

COI GUIDELINES: SBIR/ STTR PROJECTS

Weill Cornell Medicine (“WCM”) supports participation in Small Business Innovation Research (“SBIR”) and Small Business Technology Transfer (“STTR”) programs by its faculty, as this may allow faculty and their start-ups to make rapid progress towards commercialization of important inventions. This guidance document has been developed to explain how WCM manages potential conflicts that may arise from involvement in such projects.

To ensure that WCM can support and conduct SBIR/STTR projects in a manner that is consistent with its principles of academic integrity, protection of students, stewardship of university resources and research data, and open and fair publication of research results, and in accordance with its tax-exempt status, all personnel are strongly encouraged to contact WCM’s Conflict of Interest (“COI”) Office, at conflicts@med.cornell.edu, as well as the Center for Technology Licensing (“CTL”) and the Office of Sponsored Research Administration (“OSRA”), prior to applying for SBIR/STTR projects. Late notice to these offices may lead to project delays.

SBIR/STTR Grants Explained

SBIR and STTR are federal award mechanisms that allow US-based start-ups and small companies (referred to as Small Business Entities or “SBEs”) to compete for federal funding. The goal of these awards is to support the SBE’s efforts to develop high-risk/high-reward technological innovations into commercially viable products, in order to accelerate the transfer of scientific discovery and innovation to the public. SBIR and STTR are not meant to support primarily university-based translational research.

SBIR/STTR Application and Award Requirements

Specific requirements for each program are detailed in the Request for Proposal (“RFP”) and the SBIR/STTR websites of the awarding agency ([NSF SBIR/STTR guidance](#); [NIH guidance](#)). Included are the program-specific requirements for eligibility of the SBE and Principal Investigator at the time of application and at the time of award. The SBE and Principal Investigator are responsible for compliance with all eligibility requirements and terms and conditions at the time of application and grant award. A failure to comply with such requirements and terms can be considered fraud. ([SBIR STTR Fraud Tutorial](#))

COI Oversight

A situation in which the faculty member or any member of the WCM research team has a financial interest in the SBE applying for the funding, and will also conduct research funded by the SBE, creates a COI for that individual and potentially the institution. This COI could lead to the following types of problems:

1. Concern that the individual may be using their WCM lab, students, staff, funds or other WCM resources to support their SBE, jeopardizing academic research, the progress of their students or staff, and commitments to federal funders; and
2. Blurring of the non-profit/for-profit boundary (e.g., use of WCM tax-exempt facilities or other resources without commensurate compensation in a way that competitively advantages, or otherwise provides benefit for, a for-profit SBE).

Institutional Conflict of Interest

If the SBE has licensed, or intends to license, intellectual property from WCM, there is the possibility of an institutional COI, whereby WCM might benefit financially from the success of the SBE that has licensed its technology. Therefore, a COI management plan must be implemented to manage not only the personal financial COI for the involved faculty, but also the institutional COI for WCM.

SBIR/STTR Phase I Project Requirements

For the subaward to WCM, the WCM PI is responsible for ensuring that the following requirements are met:

1. The WCM PI, or their close family members¹, may not also serve as the SBE PI on the SBE's proposal to the funding agency.
 - For SBIR projects, the PI at the SBE must be primarily employed at the SBE (effort for the SBE > 50%).
 - Unless a waiver is granted by the awarding agency (see [reference link](#)).
 - For STTR projects, the SBE must partner/collaborate with a research institution.
 - No such requirement exists for SBIR projects.
2. The SBE's proposal to the sponsor must clearly describe the relationship between the WCM PI and the SBE, so that the sponsor can make the funding decision with full knowledge of the potential conflict.
3. When submitting a proposal to the SBE for a sub-award to WCM, the WCM PI must provide to OSRA and CTL: (1) a copy of the solicitation and the completed proposal and budget for

¹ "Close family member" refers to the individual's spouse, domestic partner, parent, sibling, child, or any other blood relative, if that other blood relative resides in the same household.

the WCM sub-contract; (2) the complete proposal submitted by the SBE to the prime sponsor (if not available at the time of submission, the documents should be provided immediately post-submission); and (3) indicate:

- any financial interest the WCM PI, including his or her close family members, has, or anticipates having, in the SBE;
 - the labs and other WCM locations where work will be conducted;
 - the role of any WCM students and staff in the research;
 - whether any SBE employees or representatives will be involved in the WCM portion of the work and if so, a description of their involvement, including proposed activities at WCM (These documents should, to the extent possible, be submitted to the COI Office); and
 - documentation from the SBE that it has a primary operating space outside of WCM suitable to carry out the proposed project;
 - NOTE: If the information is not provided in time for OSRA and CTL to conduct a full review before submitting the proposal to the SBE sponsor, it must be provided before the award is received. If the proposal does not meet the requirements laid out in this document, OSRA may need to withdraw the proposal, may not be able to accept the award from the SBE, or the award may need to be modified to comply with the COI management terms.
 - WCM's DHHS IDC rate agreement applies to the SBE subaward to WCM, and Indirect Cost Recovery (ICR) must be included at the time of application.
4. A Conflict Management Plan ("CMP") must be in place for the WCM PI before the sub-award from the SBE is accepted. Any involvement of a close family member as PI of the SBE will need approval of the WCM Conflicts Advisory Panel.
 5. In cases where the SBIR/STTR award to the SBE includes the use or practice of WCM data or intellectual property, the SBE will be required to take an option or license to the underlying intellectual property. The terms of the license or option must be negotiated by CTL and the SBE, before the sub-award is accepted.

Involvement of WCM personnel and resources on a WCM sub-award funded by the SBE:

1. All WCM individuals involved in the project (i.e., students, staff or other researchers) must be informed of the WCM PI's relationship with the SBE, before the award is accepted.
2. Students, staff and postdocs may be involved in the SBIR/STTR project only under the following conditions: (1) their involvement is approved by the Conflicts Advisory Panel ("CAP"); (2) the WCM Graduate School of Medical Sciences has been informed of the relationship between the WCM PI and the SBE; and (3) milestones for the students' progress toward their degrees have been established.

3. Postdocs, students or staff involved in the SBIR/STTR project and working under the academic supervision of the WCM faculty member, may not also have a direct financial relationship with the SBE. The CAP must approve any exceptions to this rule.
4. SBE employees or representatives may not use WCM facilities or resources, other than those that are routinely available on a fee for use basis, such as the central research centers, facilities specifically set aside for entrepreneurial work, or those open to the general public without fees (such as general use of the library).
5. SBE employees may not be appointed as Visitors, Adjuncts or Volunteers at the university, unless such appointments are approved by the CAP.
6. WCM resources, including, without limitation, all data and intellectual property, may be used only as described in the sub-award or terms and conditions of an option or license agreement negotiated by CTL (as long as those terms comply with institutional requirements).

Financial Controls:

1. The chair and administrator for the WCM PI's department must be informed of the relationship between the SBE and the WCM PI at the time of award.
2. No advance spending on these awards will be allowed. Money may not be spent on the award until the CMP has been finalized and the award has been finalized by OSRA.
3. Any purchases from, or other payments to, the SBE, must be approved by the COI Office.

SBIR/STTR Phase II Project Requirements

In addition to the requirements for managing COIs outlined in the SBIR/STTR Phase I projects above, the following conditions will apply:

1. In addition to serving as SBE PI, a WCM faculty member may not also serve as the sole WCM PI on the SBE-funded project. However, they may serve as Co-PI, if joined by another WCM Co-PI, who has the same rights and responsibilities. This newly appointed individual, must not have a relationship with the SBE, must not be a subordinate of the WCM PI, and must be mutually selected by the CAP and WCM PI.
2. The Co-PI must sign off on, and the COI Office must review, budgets and any financial reports submitted to the sponsor.

Please contact WCM's COI Office at conflicts@med.cornell.edu, if you have any questions or would like more directed guidance.