VCU Office of Research and Innovation

Sponsor Instructions for Completion of Financial Interests for VCU/VCUHS Faculty Held IND/IDEs

1. For all covered clinical studies, determine who are Clinical Investigators at all Sites.

2. Determine the Sponsor(s) as defined in 21 CFR 54. Add these sponsor(s) to the Certification of Financial Interest of Clinical Investigators prior to distribution to the investigators for completion.

3. Assure that ALL Clinical Investigators at all sites complete the VCU Certification of Financial Interests and as required a VCU Disclosure of Financial Interests.

4. Assure that all VCU/VCUHS employee Clinical Investigators complete AIRS.

5. Obtain a Subrecipient Commitment form from each external site that is receiving funding from a PHS or PHS adherent funded study. Depending on their response, if deferring to VCU then the external Clinical Investigators will need to complete AIRS.

6. Maintain documentation and comply with all COI management plans from the VCU COI Committee as well as external Management Committees if PHS, PHS adherent funded.

7. Complete form 3454 if none of the investigators have any FDA required disclosures. Complete form 3455 if any clinical investigator has a financial disclosure that is significant.

8. The faculty sponsor for the IND/IDE must keep in their records: all VCU Certification of Financial Interests of Clinical Investigators, VCU Disclosure of Financial Interests of Clinical Investigators (as applicable), the Subrecipient Commitment Form, all COI management plans and FDA form 3454 and 3455 (as applicable).

Key Definitions: 321 CFR parts 54, 312, 314, 320, 330, 601, 807, 812, 814, and 860

Definitions from Guidance for Clinical Investigators, Industry, and FDA Staff: Financial Disclosure by Clinical Investigators

Clinical Investigator – For purposes of part 54, "clinical investigator" means a "listed or identified investigator or subinvestigator who is directly involved in the treatment or evaluation of research subjects," Reporting must also include the spouse and each dependent child of the investigator or subinvestigator. (See 21 CFR § 54.2(d).) See Section IV.D, Clinical Investigator, for additional information. Clinical investigators are included in the definition even if they did not participate for the entire length of the study. If a clinical investigator did not participate in the entire study, information collected should be for the period of time he or she participated in the study and for one year following the end of his or her participation.

Covered clinical study – The part 54 regulations define "covered clinical study" to mean "any study of a drug or device in humans submitted in a marketing application or reclassification petition subject to this part that the applicant or FDA relies on to establish that the product is effective (including studies that show equivalence to an effective product) or any study in which a single investigator makes a significant contribution to the demonstration of safety. This would, in general, not include phase 1 tolerance studies or pharmacokinetic studies, most clinical pharmacology studies (unless they are critical to an efficacy determination), large open safety studies conducted at multiple sites, treatment protocols and parallel track protocols." (See 21 CFR § 54.2(e).) This definition includes clinical studies submitted in support of new drug applications (NDAs) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), abbreviated new drug applications (ANDAs) under section 505(j) of the FD&C Act, premarket notification submissions under section 510(k) of the FD&C Act, reclassification petitions under section 513 of the FD&C Act, premarket approval applications (PMAs) under section 515 of the FD&C Act, and biologics licensing applications (BLAs) submitted under section 351 of the Public Health Services Act (PHS Act), as well as studies submitted in support of amendments or supplements to any such applications. (See 21 CFR §§ 54.3 and 54.4(a).) Covered clinical studies would generally not include expanded access under section 561 of the FD&C Act. If an applicant is unsure of whether a particular study is included in this definition, it may consult with FDA as to which clinical studies constitute "covered clinical studies" for purposes of complying with financial disclosure requirements. (21 CFR § 54.2(e).) See Section IV.G, Covered Clinical Study, for additional information.

Applicant – "Applicant" means the party who submits a marketing application to FDA for approval of a drug, device or biologic product or who submits a reclassification petition. The applicant is responsible for submitting the required certification and disclosure statements. (See 21 CFR § 54.2(g).) Note that for purposes of financial disclosure the term "applicant" includes "submitter" and the term "application" includes "510(k) submission." See Section IV.F, Applicant, for additional information.

Sponsor of the covered clinical study – For purposes of part 54, "sponsor of the covered clinical study" means "a party supporting a particular study at the time it was carried out." (See 21 CFR § 54.2(h).) A covered clinical study may have more than one sponsor for whom financial information will need to be collected. For example, if one party designed and conducted the covered clinical study, a second party provided funding, and a third party provided the test product, there would be three sponsors of the covered clinical study. However, if the third party in this example was reimbursed for the test product, it would not be considered a sponsor of the covered clinical study and the study would be considered to have two sponsors. Note also that the definition of "sponsor" for purposes of part 54 is different than the definition of "sponsor" for purposes of investigational new drug applications (INDs) and investigational device exemptions applications (IDEs) (see 21 CFR §§ 312.3(b) and 812.3(n)). See Section IV.E, Sponsor, for additional information.

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: 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: July 13, 2014
Version2: August 26, 2015
Version3: September 22, 2017