

**Financial Interest Forms for All Clinical Investigators on a VCU Faculty Held IND or IDE**

1. All VCU employees who are Clinical Investigators must complete the AIRS system using the reporting guidelines in the PHS Compliant VCU COI Management Policy.
2. All Clinical Investigators at all sites must complete the VCU Certification of Financial Interests. If any items are marked yes also complete a VCU Disclosure of Financial Interests form. Review the FDA disclosable Financial Interests below prior to completing the forms.
3. External to VCU Clinical Investigators receiving PHS, PHS adherent funding for the conduct of this study must complete the Subaward Recipient Commitment Form. If deferring COI management to VCU you must also complete the AIRS system. The VCU study team can assist you with this. If not deferring, you must comply with your institutions COI management system.
4. Return the forms to the VCU IND/IDE Sponsor
  - a. Secure Fax \_\_\_\_\_
  - b. Secure Email \_\_\_\_\_
  - c. Mail \_\_\_\_\_

**FDA Disclosable Financial Interests and Arrangements from Guidance for Clinical Investigators, Industry, and FDA Staff: Financial Disclosure by Clinical Investigators**

The financial interests, arrangements, and payments that must be disclosed (see 21 CFR § 54.4(a)(3), referred to herein as “disclosable financial interests and arrangements”) are described below. Note that the dollar amounts that trigger reporting are the combined financial interests of the investigator, spouse, and dependent children.

1. Any compensation made to the investigator by any sponsor of the covered clinical study in which the value of compensation could be affected by study outcome.
2. A proprietary interest in the tested product including, but not limited to, a patent, trademark, copyright or licensing agreement.
3. Any equity interest in any sponsor of the covered clinical study, i.e., any ownership interest, stock options, or other financial interest whose value cannot be readily determined through reference to public prices. The requirement applies to interests held during the time the clinical investigator is carrying out the study and for one year following completion of the study.
4. Any equity interest in any sponsor of the covered study if the sponsor is a publicly held company and the interest exceeds \$50,000 in value. The requirement applies to interests held during the time the clinical investigator is carrying out the study and for one year following completion of the study.

5. Significant payments of other sorts (SPOOS) are payments that have a cumulative monetary value of \$25,000 or more and are made by any sponsor of a covered study to the investigator or the investigator's institution during the time the clinical investigator is carrying out the study and for one year following completion of the study. This would include payments that support activities of the investigator (e.g., a grant to the investigator or to the institution to fund the investigator's ongoing research or compensation in the form of equipment), exclusive of the costs of conducting the clinical study or other clinical studies, or to provide other reimbursements such as retainers for ongoing consultation or honoraria. See Section IV, Questions C.4, C.5, and C.6 for additional information on SPOOS.

Reference: <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM341008.pdf>

VCU Policy: Conflicts of Interest in Research

<http://policy.vcu.edu/sites/default/files/Conflict%20of%20Interests%20in%20Research.pdf>

Revision History:

Version1: June 13, 2014

Version2: August 26, 2015



## VCU Certification of Financial Interest of Clinical Investigators

Title of Clinical Study: \_\_\_\_\_

Principal Investigator: \_\_\_\_\_

Identity of Investigational Drug/Device: \_\_\_\_\_

The Sponsors (as defined in [21 CFR Part 54](#)) for this study are listed in the table. For each indicate if you are a full or part-time employee of that sponsor.

| Sponsor   | Employee Yes/No |
|-----------|-----------------|
| VCU/VCUHS |                 |
|           |                 |
|           |                 |
|           |                 |

As a clinical investigator who will be participating in the above-named clinical study being conducted under a VCU-based (i.e., investigator-sponsored) or VCU-sponsored IND or IDE application, **I certify that myself, my spouse and children collectively (check the appropriate box for each statement):**

- ☐ I do ☐ I do not      Have an ownership interest, stock options, or other financial interest (i.e., *equity interest*) in the company (public or non-public) that owns the investigational drug or device being evaluated in the clinical study.
- ☐ I do ☐ I do not      Have property or other financial interest (i.e., *proprietary interest*) in the investigational drug or device being evaluated in the clinical study; including, but not limited to, a patent or patent interest, trademark, copyright, licensing agreement, or any arrangement tied to a current or future right to receive royalties associated with the development or eventual commercialization of the drug or device.
- ☐ I will ☐ I will not      Receive payments from the company (other ones for which I am an employee) that owns the respective investigational drug or device during the term of the conduct of the clinical study; nor do I anticipate receiving payments from the company during a 1 year period following completion of the clinical study. Applicable payments (i.e., *financial interest*) include, but are not limited to, grants to fund projects or research or compensation in the form of monetary payments, equipment, or retainers for consultation or honoraria.

If the response to any of the above statements is affirmative, completion of the Disclosure of Financial Interest of Clinical Investigators is required. For VCU/VCUHS employees you must also complete the AIRS system. For External Clinical Investigators receiving PHS, PHS adherent funding for this study and deferring to VCU for COI management you must also complete the AIRS system.

Name of Clinical Investigator (Printed or Typed) \_\_\_\_\_

Signature of Clinical Investigator \_\_\_\_\_ Date \_\_\_\_\_



## VCU Disclosure of Financial Interest of Clinical Investigators

Title of Clinical Study: \_\_\_\_\_  
Principal Investigator: \_\_\_\_\_  
Identity of Investigational Drug/Device: \_\_\_\_\_  
Sponsor(s) of this study \_\_\_\_\_

In compliance with the provisions of [21 CFR Part 54](#), Financial Disclosure by Clinical Investigators, I hereby disclose that I have participated in financial arrangements or hold financial interests as follows (this collectively includes myself, my spouse, and children): (*Check all applicable boxes.*) Do not include financial arrangements or financial interests if you are employed full time or part time by the Sponsor. FDA disclosable financial interests.

- ☐ Any financial arrangement entered into between the company (other than those marked as sponsors for which I am an employee) that owns the investigational drug or device being evaluated in the above named clinical study, whereby the value of the compensation to me for conducting or participating in the clinical study could be influenced by the outcome of the study;
- ☐ Any significant payments (i.e. *financial interests*) of other sorts from the company (other than those marked as employee) that owns the investigational drug or device being evaluated in the abovenamed clinical study; such as a grant to fund ongoing research, compensation in the form of equipment, retainer for ongoing consultation, or honoraria;
- ☐ Any *proprietary* interest in the investigational drug or device being evaluated in the above-named clinical study;
- ☐ Any significant *equity interest* held by me in the company (i.e., other than VCU/VCUHS) that owns the investigational drug or device being evaluated in the above-named clinical study.

Attach to this form the details of your financial arrangements and interests. Also attach to this form, a description of the steps (i.e., management plan) taken by your department chair and/or dean, the University, or the principal investigator of the clinical study to minimize the potential bias of clinical study results related to your disclosed financial arrangements or interests.

For VCU/VCUHS employees you must also complete the AIRS system. For External Clinical Investigators receiving PHS or PHS adherent funding for this study and deferring to VCU for COI management you must also complete the AIRS system.

Name of Clinical Investigator (Printed or Typed) \_\_\_\_\_

Signature of Clinical Investigator \_\_\_\_\_ Date \_\_\_\_\_