



December 19, 2005

**Questions and Answers Regarding
the ASCO Conflict of Interest Policy**
(Based on March 2005 Policy)

Questions Regarding Disclosure
Questions Regarding the Principal Investigator
Question Regarding NIH-Funded Trials
Questions Regarding Date of Implementation

Questions Regarding Disclosure

- 1. Does a researcher have to disclose funding received from a contract research organization (CRO) coordinating the trial for the sponsor?**

Yes. The ASCO policy requires disclosure of all payments associated with the conduct of the clinical trial in question if provided by the trial sponsor or agents employed by the sponsor. The CRO is an agent acting on behalf of the sponsor.

- 2. If a pharmaceutical company provides research funding directly to the researcher's academic institution, cooperative group, or clinical division, rather than directly to the researcher, should the researcher disclose this industry funding to ASCO?**

Yes. The ASCO conflicts policy requires disclosure of all payments associated with the conduct of the clinical research in question. In the first instance, the policy is intended to focus on the personal financial interests of the covered individual. However, in some cases company funds may be paid to the covered individual's *institution, cooperative group, division, or other unit*. Where the covered individual knows that institutional payments associated with the research project (possibly including the researcher's salary) will be covered by the sponsor's funds, it is appropriate to make the disclosure.

- 3. Does a researcher have to disclose honoraria received from a third party continuing medical education organizer, NOT the trial sponsor – even if the researcher knows that the trial sponsor is sponsoring the CME event?**

No. Honoraria paid directly to the covered individual by the company must be disclosed. A researcher does not need to disclose to ASCO honoraria paid by accredited CME providers, because the CME planning process has other safeguards to avoid conflicts when accepting industry support.

Questions Regarding the Principal Investigator

- 4. When the policy defines principal investigator as “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,” is it envisioned that there may be an unlimited number of principal investigators?**

This reference to “individuals” is intended to be limited to relatively rare circumstances, such as a trial in which there are two co-equal principal investigators, one for domestic sites and the other for international sites. In addition, a multi-faceted trial may have more



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than one principal investigator with responsibility for separate and distinct subsections of the protocol. This situation might occur if a trial assigns primary responsibility of distinct disciplinary sections (e.g., medical oncology, radiation, etc.) to separate researchers – another relatively rare circumstance. Generally, it is expected that the restrictions on principal investigators will apply to the sole individual designated as the principal investigator and having the unique leadership responsibilities described in the policy.

5. Does the policy impose restrictions when a pharmaceutical company pays for international attendees' travel to the annual meeting if those attendees are investigators for that company, but NOT principal investigators (according to ASCO's definition) for the company's trials?

No. The ASCO policy restrictions apply only to the individual or individuals who serve as principal investigator, as defined in the policy, and to those individuals' relationships with the sponsor of the clinical trial for which they are principal investigator. The policy restrictions do not apply to relationships between companies and those who are not principal investigators of the sponsor's trials.

6. For purposes of requesting an exception to the restrictions placed on principal investigators, does the principal investigator of ANY trial with international sites qualify for an exception?

This available exception is designed to recognize different standards of conflict of interest that may apply in other countries. The ASCO policy generally does not disqualify a principal investigator whose conduct complies with the ethical standards that prevail in his or her own country. A request for an exception might be appropriate where the *entire* clinical trial was conceived and conducted outside the United States in compliance with the local rules and ethical standards. In contrast, a trial developed by a United States-based sponsor, such as the U.S. Centers for Disease Control and Prevention (CDC), would not qualify for an exception even if some or all of its trial sites were outside the United States.

7. If the trial is investigator-initiated (i.e., where the principal investigator holds the investigational new drug application) with minimal support from a pharmaceutical company, is the company considered the trial sponsor? Do the restrictions apply to the principal investigator?

The policy restrictions do not apply to an investigator-initiated trial, *so long as the trial receives less than half of its funding from a single industry source and is subject to independent (i.e., non-industry) peer review of the trial's design and execution*, including management and dissemination of trial results. If an investigator-initiated trial meets these criteria, the principal investigator would not be subject to the policy restrictions, but remains obligated to disclose the industry funding when submitting the study for ASCO presentation or publication. Investigators submitting an investigator-initiated trial to ASCO will be asked to affirm that their trial meets the above criteria.



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8. May a principal investigator accept travel and housing reimbursement for advisory board service?

Yes. The ASCO policy does not impose restrictions when a principal investigator receives travel and housing reimbursement for attendance at an advisory board meeting to report on the status of the clinical trial. The principal investigator may NOT receive honoraria, consulting fees, or other payments that are not for travel and housing expenses.

9. Does the policy impose restrictions if a principal investigator is compensated for service on an advisory board that begins prior to development of a trial's protocol or opening the trial to accrual?

No. The ASCO policy restrictions apply to a principal investigator once a trial opens for accrual. The policy places no restrictions on financial relationships between the principal investigator and the company, as long as the relationships are concluded before the trial opens.

10. What is the definition of "widely attended and independently sponsored" scientific meetings that a principal investigator may be permitted to attend at the expense of the trial sponsor?

"Widely attended and independently sponsored" meetings are not intended to refer only to large medical meetings with numerous attendees, but instead to emphasize that such meetings should be independent of and not controlled by the trial sponsor. For example, grand rounds at an academic institution would qualify as a widely attended and independently sponsored scientific meeting.

11. How should authors or presenters determine whether they are in compliance with the requirement that research payments not substantially exceed trial costs?

Principal investigators are uniquely positioned to determine actual costs of the trial. Barring evidence to the contrary, ASCO will accept the principal investigator's assessment of actual research costs in relation to research-related payments.

12. Are there policy restrictions if a principal investigator receives increased payments from a sponsor when the workload at his or her trial site increases?

No. The ASCO policy recognizes that principal investigators (and other researchers as well) should be fairly compensated for all actual costs of conducting the trial, including related expenses for trial-related travel. Policy restrictions are not triggered when documented workload increases result in increased compensation.

13. Does the policy impose restrictions when any portion of a principal investigator's academic salary is supported by funds from the trial sponsor?

No. The ASCO policy restrictions are directed primarily at funds received by the investigator *directly* from the trial sponsor. When a trial sponsor pays grant funds to the investigator's institution to support the investigator's salary, disclosure obligations apply but policy restrictions do not.



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14. Does the policy permit a principal investigator to receive compensation from continuing medical education (CME) programs funded, in whole or in part, by the trial sponsor?

Accredited CME programs funded, in whole or in part, by the trial sponsor may provide honoraria to the principal investigator, consistent with his or her contribution to the programs, so long as such programs meet all applicable accrediting standards, which include assurances of independence, objectivity and fair balance in the presentations.

15. May a principal investigator serve on a speakers bureau for the trial sponsor for the drug under investigation?

No. Absent an exception, the principal investigator would be restricted under the policy from publishing or presenting the research with ASCO if he or she served on a speakers bureau or had another consulting engagement with the trial sponsor during the course of the trial and prior to peer-reviewed publication of trial results, regardless of the subject matter.

16. May a principal investigator be paid for training medical liaisons or sales representatives?

No. With the exception of compensation for the actual costs of conducting the trial and certain related expenses, such as travel and housing expenses to attend investigator meetings concerning the trial, all payments to a principal investigator from the trial sponsor are prohibited during the course of the trial and prior to peer-reviewed publication of trial results.

Question Regarding NIH-Funded Trials

17. What is the definition of “clinical trials sponsored by the National Institutes of Health”?

The automatic exception applies to trials that receive *direct* NIH funding for their conduct, including cooperative group trials.

Questions Regarding Date of Implementation

18. How does the policy apply to trials that are already in progress?

The policy applies to any trial that accrued its first patient (across all trial sites) after April 29, 2004.

19. When will the March 2005 changes go into effect?

The changes will be effective immediately, and the revised restrictions will apply to all clinical trials that accrued the first patient (across all trial sites) after April 29, 2004.