

Disclosure of Financial Relationships

In accordance with the Accreditation Council for Continuing Medical Education's Standards for Commercial Support and the Accreditation Council for Pharmacy Education's Guidelines for Standards for Commercial Support, all planners, committee members, faculty, reviewers, authors, and staff in a position to control the content of accredited education programs are required to disclose to the accredited provider their *relevant financial relationships*. An individual has a relevant financial relationship if the individual or his or her spouse/partner has a financial relationship in any amount occurring in the last 12 months with an ACCME-defined commercial interest whose products or services are discussed in the educational activity content over which the individual has control. Relevant financial relationships will be disclosed to the activity audience.

Refusal or failure to provide disclosure information in a timely manner will result in the disqualification from participation in the activity.

Name (please print): _____

1. Does the educational content over which you have control contain information about healthcare products or services used on patients?

Circle one: Yes No

If Yes, please move to Questions 2 and 3. If No, please sign and return this form.

2. Regarding the health care products or services that will be discussed in the educational content over which you have control, have you or your spouse/partner had a financial relationship in any amount in the last 12 months with the manufacturers of the products or providers of the services?

Circle one: Yes No

If "Yes" to #2 or #3, please complete the chart below. If No, please sign and return this form.

Manufacturer or Service Provider	Nature of Relationship (e.g., employee, consultant, research grant recipient, speakers' bureau, stockholder, etc.)	Does this relationship still exist? Circle
		YES NO
		YES NO

Signature: _____

Date: _____

[Glossary of Terms](#)

[Commercial interest](#)

The ACCME defines a "commercial interest" as any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.

[Financial relationships](#)

Financial relationships are those relationships in which the individual benefits by receiving a salary, royalty, intellectual property rights, consulting fee, honoraria, ownership interest or other financial benefit. Financial benefits are usually associated with roles such as employment, management position, independent contractor (including contracted research), consulting, speaking and teaching, membership on advisory committees or review panels, board membership, and other activities from which remuneration is received, or expected. ACCME considers relationships of the person involved in the CE activity to include financial relationships of a spouse or partner.

[Relevant financial relationships](#)

ACCME focuses on financial relationships with commercial interests in the 12-month period preceding the time that the individual is being asked to assume a role controlling content of the CE activity. ACCME has not set a minimal dollar amount for relationships to be significant. Inherent in any amount is the incentive to maintain or increase the value of the relationship. The ACCME defines "relevant" financial relationships as financial relationships in any amount occurring within the past twelve months that create a conflict of interest.

[Conflict of interest](#)

Circumstances create a conflict of interest when an individual has an opportunity to affect CE content about products or services of a commercial interest with which he/she has a financial relationship.

Disclosure/COI Grid

Title of Activity:

Prepared by: _____ Date Completed: _____

Name and Role of All Persons in a Position to Control Content	Date Disclosure Information was Received	Mechanism by which Disclosure Information was Received	Relationships Disclosed with Commercial Interests (1, 2)	Conflict of Interest Identified? YES or NO	Mechanism by which Conflict was Resolved (3)	Mechanism by which Relevant Financial Relationships (or lack thereof) were Disclosed to Audience
Dr. X Presenter/Subject Matter Expert	xx/xx/xxxx	Survey Monkey	Dr. X declared she is a speaker for Nanosphere and Merck, received grant support from Merck and Cubist, and serves on an advisory board for Forest	Yes	All content, including Dr. X's slides, were peer-reviewed by Dr. Z (who had no relevant financial relationships to disclose)	Disclosed to learners in opening slides and handout
Course Directors						
Planners						
Faculty						
Reviewers						
Staff						

Footnotes:

- An commercial interest is any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients. Providers of clinical service directly to patients are not commercial interests, unless the provider of clinical service is owned, or controlled by, a commercial interest.
- Is there a relevant financial relationship? If you can check all 4 boxes below, you've identified a relevant financial relationship with an commercial interest that must be resolved before the activity occurs.
 - Financial relationship exists between person in control of content (or their spouse/partner) and an ACCME-defined commercial interest
 - In any dollar amount
 - In the last 12 months
 - Products/services of the ACCME-defined commercial interest with which the respondent has the financial relationship are discussed in the content of the activity over which the person has control.
- Mechanisms to resolve conflicts include, but are not limited to:
 - ✓ Requiring the conflicted person to **recuse himself or herself** from controlling aspects of planning and content with which they have a conflict of interest *and/or*
 - ✓ Engaging person who does not have conflicts of interest to **peer-review** the planning decisions of a conflicted planner *and/or*
 - ✓ Engaging person who does not have conflicts of interest to **peer-review** the content of a conflicted author or faculty member prior to the activity taking place *and/or*
 - ✓ Communication of higher standards to the conflicted person *and/or*
 - ✓ Removing the person from participating in the activity

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](#) for Criterion 7 at www.accme.org and review the [Flowchart for the Identification and Resolution of Personal Conflicts of Interest](#).

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. Visit [this Ask ACCME frequently-asked-question](#) regarding commercial employees.

Perceived Commercial Bias Investigation

-Note to File-

Purpose: For the investigation, findings, and actions where potential bias has been reported

Date of Activity	
Activity Title	
UAN	
Activity Time	
Name of Investigator	
Date of Investigation	
Presenter Name(s)	
Presenter Name(s) in question (if indicated)	
Complainant Role (e.g. attendee, staff, etc.)	
Nature of Complaint (verbatim)	
Was a Disclosure Made by the Presenter Prior to the Session (if yes, please describe)	
Did this represent a commercial interest as defined by ACCME (if yes, explain in detail)	
% of Bias Reporting on Evaluation	
Investigation Results	
Action Required (if none, indicate none)	

Investigator Name: _____

Investigator Signature: _____

Date: _____

Risk Assessment Tool for COI

Level of Risk	Provider/Staff Actions	Participant Actions
LOW	<input type="checkbox"/> Complete COI disclosure grid for all faculty and planners. <input type="checkbox"/> Validate content is non-promotional, evidenced based, free from commercial bias, and all conflicts of interest have been resolved. <input type="checkbox"/> Review evaluations for perception of bias prior to development of archive. If 5% or more agree activity is biased, staff will initiate an investigation.	<input type="checkbox"/> Learners informed of faculty and planner disclosures in opening slide, handout, or pages preceding content in publications. <input type="checkbox"/> Learners rate perception of commercial bias on the evaluation.
MEDIUM	<p>All actions performed for low risk activity plus:</p> <input type="checkbox"/> Conduct secondary review of content by a qualified reviewer. <input type="checkbox"/> Document required actions (such as revision of content). <input type="checkbox"/> Notify faculty of required actions and approve final content.	<input type="checkbox"/> Learners informed of faculty and planner disclosures in opening slide, handout, or pages preceding content in publications. <input type="checkbox"/> Learners rate perception of commercial bias on the evaluation.
HIGH and VERY HIGH	<p>All actions performed for medium risk activity plus:</p> <input type="checkbox"/> Audit live activity and evaluations for commercial bias (prior to development of archive) to determine if bias was introduced in the live remarks, Q and A, etc. <input type="checkbox"/> If bias is identified during staff review, document actions such as revision of content prior to the development of the archive. Staff may also conduct secondary review of content by a qualified reviewer. <input type="checkbox"/> Notify faculty of identified commercial bias and required actions for enduring activity such as revision of slides/handout, editing of recording, or new recording of live remarks. Approve final content for enduring activity. <input type="checkbox"/> Notify commercial supporter of actions taken (if applicable).	<input type="checkbox"/> Learners informed of faculty and planner disclosures in opening slide, handout, or pages preceding content in publications. <input type="checkbox"/> Learners rate perception of commercial bias on the evaluation. Possibly: <input type="checkbox"/> Alert learners to bias introduced during the live activity (share new handout with revisions to slides, etc.).

Risk Stratification Tool for CPE Activities

Issue		Weight	Score
1. Joint provider			
No joint providership	No	0	
Joint provider is non-profit organization	Yes	1	
Joint provider is for-profit organization	Yes	2	
2. Experience with joint provider			
Not applicable		0	
Positive experience (all activities conducted in compliance with CME provider policies and Standards for Commercial Support)		-1	
No experience		1	
Negative experience (all activities not conducted in compliance with CME provider policies and SCS)		3	
3. Same live activity repeated on multiple occasions in commercially-supported activity (includes live and internet live activities)			
	No	0	
	Yes	3	
4. Involvement by an entity external to the CME provider in the logistical aspects (marketing, meeting planning, development of enduring material, etc.)			
All logistics coordinated entirely by the CME provider		0	
Some or all of the logistical elements delegated by the CME provider to one or more entities including a joint provider		1	
Some or all of the logistical elements delegated by the joint provider to one or more entities		2	
Some or all of the logistical elements delegated by the CME or joint provider to one or more entities engaged by the commercial supporter		3	
5. Experience with an entity external to CME provider responsible for logistics			
Not applicable		0	
Positive experience (all activities conducted in compliance with CME provider policies and SCS)		-1	
No experience		1	
Negative experience (all activities not conducted in compliance with CME provider policies and SCS)		3	
6. Responsibility for managing funds (receipt, payment, reconciliation of expenses)			
All logistics coordinated entirely by the CME provider		0	
Some or all of the logistical elements handled by a non-profit entity external to the CME provider including another department within the accredited organization.		2	
Some or all of the logistical elements delegated by a for profit entity external to the CME provider.		3	
7. Level of involvement from the commercial supporter or other agent. (Risk score is additive but total score cannot exceed 3).			
Unrestricted educational grant only		0	

Site selection		1	
Marketing		1	
Target audience		1	
Topic recommendation		1	
8. Number of commercial supporters.			
None		0	
One		1	
Two or more		2	
Positive experience with all commercial supporters (all activities conducted in compliance with CME provider policies and SCS)		3	
No experience		4	
Negative experience with one or more commercial supporter (all activities not conducted in compliance with CME provider policies and SCS)		5	
9. The primary intent of the activity involves discussion of experimental or off-label use.			
	No	0	
	Yes	2	
10. Amount of commercial support as a % of total revenue for activity.			
None		0	
Up to 50%		1	
51-99%		3	
100%		4	
11. Amount of exhibit support as a % of total revenue for activity.			
None		0	
Up to 50%		1	
51-99%		3	
100%		4	
12. Presence of a financial relationship between one or more of the speakers and/or planners and the commercial supporter.			
	Yes	2	
	No	0	
	TOTAL RISK SCORE		
Low Risk	<2		
Medium Risk	3 to 11		
High Risk	12 to 19		
Very High Risk	> 20		

Structured Assessment Related to ACCME's Definition of a Commercial Interest

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.

Does your organization, or a part of your organization, produce, market, re-sell, or distribute health care goods or services consumed by or used on patients?	Yes No
Does your organization have a parent company that produces, markets, re-sells, or distributes health care goods or services consumed by, or used on, patients? (A "parent company" is a separate legal entity that owns <u>or</u> fiscally controls an accredited provider or non-accredited organization.)	Yes No
Does your organization have a sister company that produces, markets, re-sells, or distributes health care goods or services consumed by, or used on, patients? (A "sister company" is a separate legal entity which is a subsidiary of the parent company and which maintains a governance structure and activities separate from both the parent company and the accredited provider or nonaccredited joint provider. The sister company does not control or direct, in whole or in part, the operations of the accredited provider or non-accredited organization.)	Yes No
Does your organization advocate for an ACCME-defined commercial interest?	Yes No
Does your organization have a parent company that advocates for an ACCME-defined commercial interest?	Yes No
Does your organization have a sister company that advocates for an ACCME-defined commercial interest?	Yes No