

Participation in SBIR and STTR Programs Policy

I. Purpose

The purpose of this Policy is to outline conditions under which participation in SBIR and STTR programs is permitted at Albert Einstein College of Medicine ("Einstein" or "College").

II. Scope

This Policy applies to faculty, technical staff, students, and post-doctoral researchers.

III. Policy

Einstein welcomes a range of funding opportunities that advance faculty research; further, Einstein supports collaborations between its researchers and outside companies, provided these activities comply with all pertinent Einstein policies and guidelines.

Two such funding opportunities are offered by the <u>Small Business Innovation Research (SBIR) and Small</u> <u>Business Technology Transfer (STTR) Programs</u>. These congressionally mandated funding programs set aside a specific percentage of the federal research and development budget to fund small business concerns (SBCs) that are working to commercialize new and early-stage technologies.

Federal guidelines state that SBIR and STTR grants may only be awarded to United States SBCs, and the SBC grantee must also be able to perform a percentage of the scope of work at its site or a site it controls. However, subcontracting a portion of the funds to research institutions is permitted, and, in the case of STTR grants, subcontracting to research institutions is *required*.

The SBIR and STTR awards are both structured as highly competitive three-phase Programs. Phase I is a feasibility study. Phase II expands on the results of Phase I. And, Phase III awards support commercialization of the results of Phase II and require the use of private sector or non-SBIR/STTR funding. The programs are administered by the United States Small Business Administration, which serves to coordinate the various participating federal agencies (e.g., Department of Health and Human Services, the National Science Foundation, the Department of Defense, et al.). The Department of Health and Human Services has established three standard receipt dates per year for applications corresponding to the <u>SBIR and STTR Omnibus Solicitations</u>.

Einstein faculty may collaborate with SBCs on such applications and participate in projects through subcontracting arrangements. SBIR and STTR subcontracts are processed through Einstein in the same manner as an <u>industry-sponsored research agreement</u>. Consistent with these procedures, Einstein faculty

will need to <u>submit a proposed budget and scope of work</u> to the Office of Biotechnology and Business Development for review *before* sharing it with the collaborating SBC. The Office of Biotechnology and Business Development will work with the faculty and the SBC to ensure that the contractual terms are consistent with all pertinent Einstein policies and guidelines.

The following guidelines for participation in SBIR/STTR awards by Einstein faculty, staff, post-docs, and/or students are supplementary to the current policies and guidelines instituted by Einstein and/or the federal government. In no way are these to replace or supersede such policies or guidelines.

- 1. Consistent with federal guidelines, the principal investigator (PI) for the proposed SBC grantee shall be different than the PI for the subcontract work to be done at Einstein.
- 2. No Einstein employees (including faculty, staff, and extending to post-docs and students) shall have board, managerial, executive, or administrative roles with the proposed SBC grantee without express written consent from the Conflicts of Interest committee. For PIs that want to advance their own Einstein Intellectual Property through the SBIR/STTR mechanism, they can contact the Office of Biotechnology and Business Development to discuss the Faculty-Initiated Start-Up Option.
- 3. The officials signing off on the submission of an SBIR/STTR proposal on behalf of the proposed SBC grantee shall not be Einstein employees.
- 4. The PI that will be performing the subcontract work at Einstein must have a faculty appointment.
- 5. No Einstein employees shall serve as representatives of the proposed SBC grantee responsible for negotiating any aspect of the business relationship with Einstein (including, but not limited to, a sponsored research or licensing agreement), unless already approved through Einstein's Faculty-Initiated Start-Up Option model.
- 6. There shall be a clear distinction between the work to be done by the proposed SBC grantee and the work to be performed in Einstein facilities.
- 7. Research that is funded by an SBIR/STTR subcontract agreement and conducted by an Einstein PI in Einstein facilities must be distinct from the PI's other research funded by other outside funding sources to mitigate any conflicts with an Einstein employee's other research efforts/obligations.
- 8. Einstein shall not be obligated to seek or provide funding/investment or space resources for the proposed SBC grantee.
- 9. The proposed SBC grantee must have primary functioning space that it owns or controls outside of the Einstein campus (unless the proposed SBC grantee is located in Einstein-designated, unoccupied "incubator" space) in which research, development, and/or administrative activities supported by a portion of the funds awarded to it will take place.
- 10. All aspects of these relationships and activities must conform to pertinent Einstein policies and guidelines, including, but not limited to, policies and guidelines on patents and licensing agreements, conflicts of interest, and conflicts of commitment.

IV. Definitions

None.

V. Effective Date

Effective as of: 10 May 2018

VI. Policy Management and Responsibilities

Einstein's Office of Biotechnology and Business Development is the Responsible Office under this Policy. Einstein's Executive Dean is the Responsible Executive for this Policy. Einstein's Director of the Office of Biotechnology and Business Development is the Responsible Officer for the management of this Policy.

VII. Approved (or Revised)

Rop

Responsible Executive

7/18/2012 Date