

WU Start-up Company Guide

Navigating University Collaborations, Resources, and Potential Conflicts

Advice, Considerations, and Resources, outside of the tech transfer process, for faculty/staff when establishing or investing in a start-up company or pursuing STTR/SBIR funding or company sponsored funding for your lab.

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Introduction and Purpose



The goal of this document is to provide guidance regarding general considerations associated with start-ups and associated entrepreneurial activities to provide tools to navigate specific situations that are likely to arise beyond the tech transfer process. Information from various sources have been compiled into this guidance document.

Topics include:

- Conflicts of interest considerations
- Agreements and contracts that may be necessary
- Approvals that may be required
- Applicable WU policies

This document can also be used as a tool to begin thinking through some of the specifics of forming a company and applicable guidance is provided that may be relevant. **The most common questions are outlined in the Question and Guidance section.** These questions will help to identify potential issues that may arise, and the answers will assist committees that may review the relevant activities.

Additionally this document aims to provide some transparency on requirements or restrictions particularly related to start-ups interacting with WU.

Lastly, while this document can be used as a resource or reference tool, the intention is for this to be used in conjunction in working directly with the [Faculty Fellows in Entrepreneurship](#) and Office of Research Integrity & Ethics and Compliance Office (ORIE)/COI Office.

Best Practices



Contact the [Office of Research Integrity & Ethics \(ORIE\)/COI Office](#), [Faculty Fellows](#), or [Office of Technology Management \(OTM\)](#) when you are thinking about:

- Forming a company
 - Establish a licensing agreement with the University
 - Applying for Phase I, Phase II, or Fast Track SBIR/STTR funding or pursuing company sponsored research for your lab
- A. The Faculty Fellows advise WU faculty on policies and administrative requirements as the company is being envisioned and/or collaborations between WU and the company are being considered.
- B. The COI Office assists in providing guidance on potential implications of the entrepreneurial activity and facilitate communications between faculty and staff with other programs or offices at WU that may need to be involved.
- C. The Office of Technology Management (OTM) assists faculty in the transfer of technology from the lab to the marketplace. This document does not address the tech transfer process; visit the [OTM website](#) for additional details and information.

Make contact as early as possible, preferably before initiating one of the activities listed above, as this allows you to make informed choices prior to being committed to a particular direction/path and make the most out of any feedback or guidance received.

Early communication is in the investigator's best interest to facilitate smooth transitions and expedite processes.

Approvals and Agreements Needed Prior to Initiating a Specific Activity

Conflicts of Interest Review Committee (CIRC)/Institutional Conflicts of Interest Committee (ICOIC) Approvals

- All SBIR/STTR proposals subcontracting to WU (including Phase I, Phase II, and Fast Track).^{1,2}
 - Provide a copy of any SBIR/STTR proposal to both the Faculty Fellow and ORIE, as soon as it is available, prior to submission so that appropriate reviews occur.
- To be PI/investigator on a subcontract or Sponsored Research Agreement (SRA) from a company you have an ownership interest in.²
- To be PI on both the grant to the company and the subcontract to WU, for SBIRs/STTRs (Also requires approval by the Vice-Chancellor for Research (VCR)).^{1,2}
- Research activities related to the company (sponsoring or evaluating owned or licensed IP).²

Department Chair Approvals

- Company is using or accessing resources in your lab or department.¹
- Hiring WU staff or students to work at the company.¹
- Cost sharing on company sponsored research including SBIR/STTRs.
- Utilizing WU administrative support staff to assist (in a limited capacity) in support of the company.¹

Agreements Needed

The Office of Technology Management (OTM) or Joint Research Office of Contracting (JROC) will need to establish written agreements prior to:

- Establishing a research or service agreement between WU and the company (JROC).
- Sharing WU owned materials with the company (OTM).
- Sharing WU owned data with the company (JROC).
- Company accessing or using resources at WU (including in your lab) (JROC).

VCR Approvals

- To be PI on both the grant to the company and the subcontract to WU, for SBIRs/STTRs.¹
- Company is using or accessing resources in your lab.¹

Source:

1. [WU SBIR/STTR Guidelines](#)

2. [WU Research COI Policy](#)

General Info – About the Company



Instructions:

Use these series of questions to help articulate the structure of the company as well your (and WU's) relationship with the company and identify key activities where you may need additional approvals. For example, the COI Committees will typically ask these questions during their reviews.

Questions:

1. Status of the company – has it been formed? Name of the company? Type of Company (S-corp etc..)
2. What is the purpose of the company?
 - a. Is any intellectual property developed by you / co-founders involved? If so, describe
 - b. Was the IP developed at the University? If so, has it been properly disclosed to OTM?
 - c. Is there a license agreement with WU or is one being negotiated with OTM?
3. What is your role or anticipated role in the company (e.g. CEO, board member)?
4. What is your ownership interest or anticipated interest (%)?
5. Are other individuals involved at company (WU and non-WU)?
 - a. What are their anticipated roles and responsibilities at the company?
 - b. Are they affiliated with WU? If yes:
 - i. Is there any anticipated change in their role at WU as a result of their involvement with the company?
 - ii. What is your professional relationship to these individuals (e.g., mentor, supervisor, etc.)?
 - iii. Does your spouse or partner also have an appointment at WU?
6. What are your anticipated next steps or goals related to this company (e.g., plans for research funding)?
7. Any current or pending research at WU that:
 - a. Continues to develop or evaluate^a the IP (whether or not licensed); or would be of interest or importance to the company (i.e., similar objectives or parallel pursuits)
 - b. If so, you may be asked to provide:
 - Project title, funding source, PI
 - Who is on the research team and what are their roles?
 - Are students or trainees involved?
 - Are human subjects involved?
 - What is your role in the human study (and the role of other company-affiliated individuals)?

^a *Evaluating IP is defined as assessing, comparing, enhancing, or improving the licensed IP. Experiments that evaluate IP may report results judging the worth, significance, or quality of the IP either by itself or in comparison to other IP and/or methods.*

Questions and Guidance for Company Sponsored Research @ WU (SBIRs/STTRs/SRAs)

Instructions: Identify the research plans of the company and how those research activities will relate to WU. When available, additional guidance or action items are provided.

Questions:	Additional Guidance:
8. What are the plans for the company to sponsor/support research at WU (such as SBIRs/STTRs/SRAs)?	Some arrangements may need specific contracts and/or approvals as outlined in this document.
9. What are the plans for conducting human studies research?	<p>Unless exempt, Health & Human Services (HHS) will require IRB approval for a startup company when receiving a direct HHS award to conduct human subjects research, even where all activities involving human subjects are carried out by WU.⁵</p> <p>Except in rare instances, the PI on an IRB application for human subject research is required to be an independent non-conflicted faculty member.</p>
10. For SBIRs/STTRs applications: <ol style="list-style-type: none"> a. Who will be PI for company, i.e., overall for grant or the contact PI for agency? b. Who will be PI at WU? c. What are the application due dates or anticipated award dates? 	<p>Generally, WU faculty may not serve as both PI at the company and PI at WU; Exceptions require prior approval by CIRC/ICOIC and VCR.¹, which can be initiated through the CIRC/ICOIC review</p> <p>NSF SBIRs: Equity holders cannot be paid through a subaward budget.³</p> <p>DOE STTRs: The PI's hours must be budgeted under the organization of his or her primary employment.⁴</p> <p>Provide application to the CIRC and Faculty Fellow.</p>
11. Describe individuals involved in the research at WU and the company: <ol style="list-style-type: none"> a. Who is on the research team and what are their roles? b. Are WU students or trainees involved? c. Who will have access to WU patients/PHI? What are their roles? 	<p>When a WU faculty member is a student's mentor, graduate and undergraduate students are not allowed to perform work for either WU or the company for SBIRs/STTRs. ¹</p> <p>Refer to Student/Trainee/Staff engagement section</p>

Source:

1. [WU SBIR/STTR Guidelines](#)

2. [WU Research COI Policy](#)

3. [NSF SBIR/STTR FAO](#)

4. [DOE SBIR/STTR FY2019 FOA](#)

5. [NIH Grant Policy Statement](#)

Company Interactions with WU

(May or may not be related to company sponsored research activities)



USE OF UNIVERSITY RESOURCES

Instructions: Address additional ways companies may interact with WU that fall outside of company sponsored research activities.

Questions:	Additional Guidance:
<p>12. Do you anticipate a need for the company to access or utilize any resources at WU? If so:</p> <p>a. What are the plans, and for what purpose, will company be using:</p> <ul style="list-style-type: none"> • WU core labs and/or recharge facilities; or • Resources from your lab, e.g., use of equipment, space, WU employee services (including training of company personnel)? • Access or involvement with research animals? 	<p>“Non-WU entity” rates apply for using core facilities, and can only be used with appropriate agreements in place.¹</p> <p>For use of resources from your lab, approval is required from Department Chair & VCR, and with appropriate agreements in place¹ (e.g., facility use or service agreement executed through JROC).</p> <p>Consistent with the University’s interactions with for-profit entities, start-up company employees are typically not permitted to have access or involvement with animals. Discuss with the Institutional Animal Care and Use Committee (IACUC) for consideration of special circumstances.</p>
<p>b. Do you plan to engage WU administrative support staff (e.g., assistance in submitting funding applications on behalf of company)?</p>	<p>May be allowed in a limited capacity and with written approval by the Department Chair.¹ Refer to WU SBIR/STTR Guidelines.</p>
<p>c. What other WU resources will be used by company and for what purpose?</p>	<p>Typically, written approval by the Department Chair is required.¹ Refer to WU SBIR/STTR Guidelines.</p>
<p>13. What, if any, data or materials do you intend for WU to provide to the company?</p>	<p>If documented within scope of a SRA or subaward, nothing further is needed;</p> <p>If not, arrangement must be in a written agreement through JROC (data sharing) or OTM (material transfer agreement).</p>

Source:

1. [WU SBIR/STTR Guidelines](#)

2. [WU Research COI Policy](#)

Company Interactions with WU

(May or may not be related to company sponsored research activities)



STUDENT / TRAINEE / STAFF ENGAGEMENT

Instructions: Address involvement of students or trainees in company related research at WU or direct involvement with the company.

Questions:	Additional Guidance:
<p>14. Will students or postdocs be performing work for either WU or the company, such as:</p> <p>a. Graduate or undergraduate students?</p>	<p>When a WU faculty member is a student’s mentor, graduate and undergraduate students are not allowed to perform work for either WU or the company for SBIRs/STTRs.¹</p> <p>Other research activities involving students may be allowed but will require COI review.²</p>
<p>b. Postdocs, including Postdoctoral Research Scholars or Postdoctoral Research Associates?</p>	<p>Postdocs may be permitted to:</p> <ul style="list-style-type: none"> • Work on WU’s portion of the grant under the subaward, but may not serve as the WU PI;¹ • Serve as PI or investigator for the company’s portion of the grant.¹ <p>Postdocs paid from fellowship or training awards generally should not perform work on the company’s portion of the SBIR/STTR.¹</p>
<p>15 Do you plan to hire your WU staff or students at the company? If so,</p> <p>a. Will the staff continue to work part-time at WU?</p> <p>b. Will they be engaged in research activities at WU sponsored by or evaluating IP licensed or owned by the company?</p>	<p>Prior to approaching or discussing outside employment opportunities with students or staff; engage with the department business office and human resources. Full transparency is needed around potential risks and consequences of altering employment, which should be communicated in writing by the department business office.</p> <p>Employees of the company, even if part-time employees of WU, are generally not permitted to work on company related research being conducted at WU. Rare exceptions may be granted when involving specialized training requirements or qualifications.</p>

Source:

1. [WU SBIR/STTR Guidelines](#)

2. [WU Research COI Policy](#)

Helpful Guidelines & Policies

Policy:	Description:
Consulting Guidelines within Clinical Conflict of Interest	Addresses personal FCOIs related to patient care and provides “Do’s and Don’ts” for external consulting activities.
Faculty Consulting Privileges	Addresses time commitments for faculty involved in external professional activities.
Guidelines for Faculty Participation in SBIR and STTR	Institutional guidelines for start-up companies to engage with the university on an SBIR or STTR project.
Individual (Research) Conflicts of Interest Policy	Addresses personal financial conflicts of interest (FCOIs) related to research activities at WU.
Institutional Conflict of Interest Policy	Addresses personal FCOIs for institutional officials and University FCOIs related to research activities at WU.
Intellectual Property Policy	Addresses the University’s approach to the development, ownership, and dissemination of intellectual property (IP).
Private Use of University Research Facilities Policy	Addresses the use of WU facilities by outside companies and the ‘private use’ of facilities financed with tax-exempt debt.
Procurement Policy	Addresses conflicts of interest for employees conducting business on behalf of Washington University including purchasing.
NSF SBIR/STTR FAQ NIH SBIR/STTR Application Guide DOE SBIR/STTR FY 2019 FOA	Agency specific guidance and information pertaining to SBIR and STTR funding.

Contacts

Office:	Contact Information:	Resources Provided:
COI Office in ORIE https://research.wustl.edu/offices/reco/	COI@wustl.edu 314-747-4181	Supports implementation of the individual and institutional COI programs, including COI issues surrounding company-sponsored research. Assist faculty/staff in obtaining guidance on entrepreneurial activity and facilitate communications with other programs or offices at WU that may need to be involved.
Conflicts of Interest Review Committee Chair – WUSM	Dr. Luis Sanchez sanchezl@wustl.edu 314-362-7408	The CIRC evaluates individuals' personal financial interests and assesses its relatedness and risks in determining whether a conflict of interest exists and, when applicable, in determining the appropriate management plan.
Conflicts of Interest Review Committee Chair –Danforth	Dr. Amy Eyler aeyley@wustl.edu 314-935-0129	
Institutional Conflict of Interest Review Committee Chair	Dr. Jeremiah Morrissey morrisseyjj@wustl.edu 314-454-7464	The ICOIC evaluates financial interests of Washington University or an institutional official, acting within his or her authority on behalf of the institution, may affect or appear to affect the research, education, clinical care or other activities of the institution.
Faculty Fellow in Entrepreneurship - WUMS	Dr. Jennifer Silva jennifersilva@wustl.edu 314-454-2544	Advise WU faculty on WU policies and other requirements when faculty consider forming a company and/or participating in SBIR/STTR proposals.
Faculty Fellow in Entrepreneurship - Danforth	Dr. Vijay Ramani ramani@wustl.edu 314-935-7924	
Human Research Protection Office (HRPO) https://hrpo.wustl.edu/	https://hrpo.wustl.edu/contact/ 314-747-6800	Reviews and approves applications for human subjects research.
Joint Research Office of Contracts (JROC) https://research.wustl.edu/offices/jroc/	researchcontracts@wusm.wustl.edu 314-747-5393	Provides contracting services for research-related agreements, e.g., Industry-supported research agreements, data transfers, service agreements, facility use agreements, and federal or foundation subawards and contracts.
Office of Technology Management (OTM) https://otm.wustl.edu	https://otm.wustl.edu/who-to-contact/	Assists with licensing, patents, material transfer agreements (MTAs).

Contacts last updated September 2021.