Adding/Removing Internal Investigators from an Already Approved Study (Section 3.0)
Internal Investigators

- These are BU/BMC faculty and staff
- Boston Public Health Commission and Boston Healthnet Community Health Center investigators are also “internal” investigators for BUMC IRB protocols
- Internal investigators must be listed in Section 3 of the IRB application
- In order to be listed, all internal investigators and study staff MUST have a BU or a BMC username and password and had previously logged in to INSPIR (at least once).
- Investigators from other locations and other institutions are not listed under Internal investigators (they are added in the External Investigators table)
Internal Investigators

- An “Internal Study Personnel Change Form” can be made to add/remove internal investigators from Section 3 at any time.
- An “Internal Study Personnel Change Form” can be made while another “Internal Study Personnel Change Form” is pending.
- An “Internal Study Personnel Change Form” can be made while another “standard amendment” is pending.
- An “Internal Study Personnel Change Form” can be made while a Progress Report (Continuing Review) is pending.
- An “Internal Study Personnel Change Form” cannot be used to add External Investigators – a standard amendment called “Change Request and Amendments Form” must be submitted.
Login into INSPIR and from your Home page, click on “My Studies” to list all the studies that you have access to.
You can use the filter or the “Find by ...” feature to locate the study or draft. Or you can just scroll down.

Once you locate the study or draft, click on “Open”.

This is my personal “My Studies” page
Click on “Internal Study Personnel Changes”- blue arrow
This will bring you to the Internal Study Personnel Changes page. (blue arrow)

Here you will see any previous personnel changes (yellow arrow)

To open a new “Internal Study Personnel Change” form – click on the Add New Form button (red arrow)
This will bring you to the Amendment information page. In section 1.2 describe the changes requested (e.g. We want to add Dr. Jane Doe as a Co-Investigator).
Then scroll down to complete the next section (1.3) of the form. (yellow arrow)
In section 1.3, check the box(es) for one or more options:

- To replace the current PI with someone else, check “Changing Principal Investigator” box.
- To replace the Supervising PI with someone else, check the “Changing Supervising Principal Investigator (formerly known as Faculty Sponsor)” box.
- To add new study personnel (other than the PI or Supervising PI), check the “Adding study personnel” box.
- To remove an existing study personnel, check the “Removing study personnel” box.

Depending on what boxes you have checked, the corresponding section will appear in this form to be completed. Scroll down in the form to address the next section.
Note: If you did not check the “Changing Principal Investigator” box in section 1.3 of the form, skip the next instructions to slide #29.

Changing Principal Investigator
In section 1.4, describe the reason for the requested PI change (blue arrow). Then scroll down. (green arrow)
Next, you need to download the “Principal Investigator Responsibilities” document, have the new PI sign it, and attach it to this submission:

1. Click on “see PDF Document” link to open this document.
2. Save the document to your Desktop.
3. If you have Adobe, the new PI can e-sign it and save it again to your Desktop. If you don’t have Adobe, you can print it out, have the new PI sign the printout, and then scan the signed document and save it to your Desktop.

Alternatively, you can use a PDF of an email listing these responsibilities and the new Principal Investigator responding and acknowledging them.

Once you have a signed “Principal Investigator Responsibilities” document saved on your Desktop, click on “Add a New Document” to attach it to this submission.
Clicking on the “Add a New document”, will display the “Study Document Add:” popup.

1. Give this document a title (blue arrow)
2. Click on the “Browse” button (green arrow)
This will display the “File Upload” popup (or similar popup depending on which web browser you are using).

1. Navigate to where you saved the signed document (i.e. Desktop)(blue arrow)
2. Select the signed document (green arrow)
3. Click on the “Open” button (Grey arrow)
This will bring you back to the “Study Document Add:” popup.

1. Change the “Version Date” to today’s date (green arrow)
2. Select “Signed PI or Supervising PI Responsibilities” for the “Category” (red arrow)
3. Click on the “Save Document” button (Grey arrow)
This will bring you back to the “Internal Study Personnel Change Form”.

- Notice that the PI Responsibilities document is now appearing in this form (blue arrow).

Next, you need to select one of the options under “Please select the status of the study”.
- If you selected option 1, “Additional subjects will be consented”, section 1.5 needs to be completed. Proceed to the next slide.
- If you selected any of the remaining four options (other than “Additional subjects will be consented”), skip the next instructions and go to slide # 29.
If you selected option 1, “Additional subjects will be consented”, section 1.5 will appear.

- In this section you need to revise any approved consent forms to include the new PI’s name and contact information. To revise a consent form, click on the “Select or Revise Existing” button. (blue arrow)
Clicking on the “Select or Revise Existing” button, will display a popup similar to the one shown below.

1. Scroll down and find the consent form that you want to revise, then click on the “Create Revision” icon that correspond to that consent form (same row)

(Please remember to add the new Principal Investigator’s name in the section titled “*Please add a Principal Investigator for the study:*” below)
Clicking on the “Create Revision” icon, will open the “Study Consent Revision” popup displaying the selected consent form cover sheet.

1. Click on the “Check-out Document” button to download a copy of the consent form in Word that you can modify.
You should get a “File open” prompt similar to the one shown below.

- Select “Open with” and click “OK” (this prompt might look different if you are using a different web browser)
The consent form should open in Microsoft Word.

1. Make all the changes necessary to the PI’s name and contact information to reflect those of the new PI. In this step, you should not make any other changes at all to the consent form.
2. Save this consent form on your Desktop.
Once you have the consent form revised and saved to your Desktop, go back to the INSPIR system where you left off. It should look like the screenshot below.

1. Click on the “Complete Checkout” button in order for the system to give you the option to check-in (upload) the revised consent form.
This will bring you back to the consent form’s cover sheet. But this time you have the “Check-in Document” button available to upload the revised consent form.

1. Click on the “Check-in Document” button to check-in (upload) the revised consent form.
You will get this popup to browse for that document.

1. Click on the “Browse” button to look for and select your document.
You will get this popup for File Upload (this popup might look different depending on your system and web browser used).

1. Click on “Desktop” in the left column, and in the right column, click on the document name that you want to upload to highlight it.
2. Click on the “Open” icon.
This will take you back to this popup but you will see that the selected document name appears here (blue arrow).

1. If you have the correct document listed, then you can proceed and click on the “Save Selected Document” button to upload your document (green arrow).
This will take you back to the “Study Consent Revision:” popup.

1. Change the Version Date to today’s date (blue arrow) and change any other field in this screen, if needed.
2. Click on the “Save Consent” button (green arrow).
This will take you back to the “Internal Study Personnel Changes” Form.

The revised consent form should appear in the table in section 1.5 (blue arrow).

1- Scroll down to the next section (green arrow).
Note: If you did not check the “Changing Supervising Principal Investigator (formerly known as Faculty Sponsor)” box in section 1.3 of the form, skip the next instructions to slide # 32.

Changing Supervising Principal Investigator (formerly known as Faculty Sponsor)
In section 1.6, describe the reason for the requested Supervising PI change (blue arrow). Then scroll down. (green arrow)
For this section, you can use slides 12 to 16 to download a copy of the PI’s Responsibilities PDF file, and have the new Supervising PI sign it, and then uploaded here.

Once you have executed instructions in slides 12-16, return to this slide.
Adding New Internal Investigators to a Study

Note: If you did not check the “Adding study personnel” box in section 1.3 of the form, skip the next instructions to slide # 37.
One of the sections that you will visit is the “Personnel to be added or removed”. In this section, locate the appropriate section/role; and using the Add buttons (yellow arrow), add the personnel to the application. Clicking on the Add button will bring you to the INSPIR Directory where you can search for the investigators by name.

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<table>
<thead>
<tr>
<th>1.3 Personnel to be added or removed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Below, you can click on the Add button to select any new personnel that you would like to add to the KSP section of the application. To remove an existing personnel, scroll down to “Please select any existing Personnel you wish to remove”, and click on the Add button to select any personnel that you would like to remove from the KSP section of the application. These changes will only take effect if and when the IRB approves this amendment.</td>
</tr>
</tbody>
</table>

*Please add a Principal Investigator for the study:*

[Add button]

If applicable, please select the Protocol Staff personnel:

- A) Additional Investigators
  - [Add button]
  - B) Research Staff
    - [Add button]

*Please add a Study Contact:*

The Project Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g. The project contact(s) are typically either the Study Coordinator or the Principal Investigator themselves).

If applicable, please add a Faculty Advisor:

[Add button]
When you get to the “Search User Directory” page (blue arrow)

1- Enter the last name (green arrow)

2- Click on the “Find” button (yellow arrow) to search for the person.

Tip – If you can’t find this person in INSPIR, ask that person to login to INSPIR for the first time and their INSPIR account will be created. They can use the step-by-step instructions in the link below to login and create their INSPIR account: http://www.bumc.bu.edu/irb/files/2016/10/Access-to-INSPIR.pdf
A list of people in INSPIR with that last name will be displayed. Locate the person you’re looking to add and click on the check symbol (✓) (red arrow) to add this person to the application. This will take you back to the Internal Study personnel changes form.

Note: Here, you can check the training status of the person you are adding by clicking on the head icon (green arrow)

<table>
<thead>
<tr>
<th>Check for Multiple</th>
<th>Select User</th>
<th>Training</th>
<th>User Name</th>
<th>Department</th>
<th>Email</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>BANKSON, MICHAEL</td>
<td>Pharmacology and Toxicology (primary)</td>
<td><a href="mailto:mbankson@bu.edu">mbankson@bu.edu</a></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Banks, Mara</td>
<td>Endocrine Laboratory (primary)</td>
<td><a href="mailto:mbanks98@bu.edu">mbanks98@bu.edu</a></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Banks, Mary, RN, BS, BSN</td>
<td>Pediatrics (primary)</td>
<td><a href="mailto:mbanks@bu.edu">mbanks@bu.edu</a></td>
</tr>
</tbody>
</table>
The person that you just added should show up now (yellow arrow).

Some sections, requires that you select the user’s role in the study from a drop-down menu (green arrow). Select the user’s role when required.

To add more staff, repeat the instructions in the previous three screens.
Notes for adding New Investigators

- If the new investigator(s) that you add will need to receive email notifications about the protocol and be assigned tasks in their “Incomplete Tasks”, you will also have to add their name(s) under “Add a Study Contact”.

- “Study Contact” is not a study role. So anyone that is listed as a Study Contact will also need to be listed under another study role such as “A) Additional Investigators” or “B) Research Staff”, if they are not already listed there.
Requesting the Removal of Existing Internal Investigators from the Study

Note: If you did not check the “Removing study personnel” box in section 1.3 of the form, skip the next instructions to slide # 42.
To request for someone to be removed from the study, scroll down to the section titled “Please select any existing Personnel you wish to remove:”, and click on “Select”. This will take you to the next screen with the list of all personnel that are currently listed on the study.
Select the one(s) that you want to remove by clicking on the check box(es) next to their name(s). Then click on “Save Selections”.
The list of people that you want removed from the study should appear in this section.

Note: If you make a mistake, you can unselect someone by clicking on the check box next to the name and then on “De-select” to remove that person from this list. If you de-select someone, that person will no longer be included in the list of people that you want removed from the study, and thus, will remain on the study.
Submitting the Form

- Once you have added all the new investigators/study staff, or/and selected all the existing investigators/study staff that you wish to remove, scroll to the last section “Training and COI verification” (this section is not available if you are only removing personnel). When applicable, you will need to agree to both statements before the system will allow you to proceed.

- When done, click on the “Save and Continue to the Next Section” button in the upper right hand corner.

- This will bring you to the Form Has Been Completed page. From here you will send the “Internal Study Personnel Change Form” to the PI for sign-off (even if you are the PI completing the form, you will need to go to the sign-off page to sign off).
Select the “notify PI to signoff” button to “send” this amendment to the PI for signoff before it goes to the IRB (yellow arrow).

The PI must sign off on these amendments even if the PI completed the this form.

After you click the notify PI button, you will get a pop-up message saying that the PI has been notified about this signoff.
PI Signoff

- The PI will receive an email notice that there is a protocol (in this case an “Internal Study Personnel Change Form”) awaiting his/her signoff.
- The PI will also be able to locate this “task” by going to his/her homepage and looking under “Incomplete Tasks”.
- Go to the IRB website (www.bumc.bu.edu/irb) and under Instructions for Investigator – click on How to sign off on a protocol – PI for further instructions.