Guidelines for Managing Conflict of Interest in SBIR/STTR Projects

Small Business Innovation Research ("SBIR") and Small Business Technology Transfer ("STTR") are federal award mechanisms that allow start-up and small companies (referred to as Small Business Entities, or “SBEs”) to compete for federal funding. The goal of these awards is to engage these entities in federally-sponsored research and development and accelerate the transfer of scientific discovery and innovation to the public.

Specific requirements for each program are detailed in the Request for Proposal (RFP) and the STTR/SBIR websites of the awarding agency (NSF STTR/SBIR guidance can be found at http://www.nsf.gov/eng/iip/sbir/home.jsp; NIH guidance is at https://sbir.nih.gov/). Key differences between the programs are as follows:

- For STTR projects, the SBE must partner/collaborate with a research institution; no such requirement exists for SBIR projects.
- For SBIR and some STTR projects (e.g., for STTRs from NSF), 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.¹

Cornell supports participation in SBIR/STTR programs by its faculty through an SBE, as this may allow faculty and their start-ups to make rapid progress towards commercialization of important inventions. However, a situation in which the faculty member or any member of the Cornell research team has a financial interest in the SBE applying for the funding and will also conduct research funded by the SBE, creates a conflict of interest (COI) for that individual. This COI could lead to the following types of problems:

1. Concern that the individual may be using their Cornell lab, students, staff, funds or other Cornell resources to support their SBE, jeopardizing academic research and the progress of their students or staff; and
2. Blurring of the non-profit/for-profit boundary (i.e., use of Cornell’s tax-exempt facilities in a way that competitively advantages a for-profit SBE).

Additionally, if the SBE has licensed the IP from Cornell, this also presents the possibility of an institutional conflict of interest, whereby Cornell might benefit financially from the success of the SBE that has licensed its technology. Therefore, we must implement a COI management plan to manage not only the personal financial conflict of interest for the involved faculty, but also the institutional COI for Cornell.

¹ https://sbir.nih.gov/about/critical
To ensure that Cornell is able to support and conduct SBIR/STTR projects in a manner that is consistent with its principles of academic integrity, protection of students, open and fair publication of research results and in accordance with its tax-exempt status, all personnel must follow the guidelines below in applying for and executing SBIR/STTR projects.

Case 1 - SBIR/STTR Phase I Project

Scenario: The SBE in which a Cornell researcher (hereafter referred to as “Cornell PI”) has a financial interest, seeks Phase I SBIR or STTR funding, or a similar type of funding involving university and industry partnerships. The Cornell PI intends to conduct a portion of the work under a sub-award from the SBE to Cornell. SBIR Phase I awards normally do not exceed $150,000 in total costs and are for a period of 6 months.

COI Management Principle: While the federal rules for COI regard Phase I SBIR projects as exempt from COI requirements, the principles that govern Cornell research and the issues identified above remain the same regardless of the type of funding. Therefore, Cornell policy does not exempt these relationships from review and requires the implementation of a conflict management plan (CMP). However, the terms of the CMP will reflect the relatively low risk of such relationships, as determined by the federal regulatory agencies, and in recognition of the university’s commitment to encouraging and supporting efforts to bring university research to market.

Requirements for Proposals and Awards

The Cornell PI is responsible for ensuring that the following requirements are met:

1. The Cornell PI may not also serve as the SBE PI on the SBE’s proposal to the funding agency.
2. The SBE’s proposal to the sponsor must clearly describe the relationship between the Cornell 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 Cornell, the Cornell PI must provide to the Cornell OSP (1) a copy of the solicitation and the complete proposal and budget for the Cornell sub-contract and (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:
   i. the labs and other Cornell locations where work will be conducted;
   ii. the role of any Cornell students and staff in the research;
   iii. whether any SBE employees or representatives will be involved in the Cornell portion of the work and if so, a description of their involvement, including proposed activities at Cornell. These documents should, to the extent possible, be submitted to OSP along with the Form 10, and;
   iv. documentation from the SBE that it has a primary operating space outside of Cornell University.
v. NOTE: If the information is not provided in time for OSP 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, OSP 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.

4. A Conflict Management Plan (CMP) must be in place for the Cornell PI before the sub-award from the SBE is accepted.

Involvement of Cornell personnel and resources on Cornell sub-award funded by the SBE

1. All Cornell individuals involved in the project—students, staff or other researchers—must be informed of the Cornell 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 FCOI Committee; (2) the DGS and their Special Committee have been informed of the relationship between the Cornell 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 Cornell faculty member may not also have a financial relationship with the SBE. The FCOI Committee must approve any exceptions to this rule.
4. SBE employees or representatives may not use Cornell 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 (e.g. the McGovern Center) 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 FCOI Committee.
6. Cornell resources may be used only as described in the sub-award as long as those terms comply with University requirements.

Financial Controls

1. The Business Officer or Department Manager for the Cornell PI’s department must be informed of the relationship between the SBE and the Cornell 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 COI management plan has been finalized and the award has been finalized by OSP.
3. Any purchases from, or other payments to, the SBE must be approved by the Conflict Manager.

Case 2 - SBIR/STTR Phase II Project

Scenario: The SBE in which a Cornell PI has a financial interest seeks Phase II SBIR or STTR funding, or a similar type of funding involving university and industry partnerships. The Cornell PI wishes to conduct a portion of the work on this Phase II project under a sub-award from the SBE to Cornell.
COI Management Principle: Funding for Phase II projects is based on the results achieved in Phase I and on the scientific and technical merit and commercial potential of the project proposed. Funding is capped at a higher dollar amount of $1,000,000, and is provided over a longer period of time (2 years). Therefore, intersecting relationships for faculty involved in these projects present greater potential for a real financial interest in the outcome of the research. The CMP terms for a Conflict of Interest for the Cornell faculty member reflect this elevated risk.

In addition to the requirements for managing COI outlined in Case 1 above, the following conditions will apply:

1. The Cornell faculty may not serve as the sole PI on the SBE-funded project; a Cornell Co-PI, who has the same rights and responsibilities as the Cornell PI, must be appointed. This individual must not have a relationship with the SBE, must not be a subordinate of the Cornell PI, and must be mutually selected by the FCOI Committee, the Cornell PI, and the Conflict Manager.
2. The Co-PI must sign off on, and the Conflict Manager must review, budgets and any financial reports submitted to the sponsor.