

Medical Writing Support and Its Disclosure: *Implications for Authorship and Authorial Control of Content*

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ISMPP Code of Ethics



Publication Preparation Guidelines

When preparing or developing publications (i.e., abstracts or manuscripts), members should:

- ◆ **Never misrepresent clinical research and/or clinical trial results, including the fabrication or misreporting of data.**
- ◆ **Identify appropriate trial protocols clearly, if available, when publishing clinical trial results (e.g., NCT number).**
- ◆ **Report primary results of a multi-center clinical trial first, and thereafter issue secondary publications from the same trial, when appropriate, with citation of the primary publication.**
- ◆ **Identify and report negative and inconclusive clinical trial results, as appropriate.**

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Publication Preparation Guidelines

When preparing or developing publications (i.e., abstracts or manuscripts), members should:

- ◆ **Strive for accuracy, completeness, fair balance and avoid commercial product promotion.**
- ◆ **Refrain from duplicate submissions of a manuscript, consistent with accepted professional standards.**
- ◆ **Recognize the author's ultimate responsibility for publication content, including the selection of references.**
- ◆ **Apply appropriate standards, guidelines, and position statements of professional organizations.**

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Publication Preparation Guidelines

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◆ Editors have conveyed concerns to ISMPP

- **They** are connecting publication standards with ISMPP, and (at least some) see ISMPP as a model for industry
- **We** need to understand what editors are looking for

Publications



- ◆ Dissemination of information
- ◆ Collaboration with Thought Leaders
- ◆ Credibility
- ◆ Leadership
- ◆ Trust

The “Currency”

What editors *don't* want to see

Perfectly referenced, formatted, and written reviews and commentaries that have:

- ***Biased* promotion of a single product**
- **Salami slicing of larger research**
- **Writing assistance disclosed, but with named authors lacking a track record in the field**

ICMJE criteria

Authorship should be based only on a substantial contribution to:

- ◆ **Concept and design of study, *or* acquisition *or* analysis and interpretation of data *AND***
- ◆ **Drafting the article *or* revising it critically for important intellectual content, *AND***
- ◆ **Final approval of version to be published**

All three must be met



Who is engaged in the development and publication of a manuscript?

- ◆ **Authors/investigators**
- ◆ **Editors**
- ◆ **Reviewers**
- ◆ **Commercial sponsors**
- ◆ **MECCs**
- ◆ **Writers**

What are the responsibilities of the engaged parties?

The Responsibilities...

...of a Publication Professional

- ◆ **Ensure an outline is created**
 - Key points
 - Related information
 - References
- ◆ **Discuss and get agreement with the author BEFORE the draft manuscript is started. OR,**
- ◆ **Let the author create the outline ± first draft**
 - With his/her thoughts
 - Before the editorial “assistance” kicks in

The Responsibilities...

...of the author

- ◆ The author gets *Recognition* for work done on the manuscript before publication...

therefore

The author has to stand for, and understand, the content

- ◆ The lead author is also *Responsible* for defending the content and the integrity of the manuscript after submission/publication- from editors, peers and the readership – a guarantor function

Going forward

Take home messages

- ◆ **Ensure Author is qualified as such**
- ◆ **List contributors**
- ◆ **Acknowledge appropriately**
- ◆ **Disclose all who have been involved with the manuscript development**

Going forward



Remember

The author is responsible for content and cannot abdicate this responsibility

Otherwise, it may be considered guest or honorary authorship – and editors and/or reviewers will raise strong concerns

Reading suggestions

- ◆ **Ghost marketing** B Moffatt and C Elliott. *Perspect in Biol and Med*, 50 (1)(winter 2007): 18-31
- ◆ **Publication of market-driven research to journals.** Letters to the editor, *Mayo Clin Proc.* 2006;81(6): 850-852
- ◆ **Ghost management** S. Sismondo *PLoS Medicine*, September 2007; 41(9):1429-1432
- ◆ **Pharma goes to the laundry** C. Elliott. *Hastings Center Report* September-October 2004: 18-23