Objectives

- Provide background on SBIR & STTR Programs
- Explore allowable UNC personnel scenarios under UNC Subaward and with Small Business Concern
- Detail key elements in OSR review process at pre-award and post-award stages
- Share Best Practices
Background & Overview
SBIR - Small Business Innovation Research
STTR - Small Business Technology Transfer Research

SBIR/STTR programs encourage small business concerns (SBCs) to compete and receive federal funding to undertake research & development activities, especially those with potential for technological innovation and commercialization.

- Eligible SBCs are U.S. based for-profit companies with no more than 500 employees and are more than 50% owned or controlled by U.S citizens or permanent residents.
- Codified at 15 U.S. Code 638: Research & Development
• Awarded via grants or contracts from federal agencies such NIH, CDC, FDA, NSF, DOD, and more.

• Consists of 3 phases:
  o **Phase I – Feasibility and Proof of Concept**
    Generally, for 6-12 months and funding up to $250,000
  o **Phase II – Research/Research Development**
    Generally, for up to 24 months and funding up to $1,000,000
  o **Phase III – Commercialization***

• SBC is *always* the applicant and prime recipient of the federal grant or contract; subaward agreement is issued to a Research Institution (RI) for its portion of the work.
Key Differences between SBIR & STTR Programs

SBIRs
- SBC *may* partner with a RI, but is not required
- SBC must do 66% of research for Phase I; 50% for Phase II
- RI may conduct up to 33% of research for Phase I; up to 50% for Phase II
- Principal Investigator (PI) *must* be primarily employed (over 50%) by SBC

STTRs
- SBC is *required* to partner with a RI for a portion of the award
- SBC must conduct at least 40% of research, RI at least 30% of research
- Overall PI *may* be primarily employed (over 50%) by RI
  - Effort covered under Subaward to RI
  - Exceptions may apply, such as NSF
UNC Personnel scenarios under UNC Subaward and with SBC
Why are these important?
Conflicts of Interest (COI)

- Individual COI
- Institutional COI
• Individual COI – situations in which financial or other personal considerations may compromise, involve potential for compromising, or may have appearance of compromising a Covered Individual’s objectivity in meeting UNC duties or responsibilities, including research activities.
  • Relevance to SBIR/STTR Programs
    • UNC Faculty and Staff could generate intellectual property (IP) over the course of their duties and research, create a start-up company, thus have potential to have a relationship with company
    • Relationship defined as: holding equity, family relationship, inventor of IP licensed to company, management position, consulting
Disclaimer

• Scenarios assume animal subjects or bench studies. For projects involving human subjects research, additional management and/or a change in role (from PI to Co-Investigator) may be required and determined on a case-by-case basis.

• Allowability determinations are in general terms
  • Allowability and additional considerations/requirements may vary
  • Confirmed at time of award by COI Program
PI Scenarios: #1

UNC employee is PI of SBIR/STTR Subaward to UNC and has no relationship with SBC

Allowable with no additional considerations, provided:

- SBC employee is Lead PI of the SBIR/STTR
- SBC employee is not also a UNC employee
UNC employee is PI of STTR Subaward to UNC and Overall PI of STTR award

Allowable with no additional considerations, provided:

- UNC employee has no relationship with SBC
- Effort must be covered under UNC Subaward
  - Check funding opportunity announcement (FOA) or sponsor guidelines for PI effort minimum requirements
  - 1% minimum effort should be clearly delineated for role of Overall PI for the scientific and technical matters of the project
- UNC Scope of Work must include a statement for UNC employee's role as Overall PI
UNC employee is PI of SBIR/STTR subaward to UNC and has a relationship with SBC

Allowable with additional considerations:

- SBC employee is Lead PI of the SBIR/STTR and is not also a UNC employee
  - Exception, if UNC PI is Overall PI of STTR project
- For relationship with SBC, UNC employee must have
  - Activities with SBC pre-approved as an EPAP
  - COI management plan in place
- Funding agency does not prohibit someone with equity or a paid position under SBC from being the UNC Subaward PI
UNC employee reduces UNC FTE <50% to work for SBC

Allowable with additional considerations:

• Effort reduction cleared with Department Chair
• If UNC employee has a relationship with SBC
  ○ Must have activities with SBC pre-approved as an EPAP
  ○ COI management plan in place
• UNC employee cannot also serve as PI of the SBIR/STTR Subaward to UNC
  ○ Cannot be listed as Lead PI in Ramses
  ○ UNC Subaward PI cannot be a subordinate to UNC employee who is PI for SBC or have any affiliation with SBC
• UNC employee with reduced FTE cannot engage at UNC under UNC subaward
Other UNC Personnel Considerations

**Graduate students**
- Allowable* at UNC, but no dissertations can occur
  - May require additional COI requirements if PI or other investigators have relationship with SBC
- Allowable at SBC unless
  - Faculty Advisor or dissertation committee member owns or has a relationship with SBC

**Postdoctoral researchers**
- Allowable* at UNC as budgeted
- Allowable at SBC, provided that
  - Effort reduction is approved by Office of Postdoctoral Affairs
  - Faculty advisor does not own or have a relationship with SBC
  - Also subject to EPAP policy
Other UNC Personnel Considerations

UNC Faculty and Staff

• Allowable at UNC as budgeted
• At SBC
  o Unallowable as EPAP (EHRA) or Secondary Employment (SHRA)
  o Allowable with FTE reduction
    ▪ Requires OHR approval
    ▪ Unless supervisor has relationship/COI with SBC
General rules

- UNC employee, including UNC Subaward PI, **cannot** be an Administrative or Signing Official or contact person on behalf of SBC for funding agency
- COI policy applies to all UNC employees regardless of COI status
Key Elements in OSR Review
Scope of Work

• Provide substantive detail to reflect UNC’s activities for the project

• If UNC employee is the Overall PI for STTRs, the SOW **must** have an explicit statement that the Overall PI role is only for technical and scientific matters and UNC faculty member will **not** oversee administrative activities on behalf of SBC
Detailed Budget

- F&A waived for Phase I proposals, full F&A (55.5%) for Phase II proposals

- UNC total budget should be consistent with % of research effort for RI based on anticipated funding limits indicated in FOA/proposal guidelines
  - Example: SBIR – Funding limit Phase I $250,000, Phase II $1,000,000
    - UNC portion = Phase I up to $82,500 (~33%), Phase II up to $500,000 (~50%)
  - Should not exceed funding level in guidelines without funding agency approval
SBIR/STTR Letter of Intent (LOI) template

- Required use of UNC LOI template
- Outlines important details for SBC if SBIR/STTR is awarded
  - SBC and UNC must negotiate a subcontract
  - UNC requires a copy of the prime proposal submission
  - SBC will need to provide certain certifications upon award
Copy of final application package submission
• Required prior to execution of Subagreement

Review and negotiate a Subagreement to UNC
• Recommend using [UNC SBIR/STTR Subagreement Template](#)
• Substantive edits could prolong negotiations, especially to IP section which require consultation with Office of Technology Commercialization (OTC)
• Prime Award
  • UNC email addresses and UNC personnel must **not** be listed on prime award as an AOR or SBC contact
    • Exception if UNC PI is the Overall PI of STTR
Post-award Review (cont.)

Required SBC Certifications
• Must be registered do business in NC with a non-UNC Address
• SBC personnel (PI, administrative, financial, signing authority) must not be UNC employee(s) or spouse of UNC employee(s)
• SBC certifies these assurances at Exhibit C - Certifications in UNC Subagreement template
  • If using a non-UNC template, these certifications must be incorporated

COI reviews in Ramses
• Must be completed by COI Program prior to execution
Best Practices & Resources
Best Practices

- Use available resources, especially OSR SBIR/STTR Webpage, when planning UNC participation on these types of programs at pre-award and post-award stages.
  - SBIR/STTR Administrative Guidance
- Review the specific funding agency solicitation or FOA for limitations and requirements for RI in conjunction with SBIR/STTR Administrative Guidance.
- Provide SBC contact with the link to UNC Webpage, especially Subagreement template.

Communication is key!
- Department Administrator or PI should promptly notify OSR if SBIR/STTR is funded via email to ResAdminOSR@unc.edu
- Don’t be afraid to ask questions
UNC Resources

- **Office of Sponsored Research (OSR)** [SBIR and STTR Programs](#) webpage
- OSR Central Email: [ResAdminOSR@unc.edu](mailto:ResAdminOSR@unc.edu)
  - Email assigned Sponsored Projects Specialist (SPS) directly
- Office of Technology Commercialization Central Email: [otc@unc.edu](mailto:otc@unc.edu)
  - [OTC Guide for Employees](#)
- COI Program Central Email: [coi@unc.edu](mailto:coi@unc.edu)
  - [Conflicts of Interest](#)
External Resources

• SBIR.gov - https://www.sbir.gov/about
• National Institutes of Health - https://sbir.nih.gov/
• National Science Foundation - https://seedfund.nsf.gov/about/
Questions?
1. **SBIR/STTR will need to be registered with the NC Secretary of State before we issue the award?**
   The SBC must be registered to do business in NC before UNC can execute a Subagreement. If OSR finds that SBC is not registered in NC at time of award, SPS will notify SBC of the need to register with NC and ask the SBC to provide proof of registration prior to routing Subagreement for execution.

2. **Should SBCs reach out to OSR with a JIT to prepare for the subaward, or wait until receipt of a NOA?**
   We recommend waiting until receipt of a NOA. PI and/or Department can provide SBC with a link to UNC’s SBIR/STTR Subagreement template to review upon receipt of JIT to help expedite negotiations once awarded.