

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 as its general approach 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 the *Standards for Commercial Support* of the Accreditation Council for Continuing Medical Education.

Process

I. Identification of Relevant Financial Relationships – Planners (Committee Editorial Board Members, Working Groups)

- 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 sign ASCO's Responsibilities Agreement indicating that they received, read and understand the policies and agree to comply
 - Members submit their conflict of interest disclosure in accordance with the ASCO COI Policy.
 - 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
 - Committee or Editorial Board members who fail to disclose are prohibited from participating in the planning process.
 - Committee and Editorial Board members are required to update their disclosure information annually, and as often as material changes occur.
- 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 chair prior to the first planning session.

Determination of COI and Subsequent Management – Planners

- With the assistance of ASCO staff, the Chair identifies areas of potential conflict based on the nature and extent of disclosed relationships in relation to the planning content.
- Prior to planning calls or meetings, the disclosure report is shared with the full committee.
- At the beginning of the planning process, the Chair will state the process to be followed for review of relevant financial relationships in accordance with ASCO COI Policy.
 - 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.
 - ASCO staff will assist the Chair in monitoring discussion and facilitating the recusal process.
- 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
- Planner relationships are disclosed to participants in educational product materials, meeting materials and on-site to meeting attendees.

II. Selection and Invitation of Contributors (Program/Activity Faculty/Authors/Peer Reviewers/Oral Abstract Presenters)

- 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 Expectations for Faculty Presentations and notification that peer review of presentation materials may occur for purposes of content validation.
 - Faculty or authors must sign ASCO's Faculty Responsibilities Agreement 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 conflict of interest disclosure for financial relationships over the prior 1-2 years relevant to the subject matter under consideration in their presentation.
 - 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
 - Contributors who fail to disclose information are prohibited from participating in 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 as often as material changes occur.
- 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 – Contributors (Faculty, Authors, Peer Reviewers, Oral Abstract Presenters)

Note: Sections “Determination of COI and Subsequent management – Authors/Faculty of Enduring Materials” and “Determination of COI and Subsequent Management – Peer Reviewers” have been consolidated into this section.

- The Planners (or CME Subcommittee) are responsible for reviewing the financial disclosures and determining whether a faculty COI exists and managing faculty COIs in accordance with ASCO and ACCME policies.
- 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)
- In managing COIs, the Committee may take any of the following actions, or other action it deems appropriate:
 1. Contributor relationships are disclosed to participants in educational product materials, meeting materials and on-site to meeting attendees.
 2. The committee may request that a letter be sent to the faculty member acknowledging the potential conflict and referring faculty to ASCO and ACCME policies for guidance in developing balanced and unbiased content. The letter also informs the speaker of the possibility of an onsite audit.
 3. The Committee may elect to manage the conflict through an onsite Committee audit of the program (Applicable to live meetings only).
 - If bias is detected during the presentation of a live program, the Committee evaluator may elect to interrupt or stop the program.
 - A minimum of 10% of activity sessions will be audited in accordance with ACCME policy.
 4. The Committee may elect to manage the conflict through content review of program materials submitted before the activity occurs. (Not applicable to peer reviewers.)
 5. The Committee may elect to replace the faculty presenter with someone having no conflict. (Not applicable to peer reviewers.)
 6. The Committee may elect to re-assign the roles/topics to be addressed among the faculty so that no conflicts are present.

- 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 prior to participating in the activity.
- For last-minute faculty substitutions, disclosure information will be reviewed by the committee chair. If a conflict is identified, the Chair will determine management strategies: audit or contributor replacement.
- 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.

III. 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.

IV. Documentation of COI Implementation Plan Compliance

- CME activity files will document the review of disclosure information, Committee deliberations, and implementation of the COI management process.