



Cancer Prevention Network: Conflict of Interest Disclosure Policy

Background:

A situation may occur in which a CPN member has more than a purely scientific interest in the outcome of a clinical investigation. This interest may be a professional one, due to the fact that the member has played a substantial role in the development of the product or technology being evaluated, or because the member has an ongoing affiliation with the organization holding the patent to or license for development or sale of the research product. The interest may also be proprietary or pecuniary, if the member or a member of his or her immediate family has a material interest in the product or technology, or where the member and/or family members have a substantial equity interest in a commercial enterprise that will benefit from the sale of the product or technology.

The scientific credibility and the general acceptance of the results of a clinical investigation clearly depend on the integrity and objectivity of the members involved in CPN trials. Even the perception that a member has a bias may cast doubt on the validity of the results. This policy was established to address such concerns.

This statement will define areas of conflict of interest and will identify when disclosure should be provided. Following the disclosure, the CPN chair will convene and chair an ad hoc committee that will determine on a case by case basis whether any limitations will be placed on the member's participation in CPN activities.

Policy

A. Applicability

This policy is applicable to all members of the CPN.

B. Definitions

- a. **Research Product.** A research product includes a drug, technique, or technology.
- b. **Immediate Family Member.** Immediate family member includes a spouse, dependent child, or other dependent.

C. Conflict of Interest. There are several aspects to conflict of interest.

- a. **Professional Interest**
 - i. The member has played a substantial role in the prior development of a product or technology.

- ii. The member has a substantial ongoing affiliation with an organization having a role in the development or sale of a product or technology including organizations holding patents to or licenses for the development or sale of research products. That would include instances in which the member serves as an officer, director, trustee, general partner, employee, or on a scientific advisory board, or in a similar capacity for such an organization regardless of whether the member is currently being compensated for that position. Such organizations would also include those which the member is negotiating for, or has an arrangement concerning prospective employment or affiliation, or those from which the member receives or expects to receive compensation in the amount of \$5,000 or more annually for laboratory activities, honoraria, consultative services, or other activities. The significance of the conflict will depend, to some degree, on whether reimbursement for professional activities involves compensation limited to that normally required to support the scientific process, or is substantially larger leading to actual or potential personal financial gain to the member or an immediate family member.
- b. Proprietary Interest
 - i. The member has financial interest in the research product being evaluated because the member or an immediate family member has a material interest in the product or technology that may result in financial gain, e.g., where the member may receive royalties or other compensation following the commercial sale of the product or technology. Such royalties may be in the form of personal compensation to the member or may be used in support of the member's research.
 - ii. The member has financial interest in the research product being evaluated because the member or an immediate family member has an equity interest or option of \$10,000 or more in a commercial enterprise that will benefit from the sale of the product or technology.
 - c. Miscellaneous
 - i. There may be other instances in which a member or an immediate family member has an affiliation or relationship such that objective impartiality could be questioned. In such instances, the member should disclose the nature and extent of such affiliation.

D. Proper Procedures

Members having a potential conflict of interest as outlined above may be allowed to participate in that research investigation after providing formal disclosure. However, in some instances certain activities will be prohibited. On an *ad hoc* basis, the CPN Lead Investigator will convene a committee to review possible conflicts of interest to determine whether there is sufficient basis to apply the prohibition defined below. The CPN chair will make a final determination to apply the prohibition.

Because of the potential of a conflict of interest to bias conclusions, either intentionally or unintentionally, and because even the perception by others of a conflict of interest could compromise research credibility, CPN members should make reasonable efforts to avoid the occurrence of such conflicts.

E. Disclosure

Disclosure of potential conflict of interest on the part of the member is required as follows:

- a. Prior to developing a protocol or serving in a leadership role in the conduct and/or analysis involving the research product for which there is a possible conflict of interest as defined above, a member must disclose the possible conflict of interest to the CPN chair. Conflicts which develop during the conduct and/or analysis of the trial of the research product or during the dissemination of results must also be disclosed. Disclosure is not necessary for individuals whose participation is limited to registering patients.
- b. At the beginning of any presentation of the results of a CPN clinical trial either through oral presentation or publication, a member should disclose, if applicable, private sources of funding provided specifically for conduct of the study or reporting of results.

F. Prohibited Activities

If, in the view of the *ad hoc* committee appointed to review a possible conflict, a member has a conflict of interest, that member may not serve as chair, study statistician, or monitoring committee member for any protocol involving the research product for which there is a conflict. On a case by case basis, a member might also be prohibited from other activities involving the investigation of the research product or the presentation of results for which there is a conflict. This will be decided by the *ad hoc* committee chaired by the CPN Lead Investigator.

G. Sanctions

Failure to disclose a conflict of interest as required above under "Disclosure" or participation in "Prohibited Activities" could result in the loss of privilege to participate in the activities of the Cancer Prevention Network.

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