

Appendix D - Guidance for Writing Committee/Groups

1. Disclosure Requirements

Members of the Society-documents writing committee/ groups have a special obligation for full disclosure of relationships with industry (RWIs) due to the impact of actual or perceived conflicts of interest on the integrity of the organization. All disclosures will need to be updated at the commencement of document development and reviewed by the Oversight Committee¹ prior to appointment to a writing group. Disclosures used to determine a group member's RWI status are those that are active at the start of the kickoff call.

The Ethics Committee will be consulted when potential writing committee member's disclosures may suggest a conflict that would preclude participation. Writing committee members are discouraged from establishing or engaging in new RWIs during document development and prior to publication. If new relationships are added, or being considered, this information must be verbally disclosed during any conference calls or meetings, and may lead to dismissal from the writing group, or recusal of voting for affected recommendations.

Disclosures should be updated on completion of the document. Author (Peer Reviewer/Advisor) Disclosure Tables will list all RWI and denote which ones are relevant to the document topic(s) but will not include dollar amounts.

2. Definition of Relationships Relevant to Document/Topic

At the commencement of document development, the Oversight Committee Chair and staff will determine which relationships with industry are relevant to the document. Disclosures will not include financial information, and therefore, the relevancy of an RWI will be based on the relationship and company regardless of the dollar amount.

- A relevant 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 immediate family or 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.

¹ *The Oversight Committee is the one indicated in the charge of the relevant committee*

3. Oversight of Document Development

The Oversight Committee and staff are responsible for reviewing all potential writing committee member disclosure statements for relevance to the assigned document topic. The Oversight Committee may seek additional review by the Ethics Committee as needed.

The Oversight Committee will ensure that disclosures are reported for each document and will provide oversight to make sure that the RWI policies are enforced.

The role and responsibilities of the Ethics Committee are set forth in the Code of Ethics and Professionalism.

4. Restrictions

4.1 Chair and Vice-Chair(s)

The Chair and one of the Vice-Chairs of any Society document are prohibited from having relevant RWIs as determined by the Society. (See Table 1 and Table 2 for specific details and definitions.)

For Society documents, the Chair and Vice-Chairs (and their immediate family members) should not own stock, or stock options, or have ownership, royalty income, partnership, licensing, or principal interests in a heart-rhythm related enterprise (including a start-up company), in consultation with the Ethics Committee, excluding mutual funds that may hold such stock in its portfolio, or have the potential to profit financially from the recommendations of the document.

4.2 Writing Committee Members

The inclusion of experts on writing committees strengthens the writing effort and the final published document. Experts may have RWIs, adhering to the Society's disclosure policy, but these relationships must be transparent and properly managed.

Writing committee members shall not own stock, or stock options, or have ownership, royalty income, partnership, or principal interests in a heart-rhythm related enterprise (including a start-up company), excluding mutual funds that may hold such stock in its portfolio, or have the potential to profit financially from the recommendations of the document.

Disclosures used to determine a group member's RWI status are those that are active once the assignment commences.

Any member who has divested relevant stocks, or stock options, ownership, royalty income, partnership, licensing, or principal interests in a heart rhythm-related enterprise (including a start-up company) prior to the initial meeting of the writing committee is eligible to participate.

4.3 Advisory Group/Forum

For advice and expertise, an Industry Advisory Group or Forum can be established.

The use of Industry Advisory Groups or Forums should be disclosed in the document, and the purpose and participants of the group/forum should be detailed in the appropriate section of the document.

4.4 Demographics

In keeping with HRS values, the Oversight Committees strive to maintain balance among potential biases that may stem from academic versus nonacademic physicians, race, sex, geographic location, intellectual bias/perspectives, and organizational relationships potentially competitive with the Society. The Oversight Committee and the Executive Committee must approve each writing group before the group begins its work.

5. Management of Relationships with Industry

5.1 Impact on Consensus Development

- HRS values the expertise of all writing committee members and allows open discussion to inform the writing committee's final deliberation on document content.
- The document chairs are expected to manage discussions during meetings or conference calls to prevent one or more individuals from unduly influencing the outcome of the discussion, whether they have a relevant relationship with industry related to the topic under discussion or other bias related to the discussion.

5.2 Managing Conflicts of Interest

The potential for a conflict of interest exists with any writing committee member, independent of his/her financial compensation.

- The Oversight Committee, with oversight from the Ethics Committee, shall determine whether there is an actual, potential, or perceived conflict of interest and which actions, policies, or processes can be implemented to resolve, mitigate, or manage the conflict on a case-by-case basis. The writing committee chair must review all official recommendation votes to ensure accurate recusal by all writing committee members.

- Any member of the writing committee may report a potential violation of the Society's Code of Ethics, confidentiality, or Conflict of Interest policies to the writing committee chair, the Oversight Committee staff, or the Ethics Committee. All potential violations are reviewed by the Oversight Committee and, if necessary, presented to the Ethics Committee for further action.
- If a member of the writing committee is dissatisfied with the response by the Oversight Committee, he or she may submit this concern directly to the Ethics Committee. The Ethics Committee has the authority to set and enforce all decisions. An appeals process is provided via a three-person independent appeals panel, appointed by the Ethics Committee. A written request for an appeal must be within 30 days of the date on the notification of the Ethics Committee's determination. The appeals panel's decision on sanctions is final. All disclosed intellectual property will be reviewed by the Oversight Committee and, if necessary, by the Ethics Committee.

6. External Peer Review

There are no restrictions on participation for peer reviewers; however, all reviewers must update their disclosures. (Table 1). This promotes the opportunity for comment on the document from a variety of constituencies/viewpoints to inform final document content. RWI information provided by the potential reviewer will be reviewed by the Oversight Committee. If the Oversight Committee determines that there are significant conflicts that could compromise an objective review, an alternate reviewer may be considered.

7. HRS Endorsement of Documents

Endorsement decisions for all internal or external documents are made by the appropriate Oversight Committee. A vote of two-thirds of a quorum is required for HRS endorsement.

For external documents, in order to be considered for endorsement, there must be a written policy established by the developing organization to collect and publish RWIs for all document authors.

Exceptions to this rule will be considered on a case-by-case basis and approved by the Oversight Committee and shared with the HRS Board

8. Public Disclosure of Relationships with Industry

The HRS disclosure policy is cited in the published document and all RWIs of writing committee members, peer reviewers, and Advisors are published in a document appendix, indicating which RWIs are relevant to the document topic(s), but will not include financial information.