TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER

Operating Policy and Procedure

HSC OP: 73.21, **Policy for Faculty Participation in SBIR and STTR Programs**

PURPOSE: The purpose of this HSC OP is to set forth the guidelines for TTUHSC's participation in Small Business Innovation Research (SBIR) / Small Business Technology Transfer Research (STTR) grant proposals requesting financial support from external sources.

REVIEW: This OP will be reviewed by August 1 of each even-numbered year (ENY) by the Chairperson of the TTUHSC Conflict of Interest in Research Committee (COIRC), the Associate Vice President for Research Integrity, and the Associate Vice President for Sponsored Programs with recommendations for revision forwarded to the Executive Vice President for Research & Innovation (EVPRI).

POLICY/PROCEDURE:

1. **Introduction**

   TTUHSC 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.

   TTUHSC may agree to accept subawards from small businesses that are applying for a Small Business Innovation Research (SBIR) / Small Business Technology Transfer Research (STTR) grant.

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

   a. The proposal must be submitted by the small business concern (SBC). TTUHSC is not an eligible applicant for SBIR grants.

   b. 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 SBC precludes full-time employment at another organization. Therefore, a full-time employee of TTUHSC may not serve as the PD/PI of the SBIR grant. The only mechanism by which a TTUHSC employee may serve as the PD/PI of a SBIR grant is to take a leave of absence from TTUHSC.

   c. For projects with multiple PD/PIs, at least one must meet the primary employment criteria.

   d. During Phase I, a minimum of two-thirds of the effort must be performed by the proposing SBC; a minimum of one-half of the effort in Phase II.

   e. Collaboration with a research institution is optional.

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

   a. The proposal must be submitted by the SBC. TTUHSC is not an eligible applicant for STTR grants.

   b. The PD/PI of a 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.

c. The PD/PI must commit the required effort specified by the sponsoring agency (e.g., NIH, NSF).

d. The SBCs are required to partner with research universities or other non-profit research institutions which have a formal collaborative letter of intent and established intellectual property agreement with the SBC.

e. 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.

4. 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.

5. Both programs are structured in Phases:

   a. Phase I: This is the 'proof of concept' stage, intended to establish the technical merit and feasibility of the proposed research and development, as well as to determine if the SBC is qualified to conduct quality, promising research in the project area. Support under Phase I is generally provided for six months to a year.

   b. Phase II: This phase expands 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.

   c. 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.

6. The Department of Health and Human Services (DHHS) exempts Phase I SBIR and STTR programs from federal Conflict of Interest (COI) regulations. Therefore, TTUHSC 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, TTUHSC requires that all faculty disclose financial relationships with the private sector in their annual financial disclosure, and any significant financial conflicts of interest must be managed. See the TTUHSC Financial Conflicts of Interest in Research Policy [HSC OP 73.09, Financial Conflicts of Interest in Research] The disclosures must include information about participation in SBIR or STTR grants. During Phase II, TTUHSC will impose additional restrictions to comply with federal regulations and to manage any perceived or actual conflicts of interest. The same may NOT apply to other federal agencies (e.g., NSF, DoD, DoE, etc.).

7. Faculty considering a Phase II SBIR or STTR program shall follow the guidelines outlined below in Section 8. Applicants submitting an agency's Fast Track proposal (simultaneous submission of Phase I and Phase II) will be covered under the Phase II guidelines and agency disclosure requirements. Therefore, the previously described Phase I exemption in Section 6 above will not apply.

8. Requirements Related to Participation in SBIR/STTR Programs

   a. Entrepreneurial activity by TTUHSC faculty is encouraged; however, involvement with SBCs and participation in SBIR and STTR programs can create financial conflicts as well as conflicts of commitment with their TTUHSC obligations. To assist faculty members in navigating these relationships and to ensure TTUHSC's compliance with all federal, state and institutional policies, the following are required:

      1. The Office of Sponsored Programs cannot assist the faculty member with any aspect of the SBC's portion of the SBIR/STTR application or grant award management.
      2. The PI for the SBC and the PI for the subcontract to TTUHSC must be different individuals.
      3. No TTUHSC resources or funds will be used to benefit the small business.

4. If a TTUHSC faculty member (or his/her spouse or dependent child) has a significant financial interest (including, but not limited to, ownership interest, stock options or a proprietary interest), a leadership position in, or is employed by a SBC, the faculty member may serve as the PI on the TTUHSC subcontract from that SBC **only after** developing and adhering to a management plan that addresses his/her conflicts of interest, including the rationale for choosing to serve as PI. The plan must be approved by the faculty member's supervisor[1] and TTUHSC COIRC.
5. The PI for the TTUHSC subaward may not be a subordinate (direct report) to any employee of the SBC that is involved in the SBIR/STTR grant application.
6. The PI for the subaward must meet TTUHSC requirements to serve as a PI in accordance with TTUHSC OP 73.08 (there will be no exceptions granted for subawardees to serve as the TTUHSC PI).
7. The PI for the SBC must provide a copy of both the solicitation and the complete grant proposal (including budget and description of the work to be conducted at TTUHSC), along with other OSP required documents to the TTUHSC OSP <u>at the time of submission</u>. Information specific to any proprietary or confidential information may be redacted if necessary. This is an OSP condition of TTUHSC accepting the subcontract award.
8. A faculty member with a financial interest in a SBC must have a Conflict Management Plan (CMP) that is approved by the TTUHSC COIRC. The CMP stipulates the terms to which the faculty member agrees to abide by when conducting his/her TTUHSC responsibilities as they related to the SBC.
9. The SBC grantee must have primary functioning space that it owns or controls. A TTUHSC employee who has ownership interest in a SBC, regardless of the monetary value, ordinarily may not conduct or supervise research activities in his/her TTUHSC laboratory through subcontracts on SBIT/STTR projects awarded to the SBC without cost. All exceptions are considered on a case-by-case basis by the COIRC. Any exception must be approved prior to application submission by all responsible administrators including TTUHSC Office of General Counsel and covered by an agreement (e.g., Lease, License, or Facility Use Agreement).
10. Graduate and undergraduate students are not allowed to perform work for either TTUHSC or the SBC in a SBIR/STTR award where a TTUHSC faculty member has a financial interest in the SBC and the faculty member is the student's mentor and/or the faculty member sits on the student's advisory committee.
11. Postdocs may be permitted to serve as the PI for a 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.

If these conditions are not met, TTUHSC may decline to accept the subaward, or may require modifications to the subaward in order to comply with the requirements listed here.

9. Amendments or Termination of this Policy

TTUHSC reserves the right to modify, amend, or terminate this policy at any time. Nothing in this policy should be construed as a contract between TTUHSC and its employees or agents.

The supervisor cannot have a personal or family member financial interest in the SBC, nor can that supervisor be serving as an investigator on the same SBIR/STTR project.