

# 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 internal investigators 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

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Windows Media Guide | Inter... BU Clinical Research Newsletter ... IRIS: My Studies

**BOSTON UNIVERSITY MEDICAL CAMPUS** **BOSTON MEDICAL CENTER** EXCEPTIONAL CARE. WITHOUT EXCEPTION.

Account: **Mary Banks, RN, BS, BSN**  
 Department: **BU - MED - INSTITUTIONAL REVIEW BOARD**  
 Navigation: Home Logout Help

**My Studies**

Display my studies by:  Filter my studies by study status  All  Most Recently Used:

IRB Number

19 result(s) found...

Click to open	Study Status	IRB Number	IRB Expiration		
Open	Draft			Roth, M	
Open	Draft			Baedorf	
Open	Draft			Khattar, Khaled, BA	
Open	Draft			Khattar, Khaled, BA	1-3-2011 test 2-18
Open	Approved / Open	H-30016	02/09/2012	Investigator, Principal	2-18 Testing 2/3/2011 - Amend 1
Open	Pending - Submitted for Initial Review			Banks, Mary, RN, BS, BSN	2-3-2011 Another full board protocol
Open	Draft			Banks, Mary, RN, BS, BSN	Testing FB Final Edits Protocol
					more stuff for Khaled test

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)



<p><b>Protocol Items</b></p> <ul style="list-style-type: none"> <li>Application</li> <li>Informed Consent</li> <li>Other Study Documents</li> <li>Miscellaneous</li> <li>Study Correspondence</li> <li>Submissions History</li> <li>Study Notebook</li> <li>Forms</li> <li>Recruitment Materials</li> </ul>	<p><b>Submission Forms</b></p> <ul style="list-style-type: none"> <li>Adverse Event</li> <li>Change Request</li> <li>Continuing Review</li> <li>Final/Closure</li> <li>Initial Review</li> <li>Internal Study Personnel Changes</li> <li>Protocol Deviation/Violation Form</li> <li>Protocol Exception Form</li> <li>Test form</li> </ul>	<p><b>Outstanding Submission(s)</b></p> <table border="1"> <thead> <tr> <th>Track Location</th> <th>Ref Number</th> <th>Request Type</th> <th>Process Submission</th> </tr> </thead> <tbody> <tr> <td colspan="4">There are no outstanding submissions.</td> </tr> </tbody> </table>	Track Location	Ref Number	Request Type	Process Submission	There are no outstanding submissions.			
Track Location	Ref Number	Request Type	Process Submission							
There are no outstanding submissions.										

This is study H-30016 (red arrow)  
 Click on "Internal Study Personnel Changes)- blue arrow

[Export to Excel](#) [Add New Form](#) [Compare Two Versions](#) [Delete Selected Form\(s\)](#)

List of records associated with form: Internal Study Personnel Changes.  
To view previous versions click on the folder icon.

1 result(s) found...

<input type="checkbox"/>	Show Rev	Edit/View	Created By	Date Created	Modified By	Date Modified
<input type="checkbox"/>			Mary Banks	02/22/2011 04:10:17 PM	Principal Investigator	02/24/2011 02:19:51 PM

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. From here describe the changes requested (e.g. Add Danielle Littee to protocol) Then scroll down to complete the form. (yellow arrow)

The screenshot shows a web browser window with the following elements:

- Address Bar:** iRIS: Internal Study Personnel Changes
- Page Header:** Boston University Medical Campus logo, Account: Mary Banks, RN, BS, BSN, Department: BU - MED - INSTITUTIONAL REVIEW BOARD, Navigation: Home > my studies > study mgmt. > form data list. Home, Logout, and Help links are also present.
- Form Title:** Internal Study Personnel Changes
- Form Content:**
  - 1.0 Amendment Information** (Section view of the Form)
  - 1.1 Amendment for KSP changes only** (Yellow background)
    - Text: Briefly describe below the requested changes to the KSP section of the application.
    - Text area for input.
    - Please note:** This form can only be used to add/delete personnel to the KSP section 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.
  - 1.2 Personnel to be added or removed** (Yellow background)
    - Text: 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.
    - \*Please add a Principal Investigator for the study:**

A large blue arrow points to the text area in section 1.1.

Locate the appropriate section 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.

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Account: Mary Banks, RN, BS, BSN  
Department: BU - MED - INSTITUTIONAL REVIEW BOARD  
Navigation: Home > my studies > study mgmt. > form data list

Home | Logout | Help

IRB Number: **H-30016** Study Nickname: 2-3-2011  
PI: Investigator, Principal

### Internal Study Personnel Changes


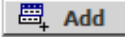
Printer Friendly | Save and Continue to the Next Section

Section view of the Form | **Entire view of the Form**

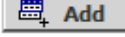
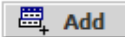
1.0 Amendment Information

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.


**\*Please add a Principal Investigator for the study:**

		
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**If applicable, please select the Protocol Staff personnel:**

A) Additional Investigators	
B) Research Staff	

**\*Please add a Study Contact:**

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

Done | Local intranet | 100% | start | 3 M... | Ime... | Micr... | 2 I... | Search Desktop | 5:00 PM

When you get to the Search User Directory page (blue arrow)  
Enter the first few letters of the first /last name (green arrow)  
Click FIND (yellow arrow) to search for the person.  
Once you have found the name you are looking for click on the check symbol (✓) (red arrow) to add this person to the application.

**BOSTON UNIVERSITY MEDICAL CAMPUS** **BOSTON MEDICAL** EXCEPTIONAL CARE. WITHOUT EXCEPTION.

Account: Mary Banks, RN, BS, BSN  
Navigation: Home > my studies > study mgmt. > form data list > form data

Home Logout Help

### Search User Directory

Back

Select User(s)

Directory Browse/Find:

Last Name:  (You may enter a partial name to search)  
First Name:   
by Department:   
Search From:  INSPIR II Database  LDAP Directory

Find  
Click to search for users

Select	Select User	Name	Department	Email
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Littee, Elizabeth, MPH	INSTITUTIONAL REVIEW BOARD (primary)	dilittee@bu.edu

Tip – If you can't find this person, 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/>

Clicking on the ✓ to select the user (Danielle Littee) added her to the application (yellow arrow).

Select this user's role in the study from the drop-down menu- (green arrow)

Click on the Add button (purple arrow) to add another investigator

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Navigation: Home > my studies > study mgmt. > form data list

Home | Logout | Help

IRB Number: **H-30016** Study Nickname: 2-3-2011  
PI: Investigator, Principal

### Internal Study Personnel Changes

Back | Printer Friendly | Save and Continue to the Next Section

**Section view of the Form** | **Entire view of the Form**

1.0 Amendment Information

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.

**\*Please add a Principal Investigator for the study:**

	<input type="button" value="Add"/>	
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**If applicable, please select the Protocol Staff personnel:**

A) Additional Investigators

<input type="checkbox"/>	Littee, Danielle Elizabeth, MPH	<input type="button" value="Add"/>	<input type="button" value="Remove"/>
	<input type="text" value="--none--"/> <input type="text" value="--none--"/> <input type="text" value="Co-Investigator/Sub Investigator"/> <input type="text" value="Participating Clinician"/>	<input type="button" value="Add"/>	

**\*Please add a Study Contact:**

	<input type="button" value="Add"/>
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# New Investigators

- If the new investigator(s) that you add will need to receive email notifications about the protocol you will also have to add their name(s) under “Add a Study Contact”.
- Once you have added all the investigators /study staff that you wish to, click on the Save and Continue 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 the this form.

The screenshot shows the iRIS web application interface. At the top, there is a navigation bar with the text "Navigation: Home > my studies > study mgmt. > form data list". Below this, the page title is "Internal Study Personnel Changes". On the right side of the page, there are buttons for "Printer Friendly" and "Notify PI to Signoff". The main content area displays a large blue banner that reads "Form has been Completed!". Below the banner, there are two buttons: "Exit Form" and "Notify PI to Signoff". A yellow arrow points to the "Notify PI to Signoff" button. On the left side, there is a sidebar with a "Section view of the Form" tab and a sub-section titled "1.0 Amendment Information".

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](http://www.bumc.bu.edu/irb)) and under Instructions for Investigator – click on How to sign off on a protocol – PI for further instructions.