



ASCO POLICY FOR RELATIONSHIPS WITH COMPANIES (COI Policy)

Frequently Asked Questions

(Based on January 2017 Conflict of Interest Policy)

Questions Regarding ASCO Policy for Relationships with Companies (Conflict of Interest Policy)

1. What is the goal of ASCO's Conflict of Interest (COI) Policy?

ASCO's COI policies embody our Society's commitment to transparency and conflict management in the development, presentation and publication of scientific and educational content that has been subject to peer review. The goal is to provide a foundation of transparency for activities such that anyone participating in the ASCO activity will be an informed consumer of the content based on the complete and accurate disclosure of participants.

2. When did ASCO most recently revise its COI Policy?

ASCO revised the COI Policy in 2017 to eliminate restrictions on authorship that had been proposed but never implemented with the full update to the Policy in 2013. Prior to the 2013 update, ASCO had last conducted a major update to its COI Policy in 2005. Since then, ASCO has become a much larger and more complex organization. The field of cancer care and research has also evolved rapidly, and ASCO has not been alone in urging complete disclosure and responsible management of financial interactions that could create real or perceived COI for scientists, health professionals, and organizations. ASCO is committed to maintaining objectivity in its scientific and educational pursuits. The Institute of Medicine framework report presented principles for analyzing financial relationships in medical research, education, and practice. In addition, healthcare institutions, professional organizations, and government agencies have implemented systems of disclosure and management over the years.

3. How is the current COI policy different from previous policies?

Under the current Policy, disclosures are submitted and reported for all relationships with any healthcare Companies, as defined by the [Council of Medical Specialty Societies Code](#). ("A Company is a for-profit entity that develops, produces, markets, or distributes drugs, devices, services or therapies used to diagnose, treat, monitor, manage, and alleviate health conditions. This definition is not intended to include non-profit entities, entities outside of the healthcare sector, or entities through which physicians provide clinical services directly to patients.")

Because ASCO requires general disclosure, the current Policy allows disclosures to be universally applied to all ASCO activities, rather than asking participants to submit activity-

specific, or relevant disclosures.

The ASCO COI Policy affirms that institutional interactions with Companies will also be transparent. ASCO, and its philanthropic affiliate, the Conquer Cancer Foundation (CC), publicly disclose financial support of their programmatic activities, including grants, sponsorships, and charitable contributions. ASCO and CC also publicly disclose the financial relationships held by the members of their Boards of Directors and officers. ASCO Journals publish disclosures of relationships held by their editors.

4. What does “general disclosure” mean? What are the advantages of general disclosure?

General disclosure means comprehensive information about an individual’s financial relationships with Companies will be disclosed, regardless of connection to a specific ASCO activity. While ASCO moved to general disclosure in 2013, many other entities in the biomedical arena request relevant disclosure, meaning disclosure of financial relationships that are specifically connected to the subject matter of a particular article, abstract, or professional role. Under the ASCO COI Policy, participants broadly and generally disclose their relationships with Companies and either confirm or update this information with each new ASCO activity. This allows for one master disclosure record to be used across all of an individual’s concurrent ASCO activities.

This system enables participants in ASCO activities to disclose one time, and aims to improve transparency across all activities – journal manuscripts, meeting abstracts, committee service, etc. In addition to one uniform disclosure format, general disclosure also makes disclosing easier for members who have to disclose relationships to multiple other entities and eliminates the issue of the discloser subjectively determining what is relevant, versus leaving that to the consumer of the information to decide.

5. What will I have to disclose?

The COI Policy identifies eleven categories of financial relationships that must be disclosed and two optional categories: (1) employment, (2) leadership positions, (3) stock and other ownership interests, (4) honoraria, (5) consulting or advisory roles, (6) speakers’ bureaus, (7) research funding, (8) patents, royalties, and other intellectual property interests, (9) expert testimony, (10) travel, accommodations, expenses, (11) other relationships, (12) Uncompensated relationships (optional), and (13) links to individual Open Payments pages (optional).

The two optional categories exist so disclosers can provide more information if they wish: 1) any relationship that is Uncompensated but otherwise meets the disclosure criteria; and 2) an option to include one’s personal link to the US federal Open Payments database. The federal Open Payments database is a public record kept by the US government containing information about payments by companies to physicians, other health care providers, and teaching hospitals. This information is provided to the US government by the companies and is not verified or reviewed by ASCO. The Open Payments database can be found on the Center for Medicare and Medicaid Services website [here](#). Each individual physician who has been reported as having received a payment will be searchable in the database and will have a personal page detailing

reported payments. The link to this page can be provided to ASCO in the optional question to be published as part of the ASCO disclosure. ASCO does not review or verify Open Payments information. (Please see question 7 below for more information).

6. Does the ASCO COI Policy address only research activities related to clinical trials?

No. All research is covered by the ASCO COI Policy. In ASCO's view, many kinds of research, including clinical trials, retrospective studies, and health services research, have the potential to impact patient care and may have a perception of bias due to multiple relationships of authors and researchers. ASCO requires disclosure of relationships with Companies that fund clinical, translational, and laboratory research. When funded by a Company, such research can be vulnerable to actual or perceived bias.

7. What is the Open Payments database and the Physician Payment Sunshine Law? Does this law have any relationship to the new ASCO COI Policy?

The Physician Payment Sunshine law was enacted as part of the Affordable Care Act. It requires companies to publicly report payments they make to physicians, teaching hospitals, and other health care providers. These payments are subsequently posted in the US government's Open Payments database. Additional information about the program and the database can be found on the [CMS website](#). ASCO's COI Policy has no direct relationship with the Sunshine Law. ASCO's disclosure categories are not identical to the categories reported in the Open Payments database. ASCO encourages all disclosers to consult their Open Payments record to make any necessary updates to their ASCO disclosure. ASCO offers the opportunity for disclosers to include a link to their individual page within the Open Payments database; however, ASCO does not review or verify the information in the Open Payments database.

8. If a Company reviews a speaker's slides for legal or regulatory compliance, will this meet the definition of a speaker's bureau?

No. The ASCO COI Policy defines a speaker's bureau presentation as one where any of the following three criteria are met:

- 1) "a Company has a contractual right to dictate or control the content of the presentation or talk;
- 2) a Company creates the slides or presentation material and has final approval of the content and edits; or
- 3) the presenter is expected to act as a Company's agent or spokesperson for the primary purpose of disseminating company or product information."

A Company may review a speaker's slides strictly for regulatory or compliance purposes. So long as the speaker has control and approval rights over scientific content and is not acting as the Company's agent or spokesperson, the activity does not fall within the definition of a speaker's bureau.

9. Is additional assistance available if I have any questions about the ASCO COI Policy?

Yes. ASCO is committed to working with its members and the larger oncology community to achieve full compliance with its COI Policy. Additional information about ASCO's COI policies can be found at www.asco.org/rwc. Email specific questions to coi@asco.org.

Questions Regarding Disclosure

10. Does an individual covered by the ASCO COI Policy have to disclose funding received from a contract research organization (CRO) coordinating the research for the sponsor?

Yes. The ASCO COI Policy requires disclosure of all payments associated with the conduct of the research in question. A CRO is an agent acting directly on behalf of the sponsor, so disclosure is required.

11. If a pharmaceutical company provides research funding directly to a covered individual's academic institution, cooperative group, or clinical division for that individual's research, rather than to the individual directly, should the individual disclose this industry funding to ASCO?

Yes. The ASCO COI Policy requires disclosure of any and all payments associated with the conduct of the research in question. While the Policy is intended to focus on the personal financial relationships of the covered individual, in some cases company funds may be paid to the covered individual's *institution, cooperative group, division, or other unit*. Where the covered individual knows that institutional payments associated with the research project (possibly including the researcher's salary) are covered by the sponsor, it is appropriate to make the disclosure.

12. Does the ASCO COI Policy require authors of abstracts and manuscripts to disclose financial relationships with government or non-profit entities?

You may but you are not required to. When disclosing relationships in accordance with the ASCO Policy for Relationships with Companies, required disclosure is limited to for-profit health care companies. This does not include government agencies, charitable foundations, academic institutions and other non-profit entities.

13. Does a researcher have to disclose honoraria received from a third party continuing medical education organizer, NOT the research sponsor – even if the researcher knows that the sponsor is sponsoring the CME event?

Honoraria paid directly to an individual by the sponsor must be disclosed. However, a researcher does not need to disclose honoraria paid by accredited CME providers, because the CME planning process has other safeguards to avoid conflicts when accepting industry support. For more information, please see our [Implementation Plan](#).

14. What does it mean to disclose “within two years” of submission of an article

or abstract?

The ASCO COI Policy requires disclosure of financial relationships with for-profit health care companies within two years of the activity. For example, for those who seek to present at an ASCO-sponsored meeting or to submit an article to an ASCO-sponsored publication, this window is intended to encompass the time period beginning two years prior to accrual of the first participant to the research that forms the basis of an article or abstract.

15. Does the ASCO COI Policy require disclosure of consulting relationships with investment firms?

Yes. As stated in ASCO's COI Policy, "Disclosure under this Policy generally includes but may not be limited to the following financial relationships: compensation received for employment, leadership positions, consulting activities, speaking engagements, and expert testimony, as well as ownership interests, research funding (to the individual or the institution), and licensing fees and royalties associated with intellectual property interests." Question 11 on our COI Disclosure Form in ASCO's Disclosure Management System asks "Have you or an immediate family member had another relationship, role, activity, or interest, currently or during the past 2 years, that could be perceived to influence your work or your professional activities?" Investment firms and investment firm intermediaries may have a commercial interest in the practice of oncology and can be perceived to influence your professional activities, and ASCO encourages disclosure of these relationships.