

SBIR/STTR Background

The Federal government established the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs to strengthen the role of innovative small business concerns (SBCs) in federally funded research and development.

Participation in SBIR/STTR programs by UM faculty through a SBC can create conflicts of interest (COIs) on the part of the faculty members. This happens when a faculty member is the co-founder or owner of the SBC applying for the funding, and simultaneously will do research on a subaward between the SBC and UM. Among the reasons for the COI are:

1. Lack of control of the UM faculty (i.e., is the PI using the UM lab to support his/her own company);
2. Blurring of the non-profit/for-profit boundary (i.e., use of UM's tax-exempt facilities in a way that competitively advantages a for-profit entity); and
3. COI in the research since the investigator may want to produce certain results for financial reasons, to advance the company's fortunes rather than to advance science.

Institutional Conflict of Interest is another potential problem in SBIR/STTRs granted to start-ups. In many cases UM may have relationships with the SBCs; e.g., licensed intellectual property to the SBC in exchange for equity. It could be perceived that UM would be less assertive in its oversight of the research if the institution stood to profit financially from the research.

UM nevertheless expects that faculty will want to be involved in SBCs and in the SBIR/STTR proposal process, and UM knows that these activities can be beneficial to the faculty member's career as well as to the institution and to the community at large. However, a few compliance steps must be undertaken.

UM Faculty must notify UM when the SBC in which they have an interest or a relationship applies for SBIR/STTR funding and the faculty member (or another UM employee) expects to work on the subaward to UM from the SBC. This notification can be done through the [PCRFL form](#) used with the pre-award process or by directly contacting the [Office of Research Administration](#). In certain circumstances, the Office of Disclosures and Relationship Management (DRM) and/or the Conflict of Interest Committee may be involved in review of the relationship. In addition to Intellectual Property licenses, contracts between UM and the SBC should address contracting costs and anticipated research utilization (if any).

Role of the Conflict of Interest Committee

The DRM and the Conflict of Interest Committee are responsible for review and management of COIs between UM employees and the SBC as they relate to sponsored research. Generally, these entities will be alerted in the following situations to allow for their review and determination:

1. The UM faculty member seeks to be the PI for the SBC (or has a supervisory relationship with the SBC PI) or wishes to work on the subaward from the SBC to UM; and
2. The UM faculty member seeks to be PI on a subaward from the SBC (or has a supervisory relationship with the SBC PI) and has a significant ownership interest in, or ≥\$10,000/year financial relationship with, the SBC.

For Phase I programs, there is an alternative procedure, as discussed below.

Standard Operating Procedure for Phase I SBIR/STTR Projects

The UM COI Committee has approved a procedure for Phase I SBIR/STTR projects through which a UM faculty member with a significant financial interest in a SBC can serve as lead PI on the subaward between the SBC and UM, as long as the following conditions are met:

1. The sponsoring agency does not have a rule stating that the faculty member's interest in the SBC must be considered a significant financial interest for determining a COI;
2. The UM faculty member does not serve as the lead PI, investigator or consultant for the SBC on the award from the sponsor;
3. The UM faculty member does not hire a UM student she/he mentors to conduct work on the subaward without contacting the Office of Disclosures & Relationship Management to discuss appropriate COI management;
4. The UM faculty member does not apply UM's resources or any federal funds to benefit the SBC's interests in a manner inconsistent with UM's non-profit status;
5. The UM faculty member informs the Office of Research Administration and provides copies of each invoice and progress report submitted to the SBC, which can be provided at the halfway point of the subaward and upon submitting a final report;
6. The UM faculty member alerts the COI Committee's designated representative if the subaward is modified and a human subject protocol is submitted to the Institutional Review Board for approval; and
7. The UM faculty member contacts the COI Committee's designated representative if the sponsoring agency requests additional information about the faculty member's financial interest in the SBC.

Standard Operating Procedure for All Phase I SBIR/STTR Projects

In order to protect non-licensed UM IP and facilitate submission, all UM PIs will be required to disclose whether or not non-published data, know-how, software or any other potential UM IP (including IP that is not patentable) is being incorporated into the grant submission. The SBC must indicate willingness to negotiate an option or license agreement to UM-IP in the event that the grant is awarded. An option agreement will enable development of existing UM innovations exclusively by the SBC. The level of funding to the SBC is minimal in comparison to the UM work done/resources utilized to enable grant submission. Unless the IP is licensed upon award of the grant, any results developed through an option agreement will belong to UM.

Please contact the Office of Research Administration at mra@miami.edu to request additional information about pursuing this option.

NATIONAL INSTITUTES OF HEALTH
[SBIR/STTR FAQs](#)

What are the main goals of the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs?

The SBIR and STTR programs are congressionally-mandated set-aside programs for domestic small business concerns to engage in Research/Research and Development (R/R&D) that has the potential for commercialization. The SBIR Program includes the following objectives: using small businesses to stimulate technological innovation; strengthening the role of small business in meeting federal R/R&D needs; increasing private sector commercialization of innovations developed through federal SBIR R&D; increasing small business participation in federal R/R&D; and fostering and encouraging participation by socially and economically disadvantaged small business concerns and women-owned business concerns in the SBIR program.

The STTR and SBIR programs are similar in that both programs seek to increase the participation of small businesses in federal R&D and to increase private sector commercialization of technology developed through federal R&D. The unique feature of the STTR program is the requirement for the small business concern applicant organization to formally collaborate with a research institution in Phase I and Phase II.

What are the differences between the SBIR and STTR programs?

There are 2 major differences - one relates to the PI and the other relates to a research partner. Under SBIR, the PI must be primarily employed with the small business concern at the time of award and for the duration of the project period, unless a waiver is granted by the NIH. Under the STTR Program, primary employment is not stipulated so the PD/PI may be from the small business or the collaborating non-profit research institution.

With regard to the research partner, SBIR permits, and in fact, encourages, research partnerships. However, STTR requires that the small business concern formally collaborate with a non-profit research institution. Under STTR, the SBC must perform at least 40 percent of the work and the research institution must perform at least 30 percent. The remaining 30 percent may be with the SBC, the single collaborating non-profit research institution, or an additional third party. The basis for determining the percentage of work to be performed by each of the cooperative parties will be the total of direct and F&A/indirect costs attributable to each party, unless otherwise described and justified in "Consortium/Contractual Arrangements" of the PHS398 Research Plan component of the SF424 SBIR/STTR (R&R) Application Forms, located [here](#).

If I'm employed by a university and own a small business, do I need two distinct eRA Commons names for each entity?

A PI does not need two distinct eRA Commons names for each entity. An individual only needs one eRA Commons PI account, which will follow them throughout their career. A PI may have multiple affiliations with a university and a small business. However, a small business official at the small business concern must have a separate organizational eRA Commons account for the small business.

What is the five-step registration process for the small business concern?

Applicant organizations must complete and maintain the following registrations as described in the SF424 SBIR/STTR (R&R) Application Guide to be eligible to apply for or receive an award. All

registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible.

- [Dun and Bradstreet Universal Numbering System \(DUNS\)](#) - All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin both SAM, SBA Company registry, and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.
- [System for Award Management \(SAM\)](#) (formerly CCR) – Applicants must complete and maintain an active registration, which requires renewal at least annually. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
- [SBA Company Registry](#) – **New requirement as per the Reauthorization.** See “SF424(R&R) Other Project Information Component” for instructions on how to register and how to attach proof of registration to your application package. Applicants must have a DUNS number to complete this registration. SBA Company registration is NOT required before SAM, Grants.gov or eRA Commons registration.
- [eRA Commons](#) - Applicants must have an active DUNS number and SAM registration in order to complete the eRA Commons registration. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- [Grants.gov](#) – Applicants must have an active DUNS number and SAM registration in order to complete the Grants.gov registration.

My small business concern is applying for an STTR and the PI works for the partnering non-profit research organization. On the SBC budget pages, the PI is automatically entered, even though the PI is employed by the research organization. What should I do?

The STTR form incorrectly prepopulates the research organization PI's information. The applicant should put zero salary and zero effort for the academic PI on the SBC budget and relist them on the subaward budget page with the appropriate effort and dollar amount for salary.

May multiple PD/PIs be included on SBIR and STTR applications?

Yes, more than one PD/PI, or multiple PDs/PIs, may be designated on the application for projects that require a “team science” approach that clearly does not fit the single-PD/PI model. Each PD/PI must have a PD/PI role and a leadership plan is required. All PDs/PIs must be registered in the NIH eRA Commons prior to the submission of the application. The decision of whether to apply for a single PD/PI or multiple PD/PI grant is the responsibility of the investigators and applicant organizations and should be determined by the scientific goals of the project.

Please also refer to the SF424 SBIR/STTR (R&R) Application Guide for more information about the requirements for multiple PD/PIs.

Do all Project Directors/Principal Investigators (PD/PIs) on a multiple PI SBIR grant have to meet the SBIR primary employment requirement? What about STTRs?

SBIR projects: The individual who serves as the Contact PD/PI must be from the Small Business and meet the primary employment requirement, but other PDs/PIs need not meet this requirement. Primary employment means that more than one half of the PD/PI's time is spent in the employ of the SBC at the time of award and during the conduct of the proposed project. Occasionally, deviations from this

requirement may occur. Such deviations must be approved in writing by the grants management officer after consultation with the NIH SBIR/STTR Program Coordinator's Office.

STTR projects: As is the case for an STTR project with a single PD/PI, the PD/PI is not required to be employed by the SBC. However, the Contact PD/PI, the first PD/PI listed, must have a formal appointment with, or commitment to, the SBC, which 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 Contact PD/PI is not an employee of the SBC, the applicant organization must officially affiliate the PD/PI with the SBC in the Commons.

Under the Multi-PI model, is there a minimum person-months requirement to qualify as a PD/PI?

SBIR Applications: No. There is no minimum person-months requirement for individuals identified as PD/Pis. The reviewers will assess whether the level of effort is adequate to achieve the proposed goals. If there are deficiencies in this regard, it will negatively impact the score.

STTR Applications: Yes. Each PD/PI must commit a minimum of 1.2 calendar months (10 percent effort) to the project and each PD/PI must have a formal appointment with or commitment to the applicant small business concern (SBC), which is characterized by an official relationship between the SBC and that individual. Use the Person Months [website](#) and calculator as a reference.

Under the Multi-PI model, which PD/Pis must be registered in the eRA Commons?

All PD/Pis must be registered and be assigned the PD/PI role in the eRA Commons prior to the submission of the application. Note: While each PD/PI must hold a PD/PI account in the Commons, PDs/Pis do not register with Grants.gov. Only the applicant organization registers with Grants.gov.

In addition, all PDs/Pis at the applicant organization must be affiliated with that organization. When PDs/Pis are located at another organization, only the contact PI (the PI named on the SF424 SBIR/STTR (R&R) Cover) must be affiliated with the applicant small business concern (SBC); other PD/Pis need not be affiliated with the SBC, but must be affiliated with their own organization to be able to access the Commons. This affiliation must be done by the AOR/SO or their designee who is already registered in the Commons.

All PD/Pis will have equal access to information related to the application or grant (e.g., Summary Statement, Notice of Grant Award).

Does it matter in what order the Multiple PD/Pis are listed on the application?

Yes. The Contact PD/PI who must be affiliated with the applicant small business concern (SBC) submitting the application will be listed first. For both the SBIR Phase I and SBIR Phase II, the primary employment of the "Contact PD/PI" must be with the SBC at the time of award and during the conduct of the proposed project. Occasionally, deviations from this requirement may occur. Such deviations must be approved in writing by the grants management officer after consultation with the NIH SBIR/STTR Program Coordinator.

For a Multi-PI application under the SBIR/STTR Program, must the applicant organization be the small business concern or may a collaborating research institution be so designated? Which organization/institution should be designated as the lead?

The small business concern (SBC) is ALWAYS the applicant/awardee organization, regardless of whether the project is submitted as an SBIR, STTR, single-PD/PI or multiple PD/PI application. The SBC

submitting the application is ALWAYS lead organization and any other organizations (including research institutions) receive subcontracts from the SBC.

Must all of the work on an SBIR project be completed by the small business?

No, on an SBIR Phase I project, normally, a minimum of two-thirds (67 percent) of the research or analytical effort must be carried out by the small business concern. The total amount of all consultant and contractual agreements to third parties for portions of the scientific and technical effort normally may not exceed 33 percent of the total amount requested. For Phase II or Phase IIB, normally, a minimum of 50 percent of the research or analytical effort must be carried out by the small business concern. The total amount of all consultant and contractual agreements to third parties for portions of the scientific and technical effort generally may not exceed 50 percent of the total amount requested. Applicants are strongly encouraged to discuss deviations from these guidelines with NIH program staff listed in the Funding Opportunity Announcement.

How much effort must be performed by the collaborating non-profit research institution on an STTR project?

The single, collaborating research institution must perform a minimum of 30 percent of the effort and the small business must perform a minimum of 40 percent. The remaining 30 percent may be attributed to either of these organizations or an additional third party.

Are subcontractors on an SBIR or STTR application required to provide letter of support?

Yes. Each individual and/or collaborating organization must include a letter confirming their role on the proposed project. For STTR, a letter from the collaborating institution must be included.

Can a small business concern subcontract with a foreign entity?

No, all work on the SBIR project must be conducted in the US, per statute. Only exceptional circumstances can be considered and possibly granted a waiver by the NIH. Please read the exception in the [foreign involvement](#) section of the FAQs.

However, if the company is US owned and operated, the PI can be foreign. There is no US citizenship requirement for PIs; however, the PIs must have a legal residency and work status in the US.

Is it permissible to submit a budget that deviates from the time and dollars normally awarded to Phase I or Phase II?

Yes, according to statutory guidelines, total funding support (direct costs, indirect costs, fee) normally may not exceed \$150,000 for Phase I awards and \$1,000,000 for Phase II awards. Reauthorization required that budgets that exceed the hard caps (\$225,000 for Phase I and \$1,500,000 for Phase II) receive a waiver of approval from SBA. The agency – not the applicant – must apply for this waiver. SBA has recently approved a topics list, [located on this page](#), which allows budgets to exceed the hard caps as long as the project topics are included on the list.

Applicants are strongly encouraged to contact program officials prior to submitting any application. In all cases, applicants should propose a budget that is reasonable and appropriate for completion of the research project.

My company does not have a negotiated F&A (overhead) rate. What am I permitted to charge?

The payment of facilities & administrative (F&A) costs is based upon rates established through a formal agreement between the grantee organization and the Federal agency. Phase I applicants who do not have a negotiated rate with a Federal agency should propose an estimated rate not to exceed 40 percent of the total direct costs. If awarded at a rate of 40 percent or less, the rate used to charge actual F&A may not exceed the awarded rate. NIH will not negotiate F&A rates for Phase I awards.

Phase II/IIB applicants who propose a rate of 40 percent of total direct costs or less will not be required to provide further justification if selected for an award. The F&A costs will be awarded at the requested rate. The [NIH Division of Financial Advisory Services](#) will only negotiate rates with applicants who request more than 40 percent of total direct costs on a Phase II award. See notice [NOT-OD-09-038](#).

Please explain what is meant by the “fee.” Is this a direct cost or an indirect cost?

A reasonable fee, not to exceed 7 percent of total costs (direct and indirect) for each Phase (I and II/IIB) of the project, is available to small business concerns receiving awards under the SBIR/STTR program. The fee is intended to be a reasonable profit factor available to for-profit organizations, consistent with normal profit margins provided to profit-making firms for research and development work. The amount requested for the fee should be based on the following guidelines: (1) it must be consistent with that paid under contracts by the PHS for similar research conducted under similar conditions of risk; (2) it must take into account the complexity and innovativeness of the research to be conducted under the SBIR/STTR project; and (3) it must recognize the extent of the expenditures for the grant project for equipment and for performance by other than the grantee organization through consultant and subaward agreements.

The fee is not a direct or indirect "cost" item and may be used by the small business concern for any purpose, including additional effort under the SBIR/STTR award. The fee applies solely to the small business concern receiving the award and not to any other participant in the project. However, the grantee may pay a profit/fee to a contractor providing routine goods or services in accordance with normal commercial practice.

UNIVERSITY OF MIAMI SBIR/STTR FAQs

May UM submit an application for an SBIR and STTR contract or grant?

No. Although many SBIR/STTR applications include subawards to universities, under federal regulations, only small business concerns (SBCs) may apply for SBIR and STTR funding. STTR guidelines require the SBC to formally collaborate with a University or non-profit research institution. For SBIRs, this collaboration is optional.

How can UM faculty, staff and postdoctoral scholars, and students participate in SBIR and STTR awards?

Typically, this is done by conducting research at UM under a subaward from a small business that has received an SBIR or STTR award. ORA staff can assist UM PIs in completing and submitting paperwork needed to initiate the subaward application and contracting process.

Plans for proposed research to be conducted at UM under an SBIR or STTR subaward from a SBC must be reviewed by appropriate department chair and academic dean (Gables and RSMAS) before subaward proposal materials are forwarded to ORA. This review is intended to ensure that the proposed work (a) has scientific merit, (b) constitutes a good use of UM research facilities, (c) will not compromise the PI's academic responsibilities, (d) is for a unique and specific scope of work distinct from research funded by other outside entities, (e) is for work that does not overlap with the investigator's other research responsibilities, and (f) reflects full cost recovery (direct and indirect), including the PI's time, in the project budget.

The UM Faculty Manual addresses outside professional activities specific to faculty working with outside companies as consultants. From a COI and conflict of commitment perspective, it is best for UM personnel to act either as a consultant to the SBC on grant-related activities, or as a researcher on a subaward to UM, but not both. The nature of the work performed defines whether someone can act as a consultant or as a researcher on a subaward, as defined in the Uniform Guidance.

If a UM employee establishes a SBC or is an equity holder within a SBC, can the SBC apply for an SBIR or STTR award while the employee continues to work at UM?

Yes, but there are some key points to keep in mind. Faculty may not hold a full-time appointment at UM and concurrently serve as the Principal Investigator (PI) of an SBIR or STTR grant for a company. In general, the PI for the SBC should not be a UM employee. The PI for the company and the PI for the UM subaward must be separate individuals. See additional discussion below. Work performed by the SBC cannot occur in UM's facilities.

Can the PI of a UM subaward under an SBIR or STTR sit on the scientific advisory board (SAB) or board of directors (BOD) of the company that applied for and received the SBIR or STTR award?

Yes. Faculty may engage in these types of activities, subject to the time limits and reporting requirements of the Faculty Manual, and the outcome of review by the Conflict of Interest Review Committee (Applicable to those cases in which the investigator has a financial interest in the company that has applied for and received the grant).

Can a full-time UM employee serve as the PI for the SBC on SBIR or STTR proposals?

In general, no. Under federal SBIR guidelines, the small business applicant must be the PI's primary employer by the time an award is made and must remain the PI's primary employer for the duration of

the project period. Although STTR program guidelines permit University employees to serve as the small business applicant's PI, submission of an application for research support through any organization other than UM requires an exception to the UM policy. Typically, exceptions have been made when the faculty member agrees to reduce his/her employment at UM or take a temporary leave (part time or full time) from UM to conduct research as the SBC PI. Please note that the conduct of research is generally not considered the kind of outside professional activity allowed under the UM Faculty Manual. These requests for exceptions should be directed to the Vice Provost for Research.

Can a UM employee serve simultaneously as the PI for a SBC and PI or a co-investigator on the UM subaward?

In general, no. SBIR and STTR funding mechanisms involve a primary grant to the small business concern and a subaward to the University. Thus, there are two PIs: one is PI for the SBC; and one is PI for UM. Typically, the same individual may not serve as both. For example, if you will serve as the SBC PI, then you may serve as a co-investigator on the UM subaward, but you may not serve as the PI on the UM subaward.

If you will be an investigator on both the primary award to the small business concern and the University subaward, then you must disclose and manage the COI. The COI Committee advises that the tasks conducted at the SBC and at UM should be clearly distinguishable from each other. Any UM employees compensated through the subaward to UM may not receive compensation for the same task from the SBC. The COI must be managed prior to the University's execution of the subaward.

Can students work for SBCs in which their UM supervisors have financial interests while they are enrolled at UM?

No.

Can UM staff or non-faculty academic appointees take on outside responsibilities for a small business SBIR or STTR applicant?

Per UM policies and principles, including Personnel Policies for Staff Members/Conflict of Interest, non-faculty employees (such as staff and appointees in the research series) are not permitted to engage in activities that create COIs between their UM responsibilities and other interests or obligations. Additionally, outside employment should not interfere with the performance of employees' UM duties.

UM employees must not use UM resources (i.e., employee time or effort, or resources, including computers or equipment) to write an STTR or SBIR application or perform any work on behalf of an SBC. The University policies and principles prohibit the use of University resources without appropriate remuneration and agreement. The writing of an SBIR or STTR grant application and any tasks associated with administering the SBIR/STTR award and administering the subaward on behalf of the SBC must be conducted using the SBC's resources, personnel, time and effort.

Does a SBC that is applying for an SBIR/STTR award need a license from UM for intellectual property that will be used in the research?

The SBC must contact UM's Office of Technology Transfer **before** submitting its proposal to discuss the availability of the intellectual property and whether an option or license is needed. Doing so may prevent potential claims of intellectual property infringement resulting from the SBC's use of University-owned intellectual property under the SBIR-STTR award.

Can UM accept a subaward in situations where the research will take place in the lab of a University employee who has a management role, an equity stake, or who is otherwise compensated by the SBC receiving the SBIR or STTR award?

Probably. However, these situations are subject to review by the faculty Conflict of Interest Review Committee before the University can accept the research support. If the Conflict of Interest Review Committee determines that the situation creates a COI, it will try to find ways of managing the COI. The Vice Provost for Research and the Conflict of Interest Review Committee Chair are available to confer about specific situations prior to formal committee review.