**Study Staff Amendment Form**

*Complete this form to add/remove investigators and study staff and/or to change the Principal Investigator.*

**Please indicate the action being taken with this amendment:**

[ ] Add Co-Investigator/Study Staff

[ ] Remove Co-Investigator/Study Staff

[ ] Change Principal Investigator

**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

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

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

**Contact Information:**  enter text

**SECTION B: Add Study Staff** [ ]   **N/A**

1. **CRC Investigators and Study Staff:
Note:** BUMC and other non-CRC personnel should be listed below in the Non-BU Investigator/study staff section.

|  |  |  |
| --- | --- | --- |
| . **Name, Degree, & School** | **Study Role****(e.g. co-i, research coordinator, RA, etc.)** | **Human Subjects Training** |
| enter text | enter text | [ ]  CITI: enter text[ ]  Other\*:­­­­­­­­­­­­­­­­­­ enter name and date[ ]  GCP\*\*: enter date and provide copy |
| enter text | enter text | [ ]  CITI: enter text[ ]  Other\*:­­­­­­­­­­­­­­­­­­ enter name and date[ ]  GCP\*\*: enter date and provide copy |

\*If CITI was not completed, a copy of the training record must be submitted.

\*\*For NIH-funded clinical trials, Good Clinical Practice (GCP) training is required.

For more information on training requirements, please refer to the CRC [Human Subjects Training Policy](https://www.bu.edu/researchsupport/compliance/human-subjects/human-subjects-training/).

1. **Non-CRC Investigators and Study Staff**

Instructions:

* BUMC and BMC staff are considered non-BU staff and should be listed in this section.
* Add more rows as necessary.
* All the columns in the box below must be completed.
* You must complete the box that follows with a description of the activities for each staff member.
* If IRB approval will be obtained from a non-BU site, only list the lead investigator from that site.

|  |  |  |
| --- | --- | --- |
| **Name, Degree, Institution** | **Study Role****(e.g. co-i, research coordinator, RA, etc.)** | **Staff Information** |
|  |  | [ ] This staff will interact with subjects[ ] This staff will have access to subject identifiers[ ] The research is related to the staff role at their home institution.  |
|  |  | [ ] This staff will interact with subjects[ ] This staff will have access to subject identifiers[ ] The research is related to the staff role at their home institution.  |

**2a. Include a summary of research activities to be conducted by each non-BU staff person listed above.**

enter text

**SECTION C: Remove Study Staff** [ ]   **N/A**

* + - 1. **CRC Investigators/Study Staff**Add rows as needed.

|  |  |
| --- | --- |
| **Name, Degree & School** | **Study Role** **(e.g. co-i, research coordinator, RA, etc.)** |
| enter text  | enter text  |

**2. Non-CRC Investigators/Study Staff**

|  |  |
| --- | --- |
| **Name, Degree & Institution** | **Study Role** |
| enter text  | enter text  |

**SECTION D: Change Principal Investigator**Instructions:

* Update all study documents with the new PI name and contact information.
1. **Incoming Principal Investigator Information:**

|  |  |
| --- | --- |
| **Name of Proposed Principal Investigator:** | enter text  |
| **Department/School:** | enter text  |
| **Email:** | enter text  |
| **Telephone:** | enter text  |

1. **Provide the reason for the change in Principal Investigator (PI)**

|  |
| --- |
| enter text  |

1. **Provide the qualifications of the PI to assume responsibility for this research**

|  |
| --- |
| enter text  |

\*The Department Chair for the new Principal Investigator must sign this Application

 **SECTION E: Conflict of Interest**

|  |  |
| --- | --- |
| [ ] No [ ] Yes | Have any newly-added Investigators or Study staff for this amendment disclosed a Financial Conflict of Interest related to the research? If yes, provide the name of the individual(s): enter text *If yes, the IRB office will contact the FCOI office for more information.***Note:** Allthose responsible for the design, conduct, or reporting of the proposed research, including at minimum, all Senior/key personnel in the grant application, have completed financial conflict of interest disclosures and training as required by the [BU FCOI Office](https://www.bu.edu/researchsupport/compliance/conflicts-of-interest/) and as provided under [*the Boston University Investigator Conflicts of Interest Policy for Research*](https://www.bu.edu/researchsupport/forms-policies/investigator-financial-conflicts-of-interest-policy-for-research/)*.*  |

**SECTION F: Principal Investigator Certification**

The signature line below must be signed by the PI of the study. If the PI is a student then this form must also be signed by the Faculty Advisor.

By signing below, I certify that:

* The information in this Application is true, complete, and accurate
* I will conduct this research in accordance with applicable laws, regulations, and BU CRC IRB policies.

PI Printed Name: enter text

Principal Investigator Signature:  Date:

**If PI is Changing**

Outgoing PI Printed Name: enter text

Principal Investigator Signature:  Date:

Incoming PI Printed Name: enter text

Principal Investigator Signature:  Date:

**STUDENT Research**

**Student research:** Student research must be signed by the faculty advisor AND PRIOR TO submission to the IRB.

By signing, the faculty advisor is also indicating agreement with the statements above.

Faculty Advisor Printed Name: enter text

Faculty Advisor Signature:  Date:

**Department Chair for Incoming Principal Investigator**

**The Department Chair signature is required for change of principal investigator:** If the new PI is the Department Chair, then signature by the appropriate Dean is required. Department Chair signature is not required for student research.

By signing this form, you are indicating that you have reviewed the application, the faculty/staff person listed as PI on this protocol is a member of your department, and that he/she is qualified to serve as the PI for this study.

Department Chair Printed Name: enter text

 Department Chair Signature:  Date:

**Submission**

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 all relevant attachments.