Guidelines for Faculty Participation in SBIR and STTR

Background

Washington University (WU) is committed to the enhancement and support of faculty efforts to translate the results of their research to benefit the community and enhance public good.

The federally funded Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs encourage domestic small business concerns (SBC) to engage in research and development that has the potential for commercialization. Through a competitive awards-based program, grants are made directly to the small business concern to support the financing of cutting edge technologies. Since the success rate for these grants is significantly higher than individual PI research proposals, they would not only result in the support of faculty research but can lead to successful launch of a commercial entity.

The program grants are generally structured in three phases:

- Phase I is to establish the technical merit, feasibility, and commercial
 potential of the proposed R&D efforts and to determine the quality of
 performance of the small business awardee prior to providing further federal
 support.
- Phase II is available to companies whose technology shows commercial promise during the Phase I study.
- Fast-track incorporates a submission and review process in which both Phase I and Phase II grant applications are submitted and reviewed together as one application.
- Phase III, which is not federally funded, is initiated when the SBC pursues commercialization based on its successful Phase I/II research and development activities.

SBCs collaborate with a research institution, such as WU, in Phase I and Phase II through the issuance of a subaward between the two parties.

Due to the unique potentials for conflicts of interest and conflicts of commitments/use of resources, the following guidelines have been developed to guide faculty as they prepare SBIR and STTR proposals and manage grant subawards.

WU Principles for participating in SBIR and STTR grants

Notification to Faculty Fellow

Notification to the Faculty Fellow should be done early in order to best manage any administrative, compliance, or operational issues raised by the proposal. For example, the WU faculty must notify WU's Faculty Fellow when the SBC in which they have a personal financial interest¹ or a financial relationship applies for SBIR/STTR funding and the SBC will subcontract part of the research to WU. Ultimately, a copy of the SBC's full proposal must be provided to the Faculty Fellow, once it is available, to enable appropriate reviews to take place.

For additional information relating to the Faculty Fellow, see the <u>Research News</u> <u>Announcement</u>.

Principal Investigator Role

<u>Faculty Serving as PI for BOTH the SBC and for WU</u>: In general, a WU faculty may not serve as both the SBC principal investigator and the university principal investigator on the subaward from a faculty-owned company. However in rare cases, there may be compelling circumstances that warrant an exception. Such compelling circumstances must first be reviewed and approved by the Conflict of Interest Committee (CIRC), and if approved, then approved by the Vice Chancellor for Research.

<u>Faculty serving as PI for either SBC or for WU</u>: A WU faculty may serve as the PI for either the SBC or WU involving a faculty owned company in accordance with WU's COI policies.

Conflicts of Interest Review

Prior to initiating the research, a review and potentially a management determination by the CIRC (and ICOIC as applicable) is required in the following two situations:

• The WU faculty seeks to be the PI on the subcontract from the SBC and the PI has an ownership interest in the SBC¹; or

¹ Includes the financial interests of individual's spouse/partner or dependent child

• The WU faculty seeks to be the PI on the award to the SBC and the SBC will subcontract to WU for part of the research.

A Phase I SBIR/STTR may be eligible for an expedited COI Review. Factors that will assist in allowing the Phase I SBIR/STTR award to undergo an expedited review include the following:

- The WU faculty that has a financial interest in the SBC does not hire a subordinate WU employee or a WU student/postdoc he/she mentors to conduct work on behalf of the SBC.
- The WU faculty does not propose to use WU resources or subordinate personnel to achieve the SBC's portion of the grant.
- A representative from the faculty member's departmental business office reviews copies of invoices and progress reports submitted to the SBC.
- Postdocs working on the project for WU are provided a safe haven.
- The research does not involve human subjects research.

For clarity, Phase II SBIR/STTRs involving a faculty owned SBC are typically not eligible for an expedited COI review.

Use of University Resources

<u>Core Labs and Recharge Facilities</u>: SBC's may use a WU core lab or recharge facility for the SBC's portion of the work provided that the SBC is charged the same rate as other non-WU entities and under appropriate agreements.

Laboratories & Resources: In the event a faculty proposes to use resources (i.e., equipment, space, employee services) from a WU laboratory (or other facility that is not a core lab or recharge facility) to complete the SBC's portion of the work on an SBIR/STTR, approval from the Department Chair² and Vice Chancellor for Research is required and will only be permitted under appropriate agreements (e.g., a facility use agreement, service agreement, etc.). When evaluating whether to approve such a request, Department Chairs and the Vice Chancellor for Research will consider the following factors: (i) whether the request diverts resources to the SBC at the expense of the university and/or other faculty, (ii) whether the work could adversely affect the ability of the WU staff to perform their university-related work, and (iii) the capacity of the resource being requested and whether granting use to the SBC would limit use by other WU faculty. Approval to use university laboratories and resources is more likely to be granted in the event the faculty has a documented plan to move the work out of WU space and into SBC-owned space during any phase II SBIR/STTR. In order to utilize university laboratories and resources, the SBC must pay for such resources or services, and such payment

² In the event the faculty is a Department Chair then approval must be sought from the Dean.

should be documented in appropriate agreements (e.g., a facility use agreement or service agreement).

<u>Support Staff:</u> Faculty may engage university support staff in support of the SBC in a limited capacity and only with the Department Chair's prior approval. For example, the faculty may engage support staff in scheduling the faculty member's time and reserving meeting rooms. Support staff should not be asked to make arrangements or handle reimbursements for SBC travel or hospitality. Developing a budget and proposal on behalf of the SBC (which excludes a budget proposal on behalf of WU as a subcontractor) would not be considered use of support staff in a "limited capacity." When evaluating whether to approve a request to use university support staff, the Department Chair should ensure use of the university employees is in a limited capacity and that such use is documented in an appropriate agreement (e.g., a service agreement).

Use of Students and Post Docs in an SBIR/STTR award

Graduate and undergraduate students are not allowed to perform work for either WU or the SBC in an SBIR/STTR award where a WU faculty member has a financial interest in the SBC and the faculty member is the student's mentor.

Postdoctoral Research Scholars (PRS) or Postdoctoral Research Associates (PRA) may be permitted to work on WU's portion of the grant under the subaward provided that (i) full disclosure is provided in writing by the faculty regarding his/her interest in the SBC, (ii) the Department Chair provides approval, and (iii) the postdoc is provided a safe haven. For clarity, postdocs working on WU's portion of the grant under the subcontract would not be in a PI capacity.

Postdocs³ may be permitted to serve as the PI for an SBC, or work on the SBC's portion of the grant, however, faculty may not require that postdocs work on behalf of the SBC as a condition of their continued participation in their training program. It is generally recognized that an employment opportunity with a SBC may be beneficial to the postdoc's career. In this case, the postdoc may be required to reduce or sever his/her university appointment to become an employee of the SBC. The postdoc should be made aware of potential risks or consequences which may include: (i) severance of university appointment, (ii) severance of university employment and benefits, (iii) disruption of academic career path, and (iv) the postdoc's former position at the university is not held and there is no guarantee of return to the university. Postdocs working on behalf of an SBC must be informed in

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³ Postdocs who are paid from fellowship or training awards (e.g., PRS) generally should not be performing work on the SBC's portion of the SBIR/STTR.

writing of the potential risk and consequences prior to accepting employment with the SBC.