Where and How Does COI Fit into IRB Review

Kate Booth

Director, Conflict of Interest

2/15/2019

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?

"All the News That's Fit to Print"

The New York Times

National Edition

Mostly cloudy. Some morning rain southeast. Breezy. Highs in the mid-dle 60s to the lower 70s. Mostly cloudy east tonight. Mostly clear west. Weather map is on Page 22.

VOL. CLXVII ... No. 58,080 © 2018 The New York Times Company SUNDAY, SEPTEMBER 9, 2018 Printed in Chicago $6.00

Cancer Doctor Didn't Disclose Corporate Ties

Paid Millions by Firms Linked to Research

By CHARLES ORNSTEIN and KATIE THOMAS

One of the world's top breast cancer doctors failed to disclose millions of dollars in payments from drug and health care companies in recent years, omitting his financial ties from dozens of research articles in prestigious publications like The New England

U.S. MET REBELS FROM VENEZUELA ABOUT COUP PLOT

RISK BY TRUMP OFFICIALS

Dissidents' Secret Plans to Overthrow Maduro Eventually Stalled

By ERNESTO LONDOÑO and NICHOLAS CASEY

The Trump administration held

"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 in 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?

"All the News That's Fit to Print"

The New York Times

National Edition

Mostly cloudy. Some morning rain southeast. Breezy. Highs in the middle 60s to the lower 70s. Mostly cloudy east tonight. Mostly clear west. Weather map is on Page 22.

VOL. CLXVII ... No. 58,080 © 2018 The New York Times Company SUNDAY, SEPTEMBER 9, 2018 Printed in Chicago $6.00

Cancer Doctor Didn't Disclose Corporate Ties

Paid Millions by Firms Linked to Research

By CHARLES ORNSTEIN and KATIE THOMAS

One of the world's top breast cancer doctors failed to disclose millions of dollars in payments from drug and health care companies in recent years, omitting his financial ties from dozens of research articles in prestigious publications like The New England

U.S. MET REBELS FROM VENEZUELA ABOUT COUP PLOT

RISK BY TRUMP OFFICIALS

Dissidents' Secret Plans to Overthrow Maduro Eventually Stalled

By ERNESTO LONDOÑO and NICHOLAS CASEY

The Trump administration held

"I took part in a Sloan-Kettering drug trial with taselisib, 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?

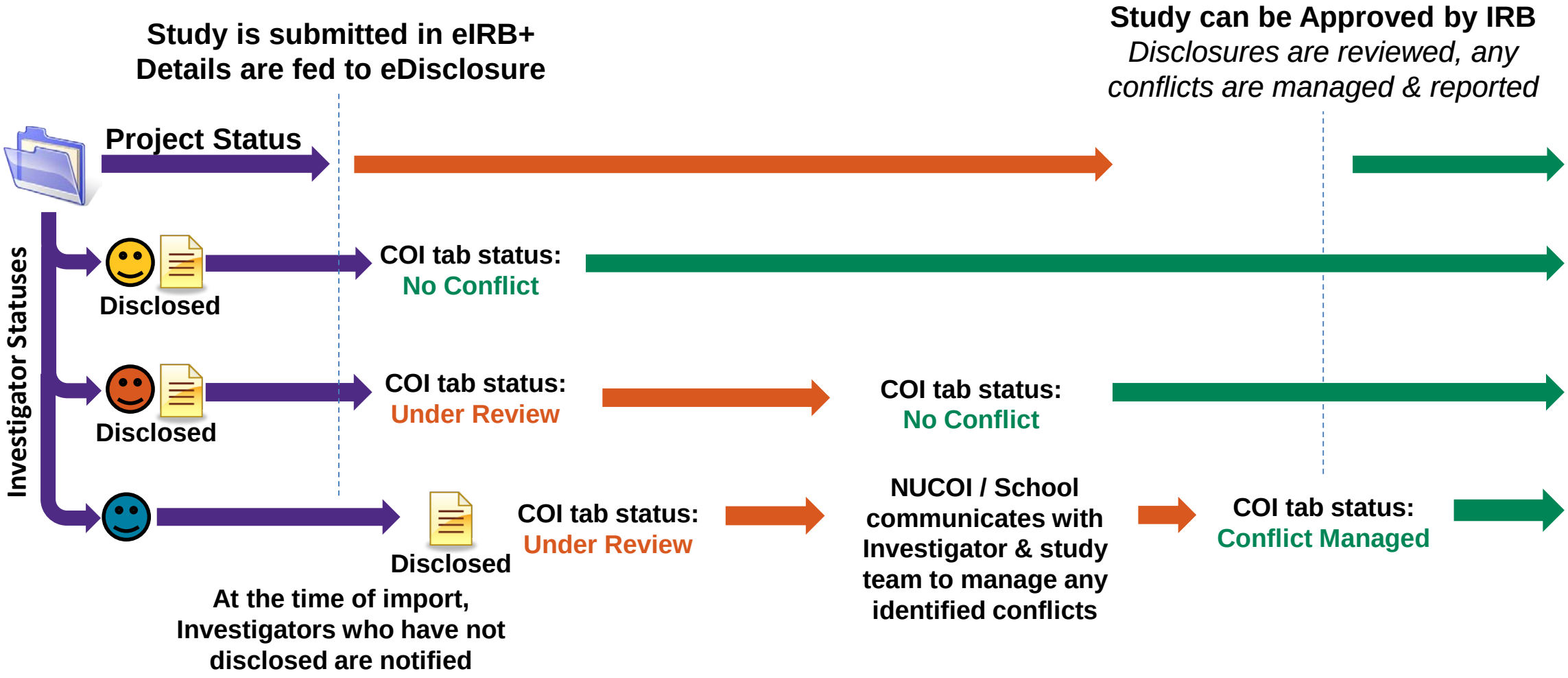
Disclosure of external interests and relationships

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;

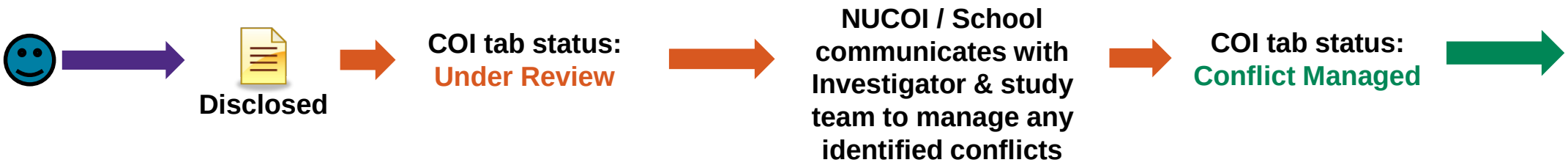
- If study already exists in eDisclosure, Investigator list and other information is updated
- If study does not exist, it is created

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: *Management strategies implemented depending on extent of relationship*	☼ 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	☼ 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 *solely* 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.

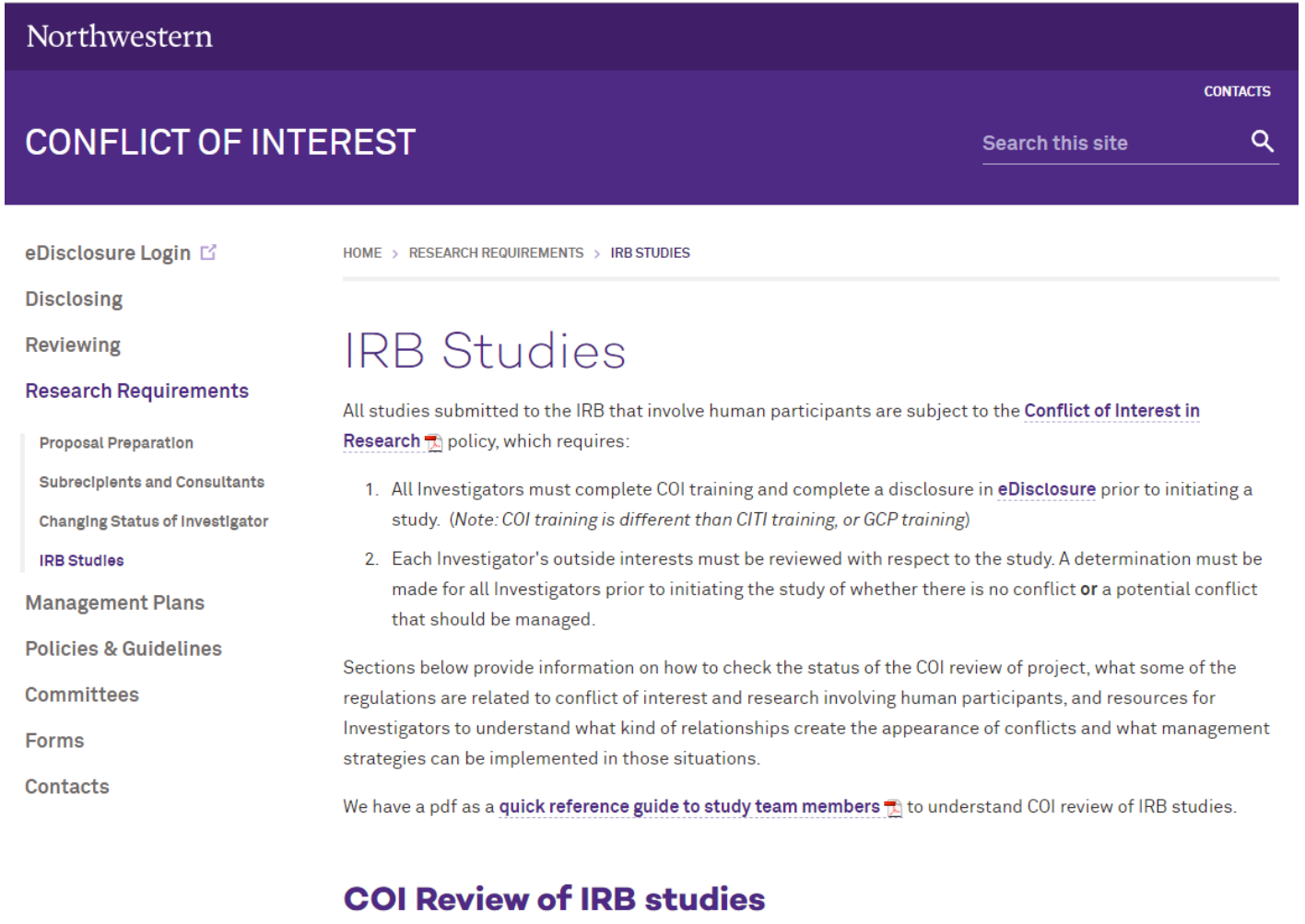
Tool: COI tab in eIRB+

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 <u>all</u> 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/



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

nucoi@northwestern.edu | 847-467-4515

QUESTIONS?