**Amendment Request Form**

This form is to be completed when a change (amendment) is requested to a CRC IRB-approved study. This applies to Full Board and Expedited Studies. **NOTE:** All changes must be approved by the IRB **PRIOR** to implementation.

If the changes in this amendment require modification to the informed consent, a new version of the informed consent will be approved and validated with an approval date. The expiration date of the study **WILL NOT CHANGE**. Previously approved versions of the consent forms should be archived as they are no longer valid and only the newly approved version(s) should be used.

**Study Staff Changes:** Changes to study staff can be made by submitting the Study Staff Amendment Form. This form is located on the IRB website at: <http://www.bu.edu/researchsupport/compliance/human-subjects/>.

**SECTION A: Protocol and Contact Information**

**Protocol Title** : enter text **Protocol Number:** enter text

**PI Name and Degrees**: enter text **Preferred Pronoun:** enter text

**PI Email Address**:  enter text **PI Phone Number:**  enter text

**Preferred Mailing Address:**  enter text **PI Department:**  enter text

**Additional Contact/Faculty Advisor:**  enter text

**Contact Information:**  enter text

**SECTION B: Changes Made To: (Check all that apply)**

**NOTE: You must submit a tracked copies of any documents (Application, consent form, letters, recruitment materials, etc.) that are affected by the change**

|  |  |
| --- | --- |
| [ ]  | **Protocol Title**New Protocol Title: enter text   |
| [ ]  | **Consent/Assent Forms**Submit a tracked copy of the revised form |
| [ ]  | **Funding**Submit a tracked copy of the revised IRB application |
| [ ]  | **Eligibility Criteria**Submit a tracked copy of the revised IRB application |
| [ ]  | **Study Procedures**Submit a tracked copy of the revised IRB application |
| [ ]  | **Total Number of Subjects**Submit a tracked copy of the revised IRB application* Current Number Approved: enter text
* Requested New Number: enter text
 |
| [ ]  | **Research Sites (Addition or Removal; provide a copy of the site approval for each site being added)** Submit a tracked copy of the revised IRB application* Name of Site: enter text
* If IRB approval will not be obtained from the site, provide an explanation: enter text
 |
| [ ]  | **Questionnaire/Survey (Revised/Addition/Removal)**Submit a tracked copy of the revised IRB applicationSubmit copies of any new or revised questionnaires/surveys. Revised documents should include tracking to indicate the location of the changes. |
| [ ]  | **Recruitment Methods or Materials**Submit a tracked copy of the revised IRB applicationSubmit copies of any new or revised recruitment materials. Revised documents should include tracking to indicate the location of the changes. |
| [ ]  | **Device**Submit a new or revised [Form C – Use of Devices in Research](https://www.bu.edu/research/forms-policies/appendices-c-device/) as necessary and revised study documents (e.g. revised IRB application, consent form etc.)  |
| [ ]  | **Other**  Provide a description of the change: enter text  |

**SECTION C: Amendment Description**

Provide a Brief Summary of the Change

|  |
| --- |
|  enter text  |

Provide the Justification/Rationale for the Change

|  |
| --- |
|  enter text   |

Will there be a change to the Risks or Benefits to the Subjects

|  |
| --- |
|  |

**SECTION D: RE-CONSENTING OF ALEADY ENROLLED SUBJECTS**

If the requested change could affect a subject’s willingness to continue taking part in the study, these subjects must be re-consented.

|  |  |
| --- | --- |
| [ ] No [ ] Yes | Could the requested change affect a subject’s willingness to continue taking part in this research study? If yes, please provide the plan for re-consenting already enrolled subjects: enter text  |

**SECTION E: PRINCIPAL INVESTIGATOR CERTIFICATION**

**Certification / Signatures**

* By submitting this protocol I attest to the fact that all research activities to be implemented related to human subjects have been completely and accurately described herein.
* I agree to conduct the describe research in an ethical manner.
* I agree to comply with all institutional policies and procedures related to human subjects research and will not begin any human subjects research activities until I have obtained full approval from the IRB.
* I agree to conduct the research as described in this protocol and not to make any changes (except to eliminate immediate harm to subjects) without first obtaining approval for the changes from the IRB.
* I agree to immediately report any unanticipated problems involving risks to subjects or others, any subject complaints, and any incidents of non-compliance with the requirements of this protocol as soon as I become aware of them.
* I agree to comply with any relevant HIPAA and FERPA regulations if applicable.
* I verify that allthose responsible for the design, conduct, or reporting of the proposed program, including at minimum, all Senior/key personnel in the grant application, have completed the financial conflict of interest disclosures and completed training as required by University [Policy](https://www.bu.edu/researchsupport/compliance/conflicts-of-interest/).

Principal Investigator Printed Name: enter text

Principal Investigator Signature:  Date:

**STUDENT Research**

**Student research:** Student research must be signed by the faculty advisor AND the designated School IRB pre-reviewer (if applicable) PRIOR TO submission to the IRB. Students should check with their School to determine if School IRB pre-review is required. Students must submit a copy of their dissertation with the IRB Application

By signing this form, you are indicating that you have reviewed the application, that you agree to serve as the Co-PI for this study with the student and that you will be responsible for the ethical conduct of this student’s human subjects research.

Faculty Advisor Printed Name: enter text

Faculty Advisor Signature:  Date:

**Submission:** Electronic signatures are acceptable, as are emails confirming the certification information. This form can be completed, signed, scanned and submitted to the IRB at irb@bu.edu. Faxed documents and handwritten materials are not accepted. Be sure to include a