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

Office of Research Integrity and Ethics Conflict 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 a variety of funding mechanisms to support research and development and technology commercialization. Examples include SBIR (Small Business Innovation Research) and STTR (Small Business Technology Transfer) grant programs, which are early-stage federal funding sources, as well as funding opportunities through the Commonwealth or other non-profit entities.
- While SBIR/STTR programs and other funding mechanisms encourage both the commercialization of technologies and involvement of start-up companies, they pose inherent conflict of interest issues.

COI in Research

- 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.
 - An unidentified COI can be especially problematic in human subjects research if the investigator's objectivity appears to be compromised.
- Although conflicts of interest are expected with faculty/staff start-up companies, they threaten the integrity of the research if not appropriately reported, identified, and managed.

VCU Conflicts of Interest in Research policy



Institutional COI in Research

- An institutional conflict of interest (ICOI) is a situation in which the financial interests of VCU or its senior leadership might reasonably appear to influence institutional activities involving research.
- Financial interests include:
 - Gifts and license-related payments made to the university
 - Gifts and license-related payments received by senior leadership
 - Ownership interests in outside businesses held by the university or senior leadership
- Interests related to start-up companies may represent an ICOI subject to management via disclosure in presentations/publications and to colleagues (at a minimum).

VCU Institutional Conflicts of Interest in Research policy

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
 - Code of Virginia State and Local Government 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. > 3% equity, earn (or anticipate to earn) > \$5,000 income, or have other significant investments) represents a stateprohibited 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 that the contract is in the best interest of VCU;
 - Concludes the conflict can be managed;
 - Issues a management plan in order to mitigate the COI; and
 - Recommends that President Rao approves the contract.

VCU <u>Research and Development Exception for the Virginia Conflict of Interests Act</u> policy



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 related to the proposed research:
 - Equity interests
 - Board membership or serving as an officer
 - Consulting relationships
 - Use of IP
- 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), the type of research, and the research role of the conflicted individual.

Equity Interests

- It is possible for faculty and staff to hold equity interest in start-up companies.
- The conflicted individual's involvement in research sponsored by their company may be restricted based on the type of research and/or the amount of ownership interest.
 - The COIC may consider:
 - Whether the conflicted individual should be the project PI, a co/sub-investigator, or the designated PI's supervisor
 - Whether the conflicted individual should be involved in recruitment/enrollment
 - Whether the conflicted individual should have access to identifiable data
 - Recommending disclosure in the informed consent form
 - An alternate contact for study personnel
 - This scenario could represent a state-prohibited contract (requiring an exception) and may also involve an ICOI.

Board Membership or Serving as an Officer

- It is possible for faculty and staff to hold positions with start-up companies, whether paid or unpaid.
- The conflicted individual's involvement in company-sponsored research may be restricted due to the type of research and/or the nature of the position.
 - The COIC may consider research role restrictions.
 - This scenario could represent a state-prohibited contract (requiring an exception) if it is a paid position.
 - 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 (next).



Consulting Relationships

- It is possible for faculty and staff to have consulting relationships with start-up companies.
- The conflicted individual's involvement in company-sponsored research may be restricted based on the type of research and/or the amount of consulting remuneration that is received annually.
 - The COIC may consider research role restrictions.
 - 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.
 - Faculty and staff should ensure that OPA reporting matches the activities reported in the Financial Interest Report (FIR), the SmartForm in VCU's Activity and Interest Reporting System (RAMS-AIRS) that contains reported interests.



Use of IP

- Faculty/staff start-up companies will generally license IP invented by faculty/staff founders.
- The conflicted individual's involvement in company-sponsored research may be restricted based on the type of research and/or the amount of license-related income that has been received to date.
 - The COIC may consider research role restrictions.
 - If the IP was developed at VCU, this scenario may represent an ICOI.
 - 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

- Considerations for recommending a state-prohibited contract exception:
 - What is the nature of the research?
 - Is the subaward/subcontract to VCU in the best interest of VCU?
 - If it's an STTR subaward, 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?
 - 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 interest in publications and presentations of the study results
 - Disclosure of the interest to those working on the project with documented affirmation on the COI notification form (provided to the VCU PI)
 - If any VCU students are working on the research, a designated alternate contact person will be identified to assess, as needed, whether the students' academic progress is being compromised due to their involvement in the project.
 - If the research involves human subjects, management may also include:
 - Restriction of the conflicted individual's research role.
 - Recommended disclosure in the informed consent form.
 - Review by an external IRB.

COI Management Plan

- An update regarding how the management plan was fulfilled must be provided to the COIC upon request.
 - At a minimum, an update will be requested twelve months from the date of the management plan's digital signature and annually thereafter for the duration of the project plus one year post-closure of the study at VCU.
- This update will include:
 - Disclosures associated with publications and presentations.
 - Disclosures to onboarded personnel (i.e. returned COI notification form).
 - Other evidence of COI management plan adherence, as applicable.



Other Considerations

- Outside employment of students and/or trainees
 - Should be approved according to school policies. If the student is an employee of the start-up company, the student should not
 perform company work at VCU.
- Students and/or trainees working on a start-up company's subaward/subcontract to VCU
 - Students and trainees should be notified about the managed conflict at the initiation of the project or when they join the
 project. The conflicted individual should not supervise the trainee in the context of the subaward/subcontract or direct the
 student's thesis or dissertation committee.
- 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/subcontract from the start-up to VCU and that subaward/subcontract is fully executed prior to when work begins. Only the subawarded/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 involvement with start-up companies.
- Ensure your chair/dean is aware and in support of your start-up company as well as your VCU time/effort commitment and any proposed use of VCU resources as they relate to your start-up.
- 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.
- Complete your FIR in the <u>AIRS</u> and keep interests related to the start-up company up-to-date.
- Schedule an appointment with the COIC Chair and/or designee by emailing AIRS@vcu.edu.
- Because a VCU subaward/subcontract from a faculty/staff start-up represents a state-prohibited contract, no funds can be charged and no research may begin until the contract is fully approved by the president and the COI management plan is finalized in the AIRS.

Resources

- VCU
 - <u>Conflicts of Interest in Research</u> policy
 - Institutional Conflicts of Interest in Research policy
 - Research and Development Exception for the Virginia Conflict of Interests Act policy
 - <u>Computer and Network Resources Use</u> policy
 - <u>Outside Professional Activity and Employment, Research, and Continuing Education (Faculty Specific)</u> policy
 - <u>Outside Professional Activity, Consulting and Continuing Education Instruction for University and Academic Professionals</u> <u>and Classified Staff - Interim</u> policy
- Federal/state
 - <u>SBIR/STTR programs</u>
 - State and Local Government Conflict of Interests Act (§ 2.2-3106)

Questions? Contact the COI in Research Program at AIRS@vcu.edu.