

**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

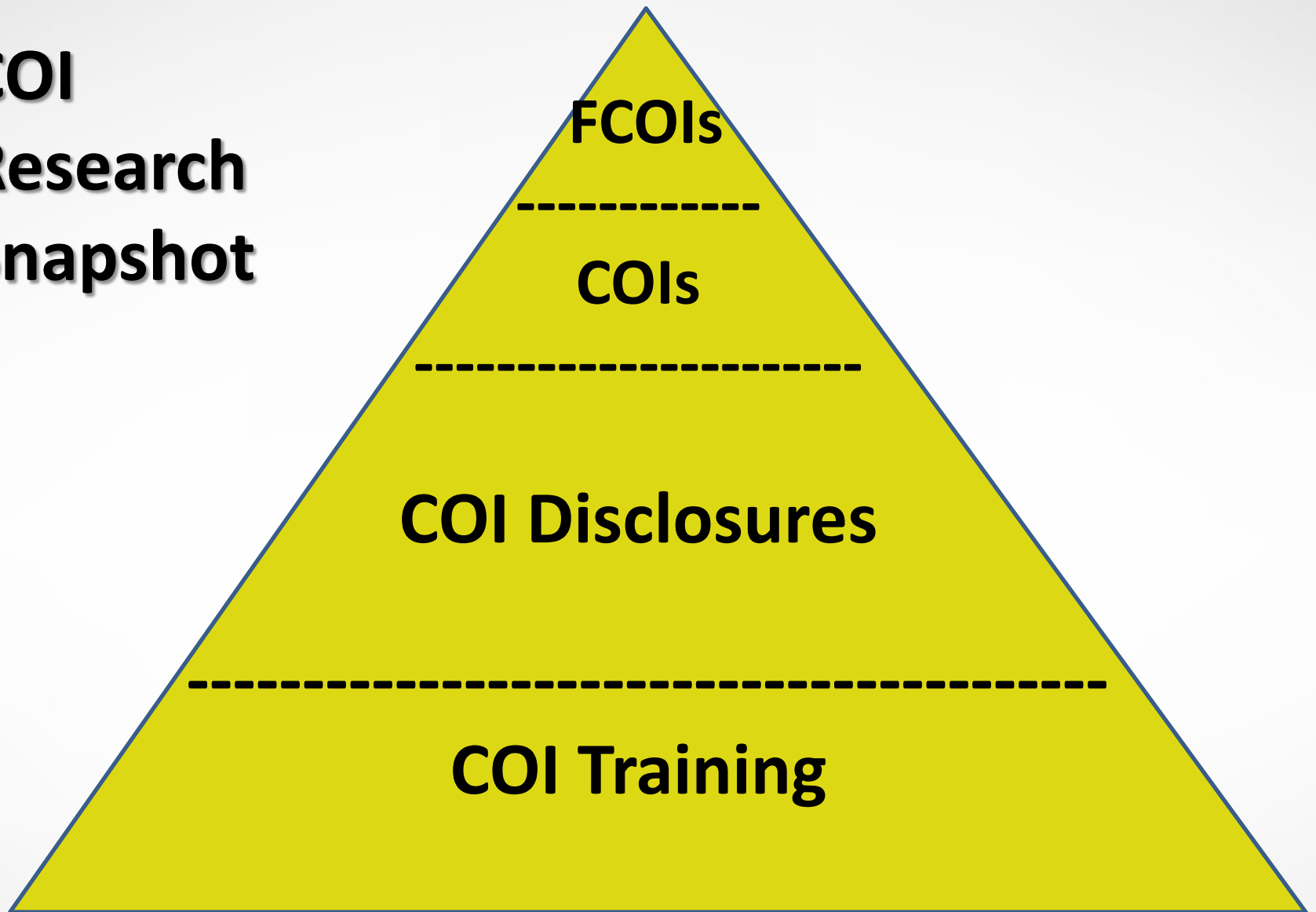
- The presenter has \$0 financial interests to report.
- The presenter would like the audience to be aware she has a significant personal interest in educating researchers and staff about COI since:



Who is Covered by the Policy on Individual Conflicts of Interest (COI) and Commitment?



**COI
Research
Snapshot**



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.

42 CFR Part 50

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.

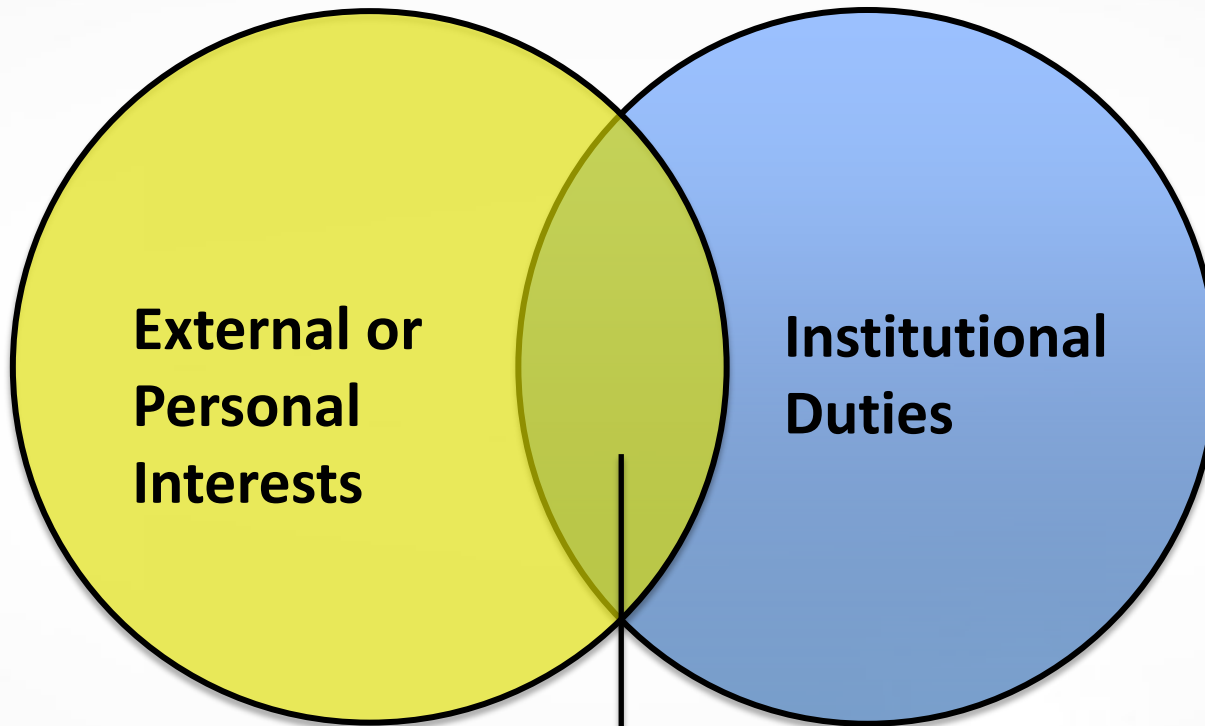
Stanford University

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



- 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

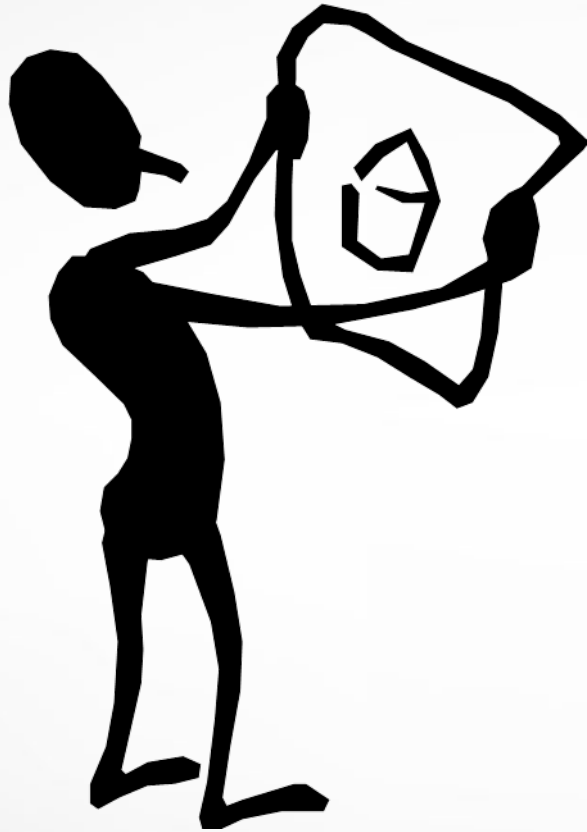
IRB (IRBIS)

- 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



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Grants Affected by the Sponsor's Sub-Recipient Rule

Per 42 CFR 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



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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

Ramses - Mozilla Firefox

https://apps.research.unc.edu/ramses/index.cfm?event=proposal.subcontractorEdit&id=10775

Edit Subcontractor Information [Help](#)

Subcontractor: 

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



If Sub is Using UNC's COI Policy

- Need to enter principal investigator's name and email address for sub-contractor. 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 process?

How is Sub accessing COI disclosures and timing?

For PHS grants, when/how is Sub doing COI training?

Who is 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.

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

*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

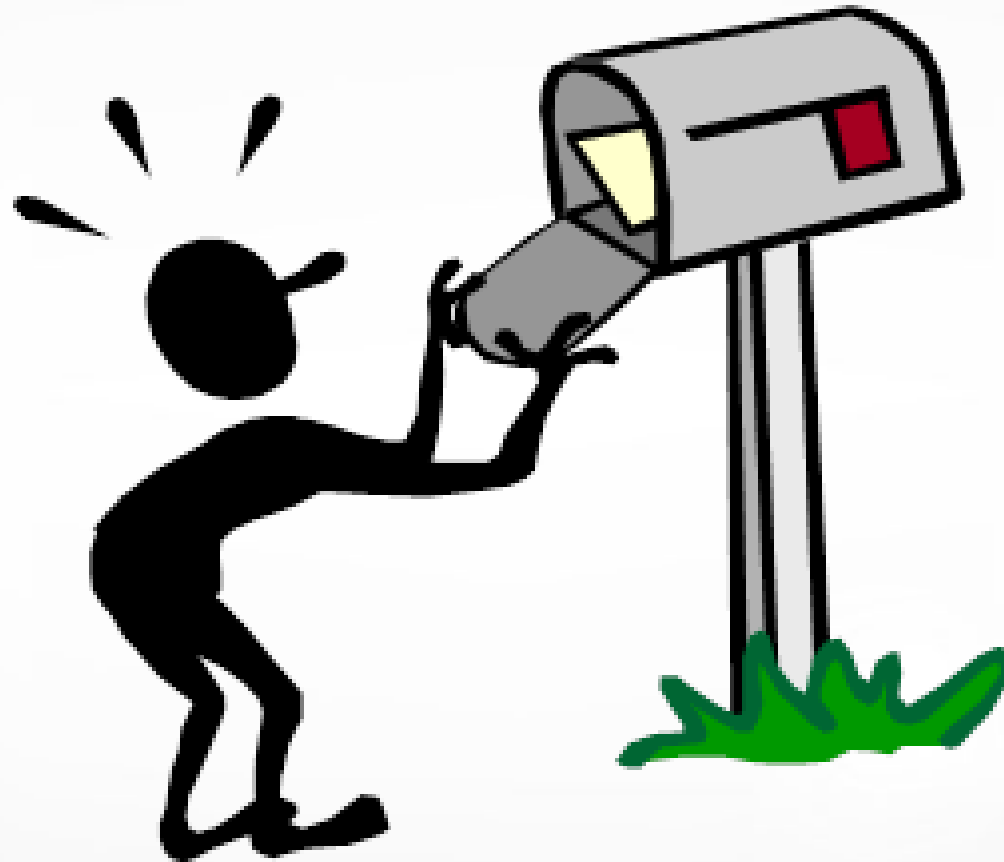
Special Considerations (con'd)

- 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!



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Item List 10-4192

View or Edit completed sections by clicking the name next to the check.

- General Info >>
- Subcontractors
- Subcontractor Personnel
- Personnel
- Budget
- Research Subjects
- Export Control
- Intellectual Property
- Community Benefits
- Locations of Budget Expenditures
- Locations Relevant to Your Project
- Application Abstract
- Attachments
- Approving Depts
- Submission Notes

Administer Proposal
View Routing Status

>> General Information

Incorrect Username/Password combination. Please try again

* Indicates Required Fields

Funding Agency(ies) [Help](#)

* Funding Agency: Department of Health and Human Services (DHI) 🔍

Funding Opportunity/Sponsor Application No:

Sponsor Program Name:

Proposal Guideline URL:

Prime Funding Agency: 🔍

Address:

Contact Phone:

General Proposal Information [Help](#)

* Short Project Name: *** PLEASE DISREGARD ** TEST PROPOSAL (not project title, used for tracking purposes)

* Project Start Date: 04/30/2010 📅

* Project End Date: 04/29/2011 📅

* Activity Type/Chess Code: [Click Here to Add/Remove CHES Code](#)
Research-Training (no CHES code)

* Proposal Type: New

* Award Type: Contract
Select One: ...

* Will this proposal be submitted electronically to the sponsor ? Yes No



File Edit View History Bookmarks Tools Help

Ramses +

https://apps.research.unc.edu/ramses/index.cfm?event=proposal.admin.routingStatus&prop_id=71809

Most Visited help.unc.edu Login to MyUNC The University of Nort... Getting Started Latest Headlines ESOP%20COIC%20R...

RAMSeS UNC-CH Proposal and Award Development

Logged in as Joy Bryde on apps1
For immediate assistance contact [ORIS](#) at 919.843.2594

HOME MY DASHBOARD HELP REPORTING ADMIN LOGOUT

Proposal Dashboard

[Start New Proposal](#)

[My Proposals](#)

[Proposals In My Dept](#)

[Financial Guarantee Inbox](#)

Award Dashboard

[My Awards](#)

[Awards In My Dept](#)

[NOTR Submissions](#)

[ARRA Submissions](#)

Certifications/Approvals

[PI Certification Inbox](#)

[Dept Approval Inbox](#)

Office of Sponsored Research
104 Airport Drive
Suite 2200, CB 1350
Chapel Hill, NC 27599-1350
Phone: 919.966.3411
Fax: 919.962.5011

Proposal Routing Status

Proposal No: [10-4192](#) (coversheet) 424 Sponsor: Department of Health and Human Services (DHHS)

Lead Investigator: [Ellen Quinn](#) Deadline: 4/30/2010 New Electronic: No

Proposal Specialist: Program Administrator: [Myra Mansfield \(08\)](#)

Primary Award Contact: [Anant Pradhan](#) Account Manager: [Joann Gustafson](#)

Project Title: ***** FOR TESTING PURPOSES ONLY *****PLEASE DISREGARD**** 4/16/11 E QUINN / ORIS 962-5074

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

Investigator	Role	Decision
Lori Saddler	Principal Investigator	Not Yet Reviewed
Ellen Quinn	Lead Principal Investigator	Not Yet Reviewed

Department(s) that must authorize this proposal

Order	Department	Authorizing Person(s)	Authorizing Decision
1	Vice Chancellor Research And Econ Development	Joann Gustafson , Barbara Entwisle , Andy Johns	Authorized By Joann Gustafson on 2/09/2013 10:10 AM (Note)
2	Office of Sponsored Research	Admin Office	

Status History

Status	Person	Date
Changed to: Funded	Changed by: Ellen Quinn	9/13/2013 04:11 PM

[Dept Approval Inbox](#)

Office of Sponsored Research
 104 Airport Drive
 Suite 2200, CB 1350
 Chapel Hill, NC 27599-1350
 Phone: 919.966.3411
 Fax: 919.962.5011

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

IACUC ID	Title	Approval Date	View PDF
04-999.0	Cat in the Hat	3/19/2008	
06-000.0			
06-999.0	DLAM Testing	10/04/2010	
08-999.0	Cat in the hat 2	3/01/2011	

Conflict of Interest

Viewing 1 - 6 of 6 Records Page 1 of 1 20

Entity	Person	Role	Added Post Approval	COI ID	Disclosur Submittec	Potential Conflict	Review Status	Review Complete	Training	Send Email
UNC-CH	Ben Keller IV	Investigati	No		✗	---		✗	✓	
UNC-CH	Lori Saddler	Principal Investigat	No		✗	---		✗	✓	
UNC-CH	CP NON-UNC POSTHIL	Independ Contractor (Investiga	No		✗	---		✗	✗	
UNC-CH	ELLEN NON-UNC TEST2 QUINN 12-10-12 TEST2	Independ Contractor (Investiga	No		✗	---		✗	✗	
UNC-CH	FAKEY McFAKEN	Independ Contractor (Investiga	No		✗	---		✗	✗	



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.)



Potential Conflict	
RAMSeS:	<u>5</u>
IRB:	<u>3</u>
Alice:	<u>0</u>
Annual:	<u>0</u>
Self:	<u>6</u>
Travel:	<u>3</u>
Authorship:	<u>1</u>

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.

From: era-notify@mail.nih.gov
To: [Bryde, Joy M](mailto:Bryde_Joy_M)
Cc: mshea@niaid.nih.gov; mirnikozim@niaid.nih.gov; philip.smith2@nih.gov
Subject: Reminder Notice for Annual FCOI Report FCOI ID for grant number:
Date: Tuesday, June 17, 2014 11:07:02 PM

*** This is an automated notification - Please do not reply to this message. ***

To whom it may concern:

This email communication is to inform the institution that a Financial Conflict of Interest (FCOI) was identified for this project during the current competitive segment under the 2011 revised FCOI regulation. Therefore, an annual FCOI report must be submitted to the NIH to provide an update regarding the status of the previously reported FCOI and to describe any changes to the management plan. Please note that Annual FCOI reports are not required for the last budget year of a competitive segment, unless the project is extended.

Annual FCOI reports are required to be submitted for the duration of the current competitive segment (including extensions with or without funds) at the same time as when the Institution is required to submit the annual progress report, including a multi-year funded progress report, or at the time of the extension (e.g., submission of an extension notification in the eRA Commons or submission of a NIH prior approval request, whichever is applicable).

The annual FCOI report is submitted to NIH separately through the eRA Commons FCOI Module under the current grant year number. The delayed or delinquent submission of an annual FCOI report, when required, may jeopardize the timely issuance of the next year's Notice of Award.

Additional information on the FCOI reporting Requirements can be found in Section "H. Reporting Requirements" of the Frequently Asked Question document posted on the Office of Extramural Research - Financial Conflict of Interest webpage found at http://grants.nih.gov/grants/policy/coi/coi_faqs.htm#H.

*** 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



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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??

COI in the News....

..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,....

9/30/13

Army researcher pleads guilty to fraud - WRAL.com

Army researcher pleads guilty to fraud

Posted: September 19

A Raleigh man who managed research projects for the Army pleaded guilty Thursday to steering federal contracts to his wife's business, authorities said.

Dwight Woolard pleaded guilty to conspiring to defraud the government. He faces up to five years in prison and a \$250,000 fine when he is sentenced in January.

Woolard worked at the Army Research Office in Durham as a program manager from September 1998 until late last year. 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, Qtronika.

His wife or her company received \$842,403 in government-funded projects, authorities said. As part of his plea agreement, Woolard agreed to repay that amount to the Department of Defense.

"For almost a decade, Dwight Woolard abused the Army's trust and stole monies designated for researching and developing innovative ways to protect and defend American military personnel in battle," U.S. Attorney Thomas Walker said in a statement.

Web Editor: [Matthew Burns](#)

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And Again...

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.

12/13/13

Controversial Legal Defense Expected for UCI Ex-Professor - Voice of OC | Orange County's Nonprofit Investigative News Agency: Health News

Controversial Legal Defense Expected for UCI Ex-Professor

By REX DALTON | Posted: Thursday, June 13, 2013 7:39 am

A former UC Irvine engineering professor, charged with multiple felonies for conflicts of interest involving up to \$700,000 in payments from industry, is expected to argue he is exempt from prosecution because the UC system is a sovereign entity.

The seldom-seen legal tactic, which UC-funded lawyers also are using in a similar felony case involving a UCLA professor, has disturbed prosecutors and shows the extent to which one of the world's most prestigious public university systems will go to defend its realm.

Tatsuya Suda, 59, who until January was on UC Irvine's faculty for more than 25 years, faces six felony counts in Orange County Superior Court 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.

The UCLA case involves Michael F. Lofchie, a senior political science professor charged with a conflict of interest for hiring his wife for summer programs in Europe beginning in 2008.

A Los Angeles County Superior Court judge agreed with the defense arguments made by attorneys for Lofchie and in March dismissed the single felony count, ruling that UC employees weren't covered by the conflicts law. Los Angeles District Attorney's office is appealing that decision to the 2nd District Court of Appeal, with a prosecutor calling the Lofchie defense at times "ridiculous."

At a Superior Court hearing in Santa Ana last month, Joe Williams, the deputy Orange County district attorney prosecuting Suda, said he learned from opposing counsel that a similar exemption argument would be made by lawyers for the UC Irvine engineer.

The California Constitution grants substantial governance autonomy for the UC system of 10 campuses to thwart political meddling. But prosecutors in both Orange and Los Angeles counties insist that defense attorneys are extending immunity from state laws too far.

"The ability to ferret out criminal violations would become zero if their argument holds," said Williams of the DA's major fraud division.

Williams supports arguments by the Los Angeles district attorney's public integrity division that "the University of California is not a separate sovereign" and that its internal conflict of interest code "does not preempt the state's authority to regulate all state agencies, including UC employees" like



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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.



12/13/13

Reaching for Silicon Valley - NYTimes.com

The New York Times



November 16, 2013

Reaching for Silicon Valley

By NICK WINGFIELD

Joy Laskar was not what you'd typically think of as a threat to public safety.

At the [Georgia Institute of Technology](#) in Atlanta, where he was a professor of electrical engineering, Dr. Laskar did research on chip design. He mentored dozens of Ph.D. students and, over the years, started and sold a number of tech companies. The last one, called Sayana, created a promising wireless chip and was being courted by the likes of Samsung and Qualcomm.

But on May 17, 2010, agents from the Georgia Bureau of Investigation, wearing bulletproof vests, raided his university offices. A parallel scene played out at Dr. Laskar's home, where his wife, Devi Laskar, found armed agents in her driveway. While agents went through the house and confiscated files and computer equipment, she went to a coffee shop to call a lawyer.

"What were they looking for?" Dr. Laskar said in disbelief, recounting the event recently. "Cash under the bed? Chips in the ceiling?"

The day of the raid, there was to be an auction for Sayana. It never happened. Instead, Dr. Laskar was suspended without pay from his tenured position. He was later arrested on state racketeering charges and eventually fired by [Georgia Tech](#), accused of misusing university resources.

"It was devastating, absolutely devastating," he said.

In one day, his life was upended. But why it was upended — and why university officials and authorities in Georgia acted so aggressively — is still leaving people in high-tech circles scratching their heads.

It has been three years since Dr. Laskar, now 50, was arrested, and he has

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

Joy M. Bryde, MSW

Conflict of Interest Officer

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

Physical Address: 137 E. Franklin St. Suite 501 CVS Plaza

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

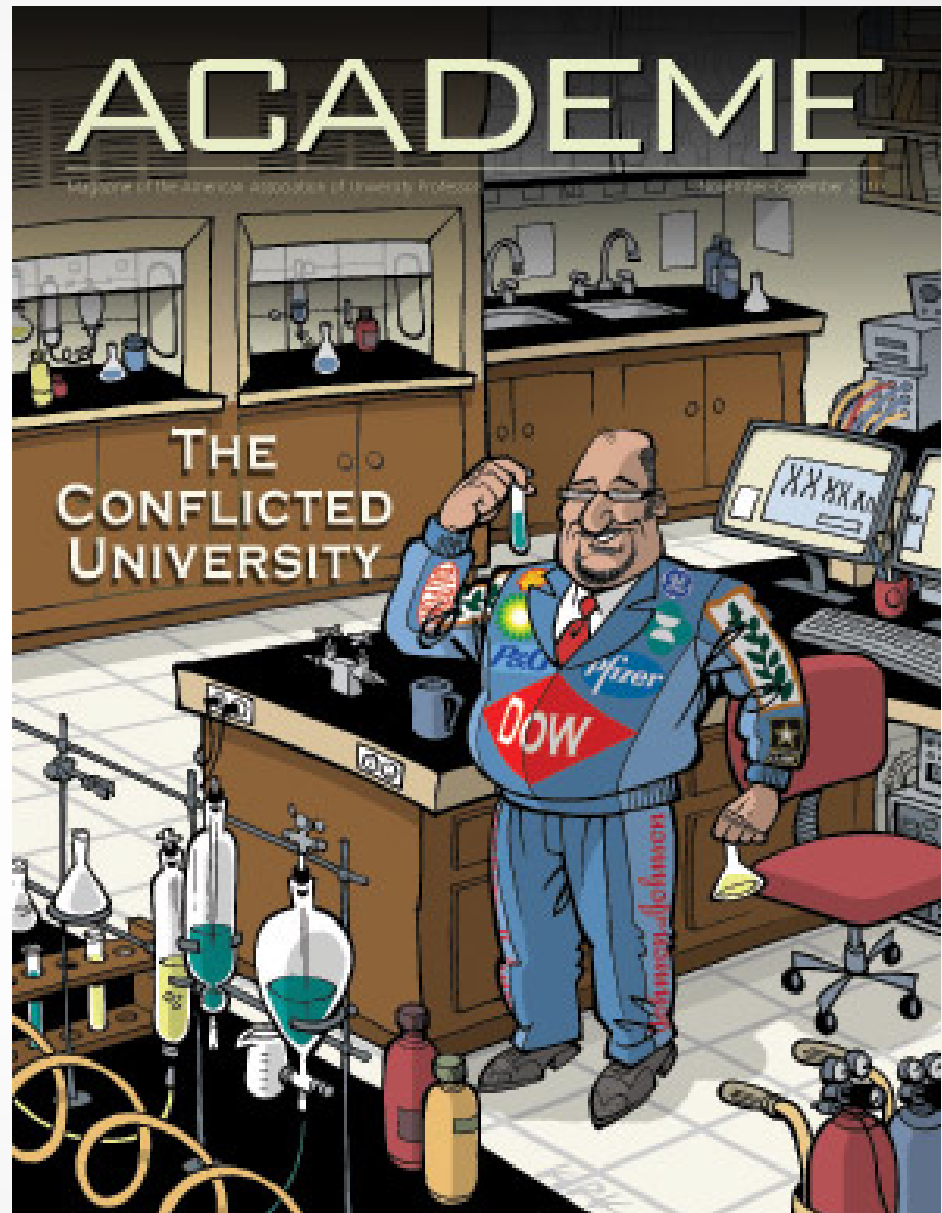


ACADEME

Magazine of the American Association of University Professors

Editor: Peter G. Peterson

THE CONFLICTED UNIVERSITY



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