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Guidelines for Navigating COI Issues when Faculty Start-Up Companies

Engage in University Research

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Purpose

Northwestern is committed to facilitating scientific discovery and advancing knowledge through innovative and translatable research. Translating ideas and intellectual property from the University to the marketplace is a critical component of Northwestern's research program. This process often creates potential or actual conflicts of interest, especially when the mechanism for translation involves entrepreneurship. We must balance promoting innovation and entrepreneurship with preserving our commitment to Northwestern and safeguarding the integrity and objectivity of University research. These guidelines are intended to help Northwestern's research community proactively navigate existing policies that touch areas in which start-up companies and university research intersect.

Introduction

Conflicts of interest (COIs) are inherent in collaborations between the university and companies in which an investigator has Significant Financial Interests (SFIs). COIs may arise when a university employee with significant financial interests in a company (ownership or other) engages in either the company or the university side of the research. Inherent COI concerns include:

- The potential for the research to be viewed as biased or not objective since the investigator may have financial benefit from the outcome of the research due to their relationship with the company and/or intellectual property resulting from the research for which the company would be a likely commercial vehicle;
- The potential for the PI to use university space, personnel and resources to benefit the company portion of the research; 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.

Investigators should disclose fully and timely to the university any and all equity interests in non-publicly traded entities, such as start-up companies, as well as disclose any other financial interests meeting the disclosure threshold for SFIs. Equity interests in non-publicly traded entities, even with zero or unknown monetary value must be disclosed.

These disclosures facilitate the research-related COI review process, in which external interests and relationships of university investigators are assessed to determine whether or not they create an actual or perceived bias in the design, conduct, or reporting of their research.

Please note that specific sponsor policies or requirements, if more restrictive, take precedence over university policies and this guidance.

Subcontracting to and from Faculty Start-up Companies

The university may accept research 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). Northwestern 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 to support decisions around selection of the company (e.g., a sole source justification) is required. When applicable, justifications should stress scientific or technical specialization or superiority in addition to cost considerations.

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In situations where an investigator has significant financial interests in a company engaged in research with the university, consideration is given on a case-by-case basis as to whether or not the investigator may be involved in the university research activity involving the company in which they have significant financial interests. General principles applying to such interactions include ensuring that the conflicted individual not be involved in any way, neither on behalf of the company nor on behalf of 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 under documented agreements that include the terms around 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 if management strategies are in place, including some or all of the following:

- Disclosure of the related financial interests to study team and collaborators
- Disclosure of the related financial interests in presentations and publications arising from the research
- Independent data analysis/independent compliance monitoring

Decisions relative to the involvement of conflicted investigators in university research involving a company in which they have significant financial interests involve consideration 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 human research participant welfare (if applicable) can be protected by COI management strategies.

An investigator may not serve as PI on a university research project involving human research participants sponsored by a start-up company or involving intellectual property licensed to 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 COI management strategies but may generally not serve as PI. Compelling circumstances may include the extent to which the investigator is (by virtue of specialized expertise) best positioned to carry out the research safely.

Considerations as to whether or not research objectivity and human participant safety can be adequately protected by COI management strategies primarily include 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. The Institutional Review Board (IRB) ultimately has responsibility for human participant safety, and will review conflict of interest management strategies associated with IRB protocols and will determine whether the conflict of interest management is sufficient, or if additional conflict of interest management is necessary to protect the rights and welfare of human research participants.

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 set-aside federal funding occurs via two 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 despite the fact that it is not required.

A university is not an SBC and is not eligible to be a direct recipient of 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).

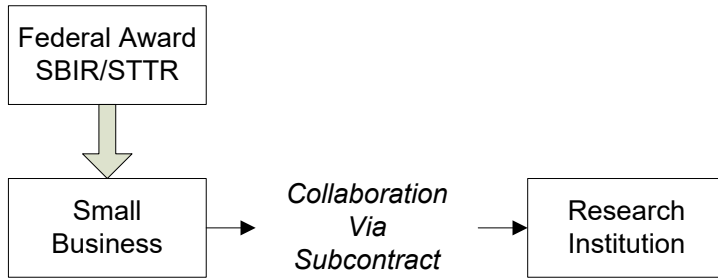
SBC = Small Business Concern

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

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STTRs	
Applicability	Eligibility Requirements
SBC	<ul style="list-style-type: none"> • Must be an American-owned business • Must be independently operated • 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 (Phase I)
Submitting PI	<ul style="list-style-type: none"> • May be primarily employed by either the SBC <u>or</u> the collaborating RI¹
SBC PI	<ul style="list-style-type: none"> • Must have an appointment with or commitment to the SBC in the form of an official relationship between parties
RI	<ul style="list-style-type: none"> • Research Institution collaborator required • Must be one of the following: <ul style="list-style-type: none"> ○ A non-profit college or university ○ 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 • For NSF awards, no person who is an equity holder, employee, or officer of the SBC may be paid under an STTR subaward.

SBIRs	
Applicability	Eligibility Requirements
SBC	<ul style="list-style-type: none"> • Must be an American-owned business • Must be independently operated • Must be a for-profit business • Must have five hundred or fewer employees • <i>If</i> sub-contract with another party, or with multiple parties: <ul style="list-style-type: none"> ○ SBC must do two-thirds of research during Phase I ○ SBC must do at least one-half of research during Phase II

¹ Only 5 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.

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SBC PI	<ul style="list-style-type: none">• Must be primarily employed with SBC. Primary employment means greater than one half of the PI's time is spent in the employ of the SBC.
RI	<ul style="list-style-type: none">• Involvement of RI not required• If the SBC sub-contracts with RI:<ul style="list-style-type: none">○ RI may conduct up to one-third of research during Phase I○ RI may do up to one-half of research during Phase II○ For NSF awards, no person who is an equity holder, employee, or officer of the SBC may be paid under an SBIR subaward.

The Same Individual Serving 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. Although STTR/SBIRs are collaborations, STTR/SBIR policy, instructions, and effort requirements make clear that establishing a separation of entities and roles is important. Having the same person on both sides of the collaboration blurs the respective parties' commitments. Most university researchers are fully committed at the university and do not have the effort available to meet the requirements of serving as the company PI of an SBIR or STTR. Ultimately, an individual may be listed on the SBC budget or the RI budget but not both.

University Personnel Serving as Company PI on SBIRs and as Company PI on NSF SBIRs and STTRs

The PI of the company side of SBIR awards must be primarily employed by the company. For NSF, this requirement also applies to the company side of 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) relative to research in which university is engaged. University employees serving as the company PI relative to SBIRs (or NSF STTRs) in which the university is party to the activity via proposed or contracted collaboration must have a university position or appointment no greater than 49%.

Proposal Preparation for SBIR/STTR Submissions

Department research administrators should help prepare Northwestern's subcontract package but they must not be asked to prepare the company's portion of the submission. The subcontract package must include a statement of work that clearly delineates Northwestern's work on the project. Faculty may not commit the University to participation in an award as a subcontract partner, rather, Sponsored Research must provide the appropriate letter of support on behalf of the institution. If the submitting PI is on the University side, the SBC must provide evidence that an SBC PI exists and that the submitting PI is not named on both budgets.

Use of Northwestern 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 under specific documented agreements between the company and university relative to use of space, equipment, etc. Agreements can take different forms depending on the situation and purpose, such as direct research agreements, testing agreements, manufacturing service agreements, equipment use agreements, memorandums of understanding, collaboration agreements, etc. Sponsored Research can serve as a starting point for helping to assess the appropriate agreement for such arrangements.

For example:

- Use of university core facilities may be allowed under documented 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 documented agreement and payment for use (unless otherwise specified) in accordance with university procedures for use (sign-up, scheduled time, etc.)

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The university takes the following factors into consideration when making decisions regarding company 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 need.
- There must be an active option or license for Northwestern intellectual property.
- Any conflicted university employee cannot be involved in negotiations or any financial or other transactions on behalf of the company (or university) with respect to the arrangement.
- The agreement terms, cost, etc. should be consistent with market considerations and rates.

The Innovation and New Ventures Office (INVO) can serve as a starting point to request company lease of university space, as there are programs and initiatives that support this type of activity. Any agreements between companies and the University should specify terms for intellectual property ownership for any intellectual property developed by the company while using 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 and other online tools and services, must be used in accordance with Northwestern'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 to access or use licensed Library resources.

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

Involvement of Students and Post-Docs in Faculty Start-up Activities

Involving students and postdoctoral fellows in faculty start-up company activities can enhance the academic experience and be valuable to the work. However, these trainee populations are in an inherently vulnerable 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.

Questions to ask with respect to involving students and postdoctoral fellows in faculty start-up activities include, as applicable:

- Will these activities interfere with the student's progress towards degree, graduation timeline or the postdoctoral fellows training timeline?
- Will these activities negatively impact the student's requirements for graduation?
- Will these activities have restrictions that could negatively impact publication of a student's thesis, dissertation, publication work, oral presentations or other requirements for degree completion?
- Is the student or postdoctoral fellow supported by a fellowship, training grant, or other funding mechanism that restricts work on for-profit enterprises?
- Will these activities and the joint external relationship negatively impact the Northwestern advisor/advisee relationship?

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- Would the student's ability to maintain full-time enrollment (whether in coursework or research registrations) be impacted? Students may not receive academic credit for efforts related to the external start-up activities.
- Is TGS's "[Permission to Work](#)" policy applicable? Relative to students that receive University assistance, the policy states that *"Graduate students are expected to be full-time students conducting their studies and research. On occasion another funding opportunity may arise. When that situation occurs permission to receive remuneration must be requested."*
- Are there possible restrictions around engagement in/payment for external activities related to a student's visa status?
- What is the anticipated duration of the start-up activities and how does that align with the student's timeline for graduation?

Prior to engaging students in any faculty start-up company activities, the faculty member should engage in a discussion with the student(s) around the topics included in the [Student-Faculty Agreement - Student Engagement in Faculty Enterprises](#). If a faculty member is the sole research advisor for a student he or she wishes to involve in his or her external start-up activities, a research co-advisor must be identified for the student. A co-advisor works with the student to develop a research topic, formulate ideas and structure, and guides the progress of the thesis/prospectus/dissertation. Per [TGS policy](#), it is the responsibility of the student's academic program to approve the appointment of a co-advisor. If the faculty member and the student mutually agree to proceed with the engagement, the faculty member must submit the completed agreement to their School Dean's Office and [Northwestern's Conflict of Interest Office](#).

Prior to engaging postdoctoral fellows in any faculty start-up company activities, the faculty member should have a discussion with the postdoctoral fellow around the topics included in this guidance. Postdoctoral fellows are considered staff members, and any external activities must be approved in advance by the individual's supervisor. External activities must occur outside of Northwestern work hours and must not involve Northwestern resources. If a faculty member is the primary postdoctoral supervisor and also engages the postdoctoral fellow 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 Northwestern responsibilities and engagement in postdoctoral training.

If postdoctoral fellows or students are involved in Northwestern University research, even if sponsored by or involving a faculty member's start-up company, it is considered university activity. 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), that is considered external activity and a COI management plan should be considered with respect to their Northwestern role and responsibilities. [Northwestern's Conflict of Interest Office](#) should be consulted for guidance.

Use of Northwestern's IRB, IACUC, and CCM Services

Northwestern's Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), and Center for Comparative Medicine (CCM) services are for Northwestern research activities (i.e. research projects awarded or contracted to Northwestern University or its affiliates (NMH, Lurie Children's, and SRALab) directly or through subcontract, and/or other research activities (funded or unfunded) that involve Northwestern researchers acting in their Northwestern capacity.

Northwestern's human research protections and animal care and use programs are heavily federally regulated, and the responsibilities and risks associated with conducting human and animal research are significant. Individuals engaged in Northwestern research involving humans or animals are subject to federal requirements overseen and administered by the IRB, IACUC, and CCM offices. 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 under the pretext of Northwestern research activity *unless* Northwestern is engaged in a particular research project through a subagreement with the company and/or there is a specific documented arrangement between the company and Northwestern. Determinations about whether Northwestern University will engage in an agreement with an external entity for the use of Northwestern's IRB, IACUC, or CCM services are at the discretion of the applicable Institutional Official(s).

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Purchasing Equipment or Services from Companies in Which Investigators Have Significant Financial Interests

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

Ensure selection of vendors for purchases follow Northwestern's [Purchasing and Payment Policy and Procedures](#).

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 Sponsored Research and Northwestern's Conflict of Interest Office 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 prior to proposal submission.

Frequently Asked Questions

1. **Question:** I am a Northwestern faculty member with a new start-up company. How can I avoid key COI pitfalls if my start-up company is going to apply for an STTR or SBIR and Northwestern University will be the research institution partner?

Answer:

- ✓ Ensure that your interests in the company have been fully disclosed in [eDisclosure](#); 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
- ✓ Carefully review the solicitation to verify your PI eligibility (e.g., some sponsors may prohibit the university PI on the STTR from having any financial interests in/with the SBC, etc.)
- ✓ Ensure that the PIs of the SBC and the University portions of the proposal are not the same individual
- ✓ Ensure that your company has the adequate resources to carry out the company portion of the work being proposed (including but not limited to personnel and effort, place of performance, space and equipment needed to carry out the research, etc.)
- ✓ Ensure you have a compliant plan around what 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 SR to ensure that appropriate agreements and budgetary issues are considered
- ✓ Reach out to your school dean's office and/or NUCOI to facilitate proactive 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

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 even willing to pay for him to attend a workshop on SBIRs and STTRs. Is this appropriate, since Northwestern is the "university partner" on the SBIR proposal?

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Answer: No; university resources (including staff) may not be used for the company's work, including proposal preparation work for SBIRs and/or STTRs.² Northwestern research administrators and Sponsored Research staff will 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.

3. **Question 3:** 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 Northwestern, and specifically to my lab. Can my colleague serve as the PI on the company side of the project?

Answer: The research scientist may not serve as PI for the company side of the SBIR unless they reduce 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.

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 Northwestern 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 or not 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), 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.

5. **Question:** Can my lab purchase equipment and/or services from my start-up?

Answer: [Purchasing and Payment Policy](#) dictates that an employee must not be in a position to make a purchasing decision if their personal, professional, or economic interests may be directly influenced or affected by the outcome. A Conflict of Interest attestation will be required when making a purchase and a [sole source justification](#) will be required. When justifications involve scientific or technical specialization or superiority, it is critical to involve individuals with the relevant scientific/technical expertise to perform an assessment of the request and aid in the university's decision.

6. **Question:** What University resources are my start-up able to use?

Answer: University resources may not be used for the activities of a company except under specific documented agreements between the company and Northwestern relative to use of space, equipment, core facilities, personnel, etc. Any proposed company use of University resources must be approved by the University under documented agreements that include the terms around the purpose, duration, cost, and other relevant specifics of such use.

7. **Question:** Can my start-up sponsor research at Northwestern and/or give a gift to Northwestern?

Answer: The university may accept sponsored research agreements from faculty start-up companies and may subcontract research to faculty start-up companies through various funding and award mechanisms, all of which must go through

² University staff can engage in outside work only if/when the following criteria are met: (1) the outside work occurs outside of University time and not using University resources; (2) the staff member's manager provides advance approval that the activity can occur because it does not interfere with or detract from the staff member's University responsibilities; and (3) the activity does not present an unmanageable conflict of interest due to the nature of the staff member's University position and the nature of the outside work. If the staff person to be engaged in such work reports directly to the faculty member whose company the external work is for, the faculty member's dean's office must provide advance approval and if approved, a COI management plan must be instituted for the staff member.

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Sponsored Research. Gifts are not the appropriate mechanism for start-ups to engage in research collaborations with the University.

Key Contact for Questions on This Guidance:

[Northwestern's Conflict of Interest Office \(NUCOI\)](#)

nucoi@northwestern.edu

847.467.4515

Internal Resources:

- [Policy on Conflict of Interest and Conflict of Commitment](#)
- [Policy on Conflict of Interest in Research](#)
- [Policy on Institutional Conflict of Interest in Research](#)
- [Guidelines on Facilitating Research where Institutional Conflicts of Interest Exist](#)
- [One-Page Guidance on Research COI Process](#)
- [Office for Sponsored Research Subcontracts Policies](#)
- [The Graduate School Policies](#)
- [Purchasing and Payment Policy and Procedures](#)
- [Patent and Invention Policy](#)
- [The Innovation and New Ventures \(INVO\) process](#)
- INVO offers periodic workshops and presentations on topics related to those covered in this guidance; refer [here](#) for more information and/or [contact INVO](#) for details

External Resources:

- [Federal SBIR and STTR Program](#)
- [Federal Online Tutorial](#)

Other Relevant Northwestern Offices:

- [Sponsored Research \(SR\)](#)
- [Innovation and New Ventures \(INVO\)](#)
- [The Graduate School](#)
- [Office of General Counsel \(OGC\)](#)