Research Conflict of Interest
Top 10 List To Know

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University Conflict of Interest Officer
Director, Conflict of Interest Program
Office of the Vice Chancellor for Research

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Conflict of Interest

Acknowledgement Statement

• The presenter has $0 financial interests to report.
• The presenter would like the audience to be aware she has a significant personal interest in educating researchers and staff about COI since:
Research Conflict of Interest

#1

There are how many types of Conflict of Interest???
3 Types of Research Related COI

Individual - personal or financial interests of researchers and/or staff intersecting with research; numerous federal regulations; mostly seen as PHS/NIH Part 50 or NSF Award Guidelines.

Institutional – No federal definitions or regulations. Understood to be when entity owns equity, intellectual property and could financially benefit (immediate or future).

Organizational – Historically FAR definitions included occasionally for contracts. Uniform Guidance requires federal agencies to have COI policies, so now may apply to grants. UG also requires Institution to have code covering this area for procurement (July 2018).
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#2

Research COI Training

≡

Research COI Disclosure
<table>
<thead>
<tr>
<th><strong>What</strong></th>
<th>Research COI Training</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Who</strong></td>
<td>All UNC personnel involved in the research (admin only exception). Anyone else covered by UNC and paid on grant.</td>
</tr>
<tr>
<td><strong>Where</strong></td>
<td>Coi-training.unc.edu</td>
</tr>
<tr>
<td><strong>When</strong></td>
<td>Must be completed before research funding can begin for award OR when individual added to grant</td>
</tr>
<tr>
<td><strong>Time</strong></td>
<td>Valid for four years</td>
</tr>
</tbody>
</table>
Research Conflict of Interest

#3

Who has to complete a COI Disclosure?
Roles generally determined to be an investigator under PHS/NSF definitions:

- Lead Principal Investigator
- Principal Investigator
- Investigator
- Postdoctoral Research Associate
- Clinical Research Coordinator
- Other Key Individuals (UNC Faculty)
- Independent Consultant Investigator* (non-UNC)
- Fellow
- Fellow (NIH)
<table>
<thead>
<tr>
<th>What</th>
<th>Individual Ramses COI Disclosure Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Who</td>
<td>Specific Roles in Ramses</td>
</tr>
<tr>
<td></td>
<td>(Exceptions – some sponsor require all paid)</td>
</tr>
<tr>
<td>Where</td>
<td>Email link or AIR.UNC.EDU</td>
</tr>
<tr>
<td>When</td>
<td>Completed when received by investigator.</td>
</tr>
<tr>
<td></td>
<td>Reviewed at time of funding.</td>
</tr>
<tr>
<td>How (proposal):</td>
<td>If named, project specific form generated on first department approval.</td>
</tr>
<tr>
<td>How (award):</td>
<td>Individuals added to awards. OSR will add and generate project specific form for email notification.</td>
</tr>
</tbody>
</table>
12. NOTICE OF FAMILY RELATIONSHIPS: Due to IRS reporting requirements, Grantee must notify the Directors of the Faculty Leaders if the individual has any family relationship to an officer or member of the Board of Directors, and if so, the specific relationship. For this purpose, the family of an individual includes only his or her spouse, ancestors, siblings or sisters (whether whole or half blood), children (whether natural or adopted), grandchildren, great-grandchildren, and spouses of brothers, sisters, children, grandchildren, and great-grandchildren.
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#4

What Is the Average Turn Around Time for Reviews?
UNC-CH COI Review Process - 1

Form Submitted

• Submitter must disclose interests for sponsor or any other involved/affected entity

• No activities, interests or relationships indicated, then automatic “no conflict” in AIR system, reflected into IRBIS or Ramses systems

• If potential conflict, either through yes or additional information, considered “potential conflict” and routed in AIR to COI Program.

  – NOTE: In keeping with federal regulations, COI disclosures to be submitted at time of proposal submission. However, Ramses reviews begin when COI Program notified AWARD IS RECEIVED.

Check for Award Received Status in General Tab on IPF
When potential conflict indicated by submitter, COI Program Office does initial evaluation.

Three possible pathways:

A. COI Analysts recommend no conflict to COI Officer

B. COI Analysts send summary of relationships, comments, synopsis of IPF or IRB protocol to applicable faculty Chair for Expedited Review

C. COI Analysts/Chairs/Officer: Decision to assign to Full Committee. COI Analysts prepare case review and supporting material for agendas.
Closing the Loop after Review

• Report submitted to the sponsor if required.
• AIR system is updated with review result
• Items specific to management on human studies included in COI Finalization letter
• COI finalization letter is sent to submitter, copied to PI, and status reflected immediately into Ramses or IRBIS

Average Time: 15 business days. Should allow 4 full weeks, more if going to full committee.
Are there things I can do as a campus user to avoid problems, such as delays?
Common Places to Stumble

- 5 Business days to OSR: 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
How can the COI Program help me?
Here’s What the COI Program

**Can Do:**
- Provide clarification on COI Policy, Procedures and questions on the forms
- Provide analysis on COI requirements in RFPs
- Teach you where & how to check any COI status for your study
- Sync COI training for duplicate PIDs

**Can NOT Do:**
- Add or Inactivate Personnel from Ramses IPF or Award (OSR) - also true for IRBIS
- Change Emails or PIDs (ITS)
- Add Sponsors to a COI Disclosure (OSR add to IPF, then re-issue COI disclosure)
The Ramses 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>Postdoctora Research Associate</td>
<td>No</td>
<td></td>
<td></td>
<td>x</td>
<td>Unsubmitted</td>
<td></td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>UNC-CH</td>
<td>Project Manager</td>
<td>No</td>
<td></td>
<td>n/a</td>
<td>✓</td>
<td>Staff Review</td>
<td></td>
<td>x</td>
<td>✓</td>
</tr>
<tr>
<td>UNC-CH</td>
<td>Technical Staff</td>
<td>No</td>
<td></td>
<td>n/a</td>
<td>✓</td>
<td>Chair Review</td>
<td></td>
<td>x</td>
<td>✓</td>
</tr>
<tr>
<td>UNC-CH</td>
<td>Technical Staff</td>
<td>No</td>
<td></td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>x</td>
<td>✓</td>
</tr>
<tr>
<td>UNC-CH</td>
<td>Technical Staff</td>
<td>No</td>
<td></td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>x</td>
<td>✓</td>
</tr>
<tr>
<td>UNC-CH</td>
<td>Lead Principal Investigator</td>
<td>No</td>
<td>17-33180</td>
<td>✓</td>
<td></td>
<td>Completed</td>
<td>No Conflict</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

This proposal does not involve Animal Research.
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#7

Know your OSR Contact
How do I find their Contact Information

• Top of IPF
• Management approach
• OSR Website – Research Admin area lists the Teams; locate your unit or department
Research Conflict of Interest

#8

Why is Org. COI a concern?
What can you do about it?
## By the Numbers - OCI

<table>
<thead>
<tr>
<th></th>
<th>Reviews</th>
<th>Assessments</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td>FY15</td>
<td>15</td>
<td></td>
<td>15</td>
</tr>
<tr>
<td>FY16</td>
<td>23</td>
<td>5</td>
<td>28</td>
</tr>
<tr>
<td>FY17</td>
<td>52</td>
<td>20</td>
<td>72</td>
</tr>
<tr>
<td>FY18</td>
<td>89</td>
<td>44</td>
<td>133</td>
</tr>
</tbody>
</table>
Organizational COI (OCI)

**PROPOSAL:** Any Federal Contracts with FAR 9.5 clause (optional):
- Unequal Access to Information
- Biased Ground Rules
- Impaired Objectivity

Some Grants regardless of Federal, State or Foundation Sponsorship:
- Incorporates FAR 9.5, use other definitions (or don’t define it)
Examples: DTRA, Sloan Foundation, City/State Agencies, CMS, DOJ

- Check the Proposal Announcement/RFP when Proposal is RECEIVED.
  Search by “conflict”. Alert OSR Contact and/or COI Program.

**AWARD:** As required by the Sponsor, unique definitions
Examples: PCORI, some NIH, industry partners, Some DOD, States
OCI 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.
Are there any other situations that are odd and deserve closer attention?
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**
  - OCI at Proposal, Individual COI at Award
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#10

What are the websites I should know and how do I contact the COI Program?
Key Websites & Contact Info

- Activities, Interests and Relationships: [air.unc.edu](http://air.unc.edu)
- All COI disclosures and External Activities for Pay
- COI Training: [coi-training.unc.edu](http://coi-training.unc.edu)
- Email: [coi@unc.edu](mailto:coi@unc.edu)
- Phone: **919-843-9953**
- Compliance Line - contact anonymously
  
Conclusion

- 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
Additional Pieces to COI Puzzle??
Joy M. Bryde, MSW
Conflict of Interest Officer

Mailing Address:  Conflict of Interest Program
UNC-CH CB 9103

Physical Location:  Bynum Hall, Suite 301D
222 E. Cameron Avenue

E-mail: jbryde@unc.edu
Phone: (919) 843-9953

General Email for questions:  coi@unc.edu