

**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 an individual covered by the ASCO Conflict of Interest Policy 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 a covered individual's academic institution, cooperative group, or clinical division, rather than to the individual directly, should the individual 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 the ASCO Conflict of Interest Policy require authors of abstracts and manuscripts to disclose research funding from government or non-profit entities?**

No. When disclosing research funding in accordance with the ASCO Conflict of Interest Policy, authors of abstracts and manuscripts should limit their disclosure to entities that have an investment, licensing, or other commercial interest in the subject matter under consideration in their work. This does not include funding from government or non-profit entities.

- 4. 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.

- 5. What does it mean to disclose “within two years” of submission of an article or abstract?**

The ASCO Conflict of Interest Policy requires disclosure of compensation for consultant or advisory services and expert testimony, along with the value of gifts and other remuneration

received from an entity having an investment licensing or other commercial interest in the subject matter under consideration in a submitted article or abstract “within two years of the activity or subject matter in question.” For those who seek to present at any ASCO meeting or to submit an article to an ASCO-sponsored publication, this is intended to encompass a time period beginning two years prior to accrual of the first participant to the trial that forms the basis of an article or abstract, and ending on the date of submission.

6. Who is considered an “immediate family member” according to the ASCO Conflict of Interest Policy?

The ASCO Conflict of Interest Policy requires disclosure of financial interest and other relationships held by “covered individuals.” Under the Policy, covered individuals are those who participate on the ASCO Board of Directors, committees and task forces, and those who seek to present at any ASCO meeting or to submit an article to an ASCO-sponsored publication, as well as their immediate family members. The Policy defines “immediate family member” as a person’s “spouse, dependent child, or adult child employed by the sponsor, or any other relationship involving the sharing of income or assets.” In most instances where disclosure of the interests held by a person’s immediate family member is required by the Policy, disclosure of the interests held by one’s spouse or dependent child is sufficient. However, ASCO recognizes that there are cases in which disclosure on behalf of additional individuals is warranted. ASCO encourages disclosure of the financial relationships of any other person with whom you share income or assets and believe disclosure is relevant.

7. Does the ASCO Conflict of Interest Policy require disclosure of consulting relationships with investment firms?

Yes. The ASCO policy requires disclosure of all consultant or advisory arrangements with an entity having an investment, licensing or other commercial interest in the subject matter under consideration. ASCO interprets this requirement to call for the disclosure of consulting relationships with investment firms and investment firm intermediaries. These relationships should be disclosed because investment firms and investment firm intermediaries may have a commercial interest in advance knowledge of drug trials, due to the impact trial results can have on the stock prices of pharmaceutical and device manufacturers.

Questions Regarding the Principal Investigator

8. 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 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.

9. 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.

10. 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.

11. The Policy says the Ethics Committee is empowered to grant exceptions in "rare" circumstances. How many exceptions to the restrictions on PIs does the Ethics Committee grant for each meeting?

While the number of exceptions is small, exceptions are granted on a regular basis. PIs that submit complete exception request materials for Ethics Committee review by the due date specified in the abstract submitter and meet the criteria for an exception are generally permitted to publish or present their abstracts, subject to conflict of interest management strategies required by ASCO that meet or exceed ACCME standards. These strategies include but are not limited to rigorous peer review by ASCO's Ethics and Scientific Program Committees, advance slide review, session audits, and documentation of safeguards employed by research institutions through institutional policies, IRBs and DSMBs to manage conflicts and prevent bias.

However, exceptions are generally not granted for PIs who have unmanageable relationships, such as stock or employment relationships with their trial's company sponsor. Abstracts that do not receive exceptions are not considered for meeting placement by the Scientific Program Committee. All abstracts published or presented pursuant to an exception are identified in the meeting Proceedings book.

12. If a trial has only minimal support from a pharmaceutical company, is the company considered the trial sponsor? Do the policy restrictions apply to the principal investigator?

A pharmaceutical company that provides financial or in-kind support for a trial is considered a trial sponsor. The policy restrictions apply to the PI of the trial, limiting the financial relationships the PI may have with that sponsor. If a PI has one of the relationships described in Section VI.B. of the policy, he or she may apply for an exception to the restriction. Exception decisions are based on the entirety of the circumstances. The PI of a trial that receives only a small portion of industry support may demonstrate that their study is subject to independent (i.e., non-industry) peer review of the trials' design and execution, including management and dissemination of trial results. Trials that are more likely to meet this standard are those funded in part by the NIH (including funding through cooperative groups and NCI designated cancer centers), because protocol safety monitoring and appropriate data

management are required. Even if NIH funding is not present, there may be cases where the support from the relevant sponsor is such a small portion of the total funding as to minimize the risk of a conflict and justify an exception.

13. May a Principal Investigator or Guideline Panel Chair accept travel and housing reimbursement for advisory board service?

Yes. When a PI or Guideline Panel Chair (or Co-Chair) serves as an unpaid advisor, he or she may accept reasonable travel, housing and meal expenses directly related to attending an advisory board meeting. Under the ASCO Conflict of Interest Policy, PIs and Guideline Panel Chairs may not accept excessive or unrelated travel payments, honoraria, consulting fees or other compensation for service on an advisory board.

14. 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.

15. 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.

16. Can a principal investigator receive compensation for his or her time and effort when asked by the sponsor to make a presentation about the trial at a meeting that is not an investigator meeting or a widely attended conference?

A principal investigator may receive research compensation from the trial sponsor related to his or her time and effort. Sometimes a PI may be asked to make a presentation about the trial, for example to a sponsor's advisory board. If making such presentations is a duty assigned to the PI under a research grant or clinical trial agreement, the research funding may include reasonable compensation for these activities. However, under the policy a PI may not receive a separate honorarium or consulting fee from the trial sponsor during the course of the trial. Reimbursement of reasonable travel expenses is permitted.

17. Can a principal investigator receive compensation for participation in an investigator meeting?

Yes. A principal investigator may receive research compensation from the trial sponsor related to his or her time and effort. This includes reasonable compensation for participation in investigator meetings.

18. 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.

19. 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.

20. 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.

21. 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.

22. 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

23. 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

24. 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.

25. 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.