



# VCU

## Conflict of Interests in Research

**Policy Type: Administrative**

**Responsible Office:** Office of the Vice President for Research

**Initial Policy Approved:** 05/15/2009

**Current Revision Approved:** 08/19/2014

[Note that compliance with this Policy was effective as of 8/24/2012 under Interim approval status]

### Policy Statement and Purpose

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The purpose of this policy on *Conflict of Interests in Research* (hereinafter, the “Policy”) is to define the process for identifying, evaluating, managing and reporting investigators’ financial relationships that have, or may appear to have, an impact on the objectivity and integrity of research conducted at Virginia Commonwealth University. This policy applies to research as well as to all sponsored projects. Investigators are required to report: 1) Financial Interests annually, 2) updates in Financial Interests and, 3) research related interests to enable identification of Conflict of Interests in research. This Policy is informed by federal regulation (Promoting Objectivity in Research at 42 CFR Part 50 Subpart F), Virginia law, and ethical practice regarding the identification and management of Conflicts of Interest in research and sponsored 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.

### Table of Contents

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Who Should Know This Policy.....	2
Definitions.....	2
Contacts.....	4
Background.....	5
Procedures.....	5
Forms.....	9
Related Documents.....	10
Revision History.....	10
FAQs.....	10

## Who Should Know This Policy

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All University Members involved in the design, conduct, review, reporting, administration or supervision of research and sponsored projects should read this Policy.

## Definitions

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### Competing Financial Interest (CFI)

Competing Financial Interests include Financial Interests, as defined below, that reasonably appear to be related to the Investigator's Institutional Responsibilities, and could appear to affect the design, conduct, or reporting of research, primarily human subjects research. CFI may include, and is not limited to, the following:

- 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

Since such Financial Interests are not actionable according to the PHS regulation they are not termed financial Conflicts of Interest, but are deemed by VCU as possibly warranting attention and internal management.

### Conflict of Interests (COI)

Conflicts of Interest exist when financial or other personal interests (as termed in the Code of Virginia) or considerations of the Investigator, or members of his or her immediate family, may directly and significantly affect, or have the appearance of directly and significantly affecting, an Investigator's professional judgment in exercising any University duty or responsibility, including the design, conduct or reporting of research. Financial Conflicts of Interest in research occur when the Investigator, or any member of that person's immediate family (spouse and any child who resides in the same household as the Investigator and who is a dependent of the Investigator), possesses a Significant Financial Interest (SFI) that is in conflict with his or her University responsibilities.

### Conflict of Interests Committee (COIC)

The Conflict of Interests Committee for research is a standing Committee of the University, composed of faculty, administrative personnel, and ex-officio members, as needed, and convened, with an appointed Chair, under the authority of the Vice President for Research. The General Counsel's office provides representation to COIC meetings. COIC membership should include individuals who are basic scientists and clinical faculty. The Committee is charged with: 1) evaluating Investigator Financial Interest reports within the context of specific proposals and research protocols, 2) determining whether Financial Interests rise to the level of Competing Financial Interests (CFI) or are Significant Financial Interests (SFI) that comprise Conflicts of Interest which could directly and significantly affect, or could appear to affect, the design, conduct, or reporting for the research, 3) developing a resolution, including the recommendation of a management plan, as appropriate, and 4) monitoring compliance. Reported

Financial Interests are subject to either expedited or full Committee review, based on amount and type of Financial Interests reported. Committee members are required to adhere to applicable rules of privacy and confidentiality when commencing Conflict of Interests assessments.

### **Financial Interests**

For the purposes of this policy, Financial Interests include anything of monetary value, including, but not limited to:

- 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);
- income from seminars, lectures, service or teaching engagements sponsored by for-profit entities;
- income from seminars, lectures, service or teaching engagements sponsored by federal, state, or local agencies or public or non-profit entities;
- equity interests (e.g., stocks, stock options, or other ownership interests), excluding investment vehicles not under direct control;
- 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 paid directly by a non-VCU entity so that the exact monetary value may not be readily available) and related to an Investigator's Institutional Responsibilities. Reported travel includes the purpose of the trip, the entity compensating for travel, the destination, and the duration of travel.

Financial Interest does not include salary, reimbursement, or travel payment originating from VCU, with the exception of payments from the VCU Intellectual Property Foundation. Financial interests also do not include grants or contracts processed by the VCU Office of Sponsored Programs.

### **Investigator**

Investigator describes any individual, regardless of title, role or position, who is **responsible** for the design, conduct, or reporting of research. Individuals with such research responsibilities may be, but are not limited to, senior/key personnel, sub/co-investigator or subrecipient investigator, medical investigator, collaborator, consultant, student, trainee, or research coordinator. Exceptions include students or other personnel whose research activities are directly supervised. By considering an individual's degree of independence relative to the research, the Principal Investigator (PI) on the proposal or protocol designates those who meet the definition of 'Investigator.'

### **Investigator's Institutional (or University) Responsibilities**

Such 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. Institutional responsibilities for subrecipient Investigators only includes the work being done for VCU under the subaward. Only financial interests related to those responsibilities must be reported by subrecipient Investigators.

### **Senior/key personnel**

For the purposes of this policy only, Senior/Key Personnel means the project director and/or principal investigator and any other person identified as Senior/Key Personnel in a Public Health Service (PHS) agency grant application or any report submitted to a PHS Sponsor by VCU.

## **Significant Financial Interests (SFI)**

Significant Financial Interests include Financial Interests, as defined above, that 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. SFI entails 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, e.g. a start up company.
- intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income, such as royalty payments, related to such rights and interests.

Investigator (or immediate family member) travel that is related to Institutional Responsibilities, and compensated, through reimbursement or third party payment, may also be viewed, either individually or combined with other Financial Interests, as SFI.

SFI exclusions:

- Salary or reimbursements, such as travel, paid by VCU
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as the investigator does not directly control the investment

To the extent to which state law deviates from, and imposes more strict criteria than federal law and/or regulations, VCU, as a public instrumentality of the Commonwealth of Virginia, and all officers and employees of the University are subject to the Virginia State and Local Government Conflict of Interests Act ("Act"). The Act provides minimum rules of ethical conduct for state officers and employees. The Act contains three general types of restrictions and prohibitions: (1) it details certain types of conduct that is improper; (2) it restricts the ability of officers and employees to have personal interests in certain contracts with their own or other governmental agencies; and (3) it restricts the participation of officers and employees in transactions with their own governmental agency in which they have a personal interest.

## **Contacts**

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

## Background

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Conflicts of Interest exist in many forms and frequently are inherent to the nature of the research enterprise. A Conflict of Interests can arise in situations in which there exists discord between an Investigator's primary duty and a secondary interest. While such interests can be either financial or non-financial, they, nevertheless, can yield conscious or subconscious bias in the conduct and/or interpretation of research. Often financial Conflicts of Interest will simply present an appearance of compromising an investigator's professional judgment in conducting or reporting the results of research. Conflicts must be identified so that they can be resolved or appropriately managed.

VCU faculty and non-faculty employees generally are encouraged to engage in outside professional activities and relationships so long as such relationships and activities are consonant with the objectives of the University and are mutually beneficial to participants as well as to society, at large. While Conflicts of Interest also may involve institutional relationships with for-profit or non-profit entities that may need to be addressed, this Policy focuses on Conflicts of Interest involving individual Investigators. This Policy is largely governed by 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](#) and the University's [Conflict of Interests Policy](#).

## Procedures

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### 1. Reporting by the Investigator

The Principal Investigator is responsible for identifying all Investigators associated with each proposed sponsored research or IRB/IACUC protocol submission and ensuring that all Investigators, including designated subrecipients and non-VCU collaborators, complete the required reporting, as appropriate.

Each Investigator is responsible for reporting 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) as indicated below:

- All Financial Interests, including compensated travel related to institutional responsibilities, on an annual basis in a secure database.
- Research relatedness concerning Financial Interests specifically related to a sponsor, product or service being tested in all proposed and on-going research.
- 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 or 2) an additional remunerated Financial Interest, that, when added to a Financial Interest in a previously reported entity, meets or exceeds \$5,000.
- Update research relatedness of financial interests within thirty (30) days, including compensated travel, for every Sponsored Program submission, IRB or IACUC submission, 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 funding of the research or the life of the IRB or IACUC protocol, whichever is longest.

## **2. Review of reported financial interests**

Investigators' reported Financial Interests that trigger a potential Competing Financial Interest or Significant Financial Interest are administratively referred for review by the Conflict of Interests Committee, or designated expedited reviewer. The COIC will determine by expedited review, or in convened committee, that: 1) no financial Conflict of Interests exists, 2) a financial Conflict of Interests exists, or 3) a Competing Financial Interest exists.

Members of the COIC who have financial or non-financial interests in a particular proposal or IRB or IACUC protocol shall recuse themselves from review of said proposal or protocol.

## **3. Managing Financial Conflicts of Interest and Competing Financial Interests**

If a Financial Conflict of Interests or Competing Financial Interest exists, or appears to exist, that would reasonably appear to compromise the objectivity of the research, the COIC develops a plan for managing, reducing, or eliminating the conflict that must be adopted: a) prior to expenditure by VCU 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. The Investigator reporting research-related Financial Interest(s) may propose a management plan to the COIC for ensuring research objectivity that will be considered by the COIC. Possible management plan components may include, but are not limited to:

- disclosure of the Financial Conflict of Interest or Competing Financial Interest in professional publications and presentations;
- disclosure of the Financial Conflict of Interests or Competing Financial Interest to students, trainees, and professional colleagues;
- disclosure of the Financial Conflict of Interests or Competing Financial Interest to prospective research participants, under IRB direction;
- written affirmation of the VCU COI and/or IP Policy;
- monitoring of research by independent reviewers who do not hold financial or non-financial Conflicts of Interest related to the project;
- modification of the research plan;
- disqualification of an Investigator(s) from participation in all or a portion of the research;
- reduction or elimination of the Financial Interest;
- severance of relationships that create Conflicts of Interest; or
- VCU declining the award.

Per the [Code of Virginia \(Sections 2.2-3100 through 2.2-3131\)](#), a prohibited Conflict of Interests arises when an employee 1) engages in prohibited conduct (section 2.2-3103), 2) has an improper personal interest in a transaction (section 2.2-3112), or 3) has an improper personal interest in a contract (section 2.2-3106). Employees of VCU should be particularly aware of

situations involving themselves, or a member of his/her immediate family, having a financial interest in a firm or business which contracts with VCU (or in some circumstances with any Virginia state agency). Such arrangements will give rise to an improper personal interest in a contract unless an exception is provided by the Act. There are exceptions for research permitted under the Act and may be granted upon the recommendation of the Conflict of Interests Committee. A management plan will also be required. A knowing violation of the Act is subject to criminal penalty (section 2.2-3120).

#### **4. Reporting of the COI management plan**

The financial COI (or Competing Financial Interests) determination and agreed-upon management plan, if relevant, must be reported to the following, as appropriate.

- The *Office of Sponsored Programs* prior to expenditure by VCU of any part of the affected award. The management strategy will become part of the sponsored program record maintained by VCU.
- 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. For example, the IRB may require disclosure in the informed consent form or the IACUC may require additional safeguards to protect the well-being of laboratory animals. The research protocol cannot be approved until the IRB or IACUC have reviewed the COIC management plan.
- The Department/Division Chair and/or Dean are notified, as appropriate, and may be asked to participate in development of the management plan, reporting on the management plan, and oversight of the management plan, as needed.
- The PI directing the research if he or she is not the conflicted individual.

At the request of the COIC, and as described in the management plan, the Investigator must provide an annual, or more frequent, update on the fulfillment of the management plan for review by the COIC. Non-compliance with the agreed-upon management plan shall be referred to the relevant Dean and notification of the IRB, IACUC, and sponsor, as applicable. Sanctions for noncompliance may include removal as an investigator, suspension or termination of the research and/or funding and termination from VCU.

#### **5. Appealing a Conflict of Interests Determination**

An appeal of a COIC determination can be made directly to the COIC Chairperson who will call for reconsideration by the COIC if additional supporting information has become available since the initial review. The conflicted individual may be required to attend the reconsideration meeting. The decision of the COIC re-review may be further appealed to the Vice President for Research (VPR) by the conflicted Investigator. The Investigator must notify the VPR of any intended appeal within 5 days of receiving notice of the management plan. The VPR will form an *ad hoc* Appeal Panel comprised of three senior faculty, and other consultants as needed, who will have 30 business days to review the relevant materials. The Appeal Panel's recommendation is made to the VPR who will render a decision within 10 work days. The decision of the VPR will be final and there shall be no further appeal within the University.

## 6. Reporting Financial Conflicts of Interest by VCU

Financial Conflicts of Interest of Investigators shall be reported to PHS sponsors, and as required, to other relevant federal agencies, such as NSF, as well as other sponsoring entities, as applicable, by the VCU Office of Sponsored Programs. State prohibited contracts eligible for exception may also be subject to reporting to federal agencies or other sponsors.

For PHS funded research, initial and ongoing Financial Conflicts of Interest must be reported to the PHS funding agency prior to the expenditure of funds, during the period of award and within 60 days of identifying a new FCOI, and annually with the annual progress report or at time of extension. Institutional reporting of Financial Conflicts of Interest to PHS and other federal research sponsors, and other sponsoring entities, begins at the SFI threshold of \$5,000. Competing Financial Interests are not reportable to PHS or other sponsors. The elements of the report to the PHS agency are described in the PHS "Objectivity in Research" policy and 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 the research is PHS funded, VCU is required to report Financial Conflicts of Interest of collaborating investigators from subrecipient institutions. VCU is also required to report Financial Conflicts of Interest of VCU Investigators to the awarded institution, if VCU is a subrecipient.

## 7. Additional required VCU responsibilities as per the PHS "Objectivity in Research" regulations (may also apply to sponsoring entities that are Final Rule adherent):

- **Certification in each PHS application:** VCU is required to certify 1) the presence of a process to identify and manage financial conflicts of interest, 2) enforcement of investigator compliance, 3) provision of initial and ongoing FCOI reports to the PHS awarding agency, 4) that upon request of the Department of Health and Human Services information will promptly be made available pertaining to investigator reporting of financial interests, VCU's review and response to such reports, and whether FCOIs were determined.
- **Subrecipients:** VCU 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 financial Conflict of Interest policy of the subrecipient institution will apply to its investigators who are collaborating with VCU investigators.
- **Training requirement:** Each Investigator must complete VCU required training prior to beginning research and at least every 4 years. Training is also required if the Policy changes substantially, if an investigator is new to VCU, and if an investigator is found to be non-compliant with the Policy or management plan.
- **Maintenance of records:** Records related to financial interests reporting and conflict of interests management are maintained for a minimum of three (3) years after final expenditures reporting.
- **Publicly available information about FCOIs:** As per regulation, VCU will make available required information about current financial COIs held by Senior/Key Personnel on PHS funded research only to any requestor within 5 business days of a request. (Please see

Frequently Asked Question (FAQ) #1 at the end of this policy for specific request and response criteria).

- **Failure to report or review SFI in a timely manner:** If such failure is identified by VCU on PHS-funded research, or for research funded by an entity adherent to the Final Rule, the SFI must be reviewed for financial COI and an interim management plan implemented within 60 days.
- **Retrospective review for bias and mitigation report for noncompliance** (for PHS funded research only): Upon a determination of non-compliance with this policy, VCU is required, as per regulation, to complete a retrospective review of the PHS-funded research project as well as the Investigator's activities within 120 days to determine if there was bias in the design, conduct, or reporting of the research. A COI mitigation report must be sent to the PHS agency if bias is found. The agency may determine that further corrective action is needed.

PHS has the authority to inquire at any time of any Investigator's reporting of Financial Interests and VCU's review and response to the Financial Interests. 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 Policy Breaches

The Vice President for Research, or his/her designee, is responsible for the implementation of this Policy, including the process and mechanism for Financial Interests reporting and management, and the appointment of members to the COIC. The Vice President for Research, or his/her designee, will oversee all identified breaches of Conflict of Interests reporting, review, and management processes, including:

- failure of Principal Investigator to designate qualified research personnel as 'investigators'
- failure of Investigators to report Financial Interests,
- failure to update Financial Interests as required,
- failure to report compensated travel
- failure to respond to COIC, IRB, or IACUC inquiries, or responding with incomplete or knowingly inaccurate information;
- failure to adhere to the COI management plan; and
- failure to comply with a prescribed monitoring plan, if applicable.

Violation of the Conflict of Interests policy is subject to action, as appropriate, under University policies and procedures, including the University's [Outside Professional Activity and Employment Policy, Research and Continuing Education](#) policy or under VCU's policy on [Misconduct in Research and Scholarly Activities](#)

## Forms

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There are no forms associated with this policy and procedures. Financial interest reporting occurs in the electronic VCU eRA Activity and Interests Reporting System (AIRS).

## Related Documents

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1. 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
2. [Conflict of Interest](#) – National Science Foundation (NSF) Rules
3. [21 CFR 54](#) – FDA regulation for Financial Disclosure by Clinical Investigators
4. [Virginia State and Local Government Conflict of Interests Act](#)
5. [Conflict of Interest Policy](#)
6. [Outside Professional Activity and Employment Policy, Research and Continuing Education](#)
7. [Misconduct in Research and Scholarly Activities](#)
8. VCU Institutional Review Board (IRB) [Written Policy and Procedure #VIII-10 Evaluating Investigator Conflicts of Interest](#)

## Revision History

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This policy supersedes the following archived versions:

Initial Approval: May 15, 2009, *Research Conflict of Interests Policy*

Approve Revision: July 18, 2012, *Conflict of Interests in Research -Interim*

Approved Revision: August 19, 2014, *Conflict of Interests in Research*

Approved Revision: December 12, 2014, *Conflict of Interests in Research (updated to be compliant with April 23, 2014 legislative approval of amendments to the Virginia State and Local Government Conflict of Interests Act)*

Approved Revision: August 3, 2015 *Conflict of Interests in Research (minor revision to Definitions)*

## FAQs

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- 1. What kind of information about financial conflicts of interest in PHS-funded research is available to the public and how is it requested?**

In accordance with the PHS regulation, VCU will make available to any requestor information concerning significant financial interest (SFI) reported to VCU which meets the following three criteria: a) The SFI was reported and is still held by senior/key personnel; b) VCU determines that the SFI is related to the PHS-funded research; and c) VCU determines that the SFI is a financial COI.

If the above criteria apply, the information made available to the requestor within five (5) 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 financial Conflict of Interest 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  
P.O. Box 980568  
Richmond, VA 23219-0568

Alternatively requests can be made via email to [ORIE@vcu.edu](mailto:ORIE@vcu.edu); "Conflict of Interest Request" must be in email subject line.

## **2. How and where do I report annual and updated Financial Interests?**

Information for accessing the Activity and Interests Reporting System (AIRS) for reporting Financial Interests can be found on the Office of Research website under [VCUeRA](#). Investigator reporting in the AIRS began August 2012. Contact [AIRS@vcu.edu](mailto:AIRS@vcu.edu) for questions about the AIRS. Contact the Office of Research Integrity and Ethics, [ORIE@vcu.edu](mailto:ORIE@vcu.edu), for questions about this policy and process.

## **3. Which financial interests need to be updated and how often?**

Financial Interests that must be updated include the following:

- 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 AND/OR 2) an additional remunerated Financial Interest, that, when added to a Financial Interest in a previously reported entity, meets or exceeds \$5,000.

For example, the human subjects research is sponsored by X Company. Dr. Z receives a \$2,000 honorarium for speaking for X Company which she reports both as a financial interest and as being related to the specific research sponsored by X Company. Three months later she receives \$1500 for consulting with X Company. Because the total is less than \$5,000, this additional remuneration need not be reported. Four months later Dr. Z receives another \$2,000 for speaking for X Company. The total is now \$5,500 received within the last 12 months. All remuneration received since the initial report must now be added to the Financial Interest Report.

- Update research relatedness of financial interests, including compensated travel related to institutional responsibilities, for every Sponsored Program submission, IRB or IACUC submission at the same time, as applicable.

Travel that is compensated through non-VCU reimbursement or direct third party payment does

not need to be updated outside of the annual reporting.

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

Reimbursed travel or travel paid by a third party to the Investigator or member(s) of that person's immediate family applies only as it relates to the Investigator's Institutional Responsibilities. For example, the Investigator's spouse is employed either by VCU or a non-VCU institution and often collaborates with the Investigator on research; the Investigator must report the spouse's reimbursed or third party travel if it relates to the Investigator's research or other Institutional Responsibilities.

**5. What kind of travel must be reported by the Investigator and how often?**

The Investigator must report travel that is reimbursed or paid by a third party (i.e., travel that is paid on behalf of the Investigator or immediate family member and not directly reimbursed so that the exact monetary value may not be readily available) related to an Investigator's Institutional Responsibilities. Reported travel includes the purpose of the trip, the entity compensating for travel, the destination, and the duration of travel. Compensated travel related to an Investigator's Institutional Responsibilities must be reported and updated in the same manner as other Financial Interests.

**6. Who has access to my reported Financial Interests?**

Reported Financial Interests are retained in the secure AIRS database which is managed by the Office of Research Information Systems. Access to reported information is limited and restricted to VCU employees with 'need to know' status. Also see FAQ #1 regarding information about public access.

**7. How is a Competing Financial Interest different from a Conflict of Interests?**

A finding of Competing Financial Interests applies to Financial Interests that reasonably appear to be related to the Investigator's Institutional Responsibilities, and could appear to affect the design, conduct, or reporting of research, primarily human subjects research. Financial Interest(s) that may be identified as Competing Financial Interest may include, and is/are not limited to: 1) financial interests in a publicly traded entity that, individually or in aggregate, exceed \$0 but are 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), 2) use of unlicensed Intellectual Property in the research, and 3) licensed Intellectual Property for which royalty payments are distributed through the VCU Intellectual Property Foundation. Since such Financial Interests are not actionable according to the PHS regulation they are not termed financial Conflicts of Interest, but are deemed by VCU as possibly warranting attention and internal management.

**8. Does this policy supersede the Virginia Conflict of Interest Act?**

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

## 9. How does the COI in Research Policy align with the Virginia Conflict of Interest Act?

State law does not permit an Investigator to have a personal interest in a separate contract (exceeding 3% equity or \$5,000 income (or anticipated income) from the contracting entity) with VCU other than his or her 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 or another company) that is subcontracting to VCU. Pursuant to a provision in the Act for research and development or commercialization of intellectual property ([2.2-3106](#), C.8), the Conflict of Interest Committee may recommend an exception when all specified conditions are met and a management plan has been executed. The exception 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 Office at [ORIE@vcu.edu](mailto:ORIE@vcu.edu) early in the research contract process.

## 10. How is organizational or institutional conflict of interests in research identified and managed?

Identification of organizational COI is addressed in a number of ways, including:

- a) The VCU Office of Integrity and Compliance leads the university's state-required Statement of Economic Interests process. Financial interests of senior leadership and other university members designated as being in 'positions of trust' are assessed annually. See <http://www.assurance.vcu.edu/COI.html> for more information about COI identification and management.
- b) Organizational financial interests related to i) license-related income from intellectual property, ii) stipulated donor gifts, iii) VCU investments, and other areas are either identified by the COIC and referred by the COIC Chair to the specific offices which have Board of Visitor-approved policies and firewalls in place to mitigate conflicts of interest, or identified by these offices through the state-required disclosure process. Relevant offices are Director, Virginia Innovation Gateway, Vice President for Development and Alumni Relations, and Vice President for Finance and Administration, respectively. Management for identified COI is facilitated through these offices.
- c) The Research Conflict of Interests Committee (COIC) described in this policy is charged to evaluate, identify and manage individual researchers' financial conflicts of interest in research. While the COIC focuses on individuals, investigators are directed in the AIRS and RAMS-IRB application to indicate whether others, to their knowledge, have financial interests related to their research. These are assessed by the COIC in the context of the research. The COIC may be able to manage the perception of organizational COI as part of an individual management plan. However, if needed, these will be referred to the relevant offices listed above. Enacted management for institutional conflict related to research is communicated to the COIC Chair. The COIC may require additional management depending on the context of the research.