

American Society of Clinical Oncology: Revised Conflict of Interest Policy

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From the American Society of Clinical Oncology, Alexandria, VA.

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I. INTRODUCTION

The American Society of Clinical Oncology (ASCO) is dedicated to advancing the prevention, diagnosis, and treatment of cancer through education and clinical research. The integrity of scientific and educational programs and clinical research sponsored by ASCO is dependent on the avoidance of conflicts of interest, or even the appearance of such conflicts. Moreover, as a continuing medical education provider accredited by the Accreditation Council for Continuing Medical Education (ACCME), ASCO must ensure fair balance, independence, objectivity, and scientific rigor in all of its educational activities through appropriate disclosure of financial interests, among other things. The following policy is intended to help guide the management of potential conflicts, primarily through disclosure of all financial or other interests that might be construed as resulting in actual, potential, or apparent conflicts.

Although the ASCO conflict of interest policy relies primarily on disclosure of financial and other interests, it also recognizes that oversight of the trial conduct and dissemination may be appropriate, and that some financial relationships are inconsistent with responsible clinical research practices and should not occur. In addition, persons in certain positions of authority in a given clinical trial should avoid ownership and other interests that could undermine confidence in the integrity of the trial or jeopardize the safety of trial participants.

Nothing in this policy statement should be regarded as creating a presumption of impropriety in the existence of financial interests or other relationships of a commercial nature. Instead, the statement represents a recognition of the many factors that can influence judgments about clinical research data and a desire to make as much information as possible available to those reviewing the data.

II. GENERAL CONFLICTS POLICY

ASCO sponsors a number of activities, many of which provide support, directly or indirectly, for

clinical research. Among these are scientific and educational programs at the ASCO Annual Meeting and other sessions; scientific journals and other publications; health services research; and other activities related to the development by ASCO of public policy positions.

ASCO requires the participants in these activities to disclose any financial interest in, or other relationships with, an entity having a commercial interest in the subject matter in question. A commercial interest may exist not only where the entity's products or services are the subject of an ASCO-related activity or otherwise under consideration by ASCO, but also where the entity's products or services are in direct competition with those under consideration. In addition, conflicts of interest may arise if individuals with whom the participant directly shares income—such as a spouse—have a financial interest in, or other relationship with, an entity having a commercial interest in the subject matter in question.

III. COVERED INDIVIDUALS

A. General Application

This policy applies to all persons who:

1. are members of ASCO;
2. are employees or staff of ASCO;
3. seek to make presentations at any ASCO meeting or to submit to any ASCO-sponsored publication; or
4. participate on the ASCO Board of Directors, committees, and task forces, or in any volunteer activity in an official capacity for the Society.

B. Persons Related to Covered Individuals

With respect to any person listed in paragraph A and thus considered a "covered individual," other persons related to them shall also be considered a "covered individual" if they have a relationship as spouse, dependent child, or adult child employed by the sponsor, or any other relationship involving the sharing of income or assets.

IV. FINANCIAL INTERESTS OR RELATIONSHIPS REQUIRING DISCLOSURE

The following interests or relationships should be disclosed:

A. Employment or Leadership Position

Any full- or part-time employment or service as an officer or board member for an entity having an investment, licensing, or other commercial interest in the subject matter under consideration must be disclosed.

B. Advisory Role

Consultant or advisory arrangements with an entity having an investment, licensing, or other commercial interest in the subject matter under consideration must be disclosed if consultation was performed or payments made for such consultation within 2 years of the activity or subject matter in question.

C. Stock Ownership

Any ownership interest (except when invested in a diversified fund not controlled by the covered individual) in a start-up company, the stock of which is not publicly traded, or in any publicly traded company must be disclosed if the company is an entity having an investment, licensing, or other commercial interest in the subject matter under consideration.

D. Honoraria

Honoraria are reasonable payments for specific speeches, seminar presentations, or appearances. Disclosure of honoraria is required when paid directly to the covered individual by an entity having an investment, licensing, or other commercial interest in the subject matter under consideration and when provided within 2 years of the activity or subject matter in question.

E. Research Funding

All payments associated with the conduct of the clinical research project in question must be disclosed if provided by the trial sponsor or agents employed by the sponsor.

F. Expert Testimony

Provision of expert testimony must be disclosed when the testimony relates to the subject matter under consideration

G. Other Remuneration

The value of trips, travel, gifts, or other in-kind payments not directly related to research activities must be disclosed if received from an entity having an investment, licensing, or other commercial interest in the subject matter under consideration and when received within 2 years of the activity or subject matter in question. De minimus payments totaling less than \$100 are excluded from disclosure requirements. These payments exclude research-related costs and travel.

V. IMPLEMENTATION

The nature of the required disclosure may vary according to the circumstances. In most instances, disclosure of the conflicting or potentially conflicting interest will itself suffice to protect the integrity of the subject activity. In other words, once such a conflict is fully disclosed to the pertinent parties, they generally will be able to evaluate the possible influence of the disclosed interest.

A. ASCO Activities

It is the responsibility of the appropriate ASCO committee chairs or other officials to interpret and apply the guidelines to fit the particular circumstances after communication with the ASCO Board in the form of a plan submitted to the ASCO Ethics Committee for review and subsequently to the ASCO Board for its approval before implementation.

B. Non-ASCO Clinical Research Activities

The conduct and reporting of clinical trials is generally outside the scope of ASCO's jurisdiction, except when trials are submitted to an ASCO publication or for presentation at an ASCO meeting. However, ASCO strongly urges voluntary adoption of a defined process for managing conflicts of interest consistent with the disclosure and other requirements of this policy in clinical research activities. Public confidence in clinical research will be bolstered by a strong disclosure stance. ASCO recommends that participants in clinical trials be routinely advised, as an integral part of the informed consent process, of any financial interest or other relationship that would fall under the disclosure requirements of ASCO's policy, including specific disclosure of all payments made to the covered individual or any affiliated institution in association with the conduct of the trial. To facilitate the disclosure process, ASCO believes each research institution or entity should constitute a standing conflict of interest (or ethics) committee (including community representation) that will administer disclosure requirements in an independent and objective manner.

VI. RESTRICTIONS AND MANAGEMENT OF CERTAIN ACTIVITIES

A. General Restrictions

ASCO believes that certain practices are inconsistent with the standards of clinical research and should be restricted. These include:

1. payment of finders' fees for referral or accrual to a trial;
2. bonuses for achieving certain levels of accrual by specified dates;
3. payments contingent on particular research outcomes; or
4. research contracts in which the sponsor has the ability to override the principal investigator's or executive committee's decision to publish or present trial results.

B. Restrictions on Principal Investigators in Clinical Trials

In addition to the General Restrictions set forth above, ASCO believes that the role of principal investigator of a clinical trial is so pivotal that further restrictions should apply in appropriate cases in order to promote public confidence in the clinical trial process. The principal investigator is the individual (or individuals) with primary responsibility for the development of the protocol, the conduct of the trial, and the interpretation and dissemination of the trial data. There may be more than one principal investigator in a multifaceted trial with separate and distinct subsections of the protocol, but lead investigators at individual sites in a multisite trial are not considered principal investigators for purposes of this policy.

During the course of a clinical trial (ie, from accrual of the first patient to publication of a substantial analysis of the trial results,

either as an abstract in a peer-reviewed presentation or as an article in a peer-reviewed journal) principal investigators for that trial should not receive or hold any of the following:

1. stock or equity interest in the trial sponsor (except when invested in a diversified fund not controlled by the covered individual);
2. royalties or licensing fees (prospective or realized) from the product or novel treatment under investigation;
3. patents for the product or novel treatment under investigation (Note: If the product or treatment is discovered after the trial is underway and the principal investigator wants to file a patent, he or she must relinquish his or her leadership role in the trial;
4. position as officer, board of directors member, or employee of the trial sponsor (Note: Individuals may serve on a trial sponsor's scientific advisory board, so long as the sponsor does not provide any honoraria or other payments for such service);
5. travel or trips paid by the trial sponsor to attend scientific or educational meetings, *not including* travel or trips for either:
 - a. widely attended and independently sponsored scientific meetings with the primary purpose of making a presentation on the trial, or
 - b. investigator meetings related to the conduct of the trial;
6. research-related payments substantially exceeding actual research costs from the trial sponsor; or
7. honoraria or gifts from the trial sponsor, excluding research compensation related to the time and efforts of the researcher and his or her staff.

C. Exceptions and Management of Conflicts of Interest

1. The ASCO Ethics Committee is empowered, in the circumstances described below, to grant rare exceptions to the restrictions set forth in VI.B. above. Procedures for seeking such exceptions will be developed and published by the Ethics Committee. Decisions by the Ethics Committee regarding requests for exceptions shall be final and not subject to appeal, except at the discretion of the ASCO Board of Directors. Among the circumstances that might justify an exception are the following:

- a. The principal investigator is a widely acknowledged expert in a particular therapeutic area so that his or her exclusion from other activities on behalf of the trial sponsor would represent a potential impediment to education or research activities affecting cancer prevention, diagnosis, or treatment.
 - b. The principal investigator is the inventor of a unique technology or treatment being evaluated in the clinical trial.
 - c. The principal investigator is involved in international clinical oncology research and has acted consistently with recognized international standards of ethics in the conduct of clinical research.
2. Clinical trials sponsored by the National Institutes of Health (NIH) are not implicated by the restrictions set forth in VI.B. above, even if those trials involve products of specific commercial interests, because NIH-sponsored trials feature sufficient safeguards to ensure objectivity and independent review of safety and other data developed in the trials.

VII. ENFORCEMENT

For those who violate this policy, the following penalties could be imposed by the ASCO Ethics Committee and/or the Board of Directors for the duration deemed appropriate:

1. prohibition from presenting at ASCO-sponsored events, including the Annual Meeting;
2. exclusion from publishing in the *Journal of Clinical Oncology* or other ASCO publications;
3. exclusion from participation in ASCO boards, committees, and task forces; or
4. revocation or prohibition of ASCO membership.

VIII. EFFECTIVE DATE

This policy was revised by the ASCO Board of Directors March 12, 2005, and, as revised, is effective as of that date.