COI: Best Practices and New Resources for Administrators

Kate Cosgrove Booth
Maria Daniele

Conflict of Interest Office
# Lifecycle of a project

<table>
<thead>
<tr>
<th>Project Stage</th>
<th>Compliance Checkpoints</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior to Proposal Submission</td>
<td>✓ All Investigators must have completed training* and disclosed either in FASIS or on a paper form</td>
</tr>
<tr>
<td>Prior to Opening a Chartstring</td>
<td>✓ All Investigators must have disclosed in FASIS</td>
</tr>
<tr>
<td></td>
<td>✓ All Investigators must have cleared COI review</td>
</tr>
<tr>
<td>Ongoing Maintenance</td>
<td>✓ All active Investigators must maintain a current disclosure in the system</td>
</tr>
</tbody>
</table>

*Northwestern does not flow-down PHS training requirements to subrecipients under non-PHS awards, e.g., NSF*
Proposal Time Overview

1. Identify which people on the project are Investigators (RA)
   – **Resource:** The PI

2. Identify which, if any, external Investigators will be following NU’s policy (RA)
   – **Tools:** FDP Clearinghouse, Subrecipient Commitment Form, or LOI

3. Ensure that all Investigators are properly entered into InfoEd
   – **Resource:** InfoEd Team in OSR

4. Confirm that all Investigators following NU’s policy have a current disclosure on file (RA & OSR)
   – **Tools:** Monitor Compliance in FASIS, Paper Disclosure Form tracking spreadsheet on NUCOI website (as necessary)
Identifying Investigators: Definition

Investigators are *anyone*, regardless of title or position, who is responsible for the design, conduct or reporting of research.

Key Personnel are *always* Investigators

Investigators may or may not include individuals *in addition to*

those listed as Key Personnel

Consultants, advisors, technicians, postdocs, graduate students, etc. may or may not be Investigators if the PI determines they meet that definition.
Identifying Investigators

**Investigators**

- Key Personnel
- Non-Key Personnel
- Research Coordinators
- Consultants
- Graduate Students

**Not an Investigator**
Identifying Investigators: PI Guidance

• Guidance for helping PIs assess whether someone is an Investigator:
  – Are they independently making decisions about research, conduct, and/or reporting of research, or are they just following protocols / PI instructions?
  – Will they be listed as a co-author on publications arising from the research?

• *If so,* they may be considered Investigators, are subject to and should complete COI requirements.
Who is Following NU’s Policy?

• All NU Investigators
• Any Subrecipient Investigators who are following NU’s policy
• All Consultant Investigators
Which Subrecipients Need to Follow NU’s Policy?

- Subrecipient Investigators from institutions that do not have a conflict of interest policy compliant with PHS regulations
- How to determine which Institutions have a compliant policy
  1. Check the FDP Clearinghouse
     - These institutions have publicly attested to having a compliant policy and are good to go.
  2. Issue OSR’s Subrecipient Commitment Form

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Conflict of Interest
(Applicable to NIH, other PHS sponsors, or non-PHS federal/non-federal sponsors that have adopted the PHS financial disclosure requirements)

- Subrecipient Organization/Institution certifies that it has an active and enforced conflict of interest policy that is consistent with the 2011 provision of 42 CFR Part 50, Subpart F “Responsibility of Applicants for Promoting Objectivity in Research.”

- Subrecipient does not have an active and/or enforced conflict of interest policy and agrees to abide by NU’s policy (located at http://www.northwestern.edu/coi/) for Subrecipient Investigators relative to this specific research activity. For purposes of establishing a profile in the NU system should this proposal be awarded, please provide investigator (s) information below:
Using the Subrecipient Commitment Form (SCF):

An Institution declaring a compliant policy is not necessarily the end of the process. If the Institution is a:

- US Higher Ed. Institution or an Academic Medical Center
- US nonprofit or for-profit entity
- Foreign Institution

Contact NUCOI to verify compliance of policy (NUCOI will contact Institution)

If they have a compliant policy, they do not need to follow NU’s policy.

If they do not have a compliant policy, they must follow NU’s policy.

We consider this declaration sufficient and trust that they have a compliant policy. The Investigators do not need to follow NU’s policy.

Include language relative to having a compliant COI policy in LOI or include the SCF in the submission.

Investigator must complete training and have a disclosure on file with NUCOI, either on paper or in FASIS.
Resources: Determining Which Subrecipients Must Follow NU’s Policy

http://www.northwestern.edu/coi/for-administrators/index.html
Consultant Investigators Must Follow NU’s COI Policy

• All Consultants who meet the definition of Investigator must follow NU’s Policy
  ✓ Consultants may or may not be an Investigator – **ASK THE PI**
  ✓ Consultants act independently and are therefore not an “institution” with compliant COI policies that they can rely on
Note: When NU Faculty serve as Independent Consultants

- NU Faculty serving as an independent Consultants on outside awards are not covered by NU’s Policy on Conflict of Interest.
  - This is not Northwestern activity, there is no subcontract, and thus no statement of work at NU
  - COI determinations are made relative to each project. If there is no project, there is nothing to monitor, and we cannot properly assess whether there is potential for bias in the research
Entering Investigators Into InfoEd

- Proper data entry into InfoEd is **essential** to ongoing COI compliance
- All **named personnel** with properly set up profiles feed to FASIS from InfoEd overnight
- Tips on entering Investigators into InfoEd:
  - **NU Personnel**: Select from drop-down list, do not type them in
    - *If you know someone has an NU appointment, but is not in the dropdown list, contact the InfoEd Team/OSR to have them added*
  - **Subcontractors**: Enter as subcontractor personnel, not TEMPs
  - **Consultants**: Only option is for TEMP profile
    - *Note that you will need to work with OSR at award time to remedy this*
  - **New (but not yet here) NU personnel**: Contact Sara Krentz in OSR to set them up in InfoEd
Confirming Compliance Prior to Proposal Submission

✔ Before a proposal can be submitted, all investigators must have a disclosure on file, dated within the last 365 days.

• **NU Investigators**: Check Monitor Compliance in FASIS

• **Non-NU Investigators**: Check Monitor Compliance in FASIS and the Paper Disclosure Form tracking document
  
  • Many external Investigators have previously collaborated with Northwestern – if they have already submitted a paper disclosure form or completed a disclosure in FASIS in the last 365 days, they are set
  
  • If not, have them **complete a paper disclosure form** and send to NUCOI
    
    – *Sponsor-specific disclosure forms and instructions are available on NUCOI’s website under “Forms”*

✔ Investigators with outdated disclosures should update them prior to proposal submission
FASIS COI Portal: Monitor Compliance Pages

- **Compliance by Proposal**: View all Investigators on a specific project and their most recent training and disclosure date
- **Compliance by Investigator**: View all projects for a specific Investigator and their most recent training and disclosure date
Knowing if an Investigator has Disclosed

Monitor Conflict of Interest (COI) Compliance - By Investigator

<table>
<thead>
<tr>
<th>Investigator Name</th>
<th>Empl ID</th>
<th>Home Department</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>NCC Engg Sci &amp; Applied Math</td>
</tr>
</tbody>
</table>

Last Submitted Disclosure: 06/27/2013
Last Training Date: 10/24/2012

Note:
Though there is a disclosure date, it is beyond 365 days (OUT OF DATE) and the disclosure needs to be updated.
Knowing if an Investigator has Disclosed

Monitor Conflict of Interest (COI) Compliance - By Proposal

<table>
<thead>
<tr>
<th>Proposal Title</th>
<th>The Robert H. Lurie Comprehensive Cancer Center</th>
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<tbody>
<tr>
<td>InfoEd Proposal Number</td>
<td>SP9021203</td>
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<tr>
<td>Originating Sponsor</td>
<td>National Cancer Institute</td>
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<tr>
<td>Managing Unit</td>
<td>Czep General</td>
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<tr>
<td>Proposal Status</td>
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<td>Proposal Submission Date</td>
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<td>Proposal Due Date</td>
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<td>Awarded Project Period</td>
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<td>Anticipated Outyear</td>
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<td></td>
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<tr>
<td>Principal Investigator (Contact):</td>
<td>Platianas, Leonidas C</td>
</tr>
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Filter by Submitted Disclosure Date:
From: 03 To: 03
Send Email

Show 90 Day Disclosure History

<table>
<thead>
<tr>
<th>Investigator Name</th>
<th>Home Department</th>
<th>Current Project Status</th>
<th>Last Email Reminder</th>
<th>Last Email Type</th>
<th>Last Training Date</th>
<th>Submitted Disclosure Date</th>
<th>Reason for Disclosure</th>
<th>Updated Prior/On Due Date</th>
<th>Updated Prior/On Submission</th>
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</thead>
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<tr>
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<td>MED-Pathology</td>
<td>Active</td>
<td>09/13/2012</td>
<td></td>
<td>09/04/2012</td>
<td>03/28/2014</td>
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<td>Proposal Submitted</td>
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<tr>
<td></td>
<td>WCAS Molecular Biosciences</td>
<td>Active</td>
<td>09/14/2012</td>
<td></td>
<td>09/14/2012</td>
<td>03/11/2014</td>
<td>Update Disclosure-Annual Load</td>
<td>Proposal Submitted</td>
<td>Yes</td>
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<tr>
<td>Rosen, Steven T</td>
<td>MED-Hematology</td>
<td>Active</td>
<td>09/20/2013</td>
<td>Reminder Email to PI</td>
<td>08/24/2012</td>
<td>01/17/2014</td>
<td>Update Disclosure-SFI</td>
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<tr>
<td></td>
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<td>Active</td>
<td>09/14/2019</td>
<td></td>
<td>09/04/2019</td>
<td>09/28/2014</td>
<td>Update Disclosure-Proposal</td>
<td>Proposal Submitted</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Clean-up: Named Personnel who are not Investigators

- Sometimes a proposal will have named personnel that do not meet the definition of Investigator
- All named personnel are fed from InfoEd → FASIS
- Use Monitor Compliance by Proposal to change the status of an Investigator
Knowing if an Investigator has Disclosed

1. Go to NUCOI website: http://www.northwestern.edu/coi/
2. Click “Procedures (requires login)”
3. Login with NetID & Password
4. Click “Paper COI Disclosure Form Tracking List”
Transitioning from a Proposal to an Award

• The FASIS system depends on information from InfoEd
• Projects enter our queue for review based on the project status (still an overnight feed)
• Statuses that will trigger review (in order of urgency): Awarded, Prespend, JIT
  – Projects that do not have one of these statuses are not in our queue and we do not know that we need to look at them
  – Prespending accounts can be opened while COI review is pending

• Times when this gets tricky:
  – Projects where NU is the subcontractor
  – Other
  – Always feel free to notify us that something is happening!
Award Time Overview

1. Set up Consultant Investigators and Subrecipient Investigators as POIs (RA/NUCOI)
   - **Resources:** Maria Daniele in NUCOI & Sara Krentz in OSR

2. Confirm that all Investigators (including Consultants and Subrecipients) following NU’s policy have a current disclosure on file in **FASIS** (RA)
   - **Tool:** Monitor Compliance in FASIS

3. Confirm that a determination is on file for all Investigators indicating either ‘no conflict’ or ‘conflict managed’ (OSR)
   - **Tool:** Monitor Compliance in FASIS
Bringing Subcontractors & Consultants in as POIs

• What is a POI?
  – “Person Outside of the Institution”
  – The title “POI” distinguishes Subrecipients and/or Consultants at award time from proposal time
  – At Award Stage, Subrecipient and/or Consultants become a POI when an NU profile is created for them in FASIS
  – **Key Contacts**: NUCOI, Maria Daniele; OSR, Sara Krentz
How to Create a POI at Award Time

- **POI Check**
  Research Administrator (RA) verifies if POI exists in FASIS Monitor Compliance Page

  - **POI in FASIS (Repeat POI)**
    RA verifies that a current disclosure is on file, dated within the last 365 days

  - **POI NOT in FASIS**
    RA emails SP#, POI full name, birthdate and email address to Maria Daniele (NUCOI)

- **Out-Of-Date Disclosures**
  RA contacts Investigator to update disclosure in FASIS

- **POI Added to Project**
  RA emails OSR GO POI name and SP# to add in InfoEd record

- **Confirmation of POI**
  NUCOI (Maria Daniele) verifies POI; POI info sent to Sara Krentz (OSR)

- **NU Profile Created**
  OSR (Sara Krentz) creates profile; works with NUCOI to send NetID, activation and COI instructions
Confirming Compliance: Disclosures in FASIS
Confirming Compliance: Clearing COI Review

Monitor Conflict of Interest (COI) Compliance - By Proposal

<table>
<thead>
<tr>
<th>Proposal Title</th>
<th>InfoEd Proposal Number</th>
<th>Project Summary/Abstract</th>
<th>Originating Sponsor</th>
<th>Managing Unit</th>
<th>Proposal Status</th>
<th>Proposal Submission Date</th>
<th>Proposal Due Date</th>
<th>Proposed Project Period</th>
<th>Involves Human Subject?</th>
<th>Sponsor Award Number</th>
<th>Awarded Project Period</th>
<th>Current Budget Period</th>
<th>Award Status</th>
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</thead>
<tbody>
<tr>
<td>Acute Coronary Syndrome Quality Improvement in Kerala (ACS GUIK)</td>
<td>SP00</td>
<td>National Heart, Lung, and Blood Institute</td>
<td>Cardiovascular Epidemiology</td>
<td>Awarded QA Check Complete</td>
<td>Yes</td>
<td>02/05/2014</td>
<td>02/01/2014</td>
<td>05/01/2014 - 04/30/2017</td>
<td>Yes</td>
<td>4R00HL107745-03</td>
<td>07/21/2014 - 08/30/2017</td>
<td>05/01/2014 - 04/30/2015</td>
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Principal Investigator (Contact):
Mark

Filter by Submitted Disclosure Date:
From: [ ] To: [ ]

Update Investigator's Project Status
View Reminders Email Logs

Show 90 Day Disclosure History

<table>
<thead>
<tr>
<th>Investigator Name</th>
<th>Submitted Disclosure Date</th>
<th>Current Project Status</th>
<th>Reason for Disclosure</th>
<th>COI Disclosure Status</th>
<th>Updated Prior One Year</th>
<th>NUCCI Review Date</th>
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<th>School Initial Review Date</th>
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<td>C - No Conflict Identified</td>
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Ongoing Award Maintenance

- Update InfoEd record as new Investigators are added to a record – as needed, and as possible within business processes (RA & OSR)
- Change the status of Investigators in FASIS if they are no longer contributing to a project (RA)
### Changing an Investigator Status in FASIS

**Monitor Conflict of Interest (COI) Compliance - By Proposal**

<table>
<thead>
<tr>
<th>Proposal Title</th>
<th>Acute Coronary Syndrome Quality Improvement in Kerala (ACS QUIK)</th>
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</thead>
<tbody>
<tr>
<td>InfoEd Proposal Number</td>
<td>SP0027631</td>
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<tr>
<td>Originating Sponsor</td>
<td>National Heart, Lung, and Blood Institute</td>
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<td>Managing Unit</td>
<td>Cardiovascular Epidemiology</td>
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<tr>
<td>Proposal Status</td>
<td>Awarded QA Check Complete</td>
</tr>
<tr>
<td>Proposal Submission Date</td>
<td>02/05/2014</td>
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<td>Proposal Due Date</td>
<td>02/01/2014</td>
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<td>Proposed Project Period</td>
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<td>Involves Human Subject?</td>
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<td>Sponsor Award Number</td>
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Filter by Submitted Disclosure Date:

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<th>From</th>
<th>To</th>
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<tbody>
<tr>
<td>2014</td>
<td>2014</td>
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</table>

**Update Investigator’s Project Status**

**View Reminder Email Logs**

**Proposal Title**

<table>
<thead>
<tr>
<th>Investigator Name</th>
<th>Home Department</th>
<th>Current Project Status</th>
<th>Last Email Reminder</th>
<th>Last Email Time</th>
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<tbody>
<tr>
<td>Washington, George</td>
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**Inactivate Investigators**

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<th>Name</th>
<th>Current Project Status</th>
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<tbody>
<tr>
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<td>Smith, John</td>
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<tr>
<td>999999999</td>
<td>Lincoln, Abraham</td>
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<td>999999999</td>
<td>Obama, Barack</td>
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<tr>
<td>999999999</td>
<td>Clinton, Bill</td>
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<tr>
<td>999999999</td>
<td>Kennedy, John</td>
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<td>999999999</td>
<td>Carter, Jimmy</td>
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</tr>
<tr>
<td>999999999</td>
<td>Roosevelt, Franklin</td>
<td>Active</td>
</tr>
</tbody>
</table>
Recap of the Process

**At Proposal Time:**
1. Identify which people on the project are Investigators (RA)
   - **Resource:** The PI
2. Identify which, if any, external Investigators will be following NU’s policy (RA)
   - **Tools:** FDP Clearinghouse, Subrecipient Commitment Form, or LOI
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   - **Tool:** Monitor Compliance in FASIS
3. Confirm that a determination is on file for all Investigators indicating either ‘no conflict’ or ‘conflict managed’ (OSR)
   - **Tool:** Monitor Compliance in FASIS

**Ongoing:**
- Update InfoEd record as new Investigators are added to a record – as needed, and as possible within business processes (RA & OSR)
- Change the status of Investigators in FASIS if they are no longer contributing to a project (RA)
New Resources Available on NUCOI Website

• “For Administrators” section has been added to the website and will be growing...
  – Administrator FAQs
  – FASIS User Guides
  – Subrecipient handy-guides
  – Powerpoint presentations

• Please contact us with any questions you have or would like to see addressed by a one-pager or FAQ

http://www.northwestern.edu/coi/for-administrators/index.html
Contact Us!

- Julia Campbell, Director
  - juliacampbell@northwestern.edu
  - 847-467-3938

- Kate Cosgrove Booth
  - k-cosgrove@northwestern.edu
  - 847-491-4163

- Maria Daniele
  - maria.daniele@northwestern.edu
  - 847-467-4515
Thank you!!!

Questions?