

NIH HIV/AIDS CLINICAL TRIALS NETWORKS
Financial Disclosure and Conflict of Interest
Standard Operating Procedure

Owner	Office of HIV/AIDS Network Coordination (HANC)
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Adopted By		
		
		

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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 for the U.S. Public Health Service (PHS), the following guidelines have been developed and are intended to identify significant financial interests of researchers in the NIH 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 and 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 collecting disclosures of significant financial interest from investigators in leadership roles. Submission of a financial disclosure statement to the network(s) does not release members from their own institutions' conflict of interest submission requirements nor the requirement for collection of financial disclosures by your site for FDA-regulated studies.¹

Disclosure of significant financial interests by network members will allow for perceived conflicts of interest to be addressed by the appropriate network 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 (i.e. stocks or shares) in a relevant entity. Members are required to disclose all equity interests in any and all relevant entities (including non-publicly traded) that amount to more than a five percent ownership interest; or when aggregated with family members' interests, exceed \$5,000 annually (per entity) determined by fair market value.

Exception: exclude ownership of diversified mutual fund shares, unless you or a family member directly controls the investment decisions.

Intellectual Property Interest

Intellectual property rights (patents, copyrights, licensures, and royalties) related to a relevant

¹ NOTE: This SOP does not address or satisfy FDA Financial Disclosure by Clinical Investigators Requirements identified in [21 CFR 321.53](#) and [21 CFR 812.43](#) which state that the IND/IDE sponsor shall obtain sufficient accurate financial information that will allow an applicant of a marketing application to submit complete and accurate certification or disclosure statements as required under [21 CFR 54](#). Members may be required to submit additional conflict of interest reports at the request of an IND holder. For more information, please view the DAIDS/RSC Protocol Registration Office [website](#).

entity, product or product line. Declare upon receipt of income from rights and interests, if those payments, in aggregate with all other stipulated sources, shall exceed \$5,000, and upon execution of a licensing or equivalent agreement that creates a right to receive income in the future that is directly and significantly related to a relevant entity.

Relevant Entity

An 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 when the investigator could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

Significant Financial Interest

“Significant Financial Interest” means any stock options, or anything of monetary value from a relevant entity (e.g., pharmaceutical, diagnostic, biologic, software, assay or related products engaged in collaborations with the networks; consultant fee including lecture/seminar fees; intellectual property income; teaching fees; equipment; equities; gifts; honoraria; travel; direct salary support or other direct benefits from industry-sponsored research; service grant; contract; or membership on scientific/clinical advisory board) from a public or nonprofit entity that when aggregated for the network member and family members **exceed \$5,000 annually**. Whether made directly or indirectly (except as noted below), 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. This applies to financial interests in a single entity and not a total of financial interests in numerous entities combined.

Title 42CFR50 does not require the reporting of:

- Salary, royalties, 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.
- Income from seminars, lectures, or teaching engagements sponsored by and service on advisory or review panels for a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as the investigator does not directly control the investment decisions made in these vehicles.
- Sponsored travel where expenses are paid by a Network, a Clinical Research Site, a federal, state or local government agency, an Institution of Higher Education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of Higher Education. Note: ACTG does not require investigators to report their travel.

Stock Options

A “stock option” is an option to buy stock in a company at a future date at an agreed price (“strike price”). All stock options in relevant entities with significant financial interests must be disclosed. Stock options must always be disclosed, regardless of the shares’ strike price or whether the company concerned is being publically traded.

2.2 Other Definitions

Conflict Management Plan

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

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”. Disclosures will be made through AAMC’s Convey online reporting system.

Family Member

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

Grantee Institution

A “grantee institution” is defined as the entity or organization that received and manages the NIH HIV/AIDS network clinical trial research funding.

Manage

Taking action to address a financial conflict of interest, action can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

Network

A “network” is defined as an affiliated group of national and international medical research institutions and investigators supported and/or sponsored by NIH 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 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 Microbicide Trials Network (MTN), and the Pediatric HIV/AIDS Cohort Study (PHACS).

Network Members required to disclose under this policy

The following people will be asked to submit financial disclosure statements from each of the six NIH HIV/AIDS Clinical Trials Networks:

- ❑ All members of leadership (executive), endpoint, and scientific review committees;
- ❑ All members of network study monitoring committees; and/or
- ❑ Protocol team chairs, co (vice) chairs, and protocol team members that make direct and significant contribution to the data or the study as determined by network leadership (e.g., protocol virologist, immunologist, SDMC personnel, and pharmacologist).

Members of a protocol team who do not have key decision-making roles are not required to disclose under this policy. Neither are industry representatives and federal government employees, who are required to report under other federal guidelines. Community representatives are also exempt.

Recusal

“Recusal” is the act of removing oneself from deliberations or voting on a matter because of a potential or real conflict of interest. All recusals should be recorded in the relevant summaries of committee and

other group meetings.

Review Committee

“Review Committee” is the group(s) charged by each network to consider and adjudicate 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 an online “Statement of Financial, Equity, and Intellectual Property Interests” at least annually, or when joining a protocol team or committee. The FDC (via the cross-network online reporting system) will inform network members required to report of the need to submit a new or revised “Statement of Financial, Equity, and Intellectual Property Interests” annually as determined by the networks. If there is a significant change in the member’s interests in the following year, 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). Failure to provide the statement by the stated deadline will result in suspension of member participation in committee and protocol team activities until a statement is received.

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 conflict of interest identified by a network review committee.

If a conflict is identified by the network’s review committee, the individual must prepare or agree to an appropriate 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 and Network 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 conflicts;
- Severance of relationships that create conflicts;
- Recusal from voting on questions or matters involving products of the entity in question or its direct competitors (i.e., those entities having a similar scientific mission – development of HIV vaccine, topical microbicide HIV prevention product, HIV treatment products, etc.)

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 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(s) 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 significant financial interests.

3.3 Review Committee

Open disclosure is the primary means of managing 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 exists when the relevant chair(s) reasonably determines that a significant financial interest could directly and significantly affect the design, conduct, or reporting of PHS-funded research [see 42 CFR 50.603, "Financial Conflict of Interest"]. If the relevant chair(s) determines a 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 record of all Statements of Financial, Equity, and Intellectual Property Interests submitted to the operations center.

Database records of network members disclosing significant financial interests in a relevant entity will be maintained to assist the relevant committee chair(s) and protocol chairs to determine whether potential conflicts of interest exist. If a conflict is identified, the network operations center will document and assist in the administration of the resulting conflict management plan.

eRA Commons Module Reporting: The network operations center and/or grantee institution 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 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 and/or grantee institutions will report all conflicts of interest through the [online eRA Commons FCOI 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 and/or grantee institution is required to ensure public accessibility, via a publicly accessible website or written response to any requestor within five business days of a request, of information concerning any significant financial interest disclosed to the institution that meets the following three criteria:

- ❑ The significant financial interest was disclosed and is still held by the investigator;
- ❑ The institution determines that the significant financial interest is related to the network research; and
- ❑ The institution determines that the significant financial interest is a financial conflict of interest.

The information to be made public will include, at a minimum: the member's name; the title and role with respect to the research project; the name of the entity in which the significant financial interest is held; the nature of the significant financial interest; and the approximate dollar value of the significant financial interest; or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value. Information concerning the significant financial interests of an individual subject to paragraph will remain available, for responses to written requests or for posting via the network's and/or grantee institution's publicly accessible website for at least three years from the date that the information was most recently updated.

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 NIH Division of AIDS (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

Guidelines for Completing Statement of Financial, Equity, and Intellectual Property Interests

On the *NIH 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.

- Direct salary support or other direct benefits from industry-sponsored research
- Consultant fee, direct and indirect (including lecture/seminar fees)
- Teaching fees
- Service grant, contract, or membership on scientific/clinical advisory board
- Equipment
- Gift
- Honoraria
- Stock owned by you or a family member
- Stock option owned by you or a family member
- Mutual funds owned by you or a family member, only if you have/the family member has direct control over the investment decisions.
- Copyrights
- Royalties
- Travel ***Not applicable to ACTG.**
- Equity Interest
- Intellectual property rights with relevant entities with a significant financial interest (patents, pending patents, copyrights, licensures, and royalties) or potential earnings from any patent held by any other party.

If there is a significant change in the member's interests, 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.

Please confirm need to declare individual interests before submitting the Statement of Financial, Equity, and Intellectual Property Interests.

The most recent HHS rule on "Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors" can be found at: <http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>.

Additional NIH guidance can be found at: <http://grants.nih.gov/grants/policy/coi/index.htm>.

For substantive questions concerning the HHS Rule, email: FCOICompliance@mail.nih.gov.

For questions about network-specific policies and procedures (including conflict management processes), please refer to your network(s)' operation center or member website.