

PROJECT-SPECIFIC DISCLOSURE (PSD) FORM FOR INVESTIGATORS' CONFLICTS OF INTEREST

Please complete this form digitally, if possible.

Investigator Name		
School		
Department		
Section/Center <i>(if applicable)</i>		
Project Title		
Principal Investigator on Project	<i>NOTE: If you are the PI of this project, you <u>must</u> fill out the section for Principal Investigators.</i>	
Sponsorship <i>(include both Prime Sponsor and sub-sponsor to our institution, if applicable)</i>	Prime Sponsor's Name: _____ Prime Sponsor's Award #: _____ Sub-Sponsor's Name: _____ Sub-Sponsor's Award #: _____	N/A <input type="checkbox"/> (no prime sponsor) N/A <input type="checkbox"/> (no sub-sponsor)
What entity administers the funds or resources supporting your research?	BU – CRC (OSP) <input type="checkbox"/> BU – MED (ORA) <input type="checkbox"/> BMC (OGA) <input type="checkbox"/> Other: <input type="checkbox"/> (please specify): _____	
Human Subjects Research	Is this project human subjects research (whether exempt or non-exempt)? Yes <input type="checkbox"/> No <input type="checkbox"/> IRB protocol number: _____	

- Do you, your spouse, or dependent children have a “significant financial interest (SFI)” ([as defined on p. 3](#)) that would reasonably appear to be affected by your above-described “covered research” ([as defined on p. 3](#))?
 Yes No
- Do you, your spouse or dependent children have a “significant financial interest” in any business or legal entity whose financial interests would reasonably appear to be affected by this “covered research”?
 Yes No

If you are unsure whether to answer “Yes” or “No” to either of the above questions, see [Guidance](#).

If your answer to either of the above questions is "Yes," you must also provide the following information for covered research that would reasonably appear to be affected by a significant financial interest. If you need more space for your answers, kindly append a separate page to the end of your form.

3. Please briefly list all such significant financial interests ([as defined on p. 3](#)), indicating the nature of each interest, and its approximate monetary value:

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4. Please list name(s) of person(s) with significant financial interest(s) and their relationship to you:

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PRINCIPAL INVESTIGATORS ONLY (REQUIRED):

If I am the Principal Investigator for this research project, I understand and agree that I must ensure that all persons responsible for the design, conduct or reporting of the proposed "covered research" complete this Disclosure Form, and that all required Disclosure Forms are attached. The "investigators" ([defined on p. 3](#)) who must make disclosure on this research are listed here:

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INVESTIGATOR'S CERTIFICATION AND SIGNATURE:

I understand and agree that I must promptly file an update to this Disclosure Form if any of the information reported here should change materially. If I am the Principal Investigator on this project, I certify that I have provided the names of all investigators who are required to submit Project-Specific Disclosure forms for this project.

I certify that I have read and understand the [Boston Medical Center Corporation Policy on Investigators' Conflicts of Interest](#) and/or the [Boston University Policy on Investigators' Conflicts of Interest](#), whichever is applicable, that I have made all required disclosures, and that I will comply with the applicable Policy and any conditions imposed by the University or Boston Medical Center to manage, reduce or eliminate a conflict of interest.

Name	Signature	Date
BU Mailing Address:		
E-mail Address:		
Telephone #:	() - -	Fax #: () - -

When to submit this form

NEW or RENEWAL SPONSORED PROJECTS: A Project Specific Disclosure Form (PSD) must be submitted as part of the application package for **each and every** BU and BMC Investigator on the project, as identified by the Principal Investigator.

HUMAN SUBJECTS PROJECTS: A PSD must be submitted for **each and every** BU and BMC Investigator on any CRC or BUMC IRB protocol. (However, if a PSD has already been filed with a NEW or RENEWAL project application, **an additional PSD is not required.**)

MATERIAL CHANGE IN PROJECT: At any time during the life of project, the PSD form must be submitted by the Investigator in the event of any MATERIAL CHANGE, such as

- the Investigator is newly added to the project
- there is a material change in the information previously disclosed.

Where to submit this form

For externally-sponsored research:

If your research is funded through:	Boston Medical Center Office of Grants Administration (OGA)	Boston University Medical Campus Office of Sponsored Programs (OSP-MED)	Boston University Charles River Campus Office of Sponsored Programs (OSP-CRC)
Send this form along with your application package to:	Boston Medical Center Office of Grants Administration 660 Harrison Avenue, 2 nd fl. Boston, MA 02118 or fax: (617) 414-2834 or email: grants.admin@bmc.org	Boston University Office of Sponsored Programs 85 East Newton Street, M-921 Boston, MA 02118 or email the OSP Research Administrator responsible for your department	Boston University Office of Sponsored Programs 25 Buick Street, 2 nd fl. Boston, MA 02215 or fax: (617) 353-6660

For Projects of Covered Research that are not externally-sponsored:

- When a PSD is required in non-sponsored human subjects research, please **send the PSD to the office specified by the IRB**;
- When a PSD is required in other non-sponsored research, please **send the PSD to:**

[Boston University Office of Research Compliance](#)
85 East Newton Street, M-840A
Boston, MA 02118
Fax: (617) 414-4738 Email: coi@bu.edu

Definitions

The term "**investigator**" includes all BU and BMC principal investigators and co-investigators, and other researchers (e.g., graduate students, post-doctoral fellows, and technicians) who are responsible for **designing, conducting, or reporting covered research**.

"**Covered research**" refers on the Medical Campus to all research and on the Charles River Campus to all externally-funded research and all human subject research (regardless of funding).

"**Entity**" means any business or legal entity, including a corporation (profit or non-profit), partnership, limited partnership, joint ventures, voluntary association, sole-proprietorship, or trust.

"**Significant financial interest**" refers to anything of monetary value, including a salary, consulting fee, honorarium or other payment for service; equity interests, including stocks, stock options or other ownership interests; and intellectual property rights, including patent rights owned by the investigator or on which a clinical investigator is a named inventor (whether licensed or not), copyrights and royalties. This Policy on Investigators' Conflicts of Interest, however, excludes from consideration the following items:

- salary, or other remuneration (not including royalties) from Boston University;
- income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities (for definition of "entity," see footnote *** in the [Policy](#));
- income from service on advisory committees or review panels sponsored by public or non-profit entities;
- salary, royalties or other payments from a single entity (or group of affiliated entities) that, when aggregated for the investigator and members of his immediate family over the next twelve months, are not expected to exceed \$10,000.