
BU/BMC Clinical Research Seminar

September 19, 2012

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

Jodi Edelstein

Manager, Conflicts of Interest
Office of Research Compliance

Our Team

Office of Research Compliance (the ORC)

Ara Tahmassian
Associate VP
Research Compliance
BU/ BMC

Kate Mellouk
Executive Director
Research Integrity
BU/ BMC

Jodi Edelstein
Compliance Manager
Conflicts of Interest
BU/ BMC

Andre Chapman and Julie Maleck
Compliance Coordinator
Conflicts of Interest

Charles River Campus
Faculty Committee on
Research Conflicts of
Interest

BUMC
Faculty Committee on
Research Conflicts of
Interest

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**

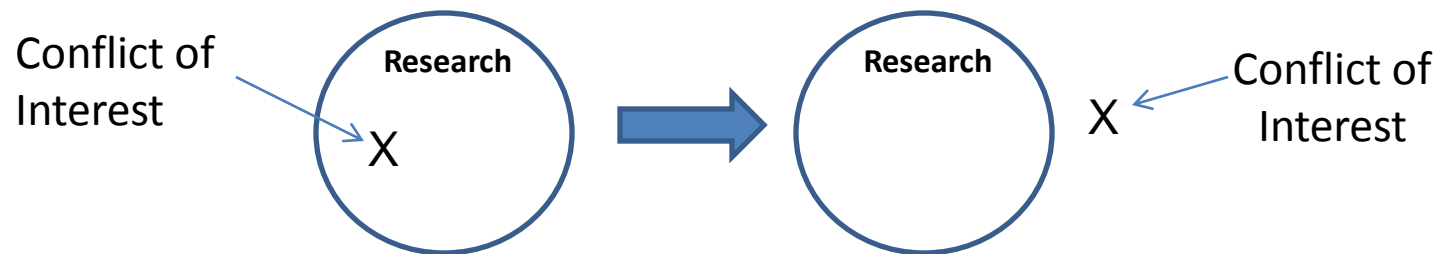
3) **Educate and advise** the BU and BMC the community



**Research
Conflicts
of Interest**

Core of What We Do

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



Protect the **Objectivity** of Research by
Reviewing and Managing Financial Conflicts of Interest

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.

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"WHILE DOING THE RESEARCH, KEEP IN MIND THERE ARE ONLY TWO KINDS OF FACTS... THOSE THAT SUPPORT MY POSITION... AND INCONCLUSIVE."

<http://www.cartoonstock.com/directory/b/biased.asp>

search ID: ear0870

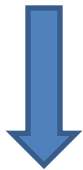


<http://evidencebasedliving.human.cornell.edu/2011/12/more-evidence-supporting-the-systematic-review/>



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

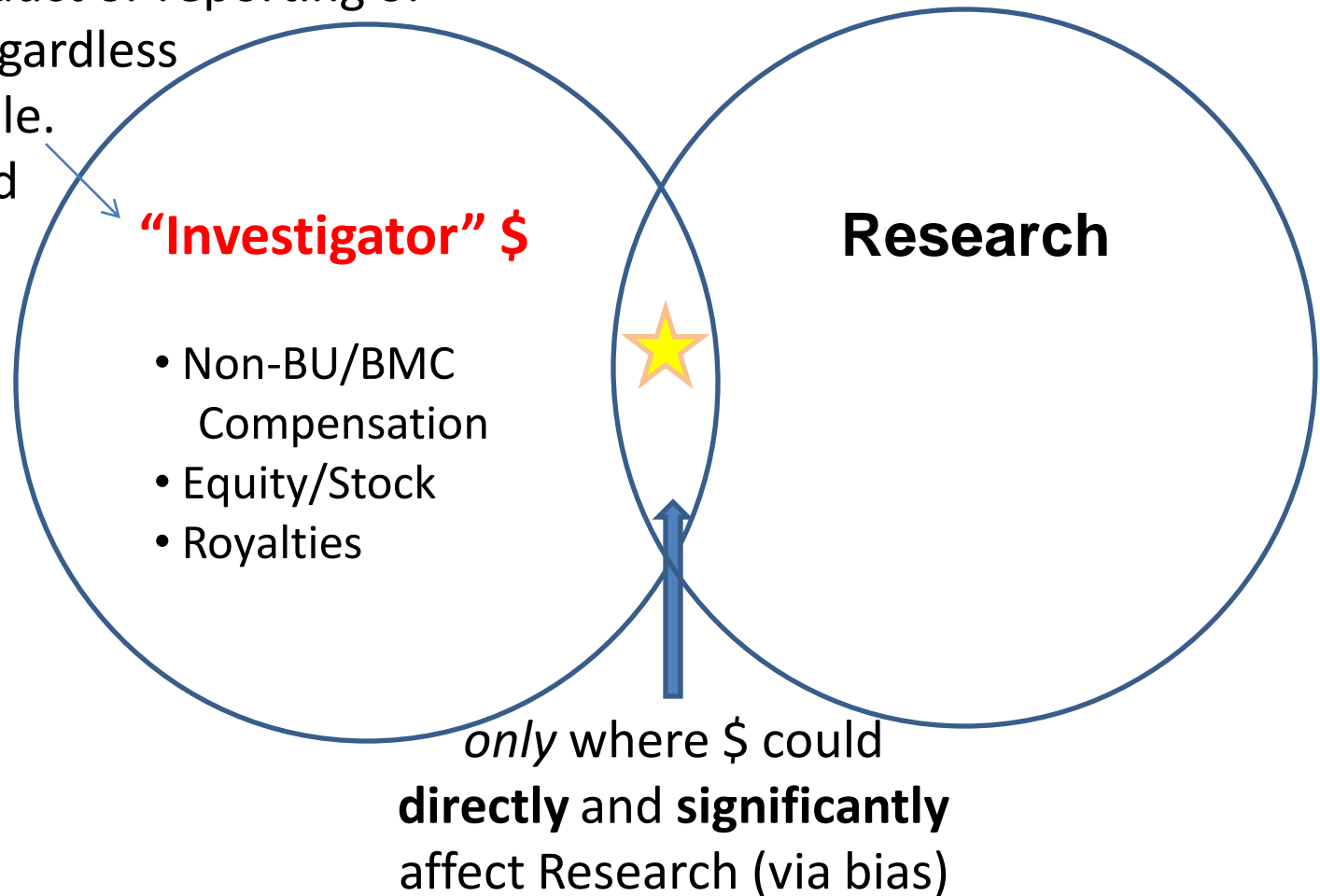
- Payments for professional services
- Patents, copyrights (IP) and related royalties
- Equity holdings (stock)
- Honorarium



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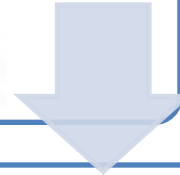
...but *only* where they *could* **directly** and **significantly** affect the design, conduct, or reporting of Research at BU or BMC.

Anyone **responsible** for
design, conduct or reporting of
research, regardless
of title or role.
(Determined
by PI).

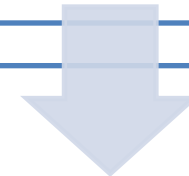




Expertise



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



Conflicts of Interest (actual or perceived)



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(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?

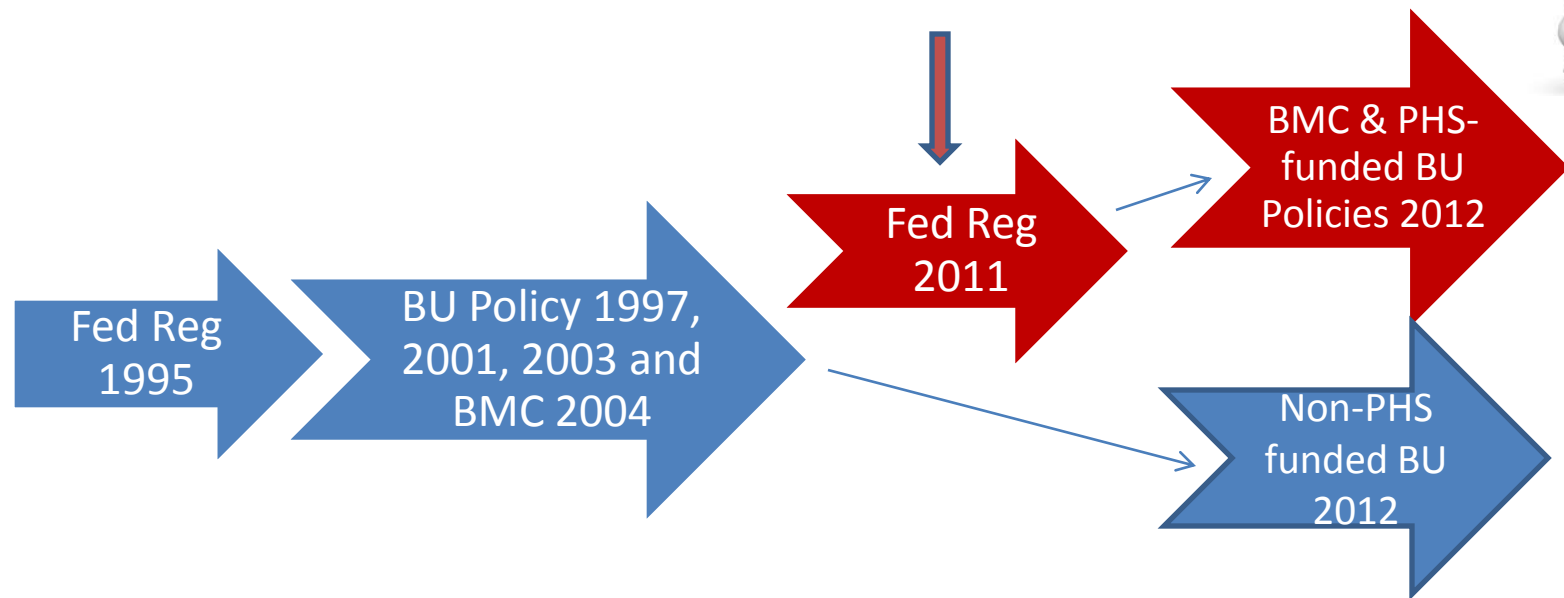
(b) Management Options:

- 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

Over concern that our institutions were missing the COIs, the government revised it's policies to capture more of them



Starting 8/24/12, these new rules apply to
PHS-funded BU Research and all BMC Research

1.Check Your Institution; 2.Check Your Sponsor

1995 Policy <u>BU-Non PHS-funded Research</u>	2011 Policy <u>BU PHS-funded & all BMC Research</u>
<p>Everything else</p> <p>**bu.edu/orc/coi/forms**</p>	<p>PHS Agencies: Agency for Healthcare Research and Quality (AHRQ), Agency for Toxic Substances and Disease Registry (ATSDR), CDC, FDA, Health Resources and Services Administration (HRSA), Indian Health Service (IHS), NIH, Substance Abuse and Mental Health Services Administration (SAMHSA)</p> <p>+ 5 Nonprofits: American Heart Association, American Cancer Society, Arthritis Foundation, Susan G. Komen Foundation, Alliance for Lupus Research</p>

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

1995 Policy <u>BU-Non PHS-funded Research</u> NON FIND 1 form	2011 Policy <u>BU PHS-funded & all BMC Research</u> FIND 1 & 2 FORMS
<p>Investigator Q: Do you have SFIs or SFIs in an entity that would reasonably appear to be affected by your research?</p> <p>“Are you conflicted?”</p>	<p>Investigator Q: Do you have SFIs that reasonably appear to be related to your institutional responsibilities?</p> <p>“Show me the money”</p>

“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)

1995 Policy <u>BU-Non PHS-funded Research</u>	2011 Policy <u>BU PHS-funded & all BMC Research</u>
<p>-Disclosure by “investigators”</p> <ul style="list-style-type: none"> -prior to the final submission of the research application, -annually thereafter, and -if there are any material changes to your reported interests. <p>-Use NON FIND 1 form, return to coi@bu.edu (stands for Non-PHS funded Financial Interest Disclosure form)</p> <p>**bu.edu/orc/coi/forms**</p>	<p>-Disclosure and training by all “investigators”</p> <ul style="list-style-type: none"> -prior to the final submission of the research application, -annually thereafter, and -within thirty (30) days of discovering or acquiring (e.g. through purchase, marriage, or inheritance) a new SFI. <p>-Use FIND 1 and FIND 2 form (if a “yes” on FIND 1), and return to coi@bu.edu</p> <p>-Email invitation to training on Blackboard will be sent via individual email afterwards. Training is only required once every 4 years.</p>

When applying for a grant, PIs fill out the new Proposal Summary Form (PSF) Section

Name: _____ Phone: _____ e-mail: _____

Compliance Information			Project Approval** (Date or "Pending")	Protocol/Approval No. for Each Project
<u>Special Reviews:</u>				
IRB	<input type="checkbox"/> Yes	<input type="checkbox"/> No		
IACUC	<input type="checkbox"/> Yes	<input type="checkbox"/> No		
IBC: Biohazards	<input type="checkbox"/> Yes	<input type="checkbox"/> No		
IBC: rDNA	<input type="checkbox"/> Yes	<input type="checkbox"/> No		
IBC: Select Agents	<input type="checkbox"/> Yes	<input type="checkbox"/> No		
Laser	<input type="checkbox"/> Yes	<input type="checkbox"/> No		
Radioisotopes	<input type="checkbox"/> Yes	<input type="checkbox"/> No		
Human Embryonic Stem Cells	<input type="checkbox"/> Yes	<input type="checkbox"/> No		
SCUBA/Snorkeling/Boats	<input type="checkbox"/> Yes	<input type="checkbox"/> No		
Financial Interest Disclosure <input type="checkbox"/> Yes (required) The PI must ensure that <u>all</u> those responsible for the design, conduct, or reporting of the proposed program have completed the financial interest disclosure forms and training as dictated at http://www.bu.edu/orc/coi/forms/ . Final disclosure for <u>this project</u> was submitted: _____ <div style="text-align: right;">Date</div>				
PI/PD Assurance I certify that: (1) in conducting the proposed program I am familiar with and will adhere to applicable Boston				

Disclosure is required 100% of the time

Even though potential COIs are reviewed only a small % of the time

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

This information is being requested in accordance with federal regulations and must be filled out if you are now or will potentially be responsible for the design, conduct, reporting of any Boston Medical Center (BMC) research activities or BRISQ Boston University (BU) research activities (not including Phase I SBIR/STTR awards), and including the list of 5 non-profits on the last page of this form. This initial disclosure is due no later than the time of application. You will receive an email invitation to an online training course consisting of slides and a short quiz after this form is submitted. If you check "Yes" to any question below, fill out an APR and BU BMC-Related Research Addendum to Branded Internet Disclosure - Form 2, posted online at www.bumc.edu/onlineforms. Send all forms to colli@bu.edu.

BASIC INFORMATION

Name: Email:
 Home Institution: School/Dept.:
 Full Project Title:
 Principal Inv.: Project Period: to
 Prime Sponsor: Subrecipients (if any):
 Award number:
 BU/BMC Grant Admin Office: ☐ BU-CRC ☐ BU-MED ☐ BMC ☐ Select Proposal ID #: ☐ Other:

QUESTIONS

1. 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: (1) sales, royalties, or other remuneration paid to you or on your behalf for your own or your dependent child's currently employed or otherwise self-employed holding an appointment as such institution, and (2) nonfees for services, lecture, teaching apparatus, or other remuneration for services rendered to the institution, or for services rendered to the institution by your dependent child, if the institution is defined as such in 2010 U.S.C. 1002(a)(1), an academic teaching hospital, a medical center, or a research institution that is affiliated with an institution of higher education. You may check "N/A" if the amount of all outside compensation is less than \$1,000 total.

²“Additional responsibilities” means an investigator’s professional responsibilities on behalf of SIU and/or SMC, including but not limited to research, research consultation, teaching, professional practice, and administration such as service on committees, boards and panels.

11. **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(p); 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

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 was less than \$5,000 based on public prices or other reasonable measure 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 GUC or BMC and agreements to share in royalties related to such rights (e.g., royalties received under the relevant Patent Policy). You may check "Yes" if the royalties or other income related to these rights and interests do not exceed \$5,000.

CERTIFICATION

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

Signature: _____ Date: _____

Principal investigators must complete the next page →

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. Social Desirability:

■ **Clinical study**

☐ Applied / applying for an IMO or IOE

(Invitational New Drug or Invitational Device Examination through the FDA)

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

3. 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 SMC (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.

[illegible]

Questions? Email cs@ibw.edu

Check "Yes?" Fill out Form 2 at www.NYCPerforms.com

Form 1 for BMC and PHS-Funded BU Research: FIND 1

QUESTIONS

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.

Check "Yes"? Fill out Form 2 at bu.edu/orc/col/foi/forms/

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.

Name	Role in Research	Email address	Home Institution (if not BU or BMC)
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

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.
Remember to sign and return the last page with the certification statement. Please be advised that you may be requested to provide additional information based on the information provided on this form. Please submit this form to Research Compliance at col@bu.edu or via fax at 617-414-4729. More information and these forms can be found online at bu.edu/oriol.
This information is being requested in accordance with federal regulations and must be filed out if you are now or will potentially be responsible for the design, conduct, reporting of any Boston Medical Center (BMC) research activities or ~~Boston University~~ Boston University (BU) research activities (not including Phase 1 SBIR/STTR awards, and including the list of 5 non-profits on the last page of Form 1). This initial disclosure is due no later than the time of application. You will receive an email invitation to an online training course consisting of slides and a short quiz after this form is submitted.

BASIC INFORMATION

Name: Email:
Home Institution: School/Department:
Full Project Title:
Principal Investigator: Project Period: to
Prime Sponsor: Sub-Sponsor (if any):
Award number:
BU/BMC Grant Admin Office: ☐ BU-CRC ☐ BU-MED ☐ BMC Admin ID# (if known): ☐ Other:

QUESTIONS

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, 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.

A.

Recipient (Name, relationship to you)	Type of Remuneration (e.g., consulting fees, honoraria)	Short description of services provided	Paid By (BMC Name)	Amount in the last 12 months
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	\$ <input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	\$ <input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	\$ <input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	\$ <input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	\$ <input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	\$ <input type="text"/>

B. Questions:

- Is the research receiving any kind of support ("in kind" or monetary) from any of the entities listed above (y/n)?
If so, which entities?
- Do any of the above entities have proprietary access to results of the research? (y/n) If so, which entities?
- Do any of the entities, above, have proprietary access to intellectual property coming out of the research? (y/n)
If so, which entities?
- Might new intellectual property result from the research that would potentially be of interest to any of the above entities? (y/n)
If so, which entities?
- Does the research involve intellectual property owned or licensed by an entity listed above (y/n)?
If so, name the entity and describe the IP.
- Could any of the above remuneration reasonably appear to be affected by the research? If so, which remuneration?

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.

Do not include travel expenses 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.

For any changes to this 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 this 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)
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

B. Questions:

- Is the research receiving any kind of support ("in kind" or monetary) from any of the entities listed above (y/n)?
If so, which entities?
- Do any of the above entities have proprietary access to results of the research? (y/n) If so, which entities?
- Do any of the entities, above, have proprietary access to intellectual property coming out of the research? (y/n)
If so, which entities?
- Might new intellectual property result from the research that would potentially be of interest to any of the above entities? (y/n)
If so, which entities?
- Does the research involve intellectual property owned or licensed by an entity listed above (y/n)?
If so, name the entity and describe the IP.

Invitation to Training

Reply Reply All Forward         

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)

Thursday, September 06, 2012 11:53

- 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.

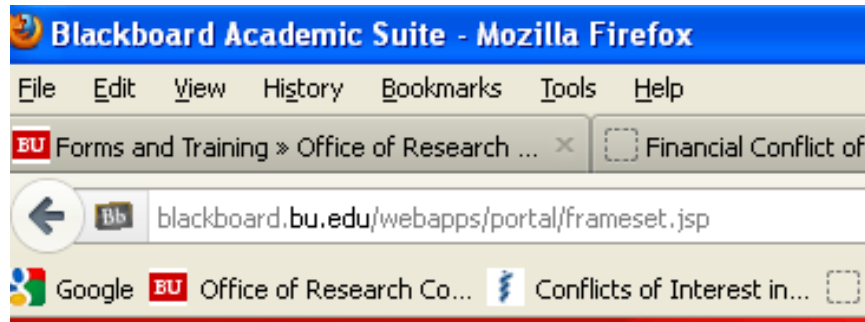
We are able to track when this step is completed, so no further action is needed unless we contact you.

Best Regards,
Jodi

Jodi R. Edelstein, J.D.
Manager, Conflicts of Interest
Office of Research Compliance
Boston University and Boston Medical Center
85 East Newton Street, Suite 810F
Boston, MA 02118
jedelste@bu.edu
Phone: (617) 638-4514
Fax: (617) 414-4738

 Research Compliance

Invitation to Training



Courses in which you are enrolled:

 [Financial Interest Disclosure Training](#)

Boston University Blackboard 8

My Courses All Courses Help

Announcements


Course Documents

Control Panel

Refresh


Detail View

EFIND TRAINING FOR INVESTIGATORS (00CWR_EFINDTRAINING) > ANNOUNCEMENTS

 **Announcements**

VIEW TODAY VIEW LAST 7 DAYS VIEW LAST 30 DAYS VIEW ALL

July 09, 2012 - July 16, 2012

 **Thu, Jun 28, 2012 -- Instructions for Training**

Welcome to the Research Conflicts of Interest (COI) Policy Training for Investigators

To complete the training:

1. Click on the "Course Documents" tab in the left panel
2. Click on the "Research Conflicts of Interest Training" - "COI Training for Investigators" - link
3. Review the slides carefully
4. Click on the "Course Documents" tab in the left panel
5. Click on the "Quiz Questions" link
6. Take the Quiz. (You must answer 8 out of 10 questions correctly to receive credit).

Training is Step 1 of 2 in the financial interest disclosure process. If you have not yet completed the financial interest disclosure forms, please go to <http://www.bu.edu/c> the instructions and click on "Financial Interest Disclosure Forms". Send completed forms to coi@bu.edu.

Financial interest disclosures and training are required of all research "Investigators" – or persons engaged in or responsible for the design, conduct or reporting of research at Boston University and Boston Medical Center. Training is required once every four years, or as otherwise dictated by the Office of Research Compliance, Conflicts of Interest and Human Subjects.

Questions? Email coi@bu.edu

A score of
80/100 is
required to
pass.

Disclosure form for Non-PHS-funded BU Research: NON FIND 1

Boston University Office of Research Compliance
22, East Newton Street, 10-3129
Boston, Massachusetts 02235-3230
Tel: 617-435-4733 Fax: 617-435-4738
oirc@bu.edu



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

This information is being requested in accordance with BU policy and must be filed 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 Service¹, (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.

This disclosure form is due no later than the time of application. Send all forms to compliance@bu.edu or via fax at 617-434-4738.

BASIC PERSONAL AND RESEARCH INFORMATION

Name: _____ Email: _____
Home Institution: _____ School/Department: _____
Full Project Title: _____
Principal Investigator: _____ Project Period: _____ to _____
Prime Sponsor: _____ Sub-Sponsor (if any): _____
Award number: _____
BU/BMC Grant Admin Office: ☐ BU-ORC ☐ BU-MED ☐ Other: _____ Proposal ID#: _____

QUESTIONS

- 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 ☐
- 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 interests" (SFI) refers to:

- anything of monetary value, including a salary, consulting fee, honorarium or other payment for services;
 - equity interests, including stocks, stock options or other ownership interests; and
 - intellectual property (IP) rights, including copyrights, royalties and patent rights, or where a clinical "biotechnology" (i.e., someone responsible for the design, conduct or reporting of the research) is inventor (whether IP is licensed or not).
- Exceptions:
- salary, or other remuneration (not including royalties) from Boston University or Boston Medical Center;
 - income from public or non-profit entities for seminars, lectures, teaching engagements, service on advisory committees, or review panels; or
 - 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.

"Reasonably appear to be affected" may refer any of the following:

- 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 ☐ for which the investigator receives royalties or has the right to receive royalties.
- 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 ☐ 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 ☐ owned by or licensed to that entity;
 - Research results could enhance the value of, or further validate, or increase the interest in ☐ owned, made or provided by that entity; and/or
 - New ☐ could result from research under this grant and potentially be of interest to that entity.

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 +

¹ Public Health Service (PHS) agencies are AHRQ, ATSDR, CDC, FDA, HHS, HHS, HHS, SAMHSA (a detailed list is on the last page), and are covered by a separate form - Rando/Internet Disclosure - which can be found at bu.edu/orc/oc/forms.

FOR PRINCIPAL INVESTIGATORS ONLY (REQUIRED)

- What is the actual/proposed award amount for the project? Proposed Year: \$ _____ One Project: \$ _____
- Human Subject? ☐ No ☐ Yes - IRB # _____
- Special Designations:
 - ☐ SBIR (Small Business Innovation Research) grant
 - ☐ STTR (Small Business Technology Transfer) grant
 - ☐ Preclinical study
 - ☐ Applied / applying for an IND or IDE (Investigational New Drug or Investigational Device Exemption through the FDA)
- Please summarize the specific aims of the research. You may attach a project summary or abstract. _____

3. 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.

Name	Role in Research	Email address	Home Institution (if not BU or BMC)

Questions? Email compliance@bu.edu

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).

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.

"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**
 - (ii) **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.

Boston University Financial Interest Disclosure

Basic Information

Name and Title: Edelstein, Jodi Your title
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



Office of Research Compliance: Conflicts of Interest

Boston University

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Boston, MA 02118

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F. (617) 414-4738

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Jodi R. Edelstein, J.D.

Compliance Manager

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jedelste@bu.edu 

<http://www.bu.edu/orc/coi/>



- NIH COI website at: <http://grants.nih.gov/grants/policy/coi/>
- Revised PHS Regulation, *Responsibility of Applicants for Promoting Objectivity in Research for which PHS funding is sought*, http://www.ofr.gov/OFRUpload/OFRData/2011-21633_PI.pdf