

Duke University SBIR/STTR Implementation Procedure

May 30, 2019

Purpose

To establish a procedure for Duke University faculty and staff participation in the Small Business Innovation Research (SBIR) or Small Business Technology Transfer (STTR) programs.

This Duke University SBIR/STTR Implementation Procedure is to be applied in concert with the University's other policies and procedures, including but not limited to Financial Conflicts of Interest in Research Policy, Institutional Conflicts of Interest in Research Policy, and other policies related to sponsored research.

Program Overview

The federally-funded SBIR and STTR programs stimulate innovations that encourage domestic small business concerns (SBC) to engage in research and development that has the potential for commercialization. SBIRs and STTRs are awarded directly to an SBC, which may issue a subcontract to Duke.

Currently, eleven separate agencies participate in the SBIR program, and five in the STTR program, and the standards can differ from program to program. Generally, the key differences between the two programs are as follows:

ISSUE	SBIR	STTR
LEAD PI	Lead PI must be primarily employed by the SBC (<i>e.g.</i> 51% of full-time effort) at the time of award and for the duration of the award. This means Duke faculty are not eligible to be lead PI on a SBIR	Primary employment of lead PI is not stipulated (can be a Duke employee) Duke faculty or employee must have at least 10% effort on the award, which must be limited to either Duke or the SBC (NOT BOTH)
TERM	Phase I: up to 6 months Phase II: up to 2 years	Phase I: up to 1 year Phase II: up to 2 years
IS COLLABORATION REQUIRED?	Allowed, but not required	Requires collaboration with a non-profit research institution
LIMITS ON SUBCONTRACTING DISTRIBUTION	Phase I - a maximum of 33% of the work may be subcontracted to third party Phase II, a maximum of 50% of the work may be subcontracted to a third party	Phase I and Phase II— a minimum of 30% of the work (maximum of 60%) must be subcontracted to a non-profit research institution (<i>i.e.</i> , must be a formal collaboration)

Procedures

Conflict of Interest

- **Personal COI.** If anyone on the proposal for Duke (faculty, student, fellow, staff, contractor, consultant, etc.) has a financial interest in the SBC (*e.g.*, equity, options, compensation, rights to IP that the SBC acquired, etc.), the Duke PI and/or the potentially conflicted individual(s) must consult with the Duke Office of Scientific Integrity COI (DOSI-COI) to determine if any perceived, potential, or actual COI exists
- **Institutional COI.** The Duke PI and/or the potentially conflicted individual(s) also must consult DOSI-COI if Duke has its own financial interest in the SBC (*e.g.*, equity, options, rights to royalties or other payments through a license)

Pre-Award Review

- **Review of SBC's Application.** The Office of Research Support (ORS) or the School of Medicine Research Administration (SOM-RA) will request a copy of the SBC's proposal **prior** to the SBC submitting it to the agency. If a copy is not available at that time, the pre-award office will require a copy of the SBC's full proposal prior to finalizing any contract with the SBC
- **Proposal Cover Letter.** The pre-award central office will prepare a proposal cover letter detailing Duke's general and SBIR/STTR-specific standards, which will be submitted to the SBC with Duke's proposal
- **Unit Review.** Proposals to conduct research at Duke for SBIR/STTR funding should be reviewed by the Department Chair or Institute/Center Director (or designee, to include Vice Chair or Business Manager) to ensure the proposal is in accord with Duke's policies and procedures for sponsored research:
 - Uses Duke research facilities (labs, IACUC, IRB, etc.) only for Duke's portion of the project
 - Has approval for use of Duke research facilities (labs, IACUC, IRB, etc.) and any use of Duke facilities is solely for Duke's portion of the project
 - Reflects full cost recovery of direct and indirect costs
- **Intellectual Property.** A request for proposals for a SBIR/STTR sometimes requires that the SBC and Duke agree to terms on ownership and licensing of intellectual property before the agency issues its award to the SBC. If so, contact the appropriate pre-award office as soon as possible to begin that process, as the negotiation may take time and requires input from the Office of Licensing & Ventures
- **Private Benefit.** The pre-award office will review to ensure that the SBC does not use Duke's resources to benefit the SBC's interest at the expense of Duke's non-profit status. The following are examples of prohibited activities:
 - Using Duke's personnel (*e.g.*, departmental research administration staff) to prepare or submit the SBC's proposal, to administer the award
 - Using Duke's resources (*e.g.*, personnel, equipment, space, etc.) to operate its business or to complete any portion of the SBC's work
- **Final Contract.** Once the SBC's proposal is awarded, the SBC and Duke must finalize and execute a subcontract or other agreement

[Proposal Cover Letter]

On behalf of Duke University, enclosed is an application submitted by [redacted] entitled “_____” in the amount of \$_____ for the period _____ in response to _____. If the proposal is funded, we agree to negotiate in good faith and administer the resulting subaward.

This letter certifies that Duke University is not delinquent on any federal debt, nor is Duke University presently debarred, proposed for debarment, declared ineligible or voluntarily excluded from covered transactions by any federal department or agency. Duke University has a written and enforced administrative process to identify and manage, reduce or eliminate conflicting financial interest with respect to all research projects for which funding is sought.

Please note that Duke University only conducts basic and applied research in science and engineering, the results of which are published and shared broadly within the scientific community. Final determination of what may be published or not published must remain with the university. Duke University cannot accept award terms which would violate our fundamental research status nor can we accept terms which would violate our University-Industry Guidelines, a copy of which is available at <https://ors.duke.edu/grants-contracts-and-compliance-responsible-conduct-rcr-university-policies/university-industry>.

Duke University submits this application with the following understandings:

- Under an SBIR application, the Principal Investigator’s primary appointment is with the company and not Duke University.
- Under an STTR application, the Duke University faculty may only provide effort either for the company or the University, but under no circumstances may the Duke faculty member represent both on this project. Financial conflicts of interest may preclude a Duke faculty member from serving as a Principal Investigator.
- Under either type of application, the company will maintain the required effort amounts.
- Duke University facilities and resources (equipment, personnel, IRB, IACUC, etc.) may only be used to carry out the Duke University portion of the project. IRB and IACUC reliance agreements are required in order to use Duke’s assurance numbers in applications.
- A copy of the full application will be required prior to entering into a subaward. Confidential information may be redacted by the company.
- Documents submitted by Duke University cannot be changed by the company prior to submission to the federal agency.
- Advance payment may be required upon execution of the subaward.

Any technical questions about this application should be addressed to the Duke Principal Investigator. Any business or budgetary questions should be directed to this office at the address listed below.

We look forward to this collaboration between our organizations. If you have any concerns or questions, please contact _____.

Sincerely,