



Implementation Plan to Manage Relationships with Companies for CE Activities

(September 2017)

Introduction

This Implementation Plan has been adopted by ASCO as its general approach to interpret and apply the ASCO Policy for Relationships with Companies (“Policy”) as it relates to accredited CE activities and complies with the *Standards for Commercial Support* of the Accreditation Council for Continuing Medical Education. This Implementation Plan sets out disclosure requirements and management strategies for relevant financial relationships held by planners, presenters and other individuals who are in a position to control the content of Society CE.

Process

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

- During the invitation process, members are provided with the ASCO Policy for Relationships with Companies (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 ASCO 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 financial relationships in accordance with ASCO Policy.
 - The Committee or Editorial Board may consider the following areas (as recommended by the CE Committee) in managing potential 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 Chair-Elect, Co-Chair or Past Chair. 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 Planners; 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 Policy for Relationships with Companies, 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 contributor is designed to ensure that all activity content is presented in compliance with ASCO and Joint Accreditation criteria and standards.
 - Faculty or authors must complete a conflict of interest disclosure for financial relationships over the prior 2 years; relationships will be reviewed for potential conflict of interest based on their relevance 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 CE 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 Chair

Determination of COI and Subsequent Management – Contributors (Faculty, Authors, Peer Reviewers, Oral Abstract Presenters)

- The Planners are responsible for reviewing the financial disclosures and determining whether a contributor COI exists and managing contributor COIs in accordance with ASCO and ACCME policies.
- The Planners are responsible for managing all cases where it is determined that the reported financial relationships constitute a contributor COI. The Planners may consider the following in managing contributor 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 Planners 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 contributor acknowledging the potential conflict and referring faculty to ASCO and Joint Accreditation criteria and standards for guidance in developing balanced and unbiased content. The letter also informs the contributor of the possibility of an onsite audit, if participating in a live activity.
 3. The Planners may elect to manage the conflict through an onsite Committee audit of the program (Applicable to live activities only).
 - If bias is detected during the presentation of a live activity, the Committee evaluator may elect to interrupt or stop the program.
 - A minimum of 10% of activity sessions will be audited to document compliance with ACCME policy.
 4. The Planners may elect to manage the conflict through content review of activity materials submitted before the activity occurs. (Not applicable to peer reviewers.)

5. The Planners may elect to replace the contributor with someone having no conflict.
 6. The Planners may elect to re-assign the roles/topics to be addressed among the contributors so that no conflicts are present.
- In the event that a scheduled faculty member cannot participate in a live 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 contributor is identified through the audit process as having failed to comply with ASCO/ACCME policies, a stepwise process will be followed:
 - A first infraction will result in a warning letter will be issued from the CE Committee Chair informing the presenter of the infraction and requesting an updated version of their presentation for the Meeting Library that addresses the policy violation be submitted. Additionally, presenters will be informed that any presentation materials for future ASCO CE activities will be reviewed prior to the activity. He/she will also be informed of further consequences of noncompliance if documented in future ASCO CE activities.
 - A second incident of noncompliance will result in the presenter being barred from participation in all ASCO CE activities for a period of two years; as before, an amended presentation will be requested for the Meeting Library that addresses the policy violation.
- If a contributor is identified as having failed to disclose accurately during the abstract submission/faculty acceptance process, a notification letter will be sent documenting the infraction and requiring that a profile be created/updated in ASCO's Disclosure Management System (coi.asco.org) so that any future transactions with ASCO will reference their disclosure on record and prompt for updates.
- Consequences of noncompliance will be determined on a per meeting basis (i.e., contributors with multiple roles in the same activity will be assessed at the same level for all presentations).
- ASCO Staff will maintain records of all infractions and notify planners when a review of presentation materials is required based on a prior infraction. ASCO Staff will also facilitate any updates necessary to presentations for the Meeting Library.

IV. Documentation of COI Implementation Plan Compliance

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

Application:

Applies to ASCO and its affiliates

History:

Adopted by the ASCO Board of Directors on October 18, 2006

Amended on October 2009, April 2014, September 2017