

# CONFLICT OF INTEREST POLICY

## American College of Cardiology and the American College of Cardiology Foundation

1. **Introduction and Overview.** A conflict of interest (“COI”) describes a situation in which the interests of the American College of Cardiology/ American College of Cardiology Foundation, collectively the (“College”), or a College employee/agent, acting within his or her authority on behalf of the College, may affect or appear to affect the College’s independence and decision-making with regard to the design, conduct, reporting, review, recommendations, or oversight of College activities.

The College should assess the potential for conflicts of interest and weigh the magnitude of any risk to the College’s actual or perceived integrity and scientific independence. Although the listed circumstances in this Policy are potential areas of concern, the goal of this Policy is not to preclude the College or individuals from entering into financial arrangements with entities that sponsor College activities/programs, or that own or control products that are being studied, tested or evaluated by the College. This policy acknowledges that financial relationships are essential for advancing scientific frontiers and enabling commercial development for the benefit of the public while also acknowledging that some arrangements may appear to inappropriately impact the scientific independence and decision-making of the College or individuals. The areas of conflicting interest mentioned in this Policy and the relations in those areas that may give rise to conflict are not exhaustive. Conceivably, conflicts might arise in other areas or through other relations.

2. **Purpose.** The College is accountable to its members for responsible and proper use of its resources. Officers, Trustees, member volunteers/leaders and employees and the College have a duty to act in the best interests of the College’s mission and individuals may not use their positions for their own financial or personal benefit. Conflicts of interest must be taken very seriously since they can damage the College’s reputation and expose both the College and affiliated individuals to legal liability if not handled appropriately. Even the appearance of a conflict of interest should be avoided, as it could undermine the College’s mission and values.
3. **Definitions.**
  - a. **Conflict of Interest:** A “Conflict” may occur whenever the interests of the College, or of a College employee, agent, or member volunteer/leader who has authority to act on behalf of the College, might affect—or reasonably appear to affect—the College’s independence and decision-making with regard to the design, conduct, reporting, review, recommendations, or oversight of College activities.
  - b. **Covered Individuals:** “Covered Individuals” include the Board of Trustees, Officers, chairs and vice chairs of committees including but not limited to the Board of Governors chair and vice chair, meeting organizations, NCDR advisors and employees of the College including the Chief Executive Officer, Executive Vice Presidents, Division Vice Presidents, Team Leads, and other individuals who have oversight and/or implementation responsibilities where a Conflict of Interest may arise.

c. **Material Interest (individual):** For Covered Individuals, a “Material Interest” includes, but is not limited to payments or activities which present a real or apparent conflict and:

- i. That fall under the College’s “Insider Trading” policies;
- ii. That exceed 5% of the individual’s total assets;
- iii. That account for more than 5% of the individual’s annual reported income;
- iv. That exceed 2% of the total investment/ownership of an entity; or
- v. That exceed \$5,000 per year.

A Material Interest may also include:

- vi. An individual holding a fiduciary role with an outside organization that competes or may conflict with the College;
- vii. Ownership of intellectual property where a conflict of interest may result; Intellectual involvement with technologies and other inventions where the College has a Material Interest as defined within this Policy; and/or
- viii. Serving on a Committee where activities of an individual’s institution are discussed.

Notwithstanding the above, a Material Interest does not include an interest in publicly traded, diversified mutual funds or an equity interest, including stock options, in a publicly traded company so long as the interest in mutual funds or the equity interest does not exceed the amounts listed in (ii), (iii), (iv) or (v) above.

In regard to Covered Individuals holding a fiduciary role with an outside organization, it is important to ensure that Covered Individuals holding leadership positions at the College honor the “Duty of Loyalty”. Conflicts of interest can place personal interests at odds with the fiduciary Duty of Loyalty owed to the College. The Duty of Loyalty requires that an officer, trustee or chair or co-chair with governing board-delegated powers refrain from using his or her position for personal gain or for the organizational or financial benefit of an organization other than, and at odds with, the College. At a minimum Covered Individuals must recuse themselves from discussions where a Material Interest exists.

d. **Material Interest (institutional):**

- i. **Royalties:** An Institutional Conflict may be present when the College has agreements to receive milestone payments and/or royalties from the sales or promotion of a product which are equal to or exceed \$10,000 and this financial arrangement might affect—or *reasonably appear to affect*—the College’s independence and decision-making with regard to the study or promotion of that entity’s product(s) or the product(s) of its competitors.
- ii. **Revenue Share Arrangements:** An Institutional Conflict may be present when the College has agreements involving revenue shares from the sales or promotion of a product which are equal to or exceed \$10,000 and this financial arrangement might affect—or *reasonably appear to affect*—the College’s independence and decision-making with regard to the study or promotion of that entity’s product(s) or the product(s) of its competitors.
- iii. **Non-publicly Traded Equity:** An Institutional Conflict may be present when the College has obtained an equity interest or an entitlement to equity of any value (including options or warrants) in a non-publicly traded company and this financial arrangement might affect—or *reasonably appear to affect*—the College’s independence and decision-making with regard to the study or promotion of that entity’s product(s) or the product(s) of its competitors.

- iv. **Publicly-traded equity:** An Institutional Conflict may be present when the College has obtained an ownership interest or an entitlement to equity or royalties (including options or warrants) exceeding \$100,000 in value (when valued in reference to current public prices, or, where applicable, using accepted valuation methods), in a publicly-traded company and this financial arrangement might affect—or reasonably appear to affect—the College’s independence and decision-making.
  
- v. **Gifts and Support from Sponsors:** An Institutional Conflict may be present when the College has received substantial gifts or sponsorship dollars (including gifts in kind) from a sponsor and the sponsor also owns or controls products that are the subject of the College’s Guidelines, an Advocacy position, or otherwise explicitly embedded in a College recommendation or program. In these circumstances, the following should be evaluated: 1. Whether it is a gift or sponsorship is of sufficient magnitude that, even when held in the general endowment for the benefit of the entire College, it might affect, or reasonably appear to affect, the College’s independence and decision-making; and 2. Whether the gift or sponsorship is held for the express benefit of the College.
  
- vi. **Panel Representation:** An Institutional Conflict may be present where the composition of a sponsored panel solely consists of the sponsoring entity, has majority industry representation, or where not all relevant manufacturers are represented on the panel.
  
- vii. **Guidelines:** An Institutional Conflict may be present when the guidelines recommend one technology including but not limited to devices and drugs over another technology. In this instance the guidelines should be evaluated to ensure that such recommendation is backed by scientific evidence and that any Material Interests are disclosed.
  
- e. **Direct Conflict of Interest:** A direct Conflict of Interest may arise where a Covered Individual has a personal or financial interest in any matter involving the College or has a financial or agency relationship with an entity involved in a transaction or other business with the College.
  
- f. **Indirect Conflicts of Interest:** An indirect Conflict of Interest may arise where someone related to a Covered Individual by business affiliation, or a “Family Member” defined as Covered Individual’s spouse, domestic partner or dependent child, or persons having such other relationships to the Covered Individual that the College may determine from time to time, has dealings with the College.
  
- g. **Adverse Interest.** An adverse Conflict of Interest may arise where a Covered Individual engages in decisions or negotiations related to a contract, transaction or other matter between the College and: (i) the Covered Individual ; (ii) an entity in which the Covered Individual or a Family Member of such person has financial interest; or (iii) an entity with which the Covered Individual has an agency relationship (such as a fiduciary role).
  
- h. **Competing Interests.** A competing Conflict of Interest may arise where a Covered Individual competes, either directly or indirectly, with the College in the purchase or sale of property or property rights, interests, or services, or, in some instances, competition directly for the same external resources.

4. **Potential and Actual Conflicts of Interest.** Acts that mix the personal or financial interests of a Covered Individual with the interests of the College can be indicative of a conflict of interest. Not every potential conflict is an actual conflict, however. A Covered Individual who has a financial or personal interest in a matter involving the College may have a conflict of interest requiring application of the management plan described in this Policy only if the Institutional Conflicts of Interest Committee designated in Section 9 decides that such a potential conflict of interest is actual or material. However, acts that even have the appearance of a conflict of interest can be damaging to the reputation of the College. Consequently, the College seeks to avoid potential and actual conflicts of interest, as well as the appearance of conflicts.
5. **Activities that May Present a Conflict of Interest.** Activities that may present a conflict of interest Covered Individuals' Material Interest, Adverse Interest, and Competing Interest shall be disclosed in accordance with Section 6.
6. **Disclosure of Individual Interests.** At least annually, Covered Individuals must submit to the Chief Compliance Officer, the Privacy and Research Compliance Officer, or his/her designee, a disclosure of Material Interest, Adverse Interest, Competing Interest and such other information as the Officer may require. This disclosure must be updated within 30 days of a Covered Individual discovering or acquiring a new interest. In addition to the disclosure of interest, the Covered Individual must provide requested information to assist in the assessment of whether any of the Covered Individuals interests are related to College's activities or the Covered Individual's role in College's activities. This attestation will be part of the on-line annual due paying process.
7. **Disclosure of Institutional Material Interests.** Upon discovery of a Material Interest at the institutional level, the member of the Legal Affairs team responsible for reviewing the contractual instrument should provide a copy of the contract to the Privacy and Research Compliance Officer for evaluation.
8. **Initial Review.** The Chief Compliance Officer and Privacy and Research Compliance Officer shall review disclosures and the Covered Individual's assessment of relatedness to the College's activities. The Officers shall review the disclosures and reasonably determine whether any of the disclosures may raise to the level of a Conflict of Interest. Potential Conflicts of Interest will then be evaluated by the Conflicts of Interest Committee or other designated bodies.
9. **Establishment of a Conflict of Interest Committee.** In order to review and manage Conflicts of Interest, a Conflict of Interest Committee will be established that includes individuals who are independent from the activities and interests which have given rise to the potential Conflict of Interest. This Committee shall include the Chief Compliance Officer, Privacy and Research Compliance Officer, the Chief Medical Officer and at least two additional individuals appointed by the Board of Trustees. This Conflict of Interest Committee will report to the College's Audit and Compliance Committee, which reports ultimately to the Board of Trustees. The decisions of the Conflict of Interest Committee, including the participants and the resulting management plan, will be made available to all impacted parties. At the discretion of the Conflict of Interest Committee, the Covered Individual may make a presentation at committee meeting or to a committee designee to discuss disclosures in order to inform the management plan in the event the committee deems a disclosure is a conflict of interest. If the committee determines that members of the committee need technical assistance, the committee shall designate a disinterested person or committee to advise on the management plan. After exercising due diligence, the Committee shall determine whether a conflict of interest exist and formalize a management plan.

10. **Management of Potential Conflicts of Interest.** Examples of conditions and restrictions that may be imposed to manage a Conflict of Interest, either as a single condition or restriction, or as a combination of conditions and restrictions, and on either an interim or permanent basis include, but are not limited to:
- a. Public disclosure of the Conflict of Interest (e.g., in public presentations or publications of the related research, guidelines or recommendations);
  - b. Disclosure of the Conflict of Interest to human subject participants in a College study, if applicable;
  - c. Appointment of an independent monitor capable and willing to take appropriate measures to protect the design, conduct and reporting of the College program or activity which gives rise to potential bias resulting from the Conflict of Interest;
  - d. Where the Conflict of Interest involves a Covered Individual, formal recusal of the Covered Individual from the chain of authority over the related project and possibly also from authority over salary, promotion, and space allocation decisions affecting related staff;
  - e. Reduction or elimination of the Conflict of Interest (e.g., sale of an equity interest); or
  - f. Severance of the relationship giving rise to the Conflict of Interest.

Establishment of a management plan also initiates responsibility for monitoring compliance with the plan for the duration of the Conflict of Interest. As part of finalizing the management plan, the Conflicts of Interest Committee will establish an ongoing monitoring program to ensure compliance with requirements of the management plan.

11. **Violations of the Conflicts of Interest Policy.** If the Committee has reasonable cause to believe that a Covered Individual has failed to disclose, it shall inform the Covered Individual of the basis for such belief and afford the Covered Individual an opportunity to explain the alleged failure to disclose. If, after hearing the Covered Individual's response and after making further investigation as warranted by the circumstances, the Committee determines the Covered Individual has failed to disclose it shall refer this matter to the Audit and Compliance Committee for resolution.
12. **Record Keeping.** The disposition of Material Interest subject to committee review as described in section 9 shall contain:
- a. The names of the Covered Individual who disclosed or whom otherwise were found to have an actual or possible conflict of interest, the nature of the financial or other interest, the Committee's decision as to whether a conflict of interest in fact existed, the associated management plan if warranted.