

ACC Relationships with Industry and Other Entities (RWI): Policies and Procedures for the Development of Clinical Documents

1.0. Introduction

The American College of Cardiology (ACC) is committed to the very highest ethical standards in all its activities, including development of clinical policy. The College considers clinical document development as core to its missions and accepts no industry funding for development. The College has always taken a stringent approach to ensuring responsible, transparent relationships, in which industry support and other relevant entities has no influence on scientific content. The College believes that including experts who have relationships with industry and other relevant entities (RWI) on writing committees, when transparent and properly managed, strengthens the writing effort and final published document. However, part- or full-time employees of industry are prohibited from serving as members of clinical document writing committees. The following statement outlines the College's policy and methods used to ensure the document development process is free of bias or improper influence.

This policy applies to the following types of ACC clinical documents: Expert Consensus Decision Pathways, Expert Consensus Systems of Care, Appropriate Use Criteria, Health Policy Statements, Competency and Training Statements, and Lifelong Learning Statements.

For ACC/AHA documents (Guidelines, Performance Measures, and Data Standards), please consult the [ACC/AHA Relationships with Industry and Other Entities Policy](#).

1.1. Scope

For those involved in the writing effort (i.e., authors, external peer reviewers, and document oversight group members), the ACC requires the disclosure of all RWI (as defined in Section 2.1.2.) involved in the production, marketing, distribution or reselling of healthcare goods, services, advice or information consumed by patients, investors and/or physicians. This may include relationships with government entities as well as not-for-profit institutions and organizations (see category definitions for detail).

1.2. Terminology

1.2.1. Relationships with Industry (RWI) Versus Conflict of Interest (COI)

The ACC prefers the term Relationships with Industry and Other Entities (RWI) as opposed to the term Conflict of Interest (COI). RWI, by definition, does NOT necessarily imply a conflict. When all relationships are disclosed with the appropriate detail regarding category and amount, and managed appropriately for building consensus and voting, the College believes that potential bias can be avoided and the final published document is strengthened since the necessary expertise is accessible.

In addition to managing RWI, the College monitors and manages other potential biases that may be relevant to the writing effort including the views of academic versus nonacademic physicians, as well as other potential biases that may stem from race, gender, geographic location, or intellectual position on a particular issue.

1.2.2. ACC Document Oversight Groups

The following Document Oversight Groups direct and oversee the development of ACC clinical policy documents:

- The ACC Competency Management Committee (oversees Competency and Training Documents)

- The ACC Solution Set Oversight Committee (oversees Expert Consensus Decision Pathways, Expert Consensus Systems of Care Documents, Appropriate Use Criteria, and Health Policy Statements)

These groups coordinate: topic selection and prioritization, writing committee formation, document development methodology and procedures, external peer review, document approval and publication.

1.2.3. Writing Committees

Writing Committees are commissioned by their respective Document Oversight Group and charged with developing a document on an assigned topic for publication in the College’s journal which reflects ACC policy.

1.2.4. Chair, Co-Chairs, Vice Chairs

The term Co-Chair refers to two or more chairs who share equal responsibility. Co-Chairs (as for Chairs) may have no relevant RWI. The term Vice Chair refers to an individual who serves in conjunction with a Chair but is subordinate to that Chair. Unlike Chairs and Co-Chairs, Vice Chairs may have relevant RWI.

2.0. General Principles for Managing RWI

2.1. Collecting RWI

Listed below is the information the College collects for the purposes of managing RWI for clinical document development.

2.1.1. Reporting Timeframe

The ACC requires the disclosure of all RWI for the past 12- 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 are discouraged from adding new RWI during the writing effort; however, if relevant relationships are added, this information must be verbally disclosed during any conference calls or meetings, as well as added to the author disclosure table.

2.1.2. Relationship Type

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

REPORTING CATEGORY	DEFINITION
Consultant*	Includes relationships resulting in 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, lecturing, travel, service on an advisory board, or for any other similar purpose in the prior calendar year. (This includes private sector payers as well as pharmaceutical, device or other mission-related companies as well as consulting or advisory board membership on any federal or state government agency such as CMS and FDA).
Speaker’s Bureau*	Includes compensation from speaker’s bureaus.
Ownership/ Partnership/ Principal	Includes status as any stock‡, stock option‡, ownership, 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 and/or royalties in any patent or other intellectual property. Ownership of interests in diversified mutual funds is excluded from this designation and need not be reported.
Personal Research	Includes principal investigator (PI) or co-PI (if so, please specify), investigator, steering committee member, collaborator or consultant for pending grants as well as grants

	already awarded or received (including commercially-funded, NIH, and university-managed grants and DSMBs). Also includes receipt of drugs, supplies, equipment or other in-kind support over which individual has direct decision-making responsibility.
Salary	Funding of a salary or position (partial or full) or “in-kind” support of program.
Institutional, Organizational <i>(including but not limited to research)</i>	<p><u>Institutional</u>: Includes any institutional relationship between individual’s employer or academic institution and a business or other entity (including NIH grants or other government agencies) for which individual has direct decision-making responsibility. Examples: If the individual’s institution is recruiting patients for a trial and the individual is a sub-investigator† or co-investigator† (as defined below) and/or if the individual is a Chief of Cardiology and therefore has fiscal authority and/or direct decision-making responsibility (such as support for research grants, fellowships, grand rounds, and institutional supplies), these relationships should be reported here.</p> <p><u>Organizational</u>: Organizational competing relationships include any leadership or governance responsibilities or roles in another professional or other nonprofit organization, whether or not remuneration is received (e.g., Officer, Director, Trustee or other Fiduciary Role, Editor) that may have interests potentially competitive with the College.</p>
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. In all cases, disclosure of expert witness testimony should be consistent with applicable requirements and restrictions, such as HIPAA, court rules, and confidentiality agreements.

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

†Sub-investigator or co-investigator in this instance are defined as an individual who has signed a Form 1572 and is NOT a primary or co-author of data analyses including abstracts and manuscripts; does NOT have oversight of the research, report data, or receive money from the trial sponsor (including direct salary support and/or staff salary support [including staff that you share], overhead charges); and does NOT receive travel funds to attend investigator meetings hosted by the sponsor. If the answer to any of these modifiers is ‘YES’, then the relationship should be disclosed under the **personal research** category and if all answers are ‘NO’, the relationship should be disclosed under the **institutional** category.

‡The divesting of stock or stock options will immediately nullify the specific relationship; therefore, the 12-month rule does not apply.

2.1.3. Financial Value/Level of Relationship

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 \$5,000 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 reporting period. 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 the individual receives no monetary reimbursement. If an individual directs where financial compensation goes, e.g., donates to charity, faith-based, educational, or other tax-exempt organizations, such funds are reported as financial relationships.

2.1.4. Relevance to Document /Topic

Authors must report ALL RWI.

For determining eligibility to serve on a writing committee, all relationships are evaluated by the respective oversight committee for relevance. A person has a **relevant** relationship 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 a reasonable potential for financial, professional or other personal gain or loss as a result of the issues/content addressed in the ***document***.

2.1.5. Disclosure Timing

Relationships are disclosed 1) in writing or online in advance of the writing effort to determine eligibility of members to serve on a writing committee and 2) during the document development process to ensure complete transparency throughout the writing and sign-off processes. Relationships that develop during the writing process must be reported to the writing group chair immediately. In cases where the new 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.

2.2. RWI Management

2.2.1. Writing Committee Balance (bias)

Chair/Co-Chairs: The Chair or Co-Chairs may have no relevant RWI.* The writing group chair 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 undermine the credibility of the writing group or its work product.

Vice Chair: A vice chair may be added to the writing effort if needed for content expertise. Vice chairs may have relevant RWI but *may not have a significant relationship in the ownership category* as defined above.

Committee: A majority of writing committee members must be free of relevant RWI.* † At least 50% of writing committee members, plus the Chair, may have no relevant RWI. The Document Oversight Group monitors writing committee composition for RWI, as well as other potential areas of bias, such as intellectual bias/perspectives or organizational relationships potentially competitive with the College, and must approve each writing committee before work begins. Once chosen, authors are requested to avoid forming any new relevant RWI during the writing effort in order to maintain the RWI balance of the writing committee.

Of note, the Document Oversight Group also reviews writing committee balance for other issues such as specialty, geographic location, private practice (versus academic setting/practice), gender, race, and appropriate organizational/content expertise.

* The Document Oversight Committee in conjunction with the WC Chair has the discretion to prospectively define “relevance” to the topic of the document in instances where the content addressed in the document is non-clinical or non-prescriptive in nature and, therefore, a disease- or procedure-based definition would not be applicable. This means that the Task Force in conjunction with the WC Chair may deem certain individual relationships disclosed by the chair, co-chair, vice-chair and/or writing committee member(s) as NOT relevant to the writing of the document, as appropriate based upon the

agreed upon definition of relevance. These may include, but are not limited to, participation in government-sponsored or university-managed Data Safety Monitoring Boards or research, as well as certain institutional/organizational and government/nonprofit relationships. To ensure transparency, the definition of relevance must be prospectively determined, noted in the RWI Table and included in the document Introduction.

2.2.2. Consensus Development

All writing committee members are invited to discuss all aspects of the document, including those for which they have relevant RWI. The College values the expertise of all writing committee members and allows open discussion to inform the writing committee's final deliberation on document content. However, if one or more individuals appear to be unduly influencing the outcome of the discussion, whether they have a relevant relationship with industry to the topic under discussion, a relevant relationship with another (nonindustry) entity to the topic (see above definition), or other bias related to the discussion, the individual may be asked to leave the room or conference call during a portion or all of the discussion at the discretion of the Chair.

2.2.3. Voting on Recommendations

In general, all committee members, even those with relevant RWI, may participate in all discussions. However, writing committee members may not vote on recommendations if they have a relevant relationship 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 document recommendation prior to external peer review and then again on recommendations that change as a result of peer review following the finalization of the draft prior to the Board review/approval process.[†] The writing committee chair must review all votes to ensure accurate recusal by all writing committee members.

[†]Appropriate Use Criteria (AUC) documents utilize a modified Delphi consensus method as outlined by RAND in their Appropriateness Criteria Method document and ACC AUC Methodology paper. This method utilizes a two-step process: Delphi Method Step 1) writing committee develops a list of typical clinical scenarios/indications; Delphi Method Step 2) technical panel members review and rate the individual clinical scenarios. The RAND Delphi method allows the contribution of a wide range of viewpoints while minimizing and controlling bias through an independent rating/recommendation panel, a review of score dispersion, use of the median rating to determine final recommendations, and a highly structured process for determining recommendations (see methodology manual for details). As such, all rating panel members, even those with RWI, will be allowed to rate as a part of the technical panel modified Delphi process.

2.2.4. External Peer Review

There are no RWI restrictions for participation in the external peer review process of a document; however, all reviewers must disclose all relevant RWI to the topic for publication in an online appendix of the document. This promotes the opportunity for comment on the document from a variety of constituencies/viewpoints to inform final document content.

2.2.5. ACC Organizational Review and Approval

The ACC has 2 official committees for the purpose of approving clinical documents:

- The Clinical Policy Approval Committee (CPAC) - provides organizational review and approval of ACC Expert Consensus Decision Pathways, Expert Consensus Systems of Care Documents, Appropriate Use Criteria, and Health Policy Statements as well as ACC/AHA practice guidelines, performance measures and data standards, and documents led by other organizations in which ACC is a partner society.

- The Lifelong Learning Oversight Committee (LLOC) - provides organizational review and approval of ACC Competence, Lifelong Learning, and Training Statements.

ACC approval committee members may comment but should not vote on clinical documents at the time of organizational review and approval if they have relevant RWI. Documents are approved as College policy by a majority vote of approval committee members who have no relevant RWI to the document under consideration.

2.2.6. Public Disclosure of RWI

The College's disclosure policy is cited in the published document and *relevant* RWI of authors are published in a document appendix. In addition, to ensure complete transparency, a hyperlink to the *comprehensive RWI* of each author and peer reviewer (in effect at the time of the writing effort is included in the document.

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