



Conflict of Interest Considerations for VCU Faculty/Staff Start-up Companies

Office of Research Integrity and Ethics
Conflicts of Interest in Research Program

What is a Faculty/Staff Start-up Company?

An entrepreneurial venture that typically involves a company in its early stages of operation, formed around disclosed intellectual property that has commercial potential but needs further development

- Start-up companies may be eligible for [Small Business Innovation Research \(SBIR\) and Small Business Technology Transfer \(STTR\) grant programs](#), which are early-stage federal funding sources for technology commercialization.
- While SBIR/STTR programs encourage both the commercialization of technologies and involvement with start-up companies, they pose inherent conflict of interest issues.

Conflict of Interest

- A conflict of interest (COI) is a situation in which financial or other personal considerations have the potential to compromise or bias professional judgment and objectivity.
 - A financial COI can simply present an appearance of compromising an investigator's professional judgment in conducting or reporting research.
 - A COI can be especially problematic in human subjects research if the investigator's objectivity is, or appears to be, compromised.
- Although COI are expected with faculty/staff start-up companies, they threaten the integrity of the research if not appropriately reported, identified, and managed.

COI Considerations for Faculty/Staff Start-ups

- In order to successfully navigate start-up ventures, faculty and staff should consider many elements, including:
 - Federal rules regarding SBIR/STTR funding
 - [Virginia Conflict of Interests Act](#)
 - VCU policies regarding COI and outside professional activities
 - The nature of the financial or non-financial interest(s)
 - Time/effort commitments
 - Whether students will be involved
 - The space or equipment to be used
- A primary consideration is that under state law, VCU is prohibited from entering into a contract in which an employee has a personal interest in the contracting entity (unless an exception is approved).

Virginia *Conflict of Interests Act*

- In § 2.2-3106, the Code of Virginia [State and Local Government Conflict of Interests Act](#) states:
 - No officer or employee of any governmental agency of state government shall have a *personal interest* in a contract with the governmental agency of which he is an officer or employee, other than his own contract of employment.
 - *Personal interest* is defined as:
 - | *A financial benefit or liability accruing to an officer or employee or to a member of their immediate family*
- A contract with VCU in which an employee has a personal interest in the contracting entity (i.e. $\geq 3\%$ equity, earn (or anticipate to earn) $\geq \$5,000$ income, or have other significant investments) represents a **state-prohibited contract**.

Requirements for a State-prohibited Contract Exception

- A state-prohibited contract exception is often possible if the following criteria are met:
 - The employee’s personal interest is disclosed and approved by VCU prior to the time at which the contract is entered into;
 - The employee promptly files a disclosure statement with the state initially and then annually on or before January 15th;
 - The conflicted individual has no role in the contract negotiation with VCU; and
 - The COI Committee (COIC) determines the conflict can be managed and recommends that President Rao approve an exception to the state-prohibited contract.
- The COIC will issue a management plan in order to mitigate the COI or its appearance.

Types of Financial Interests Related to Start-Up Companies

- Faculty and staff may have the following financial interests in a start-up company that are, or could appear to be, related to the proposed research:
 - Equity interests
 - Board membership or serving as an officer
 - Consulting relationships
 - Use of intellectual property
- Individuals with financial interests related to start-up companies that sponsor research are expected to recuse themselves from decisions that involve conflicting responsibilities to the start-up and VCU.
- COIC considerations and management plan elements depend on the nature of the interest(s).

Equity Interests

- Faculty and staff may hold equity interest in start-up companies.
- Involvement in research sponsored by an employee-owned company may need to be restricted due to the ownership interest.
 - In this case, consideration will be given as to whether the conflicted individual should be the project PI, co/sub-investigator, or the designated PI's supervisor.
 - The COI committee may consider:
 - No recruitment/enrollment by the conflicted individual
 - No access to identifiable data
 - Disclosure in the informed consent form
 - 'Safe person' for communications with peers, students, and research subjects
 - The state-prohibited contract exception related to a personal interest applies.
 - This scenario may also involve an [institutional conflict of interest](#) subject to management via disclosure in presentations/publications and to colleagues, at a minimum.

Board Membership or Serving as an Officer

- Faculty and staff may hold fiduciary, paid, and/or unpaid positions at start-up companies.
- Involvement in company-sponsored research may need to be restricted due to the nature and/or fiduciary responsibility of the position.
 - Considerations regarding research role and, if a paid position, the state-prohibited contract exception apply.
 - Note: In terms of COIC considerations, Scientific/Clinical Advisory Board membership is considered more closely related to consulting than serving as an officer or director of a company. Please see Consulting Relationships.

Consulting Relationships

- Faculty and staff may have consulting relationships with start-up companies.
- However, involvement in company-sponsored research may be restricted based on the amount of consulting remuneration that is received annually, the type of research, and/or the role of the conflicted individual in the research.
 - In general, faculty members are required to obtain the permission of the university prior to engaging in an [outside professional activity \(OPA\)](#) and must make periodic summary reports on such activities.
 - For School of Medicine (SOM) faculty, consulting relationships between faculty and a start-up receive prior approval from the department chair via the [OPA System](#) under the [SOM Guidelines and Procedures for Disclosure, Approval and Reporting of Outside Professional Activities policy](#).

Use of Intellectual Property

- Faculty/staff start-up companies will generally license intellectual property (IP) invented by faculty/staff founders.
- Involvement in company-sponsored research may be restricted due to the amount of license-related income that has been received.
 - The conflicted individual's research role may be restricted.
 - If the IP was developed at VCU, this scenario may represent an [institutional conflict of interest](#), subject to management via disclosure in presentations/publications and to colleagues, at a minimum.
 - If the IP was developed outside of VCU, the COIC will consider whether the research can be done at VCU and whether the conflicted individual can be involved at any level.

COIC Considerations for Recommending a State-prohibited Contract Exception

- Is the SBIR/STTR subaward to VCU in the best interest of VCU?
- What is the nature of the research?
- Will the STTR PI also be the VCU PI?
 - Given SBIR requirements, it will be problematic for a VCU faculty member to serve as the VCU PI for the SBIR subaward.
- What are the research roles of other company principals who are also VCU employees?
- Do faculty holding a position within the contracting entity have OPA approval from their school?
- How will the company be configured?
 - VCU employees cannot be involved in VCU's decision to contract or in the financial negotiations with the company.
- Will students be involved in the research?
 - Student effort for a company may not compromise academic progression.

COI Management Plan

- COIC recommendation for a state-prohibited contract exception is supported by a management plan. Elements may include:
 - Disclosure of the financial relationship in publications and presentations of the study results
 - Disclosure language should indicate the ownership interest, governing position, consulting relationship, licensed or unlicensed IP used in the research, and/or the receipt of royalties from the licensed IP as it relates to the company sponsoring the project.
 - Disclosure of the financial relationship to students, trainees, and other VCU personnel working on the project
 - Disclosure of the COI and its management should be affirmed on the COI notification form (provided).

COI Management Plan

(continued)

- A designated 'safe' person for any VCU students working on the research
 - The safe person is asked to provide periodic assessment to ensure the students' academic studies are not compromised due to their involvement in the project.
 - Generally, the students' thesis research should not overlap with the work done for the SBIR/STTR.
 - If the student is an employee of the start-up company, the student should not perform company work at VCU.
- If the research involves human subjects, management may also include:
 - Restriction of the conflicted individual's research role
 - Disclosure language in the informed consent form
 - COI oversight – internal and/or external to VCU
 - Review by external IRB

COI Management Plan

- An update regarding how the management plan was fulfilled will be provided to the COIC upon request.
 - At a minimum, twelve months from the date of management plan acceptance and annually thereafter for the duration of the project plus one year post-closure of the study at VCU
- This update will include:
 - Signed notification form of COI disclosure to students, trainees, and VCU personnel working on the project
 - Disclosures associated with publications and presentations
 - Other evidence of COI management plan adherence, as applicable

Other Considerations

- Employment of students and/or trainees by a start-up
 - Students and trainees should be notified about the managed conflict at the initiation of the project or when they join the project.
- Use of VCU space, equipment, or resources
 - Use on behalf of a start-up is not permitted unless VCU is performing scope of work authorized through a subaward or subcontract from the start-up to VCU and that subaward or subcontract is fully executed prior to when work begins. Only the subcontracted work is authorized to be performed using VCU resources.
- Conflict of commitment
 - Employees are expected to satisfy all of the requirements of their VCU jobs and should not permit outside activities to interfere with the performance of their university obligations.

Summary

- Be aware of your department/school's policies regarding OPA reporting relative to a company.
- Ensure your chair/dean is aware of, and in agreement with, your start-up company, your VCU time/effort commitment, and any proposed use of VCU resources.
- Be acquainted with SBIR/STTR rules regarding the company's interface with VCU.
 - STTR requires subcontracting to a non-profit research partner – SBIR does not.
 - Under SBIR, the PI must be primarily employed by the company (unless a waiver is granted by the NIH) – STTR does not stipulate PI primary employment.
- Schedule an appointment with [VCU Innovation Gateway](#) and with the [COIC Chair](#).
- Because a VCU subcontract from a faculty/staff start-up represents a state-prohibited contract, no funds can be charged and no research may begin until the state-prohibited contract exception is fully approved by the president and the COI management plan is accepted in the Activity and Interest Reporting System (AIRS).
- Enter the [AIRS](#) to complete your Financial Interest Report. Keep financial interests related to the start-up company up-to-date in the AIRS.

Resources

- NIH
 - [SBIR/STTR programs](#)
- Virginia
 - [State and Local Government Conflict of Interests Act](#) (§ 2.2-3106)
- VCU
 - [COI in Research program website](#)
 - [Conflicts of Interest in Research policy](#)
 - [Institutional Conflicts of Interest in Research - Interim policy](#)
 - [Outside Professional Activity and Employment, Research, and Continuing Education policy](#)
 - [SOM Guidelines and Procedures for Disclosure, Approval and Reporting of Outside Professional Activities policy](#)
 - [VCU Innovation Gateway](#)

For questions or concerns regarding COI considerations for faculty/staff start-ups, please contact the COI in Research program at AIRS@vcu.edu.