

# REVISITING STANDARD 3

## IDENTIFYING, MITIGATING AND DISCLOSING RELEVANT FINANCIAL RELATIONSHIPS



**June 2024**

# HOW COMFORTABLE ARE YOU WITH THE NUANCES OF STANDARD 3?



I know what I'm doing



I feel somewhat confident



I have no clue what I'm doing – help!

# WHERE DO YOU PERSONALLY STRUGGLE THE MOST?



Collecting disclosure information



Identifying relevance of financial relationships



Mitigating relationships



Understanding who's considered an employee/owner of an ineligible company



Understanding who's considered an ineligible company



Proper disclosure to learners

# HERE'S WHERE INDIANA PROVIDERS STAND WITH GENERAL NON-COMPLIANCE

CURRENT INDIANA ACCREDITED CME PROVIDERS AREAS OF NON-COMPLIANCE					
Provider #	Standard 3 Disclosure/Mitigation	Standard 4 Commercial Support	Program Analysis	Analyzes Change	Formats
1					
2					
3	X				
4	X				
5					
6					
7		X			
8	X		X	X	
9					
10					
11					
12			X	X	
13	X			X	
14	X	X	X		
15			X	X	
16					
17	X				X
18					
19	X		X	X	
20					
21	X			X	
22	X	X	X	X	
23					
24	X	X			
25					
26					
27					
<b>TOTALS</b>	<b>10</b>	<b>4</b>	<b>6</b>	<b>7</b>	<b>1</b>

Standard 4 is the only measure that does not apply to all accredited CE

# WHAT WE KNOW

Many healthcare professionals have financial relationships with ineligible companies.



Bristol Myers  
Squibb™



**MERCK**



**Abbott**



GlaxoSmithKline

However, these relationships must not be allowed to influence accredited CE.



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# **WE'RE GOING TO STUDY HOW WE PREVENT THIS INFLUENCE THROUGH THE VARIOUS SECTORS OF STANDARD 3**



# 1<sup>ST</sup> SECTOR: INDENTIFICATION, WHICH INVOLVES “COLLECTION”

You must collect disclosure from all individuals in control of educational content.

- **Planners:**
  - CME Staff, Course Director, CME Committee
- **Faculty Presenters:**
  - Speakers, Panelists, Moderators
- **Reviewers:**
  - Peer reviewers, CME Staff

# WHAT DO YOU COLLECT ?

**All** of their financial relationships with ineligible companies (commercial interests).

- Regardless of the amount
- Regardless of their view of the relevance of the relationship to the education\*
- Held within the prior 24 months

**\*The CME provider is now fully responsible for determining relevancy.**  
(per the updated Standards)



# DISCLOSURE MECHANISMS

A Disclosure Form is one mechanism that providers can use.

Other mechanisms could include:

- Collecting the information verbally and recording it in a spreadsheet, table, or database
- Collecting disclosure information electronically (i.e, via e-mail, web-based form, or database)

# FOR EACH FINANCIAL RELATIONSHIP, DISCLOSURE INFORMATION MUST INCLUDE:

- Name of ineligible company
- Nature of the relationship
  - Consultant
  - Speakers Bureau
  - Grant/Research Support
  - Principal Investigator
  - Board Member
  - Stock Shareholder (privately held vs. publicly traded)
  - Employee/Owner
  - Other

# WHAT IF A RELATIONSHIP HAS ENDED?

If a relationship has ended within the last 24 months, you no longer have anything to mitigate.

However, you should still disclose the financial relationships to your learners.

Nature of Financial Relationship	Name of Ineligible Company(s)	Has the relationship ended?
<input type="checkbox"/> Consultant	<a href="#">Click here to enter text.</a>	<input type="checkbox"/> Yes
<input type="checkbox"/> Speaker's Bureau	<a href="#">Click here to enter text.</a>	<input type="checkbox"/> Yes
<input type="checkbox"/> Grant/Research Support <input type="checkbox"/> Principal Investigator	<a href="#">Click here to enter text.</a>	<input type="checkbox"/> Yes
<input type="checkbox"/> Board Member	<a href="#">Click here to enter text.</a>	<input type="checkbox"/> Yes
<input type="checkbox"/> Stock Shareholder (Privately held, self-managed)	<a href="#">Click here to enter text.</a>	<input type="checkbox"/> Yes
<input type="checkbox"/> Stock Shareholder (Publicly traded, pension/mutual fund and/or self-managed)	<a href="#">Click here to enter text.</a>	<input type="checkbox"/> Yes
<input type="checkbox"/> Full-time/part-time Employee/Owner*	<a href="#">Click here to enter text.</a>	<input type="checkbox"/> Yes
<input type="checkbox"/> Other (Describe):	<a href="#">Click here to enter text.</a>	<input type="checkbox"/> Yes

# MANAGING THE USE OF EMPLOYEES/OWNERS OF INELIGIBLE COMPANIES

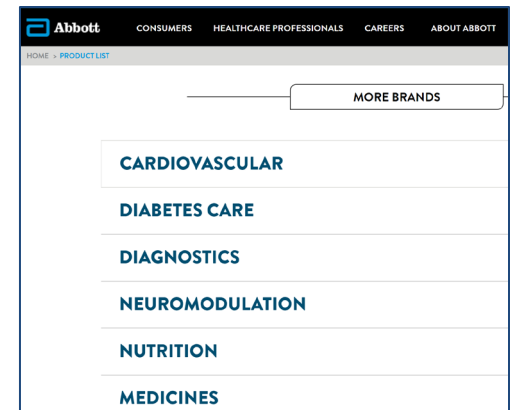
These individuals must be excluded from controlling content or participating as planners or faculty in accredited education.

The ACCME allows three exceptions to their exclusion! (Please use with caution)

# WHAT ARE THE EXCEPTIONS?

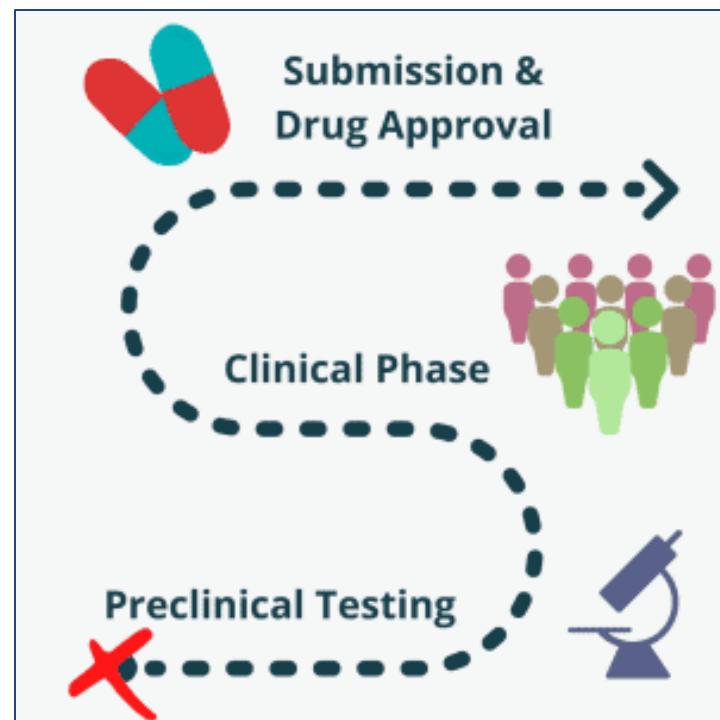
## EXCEPTION #1

When the content of the activity is not related to the business lines or products of their employer/company.



# EXCEPTION #2

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.



# EXCEPTION #3

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.



# DOES STOCK OWNERSHIP CREATE AN EMPLOYEE/OWNER RELATIONSHIP?

If an individual is an owner of stock in a company that is **privately held**, that individual would be considered by ACCME to be an owner of the company. This relationship is not mitigatable.

If stock/stock options are in **publicly traded companies**, and the financial relationships are relevant to the CME content, those relationships are mitigatable and should be disclosed to learners.

## NOTE:

ACCME does not require individuals who control CME content to disclose **diversified mutual funds**, but any other stocks or stock options should be disclosed to the provider.



# LET'S TAKE A LOOK AT HOW THESE FORMS OF STOCK OWNERSHIP DIFFER



## Publicly Traded Company

A company that has sold all or a portion of itself to the public via an initial public offering, meaning shareholders have a claim to part of the company's assets and profits.

They can tap the financial markets by selling stock to raise capital.

## Privately Held Company

The company is owned by its founders, management, or a group of private investors.

A private company cannot dip into the public capital markets and must rely on private funding.

# ISMA NOW DIFFERENTIATES STOCK OWNERSHIP ON OUR FINANCIAL DISCLOSURE FORM

Nature of Financial Relationship	Name of Ineligible Company(s)	Has the relationship ended?
<input type="checkbox"/> Consultant	Click here to enter text.	<input type="checkbox"/> Yes
<input type="checkbox"/> Speaker's Bureau	Click here to enter text.	<input type="checkbox"/> Yes
<input type="checkbox"/> Grant/Research Support <input type="checkbox"/> Principal Investigator	Click here to enter text.	<input type="checkbox"/> Yes
<input type="checkbox"/> Board Member	Click here to enter text.	<input type="checkbox"/> Yes
<input type="checkbox"/> Stock Shareholder (Privately held, self-managed)	Click here to enter text.	<input type="checkbox"/> Yes
<input type="checkbox"/> Stock Shareholder (Publicly traded, pension/mutual fund and/or self-managed)	Click here to enter text.	<input type="checkbox"/> Yes
<input type="checkbox"/> Full-time/part-time Employee/Owner*	Click here to enter text.	<input type="checkbox"/> Yes
<input type="checkbox"/> Other (Describe):	Click here to enter text.	<input type="checkbox"/> Yes

# ARE PATENT HOLDERS WHO RECEIVE ROYALTY PAYMENTS FROM INELIGIBLE COMPANIES CONSIDERED TO BE OWNERS OF THOSE COMPANIES?

## NO

The ACCME advises that individuals who receive patent royalties from ineligible companies are not considered owners or employees of those companies.

Those individuals may control content in accredited continuing education, if the appropriate steps are taken to mitigate.

# IDENTIFICATION INVOLVES “DETERMINING RELEVANCY”

The accredited provider is responsible for identifying relevant financial relationships.

- Faculty/speakers can no longer self determine relevancy -



**Individuals must disclose regardless of their view of the relevance of the relationship to the education.**

# WHEN ARE FINANCIAL RELATIONSHIPS “RELEVANT?”

## Standard 3.3 states:

“Financial Relationships are **relevant** if the educational content an individual can control is related to the business lines or products of the ineligible company.”

This is plural and not singular

I want you to consider the process you use to determine which financial relationships are relevant to the educational content.



**LETS HEAR  
FROM YOU**

# ALWAYS DO YOUR ONLINE RESEARCH OF THE INELIGIBLE COMPANY(S)



**If the ineligible company has a product line related to the topic, but the subject matter is not related to the planner or speaker's area of practice/expertise.....**

- Is there a conflict of interest?
- Is the relationship with the company relevant?
- Do you need to disclose the relationship to the learners?



# 2<sup>ND</sup> SECTOR: MITIGATION

Before a person assumes their role in a CME activity, you must take steps to prevent all those with **relevant financial relationships** from inserting commercial bias into the educational content.

# STEPS FOR PLANNERS ARE SLIGHTLY DIFFERENT THAN FOR PRESENTERS

And would occur  
before planning  
begins.



# MITIGATION FOR PLANNERS

**Those individuals making decisions related to the scope and direction of the content, educational goals, identification of practice gaps and needs, selecting speakers, authors, and reviewers.**

If a planner or reviewer discloses a financial relationship, here are options that can be considered to mitigate the relationship.

- **End the financial relationship** (including having ended the relationship within 24 months)
- **Recuse individual** 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

# MITIGATION FOR FACULTY PRESENTERS

**Those individuals who are teaching, writing, producing and delivering education.** If a faculty presenter discloses a financial relationship, here are options that can be considered to mitigate the relationship.

- **End the financial relationship** (including having ended the relationship within 24 months)
- **Recuse individual** from controlling aspects of planning and content with which there is a financial relationship
- **Peer review of content** by persons without relevant financial relationships
- **Attest that clinical recommendations are evidence-based and free of commercial bias**

# MITIGATION IN GENERAL

- Planners and other content experts can help determine relevance of relationships, if necessary.
- Keep in mind that simply monitoring the CME content for commercial bias at the time of the presentation is **not** an acceptable mitigation mechanism.
- When providers identify relevant relationships, they must direct authors/ teachers to take actions to assist in the mitigation.

# DOCUMENT THE STEPS TAKEN TO MITIGATE RELEVANT FINANCIAL RELATIONSHIPS




You will be  
asked about this  
at reaccreditation  
time during  
PIP activity review

# COI Mitigation Spreadsheet for Use with Individual Activities

Name of Individual	Individual's Role(s) in Activity	Name of Commercial Interest(s)	Nature of Relationship(s)	Mechanism(s) implemented to resolve conflict of interest appropriate to role(s) in the activity

Record the steps you took in a spreadsheet, table, or database.

# COI Mitigation Form



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CONTINUING MEDICAL EDUCATION

FOR CME OFFICE USE ONLY	
<b>MITIGATION OF CONFLICTS OF INTEREST</b>	
<b>Step 1</b>	<b>Owners/Employees of Ineligible Company (IC)</b>
	<input type="checkbox"/> Not an employee/owner of IC (go to Step 2)
	<input type="checkbox"/> Planning Committee employee/owner of IC (choose from below):
	<input type="checkbox"/> No planning has occurred – individual is fully recused from committee
	<input type="checkbox"/> Planning has occurred – activity will not be accredited
	<input type="checkbox"/> Faculty/speaker employee/owner of IC (choose from below):
	<input type="checkbox"/> Faculty/speaker is not allowed to present
	<input type="checkbox"/> Activity will not be accredited
<b>Step 2</b>	<b>Conflict of Interest (COI)</b>
	<input type="checkbox"/> No relevant financial relationship (no COI)
	<input type="checkbox"/> Potential COI – presenter (choose from below):
	<input type="checkbox"/> Presentation materials reviewed to ensure fair balance, scientific objectivity and no commercial bias
	<input type="checkbox"/> Presenter will refrain from making recommendations on topics of COI
	<input type="checkbox"/> All recommendations for patient care are based on peer review data
	<input type="checkbox"/> Discontinue contracted services that create financial relationship – must disclose such relationship to audience for <b>24</b> months
	<input type="checkbox"/> Individual excluded from content creation and delivery; was replaced with another presenter
	<input type="checkbox"/> Activity will not be accredited
	<input type="checkbox"/> Potential COI - planner
	<input type="checkbox"/> Planner recused from planning content relevant to reported COI
	<input type="checkbox"/> Another non-conflicted planner will participate in planning to ensure fair balance; non-conflicted planner will review proposed content to ensure it is free from potential bias; non-conflicted planner will oversee selection of faculty

Reviewed/Signed by: \_\_\_\_\_
Date: \_\_\_\_\_
Updated: Jan 2021

This is another mechanism some providers utilize to record the steps taken.



# NEW EXCEPTIONS TO DISCLOSURE

Accredited providers do not need to identify, mitigate, or disclose relevant financial relationships for any of the following activities:

- Education that is **non-clinical in nature**, or
- Education where the learner group is in control of content, such as **spontaneous case conversations among peers**.

## Toolkit for the Standards for Integrity and Independence in Accredited Continuing Education

The ACCME is pleased to provide this toolkit of resources to assist accredited providers in transitioning to the new Standards for Integrity and Independence. For this initial collection of tools, we have focused on Standard 1: Ensure Content is Valid and Standard 3: Identify, Mitigate, and Disclose Relevant Financial Relationships. These two standards are applicable to all accredited providers. Use of these resources is completely **optional**. Many accredited providers have their own policies, procedures, forms, and mechanisms to facilitate the planning and delivery of accredited education—as you review your own practices, you may wish to check them against these resources to ensure you are positioned to meet expectations.

We look forward to working with the continuing education community to create and refine additional tools, as necessary. As always, we remain available for questions and assistance! Contact us at [info@accme.org](mailto:info@accme.org).



### Key Steps

*Overview of the 3-step process to identify, mitigate, and disclose relevant financial relationships.*



### Sample Letter

*Language you can use to explain to prospective planners and faculty why financial relationship information is collected.*



### Template

*Compare your process or forms to this sample template to collect the right information about financial relationships.*



### Worksheet

*Step-by-step process for identifying and mitigating relevant financial relationships.*



### Examples

*Sample language that shows you how to communicate disclosure to learners.*



### Guidance

*An example of how to enlist help from planners and faculty to ensure that clinical content is valid.*



### Template

*An example of a tool to facilitate peer review to ensure that clinical content is valid.*



### Quick Tool

*Use this sample tool to simplify educational planning when identification, mitigation, and disclosure are not required.*

Later in the day we will  
be discussing the  
**Quick Tool for Planning  
Accredited CE**  
for these exceptions.

It is part of  
**ACCME's new Toolkit.**

<https://www.accme.org/standards-resources>

# Of Mention.....

The ACCME 's new **Toolkit for the Standards for Integrity and Independence in Accredited Continuing Education** contains resources that were meant to assist providers in their transition to the new Standards.

**The initial collection of tools focuses on:**

- Standard 1: Ensuring Content is Valid
- Standard 3: Identifying, Mitigating, and Disclosing Relevant Financial Relationships.

These 2 standards are applicable to all accredited providers, whether or not commercial support is received.

**Use of resources in the Toolkit is completely optional.**

# **3<sup>RD</sup> SECTOR: DISCLOSURE TO LEARNERS**

Disclosure to learners must occur in a format that can be verified at the time of accreditation, before they engage with the education.

# STANDARD DISCLOSURE TO LEARNERS MUST INCLUDE:

(either individually or as a group)

- The names of the individuals with relevant financial relationships
- The names of the ineligible companies with which they have relationships
- The nature of the relationships
- **A statement that all relevant financial relationships have been mitigated**
- The absence of relevant financial relationships (if applicable)

# IDENTIFY INELIGIBLE COMPANIES BY THEIR NAME ONLY

Disclosure to learners must not include ineligible companies' corporate or product logos, trade names, or product group messages.

# METHODS OF DISCLOSURE

You may use a variety of the following:

- Disclosure Grid
- Disclosure Slide @ beginning of presentation
- Disclosure Statement on flyer and/or other promotional materials (i.e., website)
- Verbal Disclosure to audience during presentation

# VERBAL DISCLOSURE

## The Nuance

While disclosure may be given **verbally** to participants, CME providers must be able to supply the ISMA with written verification that appropriate verbal disclosure occurred (especially if this is the only method you use).

A representative of the provider who was in attendance at the time of the education must attest in writing:

- That verbal disclosure did occur, and
- Itemize the content of the disclosed information, or that there was nothing to disclose



# NON-CLINICAL TOPIC DISCLOSURE STATEMENT

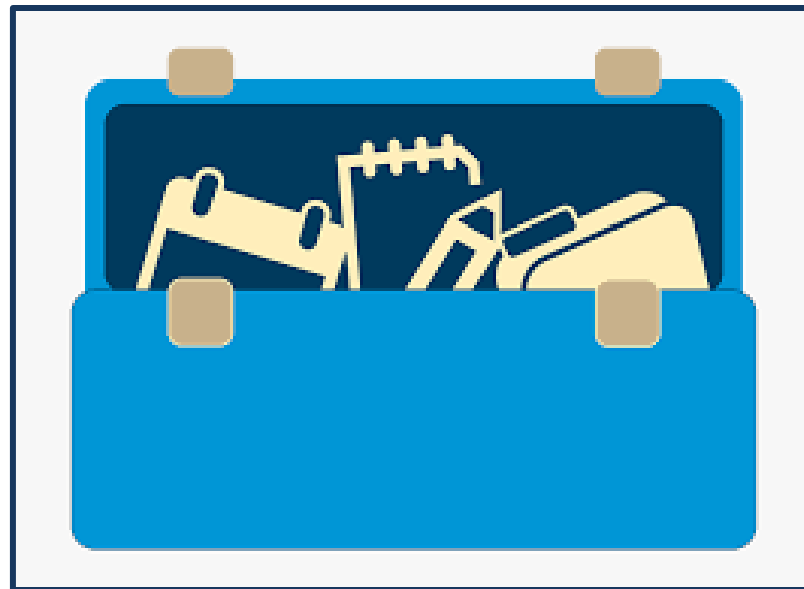
Is there a financial disclosure statement that should be provided to learners for **non-clinical** program topics?

- **No, accredited providers do not need to identify, mitigate, or disclose relevant financial relationships for non-clinical topics.**

However, ISMA does actually provide a statement, which reads as follows:

**“There are no relevant financial relationships with an ineligible company to identify, mitigate or disclose because the content of this activity is non-clinical in nature.”**

# OTHER USEFUL TOOLS IN ACCME'S NEW TOOLKIT





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

For more information, visit  
[accme.org/standards](https://accme.org/standards)  
Questions? E-mail [info@accme.org](mailto:info@accme.org)



### Note for Continuing Education Staff

If any of the following statements apply to the education, you **do not** need to identify, mitigate, or disclose relevant financial relationships for this accredited continuing education:

- ✓ It will only address a non-clinical topic (e.g., leadership or communication skills training).
- ✓ It is for a learner group that is in control of the content entirely (e.g., spontaneous case conversation among peers).
- ✓ It is a self-directed educational activity where the learner will control their educational goals and report on changes that resulted (e.g., learning from teaching, remediation, or a personal development plan). When accredited providers serve as a source of information for the self-directed learner, they should direct learners only to resources and methods for learning that are not controlled by ineligible companies.

**STEP 1:** Before you begin planning your education, 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 this definition: Ineligible companies are those whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.

*Hint: Use the **Template for Collecting Information about All Financial Relationships from Planners, Faculty, and Others**. 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 below.

There are only three exceptions that allow for owners and/or employees of ineligible companies to participate as planners or faculty in accredited continuing education.

1. When the content of the activity is not related to the business lines or products of their employer/company.
2. 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.
3. 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, and **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 the 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.

*Hint: Use the **Worksheet for the Identification and Mitigation of Relevant Financial Relationships of Planners, Faculty, and Others** to implement mitigation strategies appropriate to their role(s) in the educational activity.*



**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.

*Hint: Use the **Examples of Communicating Disclosure to Learners** to share all of the appropriate information before the activity.*

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

*A Checklist for CME Staff*  
providing an overview of the 3-step process and things that are important to consider.

**STEP 1:** Before you begin planning

**STEP 2:** Reviewing disclosures and excluding owners/employees of ineligible companies

**STEP 3:** Determining which relationships are relevant



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

For more information, visit  
[accme.org/standards](http://accme.org/standards)



### Note for Continuing Education Staff

If any of the following statements apply to the education, you **do not** need to identify, mitigate, or disclose relevant financial relationships for this accredited continuing education:

- ✓ It will only address a non-clinical topic (e.g., leadership or communication skills training).
- ✓ It is for a learner group that is in control of the content entirely (e.g., spontaneous case conversation among peers).
- ✓ It is a self-directed educational activity where the learner will control their educational goals and report on changes that resulted (e.g., learning from teaching, remediation, or a personal development plan). When accredited providers serve as a source of information for the self-directed learner, they should direct learners only to resources and methods for learning that are not controlled by ineligible companies.

At the beginning of your planning process, use the sample language below to communicate with prospective planners, faculty, and others who may be in control of content for the education. 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.

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. For more information on the Standards for Integrity and Independence in Accredited Continuing Education, please visit [accme.org/standards](http://accme.org/standards).

### 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>**.

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

At beginning of the planning process, sample language CME providers can use to communicate with prospective planners, presenters and reviewers.

### Tells them:

- Why they are receiving the communication
- Why the CME Office is collecting this information
- What the next steps are in the process of mitigation





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

For more information, visit  
[accme.org/standards](http://accme.org/standards)

### To be completed by education staff.

Name of Individual:

Title of Continuing Education:

Date and location of Education:



### Individual's prospective role(s) in education

Identify the prospective role(s) that this person may have in the planning and delivery of this education (*choose all that apply*)

- ☐ Planner  
*Examples: planning committee, staff involved in choosing topics, faculty, or content*
- ☐ Teacher, Instructor, Faculty
- ☐ Author, Writer
- ☐ Reviewer
- ☐ Other

As a prospective planner or faculty member, we would like to ask for your help in protecting our learning environment from industry influence. Please complete the form below and return it to \_\_\_\_\_ by \_\_\_\_\_.

The ACCME Standards for Integrity and Independence require that we disqualify individuals who refuse to provide this information from involvement in the planning and implementation of accredited continuing education. Thank you for your diligence and assistance. If you have questions, please contact us at \_\_\_\_\_.

### To be Completed by Planner, Faculty, or Others Who May Control Educational Content

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; we ask that you 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.

#### Enter the Name of Ineligible Company

An **ineligible company** is any entity whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.

For specific examples of ineligible companies visit [accme.org/standards](http://accme.org/standards).

#### Enter the Nature of Financial Relationship

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.

#### Has the Relationship Ended?

If the financial relationship existed during the last 24 months, but has now ended, please check the box in this column. This will help the education staff determine if any mitigation steps need to be taken.

Example: ABC Company

Consultant

☒

☐

☐

☐

☐

☐

☐

☐

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

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



### Note for Continuing Education Staff

Use this template to collect all relevant financial relationships of prospective planners, faculty, and others who may control educational content before they assume their role in the education. As an alternative to collecting disclosure information for each activity, if your planners and faculty are a set group of individuals, you might choose to collect this information on an annual or periodic basis and ask the individuals to update if any information changes during the year.

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

Basically, a sample Financial Disclosure Form that you may adopt, if desired.

Compare your process or forms to this sample template to collect the right information about financial relationships.



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# ISMA Financial Disclosure Form

ISMA did not adopt this form but did update ours to reflect changes in the new Standards.

- Removed mention of and request for disclosure of spouse/partner
- Removed columns in grid for Self vs. Spouse/Partner and added "Has relationship ended?"
- Changed look-back on relationships from 12 to 24 months
- Changed section on Relevant Financial Relationships to All Financial Relationships
- Changed term "commercial interest" to "ineligible company"
- Changed term "resolved" to "mitigated"
- Updated "Statements/Rules of ISMA Content Validation" on form to include:
  - Although accredited continuing education is an appropriate place to discuss, debate, and explore new and evolving topics, these areas need to be clearly identified as such within the program and individual presentations. It is the responsibility of the accredited provider to facilitate engagement with these topics without advocating for, or promoting, practices that are not, or not yet, adequately based on current science, evidence and clinical reasoning.
- Within Glossary of Terms, updated:
  - Definition of "Commercial Interest," now called "Ineligible Entity"
  - Definition of "Relevant Financial Relationships"



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

For more information, visit  
[accme.org/standards](http://accme.org/standards)



### Note for Continuing Education Staff

Use this sample worksheet to identify and mitigate relevant financial relationships that you have identified for planners, faculty, and others who will control educational content for your education activity. Please make sure that (1) the mitigation strategy is appropriate to the person's role in the activity, and (2) that mitigation is implemented before each person takes on their role.

### 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 persons 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. For information about exceptions to this exclusion, see [accme.org/standards](http://accme.org/standards).

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

Review the information for all persons whom you did not exclude in Step 1 and determine whether each person's financial relationships with ineligible companies are relevant to the content of the education you are planning. Financial relationships are relevant if the following three conditions are met for the prospective person 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 the education is related to the products of an ineligible company with whom the person has a financial relationship.

### STEP 3: Choose a **mitigation strategy** for each person who has a relevant financial relationship and **implement** that strategy before the person assumes their role.

Using the lists below, identify which mitigation strategy(ies) will be used for **all persons** with relevant financial relationships who control the educational content of the educational activity. You may select multiple strategies but be sure to use strategies **appropriate to the role(s)** that each person has. You can also identify your own strategies for mitigation.

#### Mitigation steps for planners (choose at least one)

- ✓ **Divest** the financial relationship
- ✓ **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
- ✓ Use **other methods** (please describe):

#### Mitigation steps for faculty and others (choose at least one)

- ✓ **Divest** the financial relationship
- ✓ **Peer review** of content by persons without relevant financial relationships
- ✓ Attest that clinical recommendations are **evidence-based** and **free of commercial bias** (e.g., peer-reviewed literature, adhering to evidence-based practice guidelines)
- ✓ Use **other methods** (please describe):

### Step 4: Document the mitigation strategy(ies) you used for each person with a relevant financial relationship.

A	B	C	D
NAME OF PERSON	ROLE(S) IN ACTIVITY	STEP(S) TAKEN TO MITIGATE RELEVANT FINANCIAL RELATIONSHIP	DATE IMPLEMENTED
Example: Dr. Jones	Planner	Recusal from topic/faculty selection	10/28/21

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

## Takes the place of the Flowchart for the Identification and Resolution of Personal Conflicts of Interest

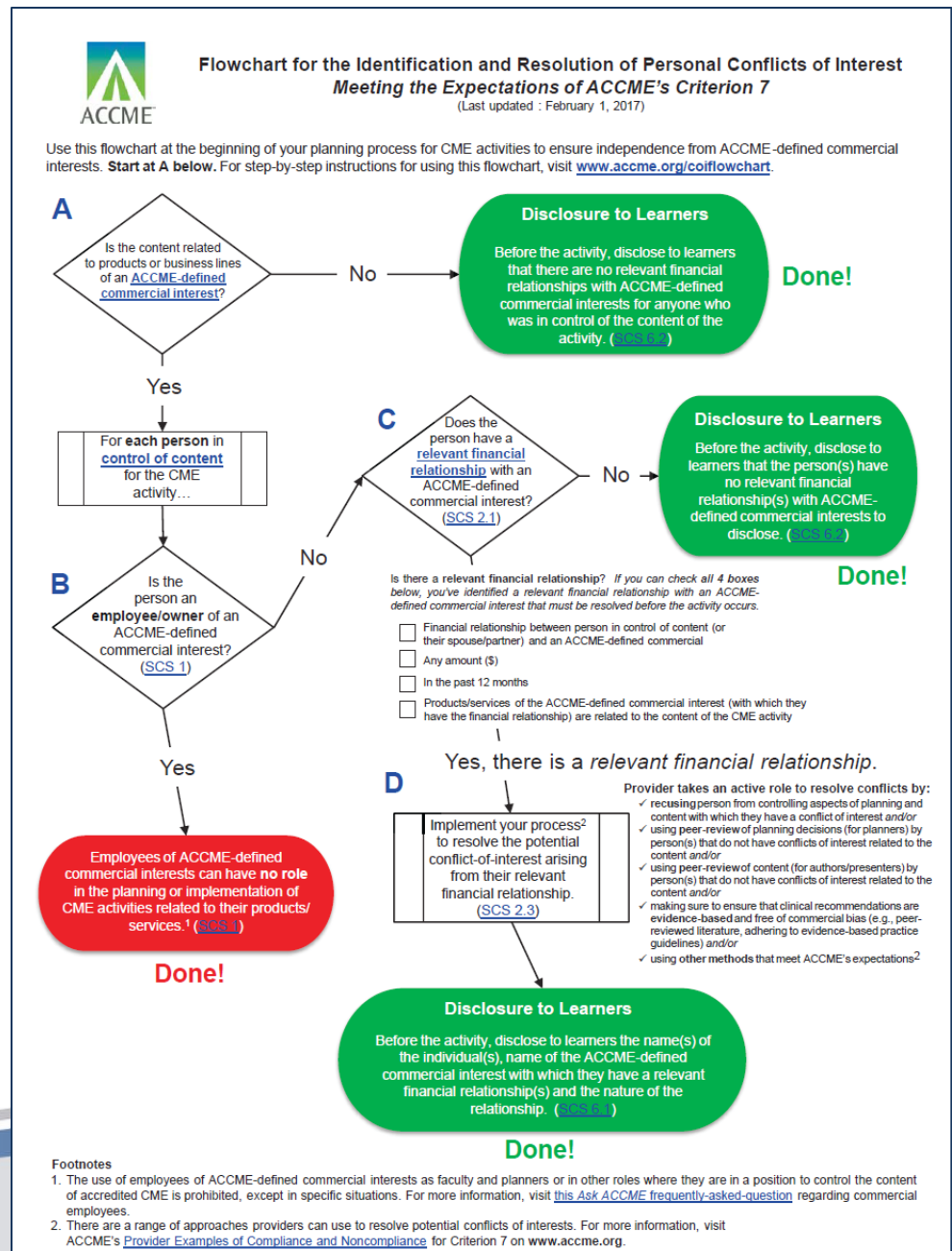
You may adopt this form to record/document how you mitigated individual relationships, if you desire.



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# What did the old Flowchart for Resolution of Personal Conflicts of Interest look like?

(established in 2017)







### Note for Continuing Education Staff

If any of the following statements apply to the education, you **do not** need to identify, mitigate, or disclose relevant financial relationships for this accredited continuing education:

- ✓ It will only address a non-clinical topic (e.g., leadership or communication skills training).
- ✓ It is for a learner group that is in control of the content entirely (e.g., spontaneous case conversation among peers).
- ✓ It is a self-directed educational activity where the learner will control their educational goals and report on changes that resulted (e.g., learning from teaching, remediation, or a personal development plan). When accredited providers serve as a source of information for the self-directed learner, they should direct learners only to resources and methods for learning that are not controlled by ineligible companies.

Use the sample language below to provide disclosure to learners in a format that can be verified at the time of accreditation. Disclosure must be provided to learners **before** engaging with the accredited education.

### What gets disclosed to learners before the education?

#### If there are **NO** relevant financial relationships:

*Inform learners that planners, faculty, and others in control of content (either individually or as a group) have no relevant financial relationships with ineligible companies.*

#### EXAMPLES:

*"Dr. Xin Lee, faculty for this educational event, has no relevant financial relationship(s) with ineligible companies to disclose."*

*"Ruth Hopkins, Dr. Maryam Elbaz, and Ken Sanders, authors of this educational activity, have no relevant financial relationship(s) with ineligible companies to disclose."*

*"None of the planners for this educational activity have relevant financial relationship(s) to disclose with ineligible companies whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients."*

#### 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...)

#### If there **ARE** relevant financial relationships:

*Disclose name(s) of the individuals, name of the ineligible company(ies) with which they have a relevant financial relationship(s), the nature of the relationship(s), and a statement that all relevant financial relationships have been mitigated.*

#### EXAMPLES:

*Nicolas Garcia, faculty for this educational event, is on the speakers' bureau for XYZ Device Company.*

*Dr. Yvonne Gbeho, planner for this educational event, has received a research grant from ABC Pharmaceuticals.*

*All of the relevant financial relationships listed for these individuals have been mitigated.*

## Examples of Communicating Disclosure to Learners

Uses sample terminology for disclosure statements when there are no relevant relationships

AND

when there are relevant relationships, in a format that can be verified at the time of reaccreditation.

Remember that disclosure must be provided to learners **before** engaging with accredited education.





## Guidance for Planners, Authors, and Faculty: Ensuring that Clinical Content is Valid

For more information, visit  
[accme.org/standards](http://accme.org/standards)



### Note for Continuing Education Staff

Use this sample template to communicate expectations to planners, authors, and faculty about ensuring valid clinical content for accredited education. For more information about these expectations, see Standard 1 of the Standards for Integrity and Independence at [accme.org/standards](http://accme.org/standards).

Dear **Prospective Planner/Faculty Member**:

As an important contributor to our accredited education, we would like to enlist your help to ensure that educational content is fair and balanced, and that any clinical content presented supports safe, effective patient care. This includes the expectations that:

- ✓ All recommendations for patient care in accredited continuing education must be based on current science, evidence, and clinical reasoning, while giving a fair and balanced view of diagnostic and therapeutic options.
- ✓ All scientific research referred to, reported, or used in accredited education in support or justification of a patient care recommendation must conform to the generally accepted standards of experimental design, data collection, analysis, and interpretation.
- ✓ Although accredited continuing education is an appropriate place to discuss, debate, and explore new and evolving topics, these areas need to be clearly identified as such within the program and individual presentations. It is the responsibility of accredited providers to facilitate engagement with these topics without advocating for, or promoting, practices that are not, or not yet, adequately based on current science, evidence, and clinical reasoning.
- ✓ Content cannot be included in accredited education if it advocates for unscientific approaches to diagnosis or therapy, or if the education promotes recommendations, treatment, or manners of practicing healthcare that are determined to have risks or dangers that outweigh the benefits or are known to be ineffective in the treatment of patients.

These expectations are drawn from **Standard 1** of the ACCME Standards for Integrity and Independence in Accredited Continuing Education. For more information, see [accme.org/standards](http://accme.org/standards). If we can help you to understand and/or apply these strategies to your education, please contact us at [provider contact information](#).



Please consider using these strategies to help us support the development of valid, high quality education.

### Consider using the following best practices when presenting clinical content in accredited CE:

- ✓ Clearly describe the level of evidence on which the presentation is based and provide enough information about data (study dates, design, etc.) to enable learners to assess research validity.
- ✓ Ensure that, if there is a range of evidence, that the credible sources cited present a balanced view of the evidence.
- ✓ If clinical recommendations will be made, include balanced information on all available therapeutic options.
- ✓ Address any potential risks or adverse effects that could be caused with any clinical recommendations.

### Although accredited CE is an appropriate place to discuss, debate, and explore new and evolving topics, presenting topics or treatments with a lower (or absent) evidence base should include the following strategies:

- ❖ Facilitate engagement with these topics without advocating for, or promoting, practices that are not, or not yet, adequately based on current science, evidence, and clinical reasoning
- ❖ Construct the activity as a debate or dialogue. Identify other faculty who represent a range of opinions and perspectives; presentations should include a balanced, objective view of research and treatment options.
- ❖ Teach about the merits and limitations of a therapeutic or diagnostic approach rather than how to use it.
- ❖ Identify content that has not been accepted as scientifically meritorious by regulatory and other authorities, or when the material has not been included in scientifically accepted guidelines or published in journals with national or international stature.
- ❖ Clearly communicate the learning goals for the activity to learners (e.g., "This activity will teach you about how your patients may be using XX therapy and how to answer their questions. It will not teach you how to administer XX therapy").

## Guidance for Planners, Authors and Faculty: Ensuring Clinical Content is Valid

A sample template to communicate expectations to planners, authors and faculty in the planning stages to ensure valid clinical content for the accredited education they will be developing.

ISMA communicates the majority of this information within the "Statements/Rules of ISMA Content Validation" on pg. 2 of our Financial Disclosure Form.



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Please answer the following questions regarding the clinical content of the education.

Are recommendations for patient care based on current science, evidence, and clinical reasoning, while giving a fair and balanced view of diagnostic and therapeutic options? *[Standards for Integrity and Independence 1.1]*

Comments:



☐ Yes

☐ No

Does all scientific research referred to, reported, or used in this educational activity in support or justification of a patient care recommendation conform to the generally accepted standards of experimental design, data collection, analysis, and interpretation? *[Standards for Integrity and Independence 1.2]*

Comments:

☐ Yes

☐ No

Are new and evolving topics for which there is a lower (or absent) evidence base, clearly identified as such within the education and individual presentations? *[Standards for Integrity and Independence 1.3]*

Comments:

☐ Yes

☐ No

Does the educational activity avoid advocating for, or promoting, practices that are not, or not yet, adequately based on current science, evidence, and clinical reasoning? *[Standards for Integrity and Independence 1.3]*

Comments:

☐ Yes

☐ No

Does the activity exclude any advocacy for, or promotion of, unscientific approaches to diagnosis or therapy, or recommendations, treatment, or manners of practicing healthcare that are determined to have risks or dangers that outweigh the benefits or are known to be ineffective in the treatment of patients? *[Standards for Integrity and Independence 1.4]*

Comments:

☐ Yes

☐ No



#### Note for Continuing Education Staff

One strategy to ensure the clinical content validity of accredited continuing education is to allow external (peer) review by persons with appropriate clinical expertise and no relevant financial relationships with ineligible companies, defined as those whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients. The questions above direct reviewers to share feedback about each of the requirements that comprise Standard 1 in the Standards for Integrity and Independence. For more information, see [accme.org/standards](http://accme.org/standards).

## Template for Peer Review: Ensuring that Clinical Content is Valid

An example of a tool to help facilitate peer review to ensure that clinical content is valid.

The questions direct reviewers to share feedback about each of the requirements that comprise Standard 1.

ISMA will continue to use our own existing Content Review Form.



## Standards for Integrity and Independence in Accredited Continuing Education

### Transition Checklist

We want to do everything we can to support the continuing education community's successful implementation of the new Standards. We encourage you to review the [Standards](#) and [resources](#) and begin working on your transition plan now, so that you are in compliance by January 1, 2022. Here's a checklist to help you get started.

#### Standard 1: Ensure Content is Valid

While there is nothing new in our approach to content validity, we suggest that you take the following steps to confirm that your processes meet our expectations.

- ✓ Check out the tips and strategies in the [clinical content validation tool](#) from the [Standards Toolkit](#).
- ✓ Review your process for ensuring that education is fair and balanced, and supports safe, effective patient care.
- ✓ Review your process for communicating your expectations to planners, authors, and faculty.

#### Standard 2: Prevent Commercial Bias and Marketing in Accredited Continuing Education

- ✓ Communicate to faculty that they cannot actively promote or sell products or services during accredited education.
- ✓ If you intend to share learners' names or contact information with an ineligible company, determine how you will obtain the explicit consent of individual learners.
  - If you ask for consent at registration, the learner must have the ability to opt out and still register for your activity.
  - The consent statement must be clearly visible—not hidden in a long list of terms and conditions.

#### Standard 3: Identify, Mitigate, and Disclose Relevant Financial Relationships

- ✓ Check out the [Tools for Identifying, Mitigating, and Disclosing Relevant Financial Relationships](#) from the [Standards Toolkit](#).
- ✓ Change your process as needed to make sure that you collect information from all planners, faculty, and others in control of educational content about:
  - all their financial relationships with ineligible companies
  - within the 24 months prior to their involvement with an accredited CE activity
- ✓ Use the correct and complete definition of ineligible company: Those whose primary business is producing, marketing, selling, reselling, or distributing healthcare products used by or on patients.

## Transition Checklist

**We encourage you to refer  
to this checklist  
to help ensure you've  
not forgotten anything  
in implementing the  
new Standards  
(which were effective 1/1/2022).**

**<https://accme.org/publications/standards-for-integrity-and-independence-transition-checklist-pdf>**

It contains all the factors for  
you to consider in:

- Reviewing your processes.....
- Changing your forms.....
- Communicating to faculty.....

**A hard copy is also available in  
your handout packet.**



# Group Discussion

