Guidance for Employee Participation in Small Business Innovation Research (SBIR) and Small Business Technology Transfer Research (STTR)

Background:
The goal of the SBIR/STTR legislation is to support small businesses to develop high-risk/high reward technological innovations into commercially viable products. A credible commercialization strategy is required as part of the proposal. SBIR/STTR funding is not meant to be the sole source of company funding. The small business must meet legislatively proscribed eligibility requirements. The program is not meant to fund “virtual companies.” It is not meant as an alternative funding source to support university based translational research.

The small business is in charge of both a SBIR and STTR award. Set in the legislation is the small business requirements (see Table 1 below). A key requirement is that the small business must have company-controlled R&D facilities suitable to do the proposed work. For an STTR award, the company must do 40% of the work. The work cannot solely be done at the university. Academic spin-outs where $ will be funneled back to the university to do all the R&D work is considered fraud.

Table 1 – Small business requirements for SBIR/STTR awards
- Requirements must be fulfilled at the time of the award (not at the time of grant submission)
- For profit business
- US owned and controlled (>50%)
- ≤ 500 employees
- Geographically located in the US
- Suitable R&D facilities to do the work
- 93% of R&D must be performed in the US

SBIR allows but does not require the involvement of a non-profit research entity (e.g. academic partner). STTR specifically requires the collaboration with a non-profit research entity. The PI and budgetary requirements are summarized below.

Table 2 – SBIR vs STTR

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<thead>
<tr>
<th>SBIR</th>
<th>STTR</th>
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<td>Principal Investigator (PI)* must be employed by the small business &gt; 50% of full time. *See information about MPI grants</td>
<td>Principal Investigator (PI) * may be employed by the small business or the primary sub-awardee (e.g. academic partner) *See information about MPI grants</td>
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Outsourcing of budget to an academic partner:

<table>
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<tr>
<th>Fraction of Budget</th>
<th>Requirement</th>
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<td>&lt;33% of phase 1</td>
<td>If PI is employed by the academic partner, the PI must be &gt;50% of full time equivalent at either the Small Business or Academic Partner and must devote 10% of effort to the project.</td>
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<td>&lt;50% of phase 2</td>
<td>Providing any percentage of the budget to an academic partner that is greater than the above requires a waiver for the funding agency prior to doing so.</td>
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<td>Minimal participation on the funded project</td>
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<td>&gt;40% small business</td>
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<td>&gt;30% academic partner</td>
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**Guidance for ISMMS Faculty Participating in SBIR/STTR Grants:**

1. All investigators participating in SBIR/STTR grants must comply with all SBIR/STTR legislative requirements.

2. Full time faculty members with an equity interest in a small business concern (SBC) cannot serve as an SBIR MPI, PI or subaward PI.

3. Full time faculty members with an equity interest in a SBC cannot serve as the Mount Sinai PI on an STTR without review and approval by the COI Office.

4. In order to serve as a sole PI or Contact MPI of an SBIR grant, the investigator is required to be employed >50% by the SBC and must adjust their ISMMS appointment accordingly.

5. SBIR and STTR grants are submitted by the qualified SBC, not by the academic partner. ISMMS investigators that are either proposed subaward PIs for SBIR/STTR grants or proposed PIs of STTR grants submitted by a SBC must review the project with COI and MSIP before submission. Please email the COI Office at Conflicts.of.Interest@mssm.edu. MSIP contacts are Lingling Liu and Felipe Araujo.

6. Confirmation of MSIP approval must be provided to the GCO office.

7. If the ISMMS PI has a financial interest with the SBC (e.g. consulting agreement, equity ownership (self or related party), or intellectual property (IP) that is licensed to the SBC or would be utilized in performance of the project,) the project must be reviewed by the COI office prior to submission to determine if the conflict can be managed.

8. Of particular concern is the potential for conflict of interest that may occur if the ISMMS PI is an equity owner in the SBC. The faculty member may not serve as both the small business PI and the ISMMS subaward PI on a subaward from the SBC.

**Multiple PI (MPI) Grants**

*excerpt from NIH SBIR/STTR FAQ*

**SBIR:** The PI who serves as the primary contact must be from the small business and meet the primary employment requirement, but other PIs need not meet this requirement. Primary employment means that more than one half of the PI's time is spent in the employ of the small business at the time of award and for the project duration.

**STTR:** As is the case for a single-PI STTR project, the PIs are not all required to be employed by the small business. However, the first PI listed must have a formal appointment with, or commitment to, the small business. This appointment must be in the form of an official relationship between the parties but need not include a salary or other form of remuneration. If the primary contact PI is not an employee of the small business, the applicant organization must officially affiliate the PI with the small business in the eRA Commons system.