Guidelines for Navigating Conflict of Interest and Conflict of Commitment Issues for Faculty Start-Up Companies

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Purpose

Stony Brook University (SBU) is committed to facilitating scientific discovery and advancing knowledge through innovative and translatable research. Consistent with SBU's mission, our community is developing novel solutions to address questions, problems, and disparities in a variety of fields and entering the entrepreneurial arena to bring these discoveries to market. Inherent in these relationships and interactions are potential for the appearance of or actual conflicts of interest with respect to competing and/or conflicting interests, commitments, and obligations. We must balance promoting innovation and entrepreneurship with preserving our commitment to SBU and safeguarding the integrity and objectivity of university research.

These guidelines are intended to help SBU's research community more proactively navigate existing policies and standards that touch areas in which start-up companies and university research intersect. While policies exist for various processes, they are often general and are "owned" by different areas and departments across the university. Many situations are nuanced and are assessed by various stakeholders on a case-by-case basis; while this provides for necessary flexibility based on the facts and circumstances of a particular situation, it also has the potential to allow for a lack of clarity and/or cause misunderstanding as to how certain things should be approached or handled. This guidance endeavors to provide greater transparency and clarity around the highlighted topics related to start-up companies and university research.

General Principles

Forming an external entity, or start-up company, is generally considered an outside activity and start-up companies are generally entities that are not affiliated with or controlled by SBU. There are funding opportunities for exploration of pre-commercial, university-based translational research, such as the NSF I-Corps regional and national Teams programs that are not external and fall within the research guidance of university-based, grant or contract-funded research. It is important that faculty* forming external start-up companies:

- Ensure that time spent on behalf of the external entity is appropriate and in accordance with SBU's <u>Outside Consulting Work policy</u>.
- Report any financial interest (e.g.; ownership interest, stock, or stock options) in your Disclosure Profile according to SBU's Disclosure of External Interest & Commitments Policy.
- Be familiar with SUNY <u>Patent Policy</u> and SUNY RF <u>Intellectual Property Policy</u> which governs intellectual property for SBU faculty, staff, and students.
- Be familiar with the guidance that is provided in this document.
- Be familiar with export control regulations and other applicable U.S. and/or international laws regarding the transfer of intellectual property and technology from SBU to the start-up company.

^{*}In this document, faculty means all individuals with an appointment at SBU.

Conflict of Interest and Commitment

Conflicts of interest (COIs) and Conflict of Commitment (COC) are inherent in collaborations between the university and companies in which an investigator has a Significant Financial Interest (SFI) or company role (e.g., scientific advisor, board of directors).

A COI may arise when a university employee with significant financial interest in a company (ownership or other) engages in either the company or the university side of research or other activities related to company interests. Inherent COI concerns include:

- The potential for the research to be viewed as being biased or not objective since the investigator may receive financial benefit from the outcome of the research due to their interest in/relationship with the company, as well as intellectual property resulting from the activity for which the company would be a likely commercial vehicle.
- The potential for the PI to use university space, equipment, personnel, or other resources to benefit the company in appropriately; and
- The potential for the blurring of the non-profit/for-profit boundary, in that the tax-exempt facilities could be used in a way that competitively advantages the for-profit company.

A COC may arise when a university employee engages in external activities (e.g., faculty startup or consulting), paid or unpaid, that interferes with their primary obligation and commitment to the university. Inherent COC concerns include:

- The potential for issues regarding time allocation.
- The potential for decisions being made or actions taken that adversely affect the university for the benefit of another entity to which the faculty may have other financial, legal, or other commitments.

Investigators must disclose to the university external financial interests and commitments as required by SBU's <u>Disclosure of External Interest & Commitments Policy</u>. This includes equity interests in non-publicly traded entities, such as start-up companies, even if worth nothing or for which the value is unknown. These disclosures facilitate the <u>research-related COI review process</u>, in which external interests and relationships of university investigators are assessed to determine whether they could relate to and impact or bias any research activity in which one is engaged.

Please note that specific sponsor policies or requirements, if more restrictive, must be adhered to in addition to university policies and this guidance.

Licensing Intellectual Property from the University

The university may license intellectual property to faculty start-up companies. The university is obligated to ensure fair and open access to all potential licensees.

• Faculty start-up companies should not receive or be perceived to receive preferential treatment.

• Faculty/employees of the university are not allowed to represent the faculty start-up company when engaging with the university and cannot negotiate directly with the university.

Examples of individuals who could negotiate a license or option agreement are a non-university employee and member/employee of the start-up, an attorney or consultant hired by the start-up.

University Subcontracting to and from Faculty Start-up Companies

The university may accept subcontracts from faculty start-up companies and may subcontract research to faculty start-up companies through various funding and award mechanisms. Note that relevant policies and practices around selection of a subcontractor apply (e.g., the ability of the subcontractor to adequately perform the programmatic goals of the research project, among other considerations). The university must demonstrate due diligence around the selection and/or engagement of subcontractors and vendors, particularly when an investigator involved in the activity has significant financial interests in the company. Sufficient documentation is required to support decisions around sole source justifications and/or selection of one company rather than a comparative company. When applicable, justifications should identify scientific or technical specialization or superiority in addition to cost considerations (e.g., fair market value for services and or products to be provided).

In situations where an investigator has significant financial interests in a company engaged in research with the university, university determinations are made on a case-by-case review as to whether the investigator may be involved in the university research activity involving the company in which he/she has significant financial interests.

General principles applying to such interactions between the university and companies in which investigators (or other faculty or staff members) have significant financial interests include ensuring that the conflicted individual does not represent the company or the university – in contract, financial, or other transactions between the company and the university. Additionally, any proposed company use of university space, equipment, or other resources must be approved by the university in accordance with its policies and procedures and occur under documented agreements that define the terms, including the purpose, duration, cost, and other relevant specifics of such use.

In general, unless the sponsor specifically indicates otherwise or as specified below, an investigator may engage in non-clinical university research involving an entity in which he or she has significant financial interests as long as a management plan (through the myResearch Grants/COI process) has been implemented. Management plans, to reduce or eliminate any perceived or real conflicts, may include some or all of the following:

- Disclosure of the related financial interests to study team and collaborators
- Disclosure of any university employees, faculty, staff, or students involved in the entity and how conflicts will be mitigated, such as appointment of second research advisors, identification of an

ombudsperson and notification of the employee/student of the conflict and means by which they may seek guidance should they feel compelled to act against their best interest

- Disclosure of how research activities at the University relate to and are separated from activities of the company.
- Disclosure of the related financial interests in presentations and publications arising from the research
- Appointment of Independent and disinterested compliance monitor or committee. Possible roles of the compliance monitor include but are not limited to:
 - Monitor the conduct and performance of the research.
 - Monitor the progress and experience of any university students or employees in the entity.
 - Validate that the research is being performed in a professionally responsible manner.
 - Perform independent data analysis under situations, real or perceived, that outcomes might be construed as being biased by the interests of the conflicted analyst.

Decisions relative to the involvement of conflicted investigators in university research involving a company in which they have significant financial interests involve university review of the nature and extent of the significant financial interest, the nature of the research, and the extent to which objectivity in research design, conduct, or reporting, as well as student and other employee involvement and human research participant welfare (if applicable) can be protected by COI management plans.

In general, an investigator may not serve as PI on a university research project involving human research participants sponsored by a start-up company in which he or she has significant financial interests absent compelling circumstances. The conflicted investigator may be involved in the research in certain capacities and under a COI management plan but may generally not serve as PI. Considerations as to whether compelling circumstances exist include the extent to which the investigator is (by virtue of specialized expertise) best positioned to carry out the research safely.

University determinations as to whether research objectivity and human participant safety can be adequately protected by a COI management plan, despite involvement of a conflicted investigator, primarily includes review of the individual's role in the study in conjunction with study structure and design. For example, a multi-site, randomized study with an external data safety monitoring board, where the conflicted investigator is not involved in data analysis, presents a situation in which there is little opportunity for bias or lack of objectivity in research design, conduct, or reporting, despite the existence of a conflict of interest.

Please note that specific sponsor policies or requirements, if more restrictive, must be adhered to in addition to university policies and this guidance.

SBIRs/STTRs

Various federal agencies provide funding to small businesses to engage them in federal research and development with the potential for commercialization. This Congressionally mandated federal funding occurs via two different award mechanisms:

- (1) Small Business Innovation Research ("SBIR")
- (2) Small Business Technology Transfer ("STTR")

Both SBIR and STTR awards are made directly to a small business concern ("SBC"). STTRs require that the SBC collaborate with a research institution ("RI") for a certain portion of the award. SBIRs do not require RI involvement, but SBCs often collaborate with RIs on SBIRs even though it is not required.

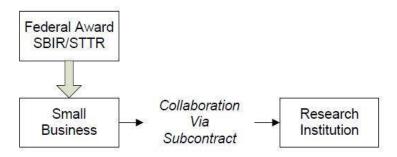
SBC = Small Business Concern

For-profit company that is the direct applicant for/recipient of SBIR/STTR awards

RI = Research Institution

Research institution partner (like a university) that collaborates with an SBC for SBIR/STTR awards via subcontract under the SBC

A university is not an SBC and is not eligible to be a direct recipient of an SBIR or STTR; but the university does meet the criteria to serve as a RI for SBIRs and STTRs. Involvement of a university in either an SBIR or a STTR occurs via a subcontract from the SBC to the university. In cases where there is a collaboration/subcontract between the SBC and the RI, there is an SBC PI and an RI PI (i.e., a PI for each side of the collaboration).



STTRs			
Applicability	Eligibility Requirements		
	Must be an American-owned business		
	Must be independently operated		
SBC	Must be a for-profit business		
	Must have five hundred or fewer employees		
	Not less than 40% of the research/research development must be performed by SBC		
SBC PI	Must be primarily employed by either the SBC <u>or</u> the collaborating RI ¹		
	Research Institution collaborator required		
	Must be one of the following:		
	 A non-profit college or university 		
RI	 A domestic non-profit research organization 		
	 A federally funded Research and Development Center 		
	RI required to conduct at least 30% of research and development but may conduct up to 60%.		
	of research and development		

Only five agencies have STTR programs (Department of Defense, Department of Energy, the National Aeronautics and Space Administration, the National Institutes of Health, and the National Science Foundation) and the PI eligibility requirements differ slightly for NSF. For NSF-funded STTRs, PI eligibility requirements are the same as they are on an SBIR project (i.e., the PI must be primarily employed by the small business). At the other four agencies, the PI can be primarily employed by either the small business applicant or the non-profit organization with which the small firm is collaborating on the STTR project.

SBIRs		
Applicability	Eligibility Requirements	
	Must be an American-owned business	
	Must be independently operated	
cnc.	Must be a for-profit business	
SBC	Must have five hundred or fewer employees If sub-contract with another party or with multiple parties.	
	If sub-contract with another party, or with multiple parties: SBC must do two-thirds of research during Phase I	
	o SBC must do at least one-half of research during Phase II	
SBC PI	Must be primarily employed with SBC	
	Involvement of RI not required	
RI	• If the SBC sub-contracts with RI:	
	o RI may conduct up to one-third of research during Phase I	
	o RI may do up to one-half of research during Phase II	

The Same Individual May Not Serve as PI on Both Sides of SBIR/STTR Collaborations

The PI of the company portion of the research and the university portion of the research may not be the same individual. STTRs require that the company formally collaborate with a non-profit research institution (e.g., a university). STTR Phase I awards require that at least 40% of work on the project be performed by the company and that the collaborating university performs at least 30% of the work. STTR Phase I awards require that the company PI commit a minimum of 1.2 calendar months (10% effort) and must have a formal appointment with, or commitment to, the company. The collaborating university PI has no minimum effort requirement. Although STTRS/SBIRs are indeed collaborations, the STTR/SBIR policy, instructions, and project percentage requirements/effort make clear that establishing a separation of entities and roles is important. The company and collaborating research institution are referred to as separate parties. Having the same person on both sides of the collaboration blurs the respective parties' project and effort requirements/commitments. Most university researchers are committed 100% institutionally at the university among their academic, research, and other commitments, and therefore, do not likely have the effort available to meet the effort requirements of serving as the company PI of an SBIR or STTR.

Please note that specific sponsor policies or requirements, if more restrictive, must be adhered to in addition to university policies and this guidance.

University Personnel Serving as Company PI on any federally funded SBIRs and as Company PI on NSF STTRs

The PI of the company side of SBIR awards must be primarily employed by the company. For NSF, this company's primary employment requirement also applies to the company PI for STTRs. Primary employment is measured and determined by percentage employment/appointment. Therefore, university employees who have a university appointment or position of 50% or greater may not serve as the company PI on SBIRs (or NSF STTRs). University employees serving as the company PI relative to SBIRs (or NSF STTRs) must have a university position or appointment no greater than 49%.

Please note that specific sponsor policies or requirements, if more restrictive, must be adhered to in addition to university policies and this guidance.

Special Note for Individuals Involved in SBIR/STTR Research Proposed To/Funded By NSF

NSF guidance specifies: "No person who is an equity holder, employee, or officer of the proposing small business may be paid as a consultant unless an exception is recommended by the Program Director and approved by the Division Director for the Division of Industrial Innovation and Partnerships," and "No person who is an equity holder, employee, or officer of the proposing small business may be paid through a subaward budget unless an exception is recommended by the Program Director and approved by the Division Director for the Division of Industrial Innovation and Partnerships."

Use of University Resources

University resources may not be used for the activities of a company, including the company portion of a research collaboration in which the university is engaged, except as defined under specific agreements between the company and university regarding use of space, equipment, or other resources. Agreements can take different forms depending on the situation and purpose, such as direct research agreements, testing agreements, facilities and equipment use agreements, memorandums of understanding, collaboration agreements, etc. The Office for Sponsored Programs (OSP) can serve as a starting point for helping to assess the appropriate agreement for such arrangements (e.g., OSP, Procurement). For example:

- Use of university core facilities may be allowed under a written agreement and payment of
 external rates as well as in accordance with university core facility procedures (sign-up,
 scheduled time, etc.)
- Use of university equipment may be allowed under a written agreement and payment for use (unless otherwise specified) as well as in accordance with university procedures for use (sign-up, scheduled time, etc.)

The university takes the following factors into consideration when making decisions regarding company requests for lease of university space:

- There should be a specific reason that relates to an aspect of the university mission that the company has to lease university space and not non-University space (e.g., specific collaboration where close access to university space/specialized equipment being used via documented research/use agreement, etc. is needed).
- The agreement should include a specific and limited duration consistent with the company's needs.
- Any conflicted university employee cannot represent the company or university with respect to
 the negotiations or any financial transactions relative to the arrangement. The agreement
 terms, cost, etc. should be consistent with SBU established rates (periodically updated by
 accounting) or current market and rates for similar facilities.

Procurement can serve as a starting point to request company lease of university space or use of core facilities, as there are programs and initiatives around support for and appropriate handling of this type of activity. Agreements between companies and the University should specify terms for intellectual property ownership if any intellectual property developed by the company involves the use of university resources, space, or equipment.

Small businesses certify in their SBIR and STTR applications and award documents to the federal government that the small business portion of the research and research development will occur in company facilities using company employees unless otherwise indicated in the SBIR or STTR application and approved in the funding agreement. Therefore, performing the company portion of such research in university space using university resources -- unless specifically approved by the funding agency and

allowed by the university under documented agreement – subjects the company to potential criminal, civil, or administrative sanctions.

Licensed electronic information resources, including Library databases, software and other online tools and services, must be used in accordance with the University's license terms and conditions. These resources are restricted to university research and educational purposes and may not be used for activities of a company or a commercial service. The University cannot enter into any agreement that allows companies access to or use of licensed University (including University Library) resources.

The Office for Sponsored Programs (OSP) may not assist companies/small businesses with the company portion of an SBIR/STTR or other company proposal for research. OSP provides research support services for university research, and with respect to SBIR/STTR or other collaborations with companies, OSP provides service and support only for the university side of the research (e.g., letter of intent for collaboration, subcontract execution, etc.).

The University's Institutional Review Board (IRB) and Institutional Animal Care and Use Committee (IACUC) services are for University research activities (i.e., research projects awarded or contracted to the University directly or through subcontract from another institution, and/or other research activities (funded or unfunded) that involve University researchers acting in their University capacity). The University's human research protections and animal care and use programs are federally regulated, and the responsibilities and risks associated with conducting human and animal research are significant. Individuals engaged in university research involving humans or animals are subject to federal requirements overseen and administered by the IRB and IACUC. In no circumstances may external entities or parties, such as faculty start-up companies or a physician's private practice, use the services of these offices for IRB or IACUC approval or animal services unless the University is engaged in a particular research project through a sub-agreement with the company and/or there is a specific documented arrangement between the company and the University (the IRB or IACUC).

Please note that specific sponsor policies or requirements, if more restrictive, must be adhered to in addition to university policies and this guidance.

Involvement of Trainees in Faculty Start-up Activities

Involving students and postdoctoral scholars in faculty start-up company activities (on or off campus) can enhance the academic experience and be valuable to their training and professional development. However, these trainee populations are in an inherently unequal position and care should be taken to ensure that they are engaged voluntarily, that the involvement is beneficial to their development, and that the activity does not interfere with their training and/or academic progress.

We recommend the following questions be considered before engaging with a graduate student or postdoc in faculty start-up activities:

• Will these activities interfere with the student's progress towards degree, graduation timeline or the postdoctoral scholars training timeline?

- Will these activities negatively impact the student's requirements for graduation?
- Will these activities result in restrictions on the publication of a student's thesis, dissertation, or other work; oral presentations or other requirements for degree completion; or the postdoctoral scholar's continuing professional growth and advancement?
- Is the student or postdoctoral scholar supported by a fellowship, training grant or other funding mechanism that restricts work on for-profit enterprises, or that restricts outside work altogether?
- Will these activities and the joint external relationship negatively impact the University advisor/advisee relationship?
- Would the student's ability to maintain full-time enrollment (whether in coursework or research registrations) be impacted?
- Are there possible restrictions around engagement in/payment for external activities related to a student's visa status?
- How will the faculty-student power relationship impact or be impacted by any student-faculty financial partnership created through the company?

The answers to these questions may indicate the need for the creation of a conflict-management plan to manage the student-faculty relationship and its impact on the student's success in their university role.

Involvement of Graduate Students in Faculty Start-up Activities

Prior to engaging students in any faculty start-up company activities, the faculty member must engage in a discussion with the student(s) around the topics included in the Student-Faculty Agreement - Student Engagement in Faculty Enterprises (attached Appendix 1). If (a) a faculty member is the sole research advisor for a student or (b) an existing co-advisor for a student has an actual or perceived conflict of interest and wishes to involve the student in their external start-up activities, then the faculty member must identify a co-advisor (for research) with no relationship to the start-up to serve as an advocate for the student. The co-advisor will work with the student and primary advisor to define the scope of the dissertation research project, formulate ideas, and structure for the research, and guide the progress of the thesis/prospectus/dissertation. Importantly, the co-advisor will have a primary responsibility in assessing the student's research progress. The co-advisor will provide a yearly progress report to the Graduate Program Director (with a copy to the Department Chair and SBU's Conflict of Interest Administrator in the Office of the Vice-President for Research) and, when applicable, participate in meetings of the research advisory committee and grade research courses. It is the responsibility of the student's Graduate Program Director to approve the appointment of the advocate/co-advisor and the proposed work arrangement ensuring the absence of a conflict of interest. If the faculty member and the student mutually agree to proceed with the engagement, the faculty member must submit the completed agreement to their Department Chair, the student's Graduate Program Director, the College Dean, the Graduate School Dean, and to SBU's Conflict of Interest Administrator in the Office of the Vice-President for Research.

Involvement of Postdocs in Faculty Start-up Activities

Prior to engaging postdoctoral scholars in any faculty start-up company activities (on or off campus), the faculty member must have a discussion with the postdoctoral scholar around the topics included in the Postdoc-Faculty Agreement - Postdoc Engagement in Faculty Enterprises (Appendix 2). External activities must occur outside of university work hours and must not involve University resources, unless a facilities-use agreement or other prior, written agreement is in place. It is the responsibility of the Department Chair to approve external activities if a faculty member is the primary postdoctoral supervisor and engages the postdoctoral scholar in their external start-up activities. A COI management plan should be established that adjusts the individual's administrative reporting line or assigns independent oversight, as the faculty member may not be in the most objective position to assess whether the postdoctoral training and the activities within the start-up company are in conflict and whether the external activities are interfering with or detracting from the individual's University responsibilities and engagement in postdoctoral training. The faculty member must submit the completed signed management plan to their College Dean, the Office of Postdoctoral Affairs and to SBU's Conflict of Interest Administrator in the Office of the Vice-President for Research. If postdoctoral scholars or students participate in university research, even if sponsored by or involving a faculty member's start-up company, it is considered university activity (and effort) in which the individual is engaged. Conversely, if they are engaged on the company side of research (e.g., serving as a PI or researcher on the company side of an SBIR or STTR award to the faculty start-up company {if they meet sponsor eligibility requirements to serve in that role)), that is considered external activity, and a COI management plan should be considered with respect to their university role and responsibilities. SBU's Conflict of Interest Officer in the Office of the Vice-President for Research should be consulted and can provide guidance around establishing COI management plans for these and similar circumstances.

Please note that specific sponsor policies or requirements, if more restrictive, must be adhered to in addition to university policies and this guidance.

Purchasing Equipment, Materials, Products, or Services from Companies in Which University Investigators Have Significant Financial Interests

The university is obligated to perform due diligence around the selection and/or engagement of subcontractors and vendors, particularly when a faculty member participates in the purchase and/or has significant financial interests in the company. Sufficient documentation is important to support decisions around sole source justifications and/or selection of companies of university employees rather than comparative companies. When justifications involve scientific or technical specialization or superiority, it is critical to engage individuals with the relevant scientific/technical expertise to perform an assessment of the request and aid in the university's decision. If the faculty member (or other individual) has an interest in the selected start-up company being proposed or selected for the purchase by the University the relationship must be disclosed on the vendor selection form, sole source justification form, or bid documentation form (as applicable).

Ensure selection of vendors follows the <u>RF Procurement Policy</u> for RF funded purchases and the <u>SUNY Purchasing and Contracting Procedures (policy)</u> for State funded purchases. Some research sponsors consider conflicts of interest in procurement actions something that needs to be requested of or disclosed in advance to the sponsor or reported to the sponsor. Please engage the Office for Sponsored Research and Conflict of Interest Administrator if there is a request or intent to purchase equipment or services from a company in which a faculty member on the award has significant financial interests.

Please note that specific sponsor policies or requirements, if more restrictive, must be adhered to in addition to university policies and this guidance.

Case Studies

Case Study 1

Question: I am a SBU faculty member with an ownership interest in a start-up company. What are some of the key COI pitfalls to avoid if my start-up company is going to apply for an STTR, with SBU (specifically, my lab) as the research institution partner?

Answer:

- Ensure that your interests in the company have been fully disclosed in myResearch COI; any
 equity (e.g., ownership) interests in a start-up company, even if the value is currently nothing or
 unknown, meet the criteria for "significant financial interest" and need to be disclosed.
- Verify that the sponsor does not have specific prohibitions around such arrangements that you should be cognizant of when planning the research proposal (e.g., ensure that the sponsor does not prohibit the university PI on the STTR from having any financial interests in/with the company that is the prime proposal applicant, etc.)
- Ensure that you have named the PI of the company portion of the research and the university portion of the research, respectively, and that they are not the same individual.
- Ensure that the company has adequate resources to conduct the company portion of the work being proposed, from both technical and administrative standpoints (including but not limited to personnel and effort, place of performance, space and equipment needed to conduct the research, etc.)
- Ensure you have a compliant plan around what exactly the company portion of the work, and
 the university portion of the work, respectively, will entail (including but not limited to
 personnel and effort, place of performance, space and equipment needed to carry out the
 research, etc.); if university resources or equipment are needed for any aspect of the company
 portion of the research, engage OSP to ensure that appropriate agreements and budgetary
 issues are considered
- Reach out to the Director of Research Security to facilitate initiative-taking consideration of the situation, to ensure that the COI can be adequately managed, and a COI plan instituted (if/as needed) for all relevant parties.

Case Study 2

Question: I would like the research administrator in my department to help me prepare the SBIR application my company is going to submit. My company is willing to pay for him/her to attend a workshop on SBIRs and STTRs. Is this appropriate, since SBU is the "university partner" on the SBIR proposal?

Answer: In general, no; university resources (including staff) may not be used for the company's work, including proposal preparation work for SBIRs and/or STTRs. University research administrators and OSP staff could be involved, however, in providing support for the university side of the research collaboration (if applicable), such as preparing the letter of support, budget, and subcontract for the university portion of an SBIR/STTR collaboration.

If, however, the research administrator was engaged in an outside activity and reported as such in their annual report of non-university activities, and engaged as a contractor for the company, this may be permissible. However, all the guidance in this document regarding engaging university employees in outside entities must be adhered to.

Case Study 3

Question: A colleague and I have started a company, and we are ready to apply for an SBIR award. I am a faculty member; my colleague is a full-time staff research scientist in my department. The project will involve a subcontract to SBU, and specifically to my lab. Can my colleague serve as the PI on the company side of the project, while I will serve as PI on subcontract to the university?

Answer: While you may be able to serve as the PI on the SBIR subcontract to the University (if the sponsor does not prohibit it and if the COI is manageable through a COI management plan), the research scientist may not serve as PI for the company side of the SBIR unless he/she reduces their university appointment to no greater than 49%. Eligibility requirements to serve as the company PI for an SBIR require that the individual be primarily employed by the company, which is 51% or greater employment at the company; one cannot be primarily employed by the company and meet these eligibility requirements if they are employed by the university at greater than 49%. Reducing one's university appointment to 49% or less, taking a temporary leave of absences from the university for entrepreneurial pursuit, or assigning a non-University employee to be PI of the company SBIR are ways to ensure that the company SBIR PI eligibility requirements are met. Additionally, if you serve as the PI on the company side, then you are not permitted to work on the project on the company side. Similarly, if your colleague serves as the PI on the company side, then they are not permitted to work on the project on the company side.

Case Study 4

Question: My start-up company is new and very small. I am the only person qualified to be PI, and we will need to use SBU as our collaborating research institution to complete some parts of the research on an upcoming STTR proposal. If I cannot be PI on both the company and research institution side, how can I proceed?

Answer: Consider whether a qualified colleague could truly contribute to the university side of the research collaboration as university PI, with your guidance (and you serving as company PI). If you truly are the only qualified individual to serve as PI on both sides of the research (i.e. company and university), you may wish to consider applying for a different research award mechanism (rather than an SBIR or STTR), such as the NSF I-Corps National Teams grant, or consider mentoring/training a colleague in the research area to be at a point in the near future where they would appropriately have the qualifications to serve as university PI on an SBIR or STTR collaboration with your company.

Case Study 5

Question: I would like my graduate student to work on a research project funded by my start-up company. What are some of the things that I should consider?

Answer: Faculty should consider how the student's engagement with the work might affect the student's academic and/or professional growth; delay publications or graduations. The Student-Faculty Agreement is intended to permit thoughtful and productive engagement of students in faculty enterprises while protecting the academic interests of the students.

Key Contact for Questions on This Guidance

Susan Gasparo, Director of Research Security, Office of the Vice-President for Research (OVPR) David Rubenstein, Graduate Associate Dean, Graduate School Kathleen Ehm, Assistant Dean, Graduate and Postdoctoral Affairs, Graduate School Michael Kinch, Chief Innovation Officer, Stony Brook University

Relevant Policies

Disclosure of External Interests and Commitments

Responsible Conduct of Research (RCR) and Scholarship (RCRS)

Export Control Policy

Business Relationships & Financial Transactions

Use of Campus Facilities

University Procurement of Goods & Services Policy

SUNY Patent Policy

SUNY RF Intellectual Property Policy

New York State Joint Commission on Public Ethics: Public Officers Law §73 and Public Officers Law §74

SUNY RF Sponsored Programs Application Policy

Office of the Provost Outside Consulting Work

Office of the Provost <u>Approval Process for Faculty Members who are Offered Appointments at Foreign</u> and <u>Domestic Institutions</u>

Appendix 1: Student-Faculty Agreement

STUDENT-FACULTY AGREEMENT

Student Engagement in Faculty Enterprises

This Agreement and the guidelines within it are intended to permit thoughtful and productive engagement of students in faculty enterprises, including startup companies and consulting activities, while protecting the academic interests of such students.

As part of Stony Brook University's commitment to the academic pursuits and integrity of its students, the College and Graduate School Deans' offices requires advance notice and approval of student engagement, compensated or uncompensated, in faculty enterprises through receipt and signature of this Agreement. Please submit completed forms to your college dean and to the Graduate School at studentandpostdoc.startup@stonybrook.edu.

(*Faculty member name*) wishes to engage (*student name*) in the following activity:

(Please provide 25-50-word description)

During the period from: (start date, month, and year to end date, month, and year)

Both student and faculty member understand and agree that:

- 1. A conflict-of-interest management plan must be developed and attached to this Agreement when the activity involves (1) a time commitment from the student (paid or unpaid) and (2) the work is not for Stony Brook University or the Research Foundation. The management plan shall describe procedures to be followed by the student and the faculty member for mitigating any conflicts of interest in the direction and execution of the student's primary research responsibilities and academic progress, including: the scheduled hours and location of the activity, a statement that the work will take place outside regular work hours and will not involve University resources, a plan for ensuring that the student's training goals and academic progress will not be negatively affected, and a description of how the proposed activities will benefit the student's professional development.
- 2. Students always have the voluntary choice of whether to participate in faculty enterprise activities. Coercion in any form by faculty is strictly forbidden.
- 3. The work assigned to the student must promote education and professional growth.
- 4. The work of the student must not interfere with his/her academic progress. Publications should never be restricted, and a graduation date should never be delayed because of faculty enterprise or consulting activities.
- 5. The magnitude of student work in a faculty enterprise should be kept to a reasonable level. Specifically, subject to the general limitations specified in item 3, activities should involve no more than one day per week.
- 6. If during the engagement the student finds the enterprise work to be in conflict with academic progress, he/she has the right to cancel the arrangement.

- 7. If during the engagement a professional conflict develops between the student and the faculty member the student may terminate this agreement immediately.
- 8. A faculty member supervising the thesis work of a student concurrently involved in an outside enterprise in which that faculty member has a financial interest cannot be the sole research advisor during the period of the students outside engagement. An additional and disinterested faculty member must be assigned as co-advisor and have primary responsibility for assessing the student's research progress. Similarly, if the faculty member has a supervisory role in a class taken by a student concurrently involved in an outside enterprise in which that faculty member has a financial interest, the faculty member must remove himself/herself from grading the student, thus avoiding potential conflicts of interest in the evaluation of the student's performance. For research courses, grading responsibilities should fall to the co-advisor.
- 9. Students funded on federal grants must deliver the work effort for which they are paid, and faculty enterprise activities may not displace grant-supported work.
- 10. Where possible and reasonable, students should receive professional credit for their work, and they should, where possible, have some contact with the client and investors to facilitate their professional growth.
- 11. Faculty must disclose consulting and enterprise activities as required on conflict-of-interest disclosures, and student engagement in these activities must be explicitly reported to the student's Graduate Program Director. Students subject to university conflict of interest disclosure requirements must also disclose their activity in faculty consulting and enterprise activities.
- 12. The College and Graduate School Deans' offices will maintain copies of signed *Student-Faculty Agreements* and a list of students involved in faculty enterprises.
- 13. The Department Chair will query these students on an annual basis for the duration of the work to ensure that students are engaged voluntarily in meaningful work that does not interfere with their academic progress. The Department Chair will maintain copies of the gueries.
- 14. A fully signed copy of this agreement will be provided to all signatories, the Department Chair or their delegate, and Stony Brook University's Conflict of Interest Administrator in the Office of the Vice-President for Research.

Students have the right to file a complaint with the Graduate School Dean's office if they feel that any of the guidelines outlined in this Agreement are not being followed. The Graduate School Dean's office will review the matter in coordination with the College Dean's office and may seek adjustments in arrangements where necessary or terminate the activity and arrangement. The College and Graduate School Deans will remind the student and faculty member that retaliation of any kind is against Stony Brook University policy and is strictly prohibited.

Student Printed Name	Signature and Date
Faculty Printed Name	Signature and Date
Co-Advisor Printed Name	Signature and Date

Graduate Program Director Printed Name	Signature and Date
Graduate School Dean Printed Name	Signature and Date
Department Chair or their delegate Printed Name	Signature and Date
College Dean Printed Name	Signature and Date

Appendix 2: Postdoc-Faculty Agreement

POSTDOC-FACULTY AGREEMENT

Postdoc Engagement in Faculty Enterprises

This Agreement and the guidelines within it are intended to permit thoughtful and productive engagement of Stony Brook University postdoctoral scholars in faculty enterprises, including startup companies and consulting activities, while protecting the academic interests of such scholars.

As part of Stony Brook University's commitment to the academic pursuits and integrity of its postdoctoral scholars, the College Deans' office and the Office of Postdoctoral Affairs require advance notice and approval of postdoctoral engagement, whether compensated or uncompensated, in faculty enterprises through receipt and signature of this Agreement. Please submit completed forms to your college dean and to Postdoctoral Affairs at studentandpostdoc_startup@stonybrook.edu.

The Agreement applies to scholars appointed in the State and Research Foundation (RF) titles Postdoctoral Associate and Senior Postdoctoral Associate, but also scholars in any other title who are considered to be primarily engaged in postdoctoral training, including for example, some Research Scientists and RF Fellows. These scholars shall herein be referred to as" Postdocs."

(<u>Faculty member name</u>), from (<u>Department name</u>), wishes to engage (<u>postdoc name</u>), appointed in (<u>Department name</u>), in the following activity:

(Please provide 25-50-word description)

This Agreement will begin on (start date, month, and year) and will end on (end date, month, and year). This Agreement may be renewed annually.

By signing this Agreement, both the Postdoc and faculty member understand and agree that:

1. A conflict-of-interest management plan must be developed and attached to this Agreement when the activity involves (1) a time commitment from the Postdoc (paid or unpaid) and (2) the work is not for Stony Brook University or the Research Foundation. The management plan shall describe procedures to be followed by the Postdoc and the faculty member for mitigating any conflicts of interest in the direction and execution of the Postdoc's primary research responsibilities and academic progress, including: the scheduled hours and location of the activity, a statement that the work will take place outside regular work hours and will not involve University resources, a plan for ensuring that the Postdoc's training goals and academic progress will not be negatively affected, and a description of how the proposed activities will benefit the Postdoc's professional development.

- 2. A faculty member who serves as the supervisor of the Postdoc concurrently involved in the outside enterprise in which that faculty member has a financial interest must delegate supervisory responsibility for the Postdoc to an additional and disinterested faculty member (herein referred to as the supervisory designate). The role of the supervisory designate shall also be described in the management plan (as applicable), and their signature in this document will certify their approval of the proposed management plan. Where possible, all future recommendations and letters of reference evaluating the Postdoc's performance must be co-authored by the faculty member and the supervisory delegate in order to minimize potential conflicts of interest.
- 3. Postdocs always have the voluntary choice of whether to participate in faculty enterprise activities. Coercion in any form by faculty is strictly forbidden.
- 4. The work assigned to the Postdoc must promote training and professional growth.
- 5. The outside work of the Postdoc must not interfere with their primary research obligation or academic progress. Publications should never be restricted because of faculty enterprise or consulting activities. The duration of postdoctoral training must not be extended by more than a year due to these additional obligations and may not exceed Stony Brook's maximum allowable time in the Postdoctoral Associate title (5 years for RF and 3 years for State employees).
- 6. The magnitude of Postdoc work in a faculty enterprise should be kept to a reasonable level. Specifically, subject to the general limitations specified in item 5, activities should involve no more than one day per week.
- 7. If during the engagement the Postdoc finds the enterprise work to be in conflict with the responsibilities of their primary appointment and/or academic progress, they have the right to cancel the arrangement with reasonable notice to the faculty member (e.g., two weeks). Cancellation of this Agreement shall not negatively affect the Postdoc's primary appointment.
- 8. Postdoc employees and Postdocs funded on fellowships must deliver the research work and deliverables for which they are compensated, and faculty enterprise activities may not displace this primary research obligation. Time and effort reporting procedures must assure this.
- 9. Where possible and reasonable, Postdocs should receive professional credit for their work, and they should, where possible, have some contact with the client and investors to facilitate their professional growth.
- 10. Faculty must disclose consulting and enterprise activities as required on conflict-of-interest disclosures, and Postdoc engagement in these activities should be explicitly reported. Postdocs subject to university conflict of interest disclosure requirements must also disclose their activity in faculty consulting and enterprise activities.
- 11. The College Deans' office and the Office of Postdoctoral Affairs will maintain copies of signed *Postdoc-Faculty Agreements* and a list of Postdocs involved in faculty enterprises.
- 12. The Department Chair or their delegate will query these Postdocs on an annual basis for the duration of the work to ensure that Postdocs are engaged voluntarily in meaningful work that does not interfere with their academic progress.
- 13. A fully signed copy of this agreement will be provided to all signatories, the Department Chair and Stony Brook University's Conflict of Interest Administrator in the Office of the Vice-President for Research.

Postdocs have the right to file a complaint with the Office of Postdoctoral Affairs if they feel that any of the guidelines outlined in this Agreement are not being followed. The Office of Postdoctoral Affairs will review the matter in coordination with the College Dean's office and may seek adjustments in arrangements where necessary or terminate the activity and arrangement. The College Dean and Director of the Office of Postdoctoral Affairs will remind the Postdoc and faculty member that retaliation of any kind is against Stony Brook University policy and is strictly prohibited.

Postdoc Printed Name	Signature and Date
Faculty Printed Name	Signature and Date
Supervisory Designate Printed Name	Signature and Date
Department Chair or their delegate Printed Name	Signature and Date
Director, Office of Postdoctoral Affairs Printed Name	Signature and Date
College Dean Printed Name	Signature and Date