



Research
Administration
Support

Demystifying the COI Requirements and Process for Industry-Funded Research

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Agenda

- Overview
 - What is a research-related conflict of interest (COI)?
 - Key types of industry-funded research
- Key considerations
- Approaches for management
- What to expect at the proposal stage
- What to expect at the award stage
- What to expect for the duration of the project
- Proposal and Award Process
- Appendices: Resources and SBIR/STTR Checklist

Overview

- What is a research-related conflict of interest (COI)?
 - A research-related conflict of interest arises when an individual has a financial interest that could influence—or appear to influence—the objective design, conduct or reporting of research
 - Perception of COI as important as real COI
 - What are these possible behaviors?
 - Design the research to yield favorable outcomes
 - Use students, Cornell resources, make other decisions that unduly favor the company
 - Manipulate the results to benefit the company

Overview

- Main types of COI in research where industry is involved
 - Direct Company Funding
 - A member of the research team—or their immediate families—has a financial interest (e.g., consulting, management role, equity) in the company sponsoring the project
 - STTR or SBIR, Phase I or II
 - A member of the research team—or their immediate families—has a financial interest (e.g., consulting, management role, equity) in the company seeking proof-of-concept funding from the federal government via the STTR or SBIR program
 - Funds to company (subcontract or purchase of goods or services from a company)
 - A member of the research team—or their immediate families—has a financial interest (e.g., consulting, management role, equity) in the company that will provide paid services or goods for the project

Key Considerations

Type of Funding	Considerations
Direct Company Funding	<ul style="list-style-type: none">• Direct effect of the outcomes of research on the company's success• Research could be narrowly designed to benefit the company• Researcher is decision maker on both sides; accountability is unclear
SBIR/STTR Phase I	<ul style="list-style-type: none">• Early stage proof of concept; typically need university involvement• Potential mitigation of concerns due to:<ul style="list-style-type: none">• Small \$ amount (<\$150k/year) and short duration• Federal government oversight built in
SBIR/STTR Phase II	<ul style="list-style-type: none">• Federal support and oversight, but larger \$ amount (<\$500k/year)• Close to commercialization → results of study may be used to promote a product → \$ in the company's pocket
Funds to company	<ul style="list-style-type: none">• Ensuring that the purchase/subcontract is appropriate and justified

Approaches for management

Funding	Considerations	Conflict Management Approaches
Direct Company Funding	<ul style="list-style-type: none"> • Perception of bias • Use of Cornell resources • Use of Cornell staff/students 	<ul style="list-style-type: none"> • Appoint a non-conflicted Co-PI • Appoint a Conflict Manager (usually Dept Chair) • Transparency: disclosures • Protect students
SBIR/STTR Phase I	<ul style="list-style-type: none"> • Separation of company/Cornell role • Federal support, small \$, oversight built in 	<ul style="list-style-type: none"> • Conflicted investigator cannot serve as both the company PI and the Cornell PI, but can serve as the only Cornell PI on the project • Management plan, Conflict Manager, disclosures, periodic check-in
SBIR/STTR Phase II	<ul style="list-style-type: none"> • Larger \$ amount • Close to commercialization 	<ul style="list-style-type: none"> • Additional controls : <ul style="list-style-type: none"> • Ensure that proposal does not commit Cornell to unacceptable terms • Appoint a non-conflicted Co-PI • Management plan, Conflict Manager, disclosures, periodic check-in • Co-PI and Conflict Manager review budgets and financial reports
Funds to company	<ul style="list-style-type: none"> • Purchase/subcontract is appropriate and justified 	<ul style="list-style-type: none"> • Disclosure to sponsor that includes justification • Approval by Conflict Manager

What to expect: proposal stage

Type of Funding	OSP will look for the following in the proposal package:
Direct Company Funding	<ul style="list-style-type: none"> • Role of any company personnel involved in the project • Cornell locations where work will be conducted • OSP will refer to COI office to ensure there are no concerns • COI office may ask for clarification from the conflicted PI • Proposal likely to go forward; with the expectation that there will be a management plan when the award comes in
SBIR/STTR Phase I	<p>Same as for Direct Company Funding, plus:</p> <ul style="list-style-type: none"> • The proposal from the company to the sponsor (when available) • Assurance that the PI for the company's proposal to the sponsor is not the Cornell PI for the subaward • Conflicted Cornell investigator's relationship with the company
SBIR/STTR Phase II	<p>Same as for Direct Company Funding <i>and</i> Phase I, plus:</p> <ul style="list-style-type: none"> • A non-conflicted Cornell Co-PI • Review by Department manager and Chair
Funds to company	<ul style="list-style-type: none"> • None required, but if the purchase or work is written in the proposal, a disclosure to the sponsor may be appropriate

Note: If this information is not available before the submission, OSP may proceed to submit the proposal but reserves the right to withdraw or seek to amend the proposal or negotiate award terms.

What to expect: award stage

Type of Funding	At Point of Award Acceptance
Direct Company Funding	<ul style="list-style-type: none"> • OSP will seek COI clearance • COI office will work with PI to implement a Conflict Management Plan and appoint a non-conflicted Co-PI • COI committee will review and approve the management plan (takes time) • A Conflict Manager will be appointed • A process for periodic oversight, including budget review will be established • Disclosures and other controls are part of the management plan
SBIR/STTR Phase I	<p>Same as for Direct Company Funding (excluding the Co-PI requirement), plus:</p> <ul style="list-style-type: none"> • Advance spending on the award is not allowed • Company personnel and resources may not use Cornell facilities/resources besides those available to the public, or fee-for-use, or as agreed in the award • Administrative Director are informed
SBIR/STTR Phase II	<ul style="list-style-type: none"> • Same as for Direct Company Funding (including Co-PI) <i>and</i> Phase I
Funds to company	<ul style="list-style-type: none"> • None; only applies at the time of subcontract or procurement

Note: If research involves animals or human subjects additional review and conditions may be required by the IRB or IACUC committees. This will take a bit longer.

What to expect: duration of the project

Type of Funding	Post-Award
Direct Company Funding	<ul style="list-style-type: none">• Annual review and update of Conflict Management Plan• Disclosure of relationship made to any new Cornell personnel• Compliance with terms of the plan• Progress of students• Financial reviews
SBIR/STTR Phase I	Same as for Direct Company Funding
SBIR/STTR Phase II	Same as for Direct Company Funding
Funds to company	<ul style="list-style-type: none">• At the time of subcontract or procurement, disclosure to sponsor (COI office writes the letter; OSP sends it to the sponsor)• Disclosure to Cornell procurement• Conflict Manager approval

Proposal and Award Process

- Proposal
 - Provide RFPs (prime (in the case of SBIR/STTR) and company's) to OSP
 - In the proposal cover letter, OSP will acknowledge the relationship between PI and company and advise that all project activities will be conducted in a manner consistent with Cornell's COI policies.
- Post-Proposal/Pre-Award
 - SBIR/STTR: Provide company's prime proposal to OSP after submission to Prime Sponsor (ie. DARPA/NIH/NSF)
 - SBIR/STTR: OSP will work with company to ensure Fundamental Research Determination is included in the Prime Award prior to company executing their award
- Award
 - SBIR/STTR: OSP requires the company to provide them a copy of their prime contract along with the Sponsored Research Agreement

Appendix A: Resources

- [Cornell Policy 1.7, Financial Conflict of Interest Related to Research](#)
- [Cornell Policy 4.14, Conflicts of Interest and Commitment](#)
- [Cornell Guidelines for Managing Conflict of Interest in SBIR/STTR Projects](#)
- [Cornell Guidelines for Managing COI Issues in Faculty Startups](#)

Appendix B: SBIR/STTR Checklist

Phase I

Proposal stage

- Cornell PI may not be the PI on the Small Business Entity's (SBE's) proposal to the funding agency.
- Relationship between SBE and Cornell PI described in the proposal to the sponsor.
- At the time of proposal submission, Cornell PI provides to OSP:
 - A copy of the solicitation;
 - The complete proposal to the sponsor (when available); and
 - The complete proposal and budget for the sub-award to Cornell.

These materials must describe:

- All Cornell locations where the work will be conducted;
- The role of all Cornell personnel involved in the work;
- The role of any SBE employees/representatives involved in the work; and
- Documentation that the SBE has primary operating space outside Cornell.

Appendix B: SBIR/STTR Checklist, cont.

Phase I

Award stage

- Conflict Management Plan (CMP) for the Cornell PI must be in before the sub-award is accepted.
- Cornell PI's Department Manager or Business Officer must be informed
- No advance spending is allowed on these sub-awards.
- Any purchases from, or other payments to, the SBE must be approved by the Conflict Manager.
- All Cornell personnel involved in the project—as well as students' DGSs and Special Committees—must be informed of the Cornell PI's relationship with the SBE.
- Any involvement of Cornell students, staff, or postdocs must be approved by the FCOIC Committee, and milestones for students' progress toward their degrees must be established.
- SBE employees/ reps may not use Cornell facilities or resources other than those open to the public for free, available on a fee-for-use basis, or set aside for entrepreneurial work.
- SBE employees may not be appointed as Visitors, Adjuncts, or Volunteers at Cornell, unless approved by the FCOI Committee.
- Cornell resources may be used only as described in the sub-award, as long as those terms comply with University requirements.

Appendix B: SBIR/STTR Checklist, cont.

Phase II

Proposal stage

- Cornell PI may not be the PI on the Small Business Entity's (SBE's) proposal to the funding agency.
- A Cornell Co-PI must be appointed on the Cornell sub-award. This Co-PI must:
 - Have the same rights and responsibilities as the conflicted Cornell PI
 - Not have a relationship with the SBE
 - Not be a subordinate of the conflicted Cornell PI
 - Be selected by the FCOI Committee, the Cornell PI, and the Conflict Manager
- Relationship between SBE and Cornell PI described in the proposal to the sponsor.
- At the time of proposal submission, Cornell PI provides to OSP:
 - A copy of the solicitation;
 - The complete proposal to the sponsor (when available); and
 - The complete proposal and budget for the sub-award to Cornell.

These materials must describe:

- All Cornell locations where the work will be conducted;
- The role of all Cornell personnel involved in the work;
- The role of any SBE employees/representatives involved in the work; and
- Documentation that the SBE has primary operating space outside Cornell.

Appendix B: SBIR/STTR Checklist, cont.

Phase II

Award stage

Before the award is accepted:

- Co-PI must be appointed
- Conflict Management Plan (CMP) for the Cornell PI must be in before the sub-award is accepted.
- Cornell PI's Department Manager or Business Officer must be informed
- No advance spending is allowed on these sub-awards.
- Any involvement of Cornell students, staff, or postdocs on the project must be approved by the FCOIC Committee, and milestones for students' progress toward their degrees must be established.
- All Cornell personnel involved in the project—as well as students' DGSs and Special Committees—must be informed of the Cornell PI's relationship with the SBE.
- SBE employees/ reps may not use Cornell facilities or resources other than those open to the public for free, available on a fee-for-use basis, or set aside for entrepreneurial work.
- SBE employees may not be appointed as Visitors, Adjuncts, or Volunteers at Cornell, unless approved by the FCOI Committee.
- Cornell resources may be used only as described in the sub-award, as long as those terms comply with University requirements.
- Any purchases from, or other payments to, the SBE must be approved by the Conflict Manager.
- All budgets and financial reports to the sponsor must be reviewed by the Conflict Manager and signed off on by the Co-PI.