

ASCO COI Policy FAQ's

ASCO Policy for Relationships with Companies

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

ASCO's COI Policy embodies the Society's commitment to transparency, integrity, and conflict management. The goal of ASCO's COI Policy is to provide a foundation of disclosure and management of potential conflicts for ASCO activities.

2. What does "general disclosure" mean? What are the advantages of general disclosure?

Other organizations and 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. ASCO differs from these organizations in that we request *general disclosures*. *General disclosures* mean that ASCO requests a single, comprehensive disclosure of information about an individual's financial relationships, regardless of their connection to a specific ASCO activity.

One master disclosure record for an individual can be used for all their ASCO activities, allowing ASCO participants to disclose one time in a way that improves transparency across all activities. ASCO can use the single general disclosure to manage conflicts with tailored, appropriate strategies for activities from journal manuscript submissions, meeting abstracts, committee service, guideline development, etc.

3. 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.

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.

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

No. All research, including research related to clinical trials, 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.

5. 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, so the two should not be conflated or confused with each other. 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.

The federal Open Payments database is a public record kept by the US government, which contains 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 [here](#). Each physician reported as receiving 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.

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

No, so long as the speaker retains full control over the content of the slides and full accountability for the analysis. 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.

7. 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. You can also email specific questions to coi@asco.org for any disclosure or COI-related questions.

Questions Regarding Disclosure

1. 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 research's conduct. A CRO is an agent acting directly on behalf of the sponsor, so disclosure is required. If the discloser is aware of the company sponsoring the research through the CRO, and/or if Open Payments reports are being made by the company to the discloser, it is appropriate to disclose the company name directly. Otherwise, the discloser can disclose the name of the CRO.

2. 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 all payments associated with the research's conduct. While the Policy is intended to focus on the personal financial relationships of the covered individual, typically, company funds are paid to the covered individual's institution, cooperative group, division, or other unit, and should still be disclosed. 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 disclose. The ASCO COI disclosure allows the covered individual to indicate that the payments go to "my institution", and this information will be displayed when disclosures are published.

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

You may disclose this information, 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 or other non-profit entities. Relationships that include more than one entity, such as a research trial funded by a foundation *and* Company, or a governmental entity *and* a Company, should be disclosed to include the Company name.

4. Does a researcher have to disclose honoraria received from a third party continuing medical education organizer, NOT the research sponsor – even if the discloser 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. If the engagement is likely to result in an Open Payments report of a third-party payment to the individual, ASCO strongly recommends disclosure. For more information, please see our Implementation Plan.

5. What does it mean to disclose “within two years” of submission of an article or abstract?

The ASCO COI Policy requires general disclosure of financial relationships with for-profit health care companies within two years. In the context of research, 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 period beginning two years prior to accrual of the first participant to the research that forms the basis of an article or abstract.

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

Disclosure is strongly encouraged, particularly for investment firms that work routinely or exclusively in the health care space. 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.