COI Dos and Don'ts: Avoid Having COI Issues Slip through the Cracks

NUCOI:

Julia Campbell, Director Kate Cosgrove, Sr. Compliance Analyst Maria Daniele, Compliance Coordinator



Today's Topics

- Conflict of Interest (COI) policy overview & refresher
- NUCOI who we are, what we do, & why
- The who/what/when/where of research COI disclosures
 - Who must submit research COI disclosures?
 - What exactly needs to be disclosed
 - When exactly, and how often, must research COI disclosures be submitted?
 - Where are research COI disclosures submitted?
- Trickier COI issues
 - Special award mechanisms & COI issues (fellowships, training grants, etc.)
 - Subrecipients & consultants
 - Triggering review by the NUCOI office
- Examples & scenarios
- Q&A

COI Policy Refresher

5 Key policy points effective 8/24/12:

- 1. Institutions must solicit and review all significant financial interests (SFIs) of all investigators related to their institutional responsibilities and determine whether or not a COI/financial conflict of interest (FCOI) exists
 - a. Previously, investigators only had to disclose SFIs they thought were related to research; investigators made this determination themselves, not the institution
- 2. The definition of SFIs changed (see Appendix slide)
- There are more detailed and frequent institutional COI reporting requirements



COI Policy Refresher

5 Key policy points effective 8/24/12 (continued):

- 4. Every investigator on every proposal funded by a sponsor subject to NU's COI policy must have undergone COI training and have a current* COI disclosure on file in the FASIS COI system *prior to proposal submission*
- 5. Every investigator on every proposal funded by a sponsor subject to NU's COI policy must have a COI determination *prior* to funding release (i.e., chart string set-up)
 - a. This also means that every investigator must have a COI disclosure submitted in FASIS by award time: a review cannot occur and a determination cannot be made if there is no COI disclosure in FASIS



Disclosure date must be within the previous year (365 days)

Policy Applicability

- NU's COI policy applies PHS COI regulations to:
 - PHS agencies
 - Agencies that have adopted PHS COI regulations:

http://www.northwestern.edu/coi/policy/coi_by_sponsor.pdf

- NSF
- All industry-sponsored clinical trials
- Other sponsors with specific COI requirements
- New proposals submitted to these sponsors on or after 8/24/12
- New awards and/or new budget periods awarded from these sponsors with start dates on or after 8/24/12

NUCOI Mission

Northwestern is dedicated to integrity in its academic, research, and business activities. As part of this mission, NUCOI:

- Oversees and implements the University faculty, staff, and research COI policies and procedures
- Ensures University compliance with applicable COI regulatory requirements
- Provides guidance and support to the University community regarding COI policies, systems, standards, and procedures
- Administers and supports the activities of University COI Committees



What NUCOI Does



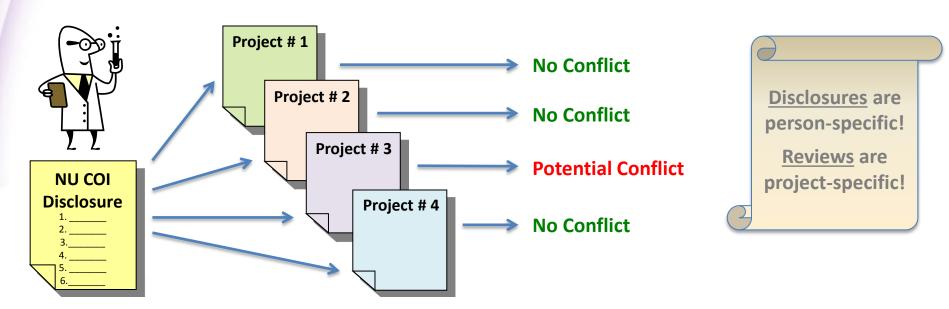


What NUCOI Really Does (for Research COI)

- Solicit and review all research COI disclosures submitted in FASIS
- Compile and review information from various offices and systems
 (FASIS, InfoEd, eIRB, INVO, eRA Commons, NSF Fastlane, and others) in
 order to make or refer to the School to make determinations of
 whether an investigator's SFIs are COIs relative to specific research
 activity
- Work with School Dean's Offices and institutional COI committees to come to appropriate solutions if COIs do exist (i.e., reduce, manage, eliminate)
- Perform sponsor reporting on an initial and ongoing basis
- Monitor compliance of timely COI disclosure submission, review, management, and reporting
- Provide guidance and assistance to researchers and administrators regarding COI requirements, policies, systems, etc.

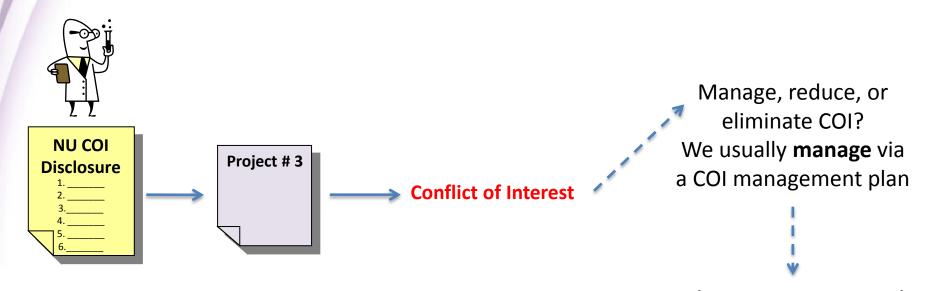
Research COI Reviews

- NUCOI and School Dean's Offices review investigator disclosures to assess
 SFIs compared to each body of research activity in order to identify any real or perceived COIs that could impact or bias the research activity
- Not every SFI is an COI! A COI is an SFI that could directly and significantly impact the design, conduct, or reporting of research



Research COI Reviews

Working with the investigators and School Dean's Offices, we **review and make determinations** regarding the reduction, elimination, or management of COIs and **report to sponsors**, as required.





COI determinations must be made prior to funding release Some sponsors (such as PHS) require **specific reporting** of COIs prior to funding release

Who Must Disclose?

<u>Investigators</u>: individuals responsible for the design, conduct, or reporting of research.

Key personnel? Consultants? Other significant contributors?

Individuals in these categories *may* or *may not* be Investigators subject to COI requirements.

If there is any question as to an individual being an Investigator or not an Investigator, the PI must confirm the assignation.

Department administrators or NUCOI may "deactivate" someone as an Investigator on a particular project in FASIS, with PI affirmation.

Who Must Disclose?

Anyone determined by the PI to be responsible for the design, conduct, or reporting of research.

Investigators Not an Investigator Non-Key Personnel Research Coordinators **Key Personnel Statisticians Graduate Students**

What Needs to be Disclosed?

New regulations broadened what needs to be disclosed

• Investigators must disclose significant financial interests (SFIs) that relate to any of their *institutional* responsibilities (e.g., clinical, research, teaching) – not just interests that may relate to the specific research activity



Institutional Responsibilities

- Things that are relevant to your institutional responsibilities:
 - Editing, Scientific Advisory Board, Consulting, Training
- Things that are likely not related to your institutional responsibilities:
 - Retirement funds, Community Involvement (church groups, PTA service), etc.



Institutional Responsibilities

Example: Your family owns a pizzeria. Disclose or not? Does it relate to your teaching, research, or clinical responsibilities?

- "Getting a bigger piece of the pie: Capturing a larger share of a crowded market"
- Taste research on a secret formula that could be commercialized by your family's restaurant
- Research on the health benefits of a gluten free crust that your restaurant uses.



When do Investigators Need to Disclose?

Investigators must disclose SFIs before proposing or engaging in research,* within 30 days of new SFIs, and annually

New Investigators / New to NU:

✓ Prior to submission of the proposal *and then...*

On an Ongoing Basis:

- ✓ Disclose new interests within 30 days of acquisition
- ✓ Disclose annually
- ✓ Complete COI training every 4 years (or more frequently if required)

*Investigators must submit initial disclosure in FASIS subsequent to 8/24/12 — disclosures "on file" in FASIS can meet the "prior to proposal submission" disclosure requirement on an on-going basis — there is no need to "acknowledge no change" for every submission **provided** that new SFIs are disclosed within 30 days, and an investigator reaffirms their disclosure at least annually

Where do Investigators Disclose?

FASIS (the Faculty and Staff Information System)

- The research disclosure has been consolidated into the annual faculty / annual staff disclosure process to satisfy the "annual" requirement.
- For initial and ongoing COI disclosure, investigators disclose in FASIS through the NUPortal (which is updating 10/7!)



Current System Status

Production: Available

Self Service: Available

There are no announcements at this time.

Announcements

Reporting

eRecruit

FACULTY AND STAFF INFORMATION SYSTEM

FASIS Login		
User ID	Password	
	Sign In	
Help & Resources		
FASIS Help Desk Assistance is available	e Monday-Friday 8:30am-5:00pm @ 847-467-4800 ern.edu	
fasishelp@northweste Login Problem?		

Life of a Research COI Disclosure

1. Investigator submits in FASIS





2. NUCOI performs initial review and may make COI determination relative to projects that meet requirements*





NUCOI may clear project ("No COI" or "COI Managed")



NUCOI may identify that School review is needed ("Potential Conflict")

^{*} Projects funded by sponsors subject to COI requirements + award/budget period start date of 8/24/12 or later + InfoEd proposal status of "Prepending," "JIT," or "Awarded" (or any clinical trial)

Life of a Research COI Disclosure

3. School Dean's Office and/or Committee perform review and make COI determination

Determination of no COI? FASIS COI status updated to "No COI"



NU COI Disclosure

1.
2.
3.
4.
5.
6. Determination of COI/FCOI?
NUCOI reports to sponsor (as required)



After reporting occurs, FASIS COI status updated to "Conflict Managed"



4. The life of *this* disclosure relative to *this* project is done for now*...project funding released!



* If investigator discloses new SFIs, the review process begins again...at least annually, a review occurs...for projects in which an FCOI was determined, NUCOI performs ongoing sponsor reporting as required

Tricky COI Issues



InfoEd/FASIS Interface

Investigator names are entered into InfoEd in Personnel Section

- Check: Subrecipients or Persons Outside the Institution? Any "TEMP" profiles?
- Key Contact: OSR, Sara Krentz

Investigator names are fed (overnight) into FASIS COI system

- Check: Do all investigators have a current disclosure on file? If not, the RA should contact the investigator to disclose
- Key Contact: NUCOI, Maria Daniele

Compliance Checkpoint: Before **submitting** the grant, ALL investigators must have disclosed within the last year (365 days)

InfoEd Proposal Status of the project is updated to "JIT" or "Awarded" – this triggers NUCOI review

- Check: Do all investigators have a status of "No Conflict" or "Conflict Managed?"
- Key Contact: NUCOI, Kate Cosgrove



Compliance Checkpoint: Before <u>opening chartstrings</u>, ALL investigators must have "clear" COI statuses (either "No Conflict" or "Conflict Managed")

Getting Investigators into the System & Assigning them to the Appropriate Project

- All named personnel entered into InfoEd are fed into FASIS overnight
 - ✓ Potential pitfall: Personnel entered incorrectly will not be pulled into the FASIS system, and thus not reviewed for the project.

				'	·	
		M	Booth, Wilbur	Pathology	Pathology	
		×	Cosgrove, Gretel	(TEMP)	Ann & Robert H. Lurie Children's H	

> Key contact: OSR, Sara Krentz

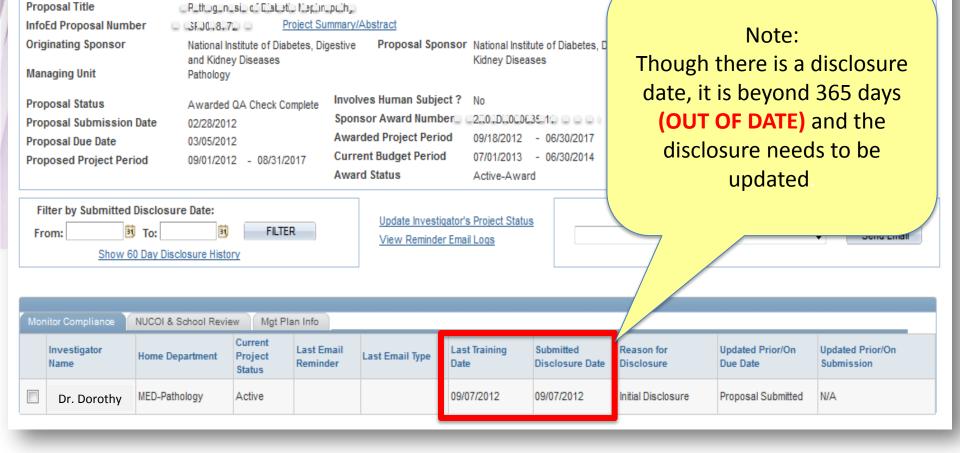


Knowing if an Investigator has Disclosed



Knowing if an Investigator has Disclosed

Monitor Conflict of Interest (COI) Compliance - By Proposal



Changing the Status of an Investigator

Monitor Conflict of Interest (COI) Compliance - By Proposal Proposal Title The Fotert Hailuie Colput neive Cancer Cente Project Summary/Abstract InfoEd Proposal Number Principal Investigator (Contact): Originating Sponsor National Cancer Institute Proposal Sponsor National Cancer Institute ____Ro_e_S_ev_n_ Managing Unit Cosq General Involves Human Subject? Yes Proposal Status Awarded Sponsor Award Number Proposal Submission Date 09/24/2012 Send Pl Email Awarded Project Period 09/16/2013 - 07/31/2018 Proposal Due Date 09/25/2012 **Current Budget Period** 08/01/2013 - 07/31/2014 Proposed Project Period 08/01/2013 - 07/31/2018 Award Status Active-Award Filter by Submitted Disclosure Date: Update Investigator's Project Status 31 To: FILTER From: Send Email Show 60 Day Disclosure History

Proposal Title

Inactivate Investigators

InfoEd Proposal Number SP0021203

The Robert H. Lurie Comprehensive Cancer Center



Investigators with the Potential for Special COI Handling

- New Investigators at NU
 - Newly hired PIs
 - Postdocs submitting K awards or NRSAs
 - Graduate students submitting NRSAs or NSF fellowships
- Subrecipient investigators
- Persons Outside of the Institutions (POIs)
- > Key contacts: NUCOI, Mari Daniele; OSR, Sara Krentz



Newly hired Pls

- Many new PIs bring already awarded projects with them, such that the award status at NU doesn't follow the normal "Submitted → JIT → Awarded" flow that the NU FASIS system relies on. This mismatch can let projects fall through the cracks.
- In cases like these, notifying our office that an award is being transferred in with the PI will help ensure a smooth transition and allow us to look for the project.
- > Key Contact: NUCOI, Kate Cosgrove



Postdocs and Graduate Students

- Postdocs & grad students can be investigators, particularly on fellowships (NRSAs, K-awards, etc.)
- Generally first time investigators who are not familiar with the process
- If they are not yet at NU for submission, new hires can be set up with a netid 90 days prior to their start date – this can facilitate the disclosure process!
- If they are outside of that 90-day window, they can disclose on paper using the *Subrecipient and Consultant COI Disclosure Form* (send to NUCOI and note they are internal person not yet here)



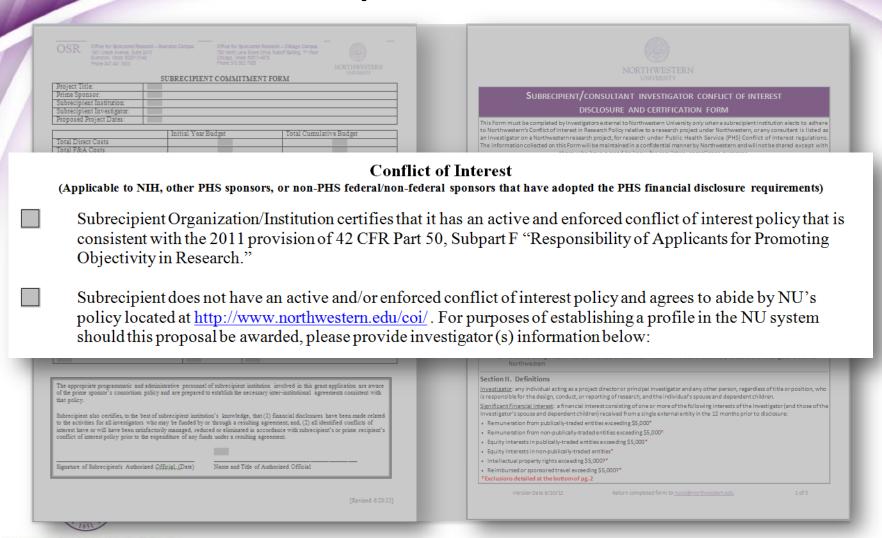
Subrecipients & Affiliates

As with many other federal regulations, Northwestern must flow down COI requirements to subrecipients

At the Proposal Stage

- To ensure compliance with COI requirements, Northwestern must secure COI compliance information prior to proposal submission.
- If the investigator is from an institution:
 - 1. In the FDP Clearinghouse that follows the PHS regulations good to go!
 - 2. NOT in the Clearinghouse, but the institution has it's own COI policy
 - OSR requires the Subrecipient Commitment Form or LOI language
 - 3. NOT in the Clearinghouse, and the investigator will abide by NU's COI policy
 - OSR requires the Subrecipient Commitment Form
 - NUCOI requires the paper Subrecipient/Consultant Investigator Conflict of Interest Disclosure and Certification Form (along with the pdf COI Training Document)
- Key Contact: NUCOI, Maria Daniele

Subrecipients & Affiliates

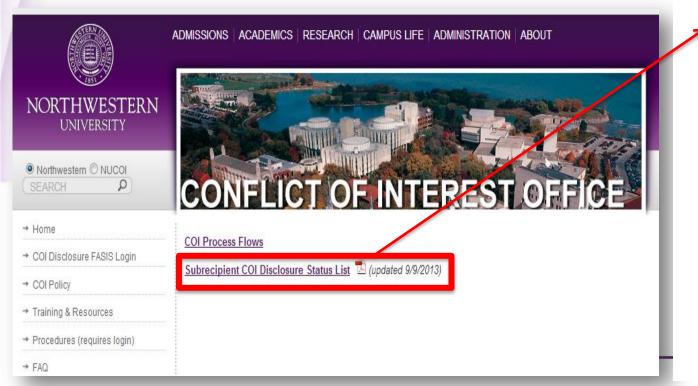


NORTHWESTERN UNIVERSITY

Knowing if a POI has Disclosed

"Repeat POIs" exist – check first!

For COI compliance at **proposal time**, we track who has disclosed through NU's paper COI process. If a paper disclosure is on file dated within the last 365 days, another paper COI form is <u>not</u> required!



SUBRECIPIENT FORMS

Investigator	Submitted to NUCOI	
Gwen McNatt	10/1/2012	
Chad Richardson	10/1/2012	
Erik Andersen	10/2/2012	
Darren Kaiser	10/2/2012	
Richard Endress	10/8/2012	
Barbara Buckley RN, BSN	10/11/2012	
Chad Richardson	10/12/2012	
Gwen McNatt	10/12/2012	
Susan L. Parish, Ph.D. MSW	10/12/2012	
Carol J. Gill, Ph.D.	10/12/2012	
Marilyn Martin	10/12/2012	
Tamar Heller	10/12/2012	
Tom Wilson	10/12/2012	
Jay Anderson	10/14/2012	

Subrecipients & Affiliates

At Award Stage

- Should a proposal be funded for which a subrecipient investigator and/or a consultant has agreed to adhere to Northwestern's COI policy, at JIT or NOA, they need to be brought into the NU system: they have just become a POI (person outside the institution)
- ✓ Check <u>first</u> in Monitor Compliance by Investigator: Is the subrecipient already in the FASIS system?
 - If yes: Email the InfoEd team the name of the investigator & the new InfoEd number
 - If no: Need to create a new profile for them (see next slide)
- Key Contact: NUCOI, Maria Daniele; OSR, Sara Krentz



Subrecipients & Affiliates

At Award Stage: new POI (not in FASIS)

- Mechanism = Profile created for the individual as "POI" (person outside the institution abiding by NU's policy for COI) in *InfoEd* and *FASIS*
- The process:
 - RAs email the Investigator Full name, DOB, email address, & SP # to Mari Daniele/NUCOI
 - Mari contacts Sara Krentz to coordinate setting up a netid & password for the POI
 - Coordinated emails are sent to POI that provide instruction on the netID setup process and COI disclosure process in FASIS
- ➤ Key Contacts: NUCOI, Maria Daniele; OSR, Sara Krentz



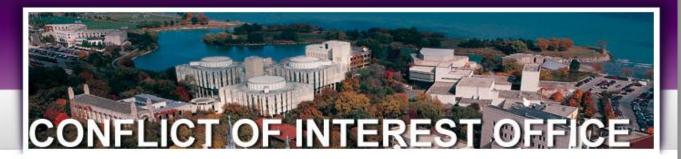


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● Northwestern ● NUCOI SEARCH ▶

- → Home
- → COI Disclosure FASIS Login
- → COI Policy
- → Training & Resources
- → Procedures (requires login)
- → FAQ
- → Committees
- → Subrecipients
- → Contacts

ADMISSIONS | ACADEMICS | RESEARCH | CAMPUS LIFE | ADMINISTRATION | ABOUT



COI Process Flows

Subrecipient COI Disclosure Status List (updated 9/9/2013)

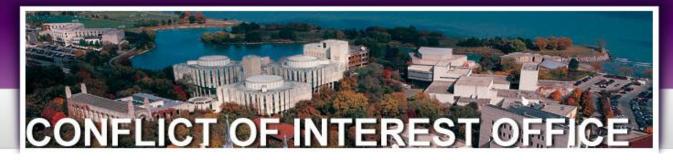
CONTACT DISCLAIMER EMERGENCY INFORMATION UNIVERSITY POLICIES MOBILE

Northwestern University Conflict of Interest Office, 720 University Place, Evanston, IL, 60208

Policy & Disclosure Questions: 847-467-4515, nucoi@northwestern.edu • Technical Assistance: 847-467-4800, fasishelp@northwestern.edu



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→ Home

SEARCH

- → COI Disclosure FASIS Login
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- → Subrecipients
- → Contacts

OSR and Research Administrators

- Proposals/Outgoing Subcontracts
- PHS JIT (and non-PHS JIT Equivalent)
- New Awards/Prespending
- Continuations Award/Outyear
- Progress Report Time

 Progress Report Time
- POI (Persons Outside the Institution Under NU's COI Policy)

ASRSP

Coming Soon

School COI Reviewers

Research COI Review Process

CONTACT NORTHWESTERN UNIVERSITY

DISCLAIMER

CAMPUS EMERGENCY INFORMATION

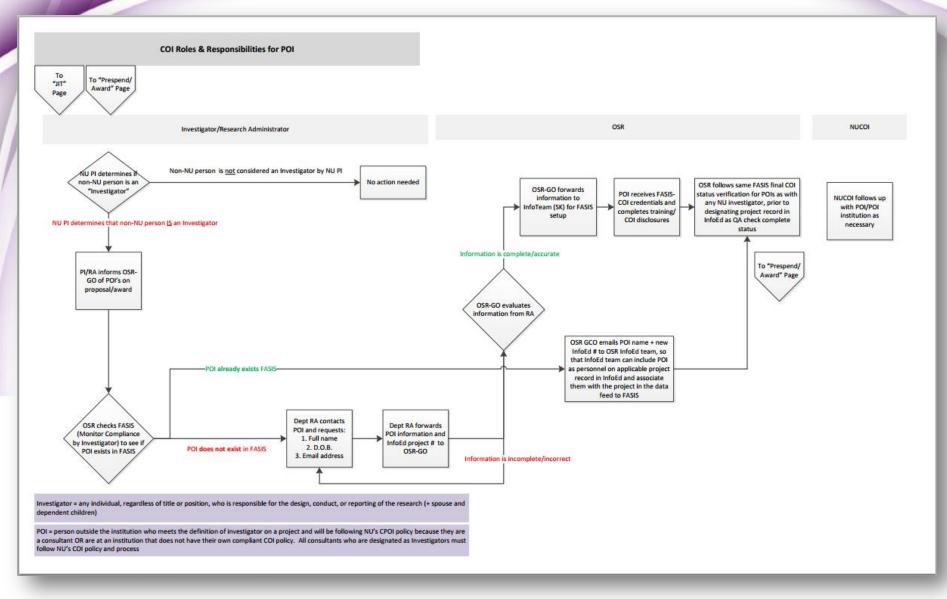
UNIVERSITY POLICIES

MOBIL F

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Subrecipients & Affiliates Process Flow



Consultants on NU Awards

- Consultants on NU awards may or may not be Investigators the PI makes that determination
 - If the consultant is independently responsible for the design, conduct, or reporting of the research, they are an Investigator and must comply with NU's COI policy and process (they are not an "institution" with compliant COI policies that they can rely on)
 - If the consultant is solely serving in an advisory capacity, for example, they may not be an Investigator



NU Faculty Serving as Consultants on Outside Awards

- If an NU faculty member is serving as a consultant on an outside award (e.g., an NIH award to the University of Chicago), they are acting independently from NU and thus are NOT covered under NU's COI policy
 - In these cases, the NU faculty member must abide by the other institution's COI policy and process
- If an NU faculty member is serving as a collaborator on an outside award for which NU and the other institution have a subagreement, the NU faculty member is absolutely covered under NU's COI policy and process and does not need to follow the other institution's COI policy and process



Key Compliance Points

Investigators

- ✓ Disclose SFIs
- ✓ Complete COI training



Proposal Submission

OSR

JIT/NOA/Contract Execution

?

NUCOI/ Schools



Award QA Check





Funding Released



How NUCOI Knows to Review the Project

- Systematic trigger:
 - Setting the status of the award to "Prespending" "JIT" or "Awarded" and including award/budget start dates puts the award in our queue
- Alternate triggers:
 - In cases of one-off situations like NCEs, renewals, etc.,
 emailing us will facilitate the process
- > Key Contact: NUCOI, Kate Cosgrove



The Monitor Compliance Screen



Monitor Conflict of Interest (COI) Compliance - By Proposal

Proposal due date 07/12/2011					ole 41_01A1 - 03/31/2017 - 03/3/31/2014	ith	Prir	Dr. Sr	gator (Contact): mith PI Email	
Filter by Submitted Disclosure Date: From: To: Filter Show 60 Day Disclosure History Update Investigator's Project Status View Reminder Email Logs Send Email										
Monitor Compliance	NUCOI & School I Submitted Disclosure Date	Current Project Status	Reason for Disclosure	COI Disclosure Status	Discl Updated Prior One Year	NUCOI Review Date	NUCOI Review Status	School Initial Review Date	School Initial Review Name	School Initial Review Status
Dr. Miller	06/05/2013	Active	Update Disclosure-New SFI	Submitted	Yes	06/07/2013	C - No Conflict Identified			C - No Conflict Identified
Dr. Smith	09/12/2013	Active	Update Disclosure-New SFI	Submitted	Yes		A - Pending Review			



The Monitor Compliance Screen



Monitor Conflict of Interest (COI) Compliance - By Proposal

Proposal Title InfoEd Proposal Number Originating Sponsor Agency for Healthcare Research and Quality Managing Unit Communication Studies Algorithm Adjustion Studies Communication Studies						ch and Quality	Principal Investigator (Contact): Dr. Wilbur			
Proposal Status Pre-Route Complete Proposal Submission Date Proposal Due Date Proposed Project Period Proposed Project Period Pre-Route Complete 08/30/2013 09/01/2013 - 08/31/2013		Involves Human Subject ? Yes Sponsor Award Number Awarded Project Period - Current Budget Period - Award Status				Send PI Email				
Filter by Submitted Disclosure Date: From: To: FILTER Show 60 Day Disclosure History Update Investigator's Project Status View Reminder Email Logs Send Email										
Monitor Compliance NUCOI & School Review Mgt Plan Info										
Investigator Name	Submitted Disclosure Date	Current Project Status	Reason for Disclosure	COI Disclosure Status	Discl Updated Prior One Year	NUCOI Review Date	NUCOI Review Status	School Initial Review Date	School Initial Review Name	School Initial Review Status
Dr. Gretel	05/30/2013	Active	No Change-Progress Report	Submitted	Yes	09/13/2013	C - No Conflict Identified			C - No Conflict Identified
Dr. Wilbur	08/26/2013	Active	Initial Disclosure	Submitted	Yes					



Key Compliance Points

Investigators

- ✓ Disclose SFIs
- ✓ Complete COI training



Proposal Submission

OSR

JIT/NOA/Contract Execution

- ✓ FCOI determination made
- ✓ FCOI managed, as applicable
- ✓ FCOI reported, as applicable

NUCOI/ Schools



Award QA Check





Free ding Dalas

Funding Released ASRSP

NUCOI Process

Investigators are entered into InfoEd

- Check: Subrecipients or Persons Outside the Institution? Any "TEMP" profiles?
- Key Contact: OSR, Sara Krentz

Investigators are fed, overnight, into FASIS

- Check: Do all investigators have a current disclosure on file? If not, the RA should contact the investigator to disclose
- Key Contact: NUCOI, Maria Daniele

Compliance Checkpoint: Before **submitting** the grant, ALL investigators must have disclosed within the last 12 months.



Status of the award is updated to "JIT" or "Awarded" and added to the NUCOI queue for review prior to opening the chartstring.

- Check: Do all investigators have a status of "No Conflict" or "Conflict Managed?"
- Key Contact: NUCOI, Kate Cosgrove



Compliance Checkpoint: Before opening chartstrings, ALL investigators must have a COI status of "No Conflict" or "Conflict Managed."



The Do's & Don'ts:

- Don't: Submit proposals without a disclosure on file for all investigators
- Don't: Open chartstrings without a determination of "No Conflict" or "Conflict Managed" for all investigators



Please DO

contact us with **ANY** questions you have related to COI

Topic	NUCOI Contact	Email Address	Phone	
FASIS system questions or issues (research, annual faculty, or annual staff)				
Subrecipient COI forms at proposal time	Maria (Mari) Daniele	maria.daniele@northwestern.edu	047 467 4515	
Setting up subrecipient investigators as POIs at JIT/Award		nucoi@northwestern.edu	847-467-4515	
General questions				
Specific research review COI status updates - investigator and/or project-specific	· Kate Cosgrove	Le construe Que enthre contente en en en	847-491-4163	
Research-related COI review questions		k-cosgrove@northwestern.edu		
Request training				
Sponsor reporting and/or requests				
NU policy applicability and interpretation			847-467-3938	
Subrecipient policy interpretation				
COI language in proposal solicitations and contract terms and conditions	Julia Campbell	juliacampbell@northwestern.edu		
COI management plans				

Scenarios for Discussion



Scenario #1

Prof Williams hands in his grant and says, "this is everything" and then gets on a 20hr flight to Australia, where he will have only loose email contact.

- You notice that Prof Williams has not disclosed.
 - Contact NUCOI!
- You notice that a consultant is named, but aren't sure if they've disclosed.
 - Check the Subrecipient Tracking document on our website.
 - IF there is a problem, contact NUCOI



Scenario #2

Polly Smith wants to submit an individual NRSA on 12/8.

- She is a graduate student who has never disclosed.
 - Because there is an overnight feed, before 12/8 enter her into InfoEd. Confirm she's in there the next day & provide disclosure instruction.
 - IF there is a problem, contact NUCOI.
- She is a postdoc currently at Vanderbilt, but will be starting at NU on 1/15.
 - Remember the 90 day rule for netids get them into FASIS

http://www.northwestern.edu/hr/managers-administrators/fasis-administrator-tools/netid-automation.html

- IF there is a problem, contact NUCOI, Maria Daniele

Scenario #3

You have received an NOA and notice that there is a foreign subrecipient listed for which you have no information regarding COI, on paper or in the system

- Contact NUCOI immediately
- We need to verify and facilitate compliance immediately, prior to subcontract execution



Appendix Slides



New PHS Regs: Highlight of Changes

Policy Area	Old Requirements	New Requirements
1. Expanded disclosure	Researchers disclose Significant Financial Interests (SFIs) related to the research activity being proposed	☑ Researchers disclose SFIs <i>relating to any Institutional Responsibilities</i> , before proposals are submitted, within 30 days of new SFIs, and annually
		✓ Institution must determine whether or not an SFI relates to specific research activity and constitutes an FCOI
2. Definition of SFI	• General \$10,000 threshold	☑ General thresholds lowered to \$5,000
	• Travel expenses not specified	☑ Sponsored or reimbursed travel
3. Training	No training requirements	☑ Specific COI training requirements
4. External Reporting	Initial sponsor reporting required	☑ Expanded and more frequent sponsor reporting
5. Public Access	None	☑ COI policy must be available on public website
		☑ The public may request, and NU must provide, information relative to certain FCOIs related to PHS-funded research

Definition of SFI

Lower monetary thresholds and greater specificity regarding what is considered an SFI:

An external financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children), when related to the investigator's institutional responsibilities, when combined for the 12 months preceding the disclosure date, from a single entity:

- Compensation and/or other payments for service (e.g., salary, consulting, advisory, and/or lecturing fees, paid authorship, gifts, and honoraria) exceeding \$5,000*;
- Equity interests (e.g., stock, stock options, or other ownership interests) in a publicly-traded entity for which the value exceeds \$5,000*;
- Reimbursed or sponsored travel exceeding \$5,000;
- Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests that exceeds \$5,000*; and
- <u>Any</u> equity interests (e.g., stock, stock options, or other ownership interests) in a non-publicly-traded entity.
 - * FSM threshold is different read each question carefully

What Must be Disclosed?

Nature of SFI	Threshold/Description
Compensation and/or other payments for service	Exceeding \$5,000 (from one entity in the 12 months prior to disclosure date)*
Equity interests in a publicly-traded entity	Exceeding \$5,000 (from one entity in the 12 months prior to disclosure date)*
Equity interests in a non-publicly-traded entity	0 (i.e., ANY and ALL equity interests in non-publicly traded entities
Intellectual property rights and interests upon receipt of income related to such rights and interests	Exceeding \$5,000 (from one entity in the 12 months prior to disclosure date)*
Sponsored or reimbursed travel Applies to PHS-funded researchers only: Investigators who have any PHS funding or any funding from agencies following PHS COI regulations must disclose any reimbursed or sponsored travel	Exceeding \$5,000 (from one entity in the 12 months prior to disclosure date)

^{*}Faculty with primary appointments in FSM have different thresholds.

Please read each question carefully.

What Is **Excluded** from Disclosure?

Nature of Interest	EXCLUDED FROM DISCLOSURE: DO NOT DISCLOSE
Compensation and/or other payments for service	 Compensation that aggregates to less than \$5,000 (from one entity in the 12 months prior to disclosure date)* Any compensation received for lectures, seminars, teaching engagements, or service on advisory committees or review panels relating to federal, state, or local government agencies, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education, and/or compensation received from or through NU funds
Equity interests in a publicly- traded entity	 Equity interests that aggregate to less than \$5,000 (from one entity in the 12 months prior to disclosure date)* Interests in any entity through personal retirement accounts and mutual funds
Equity interests in a non- publicly-traded entity	Interests in any entity through personal retirement accounts and mutual funds
Intellectual property rights and interests upon receipt of income related to such rights and interests	 Interests that aggregate to less than \$5,000 (from one entity in the 12 months prior to disclosure date)* Royalties received from NU funds, and unlicensed intellectual property that does not generate income
Sponsored or reimbursed travel Applies to PHS-funded researchers only: Investigators who have any PHS funding or any funding from agencies following PHS COI regulations must disclose any reimbursed or sponsored travel	 Interests that aggregate to less than \$5,000 (from one entity in the 12 months prior to disclosure date) Travel administered through NU funds, and travel reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

*Faculty with primary appointments in FSM have different thresholds.

Please read each question carefully.

When Do Investigators Need to Disclose?

Scenario #1: Current NU PI with current NIH money

Initial Training: 12/1/2012 (Next training due: 12/1/2016)

Initial Disclosure: 10/1/2012

Update Required: 10/1/2013







6/16/2013: New Grant Submission – no update required. 8/15/2013: Progress report due – no update required. 10/5/2013: New Grant Submission – **Must** update disclosure!



When Do Investigators Need to Disclose?

Scenario #2: Current NU PI with current NIH money

Initial Training: 12/1/2012 (Next training due: 12/1/2016)

Initial Disclosure: 10/1/2012



Updated: 8/21/2013







8/15/2013: **New Consulting** Interest – Must update disclosure within 30 days!



10/5/2013: **New Grant** Submission – no update required.

