Author agreement forms – what to include and why

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Introduction and aims

- Pharmaceutical company-sponsored clinical trials often include consultancy agreements with investigators that should be documented as a 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 sufficient of 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 of current communications 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) (Box 2) and the Pharmaceutical Research and Manufacturers of America (PhRMA) Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results (through 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:
- State that the author retains control over the decision to publish, as well as the acknowledgement, ethical approval and funding sources. The sponsor's position on financial compensation to investigators should also be stated.
- A statement should 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 responsible for the development of the manuscript/abstract.
- Make clear which pharma company is funding development of the manuscript/abstract.
- Note the link to the sponsor's policy on financial compensation (recommended: no payment for authorship; stipend payments for professional writing purposes).
- Note the link to the sponsor's position on transparency relating to manuscript development.
- Note the link to the sponsor's policy on financial compensation and transparency relating to manuscript development.

Box 2. Authorship criteria according to ICMJE criteria

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.
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Box 3. Process for constructing author agreement form


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

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.

References