Policy/Guidelines for Faculty Participation in SBIR and STTR Programs

Saint Louis University recognizes that Small Business Innovation Research (SBIR) and Small Business Technology Transfer Research (STTR) programs supported by various federal agencies are intended not only to motivate small businesses concerns to develop innovative technologies, but also to create partnerships with Research Institutions to promote the commercialization of that technology for the economic and social benefit of the public. Each agency that sponsors SBIR and STTR programs has regulations concerning those relationships, particularly with regard to financial arrangements and program direction. Participation in these programs involving University faculty and small businesses can create a conflict of interest on the part of the faculty member, particularly if that faculty member has an equity interest or close relationship with the business concern. Saint Louis University has developed the following guidelines to assist faculty in their consideration of entering into such relationships and to ensure compliance with all federal regulations, including those covering conflicts of interest.

SBIR-STTR OVERVIEW:

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

- The proposal must be submitted by the small business concern (SBC). The University is not an eligible applicant for SBIR grants.
- The primary employment (more than 50%) of the PD/PI (Program Director/Principal Investigator) must be with the SBC at the time of award and for the duration of the project. Primary employment with a small business concern precludes full-time employment at another organization. Therefore, a full-time employee of the University may not serve as the PD/PI of the SBIR grant. The only mechanism by which a University employee may serve as the PD/PI of an SBIR grant is to take a leave of absence from the University.
- For projects with multiple PD/PIs, at least one must meet the primary employment requirement. 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:

- The PD/PI of an STTR proposal 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. This may or may not involve salary or other remuneration.
- The PD/PI must commit at least 10% of his/her effort to the project. Combined with University activities, effort may not exceed 100%.

- SBC's are required to partner with research universities or other non-profit research institutions which have a formal collaborative relationship with the small business concern.
- In both Phase I and Phase II, at least 40 % of the work must be performed by the SBC and at least 30% of the work must be performed by the partnering research institution.

For both SBIR and STTR programs, the SBC must be at least 51% owned and controlled by individuals who are citizens of, or permanent resident aliens in the United States, and must have fewer than 500 employees. Work must be performed in the United States.

Both programs are structured in Phases:

> **Phase I:** This is the "proof of concept" stage, intended to establish the technical merit and feasibility of the proposed research and development and to determine if the small business organization is qualified to conduct quality, promising research in the project area. Support under Phase I is generally provided for six months to a year in amounts between $70,000 and $100,000.
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> **Phase II:** This phase expands on the results and continues the efforts in Phase I toward prototype development. SBIR and STTR Phase II awards are for a period of one to two years and in general do not exceed $750,000.
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> **Phase III:** This phase does not involve SBIR/STTR funding. It is intended 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 Conflict of Interest (COI) regulations. Therefore, the University is not required to disclose to the sponsoring DHHS agency any relationship or conflict of interest that the SBIR or STTR may create with a faculty member. However, the University requires that all faculty disclose financial relationships with the private sector in their annual Conflict of Interest in Research disclosure, and any significant financial conflicts of interest must be managed. See Conflict of Interest in Research Policy (http://www.slu.edu/x27916.xml). The disclosures must include information about participation in SBIR or STTR grants. During Phase I SBIR and STTR programs, full disclosure will be considered to be a sufficient management plan for the conflicts in most cases. During Phase II, however, the University will impose certain restrictions to comply with federal regulations and to manage any apparent or actual conflicts of interest. Faculty considering a Phase I SBIR or STTR program should consider the following guidelines, should the program progress to a Phase II level. Applicants submitting a *Fast Track* proposal (simultaneous submission of Phase I and Phase II) also will be covered under the Phase II guidelines. Two general scenarios apply to the guidelines for Phase II:

NO SIGNIFICANT FINANCIAL INTEREST

If a University employee or his/her family (includes spouse and dependent children – including birth, adopted, or step) has no ownership interests, is not employed by or has a position with the SBC or has no other significant financial interests, then the following guidelines will apply:

1. In most cases, the University employee may not be the submitting official for the SBIR or STTR proposal for the company.

2. In most cases, the University employee may participate in or serve as a PI of a subcontract on SBIR or STTR projects.

3. In some cases, the University employee may serve as a PI/PD of STTR projects.

OWNERSHIP INTEREST, EMPLOYMENT, or FINANCIAL INTEREST RELATED TO INTELLECTUAL PROPERTY BEING STUDIED:

If a University employee or his/her family (includes spouse and dependent children – including birth, adopted, or step) has ownership interests, is employed by or has a position with the SBC or has significant financial interest related to intellectual property being studied then the following guidelines will apply: (Royalties related to patents owned by the University and licensed through the University technology transfer office are not considered as significant financial interest.)

1. In most cases, the University employee may not be the submitting official for the SBIR or STTR proposal for the SBC.

2. In most cases, the University employee cannot be the PI/PD for the company (i.e. the PI/PD of the project) and the PI/PD of a subcontract on the same SBIR or STTR project.

3. The University employee cannot work at both the company and the University on research related to SBIR or STTR projects.

4. A University employee who has an ownership interest in an SBC, regardless of the monetary value, may not conduct or supervise research activities in his/her SLU laboratory through subcontracts on SBIR or STTR projects awarded to the SBC.

5. A University employee paid directly from an SBC with whom they have an ownership interest, regardless of the monetary value, may not conduct research for that entity in their SLU laboratories.

6. At the end of the SBIR or STTR project, the University's Conflict of Interest in Research Policy and all guidelines and restrictions therein will apply.

Faculty members with 9-month appointments are required to maintain a separation between their company and University activities during the 3-month time-off period.

Only the Conflict of Interest Committee in Research (COIC-R) can provide exceptions to these guidelines, which will be made rarely and on a case-by-case basis. The Manager for Responsible Conduct of Research can provide necessary forms and procedures to request an exception. If an exception is granted, the Private Use of University Research Facilities Policy (www.slu.edu/Documents/provost/policies_procedures/Research_**Facilities**_Policy_Private_**Use**.pdf) applies, and a clear separation between University and private activities must be maintained, documented, and reviewed on a regular basis.

In cases wherein the University faculty member is the sole employee of the SBC or the sole research employee, the "rebuttable presumption" may be applied. This presumption states that, by virtue of his/her special expertise in the area of research, the faculty member is uniquely qualified to carry out the research, relative to any other possible investigator. This will only be applied in rare instances, and the faculty member's unique qualifications to carry out the research must be fully, clearly, and completely documented.

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

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