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SBIR/STTR Grants

ome guestions to consider and University resources to help you find the answers.

INTELLECTUAL PROPERTY	Does your application involve a discovery created at Northwestern?		Does the award application require an IP Management plan?		
	If yes, it's important that, in advance of any public discussion regarding your invention, you formally disclose it to INVO to ensure IP coverage. For questions or more urgent matters, be sure to email your Invention Manager (IM) directly.		STTR awards may require awardees to have an IP management plan in place with the university. Be sure you understand the IP rights as set forth in the IP management plan or option/license agreement in place.	-	
	How to disclose an INVO EMAIL: invention invo@northwestern.edu		Company may not be able to commercialize without an executed license/rights from the university. Contact your IM at INVO.		
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На К	Have you filed a disclosure in eDisclosure for conflict of interest (COI) review?				
CONFLICT OF INTEREST UBCONTRACTED WORI	COI is usually manageable in SBIR/STTR Phase I and II with o	a p	proper plan in place. How to complete a COI eDisclosure		
	If you have a relationship with the company, it is best practice to disclose such relationship before your SBIR/STTR application is submitted. A COI management plan must be in place prior to beginning the work under either award.		A COI management		
	SBIR/STTR application? PI through a subaway		For both SBIRs and STTRs, if you are serving as the PI through a subaward to the University, the company	d to the University, the company	
	SBIRs require the PI to be primarily employed by the company; the university appointment cannot exceed		must still complete 40% of the effort. Who will you rely on to complete that work?		

SBIRs require the PI to be primarily employed by the company; the university appointment cannot exceed 49%.

If you wish to serve as the PI and maintain your role as full-time faculty, you must submit an STTR. No reduction in appointment is required for STTRs.

If you are considering taking a reduction in time as faculty to focus on the company, whether as a PI not, prior approval is required. Discuss any reduction of appointment with your dean's office. Most often it is the associate dean for faculty affairs.

Who will serve as the Company Contact?

You get to pick one "hat" to wear for an SBIR/STTR application – you can either represent the company or your lab – but not both. You cannot be on both sides of the budget.

Can we request a F&A waiver for cost reduction for the company?

Waivers are seldom granted. However, the faculty member's Research Administrator (RA) can submit an F&A waiver request for the subcontract to the university.

Because these are federal awards, it is advised that companies budget for F&A in their proposal and not rely on the granting of a waiver.

If you have formed a company with a postdoc or other lab member, for them to serve as PI of an SBIR submission, they need to reduce their appointment to no more than 49%.

Note that this time reduction may compromise their access to university employee benefits (like health insurance). Trainees, including postdocs, should not be coerced into this role.

Can my graduate students work on subcontracted work?

Trainees in the lab need to be able to publish to move forward in their own careers. Be mindful of who is involved in any subcontract work to avoid hindering their progress.

Where do I start entering a proposal for an SBIR/ STTR submission?

All grants should be submitted on InfoEd.

Where do I go at Sponsored Research?

Sponsored Research staff are organized into "Capsules." Description of staff functions can be found here. To find your NU Capsule, visit this interactive site.

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What if my proposal involves Human Research?

In SBIR/STTR proposals where a subaward will conduct Human Research, the proposed primary applicant (i.e. the company) is **always** also engaged in Human Research.

A Single IRB must provide review for both the prime and the subaward. **External entities or parties** (such as industry/commercial entities, start-up companies or physicians' private practices) may not use Northwestern University's IRB services without a formal agreement in place prior to the initiation of research activities.

Federal regulations require the prime applicant to file a Federalwide Assurance (FWA) to receive an award that involves Human Research.

Submit your proposal for a <u>Single IRB Consultation</u> at least 2 weeks prior to proposal deadline for review and to obtain a Single IRB Letter of Support from the Northwestern IRB.

The Northwestern IRB Office will assist you with identifying an external IRB to serve as the single IRB, which includes obtaining a quote for the cost of IRB review. The prime must obtain approval from the external IRB to list them as their designated IRB on their FWA.

Are there potential Export Control issues?

Company needs to negotiate these terms out of any award. Contact COI.

What are the top concerns over DOE and DOD SBIRs/STTRs?

DOD and DOE grants can often be complicated applications and require certifications and cross-referencing. One example is cybersecurity requirements. Because Northwestern may not be able to agree to certain security requirements, it is critical to understand and confirm all aspects of the grant's requirements. Contact SR

NORTHWESTERN WEBSITES & AVAILABLE GUIDES & BOILERPLATE DOCUMENTS

INVO: invo.northwestern.edu (List of University Commercialization Programs and Resources, IP Agreements, Support Letter, etc.) COI: northwestern.edu/coi (COI Management Plan,

Startup Guide for COI) SR: osr.northwestern.edu (Letter of Endorsement, Classified information Plan, Standard Research Agreement Template for subaward) IRB: irb.northwestern.edu

RESTRICTIONS OR CONSIDERATIONS

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CONTACT IRB

What's your strategy for preparing the proposal? Who will you rely on to submit your grant?

The company is the primary applicant for SBIRs and STTRs.

University pre-award staff cannot support the submission of your company's proposal.

Your department staff work for Northwestern, not your company. They cannot help the company with the company's grant submission, but they can help with Northwestern's subcontract package.

What other resources can you leverage to support the company?

Be prepared to describe resources in your proposal that are available through your affiliation or externally, like incubators and accelerator programs.

Northwestern's Querrey InQbation Lab in Evanston

Other Chicagoland incubators and accelerators include:

- mHUB: Hardtech and manufacturing incubator
- MATTER: Healthcare incubator
- <u>1871</u>: Chicago accelerator

INVO also offers support to faculty startups that have licensed Northwestern technology through Startup Toolkit credits and access to NU Core Facilities at a discounted rate.

Donald Pritzker Entrepreneurial Law Center (DPELC) offers startups legal services by law students under the supervision of clinical faculty and staff:

FAST Center of IL

levels of help

External Sources of Proposal Support

SBIR Consultants with various

Who is the target customer and what's the status of the commercial market?

Even on a Phase I, it is important to understand the market and customer.

For Customer Discovery: NCATS@ICORPS, Great Lakes Region NSF I-CORPS and I-CORPS at Polsky

For Business Plan and Therapeutics Data Package: INVOForward Program

For Market Analysis, NU faculty, staff and students may use the NU Library to access free market research platforms (e.g. BCC Research, MarketResearch, IBISWorld).

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EXTERNAL SOURCES