

ASCO SPECIAL ARTICLE**American Society of Clinical Oncology:
Revised Conflict of Interest Policy**

Adopted on November 7, 2002, by the American Society of Clinical Oncology

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 an actual, potential, or apparent conflict.

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 significant 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.

*From the American Society of Clinical Oncology, Alexandria, VA.
Submitted April 3, 2003; accepted April 3, 2003.*

Address reprint requests to Suanna S. Bruinooge, American Society of Clinical Oncology, Cancer Policy and Clinical Affairs, 1900 Duke Street, Suite 200, Alexandria, VA 22314; email: bruinoos@asco.org.

*© 2003 by American Society of Clinical Oncology.
0732-183X/03/2112-1/\$20.00*

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 for Individuals in a Leadership Role

In the context of a clinical trial, certain individuals have leadership responsibilities that impose special obligations with respect to disclosure of financial or other interests and management of potential conflicts of interest. These include:

1. Persons who serve as principal investigators with decision-making authority over trial design and conduct (in the case of a multisite trial, this would be the principal investigator with central authority);
2. Members of the trial's executive committee; and
3. Members of the trial's data safety and monitoring board.

During the course of a clinical trial and before publication of a substantial analysis of the trial results, covered individuals in the aforementioned leadership roles 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;
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, in conjunction with the Board of Directors where appropriate, can grant an exception to the above restrictions in the following situations:
 - a. There is limited worldwide expertise and realistically the project could not be done anywhere else.
 - b. An inventor of a unique technology or treatment being evaluated in a trial also serves as the leader of

that clinical trial. In this situation, there must be a data monitoring and safety board overseeing the gathered information and its analysis.

- c. In acknowledgment of the diversity of practices within the international clinical oncology research community, the Ethics Committee, in consultation with the Board, may grant limited exceptions to those submitting materials for presentation or publication if they are deemed to have 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:

- A. Prohibition from presenting at ASCO-sponsored events, including the Annual Meeting;
- B. Exclusion from publishing in the *Journal of Clinical Oncology* or other ASCO publications;
- C. Exclusion from participation in ASCO boards, committees, and task forces; or
- D. Revocation or prohibition of ASCO membership.

VIII. EFFECTIVE DATE

This policy will be effective 12 months after its publication in the *Journal of Clinical Oncology*. It will apply prospectively to all activities initiated subsequent to the effective date. In the case of clinical trials, it will apply prospectively to trials that begin accrual subsequent to the effective date.