Policy
Policy # 1001
Code of Conduct

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CODE OF CONDUCT

Approval

Professor Emeritus Praphan Phanuphak

Co-Director

Oct 21, 2014

Date

Professor Kiat Ruxrungtham

TRC-ARC CRS Leader

21 Oct 2014

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General

This Code of Conduct is to act as a guide for staff, enabling those employed to prevent ethical misconduct and financial conflicts of interest as well as identify and resolve misconduct should it take place. Furthermore, it is designed to guide staff in their dealings with colleagues, students, national communities, and international communities (i.e. NIH, NIAID (DAIDS) that support or sponsor HIV/AIDS Clinical Trial Networks. The Code is written as a set of general principles with sufficient detail to ensure its applicability as well as compliance with 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 of Conduct stands beside but does not exclude or replace the rights and obligations of staff under common law.

Academic Staff

The organization and this document recognize that many staff are bound by more than one code of conduct or set of ethical principles as defined by their profession or other affiliations. For example, academic staff carrying out research may have allegiances to: 1) their discipline or profession at a national and/or international level; 2) their employer and colleagues'; and 3) organizational bodies that provide funding for research activities. It is the responsibility of each employee to be self-aware of these allegiances and notify the appropriate person(s) when conflicts may potentially arise or have arisen.

Self-awareness and actions that embrace transparency protects the concept and practice of academic freedom and underlies good research, teaching, and scholarship. This Code of Conduct acknowledges academic freedom as a right so long as academics use this freedom in a manner consistent with a responsible and honest search for, and dissemination of, knowledge.

When commenting on or challenging societal traditions, practices, beliefs, policies and/or structures in a public capacity/member of academia/representative of his or her organization/representative of his or her profession it is expected that the informed comments will be within their area of expertise. That expectation is not intended to restrict an individual's right to freely express their opinion in a private capacity or as an individual member of society.

Primary Obligations

Every member of staff at has three primary obligations:

1. A duty of care to observe values such as equality and justice in their interactions with all colleagues
2. An obligation to support good governance facilitating equity, coverage, access, quality, and patients' rights so that the member of staff does not undermine the organizations reputation within the wider community
3. An obligation to act appropriately when a conflict arises between a staff member's own self-interest and their duty to: the organization, his or her colleagues, and funders of research activities

Obligations to Colleagues

Every member of staff is obligated to conduct themselves with colleagues in the following manner:

1. Treat colleagues 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 openly acknowledge valid contributions of any personnel to any piece of work, especially if it leads to publication
5. Refrain from acting in any way that would unfairly harm the reputation and/or career prospects of another colleague
6. Consider appropriate intervention where a colleague's behavior is clearly in breach of this code, and be prepared to report any suspected fraud, and any corrupt, criminal or unethical conduct to an appropriate senior person
7. Consider the impact of ones decisions on the well-being of others
8. Respect an individuals' right to privacy and undertake to keep personal information in confidence

Obligations to the Organization

Every staff member is expected to:

1. Refrain from representing themselves as spokesperson for the organization unless authorized to do so
2. Refrain from representing themselves as acting for or on behalf of the organization 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 of the organization
4. Avoid improper use of organization resources for private gain or the gain of a third party
5. Foster collegiality and a positive work environment

Obligations regarding Conflict of Interest

With respect to conflict of interest, every staff member is expected to:

1. 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. Take suitable measures to avoid to using their position unfairly to the advantage or disadvantage of their colleagues when in a supervisory position or a position that involves the distribution of organizational resources
3. Take care that personal financial and other interests/actions do not conflict or seem to conflict with the obligations and requirements of their position
4. Avoid situations which may require them to supervise or assess another with whom they have (past or present) a personnel, commercial, familial or other significant relationship. Where both a supervisory role and a significant relationship between another staff member co-exists, supervision activities must be openly seen to be of the highest professional standard
5. Disclose actual or potential conflicts of interest to an appropriate senior person and, wherever feasible, the staff member(s) under review should play no role in the review decision-making process associated with the potential conflict.
6. Supervisors to act when they are aware of actual or potential conflict of interest by:
    - Informing the staff member(s) involved and utilizing the Code of Conduct as a basis for addressing the issue/situation
    - Where appropriate, elevate the matter to a more senior colleague for further attention

Procedures for Managing Financial Conflict of Interest

1. Establishment of "Conflicts of Interest Investigator"

The Director and CRS Leader appoints' an "Institute General Manager (Financial Controller)" to review all financial disclosures by Investigator(s)/key staff. If Significant Financial Interest (SFI) or a Financial Conflict of Interest (FCOI) in relation to NIH-funded research is suspected he or she will carry out a review and determine what actions are needed for resolution. Note: Significant Financial Interest may include stock, stock options, and/or any other ownership interest in a single entity valued at more than $5,000 or 5% ownership. A Financial Conflict of Interest is considered when it is reasonable to anticipate that a SFI could directly and significantly affect research design, conduct, or reporting of a sponsored program activity.

2. Disclosure of Significant Financial Interest (SFI)

2.1 Each affiliated sites' Investigator(s)/key staff participating in US PHS/NIH funded research must disclose their personal as well as their immediate family's SFI should it relate to proposed project(s). SFI includes any financial gain received from an entity in the twelve months prior to the SFI submission. Financial gain is considered funds or the value thereof, regardless of publicly traded or non-publicly traded, totaling an amount exceeding $5,000 USD. **Please See: The Significant Financial Interest Disclosure Form is available in the Attachment #1. Statement of Significant Financial, Equity, and Intellectual Property Interests Attachment #2**

The SFI Disclosure Forms are to be submitted to Institute General Manager (Financial Controller) as follows:

- At time of proposal application: It is required that each Investigator/key staff and if applicable sub recipient Investigators planning to participate in US PHS/NIH funded research submit completed SFI forms at time of proposal application
- Annually: It is required that each Investigator/key staff and if applicable sub recipient Investigators planning to participate in US PHS/NIH funded research submit updated SFI forms at least annually (30th of September of each calendar year), during the period of the award
- Within 30 days: It is required that each Investigator/key staff and if applicable sub recipient Investigators planning to participate in US PHS/NIH funded research submit updated SFI forms within 30 days of discovering or acquiring financial gain (e.g., through purchase, marriage, or inheritance) that is related to proposed/ongoing research projects

2.2 All newly added Investigators/key staff on PHS/NIH funded research must submit a completed SFI disclosure within 30 days after beginning work on research proposals/projects. The Principal Investigator or study coordinator is responsible for informing the newly added Investigator(s)/key staff of the requirements ensuring disclosure forms are submitted.

2.3 Investigator(s)/key staff must disclose the occurrence of any reimbursed or sponsored travel (i.e., travel paid for on behalf of the Investigator(s)/key staff where 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:

- Federal, state, or local government agency
- Institution of higher education as defined at 20 U.S.C 1001 (a)
- Academic teaching hospital.
- Medical center
- Research institute that is affiliated with an institution of higher education

2.4 Investigator(s)/key staff who conduct research funded by the DAIDS HIV/AIDS Network (i.e., ACTG, IMPAACT, HPTN, MTN, INSIGHT, HVTN) must comply with NIAD/DAIDS supported and/or sponsored HIV/AIDS Clinical Trials Networks Standard Operating Procedure outlined within "Financial Disclosure and Conflict of Interest Guidelines".

3. Evaluation, Management or Elimination of Financial Conflict of Interest (FCOI)

3.1 Should the Institute General Manager (Financial Controller) determine a SFI relates to NIH funded research one or more of the following measures(s) may be taken:

- The Institute General Manager (Financial Controller) determines that no FCOI exists up on further investigation and the assessment is concluded
- The Institute General Manager (Financial Controller) determines that it is reasonable to anticipate that an Investigator(s)'/key staff's financial interest could directly and significantly affect the design, conduct, or reporting of a sponsored program activity. This is then brought to the attention of the Conflict of Interest Committee and he or she may recommend that the project not proceed. Investigator(s)/key staff may be asked to prepare a management plan (see section 4) to reduce, minimize, or eliminate conflicts of interest.
- The Institute General Manager (Financial Controller) is unable to determine if a FCOI exists. He or she will then invite the Investigator(s)/key staff to meet with the Conflict of Interest Committee for further clarification, determination, and if required actions plans to resolve conflicts of interest.

3.2 Investigator(s)/key personnel may request that FCOI determinations made by the Institute General Manager (Financial Controller) or Conflict of Interest Committee are reevaluated at a higher level. A request for reevaluation must be made within ten (10) business days from decision notification by the Conflict of Interest Committee. Requests must be made in writing and directed to the HIV-NAT, TRC-ARC Director.

4. Management Plan

Management plans must be approved by the Institute General Manager (Financial Controller), CRS Leader, and HIV-NAT, TRC-ARC 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 their designee.
- Modification of the research or project plan to avoid conflicts of interest.
- Change of Investigator/key staff 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)
- Severance of relationship(s) from where the financial conflict(s) had arisen from

5. Management of Non Compliance

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
- Failure to comply with a prescribed management plan

5.2 Retrospective review

When an Investigator fails to comply with the Institution's FCOI policy or the management plan, the Institute will take the following actions within 120 days:

- Complete a retrospective review of the Investigators/key staff activities and the NIH funded research project to determine the presence of bias in the design, conduct, or reporting of research
- Document the process of investigation and the findings/outcomes of the retrospective review in compliance with the regulations. Clear delineation of any bias in the design, conduct, or reporting of NIH funded research, or portion thereof, during the period of non-compliance must be addressed within the retrospective review

5.3 If bias is found, HIV-NAT, TRC-ARC Director will notify NIH promptly and submit a mitigation report that includes the key elements documented in the retrospective review, a description of the impact of the bias on the research project and the Institution's plan, and action or actions taken to eliminate or mitigate the effects of the bias.

6. Reporting Requirements and Records Retention

Reporting Requirements

6.1 Based on recommendations from the Institute General Manager (Financial Controller), CRS Leader, the HIV-NAT, TRC-ARC Director initial and ongoing Financial Conflict of Interest reports must be submitted to NIH electronically through the eRA Commons FCOI Module as follows:

- 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, updates of previously submitted FCOI reports that detail management plans going forward
- Annually
  - FCOI status and any changes to management plans
  - Note: time corresponds to Investigator annual progress report or at a time of extension

6.2 All FCOI reports must include sufficient information enabling NIH to understand the nature and extent of FCOI and assess the appropriateness of the management plan. The key elements that must be included in the report to NIH include, but are not limited to:

- Grant number
- PD/PI or contact PD/PI
- Name of Investigator with the FCOI
- Name of the entity with which the Investigator has the FCOI
- Nature of the 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, and rationale as to why, a FCOI relates to a NIH-funded research proposal or project
- A description of the key elements of the management plan, including:
  - Role and principal duties of the conflicted Investigator(s)/key staff in the research proposal or project
  - Conditions of the management plan
  - How the management plan is designed to objectively safeguard the research project
  - Confirmation of the Investigator's agreement to the management plan

- How the management plan will be monitored to ensure investigator compliance
- Other information as needed

7. **Records Retention**

7.1 Records regarding disclosures, reviews, and screening of FCOI as identified by the Institute General Manager (Financial Controller), CRS Leader in addition to actions taken in management of FCOI must be retained for at least three years from the date of the final expenditure report submission at the completion of the grant. Furthermore, records of any integration, claim, financial management review, or audit started before the expiration of the three year period and until all such actions have been resolved must be retained. All records are to be retained as a netword file.

7.2 Records relating to unfunded projects need not be retained.

8. Public Accessibility

The written FCOI policy is available to any requestor within five business days. If the Organization determines that a FCOI exists in relation to a NIH funded research, the Investigator(s')/key staff(s') information should be disclosed via the organizations intranet website or available in a written document to any requestor within five business days of a request. The minimum information should include:

- Investigator's/key personnel's name
- Investigator's/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
- 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.

9. Training

9.1 Each Investigator(s)/key staff must complete training prior to engaging in NIH-funded research, refresher training at least every four years, and immediately under the following circumstances:

- Organizational FCOI policies changes that affect Investigator(s)/key staff requirements
- The organization finds that Investigators/key staff are not in compliance with the organizations FCOI policy or management plan

Training resources are available on NIH's Office of Extramural Research Financial Conflict of Interest Web page found at: http://grants.nih.gov/grants/policy/coi/

9.2 Before beginning a new study, related staff will be trained on this and applicable policies and annually thereafter

9.3 Related staff receives or has direct access to this and applicable policies

9.4 All policy related training activities are to be documented and tracked

9.5 New staff are to receive training on FSI/FCOI and applicable policies within 60 days of joining research activities

9.6 Relevant staff will be retrained within 60 days of approval of policy revisions

10. Contact Information:

Mrs.Kesdao Nanthapisal

HIV-NAT, the Thai Red Cross AIDS 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

11. References for Financial Conflict of Interests

1. US Department of Health and Human Services (including the Public Health Service and the National Institutes of Health).
   - 42 CFR Part 50 Subpart F: Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is sought.
   - A Final Rule amending the 1995 PHS regulation (and the companion regulation at 45 CFR Part 94: Responsible Prospective Contractors).
2. US Food and Drug Administration
   - 21 CFR Part 54: Financial Disclosure by Clinical Investigators.
3. NIAID (DAIDS) supported and/or sponsored HIV/AIDS Clinical trials Networks; Financial Disclosure and Conflict of Interest Guidelines Standard Operating Procedure Version 2.0 Effective 01 April 2011.
4. NIH Grants Policy Statement U.S.Department of Health and Human Services Naitonal Institutes of Health version October 1, 2013.

12. Attachment

12.1 Attachment #1 Significant Financial Interests Disclosure Form

12.2 Attachment #2 NIAID (DAIDS) supported and/or sponsored HIV/AIDS Clinical Trial Networks Statement of Significant Financial, Equity, and Intellectual Property Interests

Attachment #1

HIV-NAT, the Thai Red Cross AIDS Research Centre, 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: _____

Email: _____ Phone: _____

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: _____

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: _____

Attachment #2

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