**REQUEST FOR SINGLE IRB REVIEW**

**Boston University (BU)**

**BU is Institution A**

This form is used for human subject research projects in which investigators from Boston University (BU) and another assured institution are “[engaged in research](http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm). The Principal Investigator (PI) from BU completes this form to request that BU serve as the IRB of record for the protocol and allow Institution B to cede IRB review to the BU IRB.

**Institution A: BU is Institution A**, The BU IRB will be responsible for IRB review of this protocol.

**Institution B:** The other institution is Institution B. They will cede IRB review to the BU IRB.

 Institution B institution must hold a FWA with OHRP.

After completing this form, please include it in the submission to the BU IRB. The Investigator from Institution B should contact his/her IRB with this information. The BU IRB will then contact the IRB contact at Institution B determine whether (a) single IRB review is appropriate and, if so, (b) whether Institution A will agree to serve as the IRB of Record. Once the decision has been made, the BU investigator(s) will be contacted regarding the decision.

**SECTION A: BU PROTOCOL AND CONTACT INFORMATION**

|  |  |
| --- | --- |
| **Protocol Number (To be assigned by IRB Office):** |  |
| **Protocol Title:**  |  |
| **Boston University Principal Investigator (Name, degrees, licenses, etc.):**☐ Mr.☐ Ms. |  |
|  **Department/School:** |  |
| **BU Mailing Address:** |  |
|  **Email:** |  |
|  **Telephone:** |  |

**SECTION B: INSTITUTION B AND INVESTIGATORS**

|  |  |
| --- | --- |
| **Institution Name:** |  |
| **Name and Title of Investigator(s) from Institution B:** |  |
|  **Email:** |  |
|  **Telephone:** |  |

**SECTION C: INSTITUTION B IRB CONTACT INFORMATION**

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| --- | --- |
| **Institution B IRB contact person** (this is the person at the IRB office who handles Authorization agreements)**:** |  |
| **FWA Number:** |  |
| **IRB Registration Number:** |  |
|  **IRB Email:** |  |
|  **IRB Telephone:** |  |

**SECTION D: FUNDING**

Provide information regarding **ALL** funding sources in this section.

|  |
| --- |
| **Please check all that apply:** |
| ☐ | This research is funded |
| ☐ | Funding has been requested  |
| ☐ | Research is not funded |

**If the research is funded or funding has been requested, complete the box below:**

|  |  |  |
| --- | --- | --- |
| Sponsor Name |  |  |
| Title of Grant/Proposal |  |  |
| Sponsor Award #  |  |  |
| **YES** | **NO** |  |  |
| ☐ | ☐ |  | Is Boston University the Prime Awardee of the grant? |
| ☐ | ☐ |  | Is Institution B the Prime Awardee of the grant?  |
| ☐ | ☐ |  | Is Boston University receiving a sub-award?Name of Prime Recipient: |
| ☐ | ☐ |  | Is Institution B receiving a sub-award?Name of Prime Recipient: |
| ☐ | ☐ |  | Do Institution B investigators have a COI or potential COI? If YES, does Institution B have a COI Committee/process to review research COIs? |

**\*NOTE:** Provide a copy of the grant application, funding proposal, scope of work, or sub-award agreement. The University is required to verify that all funding proposals and grants have been reviewed by the IRB before funds are awarded.

**SECTION E: PROCEDURES DONE AT INSTITUTION B**

Describe ALL research activities and procedures involving human subjects that will be performed by the investigators from Institution B. This includes activities that will be performed at BU by Institution B investigators as well as activities that will occur at Institution B. (i.e. consent subjects, interview subjects, access to identifiable data, analyze data, etc..)

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| --- |
| **Procedures that will be performed by Institution B investigators at BU:** |
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| --- |
| **Procedures that will be performed by Institution B Investigators at Institution B:** |
|  |

**SECTION F: RISKS**

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| **Describe all risks associated with the activities and procedures described above. Be sure to include risks related to data storage and confidentiality.**  |
|  |

**SECTION G: HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)**

|  |  |  |
| --- | --- | --- |
| **YES\*** | **NO** |  |
| ☐ | ☐ | Is this research subject to HIPAA requirements? At what institution?\*If YES, contact the IRB office for assistance. |

I understand that, if this request is approved, **the BU 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. The BU 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 the BU IRB. I understand that an agreement is NOT considered approved until a formal determination is made by the representatives at each institution.

I understand that as PI for this study I am responsible 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 sent to the BU IRB
* Ensuring that all investigators from Institution B are listed in the BU Application
* Ensuring that all the investigators follow the IRB protocol as approved and make no changes to the protocol without the approval of the IRB (except to eliminate immediate harm to subjects)
* Reporting to the BU IRB (per policy) any adverse events or unanticipated problems involving risks to subjects or others related to the research activities conducted by the investigators from Institution B
* Reporting to the BU IRB 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
* Institution B investigators will be subject to BU IRB determinations related to conflict of interest.

If you have any questions, please contact Mary McCabe at msmccabe@bu.edu or 617-358-6922.

BU PI printed name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

BU PI Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**If the PI is a student, the Faculty Advisor must sign below:**

**Faculty Advisor Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**