

MOC Policies and Procedures Regarding Relationships With Industry for Writing Group Members

I. Definitions

Relevancy:

Each author is required to identify all relationships within the last 12 months that are **relevant** to the topic of the manuscript. A person has a *relevant* relationship with a company or other entity **IF**:

1. The *relationship or interest* relates to the same or similar subject matter, intellectual property or asset, topic, or issue addressed in the document.
2. 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.
3. The *person or a member of the person's household*, has/have a reasonable potential for financial, professional or other personal gain or loss as a result of the issues/content addressed in the document.

Levels of Support:

1. **No financial relationship** pertains to relationships for which you receive no monetary reimbursement; **Modest** < \$10,000; **Significant** ≥ \$10,000.
2. A person is deemed to have a significant interest in a business if the interest represents ownership of **5%** or more of the voting stock or share of the business entity, **OR** ownership of \$10,000 or more of the fair market value of the business entity, or if funds received by the person from the business entity exceed 5% of the person's gross income for the previous year.

Nature of Support:

I. 1. Personal Ownership/Investments*

Includes any stock, stock option, partnership, membership or other equity position in an entity regardless of the form of the entity, or any option or right to acquire such position, and any rights in any patent or other intellectual property rights. * **Exception:**
mutual diversified funds

II. 2. Personal Income

Includes consulting fees, speaker's bureau, honoraria, expert witness, gifts, "in kind" compensation

III.3. Programmatic Support

- Research grants and/or “in-kind” support from industry
- Fellowship support
- Funding of salary or position or “in-kind” support of program

4. DSMB

- ALL DSMB participation (industry, government-sponsored, and university-managed) must be disclosed.

5. “No Financial Benefit” (RWI For Which No Monies Received)

- “No financial benefit” category added: Donated honoraria to charity must be disclosed unless they fall under the ACCME noted exception.
- Disclosure of travel expenses (e.g., hotel, airfare, meals) is required if subsidized by an industry or device company.

6. Honoraria That Do NOT Have to Be Disclosed

- Honoraria received from work on ACCME-accredited programs do NOT have to be disclosed due to the ACCME firewall restrictions between industry and program content.

7. Institutional COI/RWI

- Includes any institutional relationship for which you have direct decision-making responsibility (e.g., industry grant to the Division of Cardiology and you are Division Chief) and any organizational relationship. “Organizational relationships” include any leadership or governance responsibilities or roles in another professional or other nonprofit organization with interests potentially adverse to or competitive with those of the ACCF/AHA.

II. Policy:

A. Writing Group Members (see rules below for Chair):

1. SIGNIFICANT relationships in category of personal ownership/investments (equity interest, royalty income, ownership) DO NOT automatically disqualify service on writing group (except chair and co-chair).
2. Modest or significant relationships in categories of speaker's bureau, honoraria, expert witness, consultant/advisory board, or relevant research support from industry allowed if in a minority of members.
3. Research funded by federal sources or not-for-profits must be declared but is not automatically counted as a relevant relationship.
4. The majority (50% + 1) of the writing group must be free of **ANY** (modest or significant) relationships. RWI balance will be maintained by including at least 50% of the writing committee (not counting the chair) without relevant RWI at the onset of a writing activity. The writing group chair must also have NO relevant relationships; therefore this makes the total writing group be at least 50% + 1.
5. Participation on a government-sponsored or university-managed DSMB must be disclosed but is not considered relevant for the purpose of identifying writing committee members.

B. Writing Group Chair:

The writing group chairperson is selected primarily for the competency of effectively managing the writing group. A general working knowledge and competency in the writing topic is also necessary, but the chairperson does not have to be a leading expert in that topic. The chairperson must be selected to avoid relationships that could taint or undermine the credibility of the writing group or its work product. Therefore:

1. **Chair** cannot have **ANY** relevant relationships (modest or significant) in the categories of ownership interest, equity interest, royalty income, stock, stock options, speakers bureau, honoraria, expert witness, consultant/advisory board, or relevant research support from industry. Research funded by federal sources or not-for-profits is allowed on a case by case basis. The appropriate oversight committee (e.g., Guideline Task Force or Manuscript Oversight Committee) will review and evaluate the relationship.
2. Participation on government-sponsored or university managed DSMBs must be disclosed but are not considered relevant relationships for the purpose of identifying a Chair or Co-Chair.
3. Volunteers will NOT be automatically disqualified from chairing a writing committee because of an **institutional** RWI or an organizational relationship (e.g., leadership, decision-making roles in an organization who may have a stance potentially competitive with ACCF/AHA). The appropriate oversight committee (e.g., Guideline Task Force or Manuscript Oversight Committee) will review and evaluate the relationship to determine if the individual may serve as Chair.

C. Writing Group Co-Chair:

1. **Co-Chair** can have modest or significant RWI in the categories of speakers' bureau, honoraria, consultant/advisory board, expert witness, or relevant research support from industry.
2. SIGNIFICANT relationships in category of personal investments (equity interest, royalty income, ownership, stock, stock options) are not allowed; modest RWI in this category is allowed.
3. Participation on government-sponsored or university managed DSMBs must be disclosed but are not considered relevant relationships for the purpose of identifying a Chair or Co-Chair.
4. Research funded by federal sources or not-for-profits must be declared but is not automatically counted as a relevant relationship.

See Addendum on Next Page

Addendum to “MOC Policies and Procedures Regarding Relationships With Industry for Writing Group Members”

Relationship With Industry Policy and Selection of Alternate Chair

All chairs and writing group members must disclose relationships with industry (RWI) relevant to the subject of manuscripts they author. Chairs and writing group members are asked not to accept additional relevant RWI from development of AHA document through publication.

RWI for all proposed authors is collected and reviewed by the AHA Manuscript Oversight Committee upon initial nomination to the writing group. The writing group Chair cannot have RWI relevant to the subject of the manuscript as outlined below. Authors are also contacted for updates every 90 days after writing group start-up calls to determine if there have been any RWI changes.

Chair Selection and Eligibility

As outlined in “**MOC Policies and Procedures Regarding Relationships With Industry for Writing Group Members**”:

The writing group chairperson is selected primarily for the competency of effectively managing the writing group. A general working knowledge and competency in the writing topic is also necessary, but the chairperson does not have to be a leading expert in that topic. The chairperson must be selected to avoid relationships that could taint or undermine the credibility of the writing group or its work product. Therefore:

1. Chair cannot have ANY relevant relationships (modest or significant) in the categories of ownership interest, equity interest, royalty income, stock, stock options, speakers bureau, honoraria, expert witness, consultant/advisory board, or relevant research support from industry. Research funded by federal sources or not-for-profits is allowed on a case by case basis. The appropriate oversight committee (e.g., Guideline Task Force or Manuscript Oversight Committee) will review and evaluate the relationship.
2. Participation on government-sponsored or university managed DSMBs must be disclosed but are not considered relevant relationships for the purpose of identifying a Chair or Vice-Chair.
3. Volunteers will NOT be automatically disqualified from chairing a writing committee because of an **institutional** RWI or an organizational relationship (e.g., leadership, decision-making roles in an organization who may have a stance potentially competitive with ACCF/AHA). The appropriate oversight committee (e.g., Guideline Task Force or Manuscript Oversight Committee) will review and evaluate the relationship to determine if the individual may serve as Chair.

See other RWI policies and requirements listed in “MOC Policies and Procedures Regarding Relationships With Industry for Writing Group Members.”

Chair Replacement Process

Reasons for replacement of Chair include but are not limited to:

- Chair has new relevant RWI during manuscript development
- Chair is not meeting timelines and showing appropriate committee leadership
- Chair expresses lack of interest in continuing in this role
- Other reasons determined by AHA Manuscript Oversight Committee Chair

After 3 months of reminders without resolution or reasonable response with a time frame, the Vice-Chair will become Chair of the paper.

If the Vice-Chair has no relevant RWI and the Chair becomes ineligible to serve in this capacity, the Vice-Chair will be appointed Chair of the writing group.

If the Vice-Chair has RWI, an additional meeting with the committee will be convened to determine who on the writing group meets the criteria and could serve as Chair. Council Chair steps in to mediate and determine with the writing group who will serve as the new Chair. Everything must be resolved within 3 months of notification that the Chair has RWI.

If the original Chair meets the requirements for authorship as outlined in the AHA Authorship Responsibility and Copyright Transfer Agreement required from all authors, the author will still be listed as an author of the manuscript but will not be first author or listed as Chair.