

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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Financial Conflicts of Interest

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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)
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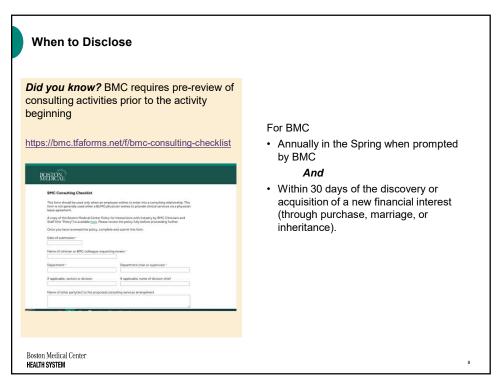
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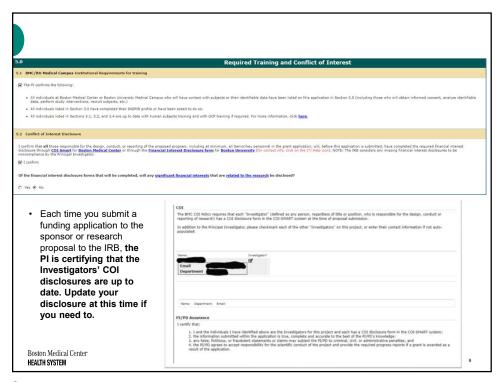
When to Disclose

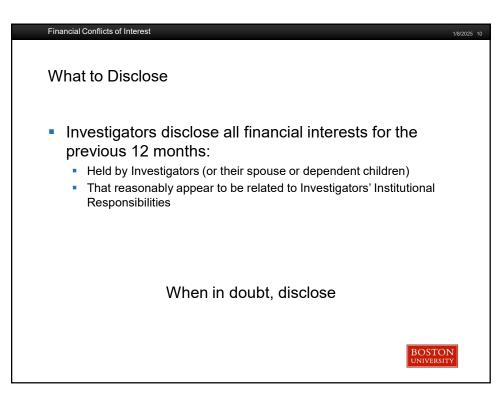
- At the time of submission of a funding application to the sponsor or research proposal to the IRB;
- When executing a contract with an Entity where no application or proposal is required;
- Within 30 days of the discovery or acquisition of a new SFI (through purchase, marriage, or inheritance); and
- 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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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.



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!
- 3rd 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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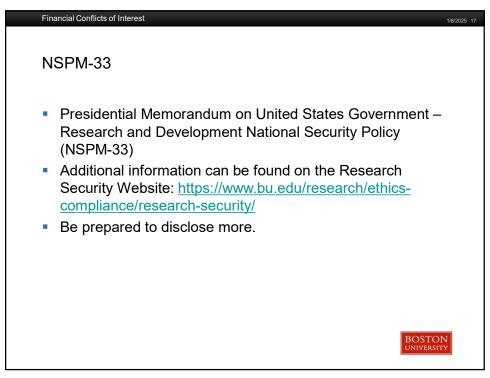
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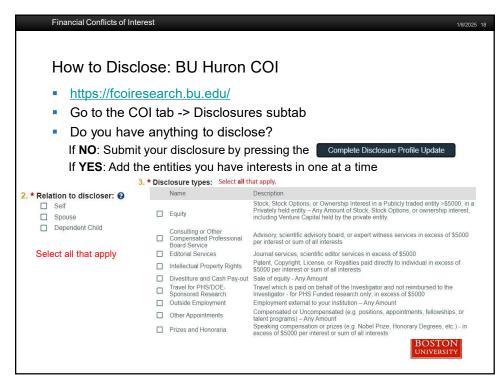
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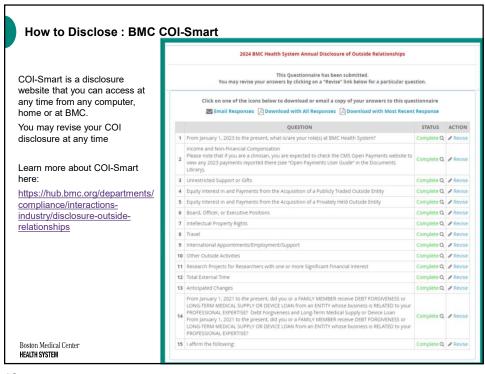
Addendum: NASA Conflicts of Interest Policy Requirements

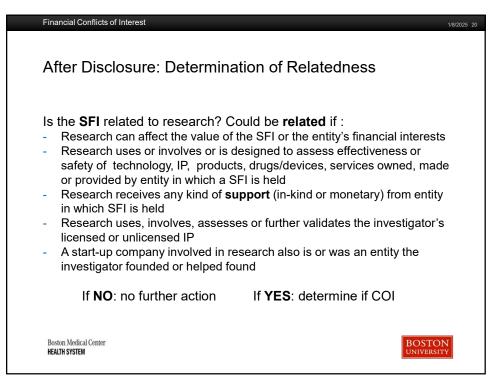
- GCAM Section 3.3, Effective 12/1/2023
- Significant Financial Interest now includes venture or other capital financing
- Disclose SFIs no later than time of application for NASA-funded award, including "venture and other capital financing"
- Not disclose certain remuneration and/or equity excluded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











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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 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

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Contact Information

Jacqueline.Presedo@bmc.org <u>COI-Compliance@bmc.org</u> (617) 638-7976

Consulting Checklist

 $\underline{\text{https://bmc.tfaforms.net/f/bmc-consulting-checklist}}$

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=browse
- Conflict of Interest, Policy #: 09.04.000 https://bostonmedicalcenter.policytech.com/dotN et/documents/?docid=4740&app=pt&source=bro

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NIH

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

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