Author agreement forms – what to include and why

Stephen Jones,[1] Angela Cairns[2]

[1]VP Medical & Scientific Services, ACUMED, Tytherington, Cheshire, UK; [2]SVP, Medical & Scientific Services, KnowledgePoint360 Group, Macclesfield, Cheshire, UK

Introduction and aims

- Pharmaceutical company-sponsored clinical trials often include consultancy agreements with investigators that include the development of a publication as part of the contract.
- Some industry-sponsored publications, including secondary publications, reviews, case studies and abstracts, may not be covered by such an author agreement or clauses included may not be of sufficient detail.
- Here we outline the key areas that should be covered in such documents and/or follow-up communications, together with the rationale and examples that will help ensure an open and transparent publication process.
- Best practice recommendations were made following an internal audit and analysis of author agreement templates utilised by Global Publication Plans across healthcare communication agencies within the KnowledgePoint360 Group.

Key points to be communicated to authors of peer-reviewed publications

Purpose of communication and authorship criteria

- A statement that informs the author of the rationale for publication development should be included as well as an explanation of why the author should be participating in manuscript development. Examples across standard publication types are shown in Box 1.
- The template should state that authorship should be based on the criteria proposed by the International Committee of Medical Journal Editors (ICMJE)[1] (Box 1) and the Pharmaceutical Research and Manufacturers of America (PhRMA) Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results[2] though journal-specific criteria will also need to be met.

Box 1. Examples of rationale statements and author selection according to publication type

- **Primary paper/abstract:** this may refer to recent completion of the clinical study and finalisation of data analysis. Authors may include principal trial investigators or those who have significantly contributed to the research. In many cases, a Publication Steering Committee will be formed to lead the development of the paper.
- **Secondary paper/abstract:** the statement may refer to further analyses that have been undertaken and interesting data that have been generated; authors may be proposed by Publication Steering Committee members. Additional authors, such as statisticians, who fulfil ICMJE criteria may be invited.
- **Review paper:** observed educational gaps and needs in the available medical literature should be investigated and presented to the author; such publications should be led by authors with the relevant expertise in the therapeutic area.

Box 2. Authorship criteria according to ICMJE criteria[1]

1. Substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data.
2. Drafting the article or revising it critically for important intellectual content.
3. Final approval of the version to be published.

Authors must meet all 3 criteria.

- As per the ICMJE statement, the letter should acknowledge that authors retain control over the decision to publish, as well as the choice of journal and the publication type.[1]
- It is recommended that such criteria should apply to all researchers involved in the publication, including those employed by the sponsor.
  - A note on the sponsor's/author's criteria for selecting contributors to the acknowledgement section of the publication may also be added at this stage and again should conform to ICMJE recommendations
  - Professional medical writers providing editorial support, who do not meet the criteria for authorship, may also be listed in the acknowledgements section of the manuscript; it is recommended that individual journal guidelines should also be consulted with regards to the acknowledgement of medical writers, in particular for review manuscripts.[3]
- Details regarding the sponsor's right to review publications before submission (together with timelines) may also be stated.

Details of manuscript/abstract and journal recommendations

- Additional information, such as further description of the study or focus of the manuscript/abstract or reference to any prior discussion/correspondence regarding the publication should be noted.
- Potential journals and suggested congresses may be highlighted to the author based on the sponsor's or agency's experience. Factors to consider include:
  - impact of data on therapeutic practice and visibility (impact factor, readership [speciality, location])
  - print/on-line availability/frequency
  - indexing.

Conflict of interest

- A potential conflict of interest exists when an author (or the author's institution or employer), reviewer, or editor has financial or personal relationships or affiliations with other persons or organisations that could influence (or bias) the author's decisions, work or manuscript.[4]
  - Disclosure of an author's potential conflicts of interest, if any, should be requested at an early stage.
  - Consultant agreements also constitute a financial relationship and should be disclosed.
- As there may be uncertainty as to what is included in an author's employment contract or institutional policy, a disclosure statement confirming the author has no contractual obligations that would prevent participation in the publication should be included in initial correspondence with the author.

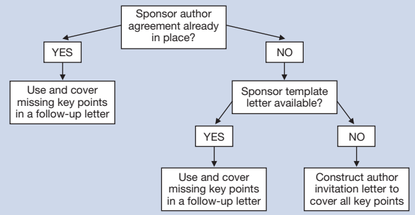
Manuscript development and timelines

- Sponsors may require publications to be submitted before posting clinical trials results (within 1 year of last patient last visit).[5] In addition, fast-track review processes and supplements may require stringent deadlines. In such cases, necessary information regarding the manuscript development process should be included.
- A statement relating to author access to relevant meaningful study results necessary to support the publication should also appear.
- Once the author agreement has been signed a detailed process timeline should be included in a follow-up letter.
- For abstracts, submission deadlines should be highlighted in the author contract.
  - Abstract category and preference for platform versus poster presentation may also be asked at this stage.

Funding and sponsorship

- The author should also be made aware that the pharmaceutical company sponsoring and/or funding the study must be disclosed, together with a statement that the pharmaceutical company is also sponsoring development of the manuscript.
- The letter should also include a statement offering the use of professional medical writing support (if relevant), the need to acknowledge such use and the funding source for this assistance.[6]
- The sponsor's position on financial compensation to investigators for authorship of clinical trial manuscripts and review papers should also be stated.
- For abstracts, a reference to reimbursement of legitimate expenses related to presentation of the data may be included, should the abstract be accepted by the congress.

Box 3. Process for constructuring author agreement form



Box 4. Contracting with authors of industry sponsored manuscripts and abstracts: checklist of confirmations needed

Items to be included in the author contract and receipt acknowledged by the author	Included?	
Rationale for developing the publication	Yes ☐ No ☐	Comment . . . . .
Reason for inviting each author	Yes ☐ No ☐	Comment . . . . .
Clarify author's position: lead or co-author	Yes ☐ No ☐	Comment . . . . .
Identify proposed focus of manuscript/abstract	Yes ☐ No ☐	Comment . . . . .
Suggest journals/congress for discussion	Yes ☐ No ☐	Comment . . . . .
Explain the manuscript/abstract development process	Yes ☐ No ☐	Comment . . . . .
Note abstract submission dates or sponsor-required manuscript submission deadlines (e.g. before data are posted to trials website)	Yes ☐ No ☐	Comment . . . . .
Make clear which pharma company is funding development of the manuscript/abstract	Yes ☐ No ☐	Comment . . . . .
Note availability of editorial support for the publication (if applicable)	Yes ☐ No ☐	Comment . . . . .
State sponsor's policy on financial compensation (recommended: no payment for authorship; explain sponsor's policy on compensation for presenting expenses at congresses)	Yes ☐ No ☐	Comment . . . . .
Statements on the sponsor's and agency's position on compliance with good publishing practice and transparency relating to manuscript development	Yes ☐ No ☐	Comment . . . . .
Note the right of the sponsor to approve and comment on the publication	Yes ☐ No ☐	Comment . . . . .
State that the author retains control over the decision to publish	Yes ☐ No ☐	Comment . . . . .
Ensure that the author is aware of the ICMJE/journal authorship criteria and confirm that he/she qualifies	Yes ☐ No ☐	Comment . . . . .
Confirm that the author has no prior contractual obligations or conflicts of interest that would prevent participation in the development of the publication	Yes ☐ No ☐	Comment . . . . .
Offer access to relevant study materials/data	Yes ☐ No ☐	Comment . . . . .

Compliance with good publication practice

- It is important that correspondence with authors includes a relevant statement regarding the writing agency's position on ethical manuscript development and adherence to good publication practice, as established by ICMJE and other guidelines.
- Relevant statements regarding the sponsor company's commitment to ethical publication practice and transparency should also be stated; some sponsor companies attach their internal publications policy to the agreement/author invitation, while others provide a link to their publications policy on their website.

Conclusions

- The provision of a standardised author invitation or agreement based on the presented checklist (Box 3 and 4) may provide several benefits including:
  - additional clinical trial details/educational objectives of the publication
  - advice to authors to better understand guidelines and policies – including best publication practice
  - adherence to transparency with regards to establishing need for professional medical writing assistance
  - enforcement of author conflict of interest statements
  - standardised documentation to support internal compliance programmes and audits.[7]

References

1. International Committee of Medical Journal Editors. Uniform Requirements for Manuscripts Submitted to Biomedical Journals (www.icmje.org).
2. Pharmaceutical Research & Manufacturers of America (PhRMA; www.phrma.org) Code on Interactions with Healthcare Professionals.
3. Chabner S. The Oncologist 2009;14:199–200.
4. Thompson DF. N Engl J Med 1993;329:573–6.
5. FDA Amendments Act of 2007, Public Law 110-85, Title VIII, Clinical Trial Databases (http://www.fda.gov/oc/initiatives/fdaaa/PL110-85.pdf).
6. Graf C, et al. Int J Clin Pract 2007;61(Suppl. 152):1–26.
7. Cairns A, Yarker Y. Curr Med Res Opin 2008;24:1371–8.

KnowledgePoint360 Group LLC