

Relationships with Industry and Other Entities: ACC/AHA Policies and Procedures for Development of Guidelines, Performance Measures and Data Standards

1.0. Introduction

The American College of Cardiology (ACC) and American Heart Association (AHA) are committed to the highest ethical standards in developing trustworthy guidelines, performance measures, and data standards. To fulfill this responsibility, policies and procedures preclude influence of industry or other relevant entities upon the scientific or clinical content of these documents. The leaders of both organizations recognize that including among the members of writing committees, experts who in some cases have relationships with industry or other entities (RWI), when properly managed and disclosed, can enhance the value of published documents.

The following statement outlines the ACC/AHA policy and methods used to ensure that the document development process is free of bias or improper influence. While these policies apply generally to all clinical practice guidelines, performance measures, and data standards, more stringent restrictions may apply to certain documents. This is the case for the suite of cardiovascular disease prevention guidelines that specifically address cardiovascular risk assessment, hypertension, hyperlipidemia, obesity, and lifestyle modification. Because of the large portion of the population potentially affected by these guidelines, a more restrictive policy requires that no writing committee members have relevant relationships with industry or other entities (see Section 2.1.1 below).

1.1. Scope

The ACC/AHA requires that those involved in writing efforts (authors and external peer reviewers), and members of the Task Forces overseeing document development, disclose all RWI (defined 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 category definitions for detail). All relationships must be declared, regardless of perceived relevance to the topic of the document. These disclosures are reviewed to ascertain the candidate's RWI status and assess eligibility to serve in various capacities in the production of ACC/AHA guidelines, data standards and/or performance measures. Employees of industry, part-time or full-time, are prohibited from serving on guideline writing committees.

1.2. Terminology

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

The term Relationships with Industry and Other Entities (RWI) is preferred over Conflict of Interest (COI) as the intent is not to imply conflict or bias. When all relationships are disclosed with detail regarding category and amount and managed appropriately when building consensus and voting, potential bias can be avoided or minimized while assuring that the final, published document reflects the necessary expertise.

In addition to managing RWI, the ACC/AHA, through the respective Task Forces, monitors for and manages other potential sources of bias pertinent to the writing effort, beginning with selection of writing committee members to assure an array of perspectives, including those of 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

Household Members: For the purposes of this policy, “Household Members” is defined to include a candidate’s spouse, domestic partner and any other person who resides in the same household as the candidate or is a dependent of the candidate.

1.3. Organizational Structure: Task Forces and Writing Committees

1.3.1. The Task Force on Clinical Practice Guidelines

The Task Force on Clinical Practice Guidelines (TFPG) oversees development of guidelines and establishes policies and procedures governing these documents. The TFPG prioritizes and coordinates topic selection, writing committee formation, document development methodology, and procedures for evidence review, peer review, document approval and publication.

1.3.2. The Task Force on Performance Measures

The Task Force on Performance Measures (TFPM) oversees development of performance measures and establishes policies and procedures governing documents of this type. The TFPM prioritizes topics and performance items, writing committee formation, methodology, document development, and procedures for peer review, document approval, and publication.

1.3.3. The Task Force on Clinical Data Standards

The Task Force on Clinical Data Standards (TFDS) oversees establishment of data standards and setting the policies for promulgation of these standards. The TFDS determines the scope, topics, and metrics for this purpose, assembles writing committees, and defines the methodology for document development, peer review, approval, and publication.

1.3.4. Writing Committees

Writing Committees commissioned by the TFPG, TFPM, and TFDS are charged with developing guidelines, performance measures, or data standards documents on assigned topics for publication in the appropriate journals of the two organizations.

1.3.5. Chair, Co-Chairs, Vice Chairs

Committees are led by either a Chair and a Vice Chair, or two Co-Chairs. The Chair has the primary responsibility for leading a writing committee to develop a document and the Vice Chair assists with document development and leads the Committee in the absence of the Chair. Co-Chairs are individuals who share equally the responsibility of leading a writing committee to develop a document.

2.0. General Principles for Managing RWI

2.1. Collecting RWI Information

The ACC/AHA collects the following information to evaluate and manage RWI during document development and to report these relationships in a published document.

2.1.1. Reporting Timeframe

ACC/AHA requires disclosure of all RWI for the 12-month period prior to the Kick-off Meeting of the writing committee, 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 RWI throughout the writing effort until the date of publication. Changes to RWI must be verbally disclosed by each member of the writing committee at the beginning of all conference calls and meetings and reflected in the author disclosure table. ACC/AHA staff will collect, review, and identify any new disclosed relationships from authors every 90 days from Kick-off Meeting through publication. ACC/AHA staff will report any new

relationships to the Writing Committee Chair, AHA’s SVP of Science Operations and Chief Science Officer, and ACC’s Senior Director, Guidelines and QI Solutions and EVP, Science, Education and Quality for review and appropriate action, including but not limited to modifying writing committee assignments.

Practice Guideline writing committees are constituted such that no more than half the members have relevant RWI for 1 year before and during the period of appointment. Prevention Guideline writing committees are constituted such that all members are entirely free of relevant RWI from 1 year before appointment until 1 year after publication of the guideline.

2.1.2. Relationship Type

The following definitions describe the categories or types of relationships used for RWI reporting:

REPORTING CATEGORY	DEFINITION
Consultant	Relationships for which honoraria are allocated or received from private sector payers, 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 (generally 12 months prior to the date of disclosure). This 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 ACC/AHA document 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) Honoraria or fees received from an accredited continuing medical education (CME) program organized through certified educational organizations need not be disclosed. Food and beverage payments related to a single instance with a single company for ≤ \$100 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 relationships in a year do not exceed \$500.
Ownership/ Partnership/ Principal	Stock holdings*, stock options*, ownership, partnership, membership or other equity positions, regardless of the form of the entity, or options or rights to acquire such positions, rights and/or royalties in patents or other intellectual property. Ownership of interests in diversified mutual funds is excluded from this designation and need not be reported.
Personal 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 ACC/AHA document development.
Employment or Salary Support	Full or partial employment or grant support of salary, position or program; may also include pension or benefits received from prior employment.

<p>Institutional or Organizational (including but not limited to research)</p>	<p>This category refers to relationships between industry and an institution or organization with which the individual is affiliated when the individual is involved in 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.</p> <p>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.</p> <p>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.</p> <p>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 ACC or AHA or cooperative or competitive with entities having business interests in the guideline topic.</p>
<p>Expert Witness</p>	<p>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.</p>

*Divesting publicly traded stock or stock options nullifies the specific relationship and in such cases the 12 month rule does not apply.

†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 ACC/AHA

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 oversight Task Force 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 document under development.

2.1.3. Writing Committee Balance (bias)

Chair/Co-Chairs: The Chair or Co-Chairs should have no relevant RWI.* The writing committee chair is selected mainly on the basis of competency to effectively manage the writing group and develop consensus on the text and recommendations. A general knowledge of the topic of the document is also necessary, but the chair need not have expertise in the topic. The chair must be free of relationships or other 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 in the **ownership** category as defined above.

Committee: The Chair and at least half the writing committee members must be free of relevant RWI*. The TFPG/TFPM/TFDS 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 document development commences. Once chosen, authors are requested to avoid relevant RWI throughout the writing effort until publication.

*In conjunction with the writing committee Chair, the TFPG/TFDS/TFPM may prospectively define relevance to the topic when the content addressed in the document 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 document. 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 ACC/AHA.

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 must be reported as a significant or modest financial relationship.

2.1.5. Relevance to Document 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 **document**; or
- **The company/entity (with whom the relationship exists)** makes a drug, drug class, or device addressed in the **document**, makes a drug or device that competes for use with a product addressed in the **document**; 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 **document**.

For determining eligibility to draft text or vote on recommendations, 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 pertains to the specific product or competing product, the member **is permitted** to participate in discussions but **is not permitted** to draft recommendations or corresponding text or 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 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 relates 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 draft recommendations and/or corresponding text and **is not permitted** to vote on recommendations to which the relationship applies.

2.1.6. Timing of Disclosures

Relationships extant during the prior 12 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 processes. 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 document.

2.1.7. Open Payments Data Review

During formation of the writing committee, ACC/AHA 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 ACC/AHA values the expertise of its writing committee members and encourages full discussion to inform deliberation on document content. All writing committee members are therefore free to discuss all aspects of the document within the confidentiality bounds that apply to the document 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. Voting on Recommendations

In general, all committee members, even those with relevant RWI, may participate in the discussions of all topics covered by the writing committee. Individual members may not draft or vote on recommendations and/or text when they have relevant relationships, as defined in Section 2.1.4 above.

For the purpose of tracking adherence to this policy, a confidential written vote is taken for every formal recommendation prior to external peer review and then again when recommendations are revised in response to peer review prior to submission of the final document for review and approval by the ACC Clinical Policy Approval Committee (CPAC) and AHA Scientific Advisory and Coordinating Committee (SACC). The writing committee chair reviews the votes to ensure appropriate recusal of writing committee members with RWI and, in the interest of transparency, the record of recusals is published in the document by author and section.

2.2.3. External Peer Review

For Prevention Guidelines, official reviewers from AHA, ACC, and partnering organizations may not have relevant RWI. For all other statements and guidelines, there are no RWI restrictions upon participation in the external peer review process, as long as all reviewers disclose all RWI related to the topic. The relevant relationships are published in an appendix to the document. This policy provides opportunity for comment from a variety of constituencies and assures that those with diverse viewpoints inform the content of the document.

2.2.4. ACC Clinical Policy Approval Committee (CPAC) and AHA Science Advisory and Coordinating Committee (SACC) and ACC Science and Quality Committee (SQC) and AHA Executive Committee (EC) Review and Approval

Documents are approved by a majority vote of the ACC's CPAC and SQC and a majority vote of each of the AHA's SACC and EC (or other committee designated by the AHA Board of Directors), in each case by members who have no relevant RWI related to the document under consideration. CPAC, SACC and EC, SQC members with relevant RWI may comment but may not vote on clinical documents at the time of review and approval.

2.2.5. Public Disclosure of RWI

The ACC/AHA disclosure policy is cited in the published document and *relevant* RWI of authors and peer reviewers is published in the document 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 TFPG/TFDS/TFPM member is included in the document. This information resides on www.acc.org and on myamericanheart.org.