

## CRRO Seminar: Disclosing Financial Conflicts of Interest in Research at BU & BMC

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### Learning Objectives

- Why COI in research matters
- When and what needs to be disclosed
- How to disclose using Huron and COI-Smart
- How FCOIs are identified and managed

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## Attendee Poll

Q1 What is your role in research

Q2 At what institution do you perform or support research?

Q3 Which part of the COI disclosure process would you most like additional clarification on?

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### Conflicts of interest: Why does it matter?

- A conflict of interest is any circumstance where the personal, professional, financial, or other private interests of a person or institution compromise or have the potential to compromise the exercise of professional judgment or obligations or may be perceived as doing so
- In order to maintain public trust in the integrity of research and to promote and obtain objectivity in research, there needs to be an effective process for identifying FCOI

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## 2011 Final Rule ([42 CFR Part 50 Subpart F](#))

- Applicable to all PHS-funded research
- Specific revisions:
  - Required training for investigators
  - Expand the scope and definition of SFIs that investigators must disclose
  - Intensify the responsibilities of institutions for review, management, and oversight of investigators' SFIs and FCOIs
  - Increase compliance oversight obligations for institutions and the government
- Institutions had to be compliant by August 24, 2012

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## Who is required to disclose?

- An Investigator is an individual, regardless of title or position, responsible for the design, conduct, or reporting of research
- If you are a BMC investigator, disclose to BU if:
  - Your grant will be or is administered through BU
  - You are an investigator on a BU project that does not have a subaward to BMC (i.e. you are participating independent of BMC)
- If you are a BU investigator, disclose to BMC if:
  - Your grant will be or is administered through BMC
  - You are an investigator on a BMC project that does not have a subaward to BU (i.e. you are participating independent of BU)

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## When to Disclose

- At the time of submission of a funding application to the sponsor or research proposal to the IRB;
- When executing a contract with an Entity where no application or proposal is required;
- Within 30 days of the discovery or acquisition of a new SFI (through purchase, marriage, or inheritance); and
- At least annually during the award period. Annual disclosures will include any new information that was not initially disclosed or in any subsequent disclosure of SFIs, and will include updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest).



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## When to Disclose

**Did you know?** BMC requires pre-review of consulting activities prior to the activity beginning

<https://bmc.tfaforms.net/f/bmc-consulting-checklist>

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For BMC

- Annually in the Spring when prompted by BMC

**And**

- Within 30 days of the discovery or acquisition of a new financial interest (through purchase, marriage, or inheritance).

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5.0

Required Training and Conflict of Interest

5.1 BMC/BU Medical Campus Institutional Requirements for training

☒ The PI confirms the following:

- All individuals at Boston Medical Center or Boston University Medical Campus who will have contact with subjects or their identifiable data have been listed on this application in Section 3.0 (including those who will obtain informed consent, analyze identifiable data, perform study interventions, recruit subjects, etc.).
- All individuals listed in Section 3.0 have completed their INSPIR profile or have been asked to do so.
- All individuals listed in Sections 3.1, 3.2, and 3.4 are up to date with human subjects training and with GCP training if required. For more information, click [here](#).

5.2 Conflict of Interest Disclosure

I confirm that all those responsible for the design, conduct, or reporting of the proposed program, including at minimum, all Senior/key personnel in the grant application, will, before this application is submitted, have completed the required financial interest disclosure through COI Smart for [Boston Medical Center](#) or through the [Financial Interest Disclosure form for Boston University](#) (for contact info, click on the (?) help icon). NOTE: The IRB considers any missing financial interest disclosures to be noncompliance by the Principal Investigator.

☒ I confirm:

Of the financial interest disclosure forms that will be completed, will any **significant financial interests** that are **related to the research** be disclosed?

☐ Yes ☒ No

Each time you submit a funding application to the sponsor or research proposal to the IRB, the PI is certifying that the Investigators' COI disclosures are up to date. Update your disclosure at this time if you need to.

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COI

The BMC COI policy requires that each "Investigator" (defined as any person, regardless of title or position, who is responsible for the design, conduct or reporting of research) has a COI disclosure form in the COI-SMART system at the time of proposal submission.

In addition to the Principal Investigator, please checkmark each of the other "Investigators" on this project, or enter their contact information if not auto-populated:

Name	Investigator?
Email	<input checked="" type="checkbox"/>
Department	

Name: Department: Email:

PI/PO Assurance

I certify that:

- I and the individuals I have identified above are the Investigators for this project and each has a COI disclosure form in the COI-SMART system;
- the information submitted within the application is true, complete and accurate to the best of the PI/PO's knowledge;
- any false, fictitious, or fraudulent statements or claims may subject the PI/PO to criminal, civil, or administrative penalties; and
- the PI/PO agrees to accept responsibility for the scientific conduct of the project and provide the required progress reports if a grant is awarded as a result of the application.

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Financial Conflicts of Interest

1/8/2025 10

## What to Disclose

- Investigators disclose all financial interests for the previous 12 months:
  - Held by Investigators (or their spouse or dependent children)
  - That reasonably appear to be related to Investigators' Institutional Responsibilities

When in doubt, disclose

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## What to Disclose

- For Publicly Traded Entities:
  - Remuneration > \$5,000;
  - Equity interest > \$5,000 at the time of disclosure; or
  - Any remaining remuneration and equity from an Entity, that when combined, > \$5,000;
- For Non-Publicly Traded Entities:
  - Remuneration > \$5,000;
  - Any equity interests in the Entity regardless of value; or
  - Any remaining remuneration and equity from an Entity, that when combined, > \$5,000;
- Intellectual Property Rights and Interests:
  - Any income related to IP, upon receipt of income related to such rights and interests
- For PHS-and DOE-Funded Investigators Only: Reimbursed or Sponsored travel
  - Travel reimbursed or sponsored by an Entity other than the Investigator's current Institution and related to their Institutional Responsibilities
- Identify the person(s) with the interest, the investigator's relationship, name of Entity, and the nature/value of the SFI



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## What to Disclose: Exclusions

- Any remuneration paid by BU to the BU investigator;
- Income from investment vehicles, as long as the Investigator does not directly control investment decisions
- Income from seminars, lectures, teaching engagements or service on advisory committees or review panels, or any travel expenses, that are sponsored by a federal, state, or local government agency within the US, a US institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a US Institution of higher education

Investigators **must** disclose all financial interests from a foreign institution of higher education or government of another country.



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## What to Disclose

### COI-Smart Website

- BMC uses the same survey to collect information related to:
  - Research COI
  - Purchasing and business COI
  - Clinical COI
  - Conflicts of Commitment
  - Foreign affiliations and activities
  - Other outside activities
- Specific questions you receive depend on your role at BMC
  - If only role at BMC is researcher (ei not a healthcare provider, director level or above, senior leader, trustee, health plan care manager), then you only need to report financial interests of self, spouse, and dependent children.

### All outside activities and financial interests of self and family, **Related to your Professional Expertise**

- Any income or non-financial compensation
- Any equity (public or private, stock options)
- Any Board, Officer, or Executive Positions
- Unrestricted Support or Gifts
- Intellectual Property Rights
- Sponsored Travel
- Moonlighting
- International Appointments & any associated income, research resources or funding, etc.
- Unpaid professional or other outside relationships
- Total External Time
- Debt Forgiveness and Long-Term Medical Supply or Device Loan

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## What to Disclose

### Keep in mind!

- Not just interests from industry or research sponsors!  
Must disclose interests relevant to your institutional expertise, which generally includes, but is not limited to, activities and interests held in healthcare, insurance, medical education or communication, and pharmaceutical companies, non-profits, professional orgs, as well as BMC Health System or WellSense vendors.
- Add interests/activities to your outside activity report as they occur
- Use the consulting checklist
- When in doubt, over-disclose
- Keep your disclosure updated throughout the year!

Top reasons the BMC disclosure was inaccurate:

- Forgot
- Did not refer to financial docs when reporting
- Did not think interests under \$5k need to be reported
- Inaccurate value due to multiple payments from same entity throughout the year. Must report the cumulative amount!
- 3<sup>rd</sup> party payment

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### Addendum: DOE Interim Conflicts of Interest Policy Requirements for Financial Assistance

- Effective 6/18/22
- Disclose SFIs no later than time of proposal, at least annually within the award period, and within 30 days of discovering or acquiring a new SFI
- Disclose any unmanaged or unmanageable FCOIs
- Disclose reimbursed or sponsored travel related to their institutional responsibilities
- Each discloser must include a DOE certification in their submission
- Investigators must complete FCOI training



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### Addendum: NASA Conflicts of Interest Policy Requirements

- GCAM Section 3.3, Effective 12/1/2023
- Significant Financial Interest now includes venture or other capital financing
- Disclose SFIs no later than time of application for NASA-funded award, including “venture and other capital financing”
- Not disclose certain remuneration and/or equity excluded from the definition of SFI in GCAM Section 1(b)(i-vii)
- Disclose any unmanaged or unmanageable FCOIs



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## NSPM-33

- Presidential Memorandum on United States Government – Research and Development National Security Policy (NSPM-33)
- Additional information can be found on the Research Security Website: <https://www.bu.edu/research/ethics-compliance/research-security/>
- Be prepared to disclose more.



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## How to Disclose: BU Huron COI

- <https://fcoiresearch.bu.edu/>
- Go to the COI tab -> Disclosures subtab
- Do you have anything to disclose?

If **NO**: Submit your disclosure by pressing the

Complete Disclosure Profile Update

If **YES**: Add the entities you have interests in one at a time

## 3. \* Disclosure types: Select all that apply.

## 2. \* Relation to discloser: ?

- ☐ Self
- ☐ Spouse
- ☐ Dependent Child

Select all that apply

Name	Description
<input type="checkbox"/> Equity	Stock, Stock Options, or Ownership Interest in a Publicly traded entity >\$5000; in a Privately held entity – Any Amount of Stock, Stock Options, or ownership interest, including Venture Capital held by the private entity.
<input type="checkbox"/> Consulting or Other Compensated Professional Board Service	Advisory, scientific advisory board, or expert witness services in excess of \$5000 per interest or sum of all interests
<input type="checkbox"/> Editorial Services	Journal services, scientific editor services in excess of \$5000
<input type="checkbox"/> Intellectual Property Rights	Patent, Copyright, License, or Royalties paid directly to individual in excess of \$5000 per interest or sum of all interests
<input type="checkbox"/> Divestiture and Cash Pay-out	Sale of equity - Any Amount
<input type="checkbox"/> Travel for PHS/DOE-Sponsored Research	Travel which is paid on behalf of the Investigator and not reimbursed to the Investigator - for PHS Funded research only, in excess of \$5000
<input type="checkbox"/> Outside Employment	Employment external to your institution – Any Amount
<input type="checkbox"/> Other Appointments	Compensated or Uncompensated (e.g. positions, appointments, fellowships, or talent programs) – Any Amount
<input type="checkbox"/> Prizes and Honoraria	Speaking compensation or prizes (e.g. Nobel Prize, Honorary Degrees, etc.) - in excess of \$5000 per interest or sum of all interests



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## How to Disclose : BMC COI-Smart

COI-Smart is a disclosure website that you can access at any time from any computer, home or at BMC.

You may revise your COI disclosure at any time

Learn more about COI-Smart here:

<https://hub.bmc.org/departments/compliance/interactions-industry/disclosure-outside-relationships>

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2024 BMC Health System Annual Disclosure of Outside Relationships

This Questionnaire has been submitted.  
You may revise your answers by clicking on a "Revise" link below for a particular question.

Click on one of the icons below to download or email a copy of your answers to this questionnaire  
[Email Responses](#) [Download with All Responses](#) [Download with Most Recent Response](#)

	QUESTION	STATUS	ACTION
1	From January 1, 2023 to the present, what is/are your role(s) at BMC Health System?	Complete	<a href="#">Q</a> <a href="#">Revise</a>
2	Income and Non-Financial Compensation Please note that if you are a clinician, you are expected to check the CMS Open Payments website to view any 2023 payments reported there (see "Open Payments User Guide" in the Documents Library).	Complete	<a href="#">Q</a> <a href="#">Revise</a>
3	Unrestricted Support or Gifts	Complete	<a href="#">Q</a> <a href="#">Revise</a>
4	Equity Interest in and Payments from the Acquisition of a Publicly Traded Outside Entity	Complete	<a href="#">Q</a> <a href="#">Revise</a>
5	Equity Interest in and Payments from the Acquisition of a Privately Held Outside Entity	Complete	<a href="#">Q</a> <a href="#">Revise</a>
6	Board, Officer, or Executive Positions	Complete	<a href="#">Q</a> <a href="#">Revise</a>
7	Intellectual Property Rights	Complete	<a href="#">Q</a> <a href="#">Revise</a>
8	Travel	Complete	<a href="#">Q</a> <a href="#">Revise</a>
9	International Appointments/Employment/Support	Complete	<a href="#">Q</a> <a href="#">Revise</a>
10	Other Outside Activities	Complete	<a href="#">Q</a> <a href="#">Revise</a>
11	Research Projects for Researchers with one or more Significant Financial Interest	Complete	<a href="#">Q</a> <a href="#">Revise</a>
12	Total External Time	Complete	<a href="#">Q</a> <a href="#">Revise</a>
13	Anticipated Changes	Complete	<a href="#">Q</a> <a href="#">Revise</a>
14	From January 1, 2021 to the present, did you or a FAMILY MEMBER receive DEBT FORGIVENESS or LONG-TERM MEDICAL SUPPLY OR DEVICE LOAN from an ENTITY whose business is RELATED to your PROFESSIONAL EXPERTISE? Debt Forgiveness and Long-Term Medical Supply or Device Loan From January 1, 2021 to the present, did you or a FAMILY MEMBER receive DEBT FORGIVENESS or LONG-TERM MEDICAL SUPPLY OR DEVICE LOAN from an ENTITY whose business is RELATED to your PROFESSIONAL EXPERTISE?	Complete	<a href="#">Q</a> <a href="#">Revise</a>
15	I affirm the following:	Complete	<a href="#">Q</a> <a href="#">Revise</a>

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## After Disclosure: Determination of Relatedness

Is the **SFI** related to research? Could be **related** if :

- Research can affect the value of the SFI or the entity's financial interests
- Research uses or involves or is designed to assess effectiveness or safety of technology, IP, products, drugs/devices, services owned, made or provided by entity in which a SFI is held
- Research receives any kind of **support** (in-kind or monetary) from entity in which SFI is held
- Research uses, involves, assesses or further validates the investigator's licensed or unlicensed IP
- A start-up company involved in research also is or was an entity the investigator founded or helped found

If **NO**: no further action

If **YES**: determine if COI

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## After Disclosure: Committee Review

- If the COI office determines that an investigator's SFI is related to the research, the Faculty Review Committee on Research Financial Conflicts of Interest reviews the investigator's disclosure in the context of their research project.
- The Committee evaluates the potential of the SFI to bias the investigator's work or the integrity of the data, create an appearance of bias, or have a negative impact on the public's trust in research, particularly research involving human subjects.

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## After Disclosure: Committee Review

### Compelling Circumstances

The Committee has established precedent that there is a **"rebuttable presumption"** against participation of a conflicted investigator in a research project that is related to that conflict.

However, that presumption can be contested under certain "compelling circumstances" such that an investigator may be allowed to proceed in the research despite the existence of a conflict of interest.

The Committee looks at the unique qualifications of the conflicted investigator, including:

- proposed role in the project,
- unique expertise,
- unique lab resources or patient population,
- ability for research to be conducted as safely and effectively without the conflicted investigator, and
- Could others in the dept or outside of BU/BMC perform this role?

Each situation is unique and determined on a case-by-case basis.

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## What if there is a conflict?

- If the institution determines any of an investigator's SFIs could directly and significantly affect the research, or is an entity whose financial interest could be affected by the research, a FCOI exists.
- Prior to the expenditure of any research funds, a management plan must be in place.
- FCOI reports are made to the NIH upon award of a grant and annually, prior to the release of funding for the next year.

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## Management Plans

- Put in place when a FCOI has been determined to exist, and specifies actions to be taken to manage the FCOI
- Management Strategies:
  - Disclosure
  - Independent Scientific Reviewer (ISR)
  - Safe Haven Monitor (SHM)
  - Modification of the research plan/protocol, including recusal
  - Reduction or elimination of a financial interest
  - Severance of relationships that create the FCOI

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Questions about BU's policy, review process, or Huron COI?  
Would you like to schedule an individual or departmental  
Huron COI training/refresher?

Feel free to reach out:

[cassiew@bu.edu](mailto:cassiew@bu.edu)

[coi@bu.edu](mailto:coi@bu.edu)

COI Website: <https://www.bu.edu/research/ethics-compliance/conflicts-of-interest/>

Huron FAQs: <https://www.bu.edu/research/ethics-compliance/conflicts-of-interest/huron-faqs/>



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## Resources

### BMC

#### Contact Information

Jacqueline.Presedo@bmc.org  
[COI-Compliance@bmc.org](mailto:COI-Compliance@bmc.org)  
(617) 638-7976

- Consulting Checklist  
<https://bmc.tfatforms.net/f/bmc-consulting-checklist>
- COI-Smart  
<https://bmc.coi-smart.com/main.php>
- Compliance Intranet Page  
<https://hub.bmc.org/departments/compliance/interactions-industry/information-bmc-investigators>

#### BMC Policies:

- Significant Financial Conflicts of Interest in the Conduct of Research, Policy #: 09.23.000  
<https://bostonmedicalcenter.policytech.com/dotNet/documents/?docid=10077&app=pt&source=brorowse>
- Conflict of Interest, Policy #: 09.04.000  
<https://bostonmedicalcenter.policytech.com/dotNet/documents/?docid=4740&app=pt&source=brorowse>

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### NIH

- NIH Policy Topics Financial Conflicts of Interest  
<https://grants.nih.gov/policy-and-compliance/policy-topics/fcoi>
- Financial Conflicts of Interest FAQ page  
<https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm?anchor=3875>

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