OSR’s Annual Symposium for Research Administrators: Conflict of Interest – The Kitchen Sink Version

July 31, 2014

Joy Bryde, MSW
Conflict of Interest Officer
Conflict of Interest Program
Office of the Vice Chancellor for Research
Conflict of Interest 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:
Who is Covered by the Policy on Individual Conflicts of Interest (COI) and Commitment?

UNC Chapel Hill
Federal Definitions

**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.

**FCOI**

Financial Conflict of Interest means a Financial Interest that could directly and significantly affect the design, conduct, or reporting of research.
Other Universities’ Definitions

University of Michigan
A situation where a faculty or staff member is in a position to influence the business, research, or other decisions of the University in relationship to an outside organization that could lead directly or indirectly to financial gain for that individual or the family of that individual, or give improper advantage to others to the detriment of the University, and could directly and significantly affect the design, conduct or reporting of the research.

Duke University
A financial interest that could directly and significantly affect the design, conduct or reporting of funded research or the performance of duties and responsibilities on behalf of Duke.

Stanford University
A conflict of interest occurs when there is a divergence between an individual's private interests and his or her professional obligations to the University such that an independent observer might reasonably question whether the individual’s professional actions or decisions are determined by considerations of personal financial gain. A conflict of interest depends on the situation, and not on the character or actions of the individual.

University of California Los Angeles
A conflict of interest exists when two or more contradictory interests relate to an activity by an individual or an institution. The conflict lies in the situation, not in any behavior or lack of behavior of the individual.
Visualizing COI at UNC

External or Personal Interests

Institutional Duties

- Actual Conflict of Interest
- Potential Conflict of Interest
- Appearance of a Conflict of Interest
Principles of COI Management

- Transparency
- Honoring the Student/Trainee Experience
- Protecting the credibility of the individual doing the work
How Does the COI Process Get Started?

Disclosure Forms

• Trigger events – created automatically by system upon certification by Department in Ramses OR PI in IRBIS for certain Roles
• Annual – currently created and required for those people in administrative “influence” positions
• Self-identified need to disclose (intellectual property, gifts, changes to information)
• Specific self generated forms (travel, book)
  – Note: Investigators on PHS funded projects only
Why is a Disclosure Required for Each Study or Reviewed for a “Known” Conflict?

- Federal regulation - at the time of application and annually thereafter
- University Policy
- Each study is different even if the “conflict” appears to be the same
  - Different study proposal and scope of work
  - Different people
  - Different drugs
- Result –
  - COI review contextual for research study
  - Human subjects research, informed consent text must be content specific
Research COI Disclosures

IRB (IRBIS)

• Principal Investigator
• Co-investigator
• Faculty Advisor
• Project Manager or Study Coordinator

OSR (Ramses)

• Lead Principal Investigator
• Principal Investigator
• Investigator
• Postdoctoral Research Associate
• Clinical Research Coordinator
• Other Key Individuals (UNC Faculty)
• Independent Consultant Investigator
Independent Consultants (IC)

Regardless of source of funding, any ICs might be subject to COI.

Upon entering name in IPF, a series of FOUR questions are asked.

If IC is determined to be ICi (IC Investigator) then COI process starts.

Frequently ICis are covered by UNC’s policy.
Grants Affected by the Sponsor’s Sub-Recipient Rule

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
How Does the COI Sub Award Process Work at Proposal?

Internal Processing Form (IPF)

- Additional screen appears when PHS or NSF is sponsor and sub-awards are indicated
- Must enter each entity name separately and now answer if the entity has a compliant COI policy. Directions provided on how to confirm.
Directional Decisions

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
If Sub is Using UNC’s COI Policy

• Need to enter principal investigator’s name and email address for subcontractor. **This person will need to complete COI disclosure form at time of proposal** and will need to complete COI training if award is made.
  
  — WARNING: Do NOT enter as an independent contractor investigator

• Additional personnel at sub-award will need to be added upon funding, complete disclosures and training if needed.

• Indicate in the Letter of Intent

NOTE: PIs or Grant personnel need to ask OSR representative for direct help with the IPF and how to create entries.
Questions for Coverage by UNC’s Policy

- Who provides guidance to Sub about the process?
- How is Sub accessing COI disclosures and timing?
- For PHS grants, when/how is Sub doing COI training?
- Who is the point person with Sub on completion of items?
Coverage by Sub’s Own Policy

Is there a need to check if Sub is a US institution?

- FDP Website
- NIH Checklist
- NSF regulations

Indicate in the Letter of Intent
Certain Sponsors Proposals
Special Considerations = Extra Time

Organizational Conflict of Interest
– CMS

TAB A: Organizational Conflict of Interest – Summary List of Contracts

Disclosed below are all contracts, both government (local, state and federal) and non-government currently held with CMS, other government health care agencies, or with non-government entities, as a Prime and/or as a Subcontractor, for [our organization], [if applicable: our parent company, subsidiaries or other affiliated entities] that a prudent business person and/or the Government would view as an actual, apparent or potential conflict of interest with the work to be performed under this task order.

<table>
<thead>
<tr>
<th>(a) Type of contract*</th>
<th>(b) Contract #</th>
<th>(c) Period of Performance</th>
<th>(d) Point of Contact</th>
<th>(e) Contract Cost</th>
<th>(f) Short Description</th>
<th>(g) OCI Y/N**</th>
</tr>
</thead>
</table>

*Note: Possible types: Prime, Subcontractor, parent company, subsidiary or other affiliated entity

**Note: If answer in block (g) is “yes”, see TAB A paragraph (g) for instructions (i.e., mitigation plan).
Certain Sponsors Proposals
Special Considerations (con’d)

• PCORI

Please list any direct or indirect links to industry, such as pharmaceutical, medical device, health insurance, and health care related companies, that Subcontractor and any PI and Key Personnel participating in the PPRN Project that have the potential to bias the PCORI-funded research. There is no need to include disclosures here that will be reported under Question 6. (Attach additional documents, if needed).

Report the existence of any financial conflicts of interests related to the PCORI-funded research under this Subcontract and attach a mitigation plan that will address identified financial conflict of interest. Please print “None” if Subcontractor has no financial conflicts of interest to report.

Additionally, PCORI is required by law to make available to the public and disclose through its website the identity of each entity and the investigators conducting PCORI-funded research and any conflicts of interest of such parties, including any direct or indirect links to industry that have the potential to bias PCORI funded research.
Certain Sponsors Proposals
Special Considerations (con’d)

• Broad Agency Announcements - DOD (DTRA, DARPA), DOE – use FAR 9.5

Without prior approval or a waiver from the DARPA Director, in accordance with FAR 9.503, a Contractor cannot simultaneously provide scientific, engineering, technical assistance (SETA) or similar support and also be a technical performer. Therefore, all Proposers as well as proposed subcontractors and consultants must affirm whether they (their organizations and individual team members) are providing SETA or similar support to any DARPA technical office(s) through an active contract or subcontract. All affirmations must state which office(s) the Proposer, subcontractor, consultant, or individual supports and identify the prime contract number(s). Affirmations shall be furnished at the time of proposal submission. All facts relevant to the existence or potential existence of organizational conflicts of interest (FAR 9.5) must be disclosed. The disclosure must include a description of the action the Proposer has taken or proposes to take to avoid, neutralize, or mitigate such conflict. If in the sole opinion of the Government after full consideration of the circumstances, a proposal fails to fully disclose potential conflicts of interest and/or any identified conflict situation cannot be effectively mitigated, the proposal will be rejected without technical evaluation and withdrawn from further consideration for award.
Award Time!
Incorrect Username/Password combination. Please try again
The above proposal has been successfully submitted. All lead/principal investigators and approving departments listed below have been notified and should electronically authorize (in routing order for departments) this proposal before it is received by the Office of Sponsored Research.

Investigator(s) who must certify this Proposal

<table>
<thead>
<tr>
<th>Investigator</th>
<th>Role</th>
<th>Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lori Saddler</td>
<td>Principal Investigator</td>
<td>Not Yet Reviewed</td>
</tr>
<tr>
<td>Ellen Quinn</td>
<td>Lead Principal Investigator</td>
<td>Not Yet Reviewed</td>
</tr>
</tbody>
</table>

Department(s) that must authorize this proposal

<table>
<thead>
<tr>
<th>Order</th>
<th>Department</th>
<th>Authorizing Person(s)</th>
<th>Authorizing Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Vice Chancellor Research And Econ Development</td>
<td>Joann Gustafson, Barbara Entwisle, Andy Johns</td>
<td>Authorized by Joann Gustafson on 2/9/2013 10:10 AM (Note)</td>
</tr>
<tr>
<td>2</td>
<td>Office of Sponsored Research</td>
<td>Admin Office</td>
<td></td>
</tr>
</tbody>
</table>

Status History

<table>
<thead>
<tr>
<th>Status</th>
<th>Person</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Changed to Funded</td>
<td>Changed by Ellen Quinn</td>
<td>9/12/2012 11:14 PM</td>
</tr>
</tbody>
</table>
Human Research

There are no human research protocols associated with this proposal.

- No JIT
- No Not Yet Submitted

Animal Research

Animal subjects are used in this research at UNC-CH. Below is a list of protocols:

<table>
<thead>
<tr>
<th>IACUC ID</th>
<th>Title</th>
<th>Approval Date</th>
<th>View PDF</th>
</tr>
</thead>
<tbody>
<tr>
<td>04-999.0</td>
<td>Cat in the Hat</td>
<td>3/19/2008</td>
<td></td>
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<tr>
<td>06-000.0</td>
<td>DLAM Testing</td>
<td>10/04/2010</td>
<td></td>
</tr>
<tr>
<td>08-999.0</td>
<td>Cat in the hat 2</td>
<td>3/01/2011</td>
<td></td>
</tr>
</tbody>
</table>

Conflict of Interest

<table>
<thead>
<tr>
<th>Entity</th>
<th>Person</th>
<th>Role</th>
<th>Added Post Approval</th>
<th>COI ID</th>
<th>Disclosure Submitted</th>
<th>Potential Conflict</th>
<th>Review Status</th>
<th>Review Complete</th>
<th>Training</th>
<th>Send Email</th>
</tr>
</thead>
</table>
The “Hard Stop”

• Federal requirements that funding cannot begin until COI review and COI training is complete.
• At UNC, rule extended to all sources of funding.

• Accounts or FPGs can be set up when COI review/training is completed for all personnel covered by UNC’s policy.
• Prime (UNC) and sub-contracts handled separately.
How Does the Review Process Work?

No conflicts indicated on disclosures

- System filters every 10 minutes
- IRBIS/Ramses automatically updated
Review Process (Cont’d)

Potential Conflicts Indicated

- Filter to COI administrative system in AIR according to origin (Ramses, IRBIS, etc.)

COI Staff sort according to different criteria:

- IRBIS: Reviews begin on all disclosures and triaged accordingly: Renewals (expedited, full board), Initials (full board, expedited)

- Ramses: **Reviews begin on disclosures only when COI knows which are funded**
  - COI copied on NOGAs (effective July 2014)
  - COI copied when Non-competitive Renewals submitted (effective Fall 2013)
Next Steps in Review Process

Potential conflicts

• Initial Evaluation by COI Staff, usually further information is needed so investigators are emailed, responses evaluated until all necessary information received

• COI Staff reviews with appropriate Committee Chair or applicable Dean/Director. Three Options
  – Expedited Review finalized with Committee Chair(s). (Existing Management plans or <$10K)
  – Decision to move to Full Committee (New conflict >10K or significant changes)
  – Need further information or additional consultation

NOTE: Five Standing COI Committees – Medicine, Public Health, Dentistry, Pharmacy and College of Arts & Sciences. Some committees meet 1x per month; others meet as needed.
Finishing the Process

Determination

• Email sent to investigator with brief summary, stating decision, providing text for consent form if needed for IRBIS.
• Final determination in AIR system is automatically reflected in IRBIS and Ramses.

Important Reminders:

• Federal regulation states funding cannot begin until COI review and COI training is complete.
• Any reports for PHS funded studies must be submitted to NIH before COI Program can send final determination.
*** NOTE: For PHS, COI Program required to submit any FCOI report 60 days prior to start of next funding cycle. NIH now directly reminding COI Program. ***
COI Places to Stumble

- IFP is not submitted in a timely fashion
- Who is named on the Sub Proposal/emails match?
- Is the personnel list correct?
- COI disclosures OR trainings are not completed
- Subs assume their policy is sufficient
Additional Pieces to COI Puzzle

How is the “hard stop” handled where UNC is ready but Sub is not complete?

Do you use the Second Golden Rule explanation for Subs?

This person has left the University but reminders keep getting sent to complete the disclosure?

The ICi states their own University will cover their COI, is that possible?

Other items??
pleaded guilty to conspiring to defraud the government. He controlled numerous government contracts and grants, and prosecutors said he steered various subcontracts for data entry, website development and conference planning to his wife's company.
Tatsuya Suda, 59, who until January [2013] was on UC Irvine's faculty for more than 25 years, faces six felony counts .... for allegedly receiving from $325,000 to $700,000 illegally from KDDI Inc. of Japan between 2006 and 2009 while committing perjury to hide the illicit payments.
And Again....

The university [Georgia Tech] also contended that Sayana [faculty startup] employees used university lab space, equipment and other resources without authorization. Dr. Laskar and the university disagreed over whether his start-up had that authorization.
Conclusions

- 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
Key Websites

- Activities, Interests and Relationships: air.unc.edu
  All disclosures, External Activities for Pay
  (items created after August 24, 2012)

- COI Training: coi-training.unc.edu
Contact Information

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Conflict of Interest Officer
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E-mail: jbryde@unc.edu
Phone: (919) 843-9953

Website: http://research.unc.edu/offices/research-compliance-program/index.htm

General Email for questions: coi@unc.edu