

Guidelines for Navigating COI Issues when Faculty Start-Up Companies Engage in University Research

June 28, 2022

Contents:

- [Purpose](#)
- [Introduction](#)
- [Universities Subcontracting to/from Faculty Start-Ups](#)
- [SBIRs/STTRs](#)
- [The Same Individual Serving as PI on Both Sides of SBIR/STTR Collaborations](#)
- [University Personnel Serving as Company PI on SBIRs and as Company PI on NSF SBIRs and STTRs](#)
- [Special Note for Individuals Involved in SBIR/STTR Research Proposed To/Funded By NSF](#)
- [Use of University Resources](#)
- [Involvement of Students and Post-Docs in Faculty Start-up Activities](#)
- [Purchasing Equipment or Services from Companies in Which University Investigators Have Significant Financial Interests \(with case studies\)](#)
- [Additional Resources](#)

Purpose

Florida State University (FSU) is committed to facilitating scientific discovery and advancing knowledge through innovative and translatable research. Consistent with the University's mission, our researchers are entering the entrepreneurial space in greater numbers, as well as developing novel solutions to address questions, problems, and disparities in a variety of fields. Translating ideas and intellectual property from the University to the marketplace is a critical component of FSU's research program. Inherent in these relationships and interactions are potential or actual conflicts of interest with respect to competing and/or conflicting interests and obligations. We must balance promoting innovation and entrepreneurship with preserving our commitment to FSU and safeguarding the integrity and objectivity of University research.

These guidelines are intended to help FSU's research community more proactively navigate existing policies and standards that touch areas in which start-up companies and university research intersect. While policies exist for various processes, they are often general and are "owned" by different areas and departments across the university. Many situations are nuanced and are assessed by various stakeholders on a case-by-case basis. While this provides for necessary flexibility based on the facts and circumstances of a particular situation, it also has the potential to allow for a lack of clarity and/or cause misunderstanding as to how certain things should be approached or handled. This guidance aims to provide greater transparency and clarity around the highlighted topics related to start-up companies and university research.

Please note that specific sponsor policies or requirements, if more restrictive, take precedence over university policies and this guidance.

Introduction

Conflicts of interest (COIs) are inherent in collaborations between the university and companies in which an investigator has Significant Financial Interests (SFIs). COIs may arise when a university employee with an SFI in a company (ownership or other) engages in either the company or the university side of the research. Inherent COI concerns are:

- The potential for the research to be viewed as biased or not objective since the investigator may have financial benefit from the outcome of the research due to their interests in/relationship with the company, as well as intellectual property resulting from the research for which the company would be a likely commercial vehicle;

- The potential for the PI to use university space, personnel, and other resources to benefit the company portion of the research; and
- The potential for the blurring of the non-profit/for-profit boundary, in that the University's tax-exempt facilities could be used in a way that provide competitively advantages the for-profit company.

Investigators should disclose¹ fully and timely to the university any and all equity interests in non-publicly traded entities, such as start-up companies, as well as disclose any other financial interests. Equity interests in non-publicly traded entities, even if worth nothing or for which the value is unknown, are *required* to be disclosed.

These disclosures facilitate the research-related COI review process in which external interests and relationships of university investigators are assessed to determine whether or not they could relate to and impact or bias any research activity in which one is engaged.

Universities Subcontracting to and from Faculty Start-up Companies

The university *may* accept research subcontracts from faculty start-up companies and *may* subcontract research to faculty start-up companies through various funding and award mechanisms. Note that relevant policies and practices around selection of a subcontractor apply (e.g., the ability of the subcontractor to adequately perform the programmatic goals of the research project, compliance with the statutes of the State of Florida, etc.). FSU must demonstrate due diligence around the selection and/or engagement of subcontractors and vendors, particularly when an investigator involved in the activity has significant financial interests in the company. Sufficient documentation to support decisions around sole source justifications and/or selection of one company rather than a comparative company is required. When applicable, justifications should stress scientific or technical specialization or superiority in addition to cost considerations (e.g., fair market value for services and or products to be provided).

In situations where an investigator has significant financial interests in a company engaged in research with the university, consideration is given on a case-by-case basis as to whether or not the investigator may be involved in the university research activity involving the company in which he/she has significant financial interests.

General principles applying to such interactions between the university and companies in which investigators, their spouse, or dependent children (or other faculty or staff members) have significant financial interests include ensuring that the conflicted individual not be involved in any way – on behalf of the company or on behalf of the university – in contract, financial, or other transactions between the company and the university. Additionally, any proposed company use of university space, equipment, or other resources must be approved by the university under documented agreements that include the terms around the purpose, duration, cost, and other relevant specifics of such use.

In general, unless the sponsor specifically indicates otherwise or as specified below, an investigator may engage in university research involving an entity in which he or she has significant financial interests if placed under a COI Management Plan that may include, but not be limited to, some or all of the following:

- Disclosure of the related financial interests to human research participants, study team, and collaborators
- Disclosure of the related financial interests in presentations and publications arising from the research
- Independent data analysis/independent compliance monitoring

Decisions relative to the involvement of conflicted investigators in university research involving a company in which they have significant financial interests involve consideration of the nature and extent of the significant financial interest, the nature of the research, and the extent to which objectivity in research design, conduct, or reporting, as well as human research participant welfare (if applicable) can be protected by a COI Management Plan.

In general, an investigator may not serve as PI on a university research project involving human research participants sponsored by his or her own start-up company or involving intellectual property licensed to start-up company in which he or she has significant financial interests absent compelling circumstances. The conflicted investigator may be involved in the research in certain capacities and under a COI Management Plan, but may generally not serve as PI. Considerations as to whether or not compelling circumstances exist include the extent to which the investigator is (by virtue of specialized expertise) best positioned to carry out the research safely.

Considerations as to whether or not research objectivity and human participant safety can be adequately protected by a COI Management Plan despite involvement of a conflicted investigator in the research primarily include review of the individual's

¹ Disclosures are made via FSU's Conflict Administration Management System (CAMS), at my.fsu.edu.

role in the study in conjunction with study structure and design. For example, a multi-site, randomized study with an external data safety monitoring board, where the conflicted investigator is not involved in data analysis, presents a situation in which there is little opportunity for bias or lack of objectivity in research design, conduct, or reporting, despite the existence of a conflict of interest.

SBIRs/STTRs

Various federal agencies provide funding to small businesses to engage them in federal research and development with the potential for commercialization. This congressionally-mandated set-aside federal funding occurs via two different award mechanisms:

- Small Business Innovation Research ("SBIR")
- Small Business Technology Transfer ("STTR")

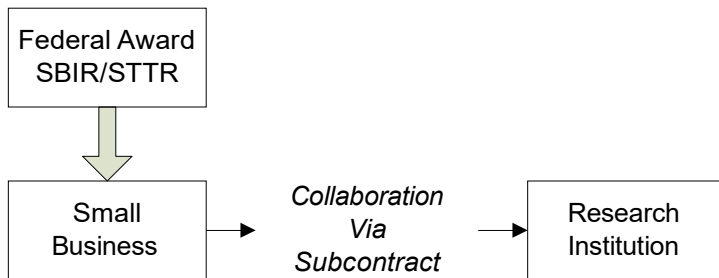
Both SBIR and STTR awards are made directly to a small business concern ("SBC").

STTRs require that the SBC collaborate with a research institution ("RI") for a certain portion of the award. SBIRs do not require RI involvement, but SBCs often collaborate with RIs on SBIRs despite the fact that it is not required.

A university is not an SBC and is not eligible to be a direct recipient of SBIR or STTR, but the University does meet the criteria to serve as a RI for SBIRs and STTRs. Involvement of a university in either an SBIR or a STTR occurs via a subcontract from the SBC to the university. In cases where there is a collaboration/subcontract between the SBC and the RI, there is an SBC PI and an RI PI (i.e. a PI for each side of the collaboration).

SBC = Small Business Concern
For-profit company that is the direct applicant for/recipient of SBIR/STTR awards

RI = Research Institution
Research institution partner (like a university) that collaborates with an SBC for SBIR/STTR awards via subcontract under the SBC



STTRs	
Applicability	Eligibility Requirements
SBC	<ul style="list-style-type: none"> • Must be an American-owned business • Must be independently operated • Must be a for-profit small-business concern • Must have five hundred or fewer employees • Not less than 40% of the research/research development must be performed by SBC
SBC PI	<ul style="list-style-type: none"> • Must be primarily employed by either the SBC <u>or</u> the collaborating RI²

² Only five agencies have STTR programs (Department of Defense, Department of Energy, the National Aeronautics and Space Administration, the Department of Health and Human Services, and the National Science Foundation), but the PI eligibility requirements differ slightly for NSF. For NSF-funded STTRs, PI eligibility requirements are the same as they are on an SBIR project (i.e. the PI must be primarily employed by the small business). At the other four agencies, the PI can be primarily employed by either the small business applicant or the non-profit organization with which the small firm is collaborating on the STTR project.

RI	<ul style="list-style-type: none"> • Research Institution collaborator required • Must be one of the following: <ul style="list-style-type: none"> ○ A non-profit college or university ○ A domestic non-profit research organization ○ A Federally-Funded Research and Development Center • RI required to conduct at least 30% of research and development, but may conduct up to 60% of research and development
-----------	--

SBIRs	
Applicability	Eligibility Requirements
SBC	<ul style="list-style-type: none"> • Must be an American-owned business • Must be independently operated • Must be a for-profit small-business concern • Must have five hundred or fewer employees • <i>If</i> sub-contract with another party, or with multiple parties: <ul style="list-style-type: none"> ○ SBC must do two-thirds of research during Phase I ○ SBC must do at least one-half of research during Phase II
SBC PI	<ul style="list-style-type: none"> • Must be primarily employed with SBC
RI	<ul style="list-style-type: none"> • Involvement of RI not required • <i>If</i> the SBC sub-contracts with RI: <ul style="list-style-type: none"> ○ RI may conduct up to one-third of research during Phase I ○ RI may do up to one-half of research during Phase II

The Same Individual Serving as PI on Both Sides of SBIR/STTR Collaborations

Although STTRs/SBIRs are indeed collaborations, the STTR/SBIR policy, instructions, and project performance percentage requirements and effort percentage make clear that keeping entities and roles separate is important. The company and collaborating research institution are referred to as separate parties. Having the same person on both sides of the collaboration blurs the respective parties’ performance percentage and effort percentage requirements/commitments. The PI of the company portion of the research and the university portion of the research may not be the same individual.

University Personnel Serving as Company PI on SBIRs and as Company PI on NSF SBIRs and STTRs

The PI of the company side of SBIR awards must be primarily employed by the company. For NSF, this company primary employment requirement also applies to the company PI for STTRs. Primary employment is measured and determined by percentage employment/appointment. Therefore, university employees who have a university appointment or position of 50% or greater may not serve as the company PI on SBIRs (or NSF STTRs) relative to research in which university is engaged. University employees serving as the company PI relative to SBIRs (or NSF STTRs) in which the university is party to the activity via proposed or contracted collaboration must have a university position or appointment no greater than 49%.

Special Note for Individuals Involved in SBIR/STTR Research Proposed To/Funded By NSF

NSF Guidance (e.g., NSF 22-551) specifically states:

- “No person who is an equity holder, employee, or officer of the proposing small business may be paid under a subaward unless an exception is recommended by the NSF SBIR/STTR Program Director and approved by the TI Division Director.”
- “No person who is an equity holder, employee, or officer of the proposing small business may be paid as a consultant unless an exception is recommended by the NSF SBIR/STTR Program Director and approved by the Division Director of Translational Impacts (TI).”

Therefore, please read all sponsor requirements for SBIR/STTR proposals and awards carefully, particularly NSF, and note what

situations may be prohibited or that may require advance sponsor approval. Please notify SRA if such language is noted and action or certification is required with respect to the FSU portion of the research, if applicable.

Use of University Resources

University resources may not be used for the activities of a company, including the company portion of a research collaboration in which the university is engaged, except under specific documented agreements between the company and university relative to the use of space, equipment, etc. Agreements can take different forms depending on the situation and purpose, such as direct research agreements, testing agreements, equipment use agreements, memorandums of understanding, collaboration agreements, etc.

Sponsored Research Administration (for public funds) or the FSU Research Foundation (for private funds) can serve as a starting point for helping to assess the appropriate agreement for such arrangements. For example, use of university core facilities or equipment may be allowed under documented agreement and payment of external rates, as well as in accordance with university core facility procedures (sign-up, scheduled time, etc.).

The Office of Commercialization (OC) can serve as a starting point to discuss terms related to intellectual property ownership for any intellectual property developed by the company while using University resources, space, or equipment.

Licensed electronic information resources, including Library databases and other online tools and services, must be used in accordance with FSU's license terms and conditions. These resources are restricted to University research and educational purposes, and may not be used for activities of a company or a commercial service. The University cannot enter into any agreement that allows companies access to or use of licensed Library resources.

SRA may not assist companies with the company portion of an SBIR/STTR or other company proposal for research. SRA provides research support services for university research, and with respect to SBIR/STTR or other collaborations with companies, SRA provides service and support only for the university side of the research (e.g., letter of intent for collaboration, subcontract execution, etc.).

Small businesses certify in their SBIR and STTR applications and award documents to the federal government that the small business portion of the research and research development will occur in company facilities using company employees unless otherwise indicated in the SBIR or STTR application and approved in the funding agreement. Therefore, performing the company portion of such research in university space using university resources – unless specifically approved by the funding agency and allowed by the university under documented agreement – subjects the company to potential criminal, civil, or administrative sanctions, and threatens the University's non-profit status.

Involvement of Students and Post-Docs in Faculty Start-up Activities

Involving students and postdoctoral fellows in faculty start-up company activities can enhance the academic experience and be valuable to the work. However, these trainee populations are in an inherently vulnerable position and care should be taken to ensure that they are engaged voluntarily, that the involvement is beneficial to their development, and that the activity does not interfere with their training and/or academic progress.

Questions to ask with respect to involving students and postdoctoral fellows in faculty start-up activities include, as applicable:

- Will these activities interfere with the student's progress towards degree, graduation timeline, or the postdoctoral fellows training timeline?
- Will these activities negatively impact the student's requirements for graduation?
- Will these activities have restrictions on publishing or presentation that could negatively impact publication of a student's thesis, dissertation, publication work, oral presentations or other requirements for degree completion?
- Is the student or postdoctoral fellow supported by a fellowship, training grant, or other funding mechanism that restricts work for for-profit enterprises?
- Will these activities and the joint external relationship negatively impact the FSU advisor/advisee relationship?
- Would the student's ability to maintain full-time enrollment (whether in coursework or research registrations) be

impacted? Students may not receive academic credit for efforts related to the external start-up activities.

- Are there possible restrictions around engagement in or payment for external activities related to a student's visa status?

Prior to engaging postdoctoral fellows in any faculty start-up company activities, the faculty member should have a discussion with the postdoctoral fellow around the topics included in this guidance. Postdoctoral fellows are considered staff members, and any external activities must be approved in advance by the individual's supervisor. External activities must occur outside of FSU work hours and must not involve FSU resources. If a faculty member is the primary postdoctoral supervisor and also engages the postdoctoral fellow in their external start-up activities, a COI Management Plan should be established that adjusts the individual's administrative reporting line or assigns independent oversight, as the faculty member may not be in the most objective position to assess whether the postdoctoral training and the activities within the start-up company are in conflict and whether the external activities are interfering with or detracting from the individual's FSU responsibilities and engagement in postdoctoral training.

If postdoctoral fellows or students are involved in FSU research, even if sponsored by or involving a faculty member's start-up company, it is considered university activity (and effort) in which the individual is engaged. Conversely, if they are engaged on the company side of research (e.g., serving as a PI or researcher on the company side of an SBIR or STTR award to the faculty start-up company (if they meet sponsor eligibility requirements to serve in that role)), that is considered external activity, and a COI Management Plan should be considered with respect to their FSU role and responsibilities. FSU's Office of Research Compliance Programs (ORCP) should be consulted and can provide guidance around establishing COI Management Plans for these and similar circumstances.

FSU's human research protections and animal care and use programs are heavily federally-regulated, and the responsibilities and risks associated with conducting human and animal research are significant. Individuals engaged in FSU research involving humans or animals are subject to federal requirements overseen and administered by the IRB and IACUC. In no circumstances may external entities or parties, such as faculty start-up companies or a physician's private practice, use the services of these offices for IRB or IACUC approval or animal services under the pretext of FSU research activity *unless* FSU is engaged in a particular research project through a subagreement with the company and/or there is a specific documented arrangement between the company and FSU (the IRB and/or IACUC).

Purchasing Equipment or Services from Companies in Which University Investigators Have Significant Financial Interests

The University must perform due diligence around the selection and/or engagement of subcontractors and vendors, particularly when an investigator involved in the purchase and/or activity has significant financial interests in the company. Sufficient documentation to support decisions around sole source justifications and/or selection of companies of university employees rather than comparative companies is important. When justifications involve scientific or technical specialization or superiority, it is critical to involve individuals with the relevant scientific/technical expertise to perform an assessment of the request and aid in the university's decision. If a start-up company is being proposed or selected for a purchase by FSU, ensure the related interest of the faculty member (or other individual with company interests) is disclosed on the vendor selection form, sole source justification form, or bid documentation form (as applicable).

Ensure selection of vendors for purchases follow FSU's [Procurement Manual](#).

Some research sponsors consider conflicts of interest in procurement actions something that needs to be requested of or disclosed in advance to the sponsor, or reported to the sponsor. Please engage ORCP if there is a request or intent to purchase equipment or services from a company in which a faculty member on the award has significant financial interests.

Case Studies

Question: I am a FSU faculty member with a new start-up company. What are some of the key COI pitfalls to avoid if my start-up company is going to apply for an STTR, and FSU (specifically, my lab) will be the research institution partner?

Answer:

- ✓ Ensure that your interests in the company have been fully disclosed in [CAMS](#); any equity (e.g., ownership) interests in a start-up company, even if the value is currently nothing or unknown, meet the criteria for “significant financial interest” and need to be disclosed.
- ✓ Ensure that you have named the PI of the company portion of the research and the university portion of the research, respectively, and that they are not the same individual.
- ✓ Ensure that your company has the adequate resources to carry out the company portion of the work being proposed, from both technical and administrative standpoints (including but not limited to personnel and effort, place of performance, space, and equipment needed to carry out the research, etc.).
- ✓ Ensure you have a compliant plan around what exactly the company portion of the work, and the university portion of the work, respectively, will entail (including but not limited to personnel and effort, place of performance, space, and equipment needed to carry out the research, etc.). If university resources or equipment are needed for any aspect of the company portion of the research, engage SRS to ensure that appropriate agreements and budgetary issues are considered.
- ✓ Reach out to ORCP to facilitate proactive consideration of the situation, to ensure that the COI can be adequately managed, and a COI Management Plan instituted (if/as needed) for all relevant parties.

Question: I would like the research administrator in my department to help me prepare the SBIR application my company is going to submit. My company is even willing pay for him to attend a workshop on SBIRs and STTRs. Is this appropriate, since FSU is the “university partner” on the SBIR proposal?

Answer: In general, no; university resources (including staff) may not be used for the company’s work, including proposal preparation work for SBIRs and/or STTRs.³ SRA staff *would* be involved, however, in providing support for the university side of the research collaboration (if applicable), such as preparing the letter of support, budget, and subcontract for the university portion of an SBIR/STTR collaboration.

Question: A colleague and I have started a company and we are ready to apply for an SBIR award. I am a faculty member; my colleague is a full-time staff research scientist in my department. The project will involve a subcontract to FSU, and specifically to my lab. Can my colleague serve as the PI on the company side of the project, while I will serve as PI on subcontract to the university?

Answer: While you may be able to serve as the PI on the SBIR subcontract to the University (if the sponsor does not prohibit it and if the COI is manageable through a COI Management Plan), the research scientist may not serve as PI for the company side of the SBIR unless he/she reduces their university appointment to no greater than 49%. Eligibility requirements to serve as the company PI for an SBIR require that the individual be primarily employed by the company, which is 51% or greater employment at the company; one cannot be primarily employed by the company and meet these eligibility requirements if they are employed by the university at greater than 49%. Reducing one’s university appointment to 49% or less, taking a temporary leave of absences from the university for entrepreneurial pursuit, or assigning a non-University employee to be PI of the company SBIR are ways to ensure that the company SBIR PI eligibility requirements are met.

Question: My start-up company is new and very small. I am the only person qualified to be PI, and we will need to use FSU as our collaborating research institution to complete some parts of the research on an upcoming STTR proposal. If I cannot be PI on both the company and research institution side, how can I proceed?

Answer: Consider whether or not a qualified University employee could truly contribute to the university side of the research collaboration as university PI. If you truly are the only qualified individual to serve as PI on both sides of the

³ University staff can engage in outside work only if/when the following criteria are met: (1) the outside work occurs outside of University time and not using University resources; (2) the staff member’s manager provides advance approval that the activity can occur because it does not interfere with or detract from the staff member’s University responsibilities; and (3) the activity does not present an unmanageable conflict of interest due to the nature of the staff member’s University position and the nature of the outside work. If the staff person to be engaged in such work reports directly to the faculty member whose company the external work is for, the faculty member’s dean’s office must provide advance approval and if approved, a COI Management Plan must be instituted for the staff member.

research (i.e. company and university), you may wish to consider applying for a different research award mechanism (rather than an SBIR or STTR), or consider mentoring/training a colleague in the research area to be at a point in the near future where they *would* appropriately have the qualifications to serve as university PI on an SBIR or STTR collaboration with your company.

Question: I am an FSU faculty member who has been asked to conduct a research project for a private company. We have a draft scope of work already. How do I begin the process of getting university approval?

Answer: If the company is paying for the research using public funds (passed through the company from a federal, state, or public university sponsor), contact Sponsored Research Administration. If the funds are not public funds, contact the FSU Research Foundation.

Key Contact for Questions on This Guidance:

Office of Research Compliance Programs
2019 Westcott North Annex
(850) 644-8648
research-compliance@fsu.edu

Internal Resources:

Mike Campbell
Chief Business and Industry Liaison
Dittmer Building, Suite 312
O 850-644-1749 C 850-545-7354
mscampbell@fsu.edu

External Resources:

- [Federal SBIR Program](#)

Other Relevant FSU Offices:

- [Office of Commercialization](#)
- [Office of Human Subjects Protection](#)