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 username and Kerberos password
- Investigators from other locations and other institutions are not listed under Internal investigators (they are added in Section 4 – External Investigators)
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
  - While another “standard amendment” is pending
  - While a Progress Report (continuing review) is pending
- An “Internal Study Personnel Change Form” cannot be used to remove study staff from Section 5 (migrated from INSPIR I) - a standard amendment is necessary
- An “Internal Study Personnel Change Form” cannot be used to add External Investigators – a standard amendment must be submitted
- An “Internal Study Personnel Change Form” should be used whenever new staff is added – this should not be done on a standard amendment or as part of a progress report
1. Log on to my Homepage and Select “My Studies”
2. That will bring you to your list of studies
3. Locate the study that you wish to amend and click on “open” (red arrow) to open the study management page for this study (H-30016)
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 1.1 describe the changes requested (e.g. Add Danielle Littee to protocol) Then scroll down to complete the form. (yellow arrow)

<table>
<thead>
<tr>
<th>1.0 Amendment Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 Study Information:</td>
</tr>
<tr>
<td>IRB Number: H-31000</td>
</tr>
<tr>
<td>Study Title: Testing</td>
</tr>
<tr>
<td>Principal Investigator: Administrator, BA</td>
</tr>
</tbody>
</table>

1.2 Amendment for KSP changes on page 1.2. Briefly describe below the requested changes to the "3.0 Grant key study personnel (KSP) access to the study" section of the application. Make sure you list the names and roles of ALL personnel that have been added or removed from this section. (Don't forget to add/remove them appropriately in the next section 1.3)

Please note: This form can only be used to add/delete personnel to the KSP section (Section 3.0) of the application. To add non-BU/BMC investigators to the protocol, or to make any other changes to the study, you will need to submit the “Change Request & Amendments” form instead.
Adding New Internal Investigators to a Study
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 Directories where you can search for the investigators by name.

<table>
<thead>
<tr>
<th>1.3 Personnel to be added or removed</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>*Please add a Principal Investigator for the study:</td>
<td>Add</td>
</tr>
<tr>
<td>If applicable, please select the Protocol Staff personnel:</td>
<td>Add</td>
</tr>
<tr>
<td>A) Additional Investigators</td>
<td></td>
</tr>
<tr>
<td>B) Research Staff</td>
<td></td>
</tr>
<tr>
<td>*Please add a Study Contact:</td>
<td>Add</td>
</tr>
<tr>
<td>If applicable, please add a Faculty Advisor:</td>
<td></td>
</tr>
</tbody>
</table>

Please note: This form can only be used to add/delete personnel to the KSP section (Section 3.0) of the application. To add non-BU/BMC investigators to the protocol, or to make any other changes to the study, you will need to submit the "Change Request & Amendments" form instead.
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, check the radio button for LDAP Directory (purple arrow), and try again. If you still can’t find him/her, then they should submit the following form to IT: http://www.bumc.bu.edu/irb/request/
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).
The person that you just added should show up now (yellow arrow).

Some sections require 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
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.
<table>
<thead>
<tr>
<th>Name</th>
<th>Role on the Study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Khaled Khattar, BA</td>
<td>Principal Investigator</td>
</tr>
<tr>
<td>Frank Le Blanc</td>
<td>Study Contact</td>
</tr>
<tr>
<td>Mary Banks, RN, BS, BSN</td>
<td>Study Contact</td>
</tr>
</tbody>
</table>

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.

Please select existing Personnel you wish to remove:

<table>
<thead>
<tr>
<th>Name</th>
<th>Study Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Khattar, Khaled, BA</td>
<td></td>
</tr>
</tbody>
</table>

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”. You will need to agree to both statements (even though they don’t apply if you’re only removing personnel from the study), 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 authenticate).
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 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.
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.