

# Research Conflict of Interests

## Training: PHS Final Rule and VCU Policy

# Introduction to Research COI Training

The following required training may be completed and submitted in the AIRS system.

Required training will address the following:

- Revised 2011 Public Health Service (PHS) regulations ‘**Promoting Objectivity in Research**’  
[http://grants.nih.gov/grants/policy/coi/fcoi\\_final\\_rule.pdf](http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf)
- Revised 2012 **VCU Research Conflict of Interests policy** and process.  
<http://www.assurance.vcu.edu/Policy%20Library/Conflicts%20of%20Interest%20Policy.pdf>
- VCU Activities and Interest Reporting System (**AIRS**)  
<http://airs.research.vcu.edu/>

PHS regulations require investigator training the first time you access the AIRS, every 4 years, and immediately under the following circumstances:

- Institutional Financial Conflict of Interests policies change in a manner that affect Investigator requirements
- An Investigator is new to the Institution
- Institution finds that an Investigator is not in compliance with the Institution’s Financial Conflict of Interests policy or management plan.

# About Conflicts of Interest in Research

**Conflicts of Interest (COI)** exist in many forms and frequently are inherent to the nature of the research enterprise. A Conflict of Interest can arise in situations in which there exists discord between primary institutional responsibilities and secondary interests.

- Financial or Non-financial, interests can yield conscious or subconscious bias in the conduct and/or interpretation of research.
- Financial conflicts of interest can simply present an appearance of compromising an investigator's professional judgment in conducting or reporting research. While financial interests with outside entities are not intrinsically unethical, they threaten research integrity if not reported, identified and managed.
- Unidentified conflicts of interest can be especially problematic in human subjects research if investigator objectivity is, or appears to be, compromised.

# 2011 PHS Final Rule

In recent years there has been increased public attention on financial relationships that compete or conflict with an investigator's institutional responsibilities, especially for federally funded research. In response to this scrutiny, the Department of Health and Human Services released a Final Rule on August 25, 2011 that revised and strengthened the 1995 PHS rules for '*Promoting Objectivity in Research*.' The Final Rule places the onus on the institution for identifying and managing financial conflicts of interest.

## Major Changes from 1995 Regulations

- De minimus threshold for significant financial interests (SFI) decreased to \$5,000.
- 'Investigator' training – at least every 4 years
- 'Investigator' must report compensated travel
- Institution has the responsibility for determining whether SFI constitutes FCOI (Financial COI)
- Public disclosure – via website or within 5 days of a request
- Increased PHS and DHHS oversight of institutional compliance

# VCU Policy + Final Rule + State Law

The VCU Research Conflict of Interests Policy is informed by federal regulation (Promoting Objectivity in Research at 42 CFR Part 50 Subpart F) **and** the [Virginia State and Local Government Conflict of Interests Act](#), which may be found in the Code of Virginia, beginning with Section 2.2-3100.

Faculty and non-faculty employees should be aware of the provisions of State law as well as VCU's Policy on [Outside Professional Activity and Employment, Research, and Continuing Education](#), the University's [Conflict of Interest Policy](#), included within the University's Financial Policies, and the VCU Research Conflict of Interests Policy.

## Highlights of VCU's Research COI Policy and Process

- COI training required of all investigators
- Electronic reporting of financial interests for all 'investigators' (including subrecipients) regardless of title and position in the VCU eRA Activity and Interest Reporting System (AIRS).
- Reporting financial interests into the AIRS initially, annually, updates within 30 days, and reporting research relatedness.
- Reported financial interests include travel
- Public disclosure of FCOI for senior/key personnel on PHS funded research within 5 days of request
- Greater emphasis on policy compliance and consequences of noncompliance

# VCU's Research Conflict of Interests Policy

**VCU's policy applies to all 'Investigators' regardless of research funding or source.**

The policy requires all PI-designated Investigators listed on proposals or protocols submitted to the IRB or IACUC to report financial interests and research relatedness via the VCU AIRS on an **annual basis** and **within 30 days of discovering or acquiring a financial interest**.

**Define 'Investigator' –**

describes any individual, regardless of title, role or position, who is **responsible for the design, conduct, or reporting of research**. By considering an individual's degree of independence relative to the research, the Principal Investigator on the proposal or protocol designates the individuals who meet the definition of 'Investigator.'

# Reporting Financial Interests by Investigators

Each Investigator **reports requested Financial Interests held by himself or herself, or any member of his or her immediate family** (spouse and any other person residing in the same household as the researcher, who is a dependent of the researcher or of whom the researcher is a dependent).

Reported Financial Interests include:

- **salary or other payments for services** (e.g., consulting fees, honoraria, or payments for serving on a corporate Board of Directors, Scientific Advisory Board, or holding a position in a company) from an entity(ies) other than VCU;
- income from **seminars, lectures, service or teaching engagements** sponsored by for-profit entities, federal, state, or local agencies or public or non-profit entities;
- **equity interests** (e.g., stocks, stock options, or other ownership interests);
- income related to **intellectual property rights** (e.g., patents, copyrights, and royalties from such rights,); and
- **travel** that is reimbursed or paid by a third party (i.e., travel that is arranged and paid for directly by an organization so that the exact monetary value may not be readily available) related to an Investigator's Institutional Responsibilities.

Financial Interest **does not** include salary, reimbursement or travel payment originating from VCU, VCUHS, or MCVP, **with the exception** of royalties/ payments from VCU IP Foundation.

# What and when to report?

Financial Interests to report in the VCU AIRS:

- ☐ All FIs, including compensated travel, initially and on an annual basis in a secure database.
- ☐ Updates within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance):
  - 1)** a new Financial Interest in an entity not previously reported (e.g. a new interest in a new company), or
  - 2)** an additional remunerated Financial Interest, that, when added to a Financial Interest in a previously reported entity, meets or exceeds \$5,000.
- ☐ Research-related questions concerning Financial Interests specifically associated with proposed and on-going research.
- ☐ Update 'research relatedness' of financial interests, including compensated travel, for every Sponsored Program submission, IRB or IACUC submission, if applicable.

**Travel** by the Investigator or immediate family that is reimbursed or paid by a third party (i.e., travel that is arranged and paid for directly by an organization so that the exact monetary value may not be readily available) related to an Investigator's Institutional Responsibilities. Travel is reported in the AIRS section titled "Payment for Consulting, Talks, Meetings, and Publications." Reported travel includes the purpose of the trip, the entity compensating for travel, the destination, the amount of compensation, and the duration of travel.

An **Investigator's Institutional Responsibilities** describe those professional responsibilities an Investigator has by virtue of being a VCU employee, student, or trainee. These may include for example: teaching, professional practice, service on committees, research and research consultation.



# Significant Financial Interests (SFIs)

SFIs reasonably appear to be related to the Investigator's Institutional Responsibilities, and could, or could appear to, directly and significantly affect the design, conduct, or reporting of research.

## SFIs include the following:

- financial interest in a publicly traded entity that, individually or in aggregate, **exceeds \$5,000** on the date of disclosure or during the 12 months preceding an investigator's report (e.g. consulting, honoraria; equity or ownership interest including stock, stock options).
- any financial interest, or ownership interest, in a non-publicly traded entity, eg. a start up company.
- income related to intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income, such as royalty payments, related to such rights and interests.
- Travel, by itself or in combination with other Financial Interests, may be SFI.

## SFI exclusions:

- Salary or reimbursements paid by VCU, with the exception of payment from the VCU Intellectual Property Foundation.
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as the investigator does not directly control the investment.

# Competing Financial Interests (CFIs)

Financial Interests, as defined earlier, are those that reasonably appear to be related to the Investigator's Institutional Responsibilities, and could appear to affect the design, conduct, or reporting of primarily human subjects research.

## CFIs may include:

- Financial interest(s) in a publicly traded entity that, individually, or in aggregate, **exceeds \$0 but is less than \$5,000** on the date of report and during the 12 months preceding an investigator's report (e.g. consulting, honoraria; equity or ownership interest including stock, stock options; compensated travel).
- Unlicensed Intellectual Property to be used within the research
- Licensed Intellectual Property for which royalty payments are distributed through the VCU Intellectual Property Foundation

Such financial interests in the context of human subjects research will be referred to the Conflict of Interests Committee for expedited or full Committee review and possible internal management. Competing Financial Interests are not reported to NIH or subject to other requirements of the PHS "Objectivity in Research" regulations.

# Investigator Responsibilities

To be in compliance with University policy, state law, and federal regulations, VCU requires Investigators to:

- Complete the AIRS Training initially, at least once every four (4) years, and on other occasions if specifically notified by University officials
- Report all financial interests annually and within 30 days of acquiring or discovering the interest by updating the Financial Interest Report (FIR) in the AIRS
- Report research relatedness with existing and updated financial interests
- Provide any additional information requested by VCU's Office of Research Integrity and Ethics or Conflict of Interests Committee
- If applicable, review each Financial Conflict of Interest Management Plan created for you, request any changes , and accept the Plan after agreement has been reached. Once you have accepted the Management Plan, any pending funding or protocol approvals related to the Plan will be released.
- If applicable, comply with all terms, conditions, and actions required under the Management Plan. You must respond to all requests for information, meetings, or reports regarding the University's responsibility to monitor compliance with the plan.

Note that pre-emptive discussion about foreseen financial conflicts of interest is welcome.

Contact [AIRS@vcu.edu](mailto:AIRS@vcu.edu) to begin a conversation with the Conflict of Interests Committee.

# VCU Office of Research Responsibilities

- Review FIR submissions to identify Financial Conflicts of Interest (FCOI).
- Develop and implement management plans for FCOI.
- Report FCOI to PHS sponsors, other federal agencies as required, and other sponsors upon request.
- Verify with subrecipient institutions the existence of a policy that meets the PHS 'Objectivity in Research' requirements; if none, subrecipients use the VCU AIRS.
- Train all Investigators prior to beginning research, at least every four years thereafter, and in certain other circumstances.
- Maintain records in accordance with regulatory requirements.
- Monitor compliance with active Management Plans.
- Respond to requests for information about Financial Conflicts of Interest held by Senior/Key Personnel on PHS funded research to any requestor within five (5) business days of a request.
- Review unreported/unreviewed Financial Interests and implement a management plan within 60 days.
- Retrospectively review the research project and the Investigator's activities within 120 days of discovery of non-compliance with the Research Conflict of Interest Policy to determine if there was bias in the design, conduct, or reporting of research. If bias is found, submit a mitigation report to PHS.

# Related Documents and Resources

42 CFR Part 50, 45 CFR Part 94 *Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors* – “[Objectivity in Research](#)” – Public Health Service (PHS) Rules

[Conflict of Interest](#) – National Science Foundation (NSF) Rules

[21 CFR 54](#) – FDA regulation for Financial Disclosure by Clinical Investigators

[Virginia State and Local Government Conflict of Interests Act](#)

Institutional Conflict of Interests in Human Subjects Research (URL Pending)

[Conflict of Interest Policy](#) within the VCU Financial Policies

[Outside Professional Activity and Employment, Research, and Continuing Education](#)

[Misconduct in Research and Scholarly Activities Policy](#)

VCU Institutional Review Board (IRB) Written Policy and Procedure [VIII-10 Evaluating Investigator and other Potential Conflicts of Interest](#)

CITI COI mini-course for additional information. Log into [www.citiprogram.org/](http://www.citiprogram.org/).

Enter the CITI username and password you usually use. Add the COI course to your menu.

Questions about completing the FIR or about the information presented?

Please contact the COI Program at [airs@vcu.edu](mailto:airs@vcu.edu)

or see the COI website at <http://www.research.vcu.edu/coi/index.htm>