

REQUEST FOR SINGLE BOSTON UNIVERSITY IRB REVIEW

For studies otherwise subject to review by both the
BU Charles River Campus IRB and the BUMC IRB

This form is used for human subject research projects in which investigators from both the Boston University Charles River Campus (CRC) and the Boston University Medical Campus (BUMC) are “[engaged in research](#),” if the investigators wish to request that IRB review be conducted by only one Boston University IRB rather than both.

The Process: The study PI completes this form and submits it to his/her IRB. The Directors of both IRBs (or their designees) will review the document. They will determine whether single IRB review is appropriate and, if so, which IRB will be the IRB of Record. Once the decision has been made, the PI will be informed in writing by the IRB to which he/she applied. To state a preference for IRB review, please check one below.

Requesting review by the BUMC IRB (BUMC is Institution A. CRC is Institution B.)

Requesting review by the CRC IRB (CRC is Institution A. BUMC is Institution B.)

Please complete ALL fields on this form. Do NOT copy and paste large sections of text from the grant or protocol. Instead please briefly answer the specific questions on this form.

<p>1. Protocol Information</p> <p>Existing IRB number (if available)</p> <p>Study Title (please spell out acronyms)</p>	
<p>2. Principal Investigator</p> <p>Name and Title</p> <p>School and Department</p> <p>Phone number</p> <p>Email Address</p>	
<p>3. Funding Source</p> <p>Sponsor</p> <p>BU Restricted Fund Account Number (if available)</p> <p>Grant PI</p> <p>Grant Title (if different from study title)</p>	
<p>4. Name all the investigators from CRC who will be engaged in this research.</p>	**Give Name, Title, and Department for each investigator.
<p>5. Name all the investigators from BUMC who will be engaged in this research.</p>	**Give Name, Title, and Department for each investigator.
<p>6. Name all other Institutions collaborating on this research.</p>	

7. Provide a very brief description of the research.	
8. List all of the human subject research activities that will be performed by EACH of the CRC investigators . Briefly describe the risks related to these activities. (For example, Joe Brown PhD will analyze data. Risks are associated with confidentiality.)	
9. List all of the human subject research activities that will be performed by EACH of the BUMC investigators . Briefly describe the risks related to these activities. (For example Susan Smith MD will consent subjects, draw blood, interview subjects. Risks related to confidentiality of data and blood draws.)	
10. Is your research subject to HIPAA requirements? At what institutions?	

I understand that, if this request is approved, Institution A's IRB will be the **IRB of Record** responsible for conducting the initial and continuing review of this protocol. I understand that the decision to cede IRB review is made jointly by both IRBs and will not be the decision of the PI. Institution A's IRB, as the IRB of Record, will have full responsibility for oversight of all aspects of the protocol. I will comply with the applicable policies of that IRB. I understand that this agreement is NOT considered approved until I have receive formal notification from the IRB to which I applied.

I understand that as PI for this study I am responsible for the ethical conduct of this study including the oversight of the researchers listed on the protocol from Institution B. Oversight responsibilities include:

- Ensuring that a copy of the Human Subjects Training Certificate for each investigator from Institution B has been submitted to Institution A's IRB with the IRB application. Certificates may be faxed to the BUMC IRB at (617) 638-7234.
- Ensuring that the investigators follow the IRB protocol as approved and make no changes to the protocol without the approval of the IRB of Record (except to eliminate immediate harm to subjects).
- Reporting to the IRB of Record (per that institution's reporting process) any adverse events or unanticipated problems involving risks to subjects or others related to the research activities (including those conducted by the investigators from Institution B).
- Reporting to the IRB of Record any changes related to the status of the Institution B investigators.
- Following all applicable HIPAA rules and using appropriate safeguards to prevent the unauthorized use or disclosure of PHI.

PI Signature: _____ Date: _____

For BUMC investigators, in lieu of the PI's signature, this form may be dated and attached to the INSPIR protocol in Section S. Submitting it to the BUMC IRB via INSPIR represents the PI's electronic signature on this form.

If this form is not submitted via INSPIR then it can be faxed to Mary Banks (mbanks@bu.edu) for BUMC IRB review or Ed Szkutak (eszkutak@bu.edu) for CRC IRB review.