Getting Conflicts: An Overview of the Changes in Conflict of Interest Regulation and How it Affects Your Research

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Manager, Conflicts of Interest
Office of Research Compliance
Our Team

Office of Research Compliance (the ORC)

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BU/ BMC

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Executive Director
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Jodi Edelstein
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Conflicts of Interest
BU/ BMC

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Compliance Coordinator
Conflicts of Interest

Charles River Campus
Faculty Committee on
Research Conflicts of Interest

BUMC
Faculty Committee on
Research Conflicts of Interest
Overview of What We Do

1) Manage cases: financial conflicts of interest (FCOI) in research at BU and BMC
   • Gather and review financial disclosures
   • Determine appropriate FCOI “management plans”

2) Design and refine the process and policies

3) Educate and advise the BU and BMC the community
Core of What We Do

**Conflict of Interest (COI) =**
when a private interest *could* unduly affect a professional decision

E.g., Dr. Jones gets *royalties* for his invention, the super stapler, and is about to conduct research to test how *effective* it is.

Private financial interest - royalties - *might* cause Dr. Jones to make personally favorable decisions – i.e., making him *biased*, even without realizing it.
Potential Conflict of Interest

- Interests of Family & Friends
- Personal Interests
- Personal Values
- Organisational Values
- Professional Values
- Public Sector Government Policy

http://legacy.communitydoor.org.au/resources/etraining/units/chccs301a/section2/section2topic06.html
Causes of COI

Of the many causes of bias (i.e., conflicts of interest) in research, we look for:

- Payments for professional services
- Patents, copyrights (IP) and related royalties
- Equity holdings (stock)
- Honorarium

...but only where they could directly and significantly affect the design, conduct, or reporting of Research at BU or BMC.
Anyone **responsible** for design, conduct or reporting of research, regardless of title or role. (Determined by PI).

**“Investigator” $**

- Non-BU/BMC Compensation
- Equity/Stock
- Royalties

**Research**

*only where $ could directly and significantly affect Research (via bias)*
We Know - Conflicts are Natural

Expertise

- Service on Boards, Panels, Committees
- Industry Relationships
- Inventions

Conflicts of Interest
(actual or perceived)

(Getting in the way of research)
• Taxpayers who support federally funded research want assurances that research is conflict-free
  • 42 CFR Part 50, Subpart F (revised 8/25/11)
  • 45 CFR Part 94

• BU and BMC want to ensure that all research at our institutions uphold the highest levels of integrity and objectivity. We’re applying old (1995) and new (2011) federal standards across the board, depending on sponsor.
HOW Do We Manage FCOIs in Research?

Submit → Review disclosures, compare to research

Find Financial Conflicts of Interest

Committee Review and recommendation

Final decision by Associate VP for Research Compliance

Management plan compliance by Investigators

“Investigators” = all those responsible for the design, conduct or reporting of research

Funds are not disbursed until process is complete!
(a) Weighing Factors:
• Unique qualifications of Investigator?
• $ nature and magnitude?
• $ is in close relation to research?
• Human subjects?
• Primary site?
• Public perception?

(b) Management Options:
• Disclosure;
• Independent monitor/statistician;
• Modification of the research plan;
• Change of personnel or responsibilities; and
• Reduction/elimination of $.

1. Committee recommendation
2. Investigator review and comment
3. Associate VP of Research Compliance final decision
Recent Changes

Over concern that our institutions were missing the COIs, the government revised its policies to capture more of them.

Starting 8/24/12, these new rules apply to **PHS-funded** BU Research and all BMC Research.
<table>
<thead>
<tr>
<th>1995 Policy BU-Non PHS-funded Research</th>
<th>2011 Policy BU PHS-funded &amp; all BMC Research</th>
</tr>
</thead>
<tbody>
<tr>
<td>Everything else</td>
<td>PHS Agencies: Agency for Healthcare Research and Quality (<strong>AHRQ</strong>), Agency for Toxic Substances and Disease Registry (<strong>ATSDR</strong>), <strong>CDC</strong>, <strong>FDA</strong>, Health Resources and Services Administration (<strong>HRSA</strong>), Indian Health Service (<strong>IHS</strong>), <strong>NIH</strong>, Substance Abuse and Mental Health Services Administration (<strong>SAMHSA</strong>)</td>
</tr>
</tbody>
</table>

**bu.edu/orc/coi/forms**

+ 5 Nonprofits: American Heart Association, American Cancer Society, Arthritis Foundation, Susan G. Komen Foundation, Alliance for Lupus Research
# New Federal → BU/BMC Policy Overview

<table>
<thead>
<tr>
<th>1995 Policy → BU-Non PHS-funded Research → NON FIND 1 form</th>
<th>2011 Policy → BU PHS-funded Research and ALL BMC Research → FIND 1&amp;2 forms</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Investigators determine relatedness of $ to research</strong></td>
<td><strong>Institution determines relatedness of $ to research</strong></td>
</tr>
<tr>
<td>Forward-looking</td>
<td>Backward-looking</td>
</tr>
<tr>
<td>$10,000 minimum threshold</td>
<td>$5,000 min. threshold; <em>any</em> private equity</td>
</tr>
<tr>
<td>Disclosing outside payments, equity and intellectual property rights</td>
<td>Disclosing outside payments, equity, royalties and travel reimbursement (with extensive exceptions)</td>
</tr>
<tr>
<td>No training requirement</td>
<td>Training requirement once every 4 years</td>
</tr>
<tr>
<td>No public accessibility requirement</td>
<td>FCOIs in PHS-funded research reported upon request</td>
</tr>
<tr>
<td>Updates with “material changes” in significant financial interests</td>
<td>Updates with 30 days of a change</td>
</tr>
<tr>
<td>1995 Policy</td>
<td>2011 Policy</td>
</tr>
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<td>BU PHS-funded &amp; all BMC Research</td>
</tr>
<tr>
<td>NON FIND 1 form</td>
<td>FIND 1 &amp; 2 FORMS</td>
</tr>
</tbody>
</table>

**Investigator Q:** Do you have SFIs or SFIs in an entity that would reasonably appear to be affected by your research?

“Are you conflicted?”

**Investigator Q:** Do you have SFIs that reasonably appear to be related to your institutional responsibilities?

“Show me the money”

“**SFI**”: Significant Financial Interest
a) salary or other payments for services
   • consulting fees
   • reimbursed or sponsored travel
   • honoraria

b) equity interests
   • stocks, stock options (from $1, if private)

c) intellectual property rights - once income is received
   • patents
     • (owned or where clinical investigator is an inventor)
   • copyrights
   • royalties

☑ Include holdings of spouse and dependent children

☑ Must be *related* to institutional responsibilities
Investigators do not disclose:

- BU or BMC salary
- Income from seminars, lectures, teaching engagements, service on advisory committees or review panels (or travel expenses) sponsored by
  - Public or non-profit entities
  - Federal, state, or local government agency, college/university, academic teaching hospital, a medical center
- Salary, royalties or other payments from a single entity (or group of affiliated entities) that, when aggregated over the
  - Next twelve months are not expected to exceed $10,000
  - Past 12 months, do not exceed $5,000.
- Mutual funds (where no direct control)
<table>
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<td><strong>BU and BMC Policy Overview</strong></td>
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<tr>
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<td><strong>BU PHS-funded &amp; all BMC Research</strong></td>
</tr>
<tr>
<td>-Disclosure by “investigators”</td>
<td>-Disclosure <strong>and training</strong> by all “investigators”</td>
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<tr>
<td>-prior to the final submission of the research application,</td>
<td>-prior to the final submission of the research application,</td>
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<tr>
<td>-annually thereafter, and</td>
<td>-annually thereafter, and</td>
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<tr>
<td>-if there are any material changes to your reported interests.</td>
<td>-within thirty (30) days of discovering or acquiring (e.g. through purchase,</td>
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<td>marriage, or inheritance) a new SFI.</td>
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<td><strong>Use NON FIND 1 form</strong>, return to <a href="mailto:coi@bu.edu">coi@bu.edu</a> (stands for Non-PHS funded Financial Interest Disclosure form)</td>
<td><strong>Use FIND 1 and FIND 2 form</strong> (if a “yes” on FIND 1), and return to <a href="mailto:coi@bu.edu">coi@bu.edu</a></td>
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<td></td>
<td>-Email invitation to training on Blackboard will be sent via individual email</td>
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<td></td>
<td>afterwards. Training is only required once every 4 years.</td>
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**bu.edu/orc/coi/forms**
When applying for a grant, PIs fill out the new Proposal Summary Form (PSF) Section

Disclosure is required 100% of the time
Even though potential COIs are reviewed only a small % of the time
Disclosure form for BMC and PHS-Funded BU Research:

**FIND 1**

**FIND 1: Financial Interest Disclosure for all BMC and BU PHS-Funded Research**

The information is being requested in accordance with federal regulations and must be filed out if you are now or will substantially be responsible for the design, conduct, reporting of any Boston Medical Center (BMC) research activities or [BMC-funded]. Boston University (BU) research activities (not including Phase I SBIR/STTR awards, and including the list of 3 schemes of the form). This initial disclosure is due no later than the time of application. You will receive an email notification to an online training course by clicking of done and a short link after this form is submitted. If you check any box and no question below, fill out all BU and BU-PHS-Funded Research Address to Financial Interest Disclosure - Form 2, posted online at [https://www.bmc.edu/forms]. Form all to [http://bmc.edu].

### BASIC INFORMATION
- **Name:**
- **Email:**
- **Home Institution:**
- **School/Dept.:**
- **Full Project Title:**
- **Principal Inv.:**
- **Project Period:**
- **Subprojects (if any):**
- **Sponsorship:**
- **Award number:**
- **BMC Grant Admin Office:**

### QUESTIONS

**I. OUTSIDE REMUNERATION.** In the last 12 months, did you receive any remuneration that reasonably appears to be related to your institutional responsibilities? **Yes** **No**

**II. REMUNERATED OR SPONSORED TRAVEL.** Have you, your spouse, or dependent children received reimbursement or sponsorship for travel that reasonably appears to be related to your institutional responsibilities? **Yes** **No**

**III. EQUITY INTERESTS.** Do you, your spouse, or dependent children hold equity interests in a publicly or non-publicly traded entity that reasonably appears to be related to your institutional responsibilities? **Yes** **No**

**IV. ROYALTIES/INCOME IN CONNECTION WITH INTELLECTUAL PROPERTY (IP) RIGHTS.** Have you, your spouse, or dependent children received royalties or other income related to intellectual property interests (e.g., patents, copyrights)? **Yes** **No**

**CERTIFICATION**

I certify that the above information is complete and true to the best of my knowledge and that I have read the Boston University or Boston Medical Center conflict of interest policies. I acknowledge that I am responsible for submitting updates to this information annually and also within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) any new financial interest. If any information is found to be incomplete or inaccurate, I will promptly submit a correction.

**Signatures:**

**Date:**

Electronically signed must indicate the next page. 

Questions? Email cm2008@bu.edu
Form 1 for BMC and PHS-Funded BU Research: FIND 1

I. OUTSIDE REMUNERATION. In the last 12 months did you, your spouse or dependent children receive any remuneration that reasonably appears to be related to your institutional responsibilities?  Yes  No

“Remuneration” includes salary and any payment for services not otherwise identified as salary, e.g., consulting fees, honoraria, paid authorship fees. Do not include the following: (i) salary, royalties, or other remuneration paid by BU or BMC to you, your spouse, or your dependent child, if the recipient is currently employed or otherwise currently holding an appointment at such institution; and (ii) income from seminars, lectures, teaching engagements, service on advisory committees or review panels that are reimbursed or sponsored by a Federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education. You may check “No” if the aggregate of all outside compensation is less than $5,000 total.

“Institutional responsibilities” means an investigator’s professional responsibilities on behalf of BU and/or BMC, including but not limited to research, research consultation, teaching, professional practice, and administration such as service on committees, boards and panels.

II. REIMBURSED OR SPONSORED TRAVEL. Have you, your spouse or dependent children received reimbursement or sponsorship for travel that reasonably appears to be related to your institutional responsibilities?  Yes  No

Sponsored travel is that which is paid on your behalf (or on behalf of your spouse or dependent children) and not reimbursed so that the exact monetary value may not be readily available. Do not include travel expenses that are reimbursed or sponsored by a Federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

III. EQUITY INTERESTS. Do you, your spouse or dependent children hold equity interests in a publicly or non-publicly traded entity that reasonably appears to be related to your institutional responsibilities?  Yes  No

Equity interests include any stock, stock options or other ownership interests. Do not include income from investment vehicles, such as mutual funds and retirement accounts if you, your spouse, or dependent children do not directly control the investment decisions made in these vehicles. You may check “No” if the aggregate value of any equity interests in a publicly traded entity is less than $5,000 based on public prices or other reasonable measures of fair market value. You must check “Yes” if any equity interest in a non-publicly traded entity is held.

IV. ROYALTIES/INCOME IN CONNECTION WITH INTELLECTUAL PROPERTY (IP) RIGHTS. Have you, your spouse or dependent children received royalties or other income related to intellectual property interests (e.g., patents, copyrights) that reasonably appear to be related to your institutional responsibilities?  Yes  No

This does not include intellectual property rights assigned to BU or BMC and agreements to share in royalties related to such rights (e.g., royalties received under the relevant Patent Policy). You may check “No” if the royalties or other income related to these rights and interests do not exceed $5,000.
For Principal Investigators Only (Required)

1. What is the actual/proposed award amount for the project?  Proposed Year: $[ ] Entire Project: $[ ]

2. Human Subjects?  [ ] No  [ ] Yes - IRB # [ ]

3. Special Designations:
   - [ ] Clinical study
   - [ ] Applied / applying for an IND or IDE
     (Investigational New Drug or Investigational Device Exemption through the FDA)

4. Please summarize the specific aims of the research. You may attach a project summary or abstract.

5. Please list all those responsible for the conduct, design or reporting of the research, even if they are from an institution other than BU or BMC. (unless they are working under a subaward, and the subaward agreement states they will follow the subaward institution's COI policy). Please ensure that all of these people fill out and submit these financial interest disclosure forms. Failure to do so may delay funding.

<table>
<thead>
<tr>
<th>Name</th>
<th>Role in Research</th>
<th>Email address</th>
<th>Home Institution (if not BU or BMC)</th>
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Form 2 for BMC and PHS-Funded BU Research: FIND 2
If you check “yes” on FIND 1

FIND 2: Addendum to Financial Interest Disclosure for all BMC and BU PHS-Funded Research

Complete this form only if you checked “yes” to any of the questions on your Financial Interest Disclosure – FIND 1.

I. OUTSIDE REMUNERATION.

If, in the last 12-months, you, your spouse or dependent children received any remuneration that reasonably appears to be related to your institutional responsibilities, please fill out the chart below, detailing those interests.

Remuneration includes salary and any payment for services not otherwise identified as salary, e.g., consulting fees, honoraria, paid authorship fees.

Do not include the following: (i) salary, salaries or other remuneration paid by Bu or BMC to you, your spouse, or your dependent child if the recipient is currently employed or formerly employed holding an appointment at such institution, and (ii) income from seminars, lectures, teaching engagements, serve on advisory committees or similar panels that are reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education as defined at 30 U.S.C. 101(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

II. REIMBURSED OR SPONSORED TRAVEL.

If you, your spouse or your dependent children have received reimbursement or sponsorship for travel that reasonably appears to be related to your institutional responsibilities, please fill out the chart below, detailing those interests.

- Include travel expenses reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education as defined at 30 U.S.C. 101(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

For any changes to the information, or new trips in the next 12 months, you must submit a new form within 30 days of returning from the trip. You may, but are not required to, provide information on anticipated travel in the space below. If more space is needed, please attach additional pages of the form.

A. Traveler (Name, relationship to you) Year of Travel Sponsor/organizer of Travel Duration Destination Purpose (e.g., Scientific meeting, research collaboration, professional service, professional development, data collection)

B. Questions:

- Is the research receiving any kind of support (‘yes’ kind or mention) from any of the entities listed above (‘yes’)?
- If yes, which criteria?
- Do any of the above criteria have prepublication access to results of the research? (‘yes’ or ‘no’)
- If yes, which criteria?
- Do any of the above criteria have prepublication access to intellectual property coming out of the research? (‘yes’ or ‘no’)
- If yes, which criteria?
- Might new intellectual property result from the research that would potentially be of interest to any of the above criteria? (‘yes’ or ‘no’)
- If yes, which criteria?
- Does the research involve intellectual property owned or licensed by an entity listed above (‘yes’)?
- If yes, name the criteria and describe the IP.
- Could any of the above remuneration reasonably appear to be affected by the research? (‘yes’ or ‘no’)
Training RE: 1R21ES021136-01/Effects of High Fat Diet and Environmental Obesogen Co-Exposure on

Edelstein, Jodi

To: Schlezinger, Jennifer J; Gerstenfeld, Louis C; Fried, Susan K
Cc: Tate, Priscilla; Badgett, Laura M

Attachments: Image007.png (3 KB)

- This message was sent with High importance.

Hi Dr. Schlezinger, Dr. Fried and Professor Gerstenfeld,

Thank you. We have received your financial interest disclosure forms.

To complete the disclosure process, please log into http://blackboard.bu.edu and click on “eFind Training for Investigators.” Instructions will be provided under the “Announcements” tab on the left side of the screen. There is a series of PowerPoint slides in PDF and a 10-question quiz.

We are able to track when this step is completed, so no further action is needed unless we contact you.

Best Regards,

Jodi

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Jodi R. Edelstein, J.D.
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Boston, MA 02118
jedelste@bu.edu
Phone: (617) 638-4514
Fax: (617) 414-4738

BU Research Compliance
A score of 80/100 is required to pass.
Disclosure form for Non-PHS-funded BU Research:
NON FIND 1

Non Find 1: Financial Interest Disclosure for Non-PHS Funded BU Research
(externally funded and/or human subject research at Boston University (BU) only)

The information is being requested in accordance with BU policy and must be filled out if you will be responsible for the design, conduct, or reporting of human subject research at BU, and/or any research activity that is externally funded by an entity other than (a) an agency under the Public Health Service, (b) the American Heart Association, (c) the American Cancer Society, (d) the Arthritis Foundation, (e) the Susan G. Komen Foundation or (f) the Alliance for Lupus Research at BU.

The disclosure form is due later than the time of application. Send all forms to research@bu.edu or call 857-444-9733.

BASIC PERSONAL AND RESEARCH INFORMATION

Name: ________________________________
Email: ________________________________
Home Institution: _______________________
Department: __________________________
Full Project Title: _______________________
Principal Investigator: ___________________
Project Period: _________________________
Funds Sponsor: _________________________
Sub-Sponsor (if any): ___________________
Award number: _________________________

BU/BMC Grant Admin Office: [ ] BU/CRC [ ] HMC [ ] OTHER [ ] Proposal ID: ___________________

QUESTIONS

1. Do you, your spouse, or dependent children have any significant financial interest in an entity whose financial interests would reasonably appear to be affected by your disclosure statement?  [ ] Yes  [ ] No

2. Do you, your spouse, or dependent children have any significant financial interest in an entity whose financial interests would reasonably appear to be affected by the research?  [ ] Yes  [ ] No

GUIDANCE

“Significant financial interest” (SFI) refers to:

1. Anything of monetary value, including a salary, consulting the honorarium or other payment for services.
2. Equity interests, including stock options or other ownership interests or an interest in the profits or income from a business, organization, or other entity.
3. Intellectual property interests, including copyrights, patents, or royalty rights.

Exemptions:

1. Financial interests held by a foreign government or international organization.

CERTIFICATION

I certify that the above information is complete and true to the best of my knowledge and that I have read the Boston University conflict of interest policy.

Signature: ____________________________
Date: ________________________________

Principal investigators must complete the next page if...
- Public Health Service (PHS) agencies are HHS, ATSDR, CDC, FDA, HHS, NCI, NIT, NHLBI, and HSA (a detailed list is on the last page), and are covered by a separate form—Financial Interest Disclosure—which can be found at BU.edu/forms.
Disclosure form for Non-PHS-funded BU Research:
NON FIND 1

QUESTIONS

1. Do you, your spouse, or dependent children have any significant financial interests that would reasonably appear to be affected by your above-described research?
   Yes ☐ No ☐

2. Do you, your spouse or dependent children have any significant financial interests in an entity whose financial interests would reasonably appear to be affected by this research?
   Yes ☐ No ☐

GUIDANCE

“Significant financial interest” (SFI) refers to:

1. anything of monetary value, including a salary, consulting fee, honorarium or other payment for service;
2. equity interests, including stocks, stock options or other ownership interests; and
3. intellectual property (IP) rights, including copyrights, royalties, and patent rights, or, where a clinical “investigator” (i.e., someone responsible for the design, conduct or reporting of the research) is inventor (whether IP is licensed or not).

“reasonably appear to be affected” may refer any of the following:

(a) Research uses or involves intellectual property (“IP”) (i.e., technology, drugs, products or services) owned by or licensed to the investigator (e.g., via patent or copyright); or
   ☐ Research uses or involves IP for which the investigator receives royalties, or has the right to receive royalties.

(b) (i) The investigator (or spouse or dependent child) -
   ☐ receives compensation from, or, ☐ has equity in - an entity
   AND –
   ☐ The research is receiving any kind of support (“in kind” or monetary) from that entity;
   ☐ Proprietary access to data or rights to IP coming out of the research is/are owned by that entity (e.g., pre-publication access to results of the research);
   ☐ Research aim(s) overlap with aims of that entity;
   ☐ Research uses or involves IP owned by or licensed to that entity;
   ☐ Research results could enhance the value of, or further validate, or increase the interest in IP owned, made or provided by that entity; and/or
   ☐ New IP could result from research under this grant and potentially be of interest to that entity.

Exceptions:

a. salary, or other remuneration (not including royalties) from Boston University or Boston Medical Center;
b. income from public or non-profit entities for seminars, lectures, teaching engagements, service on advisory committees, or review panels; or
c. salary, royalties or other payments from a single entity (or group of affiliated entities) that, when aggregated over the next twelve months, are not expected to exceed $10,000.
Paperless Disclosure & Training Process

Boston University Financial Interest Disclosure

Basic Information

Name and Title: Edelstein, Jodi
School/Department: Your department
Email Address: jedelste@bu.edu
Phone Number: Your telephone number

Status

Do you fall into any of these categories? (Check all that apply)

- [ ] I am currently engaged in research at Boston University (BU) or at Boston Medical Center (BMC)
- [ ] I plan to be engaged in research in the next 12 months at BU or BMC
- [ ] I, by virtue of my role at BU, have influence over what research is conducted and also, provide research oversight or review. If your role at BU is listed below, place a check mark next to it.
  - [ ] University President
  - [ ] Provost
  - [ ] Vice President
  - [ ] Dean (including assistant and associate presidents)
  - [ ] Department Chairperson
  - [ ] Division Chief
  - [ ] Center or institute director
  - [ ] Chairperson of the institutional Review Board
  - [ ] Technology Transfer officer
- [ ] None of the above
“If I Disclose, Will I get in Trouble?”

Disclosing your financial interests and conflicts of interest does not imply wrongdoing nor automatically preclude Investigators from receiving research awards.

**BUT...**

Undisclosed conflicts can result in serious consequences including loss of research funding.
☑ See bu.edu/orc/coi/forms for instructions and the latest disclosure forms
☑ All “investigators” must disclose and complete the training prior to final submission of research application.
  - Investigators added mid-project
  - Training 1x / 4yrs
☑ Update your interests annually and if they change
☑ Once COI review is complete, funding can be disbursed
  - a note on the transition phase
Questions?

NIH COI website at: http://grants.nih.gov/grants/policy/coi/