Standard Operating Procedure

Title: Financial Conflict of Interest in US PHS-Funded Research
SOP number: RIHES-CTU-U

Applies to : RIHES-CTU	Version number : 2.0	Supersedes : 1.0	Effective date : 24 MAY 2021

SOP Development Process

	Name/signature	Title	Date
Reviewed by :	Sineenart Nimsakul/ S. Nimsakul	THAI CTU Coordinator, COIC Member	20 May 2021
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(Due 365 days after final approve or last annual review)

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Annual Review Due Date : .....
(Due 365 days after final approve or last annual review)

	Name/signature	Title	Date
Reviewed by :			
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Reviewed by :			
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Final approved by:			

Title: Financial Conflict of Interest in US PHS-Funded Research.

1. Purpose

This document describes the policy of the Research Institute for Health Sciences (RIHES, hereafter also referred to as the "Institution") on the disclosure, management, and resolution of significant financial conflict of interest and pertains to Investigators/key personnel who are responsible for design, conduct or reporting of research funded by the United States – Public Health Service (US-PHS).

This policy is 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).

2. Scope

This policy applies to all Investigators/key personnel at RIHES who are responsible for design, conduct or reporting of research funded by the US-PHS and additionally including all individuals listed on a Form FDA1572 for a study inducted under an Investigational New Drug (IND) application with the US Food and Drug Administration.

3. References

3.1 42 CFR Part 50 Subpart F: Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is sought.
3.2 45 CFR Part 94: Responsible Prospective Contractors.
3.3 21 CFR Part 54: Financial Disclosure by Clinical Investigators.

4. Definitions

4.1. **Disclosure of significant financial interests** (SFI) means an Investigator's disclosure of significant financial interests to the Institution.
4.2. **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).
4.3. **Intellectual Property Interest** means Intellectual property rights (patents, copyrights, licensures, and royalties) related to a relevant entity, product, or product line.
4.4. **Financial Conflict of Interest (FCOI)** means a Significant Financial Interest (SFI) that could directly and significantly affect the design, conduct, or reporting of the US PHS-funded research.
4.5. **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 IND 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.
4.6. **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 includes the Investigator's spouse and dependent children.

4.7. **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.

4.8. **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).

4.9. **PHS** means the Public Health Service, an operating division of the US 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

4.10. **Senior/Key personnel** means the project director or Principal Investigator, 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 Institute under the regulation.

4.11. **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 remuneration 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.
- 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.
- 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.

5. Roles and Responsibilities

5.1 Principal Investigator (PI), Sub-investigator, Head of the Unit and individuals listed on Section 6 of Form FDA 1572 in US PHS-Funded Research is responsible to submit a completed RIHES Significant Financial Interest Disclosure Form to the Conflict of Interest Committee every year at the end of the reporting period.

5.2 Principal Investigator (PI), Sub-investigator, Head of the Unit and individuals listed on Section 6 of Form FDA 1572 in US PHS-Funded Research required to report SFI Disclosure to the Conflict of Interest Committee.

5.3 The Conflict of Interest Committee is responsible for distribution and collection of completed forms from the above personnel stated in item 5.1 every year to review and process as appropriate in compliance with this SOP.

6. Procedures

The following procedures shall be implemented at RIHES;

6.1 Establishment of "Conflicts of Interest Committee"

The RIHES Director appoints "the RIHES Conflicts of Interest Committee (RIHES-COIC)" 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 US PHS-funded research or is in an entity whose financial interest could be affected by the research.

The RIHES-COIC will meet in the third quarter of every year to review all financial disclosures by Investigators/key personnel. The report period of financial disclosures is from October to November of each year.

6.2 Disclosure of Significant Financial Interest (SFI)

6.2.1 Each RIHES Investigators/ key personnel participating in the US PHS-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 annually (per entity) determined by fair market value. The **RIHES Significant Financial Interest Disclosure Form is available in the Attachment #1.**

The completed disclosure of SFI should be submitted to the RIHES Conflicts of Interest Committee (RIHES-COIC) and the time of submission are as follows:

- At time of application: Require that each Investigators/key personnel–planning to participate in US PHS-funded research should submit at time of application.
- Annually: Require each Investigator, Investigators/key personnel to submit an updated disclose of SFI at least annually
  (by 30 September of each calendar year), during the period of the award.
- Within 30 days: Require each Investigators/key personnel, who is participating in the US PHS-funded research to submit an updated disclosure of SFI within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance).

6.2.2 All newly- added investigators/key personnel on US PHS-funded research must submit a completed SFI disclosure within 30 days after beginning work on the research. The principal investigator or study coordinator are responsible for informing newly added investigators/key personnel of the requirement and ensuring that they submit disclosure forms.

6.2.3 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 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.
- ACTG Network

6.3 Identification, evaluation and management or elimination of FCOI

6.3.1 The COIC will determine whether SFI relates to US PHS-funded research and

- If the COIC determines that no conflict of interest exists, it will conclude its assessment.
- If the COIC determines that Investigators/key personnel has Financial Conflict of Interests (FCOI) that would reasonably appear to affect the sponsored project directly and significantly, the COIC may recommend to the Director that the project not proceed. Investigators/key personnel may also be asked to prepare a Management Plan to reduce, minimize or eliminate conflicts of interest.

- If the COIC is unable to make this determination, it 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.

6.3.2 Investigators/key personnel may request reconsideration of any COIC determination that affects his/her ability to participate in US PHS-funded research. A request for reconsideration must be made within ten (10) business days from receipt of notification of a decision by in the COIC. Requests must be made in writing and directed to the RIHES Director.

6.4 Management Plan

The management plan must be approved by the COIC and the RIHES Director before any expenditure is incurred against the US federal award. Management plans may include but are not limited to:

- Public disclosure of the related financial Interest(s), including to human research participants, researchers, Institutional Review Board(s) publisher and or conference organizers.
- Monitoring of the project by independent reviewers or the (COIC) or their designee.
- 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.

6.5 Management of Non-Compliance

6.5.1 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, or otherwise);
- Failure to remedy significant financial conflicts of interest, and
- Failure to comply with a prescribed management plan.

6.5.2 Retrospective review

When an Investigator fails to comply with the Institution's FCOI policy or the management plan, the Institute shall within 120 days;

- Complete a retrospective review of the Investigators/key personnel activities and the US PHS-funded research project to determine any bias in the design, conduct or reporting of research.
- Document the retrospective review consistent with the regulation; and
- Document the Institution's determination as to whether any US PHS-funded research, or portion thereof, conducted during the period of the Investigator's non-compliance with the Institution's FCOI policy of FCOI management plan, was biased in the design, conduct, or reporting of such research.

6.5.3 If bias is found, RIHES Director will notify the NIH promptly and submit a mitigation report that includes the key elements documented in the retrospective review 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 effects of the bias.

6.6 Reporting Requirements and Records Retention

6.6.1 Reporting Requirements.

6.6.1.1 Based on the recommendation of the RIHES-COIC, the RIHES Director must provide initial and ongoing FCOI reports to NIH electronically through the eRA Commons FCOI Module:

- Prior to the expenditure of funds
- During the period of award
  - Within 60 days of identifying a new FCOI.
  - When bias is found as a result of a retrospective review.
  - If applicable, update a previously submitted FCOI report to describe actions that will be taken to manage FCOI going forward.
- Annually
  - Report on the status of FCOI and any changes in management plan.
  - Due at same time as when Investigator submits annual progress report, including multi-year progress report or at a time of extension.

6.6.2 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 of the Institution's management plan. The key elements that must be included in the FCOI report to NIH (but are not limited to) include:

- Grant number
- PD/PI or contact PD/PI.
- Name of 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 a value cannot be readily determined;
- A description how the financial interest related to US PHS-funded research and why the Institute determined that the financial interest conflict with such research.
- 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.

6.7 Records Retention

6.7.1 Records regarding disclosures, reviewing, and screening FCOI, which identify FCOI by COIC and which include the Institute's actions regarding management of FCOI, must be retained for at least 3 years from the date of submission of the final expenditures report at the completion of the grant, or if any integration, claim, financial management review, or audit is started

before the expiration of the 3 years period, until all such actions have been resolved and final action taken. All records will be filed and keep at RIHES Regulatory Compliance Unit (RCU).

6.7.2 Records relating to unfunded projects need not be retained.

6.8. Public Accessibility

This policy on Financial Conflict of Interest is available via the Institute's website. The written policy is available to any requestor within 5 business days of a request.

If the Institute determines that the SFI is related to the US PHS-funded research and the Institute determines that the SFI is a Financial Conflict of Interest, the Investigators/key personnel, information should be disclosed via the Institute intranet website or available in a written document to any requestor within 5 business days of a request. The minimum information should include the following.

- Investigators/key personnel's name.
- Investigators/key personnel's title and role with respect to the research project.
- Name of the entity in which the Significant Financial Interest is held.
- Nature of the Significant Financial Interest; and
- 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 in one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

7. Appendices

7.1 RIHES Significant Financial Interest Disclosure Form Version 02 February 2014

7.2 HANC Financial Disclosure and Conflict of Interest Guidelines SOP Version 8.0 effective 23 July 2020

8. Training

8.1 Each Investigators/key personnel must complete training prior to engaging in NIH-funded research and at least every four (4) years, an immediately under the designated circumstances.

- Institutional FCOI policies change in a manner that affects Investigator requirements.
- Investigators/key personnel are new to an Institution.
- An Institution finds that Investigators/key personnel are not in compliance with the Institution's FCOI policy or management plan.
- FCOI Tutorial Training resources are available on NIH's Office of Extramural Research Financial Conflict of Interest Web page found at: https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html

8.2 Before beginning a new study, related staff will be trained on this and applicable SOPs and annually thereafter.

8.3 Related staff receives or has direct access to this and applicable SOPs.

8.4 All SOP training is documented and tracked.

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

8.6 Related staff will be retrained within 60 days of the approval of each SOP revision.

9. Contact Information:

Research Institute for Health Sciences,
Regulatory Compliance Unit
110 Intavaroros Road, Muang
Chiang Mai 50200, Thailand.
Tel. 66 53 945051
Fax. 66 53 221849
Mailbox for inquiries: snimsakul@rihes.org
RIHES website: www.rihes.cmu.ac.th

9. Revision History

Revision History	Version	Effective Date D/M/Y	Description
1.0	**2.0**	**24 May 2021**	- Item 1. PURPOSE : Removed the last sentence. - Item 2. Change the title from "Applies to" to "Scope" to comply with DAIDS New SOP Template and remove the last sentence. - Item 3.1. References, Remove USDHHS, 3.2 and 3.3 - Item 4. Definitions, add "Interest" after Equity - Item 4. Definitions: Add sub-item 4.3, the definition of Intellectual Property Interest accordingly with an additional description in the HANC-Financial Disclosure and Conflict of Interest Guidelines SOP, version 8.0 dated 23 July 2020 - Add sub-item 4.5: Form FDA1572 - Sub-item 4.6: removed the last sentence ".. which include for example collaborators or consultants." and added "includes the Investigator's spouse and dependent children." - Sub-item 4.9 : Revised the definition of PHS with addition list of 8 divisions within the department of HHS as part of PHS. - Sub-Item 4.11 Significant Financial Interest (SFI) – Add two more bullets accordingly with an additional description in the HANC-Financial Disclosure and Conflict of Interest Guidelines SOP, version 8.0 dated 23 July 2020 as follows; o *Any ownership interest (i.e. stocks or shares) in a relevant entity. ……* o *Intellectual property rights (patents, copyrights, licensures, and royalties) related to a relevant entity, ……*

Revision History	Version	Effective Date D/M/Y	Description
			- Add Item 5. "Roles and Responsibilities" to comply with the DAIDS new SOP template, move "Materials and Equipment" to no. 7 and change the title to "Appendices" and run the item number constantly. - Item 6. Procedures revised to have "The following procedures shall be implemented at RIHES;" - Sub-item 6.1 – Add RIHES in front of COIC for more specific and add the last paragraph. - Sub-item 6.2, line 6, add "annually (per entity) determined by fair market value." at the end of sentence. Line 8, put RIHES in front of COIC for more specific. - In the 1st bullet, remove …sub recipient Investigators, if applicable, - In the 3rd bullet, remove …including sub recipient Investigator, if applicable. - Sub-item 6.2.3 – add the last bullet ACTG Network - Remove Sub-item 6.2.4 - Item 6.3. Identification, Evaluation and Management or elimination of FCOI, revised the sentence of the second bullet under sub-item - Rewrite 6.3.1 to "If the COIC determines that Investigators/key personnel has Financial Conflict of Interests (FCOI) that would reasonably appear to affect the sponsored project directly and significantly,…" - Item 7. change the title from "Materials and Equipment" to "Appendices" to comply with DAIDS New SOP and Add 2 forms under this item. 7.1 RIHES Significant Financial Interest Disclosure Form Version 02 February 2014 as a material of this SOP. 7.2 HANC Financial Disclosure and Conflict of Interest Guidelines SOP Version 8.0 effective 23 July 2020 - Item 8. Training, sub-item 8.1 - the last bullet was added; - Delete item 9. Related SOP which was cancelled.

Revision History	**Version**	**Effective Date** D/M/Y	**Description**
			- Update the address information and email address in item 10. Contact Information - Change Version from *version 1.0, version date 05 March 2012* to *Version 2.0, Version Date 13 May 2021* - Revise address from PO Box and contact email. - Change from *NIH funded or PHS funded* to *US-PHS funded* everywhere in accordance with the SOP title. - Change SOP Number from *RIHES-CTU-BBB* to *RIHES-CTU-U*

2 4 MAY 2021

Research Institute for Health Sciences
Chiang Mai University, Thailand

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 Related to NIH Study: _____

_____

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 sponsored program activity?	☐	☐
Do you, your spouse or dependent child(ren) have Significant Financial Interest in a Sponsor, a vendor or (sub) contractor related to your sponsored 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 or 5% ownership.	☐	☐
Is it reasonable to anticipate that your financial interest could be directly and significantly affected by the design, conduct, or reporting of your sponsored 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.
- I certify that the answers to the declaration are accurate and truthful to the best of my knowledge.

Signature: _____ Date: _____

2 4 MAY 2021

Research Institute for Health Sciences
Chiang Mai University, Thailand

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
- ☐ Equity Interest
- ☐ Recipient of Royalties
- ☐ Stock/stock option
- ☐ Employee
- ☐ Recipient of Honoraria
- ☐ Other (Describe):_____

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: _____

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

Owner	Office of HIV/AIDS Network Coordination (HANC)

	ACTG AIDS CLINICAL TRIALS GROUP	IMPAACT
Adopted By	HIV VACCINE TRIALS NETWORK	MTN microbicide trials network
	HPTN HIV Prevention Trials Network	pHACS A Study of the National Institutes of Health

Version History	Version 8.0	Effective 23 July 2020

24 MAY 2021

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

Table of Contents

2 4 MAY 2021

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.

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 shall not include travel expenses that 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 the cross-network online reporting system (found at https://fd.hanc.info).

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" (found at: https://fd.hanc.info) 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 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 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.

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.

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 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.