Research Conflict of Interest Top
10 Things you should know!

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Disclosure Statement

✓ THE SPEAKERS HAVE $0 FINANCIAL INTEREST.
✓ THE SPEAKERS WOULD LIKE THE AUDIENCE TO BE AWARE THEY HAVE A SIGNIFICANT PERSONAL INTEREST IN EDUCATING STUDENTS, TRAINEES, FACULTY, AND STAFF ABOUT COI SINCE:
Research Conflict of Interest Learning Objectives
Top 10 Things you should know!

1. Types of Conflict of Interest
2. Individual - RAMSeS
3. Organizational
4. Subaward
5. SBIR/STTR
6. Unusual Situations
7. Common Places to Stumble
8. Planning for Success
9. OSR Contact Information
10. COI Program Contact Information
# 1

Types of Conflict of Interest
Three Types of Research Related Conflict of Interest

1. **Individual** – Assessment required for all sponsored or funded research and any human studies. Various federal, state and sponsor specific definitions. COI Policy synthesizes regulations and standards.

2. **Organizational** – Sponsor (federal or otherwise) required certification to determine if University has overlapping research, has an advantage in proposal process or was involved in creating the outlines for funding.

3. **Institutional** – No federal definitions or regulations. Understood to be when Institution owns equity, intellectual property and could financially benefit (immediate or future) from situation, especially as result of research.
Visualizing COI at UNC

- Financial or Personal Interests
- University Duties

- Actual Conflict of Interest
- Potential Conflict of Interest
- Appearance of a Conflict of Interest
**Investigator** means the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

The term "investigator" means the principal investigator, co-principal investigators/co-project directors, and any other person at the organization who is responsible for the design, conduct, or reporting of research or educational activities funded or proposed for funding by NSF.

**FCOI**

Financial Conflict of Interest means a Financial Interest that could directly and significantly affect the design, conduct, or reporting of research.
RAMSeS Individual Conflict of Interest
## RAMSeS Individual Conflict of Interest

### New Submission
- COI disclosures created upon department approval. COI Training required for nearly ALL.
- Individuals supposed to complete before application submitted.
- COI disclosure reviewed upon notice of award “AWARD RECEIVED” status in Ramses.
- If FCOI determined, report submitted to NIH before review moved to completed status.
- “Hard Stop” on funding until COI review and training is completed.

### Non-Competitive Renewal (RPPR)
- 60 days prior to next funding
- Disclosures created w/ department approval
- Personnel list should include all personnel from prior year. Except 1) left UNC or 2) moved off grant.
- Disclosure reviewed immediately upon submission to COI Program.
- If FCOI, “annual” report submitted to NIH before moved to completed.
- **NIH will NOT fund next year of grant if “annual FCOI” report not submitted.**

### Consultants
- The four questions
  - Directly involved in the design
  - Directly involved in the conduct of the project
  - Directly involved in the analysis
  - Directly involved in the reporting
  
Crafted to determine if they meet the federal definition of “investigator”. If yes, subject to COI.

If this person was at UNC, would we list him/her as key personnel, investigator, co-author, etc.?
## The RAMSeS COI Grid

<table>
<thead>
<tr>
<th>Entity</th>
<th>Person</th>
<th>Role</th>
<th>Added Post Approval</th>
<th>AIR ID</th>
<th>Disclosure Submitted</th>
<th>Review Process</th>
<th>Review Result</th>
<th>Review Complete</th>
<th>Training</th>
</tr>
</thead>
<tbody>
<tr>
<td>UNC-CH</td>
<td></td>
<td>Postdoctoral Research Associate</td>
<td>No</td>
<td></td>
<td>×</td>
<td>Unsubmitted</td>
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<td>×</td>
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<tr>
<td>UNC-CH</td>
<td></td>
<td>Project Manager</td>
<td>No</td>
<td>n/a</td>
<td>✓</td>
<td>Staff Review</td>
<td></td>
<td>×</td>
<td>✓</td>
</tr>
<tr>
<td>UNC-CH</td>
<td></td>
<td>Technical Staff</td>
<td>No</td>
<td>n/a</td>
<td>✓</td>
<td>Chair Review</td>
<td></td>
<td>×</td>
<td>✓</td>
</tr>
<tr>
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<td></td>
<td>Technical Staff</td>
<td>No</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
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<td>n/a</td>
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</tr>
<tr>
<td>UNC-CH</td>
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<td>Technical Staff</td>
<td>No</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td></td>
<td>n/a</td>
<td>×</td>
</tr>
<tr>
<td>UNC-CH</td>
<td></td>
<td>Lead Principal Investigator</td>
<td>No</td>
<td>17-33180</td>
<td>✓</td>
<td>Completed</td>
<td></td>
<td>No Conflict</td>
<td>✓</td>
</tr>
</tbody>
</table>
Organizational Conflict of Interest
Organizational Conflict of Interest

Review each category against the proposal for:
1. Unequal Access to Information OR 2. Biased Ground Rules OR 3. Impaired Objectivity

All investigators’ funded projects or proposals

Sponsor’s Funded Proposals or Projects

Any UNC Proposals or funded projects with key project words

Note: OCOI may OR may not be acceptable per sponsor rules. UNC obligated to report. Sponsor final decider.

Need to route IPF to SPO or OSR at least 5 business days in advance of deadline - PLAN for ROUTING TIME
Organizational Conflict of Interest
Pre-Award

**PROPOSAL:**
Any Federal Contracts with FAR 9.5 clause (optional)
Some Grants regardless of Federal, State or Foundation Sponsorship
– Incorporate by reference FAR 9.5, or use other definitions, or don’t define it at all!
Examples: DOD, DOD DTRA, Sloan Foundation, City/State Agencies, CMS, DOJ

Check the Proposal Announcement/RFP when Proposal is RECEIVED. Search by “conflict”. Alert OSR Contact!

**AWARD:** As required by the Sponsor, unique definitions
Examples: PCORI, some NIH, industry partners, Some DOD, States
Organizational Conflict of Interest
Common Questions

Who is covered by UNC’s certification?
• Only UNC personnel. Not Independent Contractors or Independent Contractor Investigators. Not Subs.

Who obtains certifications from Subs at time of PROPOSAL?
• IPF Submitting Department

Is a FDP Clearinghouse Policy Sufficient?
• No. FDP Clearinghouse is for policies on Individual COI, not Organizational COI.
Sub* Awards

* By any name: sub-awardees, subrecipients, subcontractors
Sub Awards Required Coverage for Individuals

Per 42 CRF Part 50, any grant or contract administered through a PHS agency
National Science Foundation AAG Chapter IV, Section A
Any Sponsor who requires that Institution follows PHS/NSF regulations in execution of the contract
Subcontractor Process at Proposal for “Coverage” aka Theirs or Ours?

Internal Processing Form (IPF)

• Additional screen appears when PHS or NSF is sponsor and sub-awards are indicated. Other known agencies being added.
• Must enter each entity name separately
• Must answer YES or NO if the entity has a compliant COI policy. Directions provided to End User on how to confirm if policy is acceptable.
• If Sub does not have a compliant policy, then MUST fall under UNC’s.
Edit Subcontractor Information

Subcontractor: 141 Repellent, Inc.

The proposed subcontractor's scope of work includes the use of animal subjects.  
☐ Yes ☐ No

The proposed subcontractor's scope of work includes the use of human subjects.  
☐ Yes ☐ No

Before responding below, for DHHS please check the Letter of Intent AND the Federal Demonstration Partnership (FDP) website to verify that the proposed subcontractor has a compliant conflict of interest policy. For NSF, please check the Letter of Intent to verify that the proposed subcontractor has a compliant conflict of interest policy.

The proposed subcontractor has a conflict of interest policy that complies with Department of Health and Human Services (DHHS) or National Science Foundation (NSF) standards, as applicable to this subaward.  
☐ Yes ☐ No

Save Subcontractor Information  Close

PHS/NIH or NSF Subcontractor Information in RAMSeS
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SBIR/ STTR Projects
SBIR/STTR
– A Class of their Own

• See presentation from Research Symposium 2019:

• Information on OSR Website – applies to all SBIR and STTR regardless of whether a COI exists
  https://research.unc.edu/sponsored-research/resources/sbir-and-sttr-programs/

• See SBIR/STTR Administrative Guidance worksheet on this page
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Unusual Situations
ALERT: Unusual Situations

• **Sub Contracts to Startups** – Additional COI Review process to determine if Individual COI is present AT PROPOSAL

• **Purchases from Startups**
  Alternative options have to be reviewed

• **PI Eligibility Waivers**
  • Can be part-time UNC employees
  • Can create potentially unmanageable COI situations if the grant subcontracts to their “other” employer.

• **Divided COI Requirement**
  • OCOI at Proposal, Individual COI at Award
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Common Places to Stumble
Common Places to Stumble

5 Business days to OSR/SPO:
IFP is not submitted in a timely fashion

Data Check: Who is named on the Sub Proposal/emails match?

Data Check: Was the right “Emmet Smith” chosen on the personnel list?

Manage: COI disclosures OR trainings are not completed

Know: Subs assume their COI policy is sufficient
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Planning for Success
Planning for Success

- Failure to plan means... plan to have the process delayed
- Arrange easy communication with possible externals early in planning
- Good data at time of proposal is KEY
- Easier with practice
OSR Contact Information
OSR Contact Information

ResAdminOSR@unc.edu

- ResAdminOSR is responsible for all general inquiries, proposal requests, new awards, modifications/amendments, audit requests, and research system access requests.

RAMSeS Help Function: Contact Project-Related Support

- Use this tool if you need to find the appropriate SPS
- Search: Proposal #, Award Project #, Department, or PS Project ID
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COI Program Contact Information
COI Program Contact Information

COI Program Main Website: http://research.unc.edu/offices/coi/
- RAMSeS COI Grid pdf available

General Email for questions: coi@unc.edu

General Phone number: 919-843-9953

Additional Websites:
- UNC Activities, Interests, and Relationships Management System (AIR): http://air.unc.edu
- Required Research COI Training: http://coi-training.unc.edu
CONTACT US

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