In this Medical Writing Tip of the Month, Christiansen focuses on the chapter on Ethical and Legal Considerations. We encouraged her to do so because we will be requiring authors to adhere to all of the updates discussed beginning February 1, 2009, with all new submissions. These requirements will be incorporated into our Instructions to Authors.

—Richard S. Irwin, MD, FCCP, Editor in Chief.
(*CHEST* 2008; 134:1344–1346)

The *AMA Manual of Style* is the bible of style and presentation for *JAMA* and its sister publications, the *Archives* specialty journals. The Manual is used not only by *JAMA* editorial and production staff but also by research authors, medical writers, editors, proofreaders, and many others involved in the creation and editing of scientific publications. The book was born in 1962 and has grown from a small in-house document (68 pages) to the newly released tenth edition, weighing in at 1,010 pages.¹

One section that contributed significantly to this increase is the chapter on Ethical and Legal Considerations (chapter 5), which doubled in size from the ninth to tenth edition. The chapter focuses on myriad ethical and legal aspects of biomedical publishing, including descriptions of actual cases, examples of how to handle certain situations, and comprehensive reference lists. Herein is a brief summary of the updates to this important chapter.

*From *JAMA*, Chicago, IL.

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AUTHORSHIP

The first section of chapter 5 provides a thorough update on article authorship. The definition of "author" has not changed, but the reporting and publication of author contributions to an article is a new step toward ensuring appropriate authorship. In *JAMA*, the author-supplied contribution lists are published in the "Acknowledgment" section for articles reporting original research, including research letters.^{2(p129)} In addition, the International Committee of Medical Journal Editors recommends that authors of studies funded by an entity with a potential proprietary or financial interest sign a statement regarding their access to the data.³ *JAMA* requires that all reports containing original data have such a statement from at least one author declaring that he/she "had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis."⁴

The *Manual of Style* also spells out the need for a corresponding author on each article who will take responsibility for contact with the editorial office during the editing and production phases. This person also signs a statement that all individuals who contributed to the article are listed either in the byline or the "Acknowledgment" section. The corresponding author should provide information on the contributions of a deceased or incapacitated author. An authorship form is still required in such cases, signed by a family member or individual with power of attorney on behalf of the deceased or incapacitated author.

Also updated in the *Manual of Style* is the number of authors allowed in an article byline. Previously, Medline had functionality to list just 25 individuals.⁵ This restriction has been lifted, and there is now no maximum allowable number on Medline.² *JAMA* does not set arbitrary limits on the author byline of original research but does have guidelines for the number of authors of commentaries, editorials, and

letters. Other journals request justification for long lists of authors. Importantly, all individuals listed in the byline must meet full authorship criteria and submit a signed authorship form.

Group and collaborative authorship is another section that has been expanded and updated. New options for presenting large multiauthor studies are provided, including the study group as a whole (all individuals are authors), one or more authors taking responsibility for the group (only those named in the byline are authors), and a new option whereby only the study name appears in the byline but individual named authors are listed in a footnote, clearly marked “authors” or “writing committee.” This ensures that accountable authors are clearly identified and that indexing will capture the individuals, not just the study group name. Other nonauthor group members can be listed at the end of the article. Regardless of the byline format, an individual corresponding author must still be named.

The citation of articles with group authors rounds out the authorship section of this chapter. Because group-authored papers sometimes have been difficult to retrieve in databases and have resulted in citation errors and miscalculated statistics,^{2(p137)} several recommendations are presented. These include naming individual authors who are responsible for the content, distinguishing true authors from other study contributors, formatting and coding group names and author lists for easy indexing and searching online (including bibliographic databases), and suggesting a preferred citation.

ACKNOWLEDGMENTS

The second section of the chapter focuses on the “Acknowledgment” and the long list of items that might appear in that section of an article. New entries to the “Acknowledgment” section include author contributions and access to data statement (discussed above), statement of independent statistical analysis and role of the sponsor (discussed below), and a catch-all “additional information” heading.

The policy on naming all individuals who contributed to the work but do not meet authorship criteria has not changed, but the heading “Additional Contributions” has been introduced. *JAMA* publishes the complete names, academic degrees, and affiliations for nonauthor contributors (including medical writers), as well as whether they received any compensation for their contributions (outside of regular job duties). Lists of study group members also can be published in the “Acknowledgment” section, but lengthy lists may pose a problem for print journals. If there is not sufficient space in print for a long group list, the editor may

consider posting it online with a note in the print journal.^{2(p141)} Alternatively, if the group list has been published previously, a citation to that publication can appear in the affiliation footnote or “Acknowledgment” section.

DUPLICATE PUBLICATION

The chapter next addresses the issues of duplicate and secondary publication. The medical publishing field still stands firmly against the submission of work for consideration by more than one journal and duplicate publication. The Manual emphasizes that this includes media in electronic format, not just print. Added to the list of duplicate reports that may be acceptable are short reports in print and longer ones online and executive summaries.^{2(p150)}

SCIENTIFIC MISCONDUCT

Also updated and expanded in this chapter is the section on scientific misconduct, including a description of the current US Department of Health and Human Services definition.^{2(pp156–157)} A new entry in this section discusses the inappropriate manipulation of digital images. A distinction is made between retouching that enhances images for publication and manipulation of images that affects how the original data will be interpreted. The Manual includes the policy of the *Journal of Cell Biology* on digital image manipulation and recommends that all journals have policies and procedures in place to detect and handle violations.^{2(p159)}

The Manual provides guidance on editorial policy and procedures for handling allegations of scientific misconduct, including steps to preserve confidentiality during investigation of the allegation. Multiple examples are provided of scientific misconduct as well as retractions (once confirmation of fabrication, falsification, or plagiarism is established) and expressions of concern, which alert readers, librarians, and the scientific community that there are concerns about scientific misconduct pertaining to an article.^{2(p162)} Situations may arise in which a journal editor needs access to the study data to investigate any allegations. *JAMA* includes in its author form a statement that authors will provide the data on which the manuscript is based to the editors or their assignees.⁴ For manuscripts not yet published, the editor should start by asking the corresponding author for a written explanation. If this explanation is unclear or not provided, the author’s institution should be contacted. If misconduct is discovered, the manuscript should be rejected. Throughout any investigation confidentiality should be protected.

CONFLICTS OF INTEREST

Potential conflicts of interest among all parties involved with a study and the resulting article receive extensive discussion in this chapter, including definitions of what such interests could be (eg, consultancies, honoraria, patents). In the interests of full disclosure, with all articles *JAMA* and the *Archives* journals publish a notice of all relevant financial disclosures or a declaration of no relevant interests (“none reported”).

Funding information—grant support or industry-sponsored funding, donation of materials—also appears in this section. A new recommendation is to provide a description of the role any funding entity played in the work reported. *JAMA* and some of the *Archives* journals require a statement for all funded works, including letters, describing the sponsor’s role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; and preparation, review, or approval of the manuscript.^{2(p145),4} Several examples appear in the Manual, ranging from the sponsors having no involvement to a detailed and thorough description of sponsor involvement in several activities related to the study and resulting manuscript.

For industry-sponsored studies or others in which proprietary concerns could lead to bias, the data analysis should be conducted by an independent statistician at an academic institution or government institute that is independent of the sponsor, rather

than being conducted only by statisticians employed by the sponsor.^{2(p142)} For studies in which the statistical analysis was conducted by the sponsor, *JAMA* editors will ask the authors to have the analysis verified by an independent statistician, who will need to declare that he/she had access to the raw data set and study protocol and has independently verified the analysis and results. A notice of this independent statistical review is published in the “Acknowledgment” section along with any funding for this additional analysis.

This synopsis covers a little less than half of the new Ethical and Legal Considerations chapter. The continuation will appear in a forthcoming issue.

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