

# SBIR STTR GRANTS: COI MANAGEMENT, INDEPENDENT DATA CONFIRMATION

## OVERVIEW

PHASE I	PHASE II
Phase 1 grant term is 6 months-1 year and usually no more than \$150K in total between company and University. Sometimes federal sponsor can increase this amount. Awarded to the company, where University can be a sub-awardee. Often characterized as “feasibility studies”.	Full R&D project with up to \$1M in funding (combined for company and University) for up to 2 years. Awarded to company, subaward to University. There are also Phase IIb grants, which requires a Phase II previously completed.

\* In accordance with NSF regulations for all NSF SBIR/STTR grants, regardless of Phase, UNC Lead PI of subcontract cannot have a FCOI (see NSF Program Solicitation, Eligibility, Subawards). NSF will review exceptions on case by case basis only, by petition from the Company/Small Business Concern

### NOTES:

1. All of the guidelines are predicated on animal or bench studies only. If human studies are involved, additional management and/or change in roles may be required as determined on a case by case analysis. Additionally, Institutional COI may also occur in human studies in addition to individual COI and further review might be necessary.
2. F/COI means someone whose relationships have been determined to be a COI (conflict of interest) or which meet the federal definition of a FCOI (financial interest which could directly and significantly affect the design, conduct and report of the research).

### **Independent Data Confirmation:**

A Data Confirmation Report will be required of the grants as listed below and may be requested by a COI Chair or Committee during the course of the review. This standard will be stated in the UNC Lead PI’s COI Finalization letter if required and copied to the applicable Chair. The UNC Lead PI will be responsible for initiating the Data Confirmation Report and transmitting it to the Department/Unit Chair, along with the supporting documents. The Department/Unit Chair will need to complete the Report and return it to the UNC Lead PI, with a copy to [coi@unc.edu](mailto:coi@unc.edu).

The Data Confirmation Report consists of a series of questions. The questions include viewing the data management plan, confirming the storage of the data and similar topics. A blank version of this form is housed on the Office of Sponsored Projects website for SBIR/STTR grants and also available from the COI Program.

The Data Confirmation Report will be required as part of the UNC Lead PI’s submission to OSR for either the interim or final reporting stages.

## **SBIRs**

**Overall PI must be company employee of at least 51%; cannot also working at the same time as a UNC employee on the SBIR grant (aka both sides of the grant).**

**NOTE: It means this individual (Overall PI) has final responsibility for data integrity and analysis. UNC employee cannot be Signing Official (SO) representing company with federal Prime.**

	<b>Scenario #1</b>	<b>Scenario #2</b>	<b>Scenario #3</b>
<b>Grant w/F/COI status</b>	<b>SBIR Phase I or II: UNC LEAD PI, NO F/COI</b>	<b>SBIR Phase I UNC Lead PI F/COI</b>	<b>SBIR Phase II UNC LEAD PI F/COI*</b>
<b>UNC Lead PI</b>	No action needed.	UNC Lead PI could have F/COI*; standard management terms and any additional as determined by applicable COI committee/chair at the time of award, including data report.	UNC Lead PI could have F/COI*; standard management terms and any additional as determined by applicable COI committee/chair at the time of award, including data report
<b>Additional Oversight</b>		If UNC Lead PI has F/COI, Unit Chair and Admin Unit Head will be copied on the COI Finalization letter to provide an alert regarding the conflict.	If UNC Lead PI has F/COI, Unit Chair and Admin Unit Head will be copied on the COI Finalization letter to provide an alert regarding the conflict.
<b>Co-Investigators</b>	Co-investigator can have F/COI; standard management terms plus any additional as determined by applicable COI committee/chair at the time of award.	Co-investigator can have F/COI; standard management terms plus any additional as determined by applicable COI committee/chair at the time of award.	Co-investigator can have F/COI; standard management terms plus any additional as determined by applicable COI committee/chair at the time of award.

**STTRs:** In keeping with federal guidance, the Overall PI (aka Scientific PI) can be the Lead Principal Investigator at the University. This role is different from the Signing Official (SO) for the Company. UNC Lead PI or UNC employee cannot be Signing Official representing company with federal Prime.

	<b>Scenario #1</b>	<b>Scenario #2</b>	<b>Scenario #3</b>	<b>Scenario #4</b>
<b>Grant w/FCOI status</b>	<b>STTR Phase I or II COMPANY PERSON IS OVERALL PI; UNC Lead PI, NO F/COI</b>	<b>STTR Phase I or II COMPANY PERSON IS OVERALL PI; UNC Lead PI F/COI</b>	<b>STTR Phase I or II UNC Lead is OVERALL PI, with NO F/COI</b>	<b>STTR Phase I OR II UNC Lead is OVERALL PI, And YES has F/COI</b>
<b>Overall PI</b>	Overall PI has to be company employee of at least 51%; cannot also be UNC employee on grant.	Overall PI has to be company employee of at least 51%; cannot also be UNC employee on grant.	Yes to Overall PI, no to SO role.	Yes to Overall PI and has F/COI, no to SO role.
<b>UNC Lead PI</b>	No F/COI for UNC Lead PI, no action necessary.	UNC Lead PI could have F/COI; standard management terms and any additional determined by applicable COI committee or chair at award, including data report. .	No F/COI for UNC Lead PI, no action necessary.	UNC Lead PI could have F/COI; standard management terms plus below and any additional determined by applicable COI committee/chair at the time of award. Copy to Unit Chair and Admin Unit Head.
<b>Additional Oversight</b>		If UNC Lead PI has F/COI, Unit Chair and Admin Unit Head will be copied on the COI Finalization letter to provide an alert regarding the conflict.		If UNC Lead PI has F/COI and is Overall PI, then an Independent Data Confirmation Report will have to be completed by the Unit Chair.
<b>Co-Investigator</b>	Co-investigator can have F/COI; standard management terms plus any additional determined by applicable COI chair or committee at the time of award.	Co-investigator can have F/COI; standard management terms plus any additional determined by applicable COI chair or committee at the time of award.	Co-investigator can have F/COI; standard management terms plus any additional determined by applicable COI chair or committee at the time of award.	Co-investigator can have F/COI; standard management terms plus any additional determined by applicable COI chair or committee at the time of award.