

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

1.0. Introduction

The American Heart Association (AHA) and American College of Cardiology Foundation (ACC) are committed to the highest ethical standards in developing trustworthy guidelines and performance measures. To fulfill this responsibility, policies and procedures preclude influence of industry or other relevant entities upon the scientific or clinical content of these documents. Both organizations recognize that including experts who have relationships with industry and other entities (RWI) among the membership of the ACC/AHA Joint Committee on Clinical Practice Guidelines (JCCPG) and ACC/AHA Joint Committee on Performance Measures (JCPM) (collectively, the “Joint Committees”) and writing committees can enhance the value of published documents when RWI is properly managed and disclosed.

The following statement outlines the AHA/ACC procedure and methods used to ensure that the document development process is free of bias or improper influence. This document seeks to ensure that the methods to collect, review, and report the RWI information for Joint Committees and writing committee members are appropriately transparent in the organizations’ approach to adjudicating RWI. These procedures apply generally to all clinical practice guidelines and performance measures.

1.1. Scope

The AHA/ACC requires that individuals* involved in writing efforts (authors and external peer reviewers), and members of the Joint Committees 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 the individual’s perceived relevance to the topic of the document, upon invitation to participate and throughout the joint document production process once selected. These disclosures are reviewed to ascertain the candidate’s RWI status and assess eligibility to serve in various capacities in the production of AHA/ACC guidelines and performance measures. Employees of industry, part-time or full-time, are prohibited from serving on Joint Committees and writing committees. Individuals are prohibited from serving on Joint Committees and writing committees if that individual or their household members serve as members of the Board of Directors of industry.

*Note that the term “individual” is used in this procedure to be broad and encompass Joint Committee and writing committee members where applicable. The use of “member” should be looked at in context as an individual may be a member of the ACC and/or AHA, as well as a member of a Joint Committee and/or writing committee.

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 the timeframe of the relationship, the nature of the relationship, and the appropriate management of the compensation, potential bias can be avoided or minimized while assuring that the final, published document reflects the necessary clinical competencies and expertise.

For the purpose of this procedure, “industry” refers to companies whose primary business is producing, marketing, selling, re-selling or distributing healthcare products used by or on patients (including services from which a member derives a *significant* proportion of income) and “other entities” refers to noncommercial, intellectual, institutional, and patient- public activities, each as pertinent to the potential scope of the document. (“*Significant*” defined in Section 2.1.4).

In addition to managing RWI, the AHA/ACC (through the Joint Committees) monitor for and manage other potential sources of bias pertinent to the writing effort, beginning with selection of writing committee members and peer reviewers 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

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: Joint Committees and Writing Committees

1.3.1. The Joint Committee on Clinical Practice Guidelines

The Joint Committee on Clinical Practice Guidelines (JCCPG) oversees development of guidelines and establishes procedures governing these documents on behalf of the AHA and ACC. The JCCPG 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 Joint Committee on Performance Measures

The Joint Committee on Performance Measures (JCPM) oversees development of performance measures and establishes procedures governing documents of this type on behalf of the AHA and ACC. The JCPM prioritizes topics and performance items, writing committee formation, methodology, document development, and procedures for peer review, document approval, and publication.

1.3.3. Writing Committees

Writing Committees commissioned by the JCCPG and JCPM are charged with developing guidelines or performance measures documents on assigned topics for publication in the appropriate journals of the two organizations.

1.3.4. Chair, Co-Chairs, Vice Chairs

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

1.4. General Principles for Managing RWI for Joint Committees

As committees responsible for oversight of their respective clinical document writing committees, the Joint Committees are exempt from most RWI strictures outlined in this procedure, excepting the Joint Committee Liaison role described below. Joint Committee members must still disclose all RWI in the ACC Disclosures database and verbally indicate any changes to their RWI at the beginning of formal meetings or teleconferences. Joint Committee members’ comprehensive RWI are included at the end of each clinical document.

Members of the Joint Committees who may serve as a Joint Committee Liaison between a clinical document writing committee and its respective Joint Committee are considered as members of that writing committee and the RWI strictures of this procedure apply. AHA and ACC senior staff leadership have responsibility for adjudicating RWI for Joint Committee members. Joint Committee Liaisons are recused from voting on sections in which they have relevant RWI as a part of the writing committee. The JCPM Liaison who may serve as a Joint Committee Liaison between a clinical document writing committee and JCPM is also considered as a member of the writing committee and the RWI strictures of this procedure apply. The JCPM Liaison is recused from voting on sections in which they have relevant RWI as a part of the writing committee.

When the Joint Committee votes to approve a clinical document, relevant RWI of the Joint Committee members is not considered, as the Joint Committee votes to approve the document in totality.

2.0. General Principles for Managing RWI for Writing Committees

2.1. Collecting RWI Information

The AHA/ACC 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

AHA/ACC requires disclosure of all RWI for the **six (6)-month period prior to the Kick-off Meeting** (i.e., officially recorded start date) of the writing committee. In addition, authors must refrain from adding new, relevant RWI throughout the writing effort until the date of publication (i.e., online release). Guidelines and performance measures writing committees are constituted such that no more than half the members have relevant RWI for six (6) months before the Kick-off Meeting until the publication of the document.

Failure to disclose a relevant relationship prior to official appointment to serve on a writing committee and throughout the duration of development will impact an individual's eligibility to participate. Late or missing disclosures are assessed by the AHA and ACC as grounds for removal from the writing committee.

Removal Procedure if New RWI Disclosed and/or Discovered

Changes to all RWI must be verbally disclosed by each member of the writing committee at the beginning of all meetings (including but not limited to conference calls, virtual meetings, and in-person meetings), followed in writing, and changes then reflected in the author disclosure table. AHA/ACC staff will collect, review, and identify any new disclosed relationships from authors every 90 days from Kick-off Meeting through publication. Additionally, the AHA/ACC Compliance Operations Manager will inquire about relationship context and investigate circumstances on a case-by-case basis.

For Chair/Co-Chair/Vice Chair, AHA and ACC senior staff leadership have responsibility for adjudicating RWI and determining any necessary changes or action. For writing committee members, AHA/ACC staff will report any new relationships to the Writing Committee Chair, AHA/ACC document advisor for guidelines or performance measures, AHA/ACC Director of Guideline Strategy and Operations, AHA/ACC Compliance Operations Manager, and AHA and ACC senior staff leadership for review and appropriate action, including but not limited to modifying writing committee assignments or removal from the writing committee.

2.1.2. Relationship Type

The following definitions describe the categories or types of relationships used for RWI reporting, clarifying expectations for disclosure, and general determinations for relevance.

REPORTING CATEGORY	DEFINITION
Consultant	<p>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 (6 months prior to the date of Kick-off Meeting).</p> <p>This includes consulting or advisory activities for federal, state, or local government agencies such as Centers for Medicare & Medicaid Services (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 AHA/ACC document development.</p>
Speaker or Member of Speakers Bureau	<p>Honoraria or fees received directly from industry for lecturing. Compensation received through contracts with industry or other entities for membership on or participation in speakers’ 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.</p> <p>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).</p>
Ownership/ Partnership/ Principal	<p>Stock holdings¹, stock equivalents², 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.</p> <p>Ownership of interests in diversified mutual funds is excluded from this designation and need not be reported.</p>
Personal Research	<p>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) or data monitoring safety board (DSMB), clinical event adjudication committee (CEAC) or clinical endpoint committee (CEC) activities, and other operational activities related to research).</p> <p>This category includes receipt of drugs, supplies, equipment, or other support when the individual has direct decision-making responsibility for allocated resources or proceeds.</p> <p>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 indicate responsibility to report.</p> <p>Research activity funded by the NIH or other federal agency should be reported but is generally not classified as relevant to AHA/ACC document development.</p>
Employment or Salary Support	<p>1) Full or partial employment; 2) member of Board of Directors; 3) grant support of salary, position, or program; or 4) pension or benefits received from prior employment.</p>

¹ Divesting publicly traded stock or stock equivalents nullifies the specific relationship, and in such cases the six (6)-month rule does not apply.

² Includes, but is not limited to, stock options, convertible notes and bonds, warrants, convertible preferred stock and contingent shares.

Institutional or Organizational <i>(including but not limited to research)</i>	<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. For example, 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 should be disclosed.</p> <p>In instances when funds are provided to the individual's institution, the following determinations would apply:</p> <ol style="list-style-type: none"> 1) If the individual is a national or international PI or Co-PI, they will be considered conflicted. 2) If the individual is a national or international study steering committee member, they will be considered conflicted. 3) 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. <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.) in professional or nonprofit organizations, whether or not remunerated, that may involve interests potentially competitive with the AHA or ACC or cooperative or competitive with entities having business interests in the document topic.</p>
Expert Witness	<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>

†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 an 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), Data Safety Monitoring Boards (DSMBs), 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 AHA/ACC 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 Joint Committee 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

Chair/Co-Chairs: 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).³ 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 does not need to 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, often to add content expertise and support for the Chair. Vice Chairs may have relevant RWI but may not have a significant relationship (see Section 2.1.4) in the ownership category (see Section 2.1.2).

Committee: Fifty-one percent or more ($\geq 51\%$) of the writing committee (including the Chair) must be free of relevant RWI.

The Joint Committees monitor writing committee composition for RWI and other potential sources of bias and approve each writing committee before document development commences. All individuals invited to serve on a writing committee must refrain from adding new relevant RWI throughout the writing effort until the date of publication (i.e., date of online release). Failure to disclose a relevant relationship within a timely manner upon invitation to serve on a writing committee and throughout the duration of development will impact an individual's eligibility to participate. Late or missing disclosures will be reviewed in compliance with the Removal Procedures set out in Section 2.1.1.

2.1.4. Financial Value or Level of Relationship

Financial relationships are classified as *significant*, *modest*, or *not monetary* and are reported by the member. A *significant* interest in a 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

³In conjunction with the writing committee chair, the Joint Committees may prospectively define relevance of a relationship to the document 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 on the approved definitions, certain relationships may be deemed not relevant to the document. These may include, but are not limited to, specified institutional/organizational and government/nonprofit relationships. Such special determinations are reviewed and approved by the organizational leadership of the AHA/ACC.

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. 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 Document Topic

Individuals invited to serve on a writing committee must report all RWI, and all relationships are evaluated for relevancy by the AHA/ACC staff and leadership. The Joint Committees take this information into account when determining eligibility of the individual to serve as a member of a writing committee. AHA and ACC senior staff leadership have responsibility for adjudicating whether RWI is considered relevant.

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 vote on recommendations or performance measures, the following considerations apply to *relevant* RWI of the individual writing committee member.

- 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 extant six (6) months prior to the Kick-off Meeting are disclosed in writing and/or online during formation of the writing committee to determine eligibility. All individuals invited to serve on a writing committee must refrain from adding new relevant RWI throughout the writing effort until the date of publication (i.e., date of online release).

To support writing committee members considering new relationships or who may be uncertain of existing relationships that may affect their RWI eligibility within the reporting timeframe, members should promptly disclose their intention and/or report all relationships to the writing committee chair(s), AHA/ACC document advisor, and AHA/ACC Compliance Operations Manager for guidance. The

appropriate Joint Committee must consider the impact of additional relevant or non-relevant RWI on the overall balance of the writing committee.

2.1.7. CMS Open Payments Data Review

During formation of the writing committee, the AHA/ACC Compliance Operations Manager will review the Open Payments database maintained by the 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. Writing committee members are encouraged to claim and manage their profiles through CMS Open Payments; this is not managed by the AHA/ACC staff. It is the writing committee member's responsibility to dispute any erroneous payments and advise AHA/ACC of the status of the dispute.

2.2. RWI Management

2.2.1. Consensus Development

The AHA/ACC 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 writing committee chair(s), 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 meeting (including but not limited to conference calls, virtual meetings, and in-person meetings) 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 writing committee members, even those with relevant RWI, may participate in the discussions of all topics covered by the writing committee. Individual writing committee members may not vote on recommendations or measures when they have relevant relationships, as defined in Section 2.1.5. For the purpose of tracking adherence to this procedure, a confidential written vote is taken for every formal recommendation or measure prior to external peer review and then again when recommendations or measures are revised in response to peer review prior to submission of the final document for review and approval by the AHA Scientific Advisory and Coordinating Committee (SACC) and ACC Clinical Policy Approval Committee (CPAC). The writing committee Chair and the AHA/ACC document advisor 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 of the relevant RWI table.

2.2.3. External Peer Review

2.2.3.1 Guideline Peer Review

Peer reviewers and Joint Committee members 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/AHA 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.

2.2.3.2 Performance Measure Peer Review

Peer reviewers for performance measures documents are required to 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. There is no requirement for any percentage of the peer reviewers for performance measures documents be free of relevant RWI.

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

Documents are approved by a majority vote of the AHA's SACC and EC (or other committee designated by the AHA Board of Directors) and a majority vote of the ACC's CPAC and SQC. Members of AHA's SACC and EC or ACC's CPAC and SQC with relevant RWI may comment on clinical documents at the time of review and approval. RWI is disclosed and recorded for all AHA and ACC participants in the review and approval process.

2.2.5. Public Disclosure of RWI

The AHA/ACC disclosure procedure is cited in the published document, and the *relevant* RWI of authors and the *comprehensive* RWI for peer reviewers are published in the document appendices. 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 Joint Committee member is included in the document. This information is accessible on <https://www.ahajournals.org/journal/circ> and on www.jacc.org.