

NURAP: COI Update

New eDisclosure System

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Topics for Discussion

- ☀ Overview of new system
- ☀ Impacts on research-related processes
 - ☀ Timeline
 - ☀ Training & resources

New disclosure system

eDisclosure

- ⚙ *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

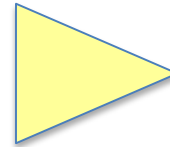


Impacts on Research-Related Processes

Process: Key Compliance Points

Investigators

- ✓ Complete COI training
- ✓ Disclose SFIs



Proposal Submission

OSR

+RAs

JIT/NOA/Contract Execution

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

NUCOI/
Schools



Award QA Check

OSR

+RAs



Funding Released

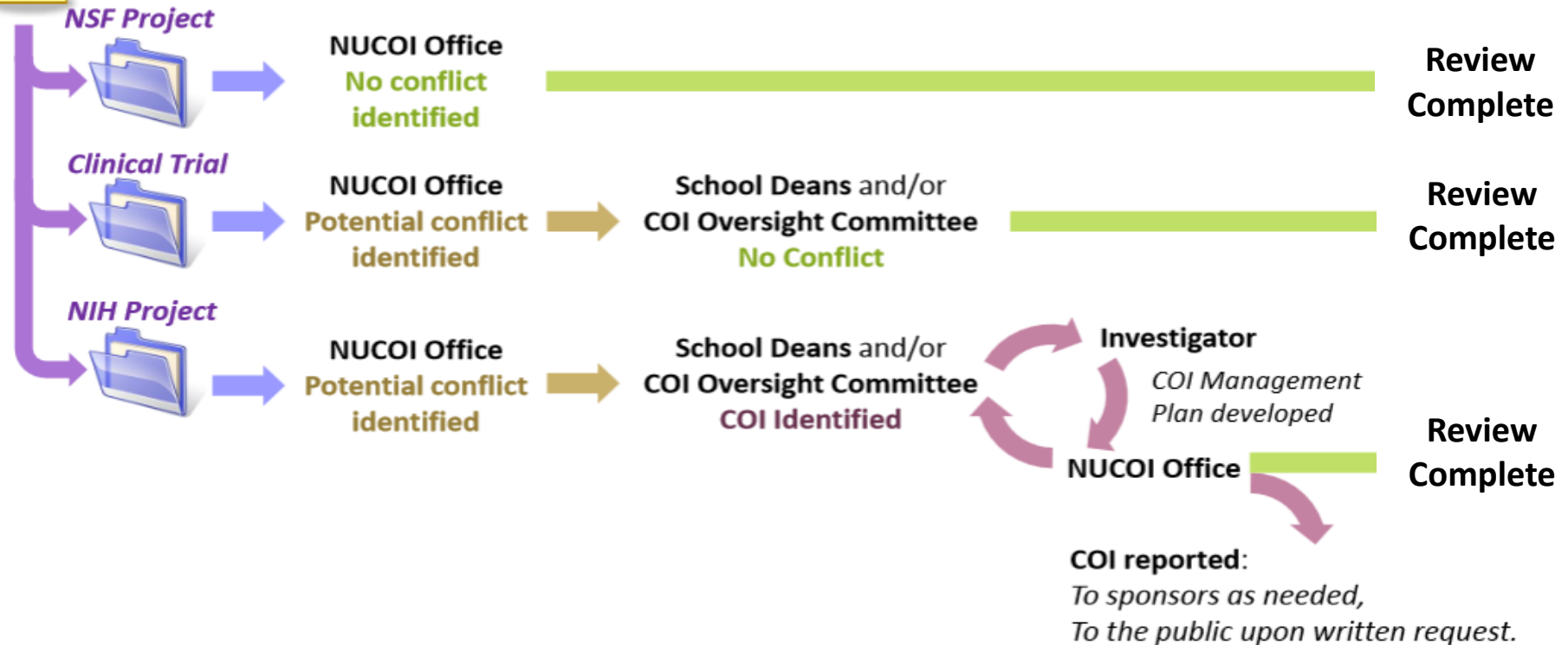
ASRSP

Process: Research Reviews

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.

Disclosure



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**

COI Compliance Page

Filter by johnson Basic

and julie

and

SP ID	Discloser's First Name	Discloser's Last Name	COI Training Date	Last Disclosure Submission Date
SP0030289	Julie	Johnson		

1 items

page 1 of 1

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 #**

COI Compliance Page

SP ID	Discloser's First Name	Discloser's Last Name	COI Training Date	▲ Last Disclosure Submission Date	Compliance Review Status
SP0030552	Rishi	Agrawal	9/2/2012	7/26/2015	Under Review

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 #**

COI Compliance Page

Filter by

SP ID	Discloser's First Name	Discloser's Last Name	COI Training Date	▲ Last Disclosure Submission Date	Compliance Review Status
SP0012345	Rishi	Agrawal	9/2/2012	7/26/2015	Review Complete
SP0012345	Kate	Cosgrove	3/16/2014	2/14/2015	Under Review

✓ 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 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*

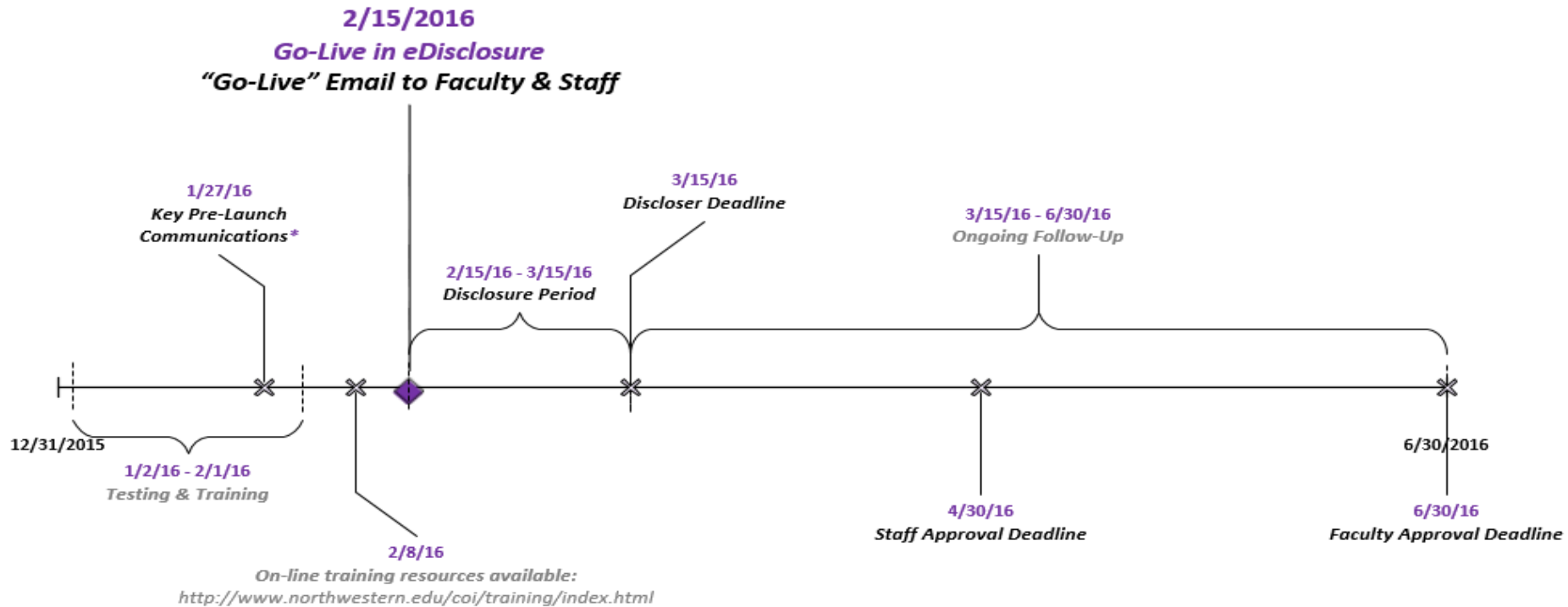
- ☀ No more paper forms or separate paper tracking of subrecipient Investigator compliance at proposal submission
- ☀ POI profiles can be easily created in *eDisclosure* at proposal time or award time
- ☀ No NetID needed
- ☀ *eDisclosure* Compliance page, by project and by person, will include POIs



Timeline

Timeline

Annual Disclosure Process: 2016 Timeline (for CY2015 Disclosure Period)



* 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!

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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

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