

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:

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**

2. Personal Income

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

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 DSMBs must be disclosed but are not considered relevant relationships 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.

Policy and Procedures Regarding Relationships With Industry and Other Entities for Writing Committee Members

I. Policy

All writing committee members must provide complete, timely, accurate, and signed disclosure statements of their **relevant** relationships using enclosed Form. They are informed of this policy during the invitation process and are further advised that publication of relevant RWI and other entities is *mandatory* for participation on the writing committee. The names and information regarding RWI for all writing committee members is published along with the manuscript in *Circulation* (or other AHA journal if applicable).

RWI statements from writing committee members are reviewed by the Manuscript Oversight Committee. To ensure transparency and full disclosure during the writing process, RWI for all writing committee members also are included in the agenda of each writing committee conference call and verbally updated as changes occur.

II. Procedure

Each writing committee member must disclose ALL **relevant** financial, personal or professional relationships with industry, individuals, or organizations as defined below (including such relationships of their spouse and dependent children). It is essential that writing committee members and reviewers are transparent and accurately disclose all **relevant** relationships to avoid even the perception of a conflict of interest with industry, which could negatively impact the hard work of others on the committee.

Using the form below, all writing committee members are required to identify relationships within the last one year that could be **relevant** to the topics or issues addressed in or implicated by the scientific statement or guideline.

A person has a *relevant* relationship with a company or other entity 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/have a reasonable potential for financial, professional or other personal gain or loss as a result of the issues/content addressed in the **document**.

All such **relevant** relationships should be noted and the financial disclosures should be classified as *significant, modest, or no financial relationship*. 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. A relationship is considered to be *modest* if it is less than *significant* under the preceding definition. *No financial relationship* pertains to relationships for which you receive no monetary reimbursement. If an individual has no conflicts or relationships to disclose, he or she must indicate *none*.

III. FORM

AMERICAN HEART ASSOCIATION Author Disclosure/Vested Interest Form

The American Heart Association (AHA) is committed to ensuring balance, independence, objectivity, and scientific rigor in its sponsored educational activities. Authors/reviewers in a position to control the content for an ACC/AHA-sponsored document are expected to disclose all **relevant** relationships during the past **12 months** with (1) the manufacturer(s) of any commercial product(s) and/or provider(s) of commercial services related to the content of the document and (2) any commercial supporters of the activity and (3) any relationships with other entities (e.g., academic institution, government, not-for-profit corp., or foundations). (All **relevant** relationships are described below.)

All writers/reviewers must complete and sign the form in order to participate in the document development process.

Author Name: _____

Employer: _____

Title: _____

Author Signature: _____

Date: _____

1. Do you have any **relevant** financial and/or institutional relationships (see above for description of relevant relationships)? ***Also note that our definition of **relevant** has been expanded so that if the **company/entity** with whom you have a relationship makes a drug, drug class, or device addressed in the **document**, or makes a competing drug or device addressed in the **document**, you must declare this as a relationship. (For example, you are on a company's speakers' bureau to talk about antihypertensive medications. You are also going to be on an AHA paper about management of lipid disorders. Blood pressure management will not be a part of the paper. If the company you have the relationship with also makes lipid management medications, you must declare this as a relevant relationship.)

Yes (please complete form below) No

| RELATIONSHIP DISCLOSURE (for individual contributor, spouse or partner within past 12 months) | | | | |
|---|---|--|---|--|
| | Relationship Category (Include ALL relevant relationships whether paid, unpaid or donated honoraria) | No Financial Relationship (unpaid) | Modest Relationship (less than \$10,000) | Significant Relationship (\$10,000 or more) (For item #3 below, a person has 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.) <small>*Additional detail required</small> |
| | | List Names of all Companies, Organizations, and/or Institutions in the Appropriate Columns | | |
| 1 | * CONSULTANT: includes honoraria from a third party, gifts or other consideration, or "in kind" compensation, including directing such honoraria be donated to a nonprofit 501 C3 organization, whether for consulting, service on an advisory board, or for any other similar purpose. Includes any paid or unpaid consultancy or service on a leadership or regulatory board of a business or enterprise with interests relevant to the document topic. | | | |
| 2 | * SPEAKER/SPEAKER'S BUREAU: includes compensation from speaker's bureaus, symposia and related entities. | | | |
| 3 | OWNERSHIP/PARTNERSHIP/PRINCIPAL (excluding mutual diversified funds): 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. | | | |
| 4 | RESEARCH: includes principal investigator, steering committee member, investigator, collaborator or consultant for pending grants as well as grants already received (including commercially funded grants, as well as research grants from NIH and not-for profits and government sponsored or university-managed and DSMBs). Also includes receipt of drugs, supplies, equipment or other in-kind support over which you have direct decision-making responsibility. | | | |
| 5 | SALARY: Funding of a salary or position (partial or full) or "in-kind" support of program. | | | |

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|---|--|--|--|--|
| 6 | INSTITUTIONAL, ORGANIZATIONAL OR OTHER FINANCIAL BENEFIT (including research): includes any known institutional relationship (ONLY those for which you have direct decision-making responsibility) and any known 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 and/or AHA. | | | |
| 7 | EXPERT WITNESS: Disclose all relevant court cases or other legal proceedings for which you served as a consultant, expert witness, or gave deposition at any time during the past year.* You need only disclose the year the involvement occurred, whether you represented the plaintiff or the defense, and the general topic of the case/testimony. This applies even if the case did not go to trial. Do not disclose confidential information, including but not limited to sealed records or signed confidentiality agreements. <small>*If you testified in a court case and that case is <i>specifically referenced in the document</i>, you must disclose your role even if the court case occurred longer than 1 year ago.</small> | | | |

*ACCME-accredited programs do NOT have to be disclosed due to firewall restrictions between industry and program content

Please note that our definition of **relevant** has been expanded so that if the **company/entity** with whom you have a relationship makes a drug, drug class, or device addressed in the **document**, or makes a competing drug or device addressed in the **document**, you must declare this as a relationship. (For example, you are on a company's speakers' bureau to talk about antihypertensive medications. You are also going to be on an AHA paper about management of lipid disorders. Blood pressure management will not be a part of the paper. If the company you have the relationship with also makes lipid management medications, you must declare this as a relevant relationship.)

***Explanation of “Significant” Relationships—For Writing Committee Members:** Please use the space below to explain the nature of each significant relationship you reported in the disclosure table above. Remember that the AHA publishes all author disclosures with the final document. (The explanatory detail listed below is for internal purposes only.) The AHA uses this information to assess writing group composition and balance.

| CATEGORY | “SIGNIFICANT” RELATIONSHIP DETAILS |
|--|------------------------------------|
| Consultant | |
| Speaker/Speaker’s Bureau | |
| Ownership/ Partnership/Principal | |
| Research (name of grant, funding entity, your role) | |
| Salary | |
| Institutional, Organizational or Other Financial Benefit | |
| Expert Witness | |

If additional space is necessary, please provide additional detail on an attached sheet.