

ASNC Disclosure of Conflicts of Interest (COI) With Industry and Other Entities: Policies and Procedures for the Development of Guidelines and Other Clinical Documents

1. Introduction

The American Society of Nuclear Cardiology (ASNC) is committed to the very highest ethical standards in all its activities, including development of clinical policy. ASNC considers clinical document development as core to its mission and accepts no industry funding for primary document development. ASNC has always taken a stringent approach to ensuring responsible, transparent relationships, in which industry support and other relevant entities have no influence on scientific content. ASNC believes that including experts who have relationships with industry and other relevant entities on writing committees, when transparent and properly managed, strengthens the writing effort and final published document. The following policy outlines ASNC's methodology for ensuring a document development process without improper bias or influence.

1.1. Scope

For those involved in the writing effort (i.e., authors, consultants, external peer reviewers, and document oversight group members), ASNC requires the disclosure of all relationships with industry and other entities (as defined in Section 2.1.2.) involved in the production, marketing, distribution or reselling of healthcare goods, services, advice or information consumed by patients, investors and/or physicians. This may include relationships with government entities as well as not-for-profit institutions and organizations.

1.2. Terminology

1.2. 1. ASNC Quality Committee

The ASNC Quality Committee oversees the development of clinical documents, such as practice guidelines, information statements, position statements, and practice points. The Committee coordinates: topic selection and prioritization, writing committee formation, document development methodology and procedures, peer review, and document approval.

1.2. 2. Writing Committees

Writing Committees are commissioned by the Quality Committee and charged with developing a document on an assigned topic for publication in ASNC's journal, *The Journal of Nuclear Cardiology*, which reflects ASNC policy.

1.2. 3. Writing Group Chair/Co-Chair

A Writing Group chair may have no relevant COI beyond moderate. In such cases where

the chair has moderate risk relevant COI, the chair must be paired with a co-chair with no relevant conflicts. General knowledge in the area is required, but expertise is not essential. The chair and co-chair are chosen based on their ability to effectively organize a writing team and help to build consensus among committee members.

2. General Principles for Managing COI

2.1. Collecting COI

Listed below is the information ASNC collects for the purposes of managing COI for clinical document development.

2.1.1. Reporting Timeframe

ASNC requires the disclosure of all COI for the past 12 months, consistent with the reporting timeframe for the National Institutes of Health and the Food and Drug Administration. In addition, authors are discouraged from adding new COI during the writing effort; however, if relevant relationships are added, this information must be verbally disclosed during any conference calls or meetings, as well as added to the author disclosure table, which is published along with the document.

2.1.2. Relationship Type

Fourteen categories are defined for reporting COI:

- Royalty
- Intellectual Property Rights
- Honoraria
- Research Grant (provided to an institution) or Contractor
- Research Grant (provided to an individual) or Contractor
- Advisory Board
- Stock Interest
- Consultant
- Speakers' Bureau
- Ownership/Partnership/Principal
- Salaried Employee
- Personal Research Salary
- Institutional or Organizational
- Expert Witness
- Other

[View definitions of COI categories.](#)

2.1.3. Risk Assessment of Conflict

COI disclosures should be classified as the following:

Level I – No or Low Risk

Level II – Moderate

Level III – High

Level IV – Very High

Level V – Unresolvable

See Appendix A for detailed information and risk assessment categories and guidelines.

2.1. 3. Relevance to Document/Topic

Authors must disclose all **relevant** COI.

For determining eligibility to serve on a writing committee, all relationships are evaluated by the chair of the Quality Committee and the respective writing committee chair or co-chair with no relevant COI for relevance. A person has a **relevant** relationship IF:

- The **relationship or interest** relates to the same or similar subject matter, intellectual property or asset, topic, or issue addressed in the **document**; or
- The **company/entity (with whom the relationship exists)** makes a drug, drug class, or device addressed in the document, or makes a competing drug or device addressed in the **document**; or
- The **person or a member of the person's household**, has a reasonable potential for financial, professional or other personal gain or loss as a result of the issues/content addressed in the **document**.

For determining eligibility to vote on and draft recommendations and text, the level of the **relevant** relationship will be taken into account:

- If a member of a writing committee has no or low level relevant COI regarding a product or competing product, the member is permitted to participate in the discussions, to draft and vote on any and all recommendations or corresponding text.
- If a member of a writing committee has a moderate risk relevant COI regarding a product or competing product, and the section of the document relates to the specific or competing product, then the member is permitted to participate in the discussions and to draft or vote on a recommendation or corresponding text however, these sections must be reviewed by the chairperson or co-chair with no relevant COI to eliminate bias and ensure balanced content
- If a member of a writing committee has a high risk relevant COI regarding a

product or competing product, and the section of the document is not related to the specific or competing product, and the company does not manufacture or sponsor any relevant product/service or competing product/service, then the member is permitted to participate in the discussions and is permitted to draft and vote on the recommendation and/or corresponding text, but whenever possible, the committee should partner the conflicted writer with someone not conflicted in those areas or limit assignment to content that does not relate to the business lines, products or services of the commercial interest, in addition, these sections must be reviewed by the chairperson or co-chair with no relevant COI to eliminate bias and ensure balanced content. If the member does have a relevant conflict they will be able to contribute to the writing process and voting but only if they work in partnership with a writing group member that has no relevant conflicts and be reviewed by the chair to ensure no bias.

- If a member of a writing committee has a very high risk relevant COI regarding a product or competing product, and the section of the document relates to the company that manufactures or sponsors the product/service or competing product/service, then the committee must **limit the role of the member to writing sections not directly related to the royalty or stock interests. In addition**, the committee should partner the conflicted writer with someone not conflicted in those areas or limit assignment to content that does not relate to the business lines, products or services of the commercial interest, in addition, these sections must be reviewed by the chairperson or co-chair with no relevant COI to eliminate bias and ensure balanced content. The member may vote on the manuscript, except those portions **directly related to the royalty or stock interests.**
- An individual that has an unresolvable COI regarding a product or competing product, may serve as a consultant to the writing group. This individual may provide expert input into the topics addressed in the manuscript, but cannot be responsible for writing/revision of the document. In addition, this individual cannot vote on any part of the document.

2.1.5. Disclosure Timing

Conflicts are disclosed 1) in writing in advance of the writing effort to determine eligibility of members to serve on a writing committee and 2) throughout the document development process to ensure complete transparency in the writing and sign-off processes. Relationships that develop during the writing process must be reported to the writing group chair immediately.

2.2. COI Management

2.2.1. Writing Committee Balance (bias)

Chair/Co-Chairs: A Writing Group chair may have no relevant COI beyond moderate. In such cases where the chair has moderate risk relevant COI, the chair must be paired with a

co-chair with no relevant conflicts. The writing group chair and co-chair are selected primarily based on their competency in effectively managing the writing group. A general working knowledge in the writing topic is also necessary, but the chairperson does not have to be a leading expert in that topic. The chairperson or co-chair must be selected to avoid relationships that could undermine the credibility of the writing group or its work product.

Committee: A majority of writing committee members must be free of relevant COI. At least 50% of writing committee members, plus the Chair and Co-chair (where relevant), may have no relevant COI. The Quality Committee monitors writing committee composition for COI, as well as other potential areas of bias, such as intellectual bias/perspectives or organizational relationships potentially competitive with ASNC, and must approve each writing committee before work begins. Once chosen, authors are requested to withhold from forming any new relevant COI during the writing effort in order to maintain the COI balance of the writing committee.

Of note, the Quality Committee in conjunction with the writing group chair or co-chair with no relevant COI also reviews writing committee balance for other issues such as specialty, geographic location, private practice (versus academic setting/practice), gender, race, and appropriate organizational/content expertise.

2.2.2. Consensus Development

All writing committee members are invited to discuss all aspects of the document, including those for which they have relevant COI. ASNC values the expertise of all writing committee members and allows open discussion to inform the writing committee's final deliberation on document content. However, if one or more individuals appear to be unduly influencing the outcome of the discussion, whether they have a relevant relationship with industry to the topic under discussion, a relevant relationship with another (non-industry) entity to the topic or other bias related to the discussion, the individual may be asked to leave the room or conference call during a portion or all of the discussion at the discretion of the chair or co-chair with no relevant COI.

2.2.3. Voting on Recommendations

In general, all committee members, even those with relevant COI, may participate in all discussions. Writing committee members with less than unresolvable COI may draft recommendations and/or text if they have a relevant relationship, however, the related sections will be reviewed by writing committee members with no relevant conflicts. Individuals with unresolvable COI can only act as consultants and therefore cannot vote on any portion of the document.

2.2.4. External Peer Review

There are no COI restrictions for participation in the external peer review process of a document; however all reviewers must disclose all relevant COI to the topic for publication in an appendix of the document. This promotes the opportunity for comment on the

document from a variety of constituencies/viewpoints to inform final document content.

2.2.5. ASNC Board Review and Approval

Board members may comment but should not vote on clinical documents at the time of board review and approval if they have relevant COI. Documents are approved as Society policy by a majority vote of board members who have no relevant COI to the document under consideration.

2.2.6. Public Disclosure of COI

ASNC's disclosure policy is cited on the ASNC website and relevant COI of authors and peer reviewers are published in a document appendix.

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