

NIAID (DAIDS)-SUPPORTED AND/OR SPONSORED HIV/AIDS CLINICAL TRIALS NETWORKS
Financial Disclosure and Conflict of Interest Guidelines
Standard Operating Procedure

Owner	HIV/AIDS Network Coordination (HANC)
-------	--------------------------------------

Adopted By		
		
		

Version History	Version 1.0	Effective 15 April 2010
-----------------	-------------	-------------------------

NIAID (DAIDS)-SUPPORTED AND/OR SPONSORED HIV/AIDS CLINICAL TRIALS NETWORKS
Financial Disclosure and Conflict of Interest Guidelines
Standard Operating Procedure

Table of Contents

1.0 General Principles 1

2.0 Definitions 1

 2.1 Reportable Interests 1

 2.2 Other Definitions 2

3.0 Responsibilities 3

 3.1 Network Members Required to Report Under This Policy 3

 3.2 Financial Disclosure Coordinator (FDC) 4

 3.3 Review Committee 4

 3.4 Network Operations Center 5

 3.5 PHS 5

APPENDIX A NIAID (DAIDS) Supported and/or Sponsored HIV/AIDS Clinical Trial Networks Statement of Significant Financial, Equity, and Intellectual Property Interests 6

APPENDIX B GUIDELINES FOR COMPLETING STATEMENT OF FINANCIAL, EQUITY, AND INTELLECTUAL PROPERTY INTERESTS 7

APPENDIX C LINKS TO NETWORK-SPECIFIC POLICIES AND PROCEDURES 8

APPENDIX D Cross-network Financial Disclosure & Conflict of Interest Reporting Workflow 9

NIAID (DAIDS)-SUPPORTED AND/OR SPONSORED HIV/AIDS CLINICAL TRIALS NETWORKS
Financial Disclosure and Conflict of Interest Guidelines
Standard Operating Procedure

1.0 General Principles

Title 42CFR50, "Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought," requires the networks to establish and manage a system that ensures the research is not biased by any conflicting financial interest.

In order to satisfy this requirement, the following guidelines have been developed and are intended to identify significant financial interests of researchers in the NIAID (Division of AIDS [DAIDS])-supported and/or sponsored HIV/AIDS Clinical Trials Networks and avoid conflicts of interest, or the appearance of such conflicts, in activities of the networks.

Network members and affiliated investigators play many professional roles. Since network members have widely valued expertise and interests, it is expected that network members have non-network professional activities. Such interactions might be viewed as ones that engender conflicts of interest and/or influence the decisions of members as they relate to the networks. This document outlines the networks' approach to dealing with financial disclosure and with any real or perceived conflicts of interest so that they may be managed or eliminated.

Routine disclosure of significant financial interests by network members will allow most potential conflicts of interest to be addressed at the appropriate network's review committee. Please contact your network(s) for more information on the review and resolution of perceived conflicts of interest.

2.0 Definitions

2.1 Reportable Interests

Equity Interest

"Equity Interest" is defined as any ownership interest in a relevant entity. Members are required to disclose all equity interests in any and all relevant entities that, when aggregated with family members' holdings, amount to more than a five percent ownership interest (excluding ownership of diversified mutual fund shares), or exceed \$10,000 annually, determined by fair market value.

Intellectual Property Interest

Intellectual property rights with a relevant entity (patents, pending patents, copyrights, licensures, and royalties) or potential earnings from any patent held by any other party.

Significant Financial Interest

"Significant Financial Interest" means anything of monetary value from a relevant entity (e.g., salary; consultant fee including lecture fees, equipment, gifts, honoraria, direct salary support or other direct benefits from industry-sponsored research; service grant; contract; or membership on scientific/clinical advisory board) that when aggregated for the network member and family members **exceeds \$10,000 annually**. Whether made directly or indirectly, all payments made on behalf of a company (including its agent or contractor reimbursements) must be considered in

determining the aggregated total of the monetary interest in an entity. Title 42CFR50 does not require the tracking of salary, royalties, or other remuneration provided from the member's institution to the network member or family member (e.g., salary support from an industry grant or contract that is given to a network member's institution and that pays a portion of his/her salary as compensation for his/her time and effort spent on a specific clinical trial or research project). Anything of monetary value given to the institution or to the member exclusively in support of research or the clinical trial need not be reported.

Stock Options

A "stock option" is an option to buy stock in a company at a future date. All stock options in relevant entities must be disclosed.

2.2 Other Definitions

Conflict Management Plan

A "conflict management plan" describes one or more actions to manage, reduce, or eliminate a conflict or potential conflict identified by the relevant committee chair.

Disclosure

"Disclosure" is the act of reporting all significant financial interests or intellectual property rights on a "Statement of Financial, Equity, and Intellectual Property Interests" form (Appendix A).

Family Member

A "family member" is defined as a spouse or dependent child of a network member required to disclose under this policy.

Network

A "network" is herein defined as an affiliated group of national and international medical research institutions and investigators supported and/or sponsored by NIAID (DAIDS) to conduct clinical HIV/AIDS research to develop safe and effective drugs, prevention strategies, and HIV vaccines. In the terms of its grant awards, DAIDS has delegated the financial disclosure reporting responsibilities to the networks. The five networks adhering to this policy include: the AIDS Clinical Trial Group (ACTG), the HIV Prevention Trials Network (HPTN), the HIV Vaccine Trials Network (HVTN), the International Maternal Pediatric Adolescent AIDS Clinical Trials Group (IMPAACT), the International Network for Strategic Initiatives in Global HIV Trials (INSIGHT), and the Microbicide Trials Network (MTN).

Network Members required to disclose under this policy

Those individuals who must disclose financial information are network-affiliated clinical trials unit (CTU) principal investigators, clinical research site (CRS) leaders, and the investigator of record and subinvestigators listed on a Form 1572; anyone participating in a key decision-making role on a protocol team (e.g., chair/co-chair, vice chair, statistician, lead specialty laboratory investigators); key personnel participating in decision-making roles at the network operations centers; and all members of the relevant decision-making and study monitoring committees. Members of a protocol team who do not have key decision-making roles, including industry representatives and federal government employees (who are required to report under other federal guidelines) are not required to disclose under this policy.

Potential Conflicts of Interest

When a network member or family member holds a significant financial interest, equity interest, stock options, or intellectual property interest (all as defined above) in a relevant entity whose product or treatment:

- ❑ Is involved in a network trial;
- ❑ Is being considered for inclusion in a study;
- ❑ Competes with a product or treatment included in a network clinical trial; and/or
- ❑ Will benefit a member voting on a matter and thereby potentially influence his/her vote.

Recusal

“Recusal” is the act of removing oneself from deliberations or voting on a matter because of a potential or real conflict of interest that has been previously identified by the member and/or relevant review committee chair and that has been fully disclosed and addressed in a conflict management plan. All recusals should be recorded in the relevant summaries of committee and other group meetings.

Relevant Entity

An example of a “relevant entity” would be a company with business interests in pharmaceutical, diagnostic, biologic, software, assay or related products engaged in collaborations with the networks.

Review Committee

“Review Committee” is the group(s) charged by each network to consider and adjudicate potential or actual conflicts of interest.

3.0 Responsibilities

3.1 Network Members Required to Report Under This Policy

All network members who are required to report under this policy must complete a “Statement of Financial, Equity, and Intellectual Property Interests” (Appendix A) and submit it to each affiliated network’s Financial Disclosure Coordinator (FDC) at least annually, or when joining a protocol team or committee. The FDC will notify each existing network member required to report under this policy of the need to submit a new or revised “Statement of Financial, Equity, and Intellectual Property Interests” by 31 May of each calendar year. If there is a significant change in the member’s interests after 31 May, it is incumbent upon the member to report said change to his/her network at the time of the change. Each completed Statement should cover the previous 12 months and present day circumstances. Members new to the network and who are required to report must submit the Statement within 60 days of joining the network. Members are obliged to report their financial, equity, and intellectual property interests until one year after the completion of the study as defined by DAIDS (i.e. primary analysis is complete, primary manuscript is accepted, and all participants are off study).

In the event that a network clinical trials site will discontinue participation in network-sponsored studies, the financial disclosure policy will continue to apply for a 12-month period subsequent to the final protocol visit completed at the site, or until the protocol database at the network statistical and data management center is officially locked, whichever is sooner. In the event of a

clinical trial staff member being involved in a manuscript, the network financial disclosure policy will continue for this member until the manuscript is completed or the staff member no longer collaborates on it.

It is a network expectation that members required to disclose under this policy are taking the appropriate actions to ensure that they are in compliance with the financial disclosure requirements of their home institutions. Network members are also required to inform their home institutions of any potential or actual conflict of interest identified by a network review committee.

If a potential conflict is identified by the network's review committee, the individual must prepare a conflict management plan describing one or more actions to manage, reduce, or eliminate such conflicts of interest. This management plan should include an answer to the question of whether the individual believes that the significant financial interest poses a conflict of interest, i.e., will a decision made by a group benefit the member voting on a matter and thus potentially influence his/her vote? The management plan may include, but is not limited to, the following:

- ❑ Monitoring of research activities by independent reviewers;
- ❑ Modification of the research plan;
- ❑ Disqualification from participation in all or a portion of the study(ies);
- ❑ Divestiture of significant financial interests that create actual or potential conflicts;
- ❑ Severance of relationships that create actual or potential conflicts;
- ❑ Recusal from voting on questions or matters involving products of the entity in question or its direct competitors.

In any case in which it is determined that network-affiliated research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by a network member with a conflicting interest that was not disclosed or managed as required, the member must disclose the conflicting interest in each public presentation of the results of the research.

If an individual does not agree with the decision of the chair(s) of the relevant committees regarding a or significant financial interest posing a conflict of interest which, in turn, requires a conflict management plan, the individual may appeal the decision. To do so, the network member should refer to his/her respective network policies and procedures guide.

3.2 Financial Disclosure Coordinator (FDC)

An FDC will collect the statements, maintain a database of records, and follow network policies on managing potential conflicts of interests.

3.3 Review Committee

Open disclosure is the primary means of managing potential conflicts of interest. If the relevant committee(s) are aware of the network members' disclosure, degrees of involvement, and status on teams, actions and/or statements of those members can be evaluated based on knowledge of the disclosure. A conflict of interest or perception of a conflict exists when the relevant chair(s) reasonably determines that a significant financial interest could be perceived as compromising objectivity in the design, conduct, or reporting of the study. If the relevant chair(s) determines a

conflict or potential conflict exists, the chair(s) will request that the network member submit in writing a proposed conflict management plan that may be approved or modified by the relevant chair(s).

The review committee members will consider the submitted conflict management plan and report their findings to the relevant network operations center.

3.4 Network Operations Center

An FDC shall be appointed by the network operations center to maintain a secure file of all Statements of Financial, Equity, and Intellectual Property Interests submitted to the operations center.

Database records of network members disclosing significant interests by relevant entity will be maintained to assist the relevant committee chair(s) and protocol chairs to determine whether potential conflicts of interest exist.

The Operations Center will inform the relevant funding agency Chief Grants Management Officer or Chief Contracting Officer, as appropriate, of the existence of any financial conflict of interest before spending any Public Health Services (PHS) funds awarded under a new award. Conflicts identified during the award period will be reported to the PHS within 60 days of identifying them. The networks will report all conflicts of interest through the online eRA Commons Module. These reports will indicate whether the conflict of interest has been managed, reduced, or eliminated.

The Network Operations Center will maintain records of all actions taken by the network with respect to each conflict of interest for at least three years from the date of the final expenditure report of the grant and make information available to the Department of Health and Human Services as necessary regarding all conflicts of interests identified by the network and how those conflicts of interest have been managed, reduced, or eliminated.

The Network Operations Center will maintain copies of the conflict management plans approved by the relevant committees.

3.5 PHS

When PHS staff has concerns that a conflict or perceived conflict of interest may exist, the concerns and relevant information will be forwarded to the relevant committee(s) for determination and appropriate action. PHS representatives at DAIDS will consult with the relevant committee(s) about any general issue or specific problem that may arise during the course of any DAIDS-sponsored trial.

The Director of DAIDS or his/her designee may review these guidelines and make appropriate recommendations.

An audit of the Financial Disclosure and Conflict of Interest Program of the network (including guidelines, education, and implementation) may be undertaken by DAIDS as part of the performance evaluation of the group.

APPENDIX A

**NIAID (DAIDS) SUPPORTED AND/OR SPONSORED HIV/AIDS CLINICAL TRIAL NETWORKS
 STATEMENT OF SIGNIFICANT FINANCIAL, EQUITY, AND INTELLECTUAL PROPERTY INTERESTS**

Name (Please Print): _____ **Date of Statement:** _____

Primary Institution: _____

Email: _____ **Phone:** _____

Address: _____

List below any relevant entity (company); e.g., pharmaceutical, diagnostic, biological, software or assay company, in which you or your family member(s) have any stock options and/or have had/have more than \$10,000 of financial, intellectual property, or equity interest, in the 12 months prior to the date of this document, as defined by the "NIAID (DAIDS)-Supported and/or Sponsored HIV/AIDS Clinical Trial Networks Financial Disclosure and Conflict of Interest Guidelines."

If no present significant financial interests exist, initial here: _____

NAME OF ENTITY	TYPE OF INTEREST	DESCRIPTION OF INTEREST/COMMENTS
	<input type="checkbox"/> Stock Options (Any) <input type="checkbox"/> Equity <input type="checkbox"/> Financial <input type="checkbox"/> Intellectual Property	
	<input type="checkbox"/> Stock Options (Any) <input type="checkbox"/> Equity <input type="checkbox"/> Financial <input type="checkbox"/> Intellectual Property	
	<input type="checkbox"/> Stock Options (Any) <input type="checkbox"/> Equity <input type="checkbox"/> Financial <input type="checkbox"/> Intellectual Property	
	<input type="checkbox"/> Stock Options (Any) <input type="checkbox"/> Equity <input type="checkbox"/> Financial <input type="checkbox"/> Intellectual Property	

I certify that I have read and understand the "NIAID (DAIDS)-Sponsored and/or Supported HIV/AIDS Clinical Trial Networks Financial Disclosure and Conflict of Interest Guidelines." [\[http://www.hanc.info/Shared%20Documents/Cross-network%20FDCOI_SOP.pdf\]](http://www.hanc.info/Shared%20Documents/Cross-network%20FDCOI_SOP.pdf)

I declare that the information provided on this form is, to the best of my knowledge and belief, true, correct, and complete. Furthermore, if my financial interests and arrangements, or those of my spouse, and dependent children, change from the information provided above during the course of the study or within one year after the last patient has completed the study as specified in the protocol, I will notify network representatives immediately. I give my permission to disclose this information to appropriate Network Leaders and PHS.

Signature **Date**

APPENDIX B

GUIDELINES FOR COMPLETING STATEMENT OF FINANCIAL, EQUITY, AND INTELLECTUAL PROPERTY INTERESTS

On the *NIAID (DAIDS)-Supported and/or Sponsored HIV/AIDS Clinical Trial Networks Statement of Financial, Equity, and Intellectual Property Interests* form, please use the following categories when listing the activities for which you or a family member receive financial compensation, have equity interest, or have intellectual property interest.

Disclosure of the following significant financial interests should be for the previous 12 months:

- Consultant fee, direct and indirect
- Equipment
- Gift
- Honoraria in direct support of your activities
- Stock owned by you or a family member
- Stock option owned by you or a family member
- Patent
- Pending patent
- Patent held by third party
- Copyrights
- Royalties

The NIH policy on conflict of interest may be found at <http://grants.nih.gov/grants/policy/coi/index.htm>. Additional guidance can be found at <http://grants.nih.gov/grants/policy/coi/tutorial/fcoi.pdf>. A Federal informational email address is FCOICompliance@mail.nih.gov.

APPENDIX C

LINKS TO NETWORK-SPECIFIC POLICIES AND PROCEDURES

AIDS Clinical Trials Group (ACTG): https://www.actgnetwork.org/about_actg/sops.aspx.

HIV Prevention Trials Network (HPTN):
<http://www.hptn.org/MOP%20NEW%20CD/MOP%20CD/HPTNMOP2008.htm> (Effective through 01 June 2010)

HIV Vaccine Trials Network (HVTN): http://www.hvtn.org/members/mop/ver3/mop_coi_0303.html;
<http://www.hvtn.org/members/groups/ops/financial.html>

International Maternal Pediatric Adolescent AIDS Clinical Trials Group (IMPAACT):
<http://www.impaactgroup.org>

International Network for Strategic Initiatives in Global HIV Trials (INSIGHT): (Revising as of April 2010)

Microbicide Trials Network (MTN): <http://www.mtnstopshiv.org/node/1639>

APPENDIX D

CROSS-NETWORK FINANCIAL DISCLOSURE & CONFLICT OF INTEREST REPORTING WORKFLOW

