



## Key Steps for the Identification, Mitigation, and Disclosure of Relevant Financial Relationships



**NOTE:** If the activity only addresses a non-clinical topic (e.g., leadership or communication skills training), the provider does not need to identify, mitigate, or disclose relevant financial relationships.

### Step 1

- Before you begin planning, collect information from all planners, faculty, and others who would be in positions to control content. Ask them to provide information about **ALL** their financial relationships with ineligible companies over the previous **24 months**.
- Ensure you use the definition of ineligible companies, i.e., those whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.
- Reminder: There is no minimum financial threshold; individuals must disclose all financial relationships, regardless of the amount, with ineligible companies.

### Step 2

- Review the disclosed relationships and **exclude owners and employees of ineligible companies from participating as planners, faculty, or other roles** unless the educational activity meets one of the exceptions listed:
  - When the content of the activity is not related to the business lines or products of their employer/company.
  - When the content of the accredited activity is limited to basic science research, such as pre-clinical research and drug discovery, or the methodologies of research, and they do not make care recommendations.
  - When they are participating as technicians to teach the safe and proper use of medical devices, and do not recommend whether or when a device is used.

### Step 3

- Determine which financial relationships are **relevant** to the content of the continuing education activity. **Mitigate** those relevant financial relationships to prevent commercial bias. **Disclose** the presence or absence of all relevant financial relationships to learners prior to the activity.



**A** Determine **relevant financial relationships** for all who will be in control of educational content.

*Financial relationships are relevant if the following three conditions are met for the individual who will control content of the education:*

- ✓ A financial relationship, in **any amount**, exists between the person in control of content and an ineligible company.
- ✓ The financial relationship existed during the past **24 months**.
- ✓ The content of education is **related to the products** of an ineligible company with whom the person has a financial relationship.



**B** **Mitigate** relevant financial relationships prior to individuals assuming their roles in the education.



**C** Before the learner engages in the education, **disclose** to learners the presence or absence of relevant financial relationship for all persons in control of content.



## Sample Letter to Explain Why Financial Relationship Information is Collected



**NOTE:** If the activity only addresses a non-clinical topic (e.g., leadership or communication skills training), the provider does not need to identify, mitigate, or disclose relevant financial relationships.

At the beginning of the planning process, the sample language below may be used to communicate with prospective planners, faculty, and others who may be in control of content for the activity. It is important to identify financial relationships before activity planning begins so that relevant financial relationships can be mitigated in a manner that is appropriate to each person's role. Consider incorporating this letter, or similar communication, into faculty guidance materials (Standard 6).

Dear **Prospective Planner/Faculty Member**:

We are looking forward to having the opportunity to include you as a **<proposed role for person, e.g. planner, faculty, reviewer, etc.>** in the accredited continuing education, **<Insert activity title or working title and date/location information, if appropriate>**.

### **Why am I receiving this communication?**

**<Insert Accredited Provider Name>** is accredited by the **<Accreditor>**. We appreciate your help in partnering with us to follow accreditation guidelines and help us create high-quality education that is independent of industry influence. In order to participate as a person who will be able to control the educational content of this accredited CE activity, we ask that you disclose all financial relationships with any ineligible companies that you have had over the past 24 months. We define ineligible companies as those whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients. There is no minimum financial threshold; you must disclose all financial relationships, regardless of the amount, with ineligible companies. We ask you to disclose regardless of whether you view the financial relationships as relevant to the education.

### **Why do we collect this information?**

Since healthcare professionals serve as the trusted authorities when advising patients, they must protect their learning environment from industry influence to ensure they remain true to their ethical commitments. Many healthcare professionals have financial relationships with ineligible companies. By identifying and mitigating relevant financial relationships, we work together to create a protected space to learn, teach, and engage in scientific discourse free from influence from organizations that may have an incentive to insert commercial bias into education.

### **What are the next steps in this process?**

After we receive your disclosure information, we will review it to determine whether your financial relationships are relevant to the education. Please note: the identification of relevant financial relationships does not necessarily mean that you are unable to participate in the planning and implementation of this educational activity. Rather, the accreditation standards require that relevant financial relationships are mitigated before you assume your role in this activity.

To help us meet these expectations, please use the form we have provided to share all financial relationships you have had with ineligible companies during the past 24 months. This information is necessary in order for us to be able to move to the next steps in planning this continuing education activity.

If you have questions about these expectations please contact us at **<provider contact information>**.



## Template for Collecting Information about All Financial Relationships from Planners, Faculty, and Others

Name of Individual: _____  Title of CE Activity: _____  Date and location of CE Activity: _____	Individual's prospective role in CE Activity (select all that apply)  <input type="checkbox"/> Planner <input type="checkbox"/> Faculty, Speaker, Instructor <input type="checkbox"/> Author, Writer <input type="checkbox"/> Reviewer <input type="checkbox"/> Other _____
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Please disclose all financial relationships that you have had in the past 24 months with ineligible companies (see definition below). For each financial relationship, enter the name of the ineligible company and the nature of the financial relationship(s). There is no minimum financial threshold; please disclose ALL financial relationships, regardless of the amount, with ineligible companies. You should disclose all financial relationships regardless of the potential relevance of each relationship to the education.

The Standards for Integrity and Independence require that individuals who refuse to provide this information be disqualified from involvement in the planning and implementation of accredited continuing education. Thank you for your diligence and assistance.

<b>Name of Ineligible Company</b>	<b>Nature of Financial Relationship</b>	<b>Has the Relationship Ended?</b>
An ineligible company is any entity whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.	Examples of financial relationships include employee, researcher, consultant, advisor, speaker, independent contractor (including contracted research), royalties or patent beneficiary, executive role, and ownership interest. Individual stocks and stock options should be disclosed; diversified mutual funds do not need to be disclosed. Research funding from ineligible companies should be disclosed by the principal or named investigator even if that individual's institution receives the research grant and manages the funds.	If the financial relationship existed during the last 24 months but has now ended, please check the box in this column. This will help determine if mitigation steps need to be taken.
Example: ABC Company	Consultant	<input type="checkbox"/>
		<input type="checkbox"/>
		<input type="checkbox"/>
		<input type="checkbox"/>
		<input type="checkbox"/>
		<input type="checkbox"/>
		<input type="checkbox"/>
		<input type="checkbox"/>
		<input type="checkbox"/>

In the past 24 months, I have not had any financial relationships with ineligible companies.

I attest that the above information is correct as of the date of this submission.

Signature: \_\_\_\_\_

Date: \_\_\_\_\_



## Worksheet for the Identification and Mitigation of Relevant Financial Relationships of Planners, Faculty, and Others

**STEP 1:** Review collected information about financial relationships and **exclude owners or employees of ineligible companies** from participating as planners or faculty.

After collecting all financial relationships from prospective planners, faculty and others, exclude any individuals who are owners or employees of ineligible companies. Ineligible companies are those whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.

**STEP 2:** Determine **relevant financial relationships**.

Review the information for all individuals not excluded after STEP 1 and determine whether each individual's financial relationships with ineligible companies are relevant to the content of the CE activity. Financial relationships are relevant the following three conditions are met for the individual who will control content of the activity:

- ✓ A financial relationship, in **ANY AMOUNT**, exists between individual and an ineligible company.
- ✓ The financial relationship existing during the past **24 months**.
- ✓ The content of the education is **related to the products** of an ineligible company with who the individual has a financial relationship.

**STEP 3:** Chose a **mitigation strategy** for each individual with a relevant financial relationship and implement that strategy before the individual assumes their role.

Using the lists below, identify which mitigation strategy(ies) will be used for individuals with relevant financial relationships who control educational content for the activity. Multiple strategies may be used. The strategy used should be **appropriate to the individual's role**.

Mitigation Steps for Planners:

- ✓ **Divest** the financial relationship(s)
- ✓ **Recusal** from controlling aspects of planning and content with which there is a financial relationship
- ✓ **Peer review** of planning decisions by persons without relevant financial relationships
- ✓ Other method: \_\_\_\_\_

Mitigation Steps for Faculty and Others:

- ✓ **Divest** the financial relationship(s)
- ✓ **Peer review** of content by individuals without relevant financial relationships
- ✓ Other method: \_\_\_\_\_

**STEP 4:** **Document** mitigation strategy(ies) used for each individual with a relevant financial relationship.

Name of Individual	Role(s) in Activity	Step(s) Taken to Mitigate Relevant Financial Relationship	Date Implemented
<i>Example: Dr. Smith</i>	<i>Planner</i>	<i>Recusal from topic/faculty selection</i>	<i>5/1/21</i>



## Communicating Disclosure to Learners

Use the sample language below to provide disclosure to learners in a format that can be verified during the accreditation review process. Disclosure must be provided to learners **before** engaging in the continuing education activity.

### Examples for Providing Disclosure to Learners

<p><b>If there are NO relevant financial relationships:</b></p> <p><i>Inform learners that planners, faculty and others in control of content (either individually or as a group) do not have relevant financial relationships with ineligible companies.</i></p>	<p><b>If there ARE relevant financial relationships:</b></p> <p><i>Disclose name(s) of the individuals, name of the ineligible company(ies) with which the individual has a relevant financial relationship(s), the nature of the relationship(s), <b>and</b> a statement that all relevant financial relationships have been mitigated.</i></p>
<p>Dr. John Doe, faculty for this CE activity, has no relevant financial relationship(s) with ineligible companies to disclose.</p> <p>-----</p> <p>Dr. Jane Smith and Jill Green have no relevant financial relationship(s) with ineligible companies to disclose.</p> <p>-----</p> <p>None of the planners for this activity have relevant financial relationships to disclose with ineligible companies.</p>	<p>Dr. John Doe is on the speakers' bureau for XYZ Company.</p> <p>Dr. Jane Smith has received a research grant from ABC Company.</p> <p>All of the relevant financial relationships listed for these individuals have been mitigated.</p>

#### NOTE:

- ✓ If commercial support is received, the accredited provider must also disclose to the learners the name(s) of the ineligible company(ies) that gave the commercial support, and the nature of the support if it was in-kind, prior to the learners engaging in the education.
- ✓ Disclosure to learners must not include ineligible companies' corporate or product logos, trade names, or product group messages.
- ✓ It may be helpful to include definitions of terms to learners to support their understanding of your processes (e.g., ineligible companies, relevant financial relationships, etc.).