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

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## Purpose

As a public university, ECU is committed to creating opportunities for scientific discovery and advancing knowledge through innovative and translatable research that has the potential to transform the lives of people throughout the rural and coastal communities we serve. Consistent with the mission of our University and in partnership with entities external to the University, we are entering the entrepreneurial space with ever increasing frequency and bold endeavors. These endeavors focus on developing novel approaches to addressing questions, challenges, and disparities in a variety of fields. Translating ideas and intellectual property from the University to the marketplace is a critical and fundamental component of ECU’s research program. These relationships do not come without risks in terms of perceived, potential, or actual conflicts of interest as competing interests and obligations are often inherent in such endeavors. With this in mind, we must balance promoting innovation and entrepreneurship with preserving our commitment to ECU’s shared values of integrity and objectivity in research to safeguard the public’s trust in our institution and its endeavors.

These guidelines are intended to assist ECU’s research community in navigating the policies, regulations, and standards that relate to areas in which start-up companies and university research intersect. While regulations cover various activities, they are often general in nature and are “owned” by different divisions or 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 for a lack of clarity as to how certain things should be handled. This guidance aims to provide greater transparency and clarity around selected topics related to start-up companies and university research.

## Introduction

Conflicts of interest (COIs) are inherent in collaborations between the university and entities in which an investigator has personal financial interests. COIs may arise when a university employee with significant financial interests in a company (ownership or other) engages in either the company or the university side of the research. These COI concerns are outlined as follows:

* 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 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 tax-exempt facilities could be used in a way that competitively advantages the for-profit company.

Investigators should disclose fully and promptly 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 meeting the disclosure threshold for SFIs. 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 ECU investigators are assessed to determine whether they could relate to and impact or bias any research activity in which one is engaged.

## 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 around the selection of subcontractors apply (for example, the ability of the subcontractor to adequately perform the programmatic goals of the research project). Due diligence must be exercised 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. Documentation must be sufficient to support decisions around sole source justifications and/or selection of one company rather than a competitor. 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 the investigator may be involved in the university research activity involving the company in which he or she has significant financial interests.

General principles applying to such interactions between the university and companies in which investigators (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 non-clinical university research involving an entity in which he or she has significant financial interests if under management strategies that may include some or all of the following:

* Disclosure of the related financial interests to members of the 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 COI management strategies.

In general, an investigator may not serve as PI on a university research project involving human research participants sponsored by a start-up company or involving intellectual property licensed to a start-up company in which he or she has significant financial interests absent compelling circumstances. Considerations as to whether compelling circumstances exist include the extent to which the investigator is (by virtue of specialized expertise) best positioned to carry out the research safely.

Specific responsibilities of the University and faculty are contained in the Policy on the University’s Relationship with a Faculty Startup Company.

**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:

***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*

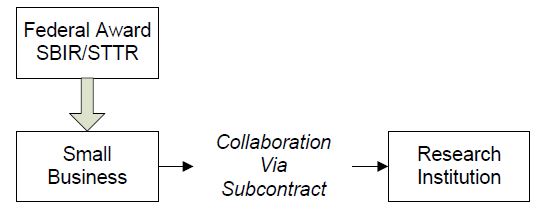
1. Small Business Innovation Research ("SBIR")
2. Small Business Technology Transfer ("STTR")

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).



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| **STTRs** | |
| **Applicability** | **Eligibility Requirements** |
| **SBC** | * Must be an American-owned business * Must be independently operated * Must be a for-profit business * Must have five hundred or fewer employees * Not less than 40% of the research/research development must be performed by SBC |
| **SBC PI** | * Must be primarily employed by either the SBC or the collaborating RI[1](#_bookmark0) |
| **RI** | * Research Institution collaborator required * Must be one of the following:   + 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 |

1 Only 5 agencies have STTR programs (Department of Defense, Department of Energy, the National Aeronautics and Space Administration, the National Institutes of Health and the National Science Foundation) and 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

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| **SBIRs** | |
| **Applicability** | **Eligibility Requirements** |
| **SBC** | * Must be an American-owned business * Must be independently operated * Must be a for-profit business * Must have five hundred or fewer employees * *If* sub-contract with another party, or with multiple parties:   + SBC must do two-thirds of research during Phase I   + SBC must do at least one-half of research during Phase II |
| **SBC PI** | * Must be primarily employed with SBC |
| **RI** | * Involvement of RI not required * *If* the SBC sub-contracts with RI:   + 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 Respective Sides of SBIR/STTR Collaborations

The PI of the company portion of the research and the university portion of the research may not be the same individual. STTRs require that the company formally collaborate with a non-profit research institution (e.g., a university). STTR Phase I awards require that at least 40% of work on the project be performed by the company and that the collaborating university perform at least 30% of the work. STTR Phase I awards require that the company PI commit a minimum of 1.2 calendar months (10% effort) and must have a formal appointment with, or commitment to, the company. The collaborating university PI has no minimum effort requirement. Although STTRS/SBIRs are indeed collaborations, the STTR/SBIR policy, instructions, and project percentage requirements/effort make clear that establishing a separation of entities and roles 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’ project % and effort % requirements/commitments. Most university researchers are committed 100% institutionally at the university among their academic, research, and other commitments, and therefore, do not likely have the effort available to meet the effort requirements of serving as the company PI of an SBIR or STTR.

## 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

Recently, specific language has been included in NSF SBIR/STTR solicitations, budget guidance, and program officer requests with respect to SBIR/STTR proposals submitted to/awards funded by the National Science Foundation (NSF). This language relates to the ability of individuals with specific financial interests/relationships with the small business applicant/awardee to be involved with/compensated by the small business and be involved in the SBIR/STTR research.

NSF guidance has also specified that *“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 Program Director and approved by the Division Director for the Division of Industrial Innovation and Partnerships*,” and that “*No person who is an equity holder, employee, or officer of the proposing small business may be paid through a subaward budget unless an exception is recommended by the Program Director and approved by the Division Director for the Division of Industrial Innovation and Partnerships.”*

Given such specifications, it is important to read all sponsor requirements for SBIR/STTR proposals and awards carefully, particularly from NSF, and note what situations may be prohibited or that may require advance sponsor approval. Please notify the Office of Research Administration (ORA) and the Office of Research Integrity and Compliance (ORIC) if such language is noted and action or certification is required with respect to ECU’s portion of the research.

## 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 use of space, equipment, etc. Agreements can take different forms depending on the situation and purpose, such as direct research agreements, testing agreements, manufacturing service agreements, equipment use agreements, memorandums of understanding, collaboration agreements, etc. The ORA can serve as a starting point for helping to assess the appropriate agreement for such arrangements.

For example:

* Use of university core facilitates 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.)
* Use of university equipment may be allowed under documented agreement and payment for use (unless otherwise specified) as well as in accordance with university procedures for use (sign-up, scheduled time, etc.)

The university takes the following factors into consideration when making decisions regarding company requests for lease of university space:

* There should be a specific reason that relates to an aspect of the university mission that the company has to lease university space and not non-University space (e.g., specific collaboration where close access to university space/specialized equipment being used via documented research/use agreement, etc. is needed).
* The agreement should include a specific and limited duration consistent with the company need.
* Any conflicted university employee cannot be involved in negotiations or any financial or other transactions on behalf of the company (or university) with respect to the arrangement.
* The agreement terms, cost, etc. should be consistent with market considerations and rates.

The Vice Chancellor for Research, Economic Development, and Engagement (REDE) or the Office of Innovation and New Ventures can serve as a starting point to request company lease of university space, as there are programs and initiatives around support for and appropriate handling of this type of activity.

Any agreements between companies and the University should specify terms for intellectual property ownership for any intellectual property developed by the company while using University resources, space, or equipment. These agreements should be reviewed by the Office of Innovation and New Ventures.

Licensed electronic information resources, including Library databases and other online tools and services, must be used in accordance with ECU’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.

ORA may not assist companies/small businesses with the company portion of an SBIR/STTR or other company proposal for research. ORA provides research support services for university research, and with respect to SBIR/STTR or other collaborations with companies, ORA 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.

## 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 on for-profit enterprises?
  + Will these activities and the joint external relationship negatively impact ECU’s 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/payment for external activities related to a student’s visa status?

If a faculty member is the sole principal research advisor for a student he or she wishes to involve in his or her external start-up activities, principal research co-advisor must be identified for the student. A co-advisor works with the student to develop a research topic, formulate ideas and structure for, and guides the progress of the thesis/prospectus/dissertation.

Prior to engaging postdoctoral fellows in any faculty start-up company activities, the faculty member should ensure to 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 ECU work hours and must not involve ECU 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 ECU responsibilities and engagement in postdoctoral training.

If postdoctoral fellows or students are involved in ECU 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 ECU role and responsibilities. ORIC should be consulted and can provide guidance around establishing COI management plans for these and similar circumstances.

ECU’s Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), and Department of Comparative Medicine (DCM) services are for ECU research activities (i.e. research projects awarded or contracted to ECU or its affiliates) directly or through subcontract from another institution, and/or other research activities (funded or unfunded) that involve ECU researchers acting in their ECU capacity).

ECU’s human research protections and animal care and use programs are federally regulated, and the responsibilities and risks associated with conducting human and animal research are significant. Individuals engaged in ECU research involving humans or animals are subject to federal requirements overseen and administered by the IRB, IACUC, and DCM offices. 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 ECU research activity *unless* ECU is engaged in a particular research project through a sub-agreement with the company and/or there is a specific documented arrangement between the company and ECU (the IRB, IACUC, and/or DCM, respectively).

## 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. Documentation must be sufficient to support decisions around sole source justifications and/or selection of companies of university employees rather than competitors. 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 ECU, 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 ECU’s Guide to Materials Management and Purchasing.

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 ORA and ORIC 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.