

CBIRD:  
**C**ommercial **B**ias, **I**nterest,  
**R**esolution and **D**isclosure

---

Separating Promotion from Education  
October 2020

Separating Promotion from Education and  
Protecting the Integrity of CME is all about:

---

Avoiding commercial bias and  
ensuring faculty and planners understand  
your expectations from start to finish

## Let's start with the definition of Commercial Bias

---

**Commercial bias** is defined as information presented in a manner that attempts to sway participants' opinions in favor of a particular **commercial** product for the express purpose of furthering a **commercial** entity's business.

# In order to avoid Commercial Bias

---

Accredited providers must **plan** and **monitor** their activities in such a manner to ensure CME content meets ACCME policies and standards.

# As You Plan: Those in control of Content

---

It's easy to understand the role that teachers and authors play, but those in control of content also include people you bring together to say:

- What subject should we be talking about?
- What speakers should we be getting?
- What aspects of the area of care or research should we be pursuing in our educational activity?

# As You Plan: Those in control of Content

---

Consider those in control of content to include:

- Educational Staff
- Planners
- Planning Committees
- Content Reviewers
- Authors/Faculty Presenters

# What are ACCME's policies around CME Content

---

SCS 5.1 – Content must promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial interest.

## What are ACCME's policies around CME Content

---

SCS 5.2 – Presentations must give a balanced view of therapeutic options. Use of generic names will contribute to impartiality. If CME content includes trade names, where available trade names from several companies should be used.



# What are ACCME's policies around CME Content

---

CCVP – Recommendations involving clinical medicine must be based on evidence that is accepted within the profession of medicine.

# What are ACCME's policies around CME Content

---

CCVP – All scientific research referred to or used in CME must conform to generally accepted standards of experimental design, data collection and analysis.

# What are ACCME's policies around CME Content

---

CCVP – Content will not promote recommendations, treatment, or manners of practicing medicine that are not within the definition of CME or known to have risks or dangers that outweigh the benefits or known to be ineffective in the treatment of patients.

# How can you **Plan** to ensure Expectations are Communicated?

---

Send expectations to Speakers with their confirmation materials.

- Include in the confirmation letter itself..... **Or**
- Incorporate into your Speaker Disclosure Form..... **Or**
- Include a singular Content Validation Form

Be explicit and require Speakers to sign/attest that they will uphold CME Standards to ensure balance, independence, objectivity, and scientific rigor in their role in planning, development and presentation of a CME activity.

# Employ Safeguards

---

Communicate to Speakers.....

“We employ several strategies to ensure the absence of commercial bias and you are integral to their successful implementation.”

# Employ Safeguards

**If a Speaker discloses relevant financial relationships,**  
in a secondary communication you might want to say:

On the basis of the information you have provided, we have determined that you have *<no/ the following>* relevant financial relationships with commercial interests that create a conflict of interest with respect to your role in this activity. *<insert relevant financial relationship information>*.

# Employ Safeguards

We will be disclosing this information to our learners before the activity and we have decided on the following strategy to resolve that conflict of interest. <You/we will <*insert strategies for resolving conflict of interest*>.

# Employ Safeguards

You might go on to say:

“Additionally, we also remind you that CME must give a balanced view of therapeutic options. Use of generic names will contribute to this impartiality. If your CME material or content includes trade names, trade names from several companies should be used where available.

Educational materials that are a part of this activity, such as slides, abstracts, and handouts, cannot contain any advertising, logos, trade names, or product-group messages.



# Employ Safeguards

## Be consistent

- Have this conversation with all speakers who have a potential conflict.
- Document that conversation in your activity file, whether it was in the form of a letter, email or phone conversation.

You may be asked to authenticate that conversation and your resolution process during reaccreditation.

# Planners can elicit Commercial Bias too

---

Though Planners are not creating content, they have the opportunity to influence the selection of topics and faculty.

**You must ensure that decisions made during the planning process are independent of commercial influence.**

Therefore, it is critical to ensure that any financial relationships they may have are identified and potential conflicts of interest resolved.

# Observations

---

Over the course of several review cycles, ACCME and ISMA have observed that some providers are not applying appropriate mechanisms to identify and resolve conflicts of interest for individuals who are engaged in **planning** CME activities (ie, CME committee members, course directors).

## Standard 2.3

---

“The provider must have implemented a mechanism to identify and resolve all conflicts of interest prior to the educational activity being delivered to learners.”

This standard applies to **all** those in control of content — including those who **plan** the activity.

# The ACCME expects that accredited providers:

---

- **Identify**/obtain information from planners and speakers about relevant financial relationships;
- **Resolve** any conflicts of interest of those planners and speakers;
- **Disclose** the relevant relationships of planners and speakers to learners (or inform learners if no relevant relationships exist); and
- Be able to **show** that conflicts of interest were identified and resolved, and disclosure was made to learners (evidence of PIP).

# Do I need to use different approaches to resolve conflicts for Planners vs. Speakers?

---

## YES

Some mechanism(s) that providers employ to resolve *conflicts of interest* for authors/speakers do not address the role that planners have in controlling decisions that occur before content is developed for a CME activity.

To resolve conflicts for planners with *relevant financial relationships*, the provider needs to implement mechanisms that ensure independence in the planning process itself.

# When do relationships create a Conflict of Interest?

---

The ACCME considers financial relationships to create actual conflicts of interest in CME when individuals have **both a financial relationship with a commercial interest and the opportunity to affect the content of CME about the products or services of that commercial interest.**

The potential for maintaining or increasing the value of the financial relationship with the commercial interest creates an incentive to influence the content of the CME – an incentive to insert commercial bias.

If Content of a CME Activity is NOT Related to the Products or Services of a Commercial Interest, Do I Still Need to Obtain Information Regarding Financial Relationships?

---

The ACCME says “No.” Standard 2.1 requires the provider to identify relevant financial relationships of those who control CME content in order to identify conflicts of interest.

**As just mentioned, TWO things must be present for there to be a Conflict of Interest.**

1. **Financial Relationship(s) with an ACCME-defined commercial interest; and**
2. **The ability to control content *related* to products/services of the commercial interest.**

**If no financial relationships exist, the content of the CME activity is not clinical in nature, and/or the content is not related to the products or services of a commercial interest, there are no *relevant financial relationships* to identify and no conflicts of interest to identify or resolve.**



# Examples of Topics “Not Clinical in Nature”

---

- Leadership Development
- Physician Burnout
- Electronic Health Records (ie, EPIC)
- Financial Wellness for Physicians
- Ethics (i.e., Patient Privacy, Relationships, Professional Behavior)

# What is a Relevant Financial Relationship?

---

Financial relationships in any amount, which occurred in the twelve-month period preceding the time that the individual was asked to assume a role controlling content of the CME activity, and which relate to the content of the educational activity, causing a **conflict of interest (COI)**.

Providers may choose to collect **all** financial relationships from an individual and make the decision which would be relevant, **OR** they may ask the person disclosing to limit their disclosures to those which are relevant to the content of the activity. *(THIS MAY CHANGE)*

# Provider Scenario

---

**An accredited provider's mechanism to resolve conflicts of interest for all persons, including those who planned the activities, is to conduct a review of the content prior to the activity, using an expert with no relevant financial relationships.**

The practice described in this example would not resolve the conflict of interest for those who planned the activity and would result in non-compliance with C7 (SCS 2.3).

# Mechanism to Resolve

---

**The mechanism to resolve a conflict must be appropriate to the individuals' roles and responsibilities in the CME activity.**

Review of **content** would not resolve conflict for individuals whose responsibilities include the selection of topics and speakers.

The provider might instead ensure that these individuals are recused from planning when it relates to their relevant financial relationships.

# Provider Scenario

---

**A provider has all speakers/planners/staff sign an attestation form at the time of the disclosure stating “I will ensure that any financial relationship that I have with a commercial interest will not affect the recommendations I make about clinical care.**

The practice described in this example would not show evidence of consistently implementing a mechanism to resolve conflicts of interest when persons in control of content reported relevant financial relationships.

Individuals with the conflict of interest may be involved in the mechanism to resolve his/her conflict, but cannot be solely responsible.

# Appropriate Mechanisms to Resolve for **Planners**

---

- Recuse person from controlling aspects of planning and content with which they have a conflict of interest, and/or
- Partner with a non-conflicted planner using peer-review of planning decisions
- Planner divests him/herself of the relationship.

# Appropriate Mechanisms to Resolve for **Speakers**

---

- Use peer-review of content/slides by persons that do not have conflicts of interest related to the content, and/or
- Ensure that clinical recommendations are evidence-based and are free of commercial bias
- Content is non-clinical in nature or not related to the products or business lines of an ACCME-defined commercial interest  
(nothing to resolve)

# SCS-1: Employees/Owners of CI

---

- Employees and owners of an ACCME-defined commercial interest can have no role in the planning or implementation of CME activities related to their products/services. Therefore, whether serving as Planner or Speaker, they would need to be recused.

**Definition of Commercial Interest:** 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.**



## 3 Exceptions for Use of Employees of ACCME-Defined Commercial Interest

---

### **EXCEPTION #1**

Employees of ACCME-defined commercial interests can control the content of accredited CME activities when the content of the CME activity is not related to the business lines or products of their employer.

# Exceptions for Use of Employees of ACCME-Defined Commercial Interest

---

## **EXCEPTION #2**

Employees of ACCME-defined commercial interests can control the content of accredited CME activities when the content of the accredited CME activity is limited to basic science research (ie, pre-clinical research, drug discovery) or the *processes/methodologies* of research, themselves unrelated to a specific disease or compound/drug.

# Exceptions for Use of Employees of ACCME-Defined Commercial Interest

---

## **EXCEPTION #3**

Employees of ACCME-defined commercial interests can participate as technicians in accredited CME activities that teach the safe and proper use of medical devices (turning on/off, changing calibration, etc.).

# Exceptions for Use of Employees of ACCME-Defined Commercial Interest

---

It is critical that accredited providers ensure that commercial employees never expand their role into areas of clinical medicine (i.e., never talk about indications for use, comparisons between competing products or comparisons between the device and/or invasive surgery and/or medical treatment).

**The ACCME considers these high risk exceptions and advises they should only be invoked with caution, as the provider remains ultimately responsible for what the individual actually presents in the CME activity.**

---

ACCME tool  
to help navigate  
identification of relevant  
financial relationships  
and  
resolution of  
conflicts of interest  
in CME activities

---

Flowchart  
for the  
Identification  
and Resolution  
of Personal  
Conflicts  
of Interest

The Flowchart can be accessed at:

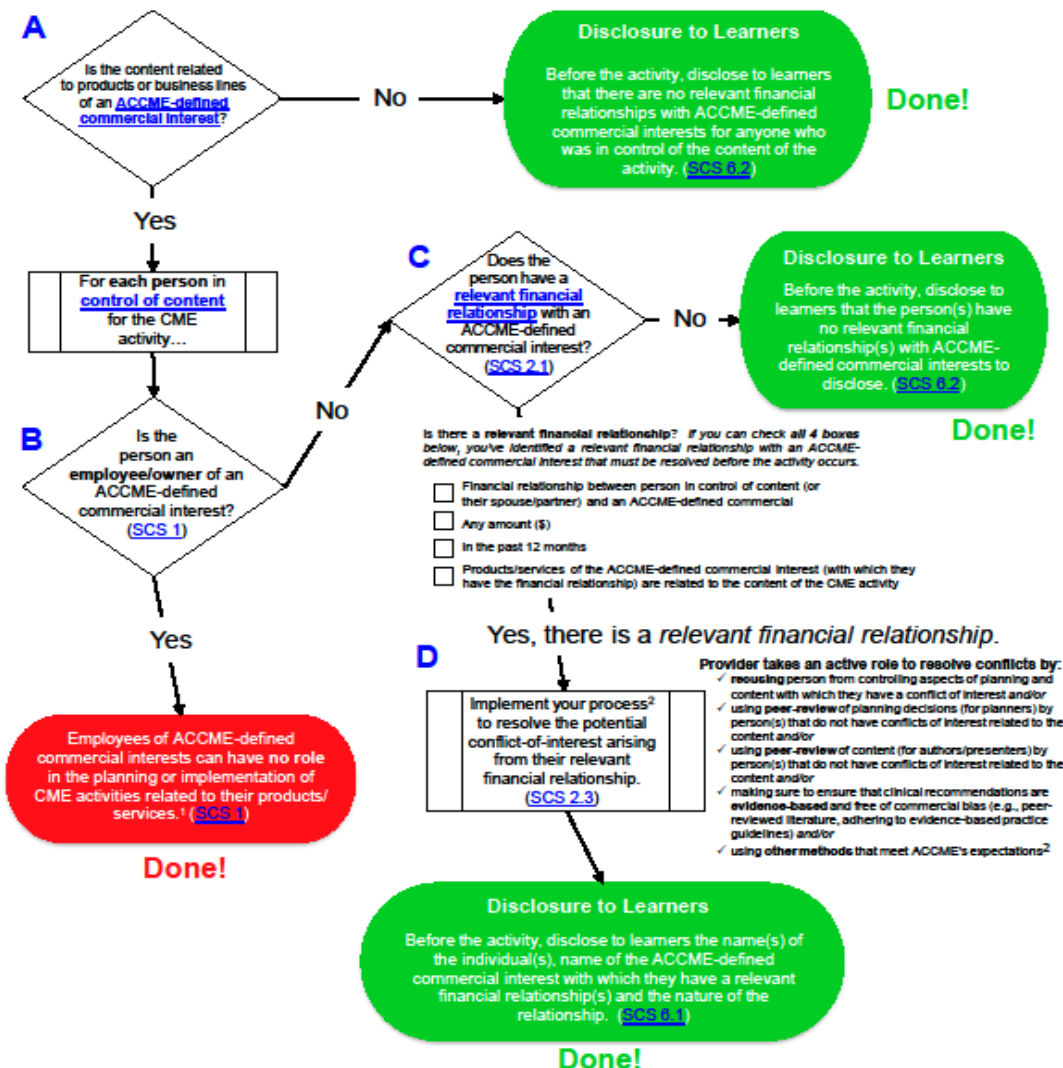
<https://www.accme.org/publications/flowchart-for-identification-and-resolution-personal-conflicts-interest>



## Flowchart for the Identification and Resolution of Personal Conflicts of Interest Meeting the Expectations of ACCME's Criterion 7

(Last updated : February 1, 2017)

Use this flowchart at the beginning of your planning process for CME activities to ensure independence from ACCME-defined commercial interests. Start at A below. For step-by-step instructions for using this flowchart, visit [www.accme.org/coiflowchart](http://www.accme.org/coiflowchart).



### Footnotes

1. The use of employees of ACCME-defined commercial interests as faculty and planners or in other roles where they are in a position to control the content of accredited CME is prohibited, except in specific situations. For more information, visit [this.Ask ACCME frequently-asked-question](http://this.Ask ACCME frequently-asked-question) regarding commercial employees.
2. There are a range of approaches providers can use to resolve potential conflicts of interests. For more information, visit ACCME's [Provider Examples of Compliance and Noncompliance](http://Provider Examples of Compliance and Noncompliance) for Criterion 7 on [www.accme.org](http://www.accme.org).

# SCS-6: Disclosure Relevant to Potential Commercial Bias

---

**SCS-6.1:** An individual must disclose to learners any relevant financial relationship(s), to include the following information:

- Name of the individual
- Name of the commercial interest(s)
- Nature of the relationship the person has with each commercial interest.

**SCS-6.2:** For an individual with no relevant financial relationship(s), the learners must be informed that no relevant financial relationship(s) exist.

# SCS-6: Disclosure to Learners

---

- **SCS 6.3** The source of all support from commercial interests must be disclosed to learners. When commercial support is “in-kind” the nature of the support must be disclosed to learners.
- **SCS 6.4** Disclosure must never include the use of a corporate logo, trade name or a product-group message of an ACCME-defined commercial interest.
- **SCS 6.5** A provider must disclose the above information to learners prior to the beginning of the educational activity.



# Methods of Disclosure

---

- Flyer/Brochure
- Verbal Disclosure
- Powerpoint Presentation Slide
- Disclosure Grid
- Disclosure Script (i.e., for Recorded CME or Joint Providership)



Activities  
must be  
**Monitored**  
for potential  
Commercial Bias

# How do you **Monitor** this?

---

- Monitor collection of all disclosures
- Monitor for proper COI resolution for all relevant financial relationships
- Conduct slide review prior to actual presentation
- Evaluate for learner perceived bias within presentation



**No BiAS**

Accredited education is designed to offer physicians and health care teams a space to learn, teach, discuss emerging science, and debate ethical or controversial issues without any commercial influence.