NURAP: COI Update

New eDisclosure System

January 25, 2016
Julia Campbell
Director, Conflict of Interest
Topics for Discussion
Overview of new system

Impacts on research-related processes

Timeline

Training & resources
eDisclosure is the new single disclosure system for the University community for all COI requirements

-- Annual faculty disclosure requirements
-- Annual staff disclosure requirements
-- Research-related disclosure requirements

eDisclosure replaces FASIS and the Joint Affiliate Disclosure System (previously used by FSM for annual disclosures) with respect to COI requirements for Northwestern
New disclosure system: Key Features

- Single disclosure point and single disclosure of record
  - While annual and research review processes differ, the disclosure record itself for each person is “live” and is one record that can be updated throughout the year
  - No longer separate disclosures in separate FSM system or in eIRB protocol application

- More user-friendly interface and elimination of technical obstacles impacting system access and user experience
  - No MFA or VPN barriers, better compatibility among browsers and platforms, and less system down time

- Enhanced functionality allows for more efficient business processes for disclosers and reviewers
Impacts on Sponsored Research Processes
Process: Key Compliance Points

- Complete COI training
- Disclose SFIs

**JIT/NOA/Contract Execution**

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

**Award QA Check**

**Funding Released**

**OSR**

**NUCOI/Schools**

**Investigators**

**Proposal Submission**

**+RAs**

**ASRSP**
How Are Disclosures Reviewed?

Disclosures/SFIs are reviewed compared to each research project subject to NU’s COI requirements. NUCOI performs an initial review; some reviews are referred to School-based reviewers or Committees.
Process: Refresh

Before Proposal Submission

☑️ Each active Investigator* must have COI training date within last 4 years
☑️ Each active Investigator must have disclosure on file dated in last 365 days

Before Project Set-Up

☑️ Each active Investigator* must have COI training date within last 4 years
☑️ Each active Investigator must have disclosure on file dated in last 365 days
☑️ Each Investigator must have a final COI review determination completed

* Investigator: someone independently responsible for research design, conduct, or reporting.
Verifying Compliance in eDisclosure

 Check compliance by Investigator name

❖ Example: is Professor Campbell compliant in her COI requirements (which would be applicable to every project on which she is listed as an Investigator?)

○ i.e. does Professor Campbell have COI training completion date in the last 4 years, and does she have a disclosure on file dated in the last 365 days?
Verifying Compliance in eDisclosure

Check compliance by Investigator Name

No training or disclosures on file 😞

🚫 No training or disclosure date on file: no proposals can be submitted and no awards set-up
Verifying Compliance in eDisclosure

☀ Check compliance by Project #

❖ Example: is project # SP0012345 compliant for proposal submission or award set-up?
  
  o i.e. @ proposal time: does each Investigator have current COI training date (w/in last 4 years) and current disclosure date (w/in last 365 days)?

  o i.e. @ award time: does each Investigator have current COI training date (w/in last 4 years) and current disclosure date and have final COI review determinations (determination = Review Complete)?
Verifying Compliance in eDisclosure

Check compliance by Project #

- Training w/in last 4 years 😊
- Disclosure w/in last 365 days 😊
- COI review not final 😞

- Training & disclosure dates are compliant: proposal can be submitted!
- COI determination is NOT FINAL: award cannot yet be set-up
# Verifying Compliance in eDisclosure

Check compliance by **Project #**

<table>
<thead>
<tr>
<th>SP ID</th>
<th>Discloser's First Name</th>
<th>Discloser's Last Name</th>
<th>COI Training Date</th>
<th>Last Disclosure Submission Date</th>
<th>Compliance Review Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>SP0012345</td>
<td>Rishi</td>
<td>Agrawal</td>
<td>9/2/2012</td>
<td>7/26/2015</td>
<td>Review Complete</td>
</tr>
<tr>
<td>SP0012345</td>
<td>Kate</td>
<td>Cosgrove</td>
<td>3/16/2014</td>
<td>2/14/2015</td>
<td>Under Review</td>
</tr>
</tbody>
</table>

- **Rishi is all set** (training & disclosure dates compliant, review final/complete)
- **Kate is not all set** (training & disclosure dates compliant, but review not yet final/complete)

**Project (SP0012345) cannot be set-up:** each Investigator must have final review status of “Review Complete”
Subrecipients & POIs
Subrecipients & POIs

Process Refresh

❖ Subrecipients either follow their own compliant COI policy or fall under NU’s COI policy

❖ When considering whether action is needed on your part with respect to subrecipient institutions and COI compliance, refer to the Subrecipient COI Decision Matrix Tool

❖ Consultant Investigators fall under NU’s COI
Subrecipients & POIs

Process Refresh

☒ Subrecipient institution in the FDP Clearinghouse? All good

☒ Subrecipient institution is U.S. institution of higher education or affiliated medical center and is \textit{not} in FDP Clearinghouse, \textit{but} institution includes language in LOI regarding having own compliance policy and/or completes OSR’s Subrecipient Commitment Form and indicates having their own compliant policy? All good

☒ Subrecipient institution is for-profit, non-profit, or foreign institution \textit{(not} in FDP Clearinghouse) and includes language in LOI regarding having own compliant policy and/or completes OSR’s Subrecipient Commitment Form and indicates having their own compliance policy? \textit{Verify with NUCOI}
Subrecipients & POIs

Subrecipient Investigators & POIs in eDisclosure

⊙ No more paper forms or separate paper tracking of subrecipient Investigator compliance at proposal submission

⊙ POI profiles can be easily created in eDisclosure at proposal time or award time

⊙ No NetID needed

⊙ eDisclosure Compliance page, by project and by person, will include POIs
Impact on IRB Processes
Current IRB/COI Process

Current State

❖ Research-related COI reviews currently originate from *InfoEd* projects + Investigators’ *FASIS* disclosures

❖ Additional protocol-based disclosure occurs in eIRB protocol applications

6. *Does the Principal Investigator have any significant financial interests related to this research?*
   - [ ] Yes
   - [ ] No

Potential Issues

❖ Inconsistent/incomplete/inaccurate disclosures

❖ Non-sponsored research involving human research participants does not go through our established systematic research-related COI review process; it is handled manually and outside of system
New COI/IRB Interface

New Process Effective 2/15/16

❖ COI question in eIRB protocol applications will be removed

❖ Language will be included in eIRB to remind PIs and co-Is that they should ensure their disclosures in eDisclosure are up-to-date

❖ eDisclosure COI review determinations for PIs and co-Is on protocols will interface from eDisclosure to eIRB

❖ Based on InfoEd project # + eIRB protocol match for sponsored research projects

❖ For non-sponsored research involving human research, reviews will be initiated and determinations recorded in eIRB based on disclosures on file for PIs and co-Is in eDisclosure

❖ Reviews can also be initiated/handled in this manner for studies that have multiple protocols associated with one InfoEd record, or studies going through CIRBs (currently handled manually)
## New COI/IRB Interface

<table>
<thead>
<tr>
<th>Current State</th>
<th>Future State</th>
</tr>
</thead>
<tbody>
<tr>
<td>One individual represents in an eIRB protocol application whether or not anyone on the study team has financial interests related to the study</td>
<td>COI determination statuses (i.e. “no conflict” or “conflict managed”) will display in eIRB application for PIs and co-Is on each study based on each individual’s full institutional COI disclosures that have been reviewed via process described in this session</td>
</tr>
<tr>
<td>Full COI management information is made available to IRB upon request (if IRB knows to request it)</td>
<td>Specific information regarding COI management for each investigator/study combination for which a COI determination has been made will be uploaded in eIRB so that the IRB Office/IRB can assess whether or not they feel COI management strategies are adequate to protect human subject safety/welfare</td>
</tr>
</tbody>
</table>
Timeline
Timeline


2/15/2016
Go-Live in eDisclosure
“Go-Live” Email to Faculty & Staff

1/27/16
Key Pre-Launch Communications *

1/2/16 - 2/1/16
Testing & Training

2/15/16 - 3/15/16
Disclosure Period

3/15/16
Discloser Deadline

3/15/16 - 6/30/16
Ongoing Follow-Up

2/8/16
On-line training resources available:
http://www.northwestern.edu/coi/training/index.html

4/30/16
Staff Approval Deadline

6/30/2016
Faculty Approval Deadline

* Key Pre-Launch Communications

Message: (from Lindsay Chase-Lansdale to non-FSM faculty, from Pam Beemer to staff, from Joint Affiliate Leadership to FSM faculty and affiliate disclosers)

- Heads-up that annual disclosure processes upcoming
- New COI system to replace FASIS and JADSS and meet all disclosure requirements for annual faculty, annual staff, and research
- Reference to online training sessions/materials for disclosers AND reviewers

- Changes to disclosure process in eIRB – from Jay Walsh to all Investigators named as Authorized Personnel on active IRB protocols
Training & Resources
Training & Resources

❖ Beginning 2/8/16, instruction manuals, tip sheets, and training videos will be available online
   http://www.northwestern.edu/coi/training/index.html

❖ Additional reporting capabilities in eDisclosure to track compliance will be made available – stay tuned for communication regarding this!

❖ Contact the Conflict of Interest Office at any time if you have questions or need assistance: we are happy to help you!

   Julia Campbell -- Kate Booth -- Mari Daniele
   nucoi@northwestern.edu
   847.467.4515
Training & Resources

The NUCOI listserv and website are utilized for important messages and release of new resources – sign up for our listserv and check our website frequently!

Listserv

To join the list, send an email to listserv@listserv.it.northwestern.edu:

- Leave the subject line blank
- In the body of the email, type: SUBSCRIBE NUCOIINFO Firstname Lastname
  - Replace Firstname and Lastname with your first and last name

Website:

http://www.northwestern.edu/coi/
Thank you! Questions?
Contact Information

Julia Campbell
Director, Conflict of Interest
juliacampbell@northwestern.edu
847.467.3938

http://www.northwestern.edu/coi/