Background

A situation may occur in which an individual who is officially associated with the CTN has more than an arms-length scientific interest in the outcome of a clinical investigation. This interest may be a professional one, a proprietary or pecuniary one, or may be due to other circumstances.

The scientific credibility and the general acceptance of the results of a clinical investigation clearly depend on the integrity and objectivity of the individuals involved in CTN trials. Even the perception that an individual has a bias may cast doubt on the validity of the results. The Steering Committee, in collaboration with NIDA, has established this Conflict of Interest Policy to address the issues of conflict of interest.

This policy defines areas of real and apparent conflicts of interest and identifies when disclosure must be provided. Following disclosure, NIDA or an ad hoc committee will determine on a case-by-case basis whether any limitations will be placed on the individual s participation in CTN activities.

Applicability

This policy is applicable to the following individuals, hereafter called participating individuals :

a. All scientists, including advisory scientists and principal investigators, including deputy and co-principal investigators
b. Other individuals who have a substantial decision-making or a direct supervisory responsibility for the design, implementation and analysis of the studies conducted within the CTN, as follows:
    1. Members of the Steering Committee and its Subcommittees
    2. Members of the Protocol Review Board and Ad-Hoc Oversight Advisory Board who are not employees of NIDA
    3. Members of the Data & Safety Monitoring Board
    4. Members of any NIDA appointed Conflict of Interest Committee
    5. Any other individuals who are officially involved with the Protocol/Concept Reviews, Protocol Design, Implementation and Data Analysis
    6. Any other individual who the Principal Investigator identifies as being subject to the disclosure reporting requirements of this Policy

The Public Health Service regulation 42 part 50, subpart F, Responsibility of Applicants for Promoting Objetivity in Research for which PHS Funding is Sought , currently requires that grantee institutions have written policy guidelines on conflict of interest. Other funding or granting organizations have similar policies either published or under consideration. Therefore, most CTN participating individuals will already be subject to the policy of their institution with respect to conflict of interest. In the event a funding or granting organization also has conflict of interest policies, those policies will also apply. NIDA or an ad hoc committee will resolve any conflicts between this policy and those of the relevant grantee or granting organization.

Definitions

1. *Research Product.* A research product includes a drug, technique, or technology and the ancillary materials produced under the aegis of the CTN, such as training materials, in support of the drug, technique or technology. .

2. *Immediate Family Member.* Immediate Family Member includes a spouse and dependent children.

3. *Conflict of Interest*. There are several types of situations that could constitute a real or apparent conflict of interest:

   A. Professional Interest

      a.1 The participating individual or an immediate family member has played a substantial role in the prior development of a product or technology (such as behavioral manuals or drug products) that is being utilized by the CTN and currently receives a financial or other material benefit from such product or technology. Disclosure is not required in the absence of a current financial or other material benefit.

      a.2 The participating individual or an immediate family member has a substantial ongoing affiliation with an organization having a role in the development or sale of a product or technology that was developed by or is being utilized by the CTN, including organizations holding patents to or licenses for the development or sale of research products. That would include instances in which the individual serves as an officer, director, trustee, general partner, or employee for such an organization regardless of whether the participating individual is currently being compensated for that position. Such organizations would also include those with which the individual is negotiating for or has an arrangement concerning prospective employment or affiliation, or those from which the participating individual receives or expects to receive compensation in the amount of $2.500 or more annually for laboratory activities, honoraria, consultative services, or other activities (such as educational grants). 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 investigator or an immediate family member.

   B. Proprietary Interest

      b.1 The participating individual has a financial interest in the research product being studied because the individual or an immediate family member has a material

interest in the product or technology that may result in financial gain, e.g., where the individual 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 individual or may be used in support of the individual s research.

b.2 The participating individual has a financial interest in the research product being studied because the individual or an immediate family member has an equity interest or option of $2,500 or more in a commercial enterprise that will benefit from the sale of the product or technology.

C. Miscellaneous

There may be other instances in which a participating individual or an immediate family member has an affiliation or relationship such that objective impartiality could be questioned. The standard that a participating individual should use in determining whether or not to disclose a real or apparent conflict of interest is how the conduct in question would look if reported in the *New York Times*.

The intent of the operating policy is to err on the side of full disclosure. Thus, the participating individuals may need to disclose any other interests, affiliations, arrangements or relationships that could lead to questions about the motives in connection with their work on behalf of the CTN if such interest, etc. were known or made public.

In **any** such instance, the participating individual should disclose the nature and extent of such affiliation or relationship using the procedures discussed below.

Proper Procedure

The purpose of this policy is to ensure that participating individuals make full disclosure of a real or apparent conflict of interest so that an informed decision is made that balances the interests of the disclosing individual with the needs of the CTN. It is not the purpose of the policy to limit or exclude an individual from participating in the CTN where the conflict of interest is remote or insignificant.

Participating individuals having a potential conflict of interest as outlined above may be allowed to take part in that research investigation after providing formal disclosure. However, in some instances certain activities will be prohibited. On an ad hoc basis, NIDA will convene a committee to review possible conflicts of interest to determine whether there is a sufficient basis to apply the prohibition described below.

Because of the potential that a real or apparent conflict of interest could bias conclusions, and because even the perception by others of a conflict of interest could compromise research

credibility, CTN scientists and participating individuals should make reasonable efforts to avoid the occurrence of such conflicts.

Following completion of a trial, individuals directly involved in the design or conduct of the study should refrain from activities primarily targeted at commercial marketing of the product. Scientific activities such as authorship of scientific articles or book chapters, and presentations at academic institutions or professional meetings do not require disclosure unless compensation exceeds standard honoraria and travel expenses.

Disclosure

Each participating individual is expected to file a Conflict of Interest Disclosure form (Appendix A) annually and must update the form during the year if a real or apparent conflict should arise. The form shall be filed with the NIDA project officer. The form shall be filed by October 1, of each year. Participating individuals entering the CTN after October 1 of each year or an individual assuming responsibility after October 1 for service on a Committee listed under the Applicability section of this policy or who is otherwise covered under that provision, shall file the Disclosure form within 60 days. The NIDA ad hoc committee is available to advise whether a particular situation requires disclosure. The Disclosure Form (Appendix A) shall be provided to the NIDA project officer where it will be kept on file.

In addition, it is important that at the beginning of any presentation of the results of a CTN clinical trial through either oral presentation or publication, participating individuals should disclose, if applicable, private sources of funding provided specifically for conduct of the study or reporting of results.

Prohibited Activities

If, in the view of NIDA Project Officer or an appointed Conflict of Interest Committee, a participating individual has a significant conflict of interest (or a potential), that individual may not serve on the protocol team, for any protocol involving the research product for which there is (or could be) a conflict.

NIDA or an appointed Conflict of Interest Committee shall consider on a case-by-case basis, whether a participating individual 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 (or potential of one).

Sanctions

Failure to disclose a conflict of interest as required above under Disclosure or par ticipation in prohibited activities could result in the loss of privilege to participate in the activities of the CTN.

Conflict of Interest Disclosure Form

To: Participating Individual
From: Betty Tai, Ph.d., Project Director

Because of your key role in the Clinical Trial Network, you have been designated a participating individual under the Conflict of Interest policy approved by the Steering Committee on April 4, 2001. As a participating individual, I request that you carefully read the enclosed policy, with particular attention to the definitions of Conflict of Interest set forth under Paragraph 3, Definitions, and then respond to the questions set forth below based upon the best information that is available to you.

1. Have you or an immediate family member played a substantial role in the prior development of a research product that is being utilized by the CTN and you or your immediate family member currently receives a financial or other material benefit from such research product? (See 3Aa.1 of COI policy)
Yes _____No _____ If, yes, please provide complete information.

2. Do you or an immediate family member have a substantial, ongoing affiliation with an organization having a role in the development or sale of a research product that was developed by or is being utilized by the CTN? (See 3Aa.2 of COI policy)
Yes _____No_____ If, yes, please provide complete information.

2a. Are you or an immediate family member negotiating for employment or have an arrangement concerning prospective employment or affiliation with an organization having a role in the development or sale of a research product that was developed by or is being utilized by the CTN? (See 3Aa.2 of COI policy)
Yes _____No_____ If, yes, please provide complete information.

2b. Have you or an immediate family member received or expect to receive $2,500 or more in compensation during the past 12 months from an organization having a role in the development or sale of a research product that was developed by or is being utilized by the CTN? (See 3Aa.2 of COI policy)
Yes _____ No _____ If, yes, please provide complete information

3. Do you or an immediate family member have a financial interest in the research product being studied due to a material interest that may result in financial gain? (See 3Bb.1 of COI policy)
Yes _____ No _____ If, yes, please provide complete information.

4. Do you or an immediate family member have an interest in the research product being studied due to an equity interest or option of $2,500 or more in a commercial enterprise that will benefit from the sale of the research product. Holdings in mutual funds need not be disclosed. (See 3Bb.2 of COI policy)
Yes _____ No_____ If, yes, please provide complete information.

5. Do you or an immediate family member have any other interest, affiliations, arrangements or relationships that you believe could lead to questions about your motives in connection with your work on behalf of the CTN if such interest, etc. were known or made public? (See 3C of COI policy)
Yes _____ No _____ If, yes, please provide complete information.

Name (please print): _____

Signature: _____ Date: _____

Please complete this document within 60 days of receipt and return it to me at (NIDA address). If, during the annual period covered by this disclosure, your situation changes, you are obligated to file an updated disclosure form. Thank you for assistance in ensuring that the conduct of those participating in the CTN will be impeccable.