



## **Introduction**

The American College of Chest Physicians (CHEST), through its Guidelines Oversight Committee (GOC), is committed to the development of independent, trustworthy, high-quality, evidence-based guidelines and consensus statements that are free from the influence of industry. To limit the potential for bias, CHEST both adheres to strict methodological standards related to the identification and assessment of available literature and enforces a strict panelist conflict of interest review and management process. While CHEST strives to form guideline panels that are free from financial and/or intellectual conflict, the inclusion of recognized clinical experts who have relationships deemed to be manageable ensures the involvement of the leading scientists and clinicians in the field. Accordingly, members of the Professional Standards Committee (PSC) will apply the standards delineated in this document and its supporting materials as they review and make decisions on panelist participation based on disclosed conflicts of interests (COIs); the guideline panel chair and GOC will ensure the application of all defined terms of participation.

## **General Policies**

1. In creating evidence-based guidelines and consensus statements that clinicians and the public will trust, CHEST must limit the potential for bias through careful vetting, evaluation, and management of the financial relationships and intellectual activities of each potential participant.
2. All potential panelists will be required to submit a complete disclosure prior to the initiation of guideline/consensus statement development. Panelists' disclosures and contributions to the field will be reviewed both as individuals and in aggregate to achieve a balanced panel.
3. The scope of disclosure will include a 3-year period and will capture (a) the personal potential COIs, (b) those of any first-degree relative (individual, their spouse, domestic or life partner, dependent children, and minors living in the same household (per IRS definition), and (c) those of the prospective panelist's spouse/domestic partner (per IRS definition). For financial disclosures, dollar amounts must be provided for both monetary and in-kind remuneration. The PSC will take into account a person's ability to divest of activities that may be viewed as disqualifying conflicts and may include divestment as a condition for participation for specific COIs.

All panelists will agree to divest from all disqualifying relationships at time of nomination and to adhere strictly to any COI management terms and will not assume any new relationships until a minimum of 1-year post-publication of the document (or another time period to be designated by the GOC) without the expressed written preapproval of the PSC Chair. Each panel meeting will begin with a verbal reminder of this policy. Panelists will also be asked to complete the CHEST® journal COI form on submission of the manuscript for consideration by the

Conflict of Interest

Guideline/Consensus Statements – January 2022

journal. If discrepancies between the original disclosure and that completed for publication emerge that were not approved in writing by the PSC, the panelist will no longer be eligible for authorship.

4. All potential COIs, even those that appear to be indirectly related to the topic, and management terms will be publicly disclosed through publication in the final article, and the COI management process will be addressed in the methodology section of the final guideline/consensus statement to ensure readers have complete and transparent detail.

## Definitions

- Commercial interest/entity is any for-profit entity producing, marketing, re-selling, or distributing health-care goods to be consumed by or used on patients (e.g., pharmaceutical or device companies).
- Conflict of Interest (COI) refers to any relationship or other set of known circumstances that has the potential to bias, or that might be reasonably perceived by others to bias, an individual's judgment, conduct, or other work.
- Financial COIs include any relationship for which one receives remuneration or in-kind benefits that could be perceived to affect one's judgment in the evaluation of specific recommendations. These include holdings in individual investments (e.g. holdings in stocks, stock options, warrants, bonds, or any form of direct investment of pharmaceutical or device companies), and patents associated with licensing, and/or financial or in-kind benefit; and these include such holdings held by the guideline participant, their spouse, domestic or life partner, dependent children, and minors living in the same household (per IRS definition).
- Intellectual COIs include any activities that create the potential for attachment to a specific predetermined point of view that could be perceived to affect one's judgment in the evaluation of specific recommendations or suggestions.
- Related content areas are those that are aligned with the clinical questions and/or PICO elements (patient-intervention-comparator-outcomes) to be addressed within the guideline.

## Guideline Development Roles

- Executive Committee consists of the guideline Chair, Co-Chair/Vice-Chair/Topic Chair, lead methodologist, and GOC liaison who collaborate on a guideline. The group may exist formally when multiple aspects of a broad content area are being addressed simultaneously through the living guidelines model and prioritization among clinical questions and targeted updates is necessary.
- GOC Chair/Vice-Chair oversees all guideline development, training, and dissemination/implementation activities and provides support and advice to GOC Liaisons and guideline Chairs, as needed.
- GOC Liaison is a standing member of the GOC who, together with GOC leadership, carries responsibility for overseeing guidelines and consensus statements developed in a particular content domain and serves as an advisor to the Chair and panelists. The GOC liaison supports the Chair and ensures adherence to COI management terms across the panel for assigned projects through participation in all project calls.
- Chair (Co-Chair/Vice-Chair/Topic Chair) is the lead of the guideline effort and should have relevant clinical expertise and experience in the subject area; and is responsible for defining the initial scope and clinical questions, making recommendations on panelists, and ensuring adherence to COI management

terms across the panel.

- Panelist is any person who contributes to the work of developing the guideline (e.g., defining the scope, forming the clinical questions, searching and evaluating the literature, developing recommendations or suggestions, voting, and drafting the manuscript) and includes an expectation of authorship, provided they meet the criteria defined by the International Committee of Medical Journal Editors.
- Definitions associated with conflict of interest policy are provided in [Appendix B: CHEST Conflict of Interest Terminology](#).

## Process

### Guideline Approval, COI Collection, Panel Formation

1. On submission of a new guideline topic for GOC consideration (or on the proactive decision to update a guideline in a specific content area), a GOC liaison is assigned, and the submitter is asked to generate a list of proposed guideline panelists, noting the recommended Chair and/or Vice-Chair/Co-Chair (if someone other than themselves).
2. Staff will initially send the disclosure of the proposed Chair and/or Vice-Chair/Co-Chair and Domain Liaison to PSC to review along with the proposal itself for context.
3. Once GOC formally approves the guideline topic, staff will invite proposed panelists to submit their disclosure forms within a 2-week period. Complete forms will be forwarded to the PSC in aggregate with the draft clinical questions (and their PICO elements) to be addressed by the guideline, enabling the PSC to review conflicts, relevance, hold discussions, and make determinations on individual panelists. In the rare circumstance that PICOs are not available, panelists who are approved with management will be re-reviewed once the PICO questions are defined.
4. A grid of all decisions made—or requests for additional information—on a panel will be sent to the GOC Chair and Vice-Chair, GOC Domain Liaison, and Panel Chair/submitter.
5. Each candidate receiving a management plan or disapproval will receive a call from the Chair or Vice-Chair of PSC prior to the formal decision letter being sent. Discussion will include divestment from COI, management terms, the process to vet any newly proposed relationships or activities that might occur while on the guideline, and a review of the appeal process.
6. Staff will issue final decision letters on behalf of the PSC, copying the PSC Chair, GOC Domain Liaison, and guidelines Chair.
7. Each approved candidate will sign a formal panel member agreement, referencing their management terms and the COI policies.

Convening a preliminary group to define the scope of a particular guideline or to prioritize the clinical questions to be addressed may be necessary. Such groups must be convened by the GOC Domain Liaison, who will communicate that no expectation of panel membership or appointment prior to the formal disclosure and review process should be held by group members. In instances in which such individuals are unable to participate on a panel, their contributions to defining the scope should be included in the acknowledgments section of the final manuscript.

## Appeals

Decisions related to Chair, Vice-Chair, and panelist-level participation and/or management terms made by the PSC may be appealed through written request. The submitter should include any additional information and the potential justification for determination of a different decision. The appeal will be considered by a joint group of five individuals from the PSC and GOC, led by the Chair of PSC, and will serve as the final arbiter. The appeals body includes the (1) PSC Chair, (2) PSC Vice-Chair, (3) GOC Chair, and (4) GOC Vice-Chair.

## Review and Categorization of COIs

In reviewing submitted disclosure forms, determining the relevance of each disclosure is paramount. Conflicts that relate directly to the disease, diagnostic techniques, interventions, or management being evaluated are said to be *primary*; those that do not relate directly are characterized as *secondary*. This distinction will often form the basis for differentiating between manageable and disqualifying conflicts. The scope of an individual's activities is also considered in aggregate. While a dollar amount on a single activity may not be particularly high, a large number of relationships (e.g., advisory board activities) that total a substantial dollar amount may lessen public trust in the document that results. In reviewing grant-related relationships, it is important to take into account who receives the funding (institution vs individual) and whether direct salary support is provided.

Disclosure of COIs over the last 3 years is required; however, emphasis will be placed on the last year of COIs when vetting candidates for guideline panel positions. COI disclosures must clearly explain the relationship, related disease topics involved in the relationship, and dates of payment for stated services.

In evaluating total panelist participation, constructing a panel wherein only a minority of members have conflicts of interest requiring management is ideal. All conflicts of interest, including those deemed acceptable and those deemed manageable, will be reported throughout the guideline development process and disclosed in final publication.

## Acceptable Relationships and Activities

In general, acceptable relationships and activities include those that are:

1. Intellectual in nature and lacking direct and indirect financial benefit; or
2. Unrelated to the content area and focus of the PICO question or recommendation, with a company that has no products in that specific topic area.

Where intellectual conflicts exist, relationships should be disclosed to the group of panelists throughout the development process and included in the final publication. The remaining types of activities listed require disclosure but no proactive management.

For full detail, refer to [Appendix A: Categorization of Relationships and Activities by Role](#).

## Manageable Relationships and Activities

For certain types of relationships, the GOC, through the Chair (and Vice-Chair/Co-Chair) and GOC Domain Liaison, will develop and oversee individualized, formal, and transparent Conflict of Interest

management plans that will delineate any limitations on participation defined as a result of the relationships. See “Decisions and Management Terms” for details. Management plans will be published with the final document.

For full detail, refer to [Appendix A: Categorization of Relationships and Activities by Role](#).

### **Disqualifying Relationships and Activities**

The scope or nature of some relationships negates management and will sometimes outweigh the content expertise an individual may bring by serving as a full panelist, resulting in disqualification.

In some cases, a potential panelist may be given the opportunity to divest of a relationship(s) instead of being disqualified. Participant must divest prior to initiating work on the guideline and for a minimum duration of 1 year post-publication.

For full detail, refer to [Appendix A: Categorization of Relationships and Activities by Role](#).

### **Review of Chair/Vice-Chair/Co-Chair/Domain Liaison**

The guideline or consensus statement Chair or Chair and Vice-Chair/Co-Chair and Domain Liaison oversee all aspects of the process, including developing and prioritizing the key clinical questions to be addressed in the document. They must have an intimate knowledge of the literature and applicable clinical experience that informs how the literature translates to practice. They should also have experience with or exposure to the science of evidence-based medicine through past participation on a guideline panel or in the development of systematic reviews and a solid understanding of how to objectively assess the literature and apply tools, such as the evidence-to-decision framework, that limit the introduction of bias into the process of developing clinical recommendations and suggestions.

The Chair, with the support of the GOC Domain Liaison, must also regularly remind panelists of the COI policies and that no new relationships or activities can be assumed without the expressed written permission of the PSC Chair and carry out the management terms assigned to individual panelists, including him/herself.

While it is ideal to have Chairs and Domain Liaisons who are free of conflict, it may be unlikely to identify someone with the desired degree of expertise who is devoid of all potential financial and intellectual relationships. If the best choice for Chair and/or Domain Liaison has conflicts, (1) the individual will be asked to divest of all related activities/relationships, and (2) CHEST in collaboration with the GOC Chair, will seek to identify a Co-Chair with no conflicts, who will be asked to lead the following activities:

- Drafting of recommendations/suggestions
- Discussion of recommendations/suggestions
- Grading of recommendations/suggestions
- Voting on recommendations/suggestions
- Provision of writing assignments to panel members

Chair divestment from related activities and relationships should occur 1-year prior to the

Conflict of Interest

Guideline/Consensus Statements – January 2022

commencement of guideline development.

### **Permission Mid-Development**

If a panelist, Chair, Co-Chair, or GOC Liaison is presented with a new opportunity to participate in a potentially relevant activity concurrent guidelines development process or defined post-publication period, it is their responsibility to seek the expressed, written permission of the PSC prior to agreeing to/taking on the activity.

Requests should be submitted in writing 6 weeks prior to the initiation of the activity, utilizing the uniform disclosure system and providing all requested detail.

On consideration, new management terms may be applied and will be communicated to the individual, staff, guideline Chair, and GOC Liaison. New activities taken on without the written permission of the PSC will impact participation and authorship eligibility.

In the event a panelist wishes to appeal a decision, the standard appeals process will apply.

### **Decisions and Management Terms**

The decisions of the PSC will result in one of the following actions:

1. Approval/Appointment
2. Appointment with management
3. Appointment on the condition of divestment from specified activities, with management
4. Disqualification

For those individuals who are approved with management, the specific terms of management will be set forth by the PSC and will relate to specific clinical questions/PICOs and limit participation in the following way:

- May participate in discussions, but may **not** draft, vote, or grade recommendations relevant to specific conflicts (note content/clinical question).

The PSC sets these terms but relies on the Chairs and GOC Domain Liaison to control the participation of those panelists who are approved with management to ensure that the terms are upheld.

## **Appendix A:**

### **Categorization of Relationships and Activities by Role**

This table is intended to provide guidance for decision-making related to activities reported as occurring in the 3-year period prior to initiation of a guideline topic. Management terms assume divestment of any existing potential disqualifying relationship from the time of appointment to the panel through 1-year post-publication, and, in all cases, the panel member agreement should stipulate that new relationships or activities will not be assumed without review and appropriate approval for the period of guideline development plus 1-year post-publication.

Conflict of Interest

Guideline/Consensus Statements – January 2022

The ability to apply management terms also assumes that there is a portion of the guideline for which the individual would be considered nonconflicted and on which they could fully participate. In instances in which a person's relationships are manageable but relate to the entire guideline and all PICO's, the result would also be disqualification.

For the purposes of this policy, a commercial entity is defined as any for-profit entity producing, marketing, re-selling, or distributing health-care goods to be consumed by or used on patients (e.g., pharmaceutical or device companies).

A Type of Relationship/Activity		B Chair, Co-Chair, GOC Liaison*	C Methodologist	D Panelist
<b>RESEARCH AND SCHOLARLY ACTIVITIES</b>				
1	Authorship in scientific peer-reviewed publications	Acceptable	Acceptable	Acceptable
2	Authorship in nonscientific publications	Acceptable	Acceptable	Acceptable
3	Authorship of textbooks/chapters	Acceptable	Acceptable	Acceptable
4	Authorship of material in support of a commercial entity			
4.1	With no product in topic area	Acceptable	Disqualifying	Acceptable
4.2	With a product in topic area	Disqualifying	Disqualifying	Acceptable
5	Investigator in grant-funded research on unrelated or related topics supported by nonprofit/government	Acceptable	Acceptable	Acceptable
6	Investigator in grant-funded research on unrelated or related topics supported by commercial entity with no product lines related to topic	Acceptable	Disqualifying	Acceptable
7	Investigator in grant-funded research on unrelated or related topics funded by commercial entity with product lines related to topic			
7.1	With funds directed to institution	Acceptable	Disqualifying	Acceptable
7.2	With funds directed to individual	Disqualifying	Disqualifying	Manageable

A Type of Relationship/Activity	B Chair, Co-Chair, GOC Liaison*	C Methodologist	D Panelist	
EDUCATIONAL ACTIVITIES ^				
8	Faculty in CME-/MOC- accredited activity	Acceptable	Acceptable	Acceptable
8.5	Faculty in a commercially sponsored, nonaccredited activity where a not- for-profit organization fully controls speaker selection and content (e.g. CHEST-run commercially sponsored symposia)	Acceptable	Acceptable	Acceptable
9	Faculty in commercially sponsored nonaccredited activity (e.g. morning symposia) in an unrelated area			
9.1	With no product lines related to topic	Acceptable	Acceptable	Acceptable
9.2	With product lines related to topic	Disqualifying	Disqualifying	Acceptable
10	Faculty in commercially sponsored nonaccredited activity (i.e., morning symposia) in a related area, where the speaker controls content.	Disqualifying	Disqualifying	Manageable
ADVISORY/CONSULTANCY ENGAGEMENTS				
11	Participation in a data- safety monitoring board	Acceptable	Acceptable	Acceptable
12	Advisor/consultant to industry on study design, education, or focus group on an unrelated topic			
12.1	With no product lines related to topic	Acceptable	Disqualifying	Acceptable
12.2	With product lines related to topic	Disqualifying	Disqualifying	Acceptable
13	Advisor/consultant to industry on study design, education, or focus group on a related topic	Disqualifying	Disqualifying	Manageable
14	Participation on a speaker's bureau on an unrelated topic for commercial entity			
14.1	With no product lines related to topic	Disqualifying	Disqualifying	Acceptable
14.2	With product lines related to topic	Disqualifying	Disqualifying	Manageable
15	Participation on a speaker's bureau on a related topic, where the company controls the content.	Disqualifying	Disqualifying	Disqualifying
PUBLIC STATEMENTS				
16	Issuing statements on an unrelated topic on behalf of a commercial entity			
16.1	With no product lines related to topic	Acceptable	Disqualifying	Acceptable
16.2	With product lines related to topic	Disqualifying	Disqualifying	Disqualifying
17	Issuing statements on a related topic on behalf of a commercial entity	Disqualifying	Disqualifying	Disqualifying
18	Providing paid expert testimony on an unrelated topic on behalf of a commercial entity			
18.1	With no product lines related to topic	Acceptable	Disqualifying	Acceptable
18.2	With product lines related to topic	Disqualifying	Disqualifying	Acceptable



19	Providing paid expert testimony on a related topic on behalf of a commercial entity	Disqualifying	Disqualifying	Disqualifying
19.5	Providing paid expert testimony on a related or unrelated topic privately for a noncommercial entity (e.g. patient, private sector).	Acceptable	Acceptable	Acceptable
A Type of Relationship/Activity		B Chair, Co-Chair, GOC Liaison*	C Methodologist	D Panelist
INTELLECTUAL PROPERTY AND INVESTMENTS***				
20	Patent holder or applicant			
20.1	Patent unrelated to topic	Acceptable	Acceptable	Acceptable
20.2	Patent related to topic	Disqualifying	Disqualifying	Disqualifying
21	Investments (e.g. stock holdings, stock options, warrants, shares, bonds, or any other form of direct investment (not as part of mutual fund) in pharmaceutical companies or any other commercial entities (e.g. device manufactures) that manufacture or sell products related to management of an individual with disorders addressed by CHEST.			
21.1	With no product lines in topic area	Acceptable	Acceptable	Acceptable
21.2	With product lines in topic area**	Manageable	Manageable	Manageable
EMPLOYMENT				
23	Full-time/part-time employment arrangement with a commercial entity			
23.1	With no product lines related to topic	Disqualifying	Disqualifying	Acceptable
23.2	With product lines related to topic	Disqualifying	Disqualifying	Disqualifying
TOBACCO				
24	Investments or engagements with tobacco-related companies and their wholly owned subsidiaries.	Disqualifying	Disqualifying	Disqualifying

\* In cases in which executive committees are empaneled to guide the development of living guidelines, all executive committee members will be treated at the Chair/Co-Chair/GOC Liaison level.

\*\*Similar to being asked to divest from activities prior to engaging in a panel, potential panelists may be required to divest of stock options.

\*\*\* Include such holdings held by the guideline participant, their spouse, domestic or life partner, dependent children, and minors living in the same household (per IRS definition).

^Carefully review all contracts to ensure that recordings, statements, and other content from educational activities cannot be re-purposed for commercial (including, but not limited to, marketing, promotional, or investment) purposes.

## **Appendix B:**

CHEST Conflict of Interest Terminology (Developed October 2019)

**Commercial Advisory Boards, Committees, or Engagements:** Serving on a committee or board organized by a commercial entity on a topic related to a company project, product or promotion.

**Authorship:** Listed among the authors of a manuscript or other publication that is intended for distribution (first, middle or last author). Being listed in the acknowledgement section does not count as authorship.

**Commercial Educational Activity:** Educational forum organized/supported by a commercial entity without conformance to standards required by the American College of Continuing Medical Education (ACCME) (i.e. non-accredited). Examples include satellite symposia, pharmaceutical or device manufacturer organized educational events, local sponsored lectures, or any talk/presentation using any industry branded, generated, or facilitated slides.

### **Commercial Entity:**

The PSC defers to the ACCME definition of a commercial entity. A *commercial interest* is any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.

The ACCME does not consider providers of clinical service directly to patients to be commercial interests - unless the provider of clinical service is owned, or controlled by, an ACCME-defined commercial interest.

A commercial interest is not eligible for ACCME accreditation. Commercial interests cannot be accredited providers and cannot be joint providers. Within the context of this definition and limitation, the ACCME considers the following types of organizations to be eligible for accreditation and free to control the content of CME in which case they would not be considered commercial entities by CHEST:

- 501-C Non-profit organizations (Note, ACCME screens 501c organizations for eligibility. Those that advocate for commercial interests as a 501c organization are not eligible for accreditation in the ACCME system. They cannot serve in the role of joint provider, but they can be a commercial supporter.)
- Government organizations
- Non-health care related companies
- Liability insurance providers
- Health insurance providers
- Group medical practices
- For-profit hospitals
- For-profit rehabilitation centers
- For-profit nursing homes
- Blood banks
- Diagnostic laboratories

**Competing Organization:** Another society or organization with which CHEST would compete (e.g. for members, annual meeting attendance, or products).

**Conflict of Interest:** Any relationship or other known set of circumstances that has the potential to bias or might reasonably be perceived by others to bias, an individual's judgement, conduct or other actions.

- **Financial COI:** Any relationship for which one receives remuneration or in-kind benefits that could be perceived to influence one's judgement in the evaluation of specific recommendations. These include relationships by the participant, their spouse, domestic or life partner, dependent children and minors living in the same household.
- **Intellectual COI:** Any activity that creates the potential for attachment to a specific predetermined point of view that could be perceived to affect one's judgement in the evaluation of specific recommendations or suggestions.
- **Related content area:** Those that are aligned with the clinical questions and/or PICO elements to be addressed within the guideline or recommendation.

**Consultancy:** Time-limited business relationship with a commercial entity, where the consultant provides professional input regarding a project, product, or medical topic. To comprise a COI, the consultant must receive some remuneration for their participation which includes in-kind payments such as travel expenses.

**Expert Testimony:** Testimony made by a qualified person about a scientific, technical, clinical, or professional issue. A key distinction is whether one provides testimony in support of (or opposition to) a pharmaceutical or device company (which must be managed or is prohibited, depending on one's leadership level/guideline position with CHEST) or for a patient which is acceptable.

**Employment:** Refers to a contractual arrangement where the employee performs a service which is paid for by the employer.

**Faculty:** Presenter or moderator at an educational or promotional event

**Guideline Panelist:** Any person who contributes to the work of developing the guideline (e.g. defining the scope, forming the clinical questions, searching and evaluating the literature, developing recommendations or suggestions, voting, and drafting the manuscript) and includes an expectation of authorship, provided they meet the criteria defined by the International Committee of Medical Journal Editors.

**Investigator:** Investigators on a project usually receive remuneration for their role on the program/project. This typically includes Principal Investigators and Co-Investigators, but not consultants (paid or unpaid). Forms of remuneration include monetary compensation, equipment, travel, or supplies.

**Speakers Bureaus:** Being identified as a company sponsored speaker for an educational event where slides or content are at least in part supplied by the company

- If Pharma gives money to an institution or not-for-profit organization (assuming that organization is not financially linked to a pharmaceutical or device manufacturer) to host an event, it is required that the talk title, the talk content, speakers, and all funds be negotiated and managed by the institution/organization

**Tobacco Company:** A tobacco company is defined as engaged in the growth, preparation for sale, shipment, advertisement, and distribution of tobacco or tobacco-related products, including one that is a wholly owned subsidiary of a tobacco company.

**Patent Holder or Applicant:** Being listed as the sole or one of several inventors of some disclosed intellectual property submitted for patent consideration.

**Promotional Activities:** Those activities that support, market, or increase sales or consumption of a specific drug, device, technology, or technique, or that are intended to enhance the image, well-being, stature or popularity of a commercial entity pertinent to chest medicine, independent of remuneration.