



Conflicts of Interest in Research

Policy Type: Administrative

Responsible Office: Office of Research Integrity and Ethics, Office of the Vice President for Research and Innovation

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Policy Statement and Purpose

A conflict of interest (COI) is a situation in which financial or non-financial interests of the investigator or the investigator’s immediate family compromise, or may appear to compromise, the investigator’s professional judgment in exercising an institutional duty or responsibility, including the design, conduct, or reporting of research. The appearance of a conflict of interest is as important as an actual conflict of interest. It is the policy of the university that research be conducted in an unbiased manner. Therefore, this policy ensures that research-related interests are reported and that potential conflicting and competing interests are evaluated and appropriately resolved or managed. This policy also ensures the university’s compliance with the Health and Human Services (HHS) PHS regulations on *Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought* (42 C.F.R. Part 50 Subpart F) and the Code of Virginia *State and Local Government Conflict of Interests Act* (§2.2-3100).

This policy applies to sponsored research projects, expedited and full board studies undergoing Institutional Review Board (IRB) review, studies undergoing Institutional Animal Care and Use Committee (IACUC) review, and other studies and projects for which a related interest has been reported to the university. This policy also applies to all Public Health Service (PHS) research grants and cooperative agreements, such as career development, center, and institutional training grants; individual fellowship, infrastructure, and research resources awards; and program projects. While a COI may involve institutional-level relationships (addressed by VCU’s *Institutional Conflicts of Interest in Research* policy), this policy focuses on COI involving individual investigators. In addition to compliance with this policy, investigators must always review and comply with the federal agency requirements applicable to their specific research projects.

Noncompliance with this policy may result in disciplinary action up to and including termination. VCU supports an environment free from retaliation. Retaliation against any employee who brings forth a good faith concern, asks a clarifying question, or participates in an investigation is prohibited.

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Who Should Know This Policy

All university members involved in the design, conduct, reporting, review, administration, or supervision of research are responsible for knowing this policy and familiarizing themselves with its contents and provisions.

Definitions

Activity and Interest Reporting System (AIRS)

The AIRS is a secure Research Administration Management System (RAMS) for the reporting of confidential financial and non-financial interests and third party relationships. COI review and COI Committee (COIC) activities are managed via the AIRS.

Competing interest (CI)

A CI is an internal designation for characterizing interests 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, depending on the context of the research. Although a CI generally pertains to financial interests that are less than \$5,000 or 3 percent value, a CI could also be a non-financial interest. The university deems CIs as warranting attention and internal management. A CI may include, but is not limited to, 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 \$0 but is less than \$5,000 or 3 percent value during the 12 month period preceding COI review
- Serving as an unpaid consultant advisory board member or in an unpaid fiduciary role for the company or organization sponsoring or providing in kind materials in support of the research
- Unlicensed intellectual property (IP) that is owned by VCU and is to be used within the research
- IP for which license-related payments are distributed through the VCU Intellectual Property Foundation (IPF)

Conflict of interest (COI)

A COI is a situation in which financial or non-financial interests of the investigator, or members of that person's immediate family, compromise, or appear to compromise, an investigator's professional judgment

in exercising an institutional duty or responsibility, including the design, conduct, or reporting of research. A financial COI (FCOI) in research occurs when the investigator, or any member of that person's immediate family, possesses a significant financial interest (SFI) that is, or appears to be, in conflict with the objectivity needed to fulfill the investigator's university responsibilities.

Conflict of Interest in Research Committee (COIC)

The COIC is a standing committee of the university composed of faculty, administrative personnel, and ex-officio members and convened with an appointed chair under the authority of the Vice President for Research and Innovation (VPRI). The COIC is charged with:

- Evaluating investigators' financial interest reports within the context of specific proposals and research protocols referred by the COI in Research Program
- Determining whether reported interests rise to the level of COI or CI
- Developing a resolution, including the recommendation of a management plan, as appropriate
- Problem solving about management plan adherence
- Advising on COI policy and process issues

COI Investigator

COI Investigators are designated by the Principal Investigator (PI) on proposals and IRB and IACUC submissions. A COI Investigator is an individual, regardless of title, role, or position, who is responsible for the design, conduct, and/or reporting of research. Individuals with such research responsibilities may be, but are not limited to, senior/key personnel, sub/co-investigators, subrecipient investigators, medical investigators, collaborators, consultants, students, trainees, or research coordinators. Exceptions include students or personnel whose research activities are directly supervised. The term denotes individuals who must report their interests in the AIRS so that these interests can be reviewed in the context of the research; it does not imply that they have a conflict of interest.

COI in Research Program

The COI in Research Program, based in the Office of Research Integrity and Ethics:

- Administers activities related to the AIRS, COI/CI assessment, dispositions, management, and COI consultation and education for the university research enterprise
- Reviews reported interests in the AIRS and other sources for information about COI or CI in the context of individual research projects (the COI in Research Program may contact COI Investigators with questions about reported interests and/or their relatedness to the given research project)
- Makes expedited COI or CI dispositions, recommends referral to the COIC for full review, and implements management plans resulting from expedited or COIC review
- Communicates with relevant individuals and/or entities about COI/CI management and oversees management plan adherence

Financial interests

Financial interests are financial benefits and other reportable interests received or held by COI Investigators and members of their immediate family, including but not limited to:

- Salary or other payments for services (e.g. consulting fees, honoraria, or remuneration for holding a position in a company)

- Income from seminars, lectures, service, or speaking/ teaching engagements sponsored by for-profit, non-profit, foreign, or individual entities
- Serving as an officer, director, or advisory board member, whether paid or unpaid
- Equity interests (e.g. stocks, stock options, or bonds) that are directly controlled by the investigator or a member of the investigator's immediate family
 - 'Direct control' means the owner of the securities has investment power, which includes the power to buy, sell, or direct the purchase or sale of the securities.
- Business ownership, in dollar amount or percent ownership, whether or not the business has made a profit
- IP rights (e.g. inventions, patents, and copyrights) and license-related payments from such rights that are paid through any entity, including VCU IPF
- Travel that is paid or reimbursed by a third party (i.e. travel that is paid directly by a non-VCU entity) and related to an investigator's institutional responsibilities. Reported travel includes the purpose of the trip, the entity compensating the travel, the destination, and the duration of travel

Financial interests do not include:

- Salary, reimbursement, or remuneration originating from VCU, with the exception of payments from VCU IPF
- Income from seminars, lectures, or teaching/speaking engagements sponsored by a federal, state, or local government agency; an institution of higher education/affiliated research institute; or an academic teaching hospital/medical center
- Income from service on advisory committees or review panels for a federal, state, or local government agency; an institution of higher education/affiliated research institutes; or an academic teaching hospital/medical center
- Mutual funds or other investment vehicles over which the COI Investigator has no direct control
- Travel that was paid by VCU or by a project processed through OSP

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.

Institutional duties or responsibilities

Institutional duties or responsibilities encompass the professional responsibilities an investigator has by virtue of being a VCU employee, student, or trainee. These may include teaching, professional practice, service on committees, research, and research consultation. Institutional duties or responsibilities for subrecipient investigators refers to the work being done for VCU under the sub-award.

Research relatedness

Research relatedness means the extent to which a financial or non-financial interest is related to the sponsor, investigational drug/device, or research project.

Senior/key personnel

Senior/key personnel means the PI and any other person identified as senior/key personnel, including research and senior scientists, depending on their intellectual contribution to the proposed scope of activity,

in a PHS agency grant application or any report submitted to a PHS sponsor. Senior/key personnel are considered COI Investigators when designated as such by the PI.

Significant financial interest (SFI)

An SFI is a financial interest, as defined above, 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. 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 in 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

Investigator (or immediate family member) travel that is related to institutional responsibilities and compensated through third party payment or reimbursement may also be viewed, either individually or combined with other financial interests, as an SFI.

Sponsored project

A sponsored project describes a planned university teaching, training, service, or research project that is supported by an extramural award from any funding source.

Contacts

The Office of the Vice President for Research and Innovation officially interprets this policy. The Office of the Vice President for Research and Innovation is responsible for obtaining approval for any revisions as required by the policy *Creating and Maintaining Policies and Procedures* through the appropriate governance structures. Please direct policy questions to the COI in Research Program in the Office of Research Integrity and Ethics within the Office of the Vice President for Research and Innovation.

Policy Specifics and Procedures

1. Reporting by the COI Investigator

The PI is responsible for designating all COI Investigators associated with each proposed sponsored research or IRB/IACUC protocol submission and ensuring that all COI Investigators, including designated subrecipients and non-VCU collaborators, complete the required financial interest reporting.

Each COI Investigator is responsible for reporting their own financial interests as well as those held by any member of their immediate family in the AIRS as indicated below:

- All financial interests on an annual basis
- The research relatedness of each reported interest, as applicable

- Updates within 30 days of discovering or acquiring (e.g. through purchase, marriage, or inheritance) a new financial interest in an entity not previously reported or additional remuneration for a reported financial interest
- Updates within 30 days to the research relatedness of reported financial interests, as applicable

Reported financial interests and research relatedness, if relevant, must be up-to-date at the time of proposal or protocol submission. Continued updates of financial interests and research relatedness are required, as appropriate, for the duration of research funding or the life of the IRB or IACUC protocol, whichever is greater. Travel that is paid or reimbursed by a third party does not need to be updated outside of annual reporting.

As an agency of the Commonwealth of Virginia, VCU and all officers and employees of the university are subject to the Code of Virginia *State and Local Government Conflict of Interests Act* (“the Act”). The Act contains three general types of restrictions and prohibitions: (1) it details certain types of conduct that is improper; (2) it restricts the participation of officers and employees in transactions with their own governmental agency in which they have a personal interest; and (3) it restricts the ability of officers and employees to have personal interests in certain contracts with their own or other governmental agencies. In regards to the last restriction, the Act states that a VCU employee cannot have a personal interest in a contract with VCU other than the employee’s own contract of employment (§ 2.2-3106). A personal interest is defined as a financial benefit or liability in the contracting entity that is held by the employee, or a member of that person’s immediate family, which meets or exceeds 3 percent equity or \$5,000 income (real or anticipated) or involves other significant investments. VCU employees are expected to be particularly aware of personal interests that they, or members of their immediate family, have in firms or businesses that contract with VCU (or, in some circumstances, with any Virginia state agency). Such arrangements represent state-prohibited contracts unless an exception is provided as described by the Act. The COIC will issue a management plan in order to mitigate the COI or its appearance. A university member’s knowing violation of the Act is subject to criminal penalty (§ 2.2-3120).

2. Review of reported financial interests

The review of reported financial interests results in a determination of whether a COI or CI exists. Investigators’ reported financial interests are reviewed in the context of each sponsored project or IRB/IACUC submission by the COI in Research Program or COIC, as appropriate. Reported interests are subject to either expedited or full COIC review based on the amount and type of interests reported, the research relatedness, the research role of the conflicted individual, and the study context. Expedited review of reported financial interests and COI and CI dispositions are administered by the COI in Research Program and reported to the COIC.

COI in Research Program or COIC members will recuse themselves from review of cases in which they have a financial interest or relationship that could appear to bias the member. Committee members are required to adhere to applicable rules of privacy and confidentiality pertaining to COI review.

3. Managing COI and CI

If the COI in Research Program or COIC determine that a COI or CI exists, it will develop a plan for managing, reducing, or eliminating the conflict that must be adopted: a) prior to VCU expenditure of any part of any sponsored research award or contract, b) before students, trainees, or staff are assigned to the research, and 3) before the research begins. If a COI or CI is determined to exist when the research is ongoing, IRB/IACUC protocol renewal may be delayed, the protocol may be suspended, and/or sponsored project funding may be frozen until a management plan is accepted by the COI Investigator. Possible management plan components may include, but are not limited to:

- Disclosure of the interest in professional publications and presentations
- Disclosure of the interest to students, trainees, and professional colleagues
- Recommendation of disclosure of the interest to prospective research participants (subject to IRB consideration)
- Monitoring of research by independent reviewers who do not hold financial or non-financial interests related to the project
- Modification of the research plan to ensure objectivity
- Protocol review by an external IRB or IACUC
- Removal of a COI Investigator(s) from participation in all or a portion of the research
- Reduction or elimination of the financial interest
- Severance of relationships that create the COI
- VCU declining the award

4. Appealing a COI or CI determination

A COI Investigator's disagreement with an expedited COI or CI disposition made by the COI in Research Program is referred to the COIC for review. A COI Investigator may appeal a COIC determination resulting from a referred or initial review directly to the VPRI within five business days of receiving notice of the COIC's decision. The VPRI will call for reconsideration by the COIC if additional supporting information has become available since the first review. The COI Investigator may be required to attend the reconsideration meeting. The COIC's recommendation will be made to the VPRI who will render a final decision within 10 business days. The decision of the VPRI is final and cannot be appealed.

5. Internal reporting of the COI management plan

The COI in Research Program will report the COI or CI determination and any agreed upon management plan to the following, as appropriate:

- The Office of Sponsored Programs (OSP) and relevant school/department personnel, as appropriate, prior to VCU expenditure of any part of the affected sponsored project
- The Office of Research Subjects Protection, as applicable, for review by the IRB or IACUC. The IRB or IACUC may not minimize the management plan developed by the COIC, but may require additional safeguards to ensure the optimal protection of research

subjects. The research protocol cannot be approved until the IRB, IACUC, or representative reviewer has reviewed the COI management plan and determined if it is sufficient or if further IRB/IACUC action is needed.

- The department/division chair and/or dean, and others, as appropriate, who may be asked to participate in the development and/or oversight of the management plan as well as reporting on management plan adherence, as needed
- The PI directing the research if that person is not the conflicted individual

As described in the management plan, the COI Investigator must provide an update, at least annually, on the fulfillment of the management plan. The COI in Research Program shall refer noncompliance with the agreed-upon management plan to the relevant dean and the IRB, IACUC, and sponsor, as applicable. Sanctions for noncompliance may include suspension or termination of the research and/or funding, removal as an investigator, and termination from VCU.

6. External reporting of the FCOI

The COI in Research Program is responsible for reporting an FCOI to PHS sponsors and, as deemed applicable by OSP, to other relevant federal agencies and sponsoring entities. State-prohibited contracts meeting the exception (as provided in the Act) may also be subject to reporting to federal agencies or other sponsors. In addition, the COI in Research Program is responsible for ensuring that the FCOI and the management plan are reported to external IRBs serving as the IRB of record for the research.

For PHS-funded research, a FCOI report must be provided to the PHS funding agency: 1) prior to VCU's initial expenditure of funds, 2) within 60 days of identifying a FCOI for an added COI investigator or a new FCOI for an existing COI investigator, and 3) annually with the annual progress report or at the time of extension. Institutional reporting of FCOI to PHS begins at the SFI threshold of \$5,000; other sponsors may utilize a different threshold. The elements of the report submitted to the PHS agency, which are described in the PHS *Promoting Objectivity in Research* regulations, include the nature of the FCOI, the value of the financial interest in monetary ranges, how the financial interest relates to the funded research, and key elements of the management plan. If VCU is the prime awardee of PHS funds, VCU is required to report the FCOI of collaborating COI Investigators from subrecipient institutions to PHS. VCU is also required to report FCOI of VCU COI Investigators to the awarded institution, if VCU is a subrecipient.

CIIs will not be reported to PHS, other sponsors, or external IRBs.

7. Additional requirements of the PHS *Promoting Objectivity in Research* regulations (may also apply to sponsoring entities that are adherent to these regulations)

- **Certification in each PHS application:** OSP is required to 1) certify the presence of a process to identify and manage FCOI and 2) promote and enforce investigator compliance. The COI in Research Program is required to 1) provide initial and ongoing FCOI reports to the PHS awarding agency and 2) make records available to HHS promptly and upon request (i.e. information pertaining to investigator reporting of financial interests, VCU's

review and response to such reported interests, and whether the reported interests resulted in FCOI determinations).

- **Subrecipients:** OSP is required to verify, by way of a written agreement with subrecipient institutions on PHS-funded research, whether this policy in its entirety or whether the FCOI policy of the subrecipient institution will apply to its COI Investigators who are collaborating with VCU investigators. If this policy is utilized by subrecipient institutions, only the financial interests related to the subrecipient investigators' responsibilities on the project must be reported in the AIRS.
- **Training requirement:** Each COI Investigator must complete required COI training, administered by the COI in Research Program, prior to beginning research and at least every 4 years. Training is also required if this policy changes substantially, if an investigator is new to VCU, and if an investigator is found to be noncompliant with the policy or management plan.
- **Maintenance of records:** The COI in Research Program must maintain records related to financial interests reporting and COI management for a minimum of three years after final expenditures reporting.
- **Publicly available information about FCOI:** As per PHS regulation, the COI in Research Program will make available required information about current FCOI held by senior/key personnel (on PHS-funded research only) to any requestor within five business days of a request.
- **Failure of an investigator to report, or for VCU to review, SFIs in a timely manner:** If such failure is identified by the COI in Research program on PHS-funded research, or for research funded by an entity adherent to the PHS *Promoting Objectivity in Research* regulations, the SFI must be reviewed and determined whether it is an FCOI. An interim management plan must be implemented within 60 days.
- **Retrospective review for bias and mitigation report for noncompliance:** Upon a determination of non-compliance with this policy, the COI in Research Program will ensure that VCU, as per regulation, completes a retrospective review of the PHS-funded research project and the investigator's activities within 120 days to determine if there was bias in the design, conduct, or reporting of the research. The COI in Research Program must send a COI mitigation report to the PHS agency if bias is found. The agency may determine that further corrective action is needed.

PHS has the authority to inquire about any investigator's reporting of financial interests and VCU's review and response to the financial interests at any time. PHS may impose special award conditions, suspend funding, or impose other mechanisms if PHS decides that a particular FCOI will bias the objectivity of the research.

8. Policy implementation and breaches

The VPRI or designee is responsible for the implementation of this policy, including the process for financial interest reporting and management and the appointment of members to the COIC. The

VPRI or designee will oversee all identified breaches of COI reporting, review, and management processes, including:

- Failure of PI to designate COI Investigators who meet the definition of COI Investigator
- Failure of COI Investigators to report financial interests
- Failure to update financial interests as required
- Failure to report compensated travel
- Failure to respond to COI in Research Program, IRB, or IACUC inquiries, or responding with incomplete or knowingly inaccurate information
- Failure to adhere to the COI management plan
- Failure to comply with a prescribed monitoring plan, if applicable

Violation of this policy is subject to action, as appropriate, under university policies and procedures, including the *Outside Professional Activity and Employment, Research, and Continuing Education* policy and the *Responsible Conduct in Research and Scholarship* policy.

Forms

There are no forms associated with this policy and procedures. Financial interest reporting occurs in the [AIRS](#).

Related Documents

1. PHS *Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought (or Promoting Objectivity in Research)* regulations (42 C.F.R. Part 50, Subpart F)
<https://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=992817854207767214895b1fa023755d&rgn=div5&view=text&node=42:1.0.1.4.23&idno=42#sp42.1.50.f>
2. *Responsible Prospective Contractors* regulations (45 C.F.R. Part 94)
<https://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=992817854207767214895b1fa023755d&rgn=div5&view=text&node=45:1.0.1.1.51&idno=45>
3. National Science Foundation Conflict of Interest Policies (NSF 05-131 510)
https://www.nsf.gov/pubs/manuals/gpm05_131/gpm5.jsp#510
4. Food and Drug Administration *Financial Disclosure by Clinical Investigators* regulations (21 CFR 54)
<https://www.gpo.gov/fdsys/granule/CFR-2011-title21-vol1/CFR-2011-title21-vol1-part54>
5. Code of Virginia *State and Local Government Conflict of Interests Act* (§ 2.2-3101)
<https://law.lis.virginia.gov/vacode/title2.2/chapter31/section2.2-3101/>
6. VCU Policy: [Research Exception for the Virginia Conflict of Interest Act Prohibited Contracts](#)

7. VCU Policy: [Outside Professional Activity and Employment, Research, and Continuing Education](#)
8. VCU Policy: [Responsible Conduct in Research and Scholarship](#)
9. VCU Policy: [Institutional Conflicts of Interest in Research - Interim](#)
10. Local IRB Policy: [IRB Written Policies and Procedures Section VIII Title 10: Evaluating and Managing Investigator Conflicts of Interest](#)

Revision History

This policy supersedes the following archived policies:

Approval/Revision Date	Title
05/15/2009	<i>Research Conflict of Interests Policy</i>
07/18/2012	<i>Conflict of Interests in Research – Interim</i>
08/19/2014	<i>Conflict of Interests in Research</i>
12/12/2014	<i>Conflict of Interests in Research</i>
08/03/2015	<i>Conflict of Interests in Research</i>
03/07/2018	<i>Conflict of Interests in Research [minor edits made]</i>
08/22/2018	<i>Conflict of Interests in Research [minor edits made]</i>

FAQ

1. Where do I report financial interests?

Financial interests are reported in the VCU AIRS, which can be found on the Office of Research and Innovation website through the RAMS tab. Contact AIRS@vcu.edu for questions about financial interest reporting.

2. How often do financial interests need to be updated?

Financial interests should be updated within 30 days of discovering or acquiring (e.g. through purchase, marriage, or inheritance) a new financial interest in an entity not previously reported or additional remuneration for a reported financial interest. The research relatedness of reported financial interests (i.e. the relation of financial interests to a sponsor or the investigational drug, device, or research project) should be updated within 30 days, as applicable. Travel that is paid or reimbursed by a third party does not need to be updated outside of annual reporting.

3. Do I need to report positions related to research that are not paid?

Yes. Although it may seem that money is not directly involved in such relationships, a monetary or beneficial relationship may be implied to the outside observer. Non-financial personal considerations can also give the appearance of compromising professional judgment and objectivity. Positions

related to research that may not be paid include, but are not limited to, scientific or clinical advisory board membership.

4. What financial interests am I not required to report?

- Salary, reimbursement, or remuneration originating from VCU, with the exception of payments from the VCU IPF
- Income from seminars, lectures, or teaching/speaking engagements sponsored by a federal, state, or local government agency; an institution of higher education/affiliated research institute; or an academic teaching hospital/medical center
- Income from service on advisory committees or review panels for a federal, state, or local government agency; an institution of higher education/affiliated research institutes; or an academic teaching hospital/medical center
- Mutual funds or other investment vehicles over which the COI Investigator has no direct control
- Travel that was paid by VCU or by a project processed through OSP

5. Do I need to report compensated travel for my spouse?

Travel that is paid or reimbursed by a third party to the investigator or a member of that person's immediate family should only be reported if it relates to the investigator's institutional responsibilities. If, for example, the investigator's spouse collaborates with the investigator on research, the investigator must report the spouse's travel paid or reimbursed by a third party if it relates to the investigator's research or other institutional responsibilities, regardless if the spouse is employed by VCU.

6. How is a CI different from a COI?

Both COI and CI involve financial or other personal interests that may, or may appear to, compromise or bias professional judgment and objectivity. A COI is determined from reported SFIs, while a CI is determined from reported interests below the SFI threshold. A CI is an internal designation deemed by VCU as warranting attention and internal management and generally pertains to human subjects research. It is not reported to the NIH or subject to other requirements of the PHS *Promoting Objectivity in Research* regulations.

7. Who has access to my reported financial interests in the AIRS?

Access to reported information is limited and restricted to VCU employees with "need to know" status. The AIRS is a secure database managed by the Office of Research Information Systems in the Office of Research and Innovation and is accessible by the COI in Research Program.

8. What kind of information about FCOI in PHS-funded research is available to the public and how is it requested?

In accordance with the PHS *Promoting Objectivity in Research* regulations, and in consultation with University Counsel, the COI in Research Program will make available to any requestor information concerning SFI reported to VCU that meet all of the following criteria:

- The SFI was reported and is still held by senior/key personnel;
- The SFI was determined to be related to the PHS-funded research.
- The SFI was determined to be a financial COI.

If the above criteria apply, the information made available to the requestor within five business days of the request will include: the investigator's name; the investigator's title and role with respect to the research; the name of the entity in which the SFI is held; the nature of the SFI; and the approximate dollar value range or a statement that the interest's value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

Requests for information about FCOI on PHS-funded research should be addressed in writing to:

Conflict of Interest Request
Office of Research Integrity and Ethics
Office of the Vice President for Research and Innovation
Virginia Commonwealth University
Box 980568
Richmond, VA 23219-0568

Alternatively, requests can be made via email to ORIE@vcu.edu. "Conflict of Interest Request" must be in the email subject line.

9. Does this policy supersede the Code of Virginia State and Local Government Conflict of Interests Act?

No, this policy is in addition to the *Virginia State and Local Government Conflict of Interests Act* and specifically addresses conflicts associated with the design, conduct, and reporting of research.

10. How does this policy align with the Code of Virginia State and Local Government Conflict of Interests Act?

State law does not permit an investigator to have a personal interest (exceeding 3 percent equity or \$5,000 income (or anticipated income) from the contracting entity) in a separate contract with VCU other than the investigator's employment contract. An example of such a prohibited dual contract in research is when an investigator (or immediate family member) has an ownership interest in a company (such as a start-up company) that is subcontracting to VCU. Pursuant to a provision in the *State and Local Government Conflict of Interests Act* for research and development or commercialization of intellectual property (§ 2.2-3106, C.8), an agreement may be executed when all specified conditions to an exception are met and a management plan is in place. The research must be approved by the president of VCU, on behalf of the Board of Visitors, prior to the allocation of funds for the research. It is recommended that investigators with a personal financial interest in a

company contact the COI in Research Program early in the company development or research contract process at AIRS@vcu.edu.

11. How does the COIC handle an individual COI that also represents an institutional COI in research?

The COIC is charged to evaluate, identify, and manage individual researcher's financial conflicts of interest in research and may be able to manage the perception of an institutional COI as part of an individual's management plan.