HIV-NAT's Financial Conflict of Interest (FCOI) policy

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Financial Conflict of Interest (FCOI) policy, regulation and process of HIV-NAT

Introduction

This document describes the financial conflict of interest (FCOI) policy, regulation and process of HIV Netherlands Australia Thailand Research Collaboration (HIV-NAT), Thai Red Cross AIDS and Infectious Diseases Research Centre (AIDSID) (HIV-NAT, hereafter also referred to as the "Institution"). This policy, regulation and process is also referred to as the Code of Conduct and will be used interchangeability throughout the document. It is intended to guide staff to identify and resolve issues of ethical conduct as well as the disclosure, management and resolution of significant financial conflict of interest that pertains to Investigators/key personnel who are responsible for the design, conduct or reporting of research funded by the United States – Public Health Service (US-PHS)/national institute of health (NIH) that may arise during their employment. It is designed to guide staff in their dealing with colleagues, students and the national and international communities i.e. NIH, NIAID (DAIDS)-supported and/or Sponsored HIV/AIDS Clinical Trial Networks Financial Disclosure and Conflict of Interest Guidelines, the Office of HIV/AIDS Network Coordination (HANC). The Code is written as a set of general principles rather than detailed prescriptions and part of Financial Conflicts of Interest intended to establish compliance with the US. Department of Health and Human Services (DHHS) regulations (42 CFR Part 50 Subpart F), 45 CFR Part 94 and US FDA regulation (21 CFR Part 54). The Code stands beside but does not exclude or replace the rights and obligations of the staff under common law.

Scope

This policy, regulation and process applies to all Investigators at HIV-NAT who are responsible for the design, conduct or reporting of research funded by the US-PHS/NIH.

References

This policy, regulation and process is based on the 42 CFR Part 50, Subpart F, Promoting Objectivity in Research, applicable to Public Health Service (e.g., NIH) grants and cooperative agreements.

Regulatory requirements	**Regulatory citation or NIH GPS**
Training requirements	42 CFR 50.604(b)
Disclosure, Review, Manage and Monitor Requirements	42 CFR 50.603 42 CFR 50.604(e)(1)-(3) 42 CFR 50.604 (f) 42 CFR 50.604(g) 42 CFR 50.605(a)(1)-(6)
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Subrecipient Requirements	42 CFR 50.604(c) and NIH GPS 15.2 1
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Maintenance of Records	42 CFR 50.604 (i)

Definitions (42 CFR 50.603)

Disclosure of significant financial interests means an Investigator's disclosure of significant financial interests to an Institution.

Equity Interest means any ownership interest in any commercial or non-profit entity, including common stock and other equity securities, and any right to acquire any options, warrants or other convertible securities (this does not include "indirect" equity interest through mutual funds).

Financial conflict of interest (FCOI) means a significant financial interest (SFI) that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

FCOI report means an Institution's report of a financial conflict of interest to a PHS Awarding Component.

Financial interest means anything of monetary value, whether or not the value is readily ascertainable.

Form FDA 1572 is FDA required document in which clinical investigators agree to conduct the clinical trials according to Federal Regulations. The Form FDA 1572 is signed and submitted to the UBD sponsor (DAIDS). It is required for each investigator that participates in any clinical trial (drug or biologic). Section 6 of the form provided the complete name of all study staff at a CRS that are responsible for making a "direct and significant contribution to the data" including study physicians, study coordinator, and study nurses, etc.

HHS means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

Institution means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS research funding.

Institutional responsibilities means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Intellectual Property Interest means Intellectual property rights (patents, copyrights, licensures, and royalties) related to a relevant entity, product, or product line.

Investigator means the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants, Investigator's spouse and dependent children.

Investigator's Institutional Responsibilities means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Manage means taking action to address a financial conflict of interest, which 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.

Management Plan means a written plan for the management, reduction, or elimination of a potential conflict of interest relating to Research arising from a Significant Financial interest (SFI).

PD/PI means a project director or principal Investigator of a PHS-funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator under this subpart.

PHS means the Public Health Service, as an operating division of the U.S. Department of Health and Human Services. As part of the Public Health Service, there are eight from eleven divisions within the Department of Health and Human Services that are listed:

- National Institutes of Health
- Centers for Disease Control and Prevention
- Indian Health Service
- Food and Drug Administration
- Agency for Toxic Substances and Disease Registry
- Health Resources and Services Administration
- Agency for Healthcare Research and Quality
- Substance Abuse and Mental Health Services Administration

PHS Awarding Component means the organizational unit of the PHS that funds the research that is subject to this subpart.

Public Health Service Act or PHS Act means the statute codified at 42 U.S.C. 201 *et seq.*

Research means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including

behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). As used in this subpart, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

Senior/key personnel means the project director (PD)/principle investigator (PI) and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the NIH by the Institution under this regulation.

Significant financial interest (SFI) means:
A financial interest consisting of one or more of the following interests of the Investigators/key personnel (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

- Remuneration (including salary, consulting fees, honoraria, paid authorship and travel reimbursement) received from a publicly traded company during the twelve-month period preceding the date on which an Investigator is making a disclosure, and/or an Equity Interest held in such publicly traded company, if the aggregate value of such remuneration, plus the value of the equity interest as of the date of disclosure, exceeds $5,000
- Remuneration (including, but not limited to, salary, consulting fees, honoraria and paid authorship) received from a non-publicly traded company during the twelve-month period preceding the date on which an Investigator is making a disclosure, if the remuneration exceeds $5,000
- 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
- Intellectual property rights (patents, copyrights, licensures, and royalties) related to a relevant 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.

SFI Exclusions:

- Salary royalties, or other renumeration paid by the Institution to the Investigators/key personnel if the Investigators/key personnel is currently employed or otherwise appointed by the institution

- Intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights
- Anything of monetary value given to the institution or to the member exclusively in support of research or the clinical trial
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigators/key personnel 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.
- Income from seminars, lectures, or teaching engagements sponsored by 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; or
- Income from service on advisory committees or review panels for a federal, state or local government agency, institution of higher education as defied 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.

Academic Staff

Recognizes that many of its academic and other professional personnel are also bound by codes of conduct or ethics defined by professional societies or groups. Academic personnel in particular have multiple allegiances: to their disciplines or profession at the national and international levels, to the academic profession, to the community at large and to HIV-NAT. It is recognized that these allegiances are not always in harmony. It is an obligation of each staff member to weigh the importance of these allegiances in each particular set of circumstances and to notify the General Manager when such conflict does or may arise.

HIV-NAT recognizes and safeguards academic freedom as essential to the proper conduct of teaching, research, and obtaining/offering scholarship. While academic freedom is a right, it carries with it the duty of academics to use such freedom in a manner consistent with a responsible and honest search for and dissemination of knowledge. Where such comments are offered by academics, it is expected that those commentaries will be within their expertise. Their expectation is not intended to restrict the right of any academic to freely express their opinions in their private capacity as an individual member of society.

STAFF at HIV-NAT

Primary Obligations

Every member of staff at HIV-NAT has three primary obligations:

1. A duty of care to observe standards of equity and justice in dealing with all colleagues;
2. An obligation to, in terms of responsible stewardship of its resources and protection of its reputation in the wider community;
3. An obligation to act appropriately when a conflict arises between a staff member's own self interest and duty to HIV-NAT.

Obligations to Colleagues

With respect to their obligations to colleagues, all personnel should:

1. Treat other personnel with respect;
2. Not allow personal relationships to affect professional relationships;
3. Refrain from all forms of harassment;
4. Give due credit to the contributions of other members of staff and acknowledge openly the valid contributions of any personnel to any piece of work, especially if the work leads to publication;
5. Refrain from acting in any way that would unfairly harm the reputation and career prospects of other staff;
6. Consider the desirability of intervening constructively where a colleague's behavior is clearly in breach of this code, and be prepared to report any suspected fraud, and any corruption, criminal or unethical conduct to the General Manager at HIV-NAT;
7. Consider the impact of decisions on the well-being of other staff;
8. Respect individuals' right to privacy and undertake to keep personal information in confidence

Obligations to HIV-NAT

With respect to their obligation to HIV-NAT, the member of staff should:

1. Refrain from representing themselves as spokespersons for HIV-NAT unless authorized to do so;
2. Refrain from representing themselves as acting for or on behalf of HIV-NAT when undertaking any outside work unless authorized to do so;
3. Refrain from engaging in any outside work that would compromise their integrity and independence;
4. Avoid improper use of the resources for private gain or the gain of a third party;
5. Foster collegiality among their colleagues at HIV-NAT

Obligations regarding Conflict of Interest

Investigators must disclose all foreign financial interests (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from any foreign entity, including foreign Institutions of higher education and foreign governments (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (e.g., income in excess of $5,000). HIV-NAT will review their FCOI policy and make any necessary changes to ensure Investigators fully understand their disclosure responsibilities.

Each investigator must disclose his/her SRIs (and those of the Investigator's spouse and dependent children) related to the Investigator's institutional responsibilities that meets or exceeds the regulatory definition of SFI (42 CFR 50.603):

With respect to conflict of interest, staff members:

1. Should take suitable measures to avoid any situation in which they may have, or be seen to have, a conflict of interest arising out of their relationship with another staff member;
2. Should take suitable measures to avoid neither advantaging nor disadvantaging those being supervised;
3. Must take care that their financial and other interests and actions do not conflict or seem to conflict with the obligations and requirements of their position at HIV-NAT.

In particular, all personnel should avoid situations which may require them to supervise or assess another employee with whom they have, or have had, personnel, commercial, familial or other significant relationship.

Where both a supervisory role and significant relationship between staff member co-exist, supervision must be openly seen to be of the highest professional standard. Where any conflict does or may arise, the issue should be disclosed to the General Manager at and, wherever feasible, the staff member who discloses such potential conflict should plan no role in decision-making that might be associated with the potential conflict.

After notification and the General Manager becomes aware of a conflict or potential conflict of interest, he or she should:

- Inform the staff member involved of the provisions of the Code of Conduct as a basis for deciding on an appropriate way to handle the issue
- Where appropriate, notify the matter to Assistant Director for further attention

Procedures for Managing Financial Conflict of Interest at HIV-NAT and affiliated sites

1. Establishment of "Conflicts of Interest Committee" and "Financial Disclose Coordinator (FDC)"

A Conflict of Interest Committee (COIC) and/or Financial Disclose Coordinator (FDC) will be established and appointed by the Director and CRS Leader to review all financial disclosures by Investigators/key personnel and determine whether any Significant Financial Interest (SFI) is related to a NIH-funded research and a Financial Conflict of Interests exists by making a reasonable determination that Significant Financial Interest could be affected by the NIH funded research or is in an entity whose financial interest could be affected by the research.

2. Disclosure of Significant Financial Interest (SFI) (42 CFR 50.603 and 42 CFR 50.604(e)(1)-(3))

2.1 Each and affiliated sites' Investigators/key personnel participating in the US PHS/NIH funded research, including spouse and dependent children, must disclose all significant financial interest (SFI) that is related to the proposed project. The SFI includes any remuneration received from an entity in the twelve months preceding the disclosure and the value of any publicly traded or non-publicly traded equity interest in the entity as the date of disclosure, when aggregated, exceeds $5,000. The **Significant Financial Interest Disclosure Form is available in the Attachment #1 and/or Attachment #2.**

The completed disclosure of SFI should be submitted to FDC and the time of submission is as follows:

- Initial (No later than at the application): Require that each Investigator/key personnel, including sub recipient Investigators submit SFI before submitting the proposal.
- Pre-research (before start): Require that each Investigator/key personnel, including sub recipient Investigators submit SFI before the start of the research study/project.
- Annually (during research study/project): Require each Investigator, including sub recipient Investigators/key personnel, if applicable, to submit an updated disclosure of SFI at least annually (by 30 September of each calendar year), during the period of the award. Such disclosure shall include any information that was not disclosed initially to the Institution, and shall include updated information regarding any previously disclosed significant financial interest (e.g., the updated value of a previously disclosed equity interest).
- New SFI (within 30 days): Require each Investigator/key personnel, including sub recipient Investigator, if applicable, who is participating in a PHS-funded research to submit an updated disclosure of SFI within 30 days of discovering or acquiring it (e.g., through purchase, marriage, or inheritance).
- Newly added investigator: All newly-added investigators/key personnel on PHS/NIH-funded research must submit a completed SFI disclosure within 30 days after beginning work on the research study/project. The principal investigator or study coordinator is responsible for informing newly added investigators/key personnel of the requirement and ensuring that they submit disclosure forms.

2.2 Investigators/key personnel must disclose the occurrence of any reimbursed travel or sponsored travel (i.e., that which is paid on behalf of the Investigators/key personnel and not reimbursed to the Investigators/key personnel so that the exact monetary value may not be readily available), related to the Investigator's Institutional responsibilities. However, the disclosure requirement does not apply to travel that is reimbursed or sponsored by the following:

- 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

2.3 Investigators/key personnel who conduct research funded by DAIDS HIV/AIDS Network (i.e., ACTG, IMPAACT, HPTN, MTN, INSIGHT, HVTN) must comply with NIAID (DAIDS)-supported and/or sponsored HIV/AIDS Clinical Trials Networks Standard Operating Procedure on "Financial Disclosure and Conflict of Interest Guidelines".

Investigators (networks members) must complete a "Statement of Financial, Equity, and Intellectual Property Interests" (Attachment #3) and submit it to each affiliated network.

Designation of a Financial Disclose Coordinator (FDC) (42 CFR 50.604(d)

-The FDC will solicit and review disclosures of SFIs from each Investigator (and those of the Investigator's spouse and dependent children) who is planning to participate in, or is participating in, the PHS/NIH-funded research as well as related to an Investigator's institutional responsibilities.

-The FDC should review disclosures of SFIs from each investigator at least annually, or when joining a protocol team or committee. The FDC will notify each investigator to report or revise his/her "Statement of Financial, Equity, and Intellectual Property Interests" by 31 May of each calendar year.

- The Institute will provide adequate guidelines to the FDC so he/she can determine whether an Investigator's SFI is related to PHS/NIH-funded research and, if so related, whether the SFI is a FCOI. An Investigator's significant financial interest is related to PHS/NIH-funded research when the Institution, through its designated official(s), reasonably determines that the significant financial interest: could be affected by the PHS-funded research; or is in an entity whose financial interest could be affected by the research. The Institution may involve the Investigator in the designated official(s)'s determination of whether an SFI is related to the PHS/NIH-funded research. A financial conflict of interest exists when the Institution, through its designated official(s), reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS/NIH-funded research.

3. Identification, evaluation and management or elimination of FCOI (42 CFR 50.605(a)(1)-(2))

3.1 The FDC will determine whether SFI relates to NIH funded research and

- If the FDC determines that no conflict of interest exists, it will conclude its assessment.
- If the FDC determines that Investigators/key personnel has Financial Conflict of Interests (FCOI) that would reasonably appear to directly and significantly affect the sponsored project, the COIC may recommend to the Director that the project cannot proceed. The investigators/key personnel may also be asked to prepare a Management Plan to reduce, minimize or eliminate conflicts of interest.
- If the FDC is unable to make this determination, he/she will invite the Investigators/key personnel who submitted the disclosure to meet with the Committee and explain the circumstances of the research and the possible conflict of interest. The COIC will determine whether a conflict of interest exists and if so, work with the Investigators/key personnel to determine how it might be managed or resolved to best protect the Investigators/key personnel, the Institute and the research results.
- Investigator who is new to participating in the research project discloses a significant financial interest or an existing Investigator discloses a new significant financial interest to the Institution, the FDC shall, within sixty days: review the disclosure of the significant financial interest; determine whether it is related to NIH-funded research; determine whether a financial conflict of interest

exists; and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest. Depending on the nature of the significant financial interest, an Institution may determine that additional interim measures are necessary with regard to the Investigator's participation in the NIH-funded research project between the date of disclosure and the completion of the Institution's review.

3.2 Investigators/key personnel may request reconsideration made by the FDC that affects the investigators'/key personnel's ability to participate in PHS/NIH funded research. A request for reconsideration must be made within ten (10) business days from receipt of notification of the decision by the COIC. Requests must be made in writing and directed to HIV-NAT's Director.

3.3 The management plan must be approved by the FDC, COIC and the Director of HIV-NAT, before any expenditure is made using the US federal award.

Key elements of the Institution's management plan include the following:

1. Role and principal duties of the conflicted Investigator in the research project;
2. Conditions of the management plan;
3. How the management plan is designed to safeguard objectivity in the research project;
4. Confirmation of the Investigator's agreement to the management plan;
5. How the management plan will be monitored to ensure Investigator compliance; and
6. Other information as needed.

Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:

- Public disclosure of the related financial Interest(s) (e.g., when presenting or publishing the research), to the participants, researchers, Institutional Review Board(s) and/or conference organizers;
- Disclosure of FCOI directly to human subjects research participants;
- Monitoring of the project by independent reviewers or their designee to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
- Modification of the research or project plan to avoid conflicts of interest;
- Change of personnel responsibilities or disqualifications of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g. sale of an equity interest); or
- Severance of relationships that create financial conflicts.

4. Management of Non Compliance (42 CFR 50.605(a)(3)(i-iii)-(4) and 42 CFR 50.604(g))

4.1 Non-compliance of this policy includes but is not limited to:

- Failure to comply with the disclosure process (by refusal to respond, by deliberately responding with incomplete, inaccurate, or misleading information
- Failure to remedy significant financial conflicts of interest, and
- Failure to comply with the management plan for significant financial conflicts of interest.

4.2 The FCD shall, within sixty days: review the significant financial interest; determine whether it is related to PHS/NIH-funded research; determine whether a financial conflict of interest exists; and, if so:

- Implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward;

4.3 The Institution shall, within 120 days of the Institution's determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS/NIH-funded research project to determine whether any PHS/NIH-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.

- The Institution is required to document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following key elements:
  (*1*) Project number;
  (*2*) Project title;
  (*3*) PD/PI or contact PD/PI if a multiple PD/PI model is used;
  (*4*) Name of the Investigator with the FCOI;
  (*5*) Name of the entity with which the Investigator has a financial conflict of interest;
  (*6*) Reason(s) for the retrospective review;
  (*7*) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
  (*8*) Findings of the review; and
  (*9*) Conclusions of the review.
- Based on the results of the retrospective review, if appropriate, the Institution shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, the Institution is required to notify the PHS/NIH Awarding Component promptly and submit a mitigation report to the PHS/NIH Awarding Component.
- The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the Institution's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, the Institution will submit FCOI reports annually, by 31 May of each calendar year.

4.4 Depending on the nature of the financial conflict of interest, an Institution may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS/NIH-funded research project between the date that the financial conflict of interest or the Investigator's noncompliance is determined and the completion of the Institution's retrospective review.

4.5 The Institution shall monitor the Investigator's compliance with the management plan on an ongoing basis until the completion of the PHS/NIH-funded research project.

5. Reporting Requirements and Records Retention

Reporting Requirements (42 CFR 50.604(h); 42 CFR 50.605(a)(3)(iii); and 42 CFR 50.605(b))

5.1 Based on the recommendation of the FDC, CRS Leader, the director of HIV-NAT, and COIC, HIV-NAT will provide initial, annual (i.e., ongoing) and revised FCOI reports, including all reporting elements required by the regulation, to NIH for the Institution and its subrecipients, if applicable, as required by the regulation, electronically through the eRA Commons FCOI Module:

Initial FCOI report will include the following information:

- Grant number and PD/PI or Contact PD/PI if the grant is awarded under the multiple PI model;
- Name of Investigator (if different from the PD/PI) with the FCOI;
- Name of the entity with which the Investigator has an FCOI;
- Nature of the FCOI (e.g., consulting fees, honoraria, paid authorship, equity interest, intellectual property rights and interests, and reimbursed or sponsored travel);
- Value of the financial interest $0-4,999; $5,000-9,999; $10,000-19,999; amounts between $20,000-100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000 or a statement that a value cannot be readily determined;
- A description how the financial interest relates to NIH-funded research and the basis for the Institution's determination that the financial interest conflicts with such research

The annual FCOI report will include the following information:

- Status of the FCOI
- Changes to the management plan, if applicable

All reporting must be done as follows:

- Prior to the expenditure of funds;
- During the period of award
  - Within 60 days of identification for an Investigator who is newly participating in the project;
  - Within 60 days of identifying a new FCOI for existing Investigators;

- Notify PHS Awarding Component/NIH promptly if bias is found with the design, conduct or reporting of NIH-funded research and submit a Mitigation Report;
    - Documentation shall include, but not necessarily be limited to, all of the following key elements:
        (*1*) Project number;
        (*2*) Project title;
        (*3*) PD/PI or contact PD/PI if a multiple PD/PI model is used;
        (*4*) Name of the Investigator with the FCOI;
        (*5*) Name of the entity with which the Investigator has a financial conflict of interest;
        (*6*) Reason(s) for the retrospective review;
        (*7*) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
        (*8*) Description of the impact of the bias on the research project and the Institution's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable);
        *(9)*Findings of the review; and
        (*10*) Conclusions of the review.
- Notify NIH promptly if an Investigator fails to comply with the Institution's FCOI policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the NIH-funded research (42 CFR 50.606(a)) so that a corrective action for noncompliance with the Institution's policy or management plan can be carried our swiftly
- For noncompliant Investigator, interim reports are required for submission
- If applicable, update a previously submitted FCOI report to describe actions that will be taken to manage FCOI going forward.
- Following a retrospective review to update a previously submitted report, if appropriate

• Annually until completion of the project
- FDC will report on the status of FCOI and any changes in the management plan;
- the Investigator must also simultaneously submit an annual progress report, including multi-year progress reports, at the time of the research's/project's extension

All FCOI report must include sufficient information to enable the NIH to understand the nature and extent of the Financial Conflict of Interest (FCOI) and to assess the appropriate management plan utilized by the Institution. The key elements that must be included in the FCOI report to NIH (but are not limited to) include:

- Grant number;
- Name of the PD/PI;

- Name of the Investigator with the FCOI;
- Name of the entity with which the Investigator has FCOI;
- Nature of FCOI (e.g. equity, consulting faces, travel reimbursement, honorarium);
- Value of the financial interest $0-4,999, $5K-9,999, $10K-19,999; amounts between $20K-100K by increments of $20K; amounts above $100K by increments of $50K or a statement that the value cannot be readily determined;
- A description how the financial interest is related to the NIH-funded research and why the Institute determined that the financial conflict of interest is what?
- A description of the key elements of the Institution's management plan, including:
  - Role and principal duties of the conflicted Investigator in the research project;
  - Conditions of the management plan;
  - How the management plan is designed to safeguard objectivity in the research project;
  - Confirmation of the Investigator's agreement to the management plan;
  - How the management plan will be monitored to ensure investigator compliance; and
  - Other information as needed

6. Retention of the Records (42 CFR 50.604(i))

6.1 Maintain records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures (whether or not a disclosure resulted in the Institution's determination of a financial conflict of interest) and all actions under the Institution's policy or retrospective review, if applicable, *for at least three years from the date the final expenditures report* is submitted to the PHS or, for federal awards that are renewed quarterly or annually, from the date of the submission of the quarterly or annual financial report, respectively, as reported to the HHS awarding agency or pass-through entity in the case of a subrecipient (45 CFR 75.361).

7. Enforcement Mechanisms and Remedies and Noncompliance

7.1 FDC and COIC will develop enforcement mechanisms that will be used to ensure Investigator compliance (42 CFR 50.604(j))

7.2 For noncompliance for SFIs not disclosed timely by the Investigator or previously reviewed or whenever an FCOI is not identified or managed in a timely manner (e.g., was not timely reviewed or reported by a subrecipient), the FDC shall, within sixty days, review the significant financial interest; determine whether it is related to PHS/NIH-funded research; determine whether a financial conflict of interest exists (42 CFR 50.605(a)(3)); and, if so:

(i) Implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward;

(ii)

(A) In addition, whenever a financial conflict of interest is not identified or managed in a timely manner including failure by the Investigator to disclose a significant financial interest that is determined by the Institution to constitute a financial conflict of interest; failure by the Institution to review or manage such a financial conflict of interest; or failure by the Investigator to comply with a financial conflict of interest management plan, the Institution shall, within 120 days of the Institution's determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS/NIH-funded research project to determine whether any PHS/NIH-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.

(B) The Institution is required to document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following key elements:

(*1*) Project number;
(*2*) Project title;
(*3*) PD/PI or contact PD/PI if a multiple PD/PI model is used;
(*4*) Name of the Investigator with the FCOI;
(*5*) Name of the entity with which the Investigator has a financial conflict of interest;
(*6*) Reason(s) for the retrospective review;
(*7*) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
(*8*) Findings of the review; and
(*9*) Conclusions of the review.

(iii) Based on the results of the retrospective review, if appropriate, the Institution shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, the Institution is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the Institution's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, the Institution will submit FCOI reports annually, as specified elsewhere in this subpart. Depending on the nature of the financial conflict of interest, an Institution may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date that the financial conflict of interest or the Investigator's noncompliance is determined and the completion of the Institution's retrospective review.

7.3 As per 42 CFR 50.606(c), if the Department of Health and Human Services determines that a PHS/NIH-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by the Institution, the Institution shall require the Investigator involved to:

- disclose the financial conflict of interest in each public presentation of the results of the research
- provide an addendum to previously published presentations.

8. Subrecipient Requirements

The Institution must enter into a formal written agreement, signed and agreed to by the recipient and each consortium participant and/or subrecipient. The agreement must establish whether the FCOI policy of the recipient Institution or that of the subrecipient will apply to subrecipient Investigators and in either case, the agreement must include required significant financial interest disclosure, review, and FCOI reporting timelines to ensure compliance with the FCOI regulations. Subrecipient Institutions who rely on their FCOI policy must report identified FCOIs to the recipient Institution in sufficient time to allow the recipient Institution to report the FCOI to NIH to meet its reporting obligations. (See Consortium Agreements, 15.2.1 Written Agreement.)

NIH will not support any agreement that does not meet the minimum requirements. If a subrecipient is unwilling to accept the requirements of the written agreement by signing the agreement, then the agreement cannot be issued. NIH reserves the right to request copies of the written agreement and relevant supporting documentation as needed as part of its oversight responsibilities. Failure to provide requested documentation may lead to remedies for noncompliance and potential enforcement actions (See 8.5, Specific Award Conditions and remedies for noncompliance).

Manage financial conflicts of interest of a subrecipient Investigator (42 CFR 50.604(c)(1)(i)-(iii))

8.1 If the Institution carries out the PHS/NIH-funded research through a subrecipient (e.g., subcontractors or consortium members), the Institution (awardee Institution) must take reasonable steps to ensure that any subrecipient Investigator complies according to the following:

- Incorporating as part of a written agreement with the subrecipient terms that establish whether the financial conflicts of interest policy of the awardee Institution or that of the subrecipient will apply to the subrecipient's Investigators.

  (i) The subrecipient's Investigators must comply according to their certified subrecipient's financial conflicts of interest policy. If the subrecipient cannot provide such certification, then the subrecipient Investigators must abide by the financial conflicts of interest policy of the awardee Institution. The subrecipient Investigator must disclose significant financial interests that are directly related to the subrecipient's work to the awardee Institution;

  (ii) Additionally, if the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the agreement referenced above shall be completed within one month. The subrecipient must report all identified financial conflicts of interest to the awardee Institution within this time frame. One month is sufficient to enable the awardee Institution to provide timely FCOI reports, as necessary, to the PHS as required;

  (iii) Alternatively, if the subrecipient's Investigators must comply with the awardee Institution's financial conflicts of interest policy, the agreement referenced above must be completed within one month. The subrecipient must submit all Investigator disclosures of significant financial interests to the awardee Institution within one month. One month is sufficient to enable the awardee

Institution to comply timely with its review, management, and reporting obligations.

NIH Grants Policy Statement 15.2.1 Written Agreement

The recipient must enter into a formal written agreement, signed and agreed to by both parties, with each consortium participant/subrecipient that addresses the negotiated arrangements for meeting the scientific, administrative, financial, and reporting requirements of the grant, including those necessary to ensure compliance with all applicable Federal regulations and policies and facilitate an efficient collaborative venture. If a subrecipient is unwilling to sign the written agreement outlining the requirements below, then a subaward cannot be issued. At a minimum, this agreement must include the following:

- Identification of the individual who will serve as the consortium lead investigator and other individuals responsible for the research activity at each consortium participant along with their roles and responsibilities.
- When multiple PD/PIs are involved at different organizations, only the Contact PD/PI is required to have the official relationship with the applicant organization. PD/PIs in the leadership team at other organizations must have a documented relationship with a consortium organization, but need not be employees. Any **consortium agreement** must address the unique aspects to these individuals holding the PD/PI role including the requirement for the pass-through entity to secure and retain all PD/PI signatures for all applications, progress reports, and post-award **prior approval** requests. Further, such signatures must be made available to NIH or other authorized DHHS or Federal officials upon request. See Multiple Program Director/Principal Investigator Applications and Awards for additional information.
- Procedures for directing and monitoring the research effort.
- Procedures to be followed in reimbursing each consortium participant for its effort, including dollar ceiling, method and schedule of reimbursement, type of supporting documentation required, procedures for review and approval of expenditures of grant funds at each organization and timing of applicable reporting requirements. This includes provisions on access to core facilities and resources and whether access will be provided as a fee-for-service.
- If different from those of the recipient, a determination of policies to be followed in such areas as travel reimbursement and salaries and fringe benefits (the policies of the consortium participant may be used as long as they meet NIH requirements).
- Terms that establish whether the Financial Conflict of Interest policy of the pass-through entity or that of the subrecipient will apply to the subrecipient's Investigators.
- If the subrecipient's Investigators must comply with the pass-through entity's Financial Conflict of Interest policy, the subrecipient shall certify as part of the written agreement that its policy complies with the 2011 revised FCOI regulation (42 CFR Part 50 Subpart F). If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the Financial Conflict of Interest policy of the

pass-through entity for disclosing Significant Financial Interests that are directly related to the subrecipient's work for the pass-through entity.

- If the subrecipient's Investigators must comply with the subrecipient's Financial Conflict of Interest policy, the written agreement shall be completed within one month for the subrecipient to report all identified Financial Conflicts of Interest to the pass-through entity. One month is sufficient to enable the pass-through entity to provide timely FCOI reports, as necessary, to the PHS as required by the regulation.
- Alternatively, if the subrecipient's Investigators must comply with the pass-through entity's Financial Conflict of Interest policy, the written agreement shall be completed within one month for the subrecipient to submit all Investigator disclosures of Significant Financial Interests to the pass-through entity. One month is sufficient to enable the pass-through entity to comply timely with its review, management, and reporting obligations under the 2011 revised FCOI regulation.
- A provision addressing ownership and disposition of data produced under the **consortium agreement**. This includes whether cell lines, samples or other resources will be freely available to other investigators in the scientific community or will be provided to particular investigators only.
- A provision making NIH data sharing and inventions and patent policy, including a requirement to report inventions to the recipient (see Administrative Requirements-Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources in IIA), applicable to each consortium participant and its employees in order to ensure that the rights of the parties to the **consortium agreement** are protected and that the recipient can fulfill its responsibilities to NIH.
- Expectations for authorship and co-authorship on publications.
- Provisions regarding property (other than intellectual property), program income, publications, reporting, and audit necessary for the recipient to fulfill its obligations to NIH.
- Provisions regarding compliance with requirements for a Unique Entity Identifier (UEI) and subrecipient reporting under Federal Funding Accountability and Transparency Act (FFATA) (see Recipient Reporting of Subrecipient Data and Executive Compensation Information for FFATA). Note, the recipient must provide the Federal Award Identification Number (FAIN) to all subrecipients to aid in this requirement.
- Incorporation of applicable public policy requirements and provisions indicating the intent of each consortium participant to comply, including submission of applicable assurances and certifications (see Public Policy Requirements, Objectives, and Other Appropriation Mandates in IIA).
- For foreign subrecipients, a provision requiring the foreign subrecipient to provide access to copies of all lab notebooks, all data and documentation that supports the research outcomes as described in the progress report, to the primary recipient with a frequency of no less than annually, in alignment with the reporting requirements for the Research Performance Progress Report (RPPR). Such access may be entirely electronic.

9. Public Accessibility Requirements (42 CFR 50.604(a) and NIH GPS 4.1.10)

9.1 This policy on Financial Conflict of Interest is available via the Institute's website (www.hivnat.org).

9.2 Identified FCOIs held by senior/key personnel (as defined by the regulation), will be available publicly (www.hivnat.org) or in response to any requestor within five business days of a request prior to the expenditure of funds under a PHS/NIH-funded research project (42 CFR 50.605(a)(5)(i)-(iv)). Information concerning any significant financial interest disclosed to the Institution that meets the following three criteria will be publicly available at www.hivnat.org or in written response to any requestor within five business days of a request:

(A) The significant financial interest was disclosed and is still held by the senior/key personnel;

(B) The Institution determines that the significant financial interest is related to the PHS/NIH-funded research; and

(C) The Institution determines that the significant financial interest is a financial conflict of interest.

9.3 The Institute shall include, at a minimum, the following information:

- the Investigator's name;
- the Investigator's 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 (dollar ranges are permissible: $0-$4,999; $5,000-$9,999; $10,000-$19,999; amounts between $20,000-$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000), 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.

9.4 The information that the Institution posts shall be updated at least annually.

9.5 The Institution shall update the Web site within sixty days of the Institution's receipt or identification of information concerning any additional significant financial interest of the senior/key personnel for the PHS/NIH-funded research project that was not previously disclosed, or upon the disclosure of a significant financial interest of senior/key personnel new to the PHS/NIH-funded research project, if the Institution determines that the significant financial interest is related to the PHS/NIH-funded research and is a financial conflict of interest.

9.6 The Web site shall note that the information provided is current as of the date listed and is subject to updates, on at least an annual basis and within 60 days of the Institution's identification of a new financial conflict of interest.

9.7 If the Institution responds to written requests, the Institution will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of the Institution's identification of a new financial conflict of interest, which should be requested subsequently by the requestor.

9.8 Information concerning the significant financial interests of an individual shall remain available, for responses to written requests or for posting via the Institution's publicly

accessible Web site for at least three years from the date that the information was most recently updated.

10. Training (42CFR50.604 (b))

10.1 Investigator/key personnel will be informed of HIV-NAT's policy, regulation and process (or also referred to the Code of Conduct), their disclosure responsibilities and the federal regulation as per 42 CFR 50.604(b). Each PHS-supported Investigator/key personnel must complete FCOI training (https://grants.nih.gov/policy-and-compliance/policy-topics/fcoi/fcoi-training) prior to engaging in NIH-funded research and at least every four (4) years thereafter or immediately if the following occur:

- Institutional FCOI policies change in a manner that affects Investigator requirements;
- Investigators/key personnel are new to the Institution;
- An Institution finds that Investigators/key personnel are not in compliance with the Institution's FCOI policy or management plan.

10.2 Before beginning a new study, the related staff will be trained on this and applicable policies immediately and annually thereafter.

10.3 Related staff receives or has direct access to this and applicable policies, particularly the institutional policy

10.4 All trainings pertaining to policies are documented and tracked.

10.5 New staff is trained on this and applicable policies within 60 days of joining the study.

10.6 Related staff will be retrained within 60 days of the approval of each policy revision.

11. Contact Information

Financial Disclose Coordinator (FDC): Miss Parawee Thongpaeng
HIV-NAT, Thai Red Cross AIDS and Infectious Diseases Research Centre,
104 Ratchadamri Road, Pathumwan, Bangkok 10330, Thailand
Tel. 66 2 652-3040 # 106; Fax. 66 2 254-7574
Mailbox for inquiries: parawee.t@hivnat.org; HIV-NAT website: www.hivnat.org

General Manager: Ms. Kesdao Nanthapisal
HIV-NAT, Thai Red Cross AIDS and Infectious Diseases Research Centre,
104 Ratchadamri Road, Pathumwan, Bangkok 10330, Thailand
Tel. 66 2 652-3040 # 123; Fax. 66 2 254-7574
Mailbox for inquiries: kesdao.n@hivnat.org; HIV-NAT website: www.hivnat.org

12. Attachments

12.1 Attachment #1 Significant Financial Interests Disclosure Form, Part I
12.2 Attachment #2 Significant Financial Interests Disclosure Form, Part II
12.3 Attachment #3 NIAID (DAIDS) supported and/or sponsored HIV/AIDS Clinical Trial Networks Statement of Significant Financial, Equity, and Intellectual Property Interests

13. Revision History

Version	Page	Description
July 16, 2025	Multiple	It was revised to be consistent with the current US-PHS/NIH policy

Attachment #1

HIV-NAT, Thai Red Cross AIDS and Infectious Diseases Research Centre, Thailand

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Significant Financial Interests Disclosure Form

Part I

Specific Instructions: Place a check in the appropriate column for each question. Once every question is answered, the investigator must certify the information by signing the bottom of the form.

Investigator Name: _____ Date of Disclosure: _____

Position: _____

Email: _____ Phone: _____

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.

Questions	**Yes**	**No**
Do you, your spouse or dependent child (ren) hold a position of management, such as board member, director, officer, partner, trustee, employee or consultant with a sponsor, a vendor or (sub) contractor related to the Public Health Service, part of the U.S. Department of Health and Human Services program activity?	☐	☐
Do you, your spouse or dependent child(ren) have Significant Financial Interest in a Sponsor, a vendor or (sub) contractor related to the Public Health Service, part of the U.S. Department of Health and Human Service program activity? ***"Significant Financial Interest" includes stock, stock options, and/or any other ownership interest in a single entity valued at more than $5,000***	☐	☐
Is it reasonable to anticipate that your financial interest could be directly and significantly affected by the design, conduct, or reporting of your Public Health Service, part of the U.S. Department of Health and Human Services program activity?	☐	☐

If you answered "*No*" to ALL of the questions above, your Disclosure is complete; you do not have to submit Part II. Please sign and date the certification below and forward to the Head, Regulatory Compliance Unit

If you answered "***Yes"* to ANY question above,** please complete a separate Part II for **every** outside organization

Investigator Certification:

- I have read and understood the Policy on Financial Conflict of Interest in PHS-funded Research.
- I agree to file a new or updated Significant Financial Interests Disclosure Form if the answer to any of the above questions changes and as per the Financial Interests Disclosure Event timeline.
- I certify that the answers to the declaration are accurate and truthful to the best of my knowledge.

Financial Interests Disclosure Event:

☐ Initial (no later than at time of application)
☐ Pre-Research (before start)
☐ Annual Update (during the period of the award)
☐ New SFI (within 30 days)
☐ Newly-added investigator

Signature: _____ Date: _____

Attachment #2

HIV-NAT, Thai Red Cross AIDS and Infectious Diseases Research Centre, Thailand

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Significant Financial Interests Disclosure Form
Part II

Complete Part II only if you answered, "YES" to at least one of the questions in Part I. Attach one Part II form for each organization with which you have the relationship(s) indicated in Part I.

Investigator Name: _____

Number of Part II forms submitted:_____, of which, this is number: _____

1. Name of organization: _____

2. Financial relationship(s) with the organization (check all that apply):

☐ Consultant ☐ Employee

☐ Equity Interest ☐ Recipient of Honoraria

☐ Recipient of Royalties ☐ Other (Describe): _____

☐ Stock/stock option

3. The financial relationship is between the organization and (check all that apply):

☐ Self

☐ Spouse

☐ Dependent Child(ren)

4. Have you received in the last twelve (12) months, or do you expect to receive in the next twelve (12) months, payments for salary, director's fees, consulting, honoraria, royalties, or any other payments that when aggregated with payments from this organization to your spouse and/or dependent child(ren) will exceed $5,000?

Y ☐ N ☐

5. Have you had in the last twelve (12) months or do you anticipate having in the next twelve (12) months, stock, stock options, or other equity interests in the organization which, when aggregated with those of your spouse and dependent child(ren) in this organization, have a fair market value exceeding $5,000 or represent an ownership interest of 5% or more?

Y ☐ N ☐

6. What relationship, if any, is there between the business or activities of the organization and your current or planned areas of research?

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, I will update immediately.

Signature: _____

Date: _____

Attachment #3

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: _____

Primacy 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 NIV/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
	❑ Stock Options (Any) ❑ Equity ❑ Financial ❑ Intellectual Property	
	❑ Stock Options (Any) ❑ Equity ❑ Financial ❑ Intellectual Property	

	❑ Stock Options (Any) ❑ Equity ❑ Financial ❑ Intellectual Property	
	❑ Stock Options (Any) ❑ Equity ❑ Financial ❑ 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]

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