

ASCO Conflict of Interest Procedures for CME Implementation Plan

IDENTIFICATION AND MANAGEMENT OF CONFLICTS OF INTEREST IN CONTINUING MEDICAL EDUCATION

Introduction

This Implementation Plan has been adopted by ASCO to interpret and apply the ASCO Revised Conflict of Interest (COI) Policy as it relates to accredited CME activities (See Section V.A, ASCO Revised COI Policy). This Implementation Plan builds on the Revised COI Policy and complies with guidelines of the Accreditation Council for Continuing Medical Education.

Process

Identification of Relevant Financial Relationships – Committee and Editorial Board Members

- During the invitation process, members are provided with the ASCO Revised COI policy, the ACCME Standards for Commercial Support, and the Committee's Responsibilities and Authorities Statement
 - Members complete a Responsibilities Agreement form indicating that they received, read and understand the policies and agree to comply
 - Members must complete a Disclosure Report form for financial relationships over the prior 1-2 years.
 - The Committee or Editorial Board Chair may be enlisted to facilitate submission of disclosure information from members failing to submit information by the requested deadline
 - Failure to provide disclosure information will prevent the offending member from participating in planning sessions for educational & scientific programs
 - Financial disclosures will be collected/updated annually by ASCO staff; immediate updates are required if changes occur to that previously reported
- Upon receipt of disclosure information by ASCO staff
 - A preliminary review of the reported information is done by ASCO staff
 - A summary report of the disclosure information will be generated for review by the Committee/Subcommittee or Editorial Board.

Determination of COI and Subsequent Management – Committee or Editorial Board Members

- At the beginning of the first Committee or Editorial Board meeting or conference call, the Chair will state the process to be followed for review of relevant financial relationships, including when and how ultimate decisions will be made on cases where potential COIs may exist.
 - A record will be kept by ASCO staff that documents group discussion and final case determinations.
 - During discussion of a specific case, the member that is the subject of the case involving the potential COI will not participate unless asked to respond to a specific question by the Chair.
 - The Committee or Editorial Board will come to consensus as to whether or not the financial relationships disclosed in each case constitute a COI – this decision will be made within the context of the educational activities to be planned and discussed by the Committee or Editorial Board. As per ACCME policy, any financial relationship with a commercial entity, regardless of the amount, constitutes a COI that must be managed.
 - The Committee or Editorial Board may consider the following areas (as recommended by the CME Subcommittee) in managing COIs:
 - Whether a scientific or editorial peer review process is to be followed during Committee planning
 - Whether the program information to be reviewed by the Committee is based on the best available evidence
 - Whether the scope of the activity is broad (addresses multiple therapeutic agents or strategies), or narrow (focuses on a single therapeutic agent)
 - Whether the degree of relationship(s) reported is minimal or significant (one minor financial link or multiple significant connections)
- If a COI is determined to exist, the Committee or Editorial Board will determine whether the conflicted member will recuse him/herself from the specific portion of Committee planning and discussion that pertains to the area of conflict, or whether the conflicted member will be replaced.
- If the Chair of a Planning Committee, Subcommittee or Editorial Board has a COI, the matter will be reviewed by the Cancer Education Committee. If the Chair of the Cancer Education Committee has a COI, deliberations will be led by the Chair-Elect (and the Chair will be excused from deliberations).
- Committee or Editorial Board meeting minutes will document the review of disclosure information, discussion of relevant financial relationships, Committee or Editorial Board vote, and identity of discussants and affected members.

Selection and Invitation of Program/Activity Faculty/Authors

- Final program faculty or authors are determined by the Planning Committee; selection is based on recognized expertise relevant to the program topic to be addressed.
- During the invitation process, faculty or authors are provided with the ASCO Revised COI policy, the ACCME Standards for Commercial Support, ASCO's Statement of Expectations for Faculty Presentations and notification that peer review of presentation materials may occur for purposes of content validation.
 - Faculty or authors must complete a response form indicating that they received, read and understand the policies and agree to comply. This contract with the faculty presenter is designed to ensure that all presentations are in compliance with ASCO and ACCME policies and standards.
 - Faculty or authors must complete a Disclosure Report form for financial relationships over the prior 1-2 years relevant to the presentation topic.
 - Faculty or presenting authors must include a disclosure slide in their presentation and make a verbal reference to it at the podium during the activity.
 - Failure to submit this information will prevent his/her participation in the activity.
 - The Committee Chair will be enlisted to assist in obtaining disclosure information from faculty or authors failing to comply by the requested deadline
 - Failure to provide disclosure information will prevent the offending faculty member or author from planning or presenting at the educational & scientific program or participating in the CME activity. Committee members will select replacements for faculty or author positions vacated by those failing to submit disclosure information.
 - Financial disclosures will be collected by ASCO staff; immediate updates are required if changes occur to that previously reported
- Upon receipt of disclosure information by ASCO staff
 - A preliminary review of the reported information is done by ASCO staff
 - ASCO staff prepares a report of the disclosure information for review by the Committee/Subcommittee Chair

Determination of COI and Subsequent Management – Program Faculty of Live Meetings

- Faculty members employed by commercial entities must submit all program materials for presentation to the Committee for the purpose of content validation. Only those materials given a final approval by the Committee may be presented at the live program or included in an enduring material subsequently produced.
 - “Commercial entity” is defined in accordance with the ACCME guidelines as “any proprietary entity producing health care goods or services, with

the exemption of non-profit or government organizations and non-health care related companies.”

- The Committee is responsible for reviewing the financial disclosures and determining whether a faculty COI exists and managing faculty COIs. As per ACCME policy, any financial relationship with a commercial entity, regardless of the amount, constitutes a COI that must be managed.
- The Committee is responsible for managing all cases where it is determined that the reported financial relationships constitute a faculty COI. The Committee may consider the following in managing faculty COIs:
 - Whether the program information to be presented is based on the best available evidence
 - Whether a scientific or editorial peer review process is to be followed during program planning
 - Whether the topic is broad in focus (addresses multiple therapeutic agents or strategies), or narrow (focus on a single therapeutic agent)
 - Whether the degree of relationship(s) reported is minimal or significant (one minor financial link or multiple significant connections)
 - 1. In managing COIs, the Committee may take any of the following actions, or other action it deems appropriate: The committee may request that a letter be sent to the faculty member noting the presence of a potential conflict and emphasizing the agreement to comply with ASCO and ACCME’s policies and expectations. The letter also informs the speaker of the possibility of an onsite audit.
 - 2. The Committee may elect to manage the conflict through an onsite Committee audit of the program (see next bullet).
 - If bias is detected during the presentation of a live program, the Committee evaluator may elect to interrupt or stop the program.
 - 3. The Committee may elect to manage the conflict through content validation of program materials submitted before the activity occurs
 - 4. The Committee may elect to replace the faculty presenter with someone having no conflict
 - 5. The Committee may elect to re-assign the roles/topics to be addressed among the faculty so that no conflicts are present
- The Committee will identify a minimum of 10% of the sessions to be presented for onsite audit. These sessions will be monitored by an assigned evaluator who will assess compliance with ASCO and ACCME policies and expectations for CME accredited activities. Session evaluators will use a specially created form to record and report observations. The sessions selected for review may include those where no conflicts were found to exist among the faculty presenters, as well as those where management of identified conflicts occurred (see #2 under previous bullet).
- In the event that a scheduled faculty member cannot participate in an activity as a result of an emergency, illness, injury or other unscheduled event, replacement faculty may be selected. Faculty selected to fill a last minute vacancy must submit disclosure for identification and management of conflicts of interest as soon as is feasible.

- For last-minute faculty substitutions, disclosure information will be reviewed by the committee chair. If a conflict is identified, the presentation will be audited on site.
- Disclosures for last minute faculty that are not included in the printed program materials must be communicated to the activity participants before the start of the activity. Speakers must use a disclosure slide and disclose orally.
- Industry employees are prohibited from participating as last minute faculty due to the requirement to review their materials before the scheduled activity.

Determination of COI and Subsequent Management – Authors/Faculty of Enduring Materials

- The Editorial Board is responsible for reviewing the financial disclosures and determining whether an author or faculty COI exists and managing those COIs. As per ACCME policy, any financial relationship with a commercial entity, regardless of the amount, constitutes a COI that must be managed.
- The Editorial Board is responsible for managing all cases where it is determined that the reported financial relationships constitute an author or faculty COI. The Editorial Board may consider the following in managing faculty COIs:
 - Whether the program information to be presented is based on the best available evidence
 - Whether a scientific or editorial peer review process is to be followed during program planning
 - Whether the topic is broad in focus (addresses multiple therapeutic agents or strategies), or narrow (focus on a single therapeutic agent)
 - Whether the degree of relationship(s) reported is minimal or significant (one minor financial link or multiple significant connections)
- In managing COIs, the Editorial Board may take any of the following actions, or other action it deems appropriate:
 1. The Editorial Board may request that a letter be sent to the author noting the presence of a potential conflict and emphasizing the agreement to comply with ASCO and ACCME's policies and expectations. The letter will remind the author of the additional peer review of content submitted, prior to release.
 2. The Editorial Board may elect to manage the conflict by identifying additional peer reviewers to provide a more thorough assessment of content submitted, prior to release.
 3. The Editorial Board may elect to replace the author with someone having no conflict.
 4. The Editorial Board may elect to re-assign the roles/topics to be addressed among the authors so that no conflicts are present.
- The Editorial Board will select topic experts to serve as peer reviewers for all enduring material content, regardless of the presence of an identified COI. Each chapter or module will be reviewed by a minimum of one topic expert.
- The Editorial Board will provide the final review and approval of all content for any enduring material.

Determination of COI and Subsequent Management – Peer Reviewers of Enduring Materials

- All peer reviewers must complete a Disclosure Report form and a Peer Reviewer Responsibilities Agreement.
- The Editorial Board is responsible for reviewing the financial disclosures and determining whether a Peer Reviewer COI exists and managing those COIs. As per ACCME policy, any financial relationship with a commercial entity, regardless of the amount, constitutes a COI that must be managed.
- In managing COIs, the Editorial Board may take any of the following actions, or other action it deems appropriate:
 1. The Editorial Board may request that a letter be sent to the peer reviewer noting the presence of a potential conflict and emphasizing the agreement to comply with ASCO and ACCME's policies and expectations. The letter will also emphasize the role of the Editorial Board in providing the final review of all content.
 2. The Committee may elect to replace the peer reviewer with someone having no conflict.
 3. The Committee may elect to re-assign the roles/topics to be addressed among the peer reviewers so that no conflicts are present.

Consequences of Noncompliance

- If a faculty presenter is identified through the audit process as having failed to comply with ASCO/ACCME policies, a warning letter will be issued from the CME Subcommittee Chair informing the presenter of the infraction and noting that any future presentation materials will be reviewed prior to the activity. In addition, he/she will be informed that a second incident of noncompliance will result in the presenter being barred from participation in all ASCO CME-accredited activities for a period of two years.
- CME activity files will document the review of disclosure information, Committee deliberations, and identification of the COI management process, if used.
- All disclosures will be published in appropriate meeting materials such as the meeting Proceedings Book.