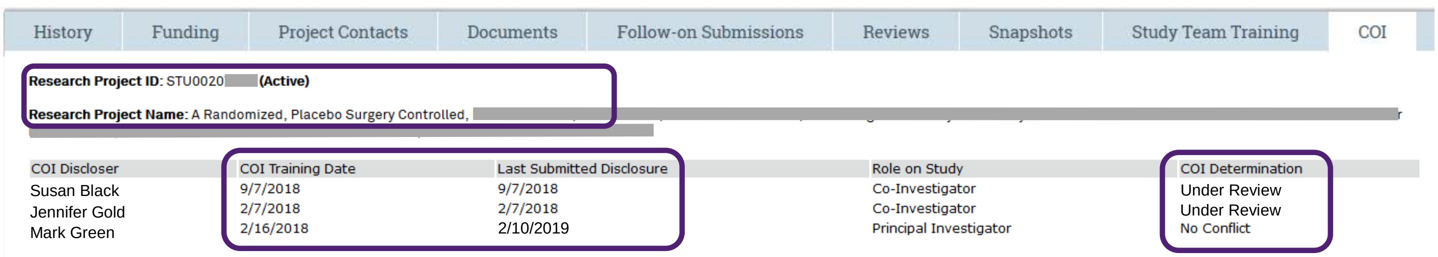
Conflict of Interest and IRB studies:

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 eDisclosure 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?

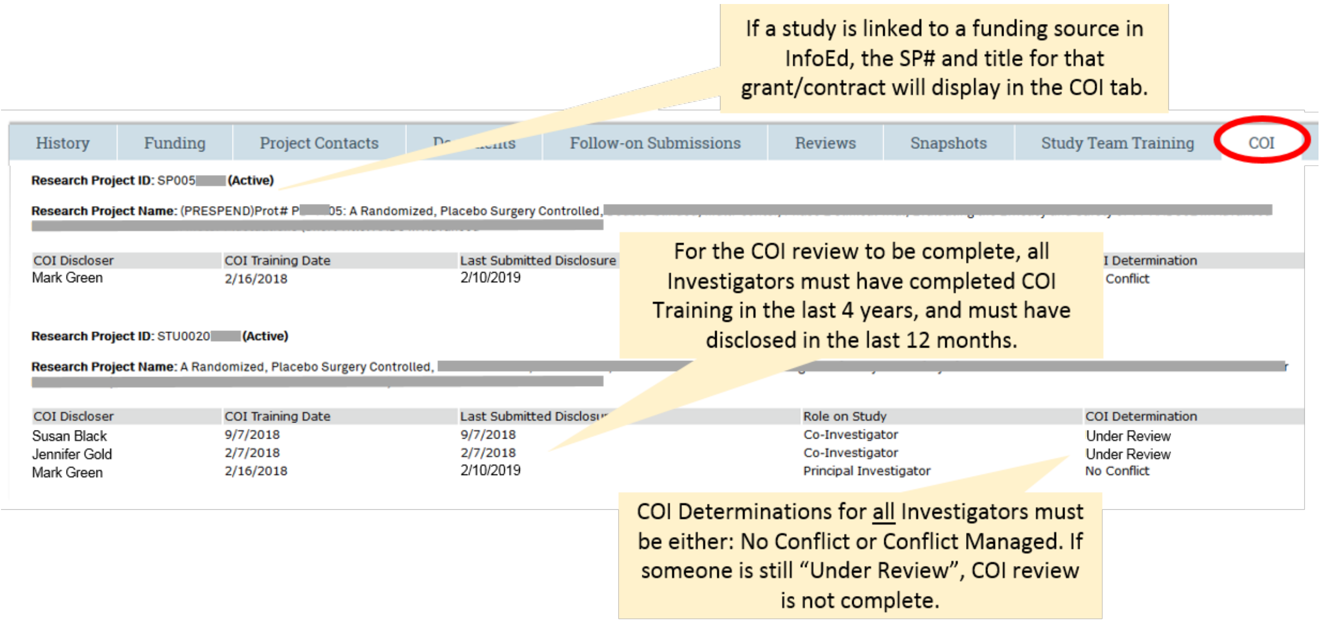
- ✓ The COI tab has project information for your study – project ID, title and list of Investigators (PI and Co-I's)
- ✓ All investigators have disclosed within the last year, and completed training within the last four years
- ✓ The COI Determination for everyone listed is either "No Conflict" or "Conflict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



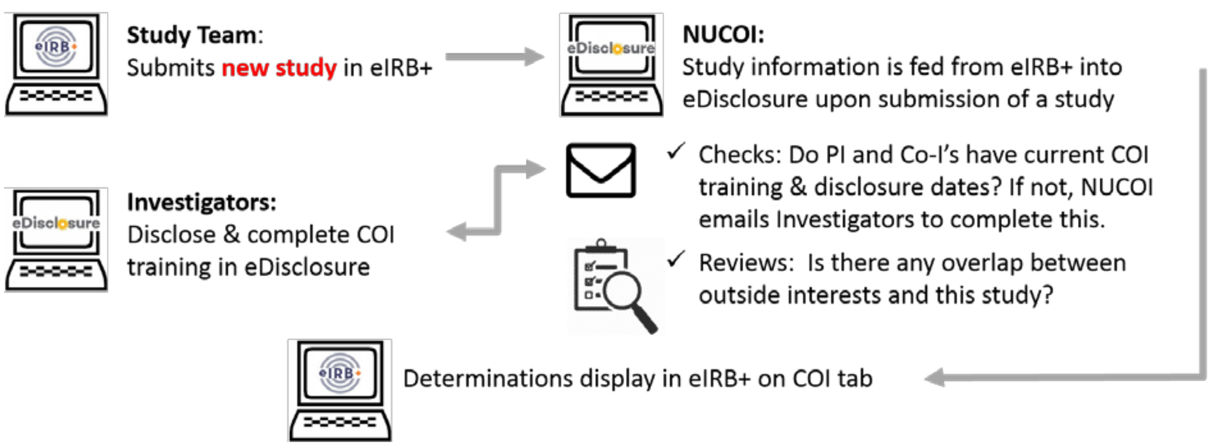
How do I interpret the information on the COI tab?

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 **urgent**, or it is not a new study, email NUCOI.
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. Email NUCOI 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.

The COI tab for my study looks more complicated…



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 not 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+ • List PI and Co-Investigators on the study • Keep personnel list accurate – removing individuals who are no longer at Northwestern • Make any requested updates to the study in response to management	• Complete disclosure and COI training in eDisclosure • Communicate with dean's office re: any requested management strategies • Comply with any implemented management strategies (e.g., disclosure in informed consent and to study team)	• Review disclosure information for each Investigator on a study • *As needed, NUCOI will:* o Ask Investigators to complete disclosures and training o Refer reviews to Investigator's dean's office or committee o Upload management plan information for IRB review