Investigator Conflicts of Interest		
VCU/VCU Health CLINICAL RESEARCH STANDARD OPERATING PROCEDURES		
SOP No.: CR-ST-205.4	Status: Final	Version Date: 10/11/2024 Effective Date:10/18/2024

1. **PURPOSE**

This SOP describes procedures pertaining to conflicts of interest in clinical research. It supplements the *Conflicts of Interest in Research* policy, which details the process for reporting, assessing, and managing individual relationships deemed to be conflicts of interest (COI) for all research, regardless of funding. Institutional relationships that may appear to influence the conduct of clinical research are addressed in the *Institutional Conflicts of Interest in Research* policy, but will not be addressed in this SOP. The COI in Research Program, which is part of the VCU Office of Research Integrity and Ethics, administers the COI policies indicated above.

Individual conflict of interest in research is any situation in which personal interests (financial or non-financial) interfere, or appear to interfere, with the design, conduct, or reporting of unbiased research. Conflicts of interest are expected in a modern academic research environment and are not inherently improper. The appearance of a conflict of interest is as important as an actual conflict of interest. Investigators' relationships with the pharmaceutical and device industries are the major source of conflicts of interest in clinical research.

2. **REQUIREMENTS**

All principal investigators and research personnel (who are specifically designated as 'COI Investigators') will adhere to federal regulations, state law, and the VCU policy requirements for reporting interests and adhering to management plans (as applicable).

3. **DEFINITIONS**

See the *Conflicts of Interest in Research* policy for definitions of terminology used in this SOP.

4. **PROCESS**

A. 'COI Investigator' designation

The PI must determine if personnel listed on grant proposals or IRB protocols qualify as 'COI Investigators'. When designating individuals as 'COI Investigators', their independence and responsibility should be near comparable to that of the PI. The individual's role in the project, rather than their title, and the degree of independence with which those individuals work should be primary considerations. The 'COI Investigator' designation triggers a COI review for a particular protocol and does not imply that a COI exists. COI Investigators must complete a Financial Interest Report (FIR) in the Activity and Interest Reporting System (AIRS), reporting their

interests as well as those of their immediate family. The AIRS is a secure, electronic data entry system for reporting financial interests, while the FIR is the report that contains these financial interests.

All COI Investigators on proposals, awarded projects, and protocols are required to update annually beginning May 10th and within 30 days of acquiring additional interests as specified in the *COI in Research* policy.

B. Responding to the COI section in the VCU IRB protocol application
The IRB protocol application contains a COI section. All members of the research team should be asked, and must consider, whether they have a financial or non-financial interest related to the proposed research. An affirmative response by any member of the team, regardless of whether they were initially designated as a COI Investigator, should prompt a 'yes' response and explanation in the COI section of the IRB protocol application. If applicable, the member should be re-designated as a COI investigator in the protocol and complete a FIR in the AIRS. An affirmative response in the COI section of the protocol may ultimately not result in a COI disposition upon review.

C. Overview of the COI review process
- Each COI Investigator must complete their own FIR in the AIRS.
- COI Investigators at external entities that are deferring to the VCU IRB are subject to COI assessment and management either by their home institution or by VCU as per VCU *Conflicts of Interest in Research* policy requirements.
- The FIR is reviewed by the COI in Research Program in the context of awarded proposals and submitted protocols. Additional sources of information may be used to assess interests including the Outside Professional Activities report, information from any relevant Office of the Vice President for Research and Innovation offices, company websites, school or department administrators, and communications with the COI Investigator. Reported interests may rise to the level of a COI or competing interest (CI) depending on the type of interests, the research, and the role of the conflicted investigator.
- The VCU COI in Research Program or COI Committee determines whether a COI or CI exists.
- A review disposition is entered into the AIRS for each COI Investigator associated with a proposal or protocol.
- In cases requiring COI Committee consideration of a state-prohibited contract exception or a complex COI situation, the COI in Research Program will be in communication with the COI investigator, the PI (if different), and the department, as necessary.

D. Notifications and follow-up
- If it is determined that a conflict exists, COI Investigators with COI or CI dispositions are contacted through the AIRS to accept or suggest modifications for a management plan.
- The VCU IRB is notified when COI review is complete for all COI Investigators.
- The VCU IRB will not approve a protocol until dispositions for all COI Investigators are complete.

- Upon a COI Investigator's acceptance of a management plan, relevant individuals and/or entities are notified when the management plan is finalized. The COI in Research Program will notify the VCU IRB about the conflict and make recommendations for further actions for IRB consideration. The IRB will contact the COI Investigator, PI (if different), and protocol editor(s) regarding any needed modifications to the informed consent form or protocol.
- If a management plan is associated with an external IRB submission, the PI is responsible for forwarding the management plan and recommendations to the external IRB with the submission packet.
- If a conflict of interest is identified after the study has been submitted to an external IRB, the external IRB will receive the relevant management plan and any recommendations for further action from the COI in Research Program.
- The COI management plan is subject to follow-up monitoring at an interval indicated in the plan. COI Investigator updates in the AIRS may result in the modification of a management plan over the duration of a protocol.

E. FDA-required reporting to sponsors
- As per FDA guidance, a marketing applicant (typically an industry sponsor) for a drug, biological product, or device is required to submit a financial disclosure to the FDA for all clinical investigators who conducted covered clinical studies via either a Form FDA 3454 (certifying no disclosable financial interests) or 3455 (disclosing financial interests). The term 'clinical investigator' in this context means a listed or identified investigator or sub investigator who is directly involved in the treatment or evaluation or research subjects including the spouse and each dependent child of the investigator or the subinvestigator. The VCU COI in Research Program does not collect or review these forms.
- An IND/IDE sponsor is required to collect the financial information before permitting an investigator to participate in a clinical study.
- Disclosure required by the FDA is relevant to a specific study and includes interests held by the investigator as well as their spouse and dependent children. VCU does not require reporting for a specific study; however, the FIR contains questions about research relatedness for reported interests. The reporting required by the FDA for payments and equity interest starts at higher levels; for VCU, reporting begins at a zero ($0) threshold. Also note that while the FDA requires limited non-financial interest reporting, VCU requires more extensive reporting of non-financial interests (e.g. serving as an unpaid advisory board member).

5. **REFERENCES**

A. VCU
- VCU Office of Research and Innovation Conflict of Interest Webpage
- VCU Policies
  - Conflicts of Interest in Research

- HRPP Policies and Guidance; HRPP Toolkit
  - HRP-103 - Investigator Manual
  - HRP-309 - Ancillary Review Matrix

B. FDA
- Financial Disclosure by Clinical Investigators: Guidance for Clinical Investigators, Industry, and FDA Staff (February 2013)

Review/Revision History CR-ST-205		
Version No.	**Effective Date**	**Description**
CR-ST-205.4	10/18/2024	● Clarified clinical investigator definition ● Clarified who is responsible for forwarding the management plan to the external IRB ● Updated references ● Links updated
CR-ST-205.3a	07-01-2020	● Links updated
CR-ST-205.3	07-01-2020	● Biennial review performed ● Minor formatting edits ● Reference links updated
CR-ST-205.2	05-01-2018	● Financial Interest Report (FIR) deadline change and minor edits
CR-ST-205.1	11-01-2017	● Original