

HOW TO ADD BU CHARLES RIVER CAMPUS STUDENTS, FACULTY, AND EMPLOYEES TO INSPIR STUDIES (Policy Change effective 12/13/18)

BU Charles River Campus Students

- If the BU-CRC student will not be doing research activities for BU-CRC academic credit, then the BU-CRC student can be added through an internal study personnel change if the student (1) is “engaged in research” (interacting with subjects for the purpose of collecting data or accessing identifiable data); (2) is being hired and brought on board at BMC with a BMC ID #; or is doing research on behalf of BU Medical Campus and not for BU-CRC academic credit; and (3) has completed CITI Medical Campus training, and GCP training for clinical trials (see <http://www.bumc.bu.edu/ohra/required-training/>). You should clarify in the internal personnel change description that “the BU-CRC student is not doing research activities for academic credit.”
- If the BU-CRC student will be doing research activities for BU-CRC academic credit, then the BU-CRC student should be added through a change amendment if the student (1) is “engaged in research” (interacting with subjects for the purpose of collecting data or accessing identifiable data); and (2) has completed CITI Medical Campus training, and GCP training for clinical trials (see <http://www.bumc.bu.edu/ohra/required-training/>). In the amendment description, you should list the BU-CRC student’s name and explain that the “BU-CRC student is doing research for BU-CRC academic credit through a Smart IRB Agreement.”

(If you have submitted an internal study personnel change in error, then please contact the IRB at medirb@bu.edu to return it to you so you can delete the BU-CRC student from the internal study personnel change and resubmit it; or request the IRB to WITHDRAW the request completely.)

The application will also need to be updated:

APPLICATION REVISIONS

Section 9.2 IRB Authorization Agreement: Select YES (this will create a new Section 10.0).

Section 10.1:

- Check the box for "A. External Investigators from a Relying Institution"
- Click ADD A NEW ROW
- Institution Information - IAA List: Select "BU-Charles River Campus"
- Does this institution have an FWA: Select YES
- FWA Number (if any): Enter, "SMART IRB"

- Leave the remaining fields blank for Contact for IRB Authorization Agreement

Section 10.2 TABLE OF EXTERNAL INVESTIGATORS

- Click ADD EXTERNAL PERSONNEL TO THE STUDY
- Complete the fields for the BU-CRC student; for Institution, enter "BU-CRC"; and assign a generic role
- In the following Role/Institution/Role Description section:
- Click ADD A NEW ROW
- Role: Select the same Role as in the above Table
- IAA List: Select "BU-Charles River Campus"
- Role Description: Enter the detailed description of the BU-CRC student's research activities explaining how he/she is engaged in research; and state that he/she is doing this for BU-CRC academic credit

Sections 10.3, 10.4, and 10.5: Complete these sections as appropriate.

BU Charles River Campus Faculty and Employees

Follow the same process above for a change amendment and application revisions as for adding a BU-CRC student who will be doing research activities for BU-CRC academic credit. In the amendment description, explain that you “are adding BU-CRC (faculty or employee – then list the person’s name) through a Smart IRB Agreement.”

Questions?

Call the BMC/BU Medical Campus IRB Office at 617-358-5372; or send an email to medirb@bu.edu.