NURAP: COI Update

New eDisclosure System

January 21, 2016
Julia Campbell
Director, Conflict of Interest
Topics for Discussion
Overview of new system

Impacts on research-related processes

Timeline

Training & resources
New disclosure system

- 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 Research-Related 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

Investigators

Proposal Submission

OSR

ASRSP

NUCOI/Schools

+RAs

Northwestern
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**

<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>
</tr>
</thead>
<tbody>
<tr>
<td>SP0030289</td>
<td>Julie</td>
<td>Johnson</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- 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?
  - 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)?
  - 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 #**

<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>SP0030552</td>
<td>Rishi Agrawal</td>
<td></td>
<td>9/2/2012</td>
<td>7/26/2015</td>
<td>Under Review</td>
</tr>
</tbody>
</table>

- **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

полнение

全流程

• 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

全流程

- Subrecipient institution in the FDP Clearinghouse? All good

- Subrecipient institution is U.S. institution of higher education or affiliated medical center and is not in FDP Clearinghouse, 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 (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? 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
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

**2/15/16 - 6/30/16**
Ongoing Follow-Up

**3/15/16 - 6/30/16**
Faculty Approval Deadline

**4/30/16**
Staff Approval Deadline

**6/30/2016**

* 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

On-line training resources available:
http://www.northwestern.edu/coi/training/index.html
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](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/