Conflict of Interest and IRB studies:

All studies submitted to the IRB that involve human participants are subject to the Conflict of Interest in Research policy, which requires:

- 1. All Investigators must complete COI training and complete a disclosure in <u>eDisclosure</u> prior to initiating a study
- 2. A determination must be made for all Investigators on a study prior to initiating a study. If a conflict is identified, that conflict must be managed prior to study initiation.

How do I know COI review for my study is complete?

- ✓ The COI tab has project information for your study project ID, title and list of Investigators (PI and Co-I's)
- \checkmark All investigators have disclosed within the last year, and completed training within the last four years
- ✓ The COI Determination for everyone listed is either "No Conflict" or "Conflict Managed"

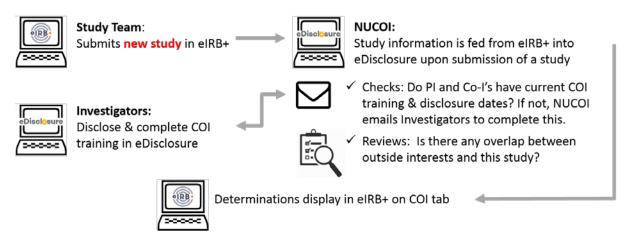
History	Funding	Project Contacts	Documents	Follow-on Submissions	Reviews	Snapshots	Study Team Training	COI
Research Proj	ect ID: STU0020	(Active)		ו				
Research Proj	ect Name: A Rando	mized, Placebo Surgery Cont	rolled,	J	· ·			
				Viselaure	Bala an Stud			
COI Discloser		COI Training Date	Last Submitted D	Disclosure	Role on Study		COI Determination	
				Disclosure	Role on Study Co-Investigal Co-Investigal	tor	COI Determination Under Review Under Review	

How do I interpret the information on the COI tab?

The COI tab in eIRB+	Action?
Is totally blank	 If it is a new study that has been submitted, the tab will refresh in the next two hours. If <u>urgent</u>, or it is not a new study, <u>email NUCOI</u>.
Has title & people, but people are wrong / some people are missing	Only PIs and Co-Is are represented in the personnel list. eDisclosure is usually updated when MODs with updates to the study team are submitted – but it can take a few minutes for the change to be captured by eDisclosure.
Has a funding source associated with it (an SP#) but it is incorrect	Use the Funding tab in eIRB+ to link the study to the correct SP#.
Has a title & people, but the project is listed as (Inactive)	 If the project ID is the STU# and it is (Inactive), email NUCOI to let us know that this study is, in fact, active. If the project ID is an SP# and it is (Inactive), it may be that the grant/contract has ended but the study is still open. <u>Email NUCOI</u> if you have questions about it.
COI tab has title & correct people, but someone is still "Under Review"	 There are multiple reasons why someone might be Under Review: 1. They have not completed their disclosure (disclosure dates are blank) 2. Their disclosure is older than a year and they need to update their disclosure 3. They have not completed a brief COI training (which is different than CITI training) 4. That person is still under review with respect to this project – either with NUCOI, a dean's office, or possibly with the Investigator. Instructions for completing a disclosure or training are below, and on our website. Log in to eDisclosure using your NetID and password, Click "Disclose" and follow the system prompts to navigate the system, Click "Submit" on the last page of the disclosure form.

		If a study is linked to a funding source in InfoEd, the SP# and title for that grant/contract will display in the COI tab.						
History Fun	ding Project Contacts	De Louis Follow	on Submissions	Reviews	Snapshots	Study Te	am Training	CO
Research Project ID: SP	005 (Active)							
Research Project Name	: (PRESPEND)Prot# P	nized, Placebo Surgery Controlled,						
COI Discloser	COI Training Date	Last Submitted Disclosure	For the CO	l review to	be complete	, all	I Determination	
Mark Green	2/16/2018	2/10/2019	Investigator	rs must ha	e completed		Conflict	
Mark Green	2/16/2018	2/10/2019	-		e completed	COI	Conflict	
		2/10/2019	Training in th	e last 4 ye	ars, and must	COI have	Conflict	
Mark Green Research Project ID: ST		2/10/2019	Training in th	e last 4 ye	•	COI have	Conflict	
Research Project ID: ST			Training in th	e last 4 ye	ars, and must	COI have	Conflict	
Research Project ID: ST	U0020 (Active)		Training in th	e last 4 ye	ars, and must	COI have	Conflict	
Research Project ID: ST	U0020 (Active)		Training in th	e last 4 ye	ars, and must st 12 months.	COI have	Conflict I Determination	_
Research Project ID: ST Research Project Name COI Discloser Susan Black	U0020 (Active) : A Randomized, Placebo Surgery Contro COI Training Date 9/7/2018	Last Submitted Disclosur 9/7/2018	Training in th	e last 4 ye	ars, and must st 12 months.	COI have	I Determination der Review	
Research Project ID: ST Research Project Name COI Discloser Susan Black Jennifer Gold	U0020 (Active) 2 A Randomized, Placebo Surgery Contro COI Training Date 9/7/2018 2/7/2018	Last Submitted Disclosi 9/7/2018 2/7/2018	Training in th	Role on Study Co-Investigal	ars, and must st 12 months.	COI have	I Determination der Review der Review	
Research Project ID: ST Research Project Name COI Discloser Susan Black	U0020 (Active) : A Randomized, Placebo Surgery Contro COI Training Date 9/7/2018	Last Submitted Disclosur 9/7/2018	Training in th	e last 4 ye	ars, and must st 12 months.	COI have	I Determination der Review	
Research Project ID: ST Research Project Name COI Discloser Susan Black Jennifer Gold	U0020 (Active) 2 A Randomized, Placebo Surgery Contro COI Training Date 9/7/2018 2/7/2018	Last Submitted Disclosi 9/7/2018 2/7/2018	Training in th disclose	Role on Study Co-Investigal Principal Inve	ars, and must st 12 months.	COI have	I Determination der Review der Review	
Research Project ID: ST Research Project Name COI Discloser Susan Black Jennifer Gold	U0020 (Active) 2 A Randomized, Placebo Surgery Contro COI Training Date 9/7/2018 2/7/2018	Last Submitted Disclosi 9/7/2018 2/7/2018	Training in the disclose	e last 4 ye d in the la Role on Stud Co-Investigal Co-Investigal Principal Inve	ars, and must st 12 months. or stigator	COI have unc unc unc voit No	I Determination der Review der Review	
Research Project ID: ST Research Project Name COI Discloser Susan Black Jennifer Gold	U0020 (Active) 2 A Randomized, Placebo Surgery Contro COI Training Date 9/7/2018 2/7/2018	Last Submitted Disclosi 9/7/2018 2/7/2018	Training in th disclose	e last 4 ye d in the la Role on Stud Co-Investigal Co-Investigal Principal Inve	ars, and must st 12 months. or stigator	COI have unc unc unc voit No	I Determination der Review der Review	
Research Project ID: ST Research Project Name COI Discloser Susan Black Jennifer Gold	U0020 (Active) 2 A Randomized, Placebo Surgery Contro COI Training Date 9/7/2018 2/7/2018	Last Submitted Disclosi 9/7/2018 2/7/2018	Training in the disclose	e last 4 ye d in the la Role on Study Co-Investigal Principal Inve tions for <u>a</u> Conflict or	ars, and must st 12 months. stigator <u>II</u> Investigator Conflict Mana	COI thave unc unc s must aged. If	I Determination der Review der Review	

How does this process work? What are the different roles and responsibilities?



Once a study is submitted in eIRB+, eDisclosure receives **study information** and the **list of Investigators** (PI's and Co-I's but <u>not</u> study team members). eIRB+ then displays COI Determinations for each Investigator on the COI tab. **Review is complete** when all Investigators have disclosed, completed training, and a determination of "No Conflict" or "Conflict Managed" is made for all Investigators on the study.

Study Team	Investigators (PI and Co-I's)	NUCOI
• Enter study information into eIRB+	 Complete disclosure and COI 	Review disclosure information for
 List PI and Co-Investigators on the 	training in <u>eDisclosure</u>	each Investigator on a study
study	• Communicate with dean's office re:	• As needed, NUCOI will:
 Keep personnel list accurate – 	any requested management	 Ask Investigators to complete
removing individuals who are no	strategies	disclosures and training
longer at Northwestern	 Comply with any implemented 	 Refer reviews to Investigator's
Make any requested updates to the	management strategies (e.g.,	dean's office or committee
study in response to management	disclosure in informed consent and	 Upload management plan
	to study team)	information for IRB review