

สถาบันวิจัยวิทยาศาสตร์สุขภาพ มหาวิทยาลัยเชียงใหม่
RESEARCH INSTITUTE FOR HEALTH SCIENCES, CHIANG MAI UNIVERSITY

บันทึกภายใน

วันที่ 24 ตุลาคม 2555

เรียน ดร.ศักดิ์ดา พริ้งลัมฏ ประชานคณะกรรมการ รักษาราชการแทนอธิการบดี
คุณบุปผา ประภาลักษณ์ กรรมการ
คุณนิลปาล ด้อยคำภีร์ กรรมการ
สินีนารถ นิ่มสกุล กรรมการและเลขานุการ

จาก ดร.สุกัญญา ลินพิศาล

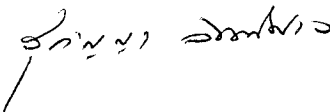
เรื่อง ปรับปรุงแบบฟอร์ม Attachment#1: Significant Financial Interests Disclosure Form Part I ใน SOP-RIHES-BBB: Financial Conflict of Interest in US PHS-Funded Research Version 1.0 Effective date: 29 MAR 2012

RIHES Ref. : Regulatory Compliance Unit Memo# 81/55

ตามที่มีการประชุมคณะกรรมการกำกับดูแลด้านผลประโยชน์ทับซ้อนด้านการเงิน สถาบันวิจัยวิทยาศาสตร์สุขภาพ การประชุมครั้งที่ 2/2555 เมื่อวันที่ 22 สิงหาคม 2555 ในวาระที่ 3: วาระอื่นๆ ทางคณะกรรมการฯ เห็นชอบให้มีการปรับปรุงแบบฟอร์ม Attachment# 1 “Significant Financial Interests Disclosure Form Part I” ใน SOP-RIHES-BBB: Financial Conflict of Interest in US PHS-Funded Research Version 1.0 Effective date: 29 MAR 2012 โดยเพิ่ม “Related to NIH Study” ต่อท้าย “Position” เพื่อความชัดเจนในการระบุตำแหน่งที่เกี่ยวข้องกับโครงการวิจัยที่รับผิดชอบ และปรับ Version Date เป็น 23 August 2012

เนื่องจากการปรับปรุงแบบฟอร์มดังกล่าวไม่กระทบกับรายละเอียดของ SOP-RIHES-BBB จึงยังใช้ Version 1.0 Effective date 29 MAR 2012 ต่อไป

จึงเรียนมาเพื่อโปรดทราบ


(ดร.สุกัญญา ลินพิศาล)

Regulatory Compliance Unit

**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: _____

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?	<input type="checkbox"/>	<input type="checkbox"/>
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?	<input type="checkbox"/>	<input type="checkbox"/>
“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?	<input type="checkbox"/>	<input type="checkbox"/>

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: _____

**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): _____

- | | |
|---|--|
| <input type="checkbox"/> Consultant | <input type="checkbox"/> Employee |
| <input type="checkbox"/> Equity Interest | <input type="checkbox"/> Recipient of Honoraria |
| <input type="checkbox"/> Recipient of Royalties | <input type="checkbox"/> Other (Describe): _____ |
| <input type="checkbox"/> 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: _____

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 personnels who are responsible for design, conduct or reporting of research funded by the United States – Public Health Service (US-PHS) or who have applied for such funding which include subawardees and collaborators.

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. Applies to

This policy applies to all Investigators/key personnels at the RIHES who are responsible for design, conduct or reporting of research funded by the US-PHS, or who have proposed for such funding.

3. References

3.1 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.
- 45 CFR Part 94: Responsible Prospective Contractors.

3.2 US Food and Drug Administration

- 21 CFR Part 54: Financial Disclosure by Clinical Investigators.

3.3 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. Definitions

4.1. **Disclosure of significant financial interests (SFI)** means an Investigator's disclosure of significant financial interests to the Institution.

4.2. **Equity** 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. **Financial Conflict of Interest (FCOI)** means a Significant Financial Interest (SFI) that could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

4.4. **Investigator** means the RIHES 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 include for example collaborators or consultants.

4.5. **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.

- 4.6. **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).
- 4.7. **PHS** means the Public Health Service, an operating division of the US Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).
- 4.8. **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 PHS by the Institution under the regulation.
- 4.9. **Significant Financial Interest (SFI)** means:

A financial interest consisting of one or more of the following interests of the Investigators/key personnels (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 equity interest in a non-publicly traded company or business, regardless of value; and
- Any intellectual property rights, regardless of value.

SFI Exclusions:

- Salary royalties, or other remuneration paid by the Institution to the Investigators/key personnels if the Investigators/key personnels 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 personnels 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 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.

5. Materials and Equipment

None

6. Procedures

6.1 Establishment of “Conflicts of Interest Committee”

The RIHES Director appoints “Conflicts of Interest Committee (COIC)” to review all financial disclosures by Investigators/key personnels 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.

6.2 Disclosure of Significant Financial Interest (SFI)

6.2.1 Each RIHES Investigators/ key personnels 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. The **RIHES Significant Financial Interest Disclosure Form is available in the Attachment #1.**

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

- At time of application: Require that each Investigators/key personnels including sub recipient Investigators, if applicable, planning to participate in US PHS/NIH funded research should submit at time of application.
- Annually: Require each Investigator, including sub recipient Investigators/key personnels, if applicable, 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 personnels, including sub recipient Investigator, if applicable, who is participating in the 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 personnels on 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 personnels of the requirement and ensuring that they submit disclosure forms.

6.2.3 Investigators/key personnels must disclose the occurrence of any reimbursed travel or sponsored travel (i.e., that which is paid on behalf of the Investigators/key personnels and not reimbursed to the Investigators/key personnels 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

6.2.4 Investigators/key personnels 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 #2)) and submit it to each affiliated networks Financial Disclose Coordinator (FDC) at least annually, or when joining a protocol team or committee. The FDC will notify each investigator required to report or revised "Statement of Financial, Equity, and Intellectual Property Interests" by 31 May of each calendar year.

6.3 Identification, evaluation and management or elimination of FCOI

6.3.1 The COIC will determine whether SFI relates to NIH 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 directly and significantly affect the sponsored project, 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 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 NIH 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 NIH funded research, or portion thereof, conducted during the period of time 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.

7. Reporting Requirements and Records Retention

7.1 Reporting Requirements

7.1.1 Based on the recommendation of the 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.

7.1.2 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 appropriateness 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 fees, 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 NIH-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

7.2 Records Retention

7.2.1 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).

7.2.2 Records relating to unfunded projects need not be retained.

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 NIH funded research and the Institute determines that the SFI is a Financial Conflict of Interest, the Investigators/key personnels, 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 personnels' name;
- Investigators/key personnels' 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.

9. Training

9.1 Each Investigators/key personnels 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 personnels are new to an Institution.
- An Institution finds that Investigators/key personnels are not in compliance with the Institution's 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 SOPs and annually thereafter.

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

9.4 All SOP training is documented and tracked.

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

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

10. Related SOPs

- RIHES-UU: Chiang Mai University and the Research Institute for Health Sciences Identification and Management of Conflict of Interest in Clinical Research Settings.

11. Contact Information:

Research Institute for Health Sciences,

Regulatory Compliance Unit

P.O. Box 80 Chiang Mai University

Chiang Mai 50202, Thailand.

Tel. 66 53 945051

Fax. 66 53 221849

Mailbox for inquiries: sukanya@rihes-cmu.org

RIHES website: www.rihes.cmu.ac.th

12. Attachments

11.1 Attachment #1

11.2 Attachment #2

13. Revision History

None

29 MAR 2012

Attachment #1

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: _____

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?	<input type="checkbox"/>	<input type="checkbox"/>
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.	<input type="checkbox"/>	<input type="checkbox"/>
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?	<input type="checkbox"/>	<input type="checkbox"/>

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: _____

**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): _____

- | | |
|---|--|
| <input type="checkbox"/> Consultant | <input type="checkbox"/> Employee |
| <input type="checkbox"/> Equity Interest | <input type="checkbox"/> Recipient of Honoraria |
| <input type="checkbox"/> Recipient of Royalties | <input type="checkbox"/> Other (Describe): _____ |
| <input type="checkbox"/> 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 #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 HIV/AIDS Clinical Trial Networks Financial Disclosure and Conflict of Interest Guidelines."

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

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

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

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 _____