Training on Conflict of Interest in Research

Office of Research Integrity and Ethics
Conflict of Interest in Research Program
Introduction

Training addresses the following conflict of interest (COI) in research directives:

- Public Health Service (PHS) regulation: *Promoting Objectivity in Research* (42 CFR Part 50 Subpart F)
- VCU *Conflicts of Interest in Research* policy
- VCU *Institutional Conflicts of Interest in Research* policy

PHS regulation requires training prior to engaging in research, at least every 4 years, and immediately after the following circumstances:

- An investigator is new to the institution.
- The VCU *Conflicts of Interest in Research* policy is revised in a manner that affects the requirements of investigators.
- The institution finds that an investigator is not in compliance with the VCU *Conflicts of Interest in Research* policy or issued management plan.
PHS Regulation

• On August 25, 2011, the Department of Health and Human Services (DHHS) released a final rule that revised and strengthened the 1995 PHS *Promoting Objectivity in Research* regulation.

• Highlights from the final rule:
  – The institution is responsible for determining whether a significant financial interest (SFI) constitutes a financial COI.
  – The threshold for an SFI is $5,000 and compensated travel must be reported.
  – Upon an appropriate request of information from the public, an investigator’s managed COI will be disclosed within 5 days.
  – PHS and DHHS oversee institutional compliance.
Key Definitions

• Activity and Interest Reporting System (RAMS-AIRS)
  – The secure management system for reporting interests and recording the completion of this training

• COI Investigator
  – A designation determined by the PI that describes any individual who is responsible for the design, conduct, or reporting of research (regardless of their title, role, or position)

• Financial Interest Report (FIR)
  – The SmartForm in the AIRS that contains reported interests held by the investigator and their immediate family
COI in Research

• A COI can arise in situations in which financial or other personal considerations have the potential to compromise or bias professional judgment and objectivity.

• Conflicts of interest are not unusual in a modern academic setting but must be addressed in order to provide transparency and to protect research integrity.
  – Financial and non-financial interests can yield conscious or subconscious bias in the conduct and/or interpretation of research.
  – While interests with outside entities are not intrinsically unethical, they threaten research integrity if not reported, identified, and managed. An unidentified COI can be especially problematic in human subjects research if the investigator’s objectivity appears to be compromised.
VCU COI in Research Policy

• Informed by:
  – Federal regulation: PHS *Promoting Objectivity in Research* (42 CFR Part 50 Subpart F)
  – State law: *State and Local Government Conflict of Interests Act* (Code of Virginia § 2.2-3100 - 2.2-3131)

• Requires all COI Investigators on proposals or protocols to report financial and non-financial interests and their research relatedness in the AIRS, regardless of research funding status or source.

• Each investigator reports interests held by themselves and any member of their immediate family.
  – *Immediate family* means the investigator’s spouse and any person who resides in the same household and is a dependent of the investigator.
VCU Institutional COI in Research Policy

• An institutional conflict of interest (ICOI) is a situation in which the financial interests of VCU or its senior leadership might reasonably appear to influence institutional activities involving research.

• Financial interests include:
  – Gifts and license-related payments made to the university
  – Gifts and license-related payments received by senior leadership
  – Ownership interests in outside businesses held by the university or senior leadership

• Financial interests of the university and senior leadership will be disclosed annually at a minimum.
Reporting Interests

Reported interests include:

• Officer, director, and advisory board positions, whether paid or unpaid
• Outside professional activities and travel
• Equity and business interests
• Gifts received directly outside of VCU
• Intellectual property (IP) and its related payments

Reported interests do not include:

• Income from federal, state, or local government agencies in the U.S. (e.g. study sections) or other U.S. institutions of higher education (e.g. teaching engagements)
• Salary, reimbursement, or remuneration originating from VCU, with the exception of payments from the VCU Intellectual Property Foundation (IPF)
• Travel that was paid by VCU or by a project processed through VCU’s Office of Sponsored Programs (OSP)
• Gifts that were recorded through a VCU foundation or processed through OSP

Note: COI Investigators external to VCU who are deferring to VCU’s COI in Research policy must report financial interests, as described herein, except they are to only include interests that are directly related to their work for VCU.
Reporting Interests

• When to report interests:
  – Annually (annual reporting begins May 10th)
  – Within 30 days of acquiring:
    • A new interest or an additional interest in a previously reported entity
    • New IP that has been disclosed to VCU Innovation Gateway
    • New research relatedness with any reported interest

• When is a FIR reviewed?
  – Prior to protocol approval and/or award dispersal
    NOTE: For proposal submissions, the FIRs of all COI Investigators must have been updated within the most recent annual update period.
  – After the investigator completes the annual update
  – After the investigator updates their FIR at any other time
Submitting your FIR

• To submit your FIR, check the box before clicking the Finish button.

End of SmartForm

Check the box below and click Finish on the toolbar to affirm agreement and fully submit your FIR.

☐ I have accurately completed my Financial Interest Report (FIR) as required by VCU policy.
I understand that I must update my FIR within 30 days upon acquiring or discovering:

- a new interest in an entity not previously reported
- an additional interest in a previously reported entity
- new intellectual property that has been disclosed to VCU Innovation Gateway
- new research relatedness with any reported interest

• Alternatively, you can click Submit My Annual Disclosure Report under My Activities on your FIR workspace.
  – This option will change to Finished Updating My Financial Interest Report if you update your FIR after the annual update is submitted.
Determining COI Findings

• The VCU COI in Research Program is responsible for determining whether a significant financial interest (SFI) constitutes a financial COI, which is an SFI that reasonably appears to be related to the investigator’s institutional responsibilities and could directly and significantly affect the design, conduct, or reporting of research.
  – *Institutional responsibilities* means an investigator’s professional responsibilities on behalf of the institution, which may include research, research consultation, teaching, professional practice, and service on committees.

• SFIs include the following:
  – Financial interest in a publicly traded entity (e.g. consulting fees or honoraria; equity interest including stock or stock options) that, individually or in aggregate, exceeds $5,000 during the 12 month period preceding COI review
  – Any financial or ownership interest in a non-publicly traded entity (e.g. a start-up company)
  – IP in which license-related payments have been received from an entity other than VCU
  – NOTE: Travel may be an SFI.
Determining CI Findings – VCU Only

- A competing interest (CI) is an internal designation for an interest that does not rise to the level of a COI but is deemed by VCU to warrant attention and internal management; it is not reportable or actionable according to PHS regulation.

- CIs may include:
  - Financial interests in a publicly traded entity (e.g. consulting fees or honoraria; equity interest including stock or stock options) that, individually or in aggregate, exceeds $0 but is less than $5,000 during the 12 month period preceding COI review
  - Unlicensed IP to be used within the research
  - IP for which license-related payments are distributed through VCU IPF
How is a COI/CI Identified?

Expedited or COI Committee review in the context of the proposed or ongoing research will determine:

- **No COI**
- **COI/CI**

COI review requested for all COI Investigators on proposal or protocol.

COI Investigator updates FIR in the AIRS.
Management Plans

• If it is deemed that a COI Investigator has a COI/CI that requires management after expedited or COI Committee review, they will be issued a management plan.
  – Management plan elements will include, at a minimum, disclosure of the financial relationship in publications and presentations of the study results as well as to project personnel

• COI Investigator responsibilities:
  – Review each issued management plan, request any changes, and digitally sign the plan after an agreement has been reached. Once the management plan has been finalized, any holds on funding or protocol approvals related to the plan will be released.
  – Comply with all terms, conditions, and actions required under the management plan. The investigator must respond to all requests for information, meetings, or documentation pertaining to the university’s responsibility to monitor compliance with the plan.
Reasons an Investigator May be Contacted

• Update of FIR needed within the AIRS
• Question regarding:
  – An interest that is not reported in the AIRS (based on OPA comparison or other information)
  – Relatedness of an interest to the research project being reviewed
  – Details/clarification of an interest
  – Use of IP in a research project
• Issued a management plan
• Follow-up on a previously issued management plan
• Non-compliance with a management plan
COI in Research Program Responsibilities

• Review the FIRs of COI Investigators to identify COI/CI
• Develop and implement management plans for COI/CI
• Report financial COI to PHS sponsors, other federal agencies as required, and other sponsors upon request
• Review unreported/unreviewed financial interests and, if necessary, implement a management plan within 60 days
• Upon a determination of non-compliance:
  – The research project and the investigator’s activities are retrospectively reviewed within 120 days of the discovery of non-compliance with the VCU COI in Research policy to determine if there was bias in the design, conduct, or reporting of research.
  – If bias is found, the PHS sponsor is notified promptly and a mitigation report is submitted.
Summary

• A COI requiring management can arise in situations in which financial or other personal considerations have the potential to compromise or bias professional judgment and objectivity.

• Report interests that you or members of your immediate family hold on an annual basis (on or after May 10th) and within 30 days of a change to your interests or their relatedness to all proposed or ongoing research.
  – Interests should be reported for the last 12 months from the date of the report.
Resources

• Federal/state
  – Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought (or Promoting Objectivity in Research) 42 CFR Part 50
  – Responsible Prospective Contractors (45 CFR Part 94)
  – National Science Foundation (NSF) Conflict of Interest Policies (NSF 05-131 510)
  – FDA Financial Disclosure by Clinical Investigators regulations (21 CFR 54)
  – State and Local Government Conflict of Interests Act (Code of Virginia § 2.2-3100 - 2.2-3131)

• VCU
  – Conflicts of Interest in Research policy
  – Institutional Conflicts of Interest in Research policy

Questions? Visit the COI in Research website or contact the COI in Research Program at AIRS@vcu.edu.