



Research Administration Practices (RAP) Sessions

Sponsor Requirements Certification and COI (Part 1)

Presented by:

Ian Cariolo, Senior Research Administration Education & Support Specialist, VPR

Rupinder Grewal Senior Conflict of Interest Officer, VPR

Jeff Sullivan Conflict of Interest Officer, VPR

Introductions

Ian Cariolo

Senior Research Administration Education & Support Specialist, VPR

Rupinder Grewal

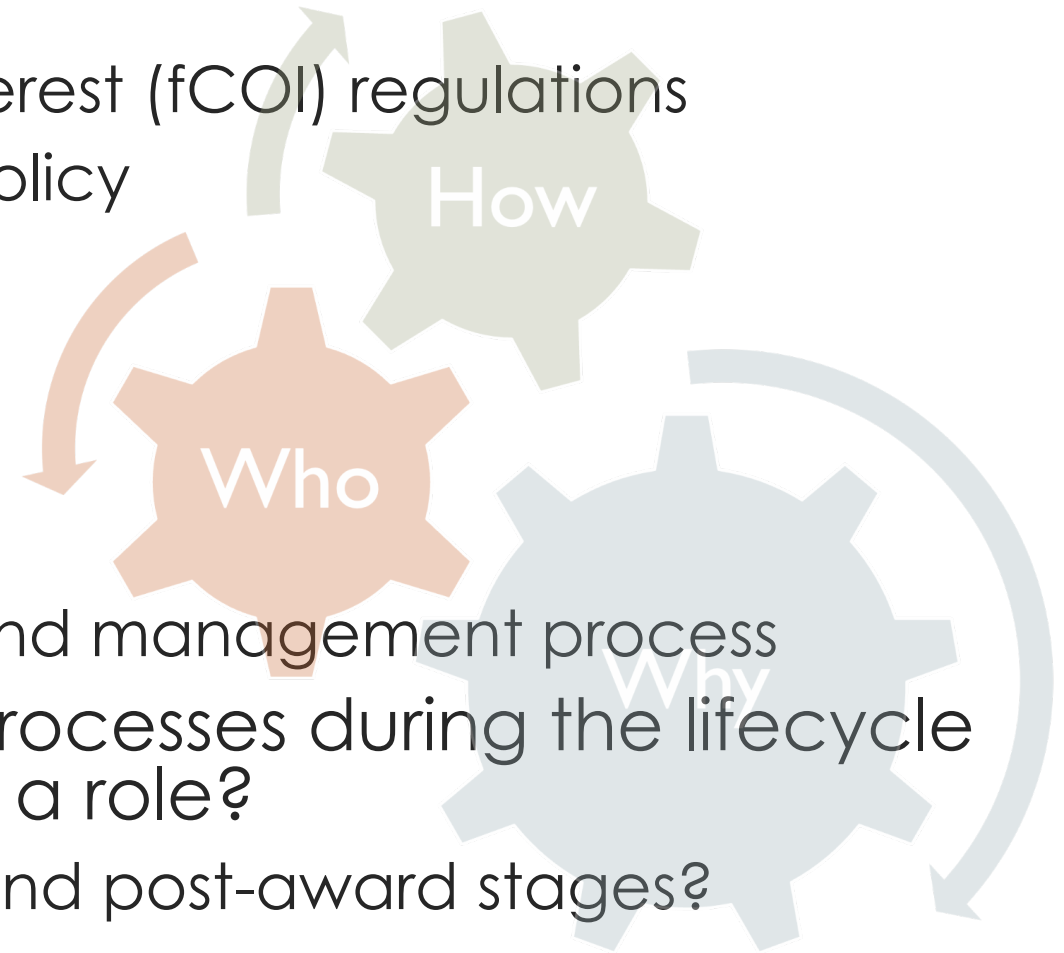
Senior Conflict of Interest Officer, VPR

Jeff Sullivan

Conflict of Interest Officer, VPR

Agenda

- Why?
 - Brief history of the financial Conflict of Interest (fCOI) regulations
 - Purpose and key definitions of the fCOI policy
- Who?
 - Key offices and processes of COI @ MIT
 - Who needs to disclose
- How?
 - Brief overview of COI disclosure, review and management process
- What are the COI requirements and processes during the lifecycle of a sponsored project and who plays a role?
 - Who does what at the proposal, award and post-award stages?



Brief History of events which triggered investigations leading to COI policy changes at NIH and NSF

Bayh-Dole Act permits universities to own inventions created using federal grants.

NIH and NSF regulations require research institutions to implement and enforce COI policies.

NIH Office of Inspector General criticizes NIH for inadequate oversight of FCOIs and calls for modification of 1995 regulation.

Senate investigates major financial conflicts of interest in research at Emory, Harvard, University of Texas, and Stanford.

New NIH regulations take effect and apply to all PHS-funded research. MIT creates COI Officer position and updates its COI policy to reflect new regulations. MIT policy is effective on August 24, 2012.

1980

1990

1995

1999

2008

2011

2012

Academic patent and licensing programs thrive, but widely publicized episodes of scientific misconduct and harm to human subjects leads to House publication *Are Scientific Misconduct and Conflicts of Interest Hazardous to Your Health?*

Jesse Gelsinger died during first clinical trial for gene therapy. Dr. James Wilson, co-Investigator, had financial interest in outcome of study and failed to disclose extent of adverse reactions during animal testing. Brought significant attention to FCOI



NIH creates rigorous standards for reporting, managing, and eliminating FCOIs in amended regulations.

Purpose: “Promoting Objectivity in Research”

- The new regulations are a response to Congressional and HHS Office of Inspector General criticism of the NIH’s oversight of grantee compliance with COI rules and negative media accounts of financial relationships between pharma and device companies and academic researchers.
- The changes aimed at increasing transparency and institutional and NIH oversight of financial interests of investigators in federally sponsored research.
- Established new standards for disclosing (investigator), reviewing, managing and reporting (institution) financial interests in an effort to provide a reasonable expectation that the design, conduct, and reporting of research funded under grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest
- MIT updated it’s FCOI in Research policy in August 2012 and 2013 in response to the new regulations (PHS regs + NSF regs + MIT P&P = MIT’s FCOI in Research policy)

2011 PHS (NIH) Regulations Increase **Institutional** Oversight

1995 Regulations	2011 Regulations
Investigators determine if financial interests and research are related	Institution determines if financial interests and research are related
Disclose if financial interest above \$10,000	Disclose if financial interest above \$5,000; any private equity
Disclose outside payments for activities like consulting, equity, stocks, royalties for intellectual property rights	Disclose outside payments for activities like consulting, equity, stocks, royalties for intellectual property rights and travel reimbursement
No training requirement	Training required every 4 years
If there are material changes in Significant Financial Interests, disclose annually.	If there are material changes in Significant Financial Interests, disclose within 30 days of change and annually
No public accessibility of FCOIs	Public access of FCOIs upon request

“When in doubt, disclose.” —
Maria Zuber,
MIT VPR



Key COI Policy Definitions

Conflict of Interest (COI)

- Situation in which \$\$ or other personal considerations w/potential to compromise professional judgement or objectivity in the design, conduct or reporting of research

Significant Financial Interest (SFI)

- \$\$ interest that could reasonably appear related to Institutional Responsibilities; meets \$ threshold for disclosure

Financial Conflict of Interest (fCOI)

- SFI that could affect research design, conduct, or reporting of research

Institutional Responsibilities

- Research, teaching, administration, etc.

Investigator

- Researcher who is independently responsible for design, conduct, or reporting of research

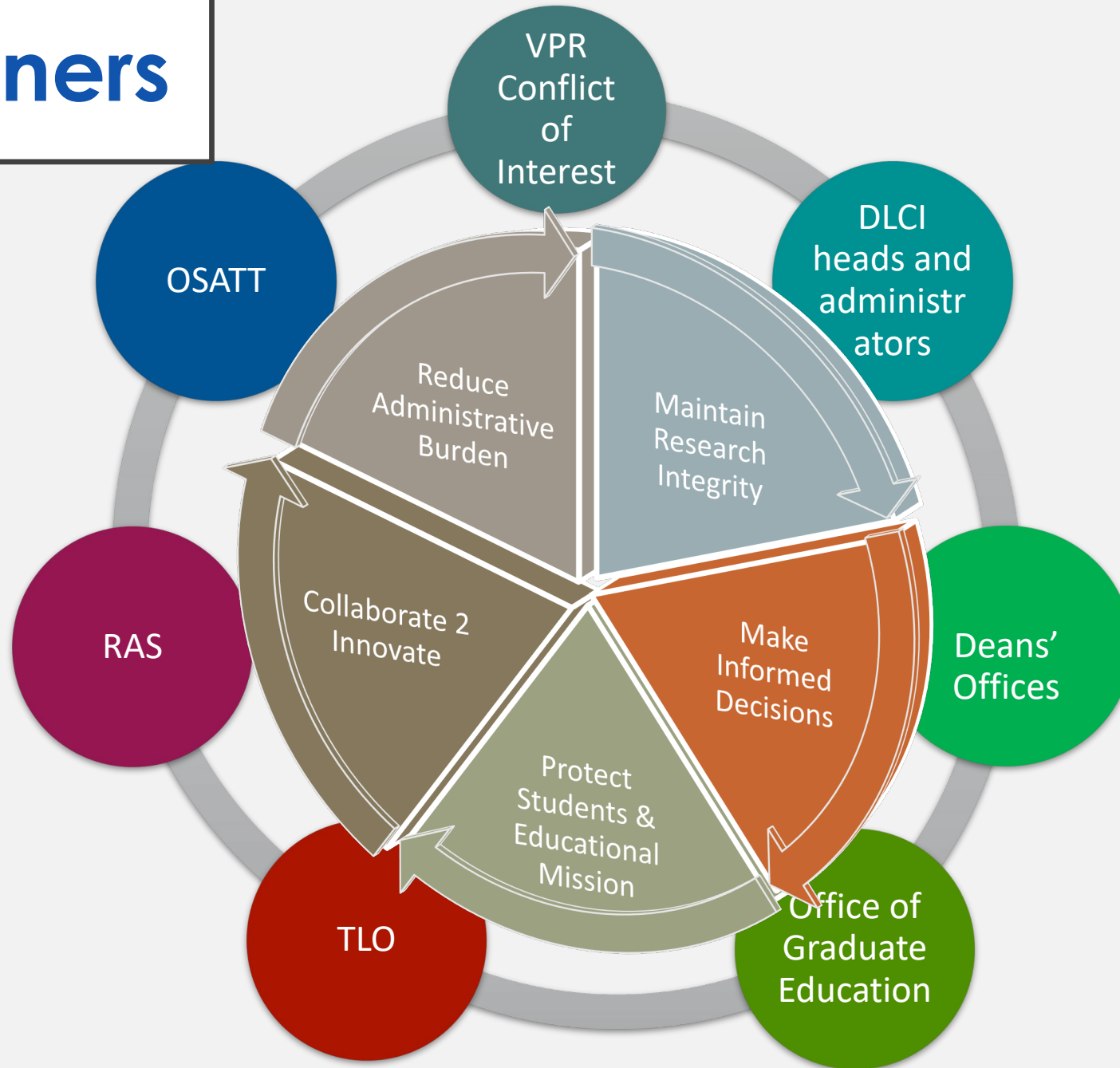
Designated Official

- Helps determine if SFI is fCOI

Institutional Official

- Vice President for Research, responsible for COI policy

Key Partners



Marc, Richard,
Rachel, Daniela,
Asu

The 4 “P’s” critical in COI

- **People**
 - **Policy**
 - **Process**
 - **Partnerships**
- ✓ **People** are the drivers in fundamental research. Researchers have devoted their lives to this endeavor, therefore understanding the end goal of the researcher is a critical starting point
 - ✓ **Policy** is not what constrains us but what provides the structure to enable us to reach the end goal. Important to read the COI policy and ask questions
 - ✓ **Process** implements the policy to gather and review information at key stages, determine appropriate steps to achieve the end goal: how to manage; what to change/eliminate; appropriate transitions; maintain separation...
 - ✓ **Partnerships** with key MIT offices enable more balanced and mindful decisions. Many of our management strategies are ‘bespoke’, not a one-size-fits-all approach!

A few COI policy Guiding Principles and how they are applied (coi.mit.edu/policy)

Guiding Principle

An [Investigator](#)'s first and primary responsibility is to support and advance MIT's mission, rather than to advance his or her personal financial interests.

Research must be undertaken to advance scholarship and new knowledge and not an [Investigator](#)'s or the [Investigator](#)'s [Family](#)'s personal financial interest.

An [Investigator](#) must not attempt to influence the activities of colleagues and subordinates with the intent of enhancing the [Investigator](#)'s or the [Investigator](#)'s [Family](#)'s financial interests.

MIT's resources, names and trademarks may not be used for personal benefit.



Application

Investigators may not accept research sponsorship or gifts, in support of the [Investigator](#)'s [Institutional Responsibilities](#) from a for-profit privately-held [Related Entity](#);

Investigators may not involve a student for whom the [Investigator](#) is a thesis supervisor in the [Investigator](#)'s [Outside Professional Activities](#);

Investigators may not negotiate with MIT on behalf of a [Related Entity](#), or negotiate with the [Related Entity](#) on behalf of MIT;

Investigators may not promote the use of products or services of a [Related Entity](#) in the course of the [Investigator](#)'s [Institutional Responsibilities](#);

Key Processes



Outside Professional Activities (OPA)

Assesses Conflicts of Commitment with respect to Institutional Responsibilities: **TIME**

- Usually **measured in time, disclosed via the annual OPA report**; applies to MIT employees (faculty, staff) not students
- **MIT faculty, staff and researcher ranks have prescribed consulting privileges**
- Faculty disclose relationships with students, staff and use of MIT resources in carrying out OPA
- Prospective discussions with department heads prior to engaging in consulting, start-ups, engaging students and staff in OPA's
- **President owns policy**



Financial Conflicts of Interest in Research (FCOI)

Assesses Financial Conflicts of Interest which could impact your MIT research: **MONEY**

- Usually **measured in money disclosed via the COI disclosure on a rolling basis and proposal stage; applies to anyone who is responsible for the design, conduct or reporting of MIT research (Investigator)**
- Disclose relationships (consulting, start-ups) based on financial thresholds (SFI's), and relationship to awards
- DLC heads play key role in assessing COI risk
- Management plans put in place for those FCOI's which can be effectively managed
- **VPR owns policy**



OK: Activities/Relationships which do not directly and significantly impact your ability to conduct your MIT research and educational responsibilities

- Institutional responsibilities
 - Service on MIT committees, uncompensated publication review, conferences, etc
- Consulting (“separate and distinct” between ongoing MIT research and consulting activities, OK to talk about published research results)
- Starting companies (no “direct”, “active” or “significant” line management responsibilities)
- Serve on SAB’s

Mitigating risk is important—timely discussions and communications with the Department Head and COI Officer to help think things through can be an effective means of mitigating risk. Informed decision making is the goal!

Not OK: Activities/Relationships which could pose a risk to:

- Reputation of MIT/researcher
 - *Think long term, reputation hard to (re)build!*
- Integrity of MIT’s educational mission
 - *Students are here to graduate on time, post-docs are here to train, faculty are here to teach and mentor*
- Sponsored research funding (industry and other sources)
 - *Research integrity and transparency is critical to building sponsor relationships*
- Ability of staff/subordinate to carry out institute responsibilities
 - *We’re here to support MIT’s mission not ensure an individual’s/company’s financial success*
- MIT IP
 - *Do not want to compromise IP rights and obligations related to MIT research*

How COI disclosures are made?

Financial Disclosure by Cariolo, Ian C

Name : User Name :
Department : 391020:Research Administration Support Phone :
Faculty : No Email : Expiration Date : 03/09/2023

Screening Questions Significant Financial Interests Relationships Certify

For your project listed below, please answer the certification questionnaire: Help

Proposal # : 00061248
Title : IAN TEST - 15% U/R
Start Date : 01-Mar-2022 End Date : 28-Feb-2023

If you need to make corrections to these answers please use the Proposal Questions link available in the left navigation menu.

Disclosure: Screening Questions

Please Answer the Following Questions:

1. Do you have a Significant Financial Interest in this sponsor? A Significant Financial Interest (SFI) is defined as salary, consulting, or other remuneration of \$5,000 or more, which you have received in the last 12 months, or expect to receive in the next 12 months; or any equity interest in a non-publicly traded company; or stock holdings in a company that is related to your area of research, and exceeds \$100,000. Yes No

2. Could the work contemplated in this project reasonably appear to affect a company or other organization in which you have a SFI? Yes No

Yes
 No

10. Do you have a Significant Financial Interest in this sponsor? A Significant Financial Interest (SFI) is defined as salary, consulting, or other remuneration of \$5,000 or more, which you have received in the last 12 months, or expect to receive in the next 12 months; or any equity interest in a non-publicly traded company; or stock holdings in a company that is related to your area of research, and exceeds \$100,000. [?](#)

Yes
 No

11. Could the work contemplated in this project reasonably appear to affect a company or other organization in which you have a SFI? [?](#)

Yes
 No

12. Does this project contemplate any purchases from or subawards to a company or other organizations in which you hold a SFI? [?](#)

Yes
 No

14. If the sponsor for this proposal is Federal - Have you lobbied, or are you aware of anyone who has lobbied government officials in support of this proposal? [?](#)

CoeusLite User: Cariolo, Ian C

Coeus Home My COI Logout

Help MIT COI Policy Travel Awards On Hold With Entities No Entities WIP In Progress Search

The MIT COI Policy requires that MIT officers, faculty, staff and others acting on its behalf, avoid ethical, legal, financial and other conflicts of interests. MIT needs to ensure that their activities and interests do not conflict with their obligations to MIT. If you have not already done so, **please read the policy before you Create or Revise a disclosure** as you will be asked during the disclosure process to certify that you have read the policy and understand it.

My COI is MIT's portal to CREATE, REVISE and VIEW your disclosures with information regarding your Significant Financial Interests (SFIs), potential relationships related to your proposals and awards, and Sponsored Travel (PHS Investigators only).

Your Master Disclosure will expire on: MARCH 09, 2023

Create **Revise** **View**

Initial COI Disclosure	Master Disclosure*	Master Disclosure*
SFI Entity	SFI Entity	SFI Entity(make Inactive)
Travel Disclosure (PHS only)	Travel Disclosure(s) in Progress	Travel Disclosure(s)
Proposal Disclosure	Other Disclosure(s) in Progress	

Here you can:

- Create your initial Conflict of Interest (COI) disclosure if you have never submitted one. If you already have an approved master disclosure, this action will be ignored.

Here you can:

*NOTE: A master disclosure contains all the approved disclosures for your awards and proposals.

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*NOTE: A master disclosure contains all the approved disclosures for your awards and proposals.

Who at MIT needs to disclose?

- Under MIT policy, **all Investigators are required to disclose SFI's**. An **Investigator** is an individual who is *independently responsible* for the design, conduct or reporting of research - usually only the PI and Co-PI but also a Key Person
- Some sponsors have specific requirements for identifying Investigators <http://coi.mit.edu/research/sponsor-specific-guidelines/nih/who-is-an-investigator>.
- An Investigator is solely responsible for the content and certification of the disclosure. MIT's COI disclosure module does not allow proxies.

What needs to be disclosed?

All SFI's: A financial interest that meets any of the criteria for significance set forth below and is received or held by the Investigator and/or his or her Family:

- Aggregate of Remuneration \geq \$5K from U.S. or foreign publicly traded entities, U.S. or foreign privately held entities, U.S. or foreign non-profit entities and foreign governmental/academic institutions or organizations
- Equity Interests \geq \$5K in U.S. or foreign publicly traded entities if entity sponsoring your research
- Equity Interests \geq \$100K in U.S. or foreign publicly traded entity if entity's business appears to be related to your Institutional Responsibilities
- ANY Equity Interest in a U.S or foreign privately held entity (your start-up for instance, regardless if value of shares is \$0!)
- Income \geq \$5K received from IP rights from entity other than MIT
- Sponsored Travel (PHS Investigators only) is considered an SFI and counts towards aggregate

Sponsored Travel, for PHS funded investigators only

Required to disclose “Sponsored Travel” which means all travel which meets the definition is now considered an SFI. Looking back 12 months at time of proposal and ‘running’ thereafter.

- Just travel (hotel, meals, transportation, etc...)
- If aggregate per entity adds to \$5k over last 12 months
- Travel and consulting
- If aggregate per entity adds to \$5k over last 12 months
- Travel by Investigator and his/her Family
- Investigator completes a separate disclosure for each traveler ‘type’

“*Sponsored Travel* (applies only to PHS Investigators) means (a) travel expenses paid to an Investigator or travel paid on an Investigator’s behalf, by a single entity in any 12-month period and (b) travel reimbursed to or paid on behalf of an Investigator’s Family by a single entity in any 12-month period ONLY if such travel reasonably appears to be related to the Investigator’s Institutional Responsibilities. See the PHS Addendum for more information.”

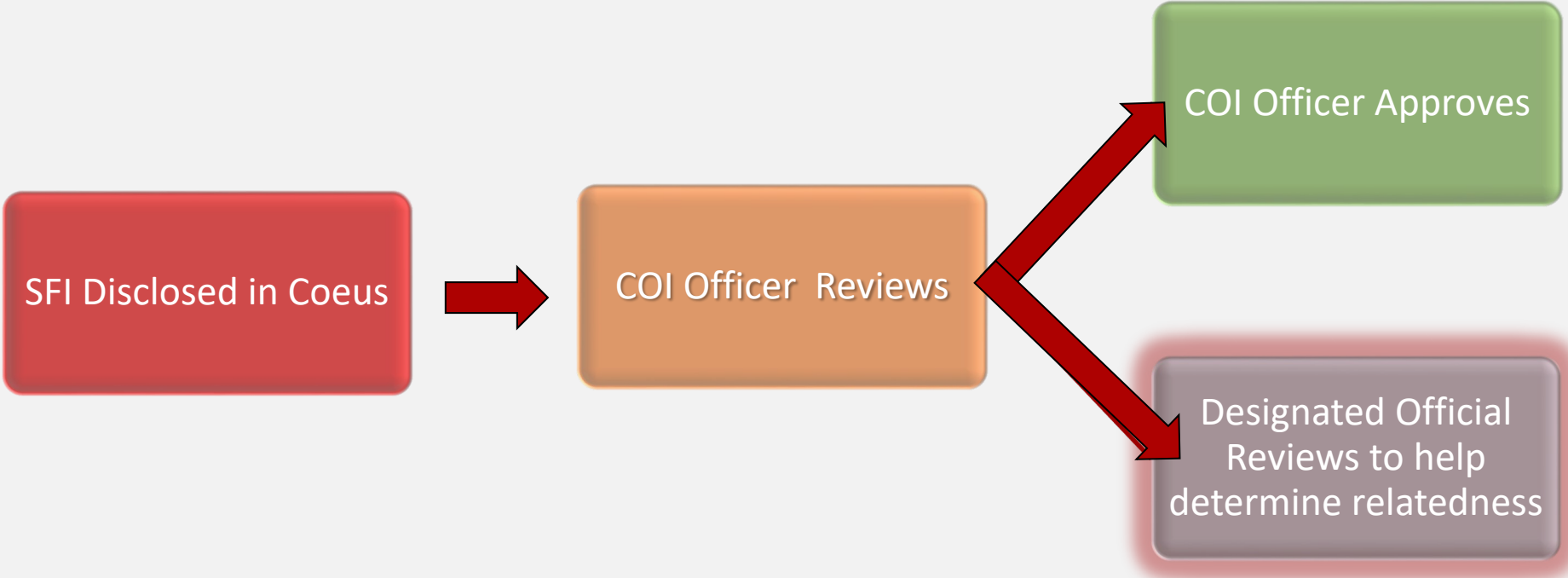
What **does not** need to be disclosed

- Any Remuneration from MIT (salary, royalties)
- Any Remuneration from authorship of academic or scholarly works, regardless of the source
- Remuneration from seminars, lectures, or teaching engagements sponsored by, or from advisory committees or review panels for, **U.S.** Federal, state, or local governmental agencies; **U.S.** institutes of higher education (e.g. Whitehead Institute and Broad Institute); **U.S.** research institutes affiliated with institutes of higher education, academic teaching hospitals, and medical centers
- Equity Interests in or income from investment vehicles, such as mutual funds and retirement accounts (401K) in which you don't directly control the investment decisions
- Any travel paid through MIT (from grants, or other sources)

An Investigator need not disclose Sponsored Travel paid for or reimbursed by:

- MIT (e.g. paid from MIT funds or from sponsored awards funds managed at MIT)
- U.S. Federal, state or local governmental agencies
- U.S. Institutes of higher education
- U.S. Research institutions affiliated with institutions of higher education
- U.S. Academic teaching hospitals and medical centers

COI Review Process



Designated Official can be either the Conflict of Interest Officer or, in complex cases, a faculty member appointed to the role by the Investigator's Department, Lab, or Center Head; School Dean

COI Review Process Expanded



Red light! A few complex disclosures will rise to level of FCOI and will require a management plan to be drafted with help of COI Officer, Investigator and Designated Official (to help determine relatedness).

Yellow light! A small number of disclosures may require more details, will work with Investigator to further understand issues presented.

Green light! All disclosures reviewed in confidence by COI Officer, majority will be approved on first review.

An SFI is not automatically an fCOI

SFI?

- Does the PI, Co-PI or Investigator have a significant financial interest?
- If yes, then ask...

Related?

- Is the SFI related to his/her research at MIT?
- If yes, then ask ...

FCOI?

- Could the SFI directly and significantly affect the design, conduct or reporting of the research?
- If yes, manage or eliminate the conflict (real or perceived)

Disclosures submitted

SFI's reported

fCOI's

Managed
or
eliminated

Where do fCOIs in research come from?

1) Research investigator receiving **intellectual property-related royalties** (e.g., patented medical device) or otherwise holding rights on IP (e.g., patent) that is involved in the research (usually assessed or improved)

Investigator



Research

2) Research investigator receives **compensation** from or has **equity** (e.g., stocks or stock options) in an entity that is interested in or involved in the research (usually sponsoring it or providing resources)

Investigator



Entity



Research



**Proposal Stage
COI Screening questions & disclosure**

What is the Kuali Coeus/COI Connection?

Yes
 No

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Yes
 No

11. Could the work contemplated in this project reasonably appear to affect a company or other organization in which you have a Significant Financial Interest?

Yes
 No

12. Does this project contemplate any purchases from or subawards to a company or other organization in which you hold a Significant Financial Interest?

Yes
 No

14. If the sponsor for this proposal is Federal - Have you lobbied on behalf of this sponsor or any of its subawards?

Yes
 No

KUALICOEUS | MIT

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2

You answered "Yes" to one or more of the COI screening questions, and must now complete a full disclosure for this proposal before it can be routed. To complete your disclosure now, click "OK", and you will be brought directly to My COI where you can begin entering your significant financial interests. Click "Cancel" to complete the disclosure later. You will need to use the "Other Disclosure(s) In Progress" option in Coeus "My COI". If you choose to hit "Cancel", your proposal will NOT route until you have completed your disclosure.

OK Cancel

Proposal Development
Certification for
Proposal was successfully certified

Proposal#: 65297
Title: TEST Proposal - Senior/Key Person
PI: Cariolo, Ian C
Lead Unit: 391020
Sponsor: NIH
Deadline Date:
Open Proposal

1. Is your current space sufficient to carry out this project, and those already proposed? ⓘ

Yes
 No

3

CoeusLite User: Cariolo, Ian C Current Location

Coeus Home My COI Logout

Help | MIT COI Policy | Travel | Awards On Hold | With Entities | No Entities | WIP | In Progress | Search |

Disclosure View

Step One
✓ Screening Questions >>

Step Two
✓ Significant Financial Interests

Step Three
Relationships

Step Four
Certify

Proposal Questions
MY COI Home

Financial Disclosure by Cariolo, Ian C

Name : User Name :
Department : 391020:Research Administration Support Phone :
Faculty : No Email : Expiration Date : 03/09/2023

Screening Questions Significant Financial Interests Relationships Certify

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2. Could the work contemplated in this project reasonably appear to affect a company or other organization in which you have a Significant Financial Interest? Yes No

3. Does this project contemplate any purchases from or subawards to a company or other organizations in which you hold a Significant Financial Interest? Yes No

Continue

SFI Screening Questions replies from KC

Create Proposal in KC / Notify Key Personnel cont'd

Three of the certification questions are SFI screening questions: **10, 11, and 12:**

Yes
 No

10 . Do you or a Family member have a Significant Financial Interest in this sponsor? A Significant Financial Interest (SFI) is defined as salary, consulting, or other remuneration of \$5,000 or more (received from an entity other than MIT), which you have received in the last 12 months, or expect to receive in the next 12 months; or any equity interest in a non-publicly traded company; or stock holdings in a company that is related to your area of research, and exceeds \$100,000. Family is defined as your spouse or domestic partner and dependent children. ⓘ

Yes
 No

11 . Could the work contemplated in this project reasonably appear to affect a company or other organization in which you or a Family member have a SFI? ⓘ

Yes
 No

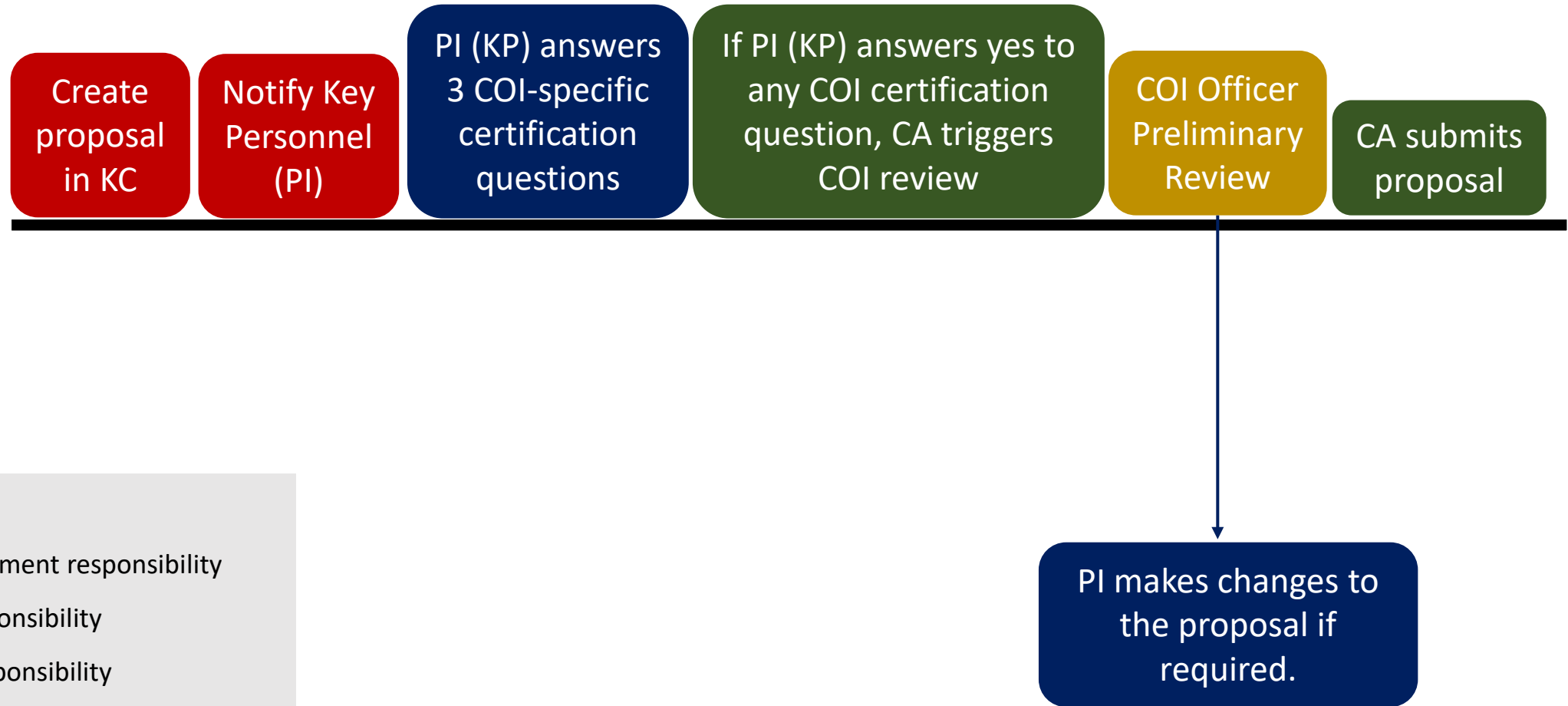
12 . Does this project contemplate receiving/using any materials/data (data sets, confidential information) or making any purchases from or subawards to a company or other organizations in which you or a Family member hold a SFI? ⓘ

Yes
 No

13 . If the sponsor for this proposal is Federal - Have you lobbied, or are you aware of anyone who has lobbied government officials in support of this project? Lobbying includes oral or written communications to government officials regarding the adoption of program funds, or execution of program funds that would specifically support this project. ⓘ

Yes
 No

Proposal Stage



Legend

- Department responsibility
- PI responsibility
- CA responsibility
- COI responsibility



If you have additional COI questions, please contact coi-help@mit.edu

Sponsor Requirements Certification and COI

Part 2

February 7 10:00 – 11:00 am [Register on Atlas](#)

How to meet COI requirements at Proposal and Award stage:

- Sponsor and Solicitation specific requirements
- Non-MIT personnel (does not have an MIT Kerberos)
- KC personnel roles and certification requirements
- Award hold for COI requirements

Feedback

We are providing a **QR Code** for you to access a **RAS-ED feedback survey** via your phone or mobile device.



I will also provide the link https://mit.co1.qualtrics.com/jfe/form/SV_6SxzH2KJW_SKXCyq to access the form via the web and in a follow up email.