



# Conflict of Interests in Research

Virginia Commonwealth University  
Office of Research and Innovation  
COI Program  
3/2016

# Introduction to COI in Research Training

**This required Conflict of Interests (COI) in Research training must be completed and submitted in the VCU Activity and Interest Reporting System (AIRS):**

<http://airs.research.vcu.edu/>

Training will address the following:

- Revised 2011 Public Health Service (PHS) regulations: '[Promoting Objectivity in Research](#)'
- [Revised 2014 VCU Conflict of Interests in Research policy](#)
- [2015 Institutional Conflicts of Interest in Research policy – INTERIM](#)

PHS regulations require training the first time an Investigator accesses the AIRS, at least every 4 years after the initial training, and immediately after the following circumstances:

- The Institution finds that an Investigator is not in compliance with the VCU COI in Research policy or issued management plan.
- The Institution's COI policies change in a manner that affect Investigator requirements.



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# 2011 PHS Final Rule

On August 25, 2011, the Department of Health and Human Services (DHHS) released a Final Rule 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 (FCOI).

## Highlights from Final Rule

- The *de minimus* threshold for significant financial interests (SFIs) is \$5,000.
- COI training is required for all Investigators every 4 years (at a minimum).
- The Investigator must report compensated travel.
- The Institution has the responsibility for determining whether an SFI constitutes a FCOI.
- Upon an appropriate request of information from the public, an Investigator's managed COI shall be disclosed within 5 days.
- PHS and DHHS oversee institutional compliance.

# Key Definitions

- **COI Investigator (or Investigator)**
  - Describes any individual, regardless of title, role, or position, who is responsible for the design, conduct, or reporting of research. This title is designated by the PI on the proposal or protocol.
- **Institutional Responsibilities**
  - An Investigator's professional responsibilities on behalf of the Institution, which may include activities such as research, research consultation, teaching, professional practice, and service on committees
- **Financial Conflict of Interest (FCOI)**
  - A significant financial interest that could directly and significantly affect the design, conduct, or reporting of NIH-funded research
- **Financial Interest Report (FIR)**
  - The SmartForm through which interests are reported in the VCU AIRS

# About COI in Research

Conflicts of interest exist in many forms and frequently are inherent to the nature of the research enterprise. A COI can arise in situations in which financial or other personal considerations have the potential to compromise or bias professional judgment and objectivity.

- 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/or managed.
- Unidentified conflicts of interest can be especially problematic in human subjects research if the Investigator's objectivity is (or appears to be) compromised.

# VCU's COI in Research Policy

**VCU's policy applies to all 'Investigators' regardless of research funding or source.** The policy requires all 'COI Investigators' listed on proposals or protocols submitted to the OSP, IRB, or IACUC to report financial interests and their research relatedness via the AIRS.

[VCU's Conflict of Interests in Research Policy](#)

## Highlights from Policy

- Electronic reporting of financial interests in the AIRS is required for all those deemed as 'COI Investigators' (including subrecipients), regardless of title or position.
- Financial interests (including travel) and their research relatedness must be reported initially, annually, and within 30 days of acquiring a new financial interest.
- There is a greater emphasis on policy compliance and consequences of noncompliance.

# Other Notable Policies

The VCU COI Policy is informed by:

- Federal regulation
  - ['Promoting Objectivity in Research' at 42 CFR Part 50 Subpart F](#)
- State regulation
  - [Virginia State and Local Government Conflict of Interests Act](#), found in the Code of Virginia beginning with Section 2.2-3100

In addition to the provisions of state and federal law, faculty and staff should be aware of:

- [Guidelines and Procedures for Disclosure, Approval and Reporting of Outside Professional Activities](#)

# VCU's Institutional COI Policy

An institutional conflict of interest (ICOI) is a situation in which the financial interests of the University or its covered members might influence (or reasonably appear to affect) institutional activities involving research. Such influence can emanate from individuals among VCU leadership who hold positions of trust as well as within the university itself, its entities, and its holdings.

- Financial interests include:
  - Gifts, pledges, or payments (including royalties) to the University  $\geq$ \$100,000
  - Equity, ownership, or financial interests held by the University in where such interests have a) a value in excess of \$50,000 in publicly traded companies or b) a value of any amount in a non-publicly traded entity
  - Covered member has business interests, license, or revenue  $>$ \$10,000 or ownership interests  $>$ 3% of the total equity in each outside firm or business
  - Covered member receives gifts, salary, wages, or payments  $>$ \$10,000
- Financial interests of covered members and University entities will be disclosed annually and updated throughout the year.

[VCU's Institutional Conflict of Interests in Research Policy](#)



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# Reporting Financial Interests

Each Investigator reports financial interests held by him or herself or any member of his or her immediate family (spouse and any child who resides in the same household as the Investigator and who is a dependent of the Investigator).

## **Reported financial interests include:**

- Officer/Director Positions (corporate Board of Directors, Scientific Advisory Board, or holding a position in a company)
- Additional salary or other payments for services (e.g. compensated travel, consulting fees, honoraria, seminars, lectures, or other teaching engagements) from an entity other than VCU
- Equity interests (e.g. stock, stock options, or other ownership interests)
- Intellectual property and its related income (e.g. patents, copyrights, and royalties from such rights)

**Financial interests do not include salary, reimbursement, or travel payment originating from VCU, VCUHS, or MCVP, with the exception of royalties/payments from VCU Intellectual Property Foundation.**

## **When to report financial interests:**

- On an annual basis (around mid-May of each year)
- Within 30 days of acquiring a financial interest

# Significant Financial Interests (SFIs)

SFIs appear to be reasonably 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, and/or equity or ownership interest including stock or stock options)
- Any financial or ownership interest in a non-publicly traded entity (e.g. a start up company)
- Serving on a Board of Directors, Scientific Advisory Board, or holding a position in a company.
- Income related to intellectual property (e.g. milestone and/or royalty payments)
- Travel in combination with other financial interests may be a SFI.

# Competing Financial Interests (CFIs) – VCU Only

## CFIs may include:

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

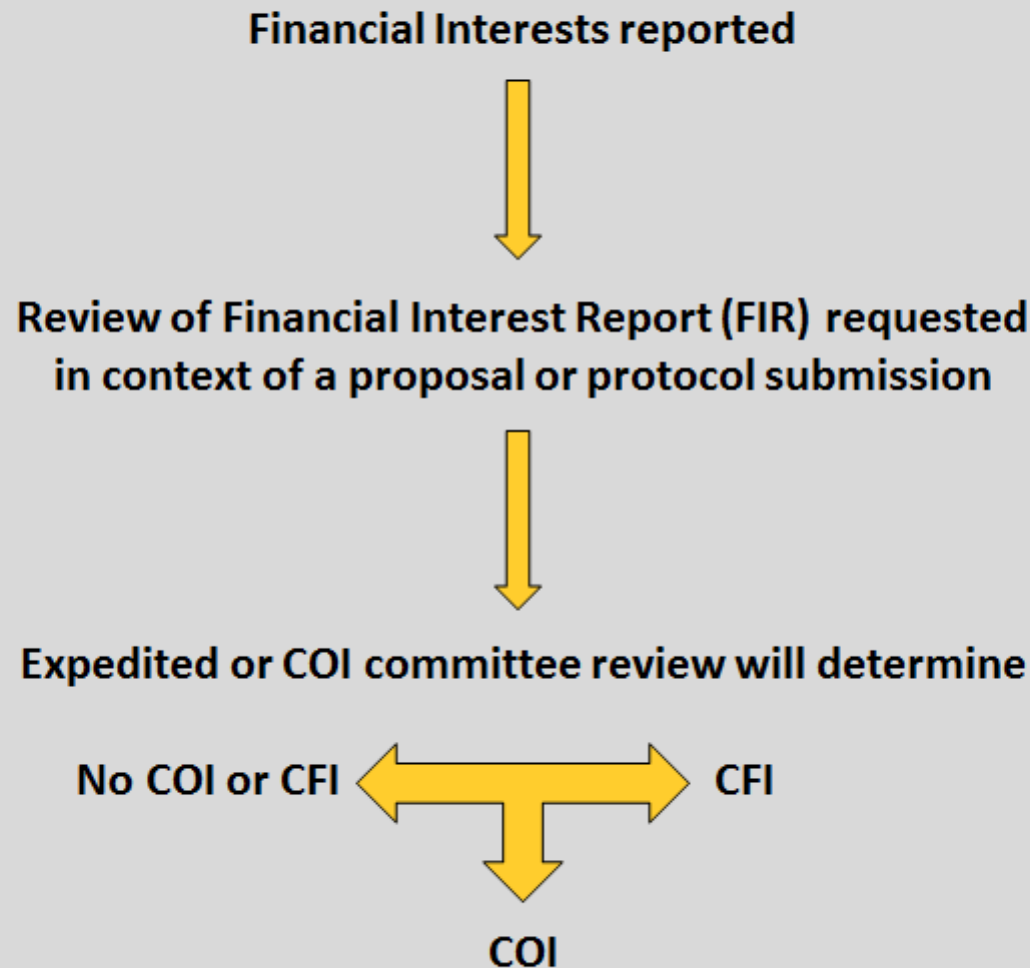
Such financial interests in the context of human subjects research will undergo expedited review or will be referred to the COI Committee for full review and possible internal management. CFIs are not reported to the NIH or subject to other requirements of the PHS 'Promoting Objectivity in Research' regulations.



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# How is a COI (or CFI) identified?



# Management Plans

If it is deemed that an Investigator has a COI/CFI that requires management after expedited or COI Committee review, they will be issued a management plan. Potential 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.

## **COI Investigator responsibilities:**

- Review each issued management plan, request any changes, and accept the plan after an agreement has been reached. Once the management plan has been accepted, 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 reports regarding the University's responsibility to monitor compliance with the plan.

Note that preemptive discussion about a foreseen COI is welcome. Contact [AIRS@vcu.edu](mailto:AIRS@vcu.edu) to begin a conversation with the COI team.



# AIRS

Financial interest reporting occurs in the electronic VCU eRA Activity and Interest Reporting System (AIRS):

<http://airs.research.vcu.edu/>


- To access AIRS outside of VCU, use the Virtual Private Network (VPN) for secure remote access:

<http://www.ts.vcu.edu/askit/network-services/rams-vpn/>

- Each Investigator enters his or her own financial interests into the AIRS by logging in with an eID & password.

The following slides show screenshots of basic AIRS components.

# Home Screen:


**VCU** Office of Research

[ACUR](#)
[AIRS](#)
[CORES](#)
[IRB](#)
[SPOT](#)
[REPORTS](#)

[Research Administration](#)
[Meetings](#)
[Analytics](#)
[Help](#)


Page for

My Financial Interest Report

Name	SmartForm	Execute Activity	Date Modified	State
Financial Interest Report for	[Financial Interest Report]		3/17/2016 9:52 AM	Active

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# Investigator FIR Workspace:


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[ACUR](#)
[AIRS](#)
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[SPOT](#)
[REPORTS](#)

[Research Administration](#)
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Page for > Financial Interest Report for

Current State

Active

My Financial Interest Report Forms

[View Financial Interest Report](#)
[Print Research FIR](#)
[View Differences](#)

Create Review

[Create Review](#)

My Activities

[Open My Financial Interest Report for Editing](#)
[Upload Reporter Documents](#)
[Log Public Comment](#)

(Active Template)

Financial Interest Report for

Reporter VCU Phone:

Reporter VCU Email:

Reporter Department:

Reporter's Security Roles:

FIR ID#:

Date FIR Last Updated:

Date FIR Last Reviewed:

Date FIR Created:

Date COI Training Last Completed(if applicable):

1 Click the Open My Financial Interest for Editing activity under My Activities

2 Click the Edit Financial Interest Report button under My Financial Interest Report Forms and follow the instructions on your screen

3 Once finished, click the Finished Updating My Financial Interest Report activity

History

Comments

Archive

Documents

Additional Information

Reviews

Management Plans

Snapshot


Activity	Author	Activity Date
Financial Interest Report Updated		3/17/2016 9:52 AM
Financial Interest Report Opened for Editing		3/17/2016 9:51 AM
Financial Interest Report Updated		3/16/2016 1:09 PM
Financial Interest Report Opened for Editing		1/14/2016 10:44 AM
Annual Disclosure Report Submitted		7/6/2015 3:39 PM
Annual Financial Interest Reporting Begins	Administrator, System	5/10/2015 2:13 PM

# Financial Interest Questions

[yes/no; if yes, directed to more questions; blue circle – Help]

## Financial Interests

### 1.0 \* Officers and Directorships -

Are you or a member of your immediate family a paid or unpaid officer, or paid or unpaid director of a business or non-profit: 

☒ Yes

☐ No

[Clear](#)

### 2.0 \* Investments and Securities -


Do you or a member of your immediate family, directly or indirectly, separately or together, own securities in a business? Statement of Economic Interest reporters must account for all investments and securities. Research financial interest reporters do not have to account for investments and securities over which they have no direct control: 

☒ Yes

☐ No

[Clear](#)

### 3.0 \* Payment for Consulting, Talks, Meetings, and Publications -


During the past 12 months did you receive in your capacity as an employee / affiliate of VCU lodging, transportation, money, or anything else of value for (i) consulting work, a talk, meeting, expert witness testimony, published work, (ii) conference, or event where your attendance was designed to (a) educate you on issues relevant to your duties as an employee/affiliate of VCU or (b) enhance your knowledge and skills relative to your duties as an employee/affiliate of VCU: 

☒ Yes

☐ No

[Clear](#)

### 4.0 \* Salary and Wages -


Do you or a member of your immediate family receive salary or wage(s) in addition to salary or wage(s) from VCU: 

☒ Yes

☐ No

[Clear](#)

### 5.0 \* Business Interests -


Do you or a member of your immediate family, separately or together, operate your own business, or own or control an interest in a business: 

☒ Yes

☐ No

[Clear](#)

### 6.0 \* Grants, Gifts, or In Kind Materials from For-Profit Entities -

Have you been the Principal Investigator or direct recipient of grants, gifts, in kind materials, etc from a company for educational or other support of your school, department, or division? 

☒ Yes

☐ No

[Clear](#)

### 7.0 \* Intellectual Property -

Do you or a member of your immediate family have an inventive or ownership interest in any Intellectual Property (e.g. inventions, tangible research materials, copyrights, etc) or Intellectual Property disclosures: 

☒ Yes

☐ No

[Clear](#)



# Details View



Office of Research

Edit: Financial Interest Report - [redacted]

<< Back

Save | Exit | Hide/Show Errors | Print... | Jump To: -- Consulting, Talks, Meetings, and Publications Details

Continue >>

Responses will be saved when pressing Continue, Save or using the Jump To menu. For help navigating the system, use the Jump To menu to go to - Introduction.

Financial Interest Report for: [redacted]

## Consulting, Talks, Meetings and Publications Details

If this section is not applicable, use the "Jump To" menu to go to the - Financial Interests view and update your selections.

- 1.0 \* List payments [lodging, transportation, money, or any other thing of value (excluding meals or drinks coincident with a meeting)] for talks, meetings, expert witness testimony, and publications (even if payment was donated to charity) ?

Add												
Payer Name	Activity Types	Activity Type - Other	Payer Type	Payment Type	Payment Type - Other	Payment Destination	Payment Duration	Payment Amount \$	Payment Date	Out of State	Related Interest	Explanation
Update American Heart Association	Serving in office or on committee for an academic/professional society or nonprofit organization Study Section		Non-Profit Organization	Travel Reimbursement		Dallas	3	400	12/4/2013	yes	no	Delete
								1000	12/4/2013			

<< Back

Save | Exit | Hide/Show Errors | Print... | Jump To: -- Consulting, Talks, Meetings, and Publications Details

Continue >>

# Submitting your FIR

Make sure to **check the 'Update is Complete' box** before clicking the 'Finish' button in order to submit your FIR.

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VIRGINIA COMMONWEALTH UNIVERSITY

Edit: Financial Interest Report: [ ]

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: [ ] Finish

Responses will be saved when pressing Continue, Save or using the Jump To menu. For help navigating the system, use the Jump To menu to go to - Introduction.

Financial Interest Report for: [ ]

End of Smartform:  
**FINANCIAL INTEREST REPORT**

CHECK IF YOUR UPDATE IS COMPLETE : ☐

Checking the box above and clicking FINISH below successfully submits the FIR into the system and places it in the ACTIVE state. If you are not ready to submit, do not check the box above. You may submit the form later by either returning to this screen and checking the box above or executing the submit activity in the report workspace.

Check the box above and click FINISH below to fully submit the FIR

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: [ ] Finish

# When is a FIR Reviewed?

- Upon annual update by the Investigator
- Prior to protocol approval and/or prior to award processing
  - Review request(s) are sent to the COI Office, at which time each Investigator's FIR is assessed for COI/CFI in the context of the research project.
  - Each Investigator's FIR must have been updated within the most recent update period.

# Reasons an Investigator may be Contacted

- FIR requires an update
- Question(s) regarding:
  - Unreported financial interest in AIRS (based on OPA comparison)
  - Relatedness of a financial interest to the research project being reviewed
  - Details/clarification of a financial interest
  - Use of intellectual property in a research project
- Management plan has been issued
- Follow up on a previously issued management plan
- Non-compliance with a management plan

# VCU ORIE Responsibilities

- Review FIR submissions to identify COI/CFI.
- Develop and implement management plans for COI/CFI.
- Report FCOI to PHS sponsors, other federal agencies as required, and other sponsors upon request.
- Verify the existence of a policy that meets the PHS 'Promoting Objectivity in Research' requirements with subrecipient institutions; if none, subrecipients use the VCU AIRS.
- 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 will be retrospectively reviewed within 120 days to determine if there was bias in the design, conduct, or reporting of research.
  - If bias is found, the PHS sponsor will be promptly notified and a mitigation report will be submitted.



# Summary

A conflict of interest requiring management can arise in situations in which financial or other personal considerations have the potential to compromise or bias professional judgement and objectivity.

COI Investigators must report all financial interests in the AIRS on an annual basis and within 30 days of a) acquiring a new financial interest or b) receiving additional remuneration for a previously reported financial interest.

- Interests should be reported for the last 12 months preceding the report date.

Preemptive discussion about a foreseen COI is welcome. Contact [AIRS@vcu.edu](mailto:AIRS@vcu.edu) to begin a conversation with the COI team.

# Related Documents and Resources

[‘Promoting Objectivity in Research’](#) 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* – 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](#)

[2015 Institutional Conflicts of Interest in Research – INTERIM](#)

[2014 VCU Conflict of Interests in Research policy](#)

[Guidelines and Procedures for Disclosure, Approval and Reporting of Outside Professional Activities](#)

[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](#)

VCU COI website: <http://www.research.vcu.edu/coi/index.htm>

For additional information, CITI offers a COI mini-course. Log into [www.citiprogram.org/](http://www.citiprogram.org/) using your CITI username and password. Add the COI course to your menu.



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Questions about completing the FIR or about the information presented? Please contact the COI Program at [AIRS@vcu.edu](mailto:AIRS@vcu.edu)  
or visit the COI website at  
<http://www.research.vcu.edu/coi/index.htm>