

APPENDIX C: GUIDANCE FOR WRITING COMMITTEES/GROUPS

1. Disclosure Requirements

Members of the Society-led scientific statements and clinical practice documents writing committee/groups have a special obligation for full disclosure of relationships with industry and other entities (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 Scientific and Clinical Documents Committee (SCDC) prior to appointment to a writing group. The Ethics Committee will be consulted when potential writing committee member's disclosures may suggest a conflict that would preclude participation, or when a financial interest is above the threshold detailed below.

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.

2. Definition of Relationships Relevant to Document/Topic

At the commencement of document development, the SCDC Chair and staff liaison will determine relevant relationships

with industry.

- 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.

3. Oversight of Document Development

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

The SCDC will ensure that disclosures are reported for each clinical 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-led document, is prohibited from having relevant RWIs as determined by the Society. (See [Table 1](#) and [Table 2](#) for specific details and definitions.)

For Society-led 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 related business 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.

At the discretion of the SCDC, as guided by the HRS Ethics Committee, certain disclosed relationships of the Chair and Vice-Chairs on HRS-led documents, such as participation in government-sponsored or university-managed Data Safety Monitoring Boards, as well as certain institutional/organizational and government/nonprofit relationships, may be considered not relevant to 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 related business 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. Writing committee members are permitted to have such financial interests if these interests are not relevant to the document. Any member who has divested relevant stocks, or stock options ownership, royalty income, partnership, licensing, or principle interests in a related business enterprise (including a start-up company) prior to the initial meeting of the writing group is eligible to participate.

4.3 Financial Restrictions

All potential writing committee members' disclosures will be reviewed by the Ethics Committee if a relationship with a single company is more than \$50,000 and/or if the total disclosure amount is more than \$100,000, excluding research and fellowship support. A member will be disqualified if a relationship with a single company is more than \$50,000 and/or if all relationships amount to more than \$100,000, if those relationships are determined to be relevant by the SCDC in consultation with the Ethics Committee.

An exception can be made for the Technology Category of clinical documents, in which writing committee members may have RWIs, with no specific dollar limit, but may not own stock or stock options, royalty income, partnership, licensing, or principle interests in a related business enterprise (including a start-up company), excluding mutual funds that may hold such stocks in its portfolio or be directly employed by industry.

4.4 Demographics

The SCDC strives 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 SCDC, the Executive Committee, and the Board of Trustees 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, a relevant relationship with another (non-industry) entity related to the topic, 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 SCDC, 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 group 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 SCDC writing committee liaison, the SCDC Chair, staff liaison, or the Ethics Committee Chair. All potential violations are reviewed by the SCDC 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 Chair or staff liaison, 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 SCDC and, if necessary, by the Ethics Committee.

6. External Peer Review

There are no restrictions on participation for peer reviewers; however, all reviewers must disclose all relationships with industry, nonprofit organizations, and government agencies ([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 assessed by the SCDC to determine whether the reviewer is suitable for the specific clinical practice document. If the SCDC determines that there are significant conflicts that could compromise an objective review, an alternate reviewer may be considered.

7. HRS Endorsement of Scientific and Clinical Documents

Endorsement decisions for all internal

or external clinical documents are made by the SCDC. A vote of two-thirds of a quorum is required for HRS endorsement. For external clinical 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 HRS President.

8. Public Disclosure of Relationships with Industry

The HRS disclosure policy is cited in the published document, and all RWIs of writing committee members and peer reviewers are published in a document appendix.