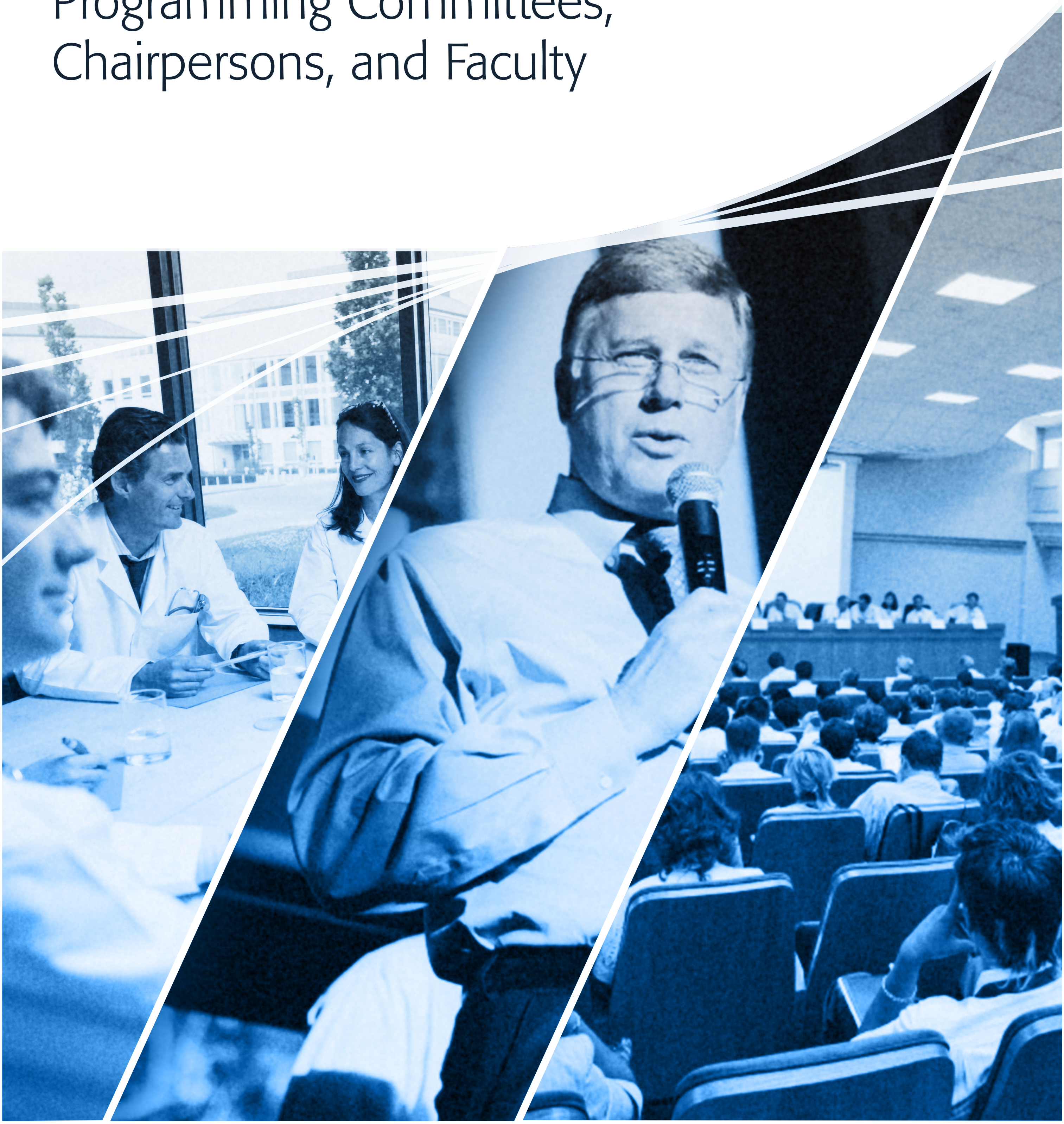
AOTRAUMA

Conflict of Interest Resolution

Disclosure Policy for Programming Committees, Chairpersons, and Faculty



1. Disclosing Conflict of Interest —The AO policy

Content

It is the policy of AO to ensure balance, independence, objectivity, and scientific rigor in all its educational programs and activities. All faculty, planners, and course chairs participating in these programs are expected to disclose to the audience any real or apparent conflict of interest related to the content of their presentation.

The intent of the disclosure is not to prevent a speaker or contributor with a significant financial or other relationship from making a presentation or creating content, but to provide participants with information that might be of importance to their evaluation of a presentation.

The process also ensures compliance with the accreditation standards of the

- ACCME (Accreditation Council for Continuing Medical Education)
- EACCME (European Accreditation Council for Continuing Medical Education)

Since "Disclosure of Conflict of Interest" is a global standard in medical education to ensure scientific independence the AO recommends to run the process for every educational activity or content creation activity provided under the AO branding.

The process is mandatory for every activity that is submitted for accreditation to a local or regional accreditation body.

Faculty participating in accredited CME activities are encouraged to include a disclosure slide to be shown at the beginning/start of your presentation.

Disclosure—When and How

Before the educational event: All individuals engaged in course planning, content development, or presentation (ie, course chairs, planning committee members, moderators, speakers, etc) must complete and submit the "Disclosure of Conflict of Interest Form" for review and approval well in advance of the event. A review process is in place to manage and resolve any possible conflicts of interest.

At the educational event: A summary statement is compiled and distributed to the event attendees as part of their course materials.

During the educational event: Each confirmed faculty should share their disclosure information verbally and with a slide to the event attendees at the beginning of the presentation. A statement should be made even if there are no financial relationships to disclose.
Sample slides are available on the AOTrauma Website for your reference.

Fair balance
Presentations should be free of commercial bias for or against any product. Statements about products should be objective and based on evidence drawn from generally accepted scientific methods in the medical community.

To facilitate fair balance, faculty should:

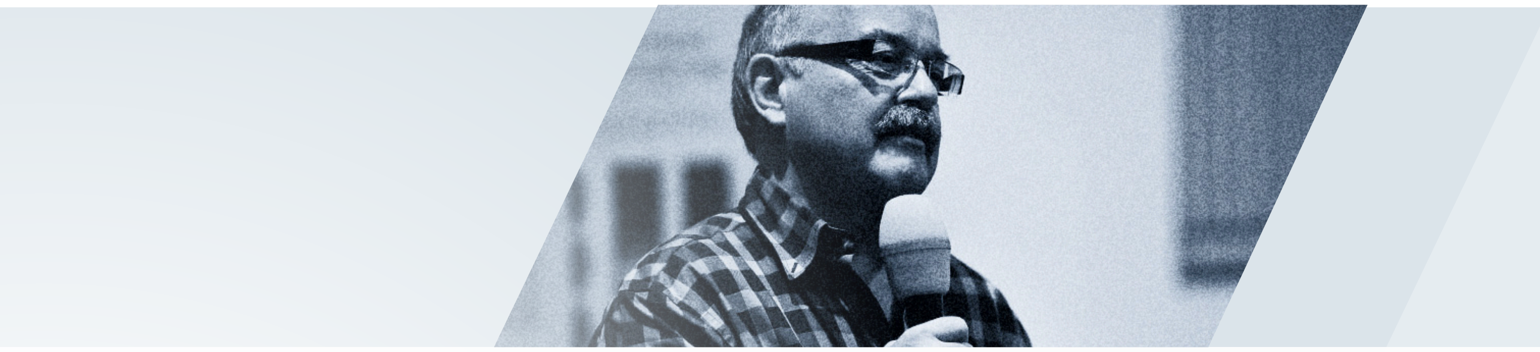
- Disregard any attempts by commercial supporters to influence the content of their presentation (to include selection of topics, speakers, and/or learning objectives).
- Use generic, rather than trade names of products.
- When using data from published studies, reference the source and highlight the study design and its limitations.

Discussion of "off-label" use
CME courses provide an educational forum in which off-label uses may be discussed. However, speakers discussing off-label uses should indicate that the product is not labeled for the use under discussion or that the product is still investigation.

2. Process and timeline

Process for educational activities
(eg, courses, seminars, congresses, symposia, webinars, webcasts)

Responsible	*Event organizer*	*Event organizer*	*Event organizer* / *Event chair*	*Event organizer*
Task	Send disclosure forms and information to chair and faculty, two week deadline for submission.	Check completeness and follow-up on missing ones—all forms handed in 18 weeks prior to event.	Send forms with reported conflict to chair for resolution decision. 1 week deadline for response.	If EACCME accreditation requested: send copy of completed forms to AO Education Institute CME accreditation office.
Support Tools	- Disclosure forms - Disclosure brochure - Q&A Website		- Disclosure forms with reported CoI - Resolution process	
Time	**Event start date minus 22 weeks (154 days)**	**Event start date minus 20 weeks (140 days)**	**Event start date minus 19 weeks (133 days)**	**Event start date minus 18 weeks (126 days)**



Event chair	Event organizer	Event chair	Event organizer
Replace faculty if no disclosure is submitted or conflict not resolvable.	Create “Disclosure of Potential Conflict of Interest” document from collected CoI forms.	Make faculty aware of useage of disclosure slides and where to find samples.	Have print-outs of listing ready for participants during registration, put list on event “blackboard”.
	- Disclosure list form - Sample list	- Sample slides - Q&A Website	- List form
Event start date minus 18 weeks (126 days)	**Event start date minus 2 weeks (14 days)**	**During precourse**	**At event registration**

3. What has to be disclosed

All faculty members participating in an AO educational activity are expected to disclose any significant financial interest or other relationship: (1) with the manufacturer(s) of any commercial product(s) and/or provider(s) of commercial services discussed in an educational presentation and (2) with any commercial supporters of the activity.

According to the ACCME, individuals need to disclose relationships with a commercial interest if both (a) the relationship is financial and occurred within the past **12 months** and (b) the individual has the opportunity to affect the content of CME about the products or services of that commercial interest.

Financial relationships are those relationships in which the individual benefits by receiving a salary, royalty, intellectual property rights, consulting fee, honoraria, ownership interest (eg, stocks, stock options or other ownership interest, excluding diversified mutual funds), 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 for which remuneration is received or expected.

ACCME considers relationships of the person involved in the CME activity to include financial relationships of a spouse or partner.

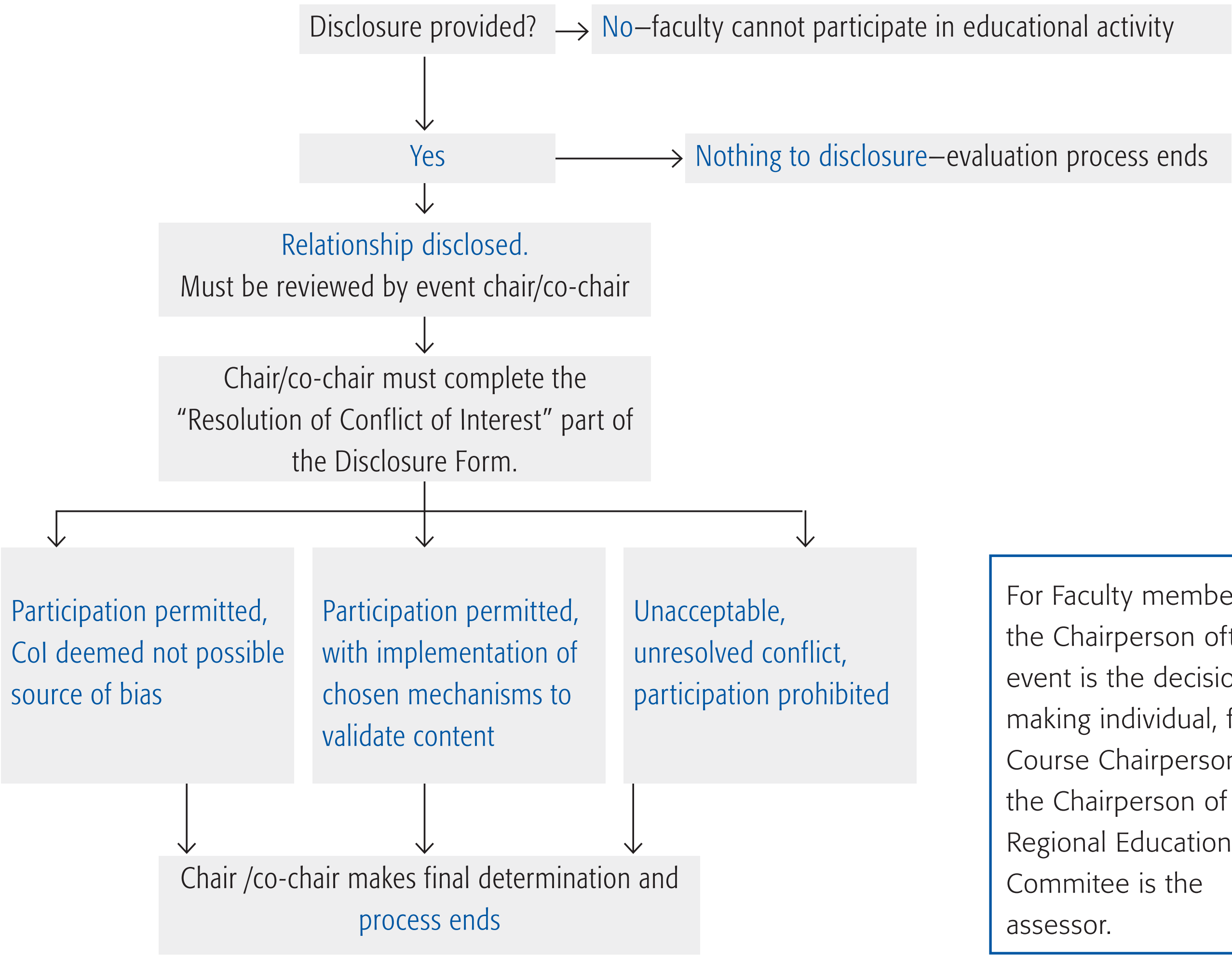
The ACCME has not set a minimum amount for relationships to be significant. Inherent in any amount is the incentive to maintain or increase the value of the relationship.

Examples of relevant financial relationships

- Salaries received
- Royalties
- Intellectual property rights/patents
- Honoraria for lectures, speakers bureaus, product education, expert testimonial
- Ownership interest (stocks, options)
- Other non-monetary benefits (International travel, gifts) unrelated to activities listed
- Board membership
- Grants/research support
- Consultancy

4. Resolution process

Chair and Faculty have to hand in the signed disclosure form in time. If a potential conflict is reported the following process is applied:



For Faculty members the Chairperson oft the event is the decision-making individual, for Course Chairpersons the Chairperson of the Regional Education Commitee is the assessor.

The following mechanisms of resolution can be applied (multiple mechanisms possible):

1. No resolution required
2. Altering financial relationship(s)
3. Peer review/independent content validation
4. Altering control over content
5. Exclusion from participation in event

The action (taken) has to be reported in the "Resolution of Conflict of Interest" part of the "Disclosure of Conflict of Interest Form".

5. Forms, templates, and samples

"Conflict of Interest Disclosure" form
To be completed by Chairpersons after nomination, by faculty members 22 weeks prior to the educational activity/event, by programming committees at the point of election.

"Disclosure of Potential Conflict of Interest" form
This form has to be compiled by the event organizer and mad public at the event. Copies of the list should be made accessible to the participants during registration.

Sample: "Disclosure of Potential Conflict of Interest"
The sample shows how to fill in the public disclosure list.

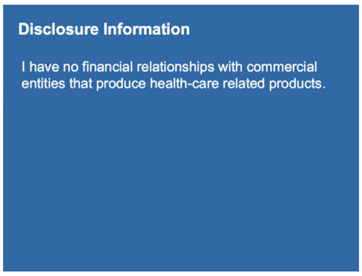
6. Sample disclosure slides

[Download PPT Slides]

Faculty should be encouraged (during the Precourse) to use disclosure slides. Sample slides are available in PowerPoint on the [AOTrauma Website] (https://aotrauma.aofoundation.org/en/education/faculty/faculty-center/Conflict-of-Interest-Resolution).

Scenario 1

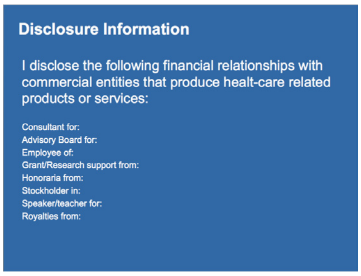
The lecturer has no conflicts of interest. Easy!



"I have no financial relationships with commercial entities that produce health-care related products."

Scenario 2

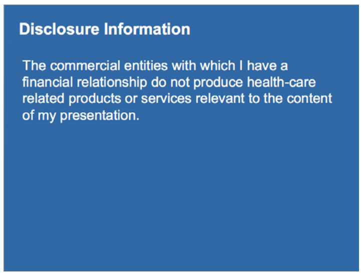
The lecturer has conflicts of interest, but they are not relevant.



"The commercial entities with which I have a financial relationships do not produce health-care related products or services relevant to the content of my presentation."

Scenario 3

The lecturer has relevant conflicts of interest to disclose to students.



"I disclose the following financial relationships with commercial entities that produce health-care related products or services:"

7. Q&A

What is a "Conflict of Interest"?
The Alliance for CME considers a conflict of interest to occur when individuals have **both**: a financial relationship with a company/entity (commercial interest) **AND** the opportunity to affect the content of an educational activity about the product or services of that particular company/entity.

A potential conflict of interest is created when a relationship with a company/entity (commercial interest) presents an opportunity or incentive to influence the content of an educational activity or to insert bias into the content in favor of the products or services of the company/entity.

What is considered to be a financial relationship?
A financial relationship is defined as: those relationships in which the individual receives a financial benefit or something of value. Examples of financial relationships include: salaries, royalties, revenue from intellectual property rights, fees for consulting or advising, honoraria for services provided to commercial companies (eg, product specific education, speakers bureaus), stocks, stock options, and other non-monetary benefits (eg, international travel).

What is a relevant financial relationship?
A financial relationship is any amount occurring within the past 12 months that create a conflict of interest. This affects the person involved in the educational activity as well as financial relationships of a spouse or partner. The amount itself has not to be disclosed.

How are potential conflicts of interest identified?
The information being disclosed will be analyzed in the context of the content of the educational activity.

How are potential conflicts of interest resolved?

- Peer review slides/handouts prior to teaching
- Limit the individual's presentation to discussing only data and results of research and not recommendations for treatment of patients
- Require that presentations and recommendations be based on best available evidence
- The individual alters the financial relationship
- Choose another faculty member who does not have a conflict of interest.
- Disqualify any faculty who refuses to disclose from having any role in the educational activity

Has teaching or serving for the AO Foundation to be disclosed?

No, the AO Foundation is a registered non-profit organization. Only work for entities producing, marketing, re-selling, or distributing health-care goods or services consumed by, or used on patients has to be disclosed.

Who is responsible for what?

The organizers have to ensure that all faculty and chairs provide their disclosure information in due time. The decision on identifying and resolving potential conflicts of interest prior to the event is in the responsibility of the chairperson of the event (or the regional education chairs if the chairperson of the event is affected).

The process is very time consuming—will it become easier and simpler in the future?

Yes, the AO Foundation is working on a simpler process by establishing a disclosure profile within our faculty database that you can simply update when you are invited to be a faculty member or chairperson. The timelines and content will still be in effect.

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More information: http://www.aotrauma.org/coi_resolution Version 1.1, May 2013