

Relationships with Industry and Other Entities: American Heart Association/American Stroke Association Policies and Procedures for Guideline Development

1.0. Introduction

The American Heart Association and American Stroke Association (collectively, “the Association”) are committed to the highest ethical standards in developing trustworthy scientific publications. To fulfill this responsibility, Association policies and procedures avoid or minimize the influence of industry or other relevant entities upon the scientific or clinical content of these scientific publications by requiring disclosure of relationships with industry or other entities (RWI) and managing the memberships of the writing committee to include sufficient members without RWI. Association also recognizes that the value of published scientific publications can be enhanced by including in some cases experts with RWI on the writing committees, if properly managed and disclosed.

This policy outlines the Association’s policy and methods used to ensure that the publication development process is free of bias or improper influence from RWI.

1.1. Scope

The Association requires that those involved in writing efforts (*e.g.*, authors and external peer reviewers) disclose all RWI (as more fully described in Section 2.1.2), including those held by Household Members, pertaining to production, marketing, distribution or reselling of healthcare goods, services, advice or information for patients, investors or physicians. This includes relationships with government entities, not-for-profit institutions, and organizations (see Section 2.1.2 for detail). Each author and reviewer must submit a disclosure statement disclosing all relationships relevant to the publication topic (including those with perceived relevance) during the prior 6 months. The Manuscript Oversight Committee reviews these disclosure statements to ascertain the individual’s RWI status and assess eligibility to serve in various capacities in the production of Association scientific publications. Employees of industry, part-time or full-time, are prohibited from serving on Oversight Committees and writing committees. Individuals are prohibited from serving on Oversight Committees and writing committees if that individual or their household members serve as members of the Board of Directors of industry.

1.2. Terminology

1.2.1. Relationships with Industry and Other Entities versus Conflict of Interest

The phrase “Relationships with Industry and Other Entities” (RWI) is distinctly different from the term “Conflict of Interest” (COI) as the existence of a relationship does not automatically represent a conflict or bias.¹ Potential bias from relationships can be avoided or minimized while assuring that the final, published scientific publication reflects the necessary expertise if all RWI are fully and accurately disclosed as required by this policy and managed appropriately when building consensus and voting.

In addition to managing RWI, the Association monitors for and manages other potential sources of bias pertinent to the writing effort, beginning with selection of writing committee members who provide a broad array of attributes and perspectives, including academic and nonacademic healthcare providers, diversity of race, ethnicity, gender, geography and setting, and a broad range of intellectual positions.

1.2.2 Household Members

¹ The Association’s Conflict of Interest Policy also applies to relationships.

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For the purpose of this procedure, “Household Members” is defined to include:

- (i) an individual’s spouse or domestic partner,
- (ii) an individual's dependent children, or
- (iii) any other person related to the individual or the individual’s spouse or domestic partner who resides in the same household as the individual.

1.3. Organizational Structure: Writing Committees

1.3.1. Science Advisory and Coordinating Committee (SACC)

SACC manages the process of commissioning, reviewing and approving appropriate medical and scientific publications of importance to the Association mission and science agenda. In addition, SACC proactively develops and approves Association positions on appropriate scientific topics, in response to requests from Association officers, directors, science volunteers and staff or as a result of Association’s Manuscript Oversight Committee process.

1.3.2. Manuscript Oversight Committee (MOC)

In concert with SACC’s annual priorities, the Association Manuscript Oversight Committee manages the process for commissioning appropriate Association scientific publications and oversees the RWI processes. The MOC also ensures manuscripts are developed in a timely fashion.

1.3.3. Stroke Scientific Statements Oversight Committee (SOC)

The Stroke Scientific Statements Oversight Committee (SOC) oversees the creation and completion of Association Stroke Council publications. SOC reports to the MOC and has a liaison representative on the MOC.

1.3.4. Writing Committees

The MOC or SOC commissions writing committees to develop publications on assigned topics for publishing consideration in Association journals.

2.0. General Principles for Managing RWI

2.1. Collecting RWI Information

The Association collects the following information to evaluate and manage RWI during scientific publication development and to report these relationships in the published scientific publication.

2.1.1. Reporting Timeframe

Association requires disclosure of all RWI for the 6-month period prior to writing committee initiation, consistent with the reporting timeframe for the National Institutes of Health and the Food and Drug Administration. In addition, authors must refrain from adding new relevant RWI throughout the writing effort until the date of publication. Each writing committee member must verbally disclose changes to RWI at the beginning of all writing committee conference calls and meetings and ensure that the changes are reflected in the author disclosure table. Scientific Publishing staff will verify author RWI every 90 days beginning when the member is appointed to the writing committee through publication and will notify the Writing Committee Chair and Science & Medicine Advisor of any changes needed to the committee membership during the term of the writing group.

Less than half of the members of a Writing Group may have relevant RWI for 6 months prior and during the period of appointment. Exceptions to this rule may be made only by MOC. It is the preferred practice of the Association to maintain a balance of 65-70% members without RWI, which allows for attrition if needed.

2.1.2. Relationship Type

The following chart describes the types of relationships to be disclosed for RWI reporting:

RELATIONSHIP TYPE	DESCRIPTION
Consultant	Consultant relationships include: • honoraria allocated or received from private sector payers, or pharmaceutical, device, or other mission-related companies; • gifts or other consideration; or • in-kind compensation, including fees donated to nonprofit organizations, whether for consulting, lecturing, traveling, service on advisory boards, or similar activities in the reporting period. Includes consulting or advisory activities for Federal, state, or local government agencies such as CMS or the FDA. Since the Federal government maintains procedures to assure freedom from bias, consulting for its agencies is generally not classified as relevant to Association scientific publication development.
Speaker or Member of Speakers' Bureau	Honoraria or fees received directly from industry for lecturing. Compensation received through contracts with industry or other entities for membership on or participation in speaker's bureaus (both domestic and international) Accredited continuing medical education (CME) programs organized through certified educational organizations need not be disclosed, since this designation requires that program content be developed without industry influence. Food and beverage payments related to a single instance with a single company for ≤\$250.00 is not considered a relevant RWI. Additionally, it will not be considered a relevant RWI if the total payments for food and beverage received from all relevant companies do not exceed \$1,000.00 during the reporting timeframe (see Section 2.1.1).
Ownership/ Partnership/ Principal	• Stock holdings • Stock options • Ownership, partnership, membership or other equity positions (including options or rights to acquire such positions) in any type of entity • Rights and/or royalties in patents or other intellectual property. If an individual divests or places stock in a blind trust the MOC will review to ensure that these actions mitigate the actual or perceived conflict of interest. Ownership of interests in diversified mutual funds is excluded from this designation and need not be reported.
Research	Roles as principal investigator (PI), • co-PI or investigator at a local, national or international level, • steering committee member or • consultant for grants pending, awarded or received (including commercially-funded, NIH or other Federal agency-funded, and university-managed grants and data monitoring committee [DMC; DSMB], clinical event adjudication

	committee [CEAC; CEC] activities and other operational activities related to research). This category includes receipt of drugs, supplies, equipment or other support when the individual has direct decision-making responsibility for allocated resources or proceeds. This type of relationship should be reported by the individual even when funds are budgeted to an institution. For investigators, sub-investigators† or co-investigators† (as defined below), affirmative responses to any question in the definition indicates responsibility to report. Research activity funded by the NIH or other Federal agency should be reported but is generally not classified as relevant to Association scientific publication development.
Employment Compensation	Full or partial funding for support of salary, position, program, or pension (stock related).
Institutional or Organizational <i>(including research)</i>	This category refers to relationships between industry and an institution or organization with which the individual is affiliated from which the individual receives a direct or indirect benefit from the relationship. The individual should report RWI when funds provided to an academic institution or organization are designated for the use of the individual, rather than awarded or paid directly to the individual. An individual participating as a co-investigator or subsidiary investigator in a study for which another individual is designated as the grant awardee or funded PI is an example of this type of relationship, which should be disclosed. In instances when funds are provided to the individual's institution, the following determinations would apply: 4) If the individual is a national or international PI or Co-PI, they will be considered conflicted. 4) If the individual is a national or international study steering committee member, they will be considered conflicted. 4) If the individual serves as the site PI for the study, they would be considered conflicted. 4) If the individual serves as the site study enroller or is a site co-investigator, they would be considered non-conflicted. When industry funds an institution for other purposes (e.g., to support a program or fellowship), the determining consideration is whether the reporting individual has decision-making responsibility over the funds. Examples of RWI that should be reported include (1) serving as an investigator, sub-investigator† or co-investigator† (as defined below) when the individual engages in or oversees recruitment of subjects to participate in a clinical trial; (2) a Department Chair or Division Chief with fiscal authority or decision-making responsibility over funds received from extramural sources for research, fellowships, educational conferences, institutional supplies, etc.; (3) funds provided by a commercial entity to an institution with which the individual has a professional or personal affiliation (e.g., faculty of a medical school) when the funds provide full or partial salary support of the individual or staff under the direction of the individual. These relationships may be considered relevant to the writing effort (see Section 2.1.5), whereas research or clinical funding obtained from Federal sources (e.g., grant support from NIH or other government agency) is not considered relevant, even when the government has received support from industry for the project. Other relationships that should be reported include leadership or governance responsibilities or roles (e.g., officer, director, trustee or other fiduciary role, editor, etc.) in professional or nonprofit organizations, whether or not remunerated, that may involve interests potentially competitive with the Association or ASA or cooperative or competitive with entities having business interests in the guideline topic.

Expert Witness	Legal proceedings in which the individual served as a consultant, expert or deposed witness, whether compensated or uncompensated, should be disclosed, reporting the year of involvement, alignment with the plaintiff or defendant, and the topic of the case/testimony, whether or not the matter proceeded to trial. Disclosure should be consistent with applicable legal requirements and restrictions, such as HIPAA or confidentiality agreements.
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†Sub-investigators or co-investigators are defined here as individuals who have signed FDA Form 1572 or an Investigator Agreement in roles other than primary or co-author of data analyses, abstracts, or manuscripts, who do not have oversight of the research, report data, or receive compensation from the sponsor (including direct salary support or salary support for staff, shared staff or overhead charges), and do not receive funds for travel or accommodation to attend investigator meetings hosted by the sponsor.

Sub-investigators or co-investigators should answer 3 questions: (1) Have you signed a FDA Form 1572 or an Investigator Agreement? (2) Do you have oversight of the research or data reporting? (3) Did you receive funds or compensation to attend investigator meetings? If the answer to any of these is affirmative, the relationship should be disclosed under the **personal research** category; if all answers are negative, the relationship should be disclosed under the **institutional** category.

Clinical trial enrollers who have signed an FDA Form 1572 but only apply study inclusion or exclusion criteria to enroll clinical patients in studies are not considered to have a relevant relationship with the study sponsor.

2.1.2.1. Data Monitoring Activities for Clinical Trials

Membership on Data Monitoring Committees ([DMCs] or Data Safety Monitoring Boards [DSMBs]) and Clinical Event Adjudication Committees [(CEACs] or Endpoint Committees [CECs]), whether commercially-funded or government- or university-managed, are not classified as relevant relationships when the committee is independent of industry influence, as recommended by the FDA. The Association recognizes that the main responsibility of the DMC is to assure the safety of trial participants and the scientific integrity of the study in the interest of advancing clinical research. DMC membership should be reported on the member's comprehensive disclosure. The MOC or SOC will review the DMC Charter to assure compliance with FDA regulations regarding independence from influence by a commercial sponsor, in which case the relationship will not be considered relevant to the scientific publication under development.

2.1.3. Writing Committee Balance

Chair/Co-Chair: The Chair or Co-Chairs of writing committees may have relevant RWI but may not have a significant relationship (see Section 2.1.4) in the timeframes defined above (see Section 2.1.1). The writing committee chair is selected mainly for the competency to effectively manage the writing group and develop consensus on the text and any suggestions for clinical practice. A general knowledge of the topic of the scientific publication is also necessary, but the chair need not have expertise in the topic. The chair must be free of RWI and other relationships or biases that could undermine the integrity or credibility of the work.

Vice Chair: A vice chair may be appointed to add content expertise. Vice chairs may have relevant RWI but may not have a significant relationship (as defined in Section 2.1.4) in the **ownership** category as defined in 2.1.2 above.

Committee: The Chair and at least half the writing committee members (at least 51%) must be free of relevant RWI*. The MOC monitors writing committee composition for RWI and other potential sources of bias, such as intellectual perspectives or organizational relationships, and approve each writing committee before scientific publication development commences. Once chosen, authors are requested to avoid relevant RWI throughout the writing effort until publication. Author RWI is verified every 90 days from kick-off call through publication.

*In conjunction with the writing committee Chair, the MOC may prospectively define relevance to the topic when the content addressed in the scientific publication is non-clinical or non-prescriptive in nature and, therefore, where disease- or procedure-based definitions do not apply. Based upon the agreed-upon definitions, certain relationships may be deemed irrelevant to the scientific publication. These may include, but are not limited to, specified institutional/organizational and government/nonprofit relationships. Such special determinations must be approved by the organizational leadership of the Association.

2.1.4. Financial Value or Level of Relationship

Financial relationships should be classified as *significant*, *modest*, or *not monetary*. A *significant* interest in a business reflects ownership of 5% or more of the voting stock or share of the entity, ownership of \$5,000 or more of the fair market value of the entity, or funds received from the entity exceeding 5% of the individual's gross annual income for the reporting period. A relationship is *modest* if less than *significant* under the preceding definition. *Not monetary* pertains to relationships for which the individual receives no financial compensation. However, if an individual directs where financial compensation goes (e.g., donates to charity, faith-based, educational, or other tax-exempt organization), such funds are reported as a significant or modest financial relationship. Relationships with industry of a total combined amount of \$10,000 or less for all relevant companies is allowable and not considered relevant for writing committee chairs, vice chairs, or members.

2.1.5. Relevance to Scientific Publication Topic

Authors must report all RWI, and all relationships are evaluated for relevancy by the respective oversight committee to determine eligibility of the individual to serve as a member of a writing committee. A person has a **relevant** relationship when:

- The **relationship or interest** relates to the same or similar subject matter, intellectual property or asset, topic, or issue addressed in the **scientific publication**; or
- The **company/entity** (with whom the relationship exists) makes a drug, drug class, device, or other health technology solutions addressed in the **scientific publication**, makes a drug or device that competes for use with a product addressed in the **scientific publication**; or
- The **person or a household member** has a reasonable possibility of financial, professional or other personal gain or loss as a result of the issues or content addressed in the **scientific publication**.

For determining eligibility to draft text, the following considerations apply to **relevant RWI** of members of the writing committee:

- If the individual has relevant RWI regarding a product or competing product, and the section of the document **is related** to the specific product or competing product, the member **is permitted** to participate in discussions but **is not permitted** to vote on recommendations or measures to which the specific relationship applies.
- If the individual has relevant RWI regarding a product or competing product, and the section of the document **is not related** to the specific product or a competing product and the company does not manufacture or market a relevant product or service or competing product or service, the member **is permitted** to participate in the discussion and **is permitted** to draft recommendations and/or corresponding text and vote on recommendations to which the relationship applies.
- If the individual has relevant RWI regarding a product or competing product, and the section of the document is related to the company that manufactures or markets the product or service or a competing product or service but not the specific product or class of products involved in the

relationship, then the member **is permitted** to participate in the discussion but **is not permitted** to vote on recommendations to which the relationship applies.

2.1.6. Timing of Disclosures

Relationships for the 6 months are disclosed in writing and/or online during formation of the writing committee to determine eligibility. New relationships should be avoided during the writing process, and those that develop or arise must be reported to the chair of the writing group immediately to ensure transparency throughout the writing, voting, and document approval. In cases where the relationship disturbs the requisite balance or more rigorous criteria restricting membership on the writing committee of persons with RWI, the individual may be required to resign from the writing committee. Such circumstances, hopefully rare, will be reported in the published scientific publication.

2.1.7. Open Payments Data Review

During formation of the writing committee, Association Scientific Publishing staff will review the Open Payments database maintained by the Centers for Medicare & Medicaid Services (CMS) for any disclosures applicable to writing committee members. This review will be conducted every six months during the writing process through publication to identify any undisclosed relationships of the members.

2.2. RWI Management

2.2.1. Consensus Development

The Association values the expertise of its writing committee members and encourages full discussion to inform deliberation on scientific publication content. All writing committee members are therefore free to discuss all aspects of the scientific publication within the confidentiality bounds that apply to the scientific publication development process, including those topic areas to which relevant RWI may apply. If, in the judgment of the chair, one or more members seem to exert undue influence or otherwise risk biasing the outcome of the discussion, whether or not they have RWI relevant to the topic under discussion or other bias, the individual(s) may be asked to leave the room or conference call during all or part of the discussion to assure that the work of the writing committee can proceed unfettered.

2.2.2. External Peer Review

For Guideline peer review, Peer reviewers must disclose all relationships regardless of perceived relevance to the topic of the document, upon invitation to participate and throughout the joint document production process once selected. RWI information is collected and reported and published with the documents. This procedure provides opportunity for comment from a variety of constituencies and assures that those with diverse viewpoints inform the content of the document.

The following criteria can be used to determine significant relevant RWI that would disqualify a prospective candidate from serving as chair of the Guideline Peer Review Committee:

- Receipt of more than \$10,000 in personal payments directly from industry per annum in aggregate (e.g., consulting, honoraria, etc.);
- Receipt of indirect payments (i.e., payments to a department or institution or any other body) when the candidate is the Principal Investigator;
- Employment (including part-time or as a contractor);
- Having significant stock ownership or stock equivalents as defined in the ACC/Association procedure (i.e., a significant interest in business reflects ownership of 5% or more of the voting stock, stock equivalents, or share of the entity, ownership of \$5,000 or more of the fair market value of the entity, or funds received from the entity exceeding 5% of the individual's gross annual income for the reporting period); and/or

- Holding an interest in any unexpired patent or intellectual property which generates substantial revenues for the individual or an industry entity.

2.2.3. Association Science Advisory and Coordinating Committee and Association Executive Committees Review and Approval

Scientific publications will be approved by a majority vote of SACC members who have no relevant RWI related to the scientific publication under consideration. SACC with relevant RWI may comment but may not vote on clinical scientific publications at the time of review and approval.

Scientific Publications approved by SACC will be escalated to the Executive Committee for approval. Executive Committee members who have no relevant RWI related to the scientific publication under consideration may vote on approving the scientific publication. Executive Committee members with relevant RWI may comment but may not vote on clinical scientific publications at the time of review and approval.

2.2.4. Public Disclosure of RWI

The Association disclosure policy is cited in the published scientific publication, and *relevant* RWI of authors and peer reviewers are published in the scientific publication appendix. In addition, to ensure transparency, a hyperlink to the updated *comprehensive RWI* of each author (in effect at the time of the writing effort) and SSOC (Stroke Oversight Committee) or SPMOC (Stroke Performance Measures Oversight Committee) member is included in the scientific publication.