

Implementation Plan to Manage Relationships with Companies for Continuing Education Activities *(November 2021)*

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 its suite of continuing education activities whether or not they are designated for CME credit. All ASCO educational activities are developed with high standards for independence, transparency, and trustworthiness. ASCO educational activities that are accredited comply with the *Standards for Integrity and Independence for Accredited Medical Education* of the Accreditation Council for Continuing Medical Education and the CMSS Code for Interactions with Companies.

This Implementation Plan sets out disclosure requirements and management strategies for relevant financial relationships held by planners, faculty, presenters, and other individuals who are in a position to control the content of Society educational activities.

Definitions

ASCO adopts the ACCME definition of relevance for accredited educational activities: “Financial relationships of any dollar amount are defined as relevant if the educational content is related to the business lines or products of the ineligible company.”

ASCO considers educational content to be related to the business lines or products of a company when:

- Business lines or products are approved for use in patients or where an Investigational New Drug application has been submitted to begin clinical research. The content aligns directly with the drug, technology or target being addressed in the educational content, not just the disease area
- In any area where ACCME provides rules or guidance about relevance for accredited activities, ASCO will adopt and follow that guidance.

Plan

A. Determination of Activity Accreditation

- When an educational activity is first being conceived, ASCO leadership will include in its deliberations a determination of whether the activity will be accredited.
- This determination will consider multiple factors such as target audience, educational goals, timelines, etc.
- Planners and Contributors will be made aware of whether an activity is accredited or not during the invitation process.

B. Collection of Financial Relationships

- Any participant under consideration for a role in an ASCO educational activity will submit a current conflict of interest disclosure in accordance with ASCO Policy. This disclosure requirement applies to planners, activity faculty, presenters, authors and reviewers, and other roles at ASCO discretion.
- Participants are asked to disclose all financial relationships with entities in the bio-medical arena that could be considered even broadly relevant to an individual’s work in

oncology, regardless of any particular subject matter. Participants also have the option of disclosing uncompensated relationships if they so choose.

- Disclosures are current for one year and must be updated whenever material changes occur.
- A current disclosure is a prerequisite for participation. Failure to disclose will result in replacement or exclusion from the activity.
- Potential participants must review and sign ASCO's Responsibilities Agreement indicating that they received, read, and understand the policies and agree to comply with the ASCO Policy for Relationships with Companies and the applicable expectations document for the role for which they are being considered. (e.g., Committee Responsibilities and Authorities, Expectations for Faculty Presentations). Participants in accredited activities must also agree to comply with the ACCME *Standards for Integrity and Independence for Accredited Medical Education*.

C. *Selection and Invitation of Planners*

- Planners (Committee, Subcommittee and Editorial Board members and chairs) are identified by the ASCO President or other ASCO leadership; selection is based on recognized expertise relevant to the activity topic to be addressed.
- ASCO Staff and leadership will review relationships of Planners prior to invitation for potential conflict of interest based on their relevance to the subject matter under consideration in their presentation if a disclosure profile is available.
 - A preliminary review of the reported information is done by ASCO Staff
 - If relevant employment or ownership relationships are identified, an alternate Planner will be selected for invitation who does not have those conflicts
 - After invitation, updated disclosures will be reviewed again to confirm eligibility to participate as a Planner
 - If a new employment or ownership relationship is added after invitation acceptance that renders a Planner ineligible to continue participating in the activity, that individual will be replaced with someone who does not have those conflicts unless their planning responsibilities ended prior to the start of the new relationship
- For accredited activities, individuals with an employment relationship or ownership interest in a privately held company with relevant products would not be permitted to participate in a Planner role in an accredited activity
 - In this scenario, a final decision will be made by ASCO Staff to either replace the individual in the Planner role or offer the activity without credit
- If an activity is Non-accredited, ASCO Staff and leadership will still be made aware of employment or ownership relationships of Planners prior to invitation, but decisions to replace or move forward with invitations will be made on a case-by-case basis

D. *Determination of COI and Subsequent Management – Planners*

- Determination
 - ASCO Staff and leadership are responsible for reviewing the financial disclosures of Planners and determining whether COI exists and managing Contributor COIs in accordance with ASCO and ACCME policies.

- Strategies used to manage potential conflicts of interest are selected based on the degree to which the relationship could be perceived to create a risk for bias toward or promotion of the company in the context of the planning role.
- Subsequent Management
 - The following issues are considered when determining potential conflicts for Planners:
 - That the activity content to be reviewed by the Committee is to be based on the best available evidence
 - The scientific and editorial peer review process to be followed during planning
 - Whether the scope of the activity is broad (addresses multiple therapeutic agents or strategies), or narrow (focuses on a single therapeutic agent)
 - The number and type(s) of relationship(s) reported with companies
 - ASCO retains complete discretion about conflict-of-interest management strategies for ASCO educational activities. ASCO Staff and leadership may take any of the following actions, or other action as appropriate:
 - For planning activities, a conflicted member may be requested to recuse themselves from the specific portion of planning and discussion that pertains to the area of conflict
 - A conflicted member may need to be replaced if they are ineligible to contribute to a meaningful portion of the activity planning.
 - ASCO Staff will assist the Chair in monitoring discussion and facilitating the recusal process.
 - If the Planner Chair requires recusal, relevant discussions will be led by the Chair-Elect
 - Planning meeting minutes will document the review of disclosure information
- Management for Planners in Non-accredited Activities
 - ASCO retains complete discretion about conflict-of-interest management strategies for ASCO educational activities, whether or not the activity is accredited. ASCO Staff and Planners may take any of the following actions, or other action as appropriate:
 - For planning activities, a conflicted member may be requested to recuse themselves from the specific portion of planning and discussion that pertains to an area of conflict
 - A conflicted member may need to be replaced if they cannot contribute to a meaningful portion of the activity planning due to their conflict
 - ASCO Staff will assist the Chair in monitoring discussion and facilitating the recusal process.
 - If the Planner Chair requires recusal, relevant discussions will be led by the Chair-Elect
 - Planning meeting minutes will document the review of disclosure information
- Disclosure of Planner relationships will be made to learners in activity materials available prior to the start of the activity whether or not it is accredited

E. Selection and Invitation of Contributors

- Contributors (activity faculty, presenters, authors, question writers and reviewers) are identified by the Planners; selection is based on recognized expertise relevant to the activity topic to be addressed.
- ASCO Staff and Planners will review relationships of Contributors prior to invitation for potential conflict of interest based on their relevance to the subject matter under consideration in their presentation if a disclosure profile is available.
 - A preliminary review of the reported information is done by ASCO Staff
 - If relevant employment or ownership relationships are identified, an alternate Contributor will be selected for invitation who does not have those conflicts
 - After invitation, updated disclosures will be reviewed again to confirm eligibility to participate as a Contributor
 - If a new employment or ownership relationship is added after invitation acceptance that renders a Contributor ineligible to continue participating in the activity, that individual will be replaced with someone who does not have those conflicts
- For accredited activities, individuals with an employment relationship or ownership interest in a privately held company with relevant products would not be permitted to participate in a Contributor role in an accredited activity
 - In this scenario, a final decision will be made by ASCO Staff to either replace the individual in the Contributor role or offer the activity without credit
- If an activity is Non-accredited, ASCO Staff and Planners will still be made aware of employment or ownership relationships of Contributors prior to invitation, but decisions to replace or move forward with invitations will be made on a case-by-case basis

F. Determination of COI and Subsequent Management – Contributors

- Determination
 - ASCO Staff and leadership are responsible for reviewing the financial disclosures of Contributors and determining whether COI exists and managing Contributor COIs in accordance with ASCO and ACCME policies with the support of Planners
 - Strategies used to manage potential conflicts of interest are selected based on the degree to which the relationship could be perceived to create a risk for bias toward or promotion of the company in the context of the Contributor role.
- Subsequent Management
 - The following issues are considered when determining potential conflicts for Contributors
 - That the activity content to be presented is to be based on the best available evidence
 - The scientific and editorial peer review process to be followed during planning
 - Whether the scope of the activity is broad (addresses multiple therapeutic agents or strategies), or narrow (focuses on a single therapeutic agent)
 - The number and type(s) of relationship(s) reported with companies
 - ASCO retains complete discretion about conflict-of-interest management strategies for ASCO educational activities. ASCO Staff and Planners may take any of the following actions, or other action as appropriate:
 - Replace the Contributor

- Re-assign the roles/topics to be addressed among the Contributors to mitigate the conflict
 - Review of activity materials submitted before the activity occurs (Not applicable to peer reviewers.)
 - Sending a letter to the Contributor acknowledging the potential conflict and providing clear criteria from ASCO and the ACCME for developing balanced and unbiased content. This communication informs the Contributor of the possibility of an audit, if participating in an educational meeting.
 - Audit of the session (Applicable to educational meetings only).
 - If bias is detected during a session of an educational meeting, the session chair or auditor may elect to interrupt or stop the presentation
- Disclosure of Contributor relationships will be made to learners in activity materials available prior to the start of the activity
- Management for Replacement Contributors
 - If a scheduled Contributor cannot participate in an activity as a result of an unforeseen circumstance, a replacement Contributor may be selected. Contributors selected to fill a last-minute vacancy must submit disclosure for identification and management of conflicts of interest prior to participating in the activity unless they are already serving in another role in the activity.
 - For last-minute Contributor replacements, disclosure information will be reviewed by ASCO staff to determine eligibility. If a conflict is identified after confirming eligibility, any of the following management strategies can be employed:
 - Replacement of the new Contributor
 - Modification of the session to mitigate the conflict
 - Audit of the session
 - Disclosures for last minute Contributors that are not included in the printed materials must be communicated to the learners before the start of the activity.
- Management for Contributors in Non-accredited Activities
 - ASCO retains complete discretion about conflict-of-interest management strategies for ASCO educational activities, whether or not the activity is accredited. ASCO Staff and Planners may take any of the following actions, or other action as appropriate:
 - Replace the Contributor with someone having no conflict.
 - Re-assign the roles/topics to be addressed among the Contributors so that no conflicts are present.
 - Review of activity materials submitted before the activity occurs. (Not applicable to peer reviewers.)
 - Audit the session

G. Consequences of Noncompliance

- If a Contributor is identified as having failed to comply with ASCO and/or ACCME policies for an accredited educational activity, a stepwise process will be followed:
 - A first infraction will result in a warning letter being issued from the Education Council Chair informing the presenter of the infraction and requesting, if needed, an updated version of their presentation for online posting that addresses the policy

violation. Additionally, presenters will be informed that any presentation materials for future ASCO accredited activities will be reviewed prior to the activity. They will also be informed of further consequences of noncompliance if documented in future ASCO accredited activities.

- A second incident of noncompliance will result in the presenter being barred from participation in all ASCO accredited activities for a period of two years; as before, an amended presentation will be requested for online posting that addresses the policy violation.
- If a Contributor is identified as having failed to comply with ASCO and/or ACCME policies for a non-accredited educational activity, a stepwise process will be followed:
 - A first infraction will result in a letter informing the Contributor of the infraction and requesting, if needed, an updated version of their presentation for online posting that addresses the policy violation. Additionally, Contributors will be informed of further consequences of noncompliance if documented in future ASCO educational activities.
 - A second incident of noncompliance will result in the presenter being barred from participation in all ASCO educational activities for a period of two years; as before, an amended presentation will be requested for online posting that addresses the policy violation.
- If a Planner or Contributor is identified as having failed to disclose accurately during the role 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.
 - Failure to disclose accurately may also trigger a Member Discipline procedure if the participant is a current ASCO member
- Consequences of noncompliance will be determined on a per activity 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 note when a review of presentation materials is required based on a prior infraction. ASCO Staff will also facilitate any updates necessary to presentations for online posting.

H. Documentation of Implementation Plan Compliance

- ASCO Staff will maintain files to document the review of disclosure information, Committee deliberations, and implementation of the COI management process for accredited and non-accredited activities.

Application:

Applies to ASCO-sponsored educational activities

History:

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

Amended on October 2009, April 2014, September 2017

Updated on November 2021