

Guidelines for Faculty Participation in SBIR and STTR Programs

Approved by the Danforth Campus and School of Medicine Disclosure Review Committees
Effective 3/4/08

Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs are for domestic small business concerns to stimulate technology innovation, increase the participation of small businesses in federal research and development, and to increase private sector commercialization of technology. There are special circumstances related to these programs that allow certain financial relationships to exist in order to further the development and commercialization of technology. The following outlines the relevant aspects of the requirements of each program and the University's established guidelines to address specific financial relationships.

Program Requirements:

In general, **SBIR Program requirements** of participating federal agencies include:

- The primary employment of the PD/PI (Program Director/Principal Investigator) must be with the small business concern at the time of award and during the conduct of the proposed project. For projects with multiple PD/PIs, at least one must meet the primary employment requirement. Primary employment means that more than one half of the PD/PI's time is spent in the employ of the small business concern. Primary employment with a small business concern precludes full-time employment at another organization. Occasionally, deviations from this requirement may occur with permission from the funding agency.
- During Phase I, a minimum of two-thirds of the effort must be performed by the proposing small business firm; a minimum of one-half of the effort in Phase II.
- Collaboration with a research institution is optional.

In general, **STTR Program requirements** of participating federal agencies include:

- Primary employment is not stipulated. The PD/PI may be employed with the small business or the participating non-profit research institution as long as s/he has a formal appointment with or commitment to the applicant small business, which is characterized by an official relationship between the small business and that individual.
- Requires research partners at universities, federally-funded research and design center, and other non-profit research institutions to have a formal collaborative relationship with the small business concern. Unless otherwise stipulated, at least 40 percent of the STTR research project is to be conducted by the small business concern and at least 30 percent of the work is to be conducted by the single, "partnering" research institution during each Phase.

Both programs require the company to be at least 51% American-owned and independently operated, located in the U.S., and of 500 or fewer employees. Work must be performed in the United States.

Both programs are structured in Phases:

- Phase I: To establish the technical merit and feasibility of the proposed R/R&D efforts and to determine the quality of performance of the small business awardee organization. Depending on the federal agency, support under Phase I is provided for six months to a year in amounts between \$70,000 and \$120,000.
- Phase II: To expand on the results and continue the R/R&D efforts initiated in Phase I toward prototype development. SBIR and STTR Phase II awards can be for one to two years and normally do not exceed \$750,000 total.
- Phase III: For the commercialization of the work started under Phases I and II and requires the use of private sector or non-SBIR/STTR Federal Funding. **No government SBIR/STTR funds are involved.**

Guidance:

The Department of Health and Human Services (DHHS) exempts Phase I** SBIR and STTR programs from federal COI regulations; therefore, the University has adopted this rule for all SBIR and STTR funding. However, during Phase II, certain restrictions will apply as outlined below, so individuals may wish to take this into consideration during Phase 1.

If a Washington University employee or his or her family member* has an ownership interest, is an employee, and/or has a position with the small business, or has a financial interest related to the intellectual property being studied, the following guidelines relate to Phase II. These guidelines specifically refer to funding to pursue development and commercialization of a technology:

1. The PD/PI for the small business and the PD/PI for the subagreement to the University must be different individuals.
2. University employees should not serve as the business official or scientific official submitting an SBIR or STTR proposal on behalf of the small business entity.
3. If a University faculty member owns or has an ownership interest in a small business entity, that same individual may not conduct or oversee research activities in his or her laboratory under a subagreement from the small business entity through the SBIR or STTR program. This includes individuals being paid directly by the company or through the SBIR or STTR subagreement. Individuals may not work at both the company and the University on research related to SBIR or STTR programs.

Subsequent to the end of the SBIR or STTR subagreement, the standard guidelines and restrictions apply for potential conflicts of interest as outlined in the University Conflict of Interest Policies.

These guidelines apply to individuals with a 9-month or 12-month appointment at Washington University. For 9-month appointments, which are full-time appointments, during the 3-month time-off period, individuals are still required to maintain a separation between their company and University roles and activities.

Only the Disclosure Review Committee can provide exceptions to these guidelines, which will be made on a case-by-case basis. The DRC Office can provide additional instructions related to requesting an exception. If an exception is permitted, there must be a clear distinction between the research activities conducted at Washington University and the research activities conducted at the company site. In addition, the Private Use of University Research Facilities Policy (<http://www.wustl.edu/policies/privateresearch.html>) is applicable to the situation.

*Includes spouse, partner, child, sibling, parent, grandparent, or grandchild (including birth, adopted, step, or in-law).

**If the subagreement is a *Fast-Track* application, exceptions to these guidelines must be granted by the DRC prior to submitting the application regardless of NIH's exemption of COI regulations for Phase I.

This replaces the School of Medicine Guidelines effective 7/19/07