

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

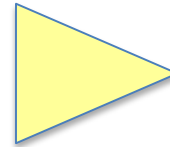


Impacts on Sponsored Research Processes

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

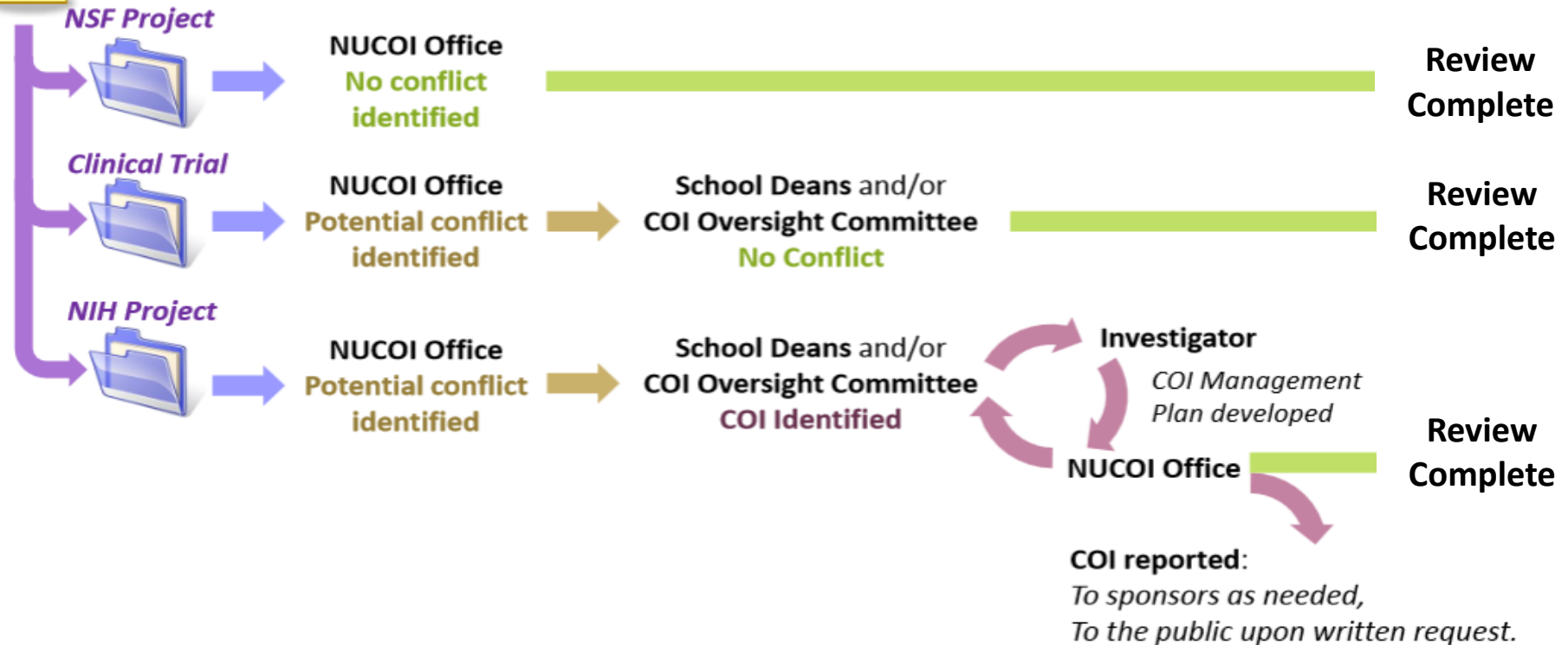
ASRSP

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

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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



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

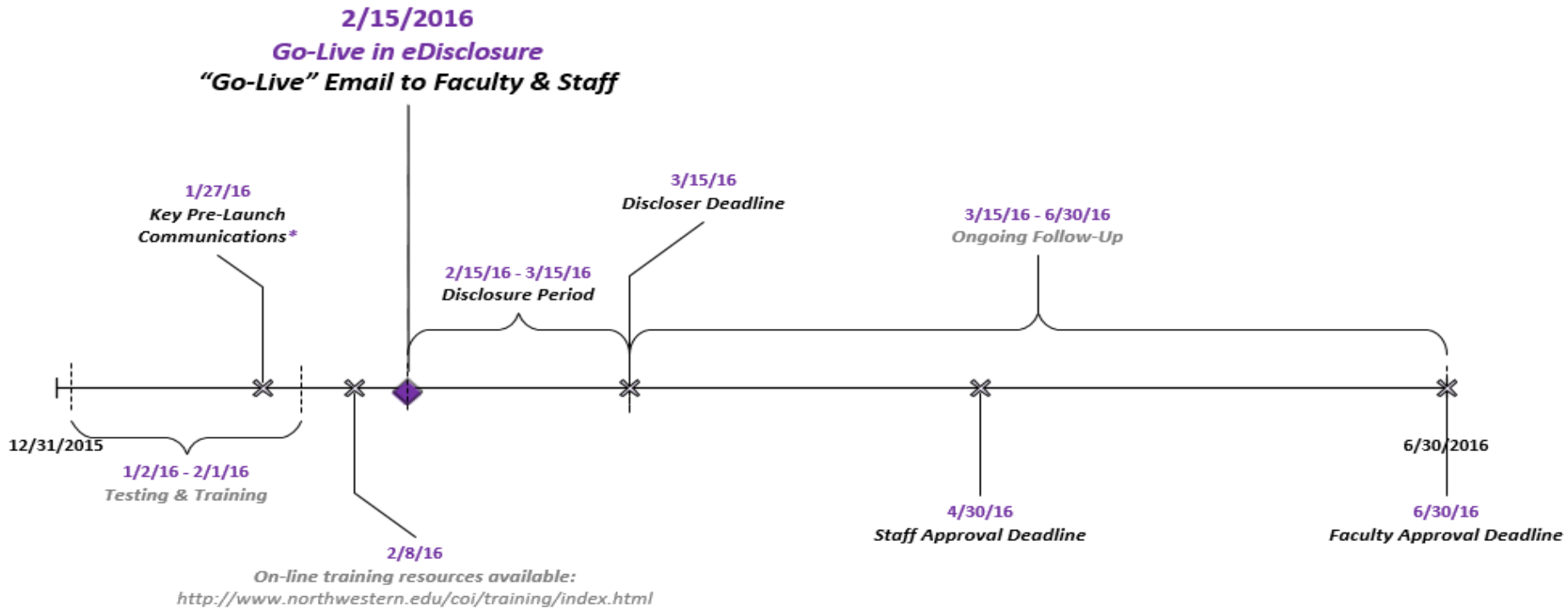
Current State	Future State
One individual represents in an <u>eIRB</u> protocol application whether or not anyone on the study team has financial interests related to the study	COI determination statuses (i.e. “no conflict” or “conflict managed”) will display in <u>eIRB</u> application for PIs and co-Is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



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