

Where and How Does COI Fit into IRB Review

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Overview

- How did we get here and why?
- Process of COI review
 - High-level overview
 - How the systems interface
 - What we look for and manage
- Available tools
- Q&A



How we got here...

Benchmark COI Cases

Jesse Gelsinger

- Gene therapy study at University of Pennsylvania
- Jesse Gelsinger died as a result of the study
- Investigation revealed that the PI had a start-up company formed around gene therapy; University of Pennsylvania was an investor

Charlie Nemeroff

- Psychiatrist at Emory University
- Failed to report significant payments from pharma companies to the university
- Example: Agreed to limit compensation to \$10,000 per year from GSK; actually earned \$170,000 in a year.
- Relationships were unmanaged or not properly managed due to Nemeroff's failure to disclose

Regulations

- PHS (NIH) updated COI regulations, effective 2012
 - Lowered disclosure thresholds
 - Added a requirement to disclose sponsored travel
- Sunshine Act / Open Payments Act
 - Requires pharmaceutical companies to make payments to physicians publically available
 - Searchable, exportable database of payments from pharm to doctors

Did we fix it?



“As a breast cancer patient at MSKCC, I find Dr. Baselga’s behavior deeply disturbing. I put my life in the hands of MSK’s doctors who direct my care based on this research. I have endured treatments that have ruined my quality of life even though there is no evidence it increases my survival rates just because my oncologist “believes” there could be a benefit.

I have no doubt oncologists throughout the field recommend treatments because they are paid by big pharma.

This is not only an ethical lapse, to me this is criminal.” – KFC, comment on NYT article

Did we fix it?



"I took part in a Sloan-Kettering drug trial with taseleisib, mentioned in this story. I am a Stage IV patient at the hospital. I was reluctant to participate because I live several states away, and the required travel to NYC every 2 weeks for the first 3 months would present financial and physical hardships.... I believe oncologists are pressured to supply patients for these research trials. Sick patients are told their sacrifices will help other cancer patients. While this may be true, at least one doctor was secretly making millions, as I suffered physically and financially." — Christy B.

Timeline of COI at Northwestern

- 2012: NUCOI and Policy on Conflict of Interest in Research are created
 - Policy initially covered certain sponsors, and industry-sponsored clinical trials – but from a contract perspective
- February 2016: Policy is revised to include all research involving human participants
 - Requires review of PIs and Co-Is on IRB studies
- August 2016: NUCOI begins pulling new studies into eDisclosure for review via reports & spreadsheets
- Summer 2018: Consistently confirming COI review is complete for all studies at time of CR
- November 2018: interface between eDisclosure & eIRB+ established

Process:

How does COI fit into review of a study?

Process: What is a COI review?



Disclosure of external interests and relationships



Review of interests and research to identify COIs

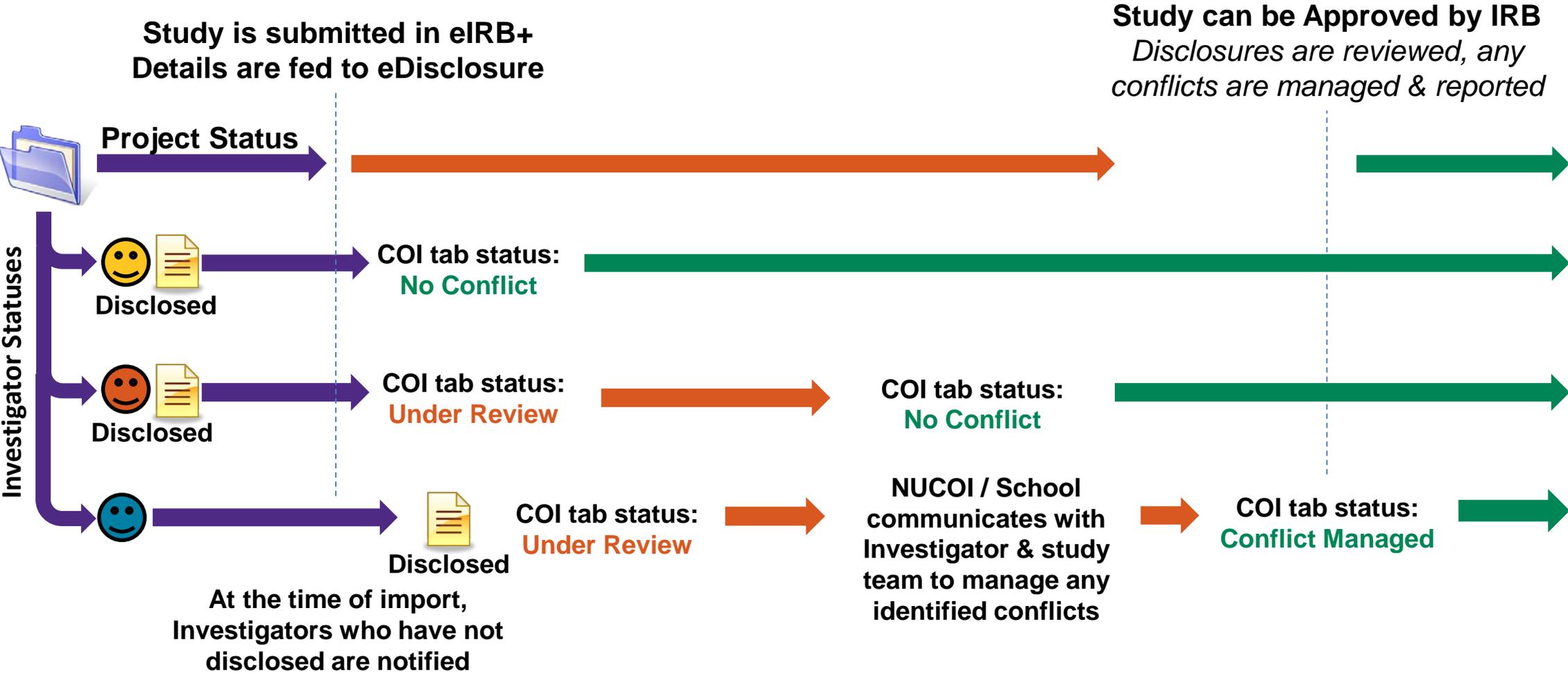


Elimination, reduction, or management of COIs



Monitoring compliance with management strategies

Process: COI Review of a Study



Process: What happens where and when?



Study Team:

Submits **new study** in eIRB+



NUCOI:

Study information is fed from eIRB+ into eDisclosure upon submission of a study



✓ Checks: Do PI and Co-I's have current COI training & disclosure dates? If not, NUCOI emails Investigators to complete this.

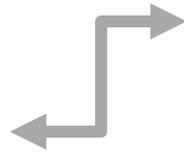


✓ Reviews: Is there any overlap between outside interests and this study?



Investigators:

Disclose & complete COI training in eDisclosure



Determinations display in eIRB+ on COI tab



Process: What happens where and when?



Study Team:
Submits **CR** in eIRB+



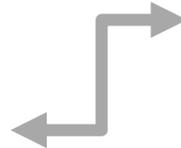
NUCOI:

Study information is fed from eIRB+ into eDisclosure upon submission of a CR;

- If study already exists in eDisclosure, Investigator list and other information is updated
- If study does not exist, it is created



Investigators:
Disclose & complete COI training in eDisclosure



✓ Checks: Do PI and Co-I's have current COI training & disclosure dates? If not, NUCOI emails Investigators to complete this.



✓ Reviews: Is there any overlap between outside interests and this study?



Determinations display in eIRB+ on COI tab



Process: Implementing Management Strategies



1. NUCOI performs an initial review of each investigator on the study
2. If there is overlap between an investigator's interests and the study, the review is referred to FSM Dean's Office
3. FSM performs their review and corresponds with the Investigator
4. If the relationship is extensive or complicated, the review can be escalated to FSM COI Committee
5. If a conflict is identified, a management plan is developed
6. The Investigator is asked to accept the plan
7. Once the Investigator accepts the plan:
 - a) A summary of the conflict and management strategies is uploaded into eIRB+ for review by IRB Office and IRB
 - b) Any requested changes are communicated to the study team
8. Study team implements changes (or acknowledges that the changes will be implemented), and the review can be closed out

Process: Common Management Strategies

Nature of relationship / Financial interest	Common corresponding COI management strategies
Payment for Services: <i>Management strategies implemented depending on extent of relationship</i>	<ul style="list-style-type: none"> ⚙ Disclosure in consent forms ⚙ Disclosure to research team and collaborators ⚙ Disclosure manuscripts, presentations, publications, and press releases ⚙ Not permitted to serve as PI absent compelling circumstances ⚙ Require an independent data safety monitoring board
Any related equity in non-public entities; OR IP interests in product or method under evaluation	<ul style="list-style-type: none"> ⚙ Not permitted to serve as PI absent compelling circumstances ⚙ If investigator is permitted to remain involved in research, any or all of the management strategies identified above may apply
Publicly-traded equity	Varies depending on value of equity relative to overall entity value
Sponsored/reimbursed travel	Varies; rarely does a relationship <i>solely</i> involving sponsored/reimbursed travel rise to the level of requiring management, but responses are evaluated.

Process: When is a COI review complete?

All investigators have:

- ✓ Disclosed significant financial interests in eDisclosure
- ✓ Completed COI training in eDisclosure (not CITI training)

NUCOI & School Deans have:

- ✓ Reviewed each Investigator and made a determination
- ✓ Managed any identified conflicts
- ✓ Reported any conflicts, as needed / applicable
- ✓ Communicated with Investigator/study team to request any needed changes to the study



**Study can be
Approved by IRB**

Tools

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.

Tool: COI tab in eIRB+

History	Funding	Project Contacts	Documents	Follow-on Submissions	Reviews	Snapshots	Study Team Training	COI
Research Project ID: SP0050000 (Active)								
Research Project Name: (PRESPEND)Prot# P00005: A Randomized, Placebo Surgery Controlled, Double-Blinded, Multi-Center, Phase 2 Clinical Trial, Evaluating the Efficacy and Safety of VEGFR2 Inhibitors in Advanced Pancreatic Ductal Adenocarcinoma (PRESPEND)								
COI Discloser	COI Training Date	Last Submitted Disclosure	Role on Study	COI Determination				
Mark Green	2/16/2018	2/10/2019	Principal Investigator	No Conflict				
Research Project ID: STU0020000 (Active)								
Research Project Name: A Randomized, Placebo Surgery Controlled, Double-Blinded, Multi-Center, Phase 2 Clinical Trial, Evaluating the Efficacy and Safety of VEGFR2 Inhibitors in Advanced Pancreatic Ductal Adenocarcinoma (PRESPEND)								
COI Discloser	COI Training Date	Last Submitted Disclosure	Role on Study	COI Determination				
Susan Black	9/7/2018	9/7/2018	Co-Investigator	Under Review				
Jennifer Gold	2/7/2018	2/7/2018	Co-Investigator	Under Review				
Mark Green	2/16/2018	2/10/2019	Principal Investigator	No Conflict				



For the COI review to be complete, all Investigators must have completed COI Training in the last 4 years, and must have disclosed in the last 12 months.

For the COI review to be complete, the COI Determinations for all Investigators must be either: No Conflict or Conflict Managed. If someone is still "Under Review", COI review is not complete.

Tool: NUCOI Website

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

Northwestern

CONTACTS

CONFLICT OF INTEREST

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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. *(Note: COI training is different than CITI training, or GCP training)*
2. Each Investigator's outside interests must be reviewed with respect to the study. A determination must be made for all Investigators prior to initiating the study of whether there is no conflict **or** a potential conflict that should be managed.

Sections below provide information on how to check the status of the COI review of project, what some of the regulations are related to conflict of interest and research involving human participants, and resources for Investigators to understand what kind of relationships create the appearance of conflicts and what management strategies can be implemented in those situations.

We have a pdf as a [quick reference guide to study team members](#) to understand COI review of IRB studies.

COI Review of IRB studies

Tool: NUCOI Contacts

- Kate Cosgrove Booth, Director
 - k-cosgrove@northwestern.edu | 847-491-4163 / 312-503-6851
- Garth Huskey, Compliance Analyst (lead on IRB studies)
- Anees Fatima, Sr. Compliance Analyst
- Paula Foster, Program Assistant

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QUESTIONS?