

Revisions of and Clarifications to the ASCO Conflict of Interest Policy

*American Society of Clinical Oncology**

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Authors' disclosures of potential conflicts of interest and author contributions are found at the end of this article.

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The Board of Directors of the American Society of Clinical Oncology (ASCO) has reviewed and revised its conflict of interest policy.¹ The previous policy, adopted in November 2002 and published in 2003,² followed ASCO's long-standing practice of relying primarily on disclosure of financial interests as a means of managing potential conflicts. However, it also established for the first time restrictions applying to certain individuals involved in the leadership of clinical trials. Those individuals were required not only to disclose financial interests, but also to refrain from financial involvement with sponsors during the course of the trial.

In response to questions raised since the policy was issued, the Ethics Committee and the Board carefully reviewed Section VI.B. and sought input to determine whether the restrictions may have swept too broadly. The Board of Directors subsequently approved changes to the policy as outlined in the following sections:

1. Clarification of the Definition of a Trial's Principal Investigator(s)

Because the restrictions are significant, the Board believes they should be reserved for those relatively few persons who have direct influence over the development and conduct of the trial and analysis of results. In order for principal investigators (PIs) to be able to make independent judgments about the design, conduct, and analysis of the trial, the Board believes there must be no real—or even perceived—financial conflicts of interest. In the case of multidisciplinary trials, the restrictions apply to the individual who leads each distinct section of the trial; therefore, these types of trials will likely have more than one PI.

2. Refinement of Restrictions on Individuals in a Leadership Role for a Clinical Trial Who Are Not PIs

The 2003 policy imposed the same restrictions on members of a trial's executive committee and its data safety monitoring board (DSMB) as on its PIs. By clarifying the definition of the PI,

ASCO has obviated the need to expand the restrictions to other individuals, including members of a trial's executive committee and DSMB. The Ethics Committee's review indicated that the 2003 policy, if unchanged, would impose restrictions on a wide range of participants, thus severely limiting the pool of knowledgeable and experienced individuals available to perform these important oversight functions. In addition, for industry-sponsored trials, the executive committee is likely to include employees of the sponsor, and it was not ASCO's intention to exclude industry-sponsored trials from publication and presentation.

3. Delineation of the Period During Which Restrictions Apply

The Board clarified that for the purposes of the policy's restrictions, the trial begins with accrual of the first patient into the trial and extends through the first publication of trial results, either as a peer-reviewed meeting presentation (abstract) or journal article.

4. Expansion of Exceptions to Restrictions on PIs

The 2003 policy recognized that restrictions on financial interests of PIs could, in some circumstances, unreasonably limit participation by qualified individuals in important research. Accordingly, the policy gave the Ethics Committee discretion to grant exemptions with respect to certain clinical trials, presentations, or publications. The Ethics Committee and the Board concluded that this approach to exceptions was too narrow and should be replaced by one that focuses not on the particular trial but rather on the unique expertise of the PI conducting the trial. This decision was based on the premise that an overly restrictive policy will inhibit participation by qualified PIs in the private sector. Thus, the policy has been revised to allow exceptions for PIs with widely acknowledged expertise in a particular therapeutic area and whose exclusion from other activities on behalf of the trial sponsor would represent a potential impediment to research and education efforts. An exception may

also be appropriate if a PI is the inventor of a unique technology being evaluated in the trial. Finally, the policy continues to recognize that international standards may be different, and allows a possible exception for a PI who complies with international ethical standards.

ASCO is committed to implementing a process that is fair, consistent, balanced, and unambiguous. ASCO is providing information on its Web site (<http://www.ASCO.org/conflictinterest>)

about policy implementation. In addition, the Board has published a set of questions and answers, which will provide guidance on an ongoing basis.

ASCO is dedicated to achieving a strong conflict of interest policy that takes into account individual circumstances as well as the changing dynamics of research. The ultimate goal is to promote integrity in the conduct of clinical trials, the results of which are key to longer lives, better outcomes, and enhanced quality of life for patients with cancer.

REFERENCES

1. American Society of Clinical Oncology: Revised conflict of interest policy. *J Clin Oncol* 24:10.1200/JCO.2005.04.8926

2. American Society of Clinical Oncology: Revised conflict of interest policy. *J Clin Oncol* 21:2394-2396, 2003