How to add external investigators

External investigators cannot be added using the “Internal Study Personnel Changes” form. Instead, you need to submit a “Change Request and Amendments” form.
Login into INSPIR II and from your Home page, click on “My Studies” and proceed to the next slide.
Locate the study and click on the "Open" icon.
This opens the Submissions/Study Management page for the protocol. From here you can

a. Make sure that there are NO current “Change Request & Amendments” form or “Continuing Review Submission Form” pending (if there is one, use that one to make these changes).

b. Create an Amendment.

a. There are no pending amendments or Continuing Review Form in “Outstanding Submissions” (yellow arrow). Also, click on “Submission History” (red arrow) to see if there are any amendments or PRs pending (in IRB office) - “Internal Study Personnel Changes” forms are allowed.
If you have determined there are no amendments or progress reports in Outstanding Submissions or in Submission History – then you can go ahead and create an amendment by clicking on Change Request & Amendments form [green arrow] from the Column titled SUBMISSION FORMS (red arrow)
Click on the “Add a New Form” button. (red arrow) This will create a new Change Request & Amendments form.
This will bring you to the Change Request & Amendments form. Complete Section 1.1 and then use the scroll bar (red arrow) to scroll down to the next section of the form.

### Amendment Information

**1.1 Study Information:**

- **IRB Number:** H-31000
- **Study Title:** Testing
- **Principal Investigator:** Administrator, BA

**1.2 Note:** This Amendment cannot be used to add/remove study personnel from "3.0 internal Study Personnel" section. To add/remove personnel from section 3.0, you need to submit the "Internal Study Personnel Changes" form instead. For instructions on how to submit the "Internal Study Personnel Changes" form, click on the (?) icon below.

Other than changes to the "3.0 Internal Study Personnel" section, this amendment can be used to make changes to the study application, consent form(s), and study documents.

If the study expiration is within 6 weeks, please do not fill out and submit this amendment. Instead, create a Continuing Review form and make any changes to the application, consent form, or study documents within the Continuing Review Form and submit it to the IRB for review.

You cannot submit multiple amendments (this form) at the same time. You need to wait until an amendment had been approved by the IRB before creating a new amendment.

You cannot submit an amendment while there is a Continuing Review form being reviewed, and vice versa.

For complex amendments or amendments involving changes to multiple sections of the IRB application, please submit a TRACK CHANGES version in MS WORD for the changes made to the IRB application. Click the help (?) icon for instructions.

**Amendment Reason:**

--none--

**Does this amendment change the risk/benefit ratio?**

- [ ] Yes
- [ ] No
To make changes to “External Non-BU/BMC Investigators” section of the study application, click on this grey bottom to create a revision of the application and attach it.
You will get a popup. Click on “Add Revision” to create a new revision and make changes to it.

Note: If you don’t see “Add Revision” on the right, this means that a revision was already created and you can use that one to make your changes. In this case, click on the “Edit/View” icon and skip to screen # 13.
Click “OK” to proceed.
This will bring into a copy (revision) of the study application.

If you get this popup, then you will need to convert to the newly published study application form:
1- Click “OK” to close the popup (green arrow)
2- Click on the “Convert to the New Form Version” button (red arrow)

If you don’t get this popup, then you are in the new form. Please skip to screen # 13.
When converted, the system will hide all sections except the first three. Don’t worry, nothing is lost!

Start clicking “Save and Continue to the Next Section” until all sections reappear and you have made all your changes along the way.
Click on the “External non-BU/BMC Investigators” tab. Or click “save and Continue to the Next Section, until you get there.”
To add a new external investigator, click on this grey button.
Fill out this short form then click on "Save External Personnel Info"
Answer the rest of the questions in this section, then click on “Save and Continue to the Next section” button.
You can keep clicking “Save and Continue to the Next Section” and go through the rest of the sections to the end. Or as a short cut, you can click on the last section in your application (each application might be different) to jump to the last section; and from there, click “Save and Continue to the Next Section” one last time. Or you can click on “Back”. Either way the system will take you to the “attach study Application” page (next screen).
Note the new version number (1.1). If you want to go back to the application for more editing, click on “Edit/View” icon (yellow arrow). If you’re done for now with your changes, follow step 1 and 2 below (blue arrows).

1- Make sure this radio button is checked (by default)

2- Click “Save Attachment” to attach this new revision of the study application to the amendment
Note the new revision (version 1.1) attached here in the amendment. You can now access this version from this screen by clicking on the “Edit/View” icon.

Scroll down here to complete the rest of the form.
If you need to add or make changes to the consent form(s), click on the appropriate button. Click on one of the links below for instructions on how to:

- Add a new consent Form
- Revise a consent form
If you need to add or make changes to a Study Document, click on appropriate button. Click on one of the links below for instructions on how to:

- Add a new document
- Revise an existing document

When you’re done with the amendment, click on “Save and continue to the next section” to close this form and/or send it to the PI for sign off.
If you want to go back into the amendment, click on “Amendment Information”.

Click on “Exit” to exit this form and come back later.

Click on “Signoff and Submit” or “Notify PI for Signoff” if you’re ready to submit to the IRB.
1. If one of the external investigators also need access to your study in INSPIR II. S/he will need a BU username and kerberos password. Here’s a link to the BU Account Request Form if they don’t have one.

2. Once they have a BU account, you need to list them as “Administrative Assistant(s)” on the study. The next few slides will tell you how.
From the Submissions/Study Management page, click on the “Study Management” tab.
Click on “Key Study Personnel”
Scroll down to the “Administrative Assistant(s)” section.
In the Administrative Assistant(s) section, click on “Add User”
Type in the last name, then click on “Find”.
If s/he is not found in the INSPIR II database, check “LDAP Directory” and try again. If s/he is not found there either, s/he needs to request a BU account at: http://wwwapp1.bumc.bu.edu/irb/helpdesk/

If s/he is found in this list, click on the check mark to select that person.
The person added will show up here.

When you’re done, (1) click on “Save Access to the Study”. (2) Click on “Study mgmt” or “Home” to exit this screen.