

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



Internal Investigators

- These are BU/BMC faculty, staff, or students
- Boston Public Health Commission and Boston Healthnet Community Health Center investigators are also considered “internal” investigators for BUMC IRB studies
- 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 institutions are not considered Internal Investigators. They need to be added to your approved study as External Investigators in the Study Application, by submitting a “Change Request and Amendments” form instead of this form.

Internal Investigators

- An “Internal Study Personnel Change Form” can be submitted to add/remove internal investigators from Section 3 at any time.
- An “Internal Study Personnel Change Form” can be submitted
 - While another “Internal Study Personnel Change Form” is pending
 - While another “Change Request and Amendments” form is pending
 - While a “Continuing Review” form (Progress Report) 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
- The addition/removal of an internal personnel occurs once the IRB approves the “Internal Study Personnel Change Form”, and not before.

Featured Study Operations

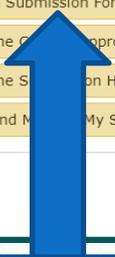
- Create a New Study
- Start a Submission Form for one of My Studies
- View the Approvals for one of My Studies
- View the Submission History for one of My Studies
- View and Manage My Studies

By the Numbers

Submissions in Process	Forms Pending Submission	Pending My Response	High
54	53	4	>

Tasks

All Tasks	35
Study Tasks	33



When you login into INSPIR II (<https://inspir.bu.edu/>), you will get to this page. This is your Home page

Click on **“Start a Submission Form for one of My Studies”**

This opens the “Start a Submission Form” pop-up page.

- Locate the study that you want to add/remove personnel.

The screenshot shows the 'Start a Submission Form' interface. At the top, there is a search bar labeled 'Search for RB Number, Title, Alias' with a 'Search' button. Below the search bar is a table of studies. The table has columns for 'Select a Study', 'Study Status', 'Review Board', 'IRB Number', 'IRB Expiration', 'Study Title', 'Study Alias', and 'Principal Investigator'. The first row is highlighted in green and has a checkbox checked in the 'Select a Study' column. A blue arrow points from the search bar to the table, and another blue arrow points from the 'Select a Study' checkbox to the first row. A yellow callout box with a blue border contains the text: 'You can use the “Search” box to locate the study. Or you can just scroll down.' Another yellow callout box with a blue border at the bottom left contains the text: 'Once you locate the study, click on the “Select a Study” icon'.

Select a Study	Study Status	Review Board	IRB Number	IRB Expiration	Study Title	Study Alias	Principal Investigator
<input checked="" type="checkbox"/>	Exempt - limited IRB review	IRB	H-31000		Testing	2-18-2011-	Administrator
	Closed - Ceded Review	IRB	H-37307		INTERFACE TESTING OF 'IRB-' APPENDING TO IRB STATUSES IN VELOSC		
	Draft	IRB	H-38072				
	Draft	IRB	H-36572				
	Draft	IRB	H-44153				
	Draft	IRB	H-34575				
	Inactive - Administratively Closed	IRB	H-35910		Dummy Expedited/Full Board 6-22-2022		Administrator
	Draft	IRB	H-38079		Chart Reviews 8/17/2018		Administrator
	Draft	IRB	H-36594		Chart Reviews 8/17/2018		Administrator
					Exempt Study 6/7/2017		Administrator
					Exempt Study 6/7/2017		Administrator
					testcs1027title		

This opens the “Submission form List” popup.

The screenshot shows a web application interface with a 'Submission Form List' popup. The popup has a search bar at the top with 'Study Status: Exempt', 'IRB Number: H-31000', and 'Study Title: Testing'. Below the search bar is a table of submission forms. The table has four columns: 'Available Forms', 'Version List', 'Start a new Submission', and 'Edit Incomplete Submissions'. A blue arrow points to the 'Start a new Submission' icon (a document with a plus sign) for the 'Internal Study Personnel Changes' form. The background shows a list of studies with columns for 'Select a Study', 'Study Status', and 'Review Board'. The 'Study Status' column has values like 'Exempt - limited IRB review', 'Closed - Ceded Review', 'Draft', and 'Inactive - Administratively Closed'.

Available Forms	Version List	Start a new Submission	Edit Incomplete Submissions
Change Request and Amendments	[Document Icon]	[Document with Plus Icon]	[Document with Plus and 1 Icon]
Contact Information Change Request Form	[Document Icon]	[Document with Plus Icon]	
Continuing Review Submission Form	[Document Icon]	[Document with Plus Icon]	
Final/Closure Report Form	[Document Icon]	[Document with Plus Icon]	[Document with Plus and 2 Icon]
Internal Study Personnel Changes	[Document Icon]	[Document with Plus Icon]	
Protocol Exception Form	[Document Icon]	[Document with Plus Icon]	
Recruitment Materials Submission Form	[Document Icon]		
Reportable Events and New Information Form	[Document Icon]		[Document with Plus and 1 Icon]

Click on “Start a New Submission” icon that corresponds to the “Internal Study Personnel Changes”- blue arrow

This opens a new “Internal Study Personnel Changes” form and 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)

IRB Number: **H-31000**
Study Nickname: 2-18-2011-
PI: Administrator

Internal Study Personnel Changes (Section 5.0)

Back

Print Friendly

Refresh Constant Fields

Save Section

Save and Continue to Next Section

Section view of the Form

Entire view of the Form

1.0 Amendment Information

1.2 Amendment for KSP changes only

All investigators engaged in human subject research, including supervising principal investigators, co-investigators, participating clinicians and research staff, must be in compliance with the [requirements](#) for training in human subjects and Good Clinical Practices (if applicable), and they must have completed the financial interest disclosure forms and submitted them to the appropriate office for Boston Medical Center or Boston University.

Use the Study Contacts section to designate study personnel in addition to the Principal Investigator who need to receive email notifications. If the Principal Investigator is a student, resident, or fellow, the Supervisor/Principal Investigator must be listed in the Study Contacts section.

If you **ONLY** need to add an administrative assistant (i.e., an individual who has no contact with subjects or identifiable data but needs to access your INSPiR application), you do not need to submit this form. Instead, see www.bumc.bu.edu/irb/files/2016/10/How-to-add-Administrative-Assistant.pdf.

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 to be added or removed in this section. (Don't forget to add/remove them appropriately in the next section 1.6) These changes will only take effect if and when the IRB administratively approves this amendment.

See the [IRB policy](#) for detailed instructions on how to add BU-CRC Students, Faculty and Employees.

1. Replacing the study PI
2. Replacing the study Supervising PI
3. Adding new personnel to the study
4. Removing existing personnel from the study

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-BMC/BU investigators to the study, or to make any other changes to the study, you will need to submit the "Change Request & Amendments" form instead.

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.

1.3 Type of personnel changes

Please indicate the type of change (choose all that apply):

- Changing Principal Investigator
- Changing Supervising Principal Investigator (formerly known as Faculty Sponsor)
- Adding study personnel
- Removing study personnel

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 # 22.

Changing Principal Investigator

In section 1.4, describe the reason for the requested PI change (blue arrow). Then scroll down. (green arrow)

IRB Number: **H-31000**
Study Nickname: 2-18-2011-
PI: Administrator

Internal Study Personnel Change (Section 5.0) Back

Print Friendly Refresh Constant Fields Save Section Save and Continue to Next Section

Section view of the Form Entire view of the Form

1.0 Amendment Information

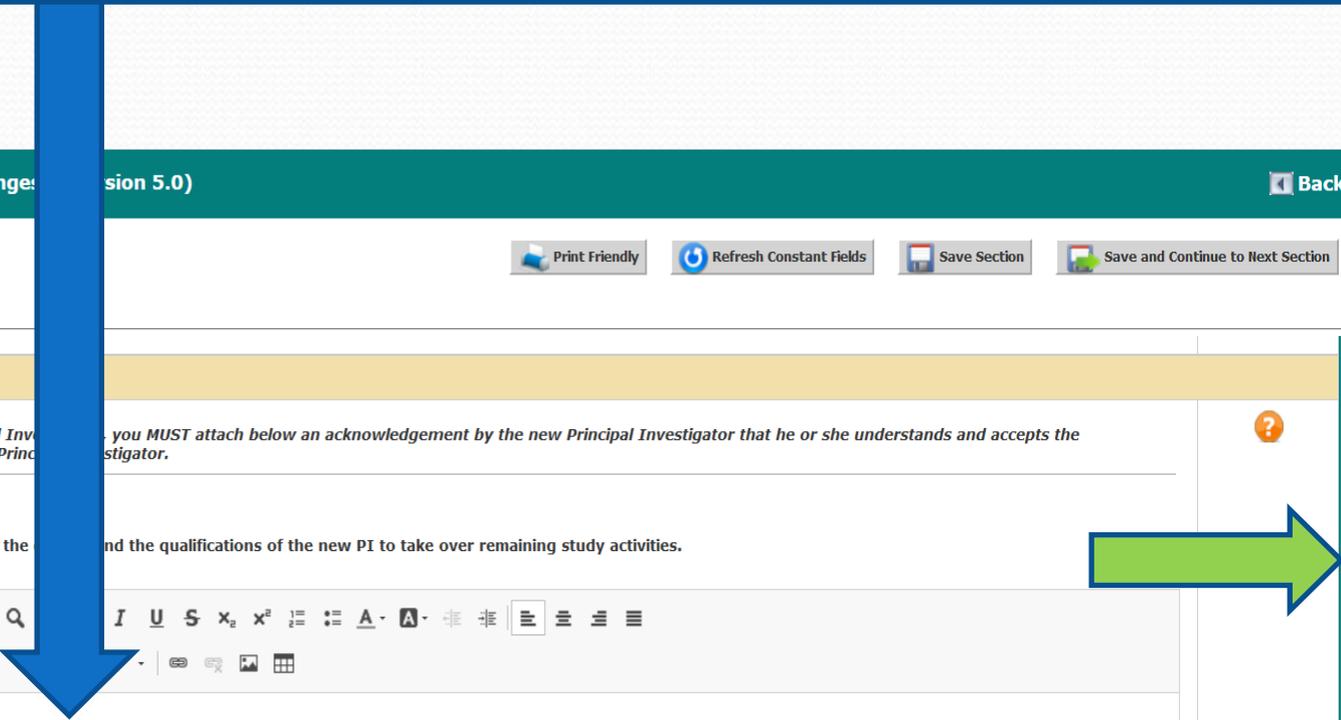
1.4 New Principal Investigator

If you are changing the Principal Investigator, you MUST attach below an acknowledgement by the new Principal Investigator that he or she understands and accepts the responsibilities for this study as Principal Investigator.

*Please describe the reasons for the change and the qualifications of the new PI to take over remaining study activities.

Normal (... Font

The current PI has left the institution and the current Supervising PI is replacing them as the Study PI.



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.

My Workspaces ▾ IRB Number: **H-31000**
Study Alias: 2-18-2011-
PI: Administrator Study **Internal Study Personnel Changes - (Version 6.0)** Back

Print Friendly Refresh Constant Fields Save Section Save and Continue to Next Section

Section view of the Form Entire view of the Form

1.0 Amendment Information

Attach below the acknowledgement from the new Principal Investigator. This may be a scan of a signed printout of Principal Investigator responsibilities ([see PDF Document](#)) or a pdf of an email listing these responsibilities and the new Principal Investigator responding and acknowledging them.

Select or Revise Existing Add a New Document Add Multiple Documents

Detach	Version	Sponsor Version	Title	Category	Expiration Date	Document Outcome	View Document
No Document(s) have been attached to this form.							

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.

This opens the “Study Document Add Verification” pop-up.

Account: Administrator
Department: BMC/BUMC - MED - Institutional Review Board
Path: Home

IRB Number: **H-31000**
Study Alias: 2-18-2011-
PI: Administrator

My Workspaces Study

Section view of the Form Entire view of the Form

1.0 Amendment Information

Attach below the acknowledgment responsibilities and the new

Select or Revise Existing

Detach Version Sponsor

No Document(s) have been attached

Please indicate the status of the

- Additional subjects will be consented
- No additional subjects will be consented
- No further contact will be made
- No consent has been or will be obtained
- Additional subjects will be consented, but this study is cedded to an external IRB that is reviewing the PI change in the consent form

(Please remember to add the new Principal Investigator's name in the section titled "Please add a Principal Investigator for the study")

Help My Profile Log out

Back

Save Section Save and Continue to Next Section

Fields

mail listing these

View Document

Study Document Add Verification

If you already have the revised document on your computer, skip downloading the document for editing and proceed to uploading the revised document.

Select Category: --none--
Version #: .
Version Date: between
Document Outcome: --none--

Title
Search level: Top All
Expiration Date: between

Filter Documents

Upload a New Document Not on the List

Here are the documents for all categories.
Please click on the Create Revision icon to revise an existing document below or click on Upload a New Document Not on the List to upload a new document to the study.

11 result(s) found...

Upload Revised Document	Title	Category	Version	Version Date	Download Document for Editing	Document Outcome	nsor Version	View Document
(Read Only)	testing pptx	Flyer	1.2	04/23/2019				247.98 KB
(Read Only)	PI Responsibilities	Signed PI or Supervising PI Responsibilities	1.0	06/26/2020				419.36 KB
(Read Only)	Recruitment Materials Test	Flyer	1.0	12/03/2019				114.55 KB
(Read Only)	test	Not Defined	1.0	08/23/2019				11.30 KB
(Read Only)	Power Point to P DF Test *Added by the IRB	Flyer	1.0	09/05/2018		Approved and Stamped		636.49 KB
(Read Only)	test	FDA Document	1.0	08/27/2018				91.06 KB
(Read Only)	testing stamp	Other	1.1	07/19/2016				360.02 KB
(Read Only)	testing doc file *Added by the IRB	Materials handed out to subjects	1.0	07/19/2016		Approved and Stamped		135.39 KB
(Read Only)	testing stamp *Added by the IRB	Materials handed out to subjects	1.0	07/19/2016		Approved and Stamped		205.14 KB

Cancel Document Add

Click on “Upload a New Document Not on the List” button

This opens the “Study Document Add” pop-up.

The screenshot shows a web application interface with a 'Study Document Add' pop-up window. The background is a form for 'Internal Study Personnel Changes - (Version 6.0)'. The pop-up window has the following fields:

- *Document Title: [Text input field]
- *Select the document to upload: [Dashed box containing 'Please drop file/click here to upload']
- *Version Number: [Input field with '1' and '.0']
- Version Date: [Date input field with '10/27/2023']
- Sponsor Version: [Input field]
- * Category: [Dropdown menu with '--none--']
- Description: [Text area]
- Comments: [Text area]

A blue arrow points to the dashed box in the 'Select the document to upload' field. At the bottom of the pop-up, there are buttons for 'e, don't save any changes' and 'Save Document'.

Drag and drop the signed “Principal Investigator Responsibilities” document in the “Select the Document to upload” box; or click inside this box and follow your system’s prompts to navigate to where you saved the document to upload it.

This will bring you back to the “Study Document Add.” popup.

- Notice the uploaded document’s name is now appearing in the popup (blue arrow)
1. Type in a meaningful document title (yellow arrow)
 2. Change the “Version Date” to today’s date (green arrow)
 3. Select “Signed PI or Supervising PI Responsibilities” for the “Category” (red arrow)
 4. Click on the “Save Document” button (Grey arrow)

The screenshot shows a web application interface with a modal popup titled "Study Document Add:". The background page is titled "Internal Study Personnel Changes - (Version ...)" and includes navigation elements like "My Workspaces", "IRB Number: H-31000", "Study Alias: 2-18-2011-", "PI: Administrator", and "Department: BMC/BUMC - MED - Institutional Review Board".

The "Study Document Add:" popup form contains the following fields and elements:

- *Document Title:** A text input field containing "Signed PI's Responsibilities document". A yellow arrow points to this field.
- *Select the document to upload:** A dashed box containing a file thumbnail for "Signed PI's Responsibilities.p" (1.1 MB) with a "Remove file" link. A blue arrow points to this area.
- *Version Number:** A text input field containing "1" followed by ".0".
- Version Date:** A date picker field showing "11/06/2023". A green arrow points to this field.
- Sponsor Version:** An empty text input field.
- * Category:** A dropdown menu with "Signed PI or Supervising PI Responsibilities" selected. A red arrow points to this dropdown.
- Description:** A large empty text area.
- Comments:** A large empty text area.
- Buttons:** "Close, don't save any changes" and "Save Document". A grey arrow points to the "Save Document" button.

At the bottom of the background page, there is a section titled "1.5 You must attach a modified consent form with the name and contact information for the new Principal Investigator. No other change may be made in the consent form. If you wish to make any other changes to the consent form, you must create and submit a separate Change Request & Amendment form with an explanation of the additional changes."

This will bring you back to the “Internal Study Personnel Change Form”.

- Notice that the PI Responsibilities document is now appearing in this form.

Account: Administrator
Department: BMC/BUMC - MED - Institutional Review Board
Path: Home > study mgmt. > form da

IRB Number: **H-31000**
Study Alias: 2-18-2011-
PI: Administrator

My Workspaces

Study **Internal Study Personnel Changes - (Version 6.0)**

Print Friendly Refresh Constant Fields Save Section Save and Continue to Next Section

Section view of the Form Entire view of the Form

1.0 Amendment Information

Attach below the acknowledgement from the new Principal Investigator. This may be a scan of a signed printout of Principal Investigator responsibilities ([see PDF Document](#)) or a pdf of an email listing the responsibilities and the new Principal Investigator responding and acknowledging them.

Select or Revise Existing Add a New Document Add Multiple Documents

Detach	Version	Sponsor Version	Title	Category	Expiration Date	Document Outcome	View Document
<input checked="" type="checkbox"/>	1.0		Signed PI's Responsibilities document	Signed PI or Supervising PI Responsibilities			1.15 MB

Please indicate the status of the study:

- Additional subjects will be consented
- No additional subjects will be consented, but research activities will continue with already-consented subjects
- No further contact will be made with consented subjects
- No consent has been or will be obtained from subjects (e.g., for chart-review-only studies)
- Additional subjects will be consented, but this study is ceded to an external IRB that is reviewing the PI change in the consent form

Next, you need to select one of the options under “Please indicate 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 # 22.

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)

My Workspaces IRB Number: **H-31000**
Study Alias: 2-18-2011-
PI: Administrator

Internal Study Personnel Changes - (Version 6.0) Back

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

1.0 Amendment Information

Attach below the amendment information from the new Principal Investigator. This may be a scan of a signed printout of Principal Investigator responsibilities ([see PDF Document](#)) or a pdf of an email listing these responsibilities and acknowledging them.

Detach	Version	Sponsor Version	Title	Category	Expiration Date	Document Outcome	Checked Out	View Document
<input checked="" type="checkbox"/>	1.0		Reduction of Explicit and Implicit Bias in Research Form	Reducing Implicit and Explicit Bias in Research Form				22.94 KB

Please indicate the status of the study:

- Additional subjects will be consented
- No additional subjects will be consented, but research activities will continue with already-consented subjects
- No further contact will be made with consented subjects
- No consent has been obtained from subjects (e.g., for chart-review-only studies)
- Additional subjects will be consented, but this study is ceded to an external IRB that is reviewing the PI change in the consent form

1.5 You must attach a revised consent form with the name and contact information for the new Principal Investigator. No other change may be made in the consent form. If you wish to make any other changes to the consent form, you must create and submit a separate Change Request & Amendment form with an explanation of the additional changes.

- To revise an existing consent form, click on the “Select or Revise Existing” button below. In the new window, click on “Create Revision” next to the appropriate consent document. Then “check-out” the document to make your revisions. Click “Check-in” the revised consent when you’re done making edits.

Detach	Version	Sponsor Version	Title	Category	Language	Expiration Date	Consent Outcome	View Document
No Consent(s) have been attached to this form.								

(Please remember to add the new Principal Investigator’s name in the section titled “Please add a Principal Investigator for the study:” below)

1.7 Personnel to be added or removed

javascript:Application_List()

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 “Download document for Editing” icon that correspond to that consent form to download a copy for editing (green arrow).
2. Once you finish your edits to the consent form, save it on your desktop
3. Come back to this screen and click on “Upload Revised Consent” icon (blue arrow) that correspond to that consent form to upload your revised consent form

Account: Administrator
Department: BMC/BUMC - MED - Institutional Review Board

Select Existing or Create Revised Study Consent

If you already have the revised document on your computer, skip downloading the document for editing and proceed to uploading the revised document.

Select Category: --none--
Version #: .
Version Date: between
Consent Outcome: --none--

Title:
Search level: Top All
Expiration Date: between

Add a New Consent Filter Documents

18 result(s) found...

Select	Show all Versions	Edit	Delete	Version	Version Date	Sponsor Version	Download Document for Editing	Title	Language	Expiration Date	Consent Outcome	View Document	Upload Revised Consent
<input checked="" type="checkbox"/>	<input type="checkbox"/>			1.0	10/14/2022			Adult Consent Form Template					
	<input type="checkbox"/>			1.1	06/26/2020			Adult Consent	English				
	<input type="checkbox"/>			1.0	08/23/2019			testing 2-22-2017	English				
	<input type="checkbox"/>			1.0	08/23/2019			Assent	English				
	<input type="checkbox"/>			1.0	08/23/2019			test					
	<input type="checkbox"/>			1.0	08/23/2019			Not Defined	English				
<input checked="" type="checkbox"/>	<input type="checkbox"/>			1.1	12/10/2014			Non-Exempt Consent Form Template					
	<input type="checkbox"/>			1.1	12/10/2014			*Revision modified by the IRB	English				
	<input type="checkbox"/>			1.0	09/07/2016			Adult Consent	English			351.58 KB	
	<input type="checkbox"/>			1.0	09/07/2016			testing 9-7-16					
<input checked="" type="checkbox"/>	<input type="checkbox"/>			1.0	06/27/2016			Parental Permission (Consent)	English			351.58 KB	
<input checked="" type="checkbox"/>	<input type="checkbox"/>			1.0	06/21/2016			test11234					
	<input type="checkbox"/>			1.0	06/21/2016			Assent	English			368.32 KB	

Clicking on the “Upload revised Consent” icon , will open the “Study Consent Revision” popup displaying the selected consent form cover sheet.

1. Click on the “Choose File” button to upload your revised copy of the consent form and follow your system’s prompts to navigate to where you saved the document to upload it.

The screenshot shows a web application interface for 'Internal Study Personnel Changes - (Version 6.0)'. A modal window titled 'Study Consent Revision' is open, displaying the following fields:

- * Consent Title:** Non-Exempt Consent Form Template
- * Select the consent to upload:** Choose File (No file chosen)
- * Version Number:** 1.2
- * Version Date:** 11/06/2023
- Sponsor Version:** (empty)
- * Category:** Adult Consent
- * Language:** English
- Description:** (empty text area)
- Comments:** (empty text area)

Buttons at the bottom of the modal include 'Close, don't save any changes' and 'Save Consent'. The background interface shows navigation options like 'My Workspaces', 'Help', 'My Profile', and 'Log out', along with a sidebar for 'Amendment Information'.

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).

The screenshot displays a web application interface for managing study consent forms. A modal window titled "Study Consent Revision" is open, allowing for updates to a consent form. The form includes fields for:

- * Consent Title:** Exempt Consent Form Template
- * Select the consent to upload:** A file selection field showing "Adult Conse... Template.rtf".
- * Version Number:** .2
- * Version Date:** 11/06/2023 (highlighted by a blue arrow labeled '1').
- Sponsor Version:** (empty field)
- * Category:** Adult Consent (dropdown menu)
- * Language:** English (dropdown menu)
- Description:** (text area)
- Comments:** (text area)

At the bottom of the popup, there are two buttons: "Close, don't save any changes" and "Save Consent" (highlighted by a green arrow labeled '2').

The background interface shows the user is logged in as "Administrator" and is viewing the "Study Personnel Changes - (Version 6.0)" page. The page includes a sidebar with "Amendment Information" and a main content area with sections for "1.0", "1.5", and "1.7".

This will bring you back to the “Select Existing or Create Revised Study Consent” page.

- If you have more consent forms that you need to revise and attach, repeat the instructions in [slides 17-20](#).
- If you are done revising consent forms, then close this page (blue arrow)

Select Existing or Create Revised Study Consent

If you already have the revised document on your computer, skip downloading the document for editing and proceed to uploading the revised document.

Select Category: --none--

Version #: [] . []

Version Date: [] between []

Consent Outcome: --none--

Title: []

Search level: Top All

Expiration Date: [] between []

Add a New Consent Filter Documents

18 result(s) found...

Select	Show all Versions	Edit	Delete	Version	Version Date	Sponsor Version	Download Document for Editing	Title	Language	Expiration Date	Consent Outcome	View Document	Upload Revised Consent
				1.0	10/14/2022			Adult Consent Form Template					
				1.1	06/26/2020			Adult Consent	English				
				1.1	06/26/2020			testing 2-22-2017					
				1.0	08/23/2019			Assent	English				
				1.0	08/23/2019			test					
				1.0	08/23/2019			Not Defined	English				
				1.1	12/10/2014			Non-Exempt Consent Form Template					
				1.1	12/10/2014			*Revision modified by the IRB					
				1.1	12/10/2014			Adult Consent	English				
				1.0	09/07/2016			testing 9-7-16					
				1.0	09/07/2016			Adult Consent	English			351.58 KB	
				1.0	06/27/2016			test consent					
				1.0	06/27/2016			Parental Permission (Consent)	English			351.58 KB	
				1.0	06/21/2016			test11234					
				1.0	06/21/2016			Assent	English			368.32 KB	

This will take you back to the “Internal Study Personnel Changes” Form.

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

1- Scroll down to the next section (green arrow).

Account: Administrator
Department: BMC/BUMC - MED - Institutional Review Board
Path: Home > study mgmt. > form data list

My Workspaces My IRB Number: H-31000 Study: Internal Study Personnel Changes - (Version 6.0) Back

Print Friendly Refresh Constant Fields Save Section Save and Continue to Next Section

Section view of the Form Entire view of the Form

1.0 Amendment Information

Please indicate the status of the study:

- Additional subjects will be consented
- No additional subjects will be consented, but research activities will continue with already-consented subjects
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- To revise an existing consent form, click on the "Select or Revise Existing" button below. In the new window, click on "Create Revision" next to the appropriate consent document. Then "check-out" the document to make your revisions. Be sure to "check-in" the revised consent when you're done making edits.

Detach	Version	Sponsor Version	Title	Category	Language	Expiration Date	Consent Outcome	View Document
<input checked="" type="checkbox"/>	1.2		Non-Exempt Consent Form Template	Adult Consent	English			1.07 MB

(Please remember to add the new Principal Investigator's name in the section titled "**Please add a Principal Investigator for the study:**" below)

1.7 Personnel to be added or removed

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 # 29.

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)

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

Account: Administrator
Department: BMC/BUMC - MED - Inst
Path: Home > study mgmt. > form da

Review Board

Help My Profile Log out

My Workspaces

IRB Number: **H-31000**
Study Alias: 2-18-2011-
PI: Administrator

Study Assistant

Internal Study Personnel Changes - (Version 6.0) Back

Print Friendly Refresh Constant Fields Save Section Save and Continue to Next Section

Section view of the Form Entire view of the Form

1.0 Amendment Information

1.6 New Supervising Principal Investigator

If you are changing or adding a Supervising Principal Investigator, you MUST also attach an acknowledgement by the new Supervising Principal Investigator that he or she understands and accepts the responsibilities for this study.

*Please describe the reasons for the requested change and the qualifications of the new Supervising Principal Investigator to oversee remaining study activities. Please include the status of the study (e.g., enrolling, interventions continuing, data analysis only).

Verdana 11

The current Supervising PI has left the

Next, you need to download the “Principal Investigator Responsibilities” document, have the new Supervising 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 Supervising 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 Supervising 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 Supervising Principal Investigator responding and acknowledging them.

The screenshot shows a web form interface. On the left, there is a sidebar with a tab labeled "1.0 Amendment Information". The main content area has a header "Section view of the Form" and "Entire view of the Form". Below the header, there is a large empty rectangular box. Underneath this box, there is a text instruction: "Attach the acknowledgment from the new Supervising Principal Investigator. This may be a scan of a signed printout of Supervising Principal Investigator responsibilities (see PDF Document) or a pdf of an email listing these responsibilities and the new Supervising Principal Investigator responding and acknowledging them." Below this text are three buttons: "Select or Revise Existing", "Add a New Document", and "Add Multiple Documents". Below the buttons is a table with columns: "Detach", "Version", "Sponsor Version", "Title", "Category", "Expiration Date", "Document Outcome", and "View Document". The table currently contains one row with the text "No Document(s) have been attached to this form." Below the table, there is a red text instruction: "(Please remember to add the new Supervising Principal Investigator name in the section titled 'If applicable, please add a Supervising Principal Investigator:' below)". At the bottom of the form, there is a section header "1.7 Personnel to be added or removed" and a text instruction: "Use the 'Add' button to select any new personnel that you want to add to the KSP section of the application. To remove an existing person, scroll down to 'Please select any". There are two blue arrows: one pointing down from the top of the form to the "Attach the acknowledgment..." text, and another pointing up from the bottom of the form to the "Add a New Document" button.

Section view of the Form

Entire view of the Form

1.0 Amendment Information

Attach the acknowledgment from the new Supervising Principal Investigator. This may be a scan of a signed printout of Supervising Principal Investigator responsibilities (see PDF Document) or a pdf of an email listing these responsibilities and the new Supervising Principal Investigator responding and acknowledging them.

Select or Revise Existing Add a New Document Add Multiple Documents

Detach	Version	Sponsor Version	Title	Category	Expiration Date	Document Outcome	View Document
No Document(s) have been attached to this form.							

(Please remember to add the new Supervising Principal Investigator name in the section titled "If applicable, please add a Supervising Principal Investigator:" below)

1.7 Personnel to be added or removed

Use the "Add" button to select any new personnel that you want to add to the KSP section of the application. To remove an existing person, scroll down to "Please select any

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.

This opens the “Study Document Add Verification” pop-up.

Account: Administrator
Department: BMC/BUMC - MED - Institutional Review Board
Path: Home

IRB Number: **H-31000**
Study Alias: 2-18-2011-
PI: Administrator

My Workspaces

Section view of the Form

Entire view of the Form

1.0 Amendment Information

Attach below the acknowledgment responsibilities and the new

Select or Revise Existing

Detach Version Sponsor

No Document(s) have been attached

Please indicate the status of the

Additional subjects will be consented, but this study is ceded to an external IRB that is reviewing the PI change in the consent form

No additional subjects will be consented

No further contact will be made

No consent has been or will be obtained

Additional subjects will be consented, but this study is ceded to an external IRB that is reviewing the PI change in the consent form

(Please remember to add the new Principal Investigator's name in the section titled "Please add a Principal Investigator for the study")

Help My Profile Log out

Back

Save Section Save and Continue to Next Section

Fields

View Document

Study Document Add Verification

If you already have the revised document on your computer, skip downloading the document for editing and proceed to uploading the revised document.

Select Category: --none--
Version #: .
Version Dates: between
Document Outcome: --none--

Title
Search level: Top All
Expiration Dates: between

Filter Documents

Upload a New Document Not on the List

Here are the documents for all categories.
Please click on the Create Revision icon to revise an existing document below or click on Upload a New Document Not on the List to upload a new document to the study.

11 result(s) found...

Upload Revised Document	Title	Category	Version	Version Date	Download Document for Editing	Document Outcome	nsor Version	View Document
(Read Only)	testing pptx	Flyer	1.2	04/23/2019				247.98 KB
(Read Only)	PI Responsibilities	Signed PI or Supervising PI Responsibilities	1.0	06/26/2020				419.36 KB
(Read Only)	Recruitment Materials Test	Flyer	1.0	12/03/2019				114.55 KB
(Read Only)	test	Not Defined	1.0	08/23/2019				11.30 KB
(Read Only)	Power Point to P DF Test *Added by the IRB	Flyer	1.0	09/05/2018		Approved and Stamped		636.49 KB
(Read Only)	test	FDA Document	1.0	08/27/2018				91.06 KB
(Read Only)	testing stamp	Other	1.1	07/19/2016				360.02 KB
(Read Only)	testing doc file *Added by the IRB	Materials handed out to subjects	1.0	07/19/2016		Approved and Stamped		135.39 KB
(Read Only)	testing stamp *Added by the IRB	Materials handed out to subjects	1.0	07/19/2016		Approved and Stamped		205.14 KB

Cancel Document Add

Click on “Upload a New Document Not on the List” button

This opens the “Study Document Add” pop-up.

The screenshot shows a web application interface for managing study documents. A pop-up window titled "Study Document Add" is open, displaying a form with the following fields:

- *Document Title:** A text input field.
- *Select the document to upload:** A dashed box containing the text "Please drop file/click here to upload". A blue arrow points to this box.
- *Version Number:** A text input field with "1" and ".0" as placeholders.
- Version Date:** A date input field with "10/27/2023" and a calendar icon.
- Sponsor Version:** A text input field.
- * Category:** A dropdown menu with "--none--" selected.
- Description:** A text area.
- Comments:** A text area.

At the bottom of the pop-up, there are buttons for "e, don't save any changes" and "Save Document".

The background interface shows a study titled "Internal Study Personnel Changes - (Version 6.0)". It includes a sidebar with "Amendment Information" and a main area with a table for document attachments. The table is currently empty, with the message "No Document(s) have been attached to this form".

Drag and drop the signed “Principal Investigator Responsibilities” document in the “Select the Document to upload” box; or click inside this box and follow your system’s prompts to navigate to where you saved the document to upload it.

This will bring you back to the “Study Document Add.” popup.

- Notice the uploaded document’s name is now appearing in the popup (blue arrow)
1. Type in a meaningful document title (yellow arrow)
 2. Change the “Version Date” to today’s date (green arrow)
 3. Select “Signed PI or Supervising PI Responsibilities” for the “Category” (red arrow)
 4. Click on the “Save Document” button (Grey arrow)

The screenshot shows a web application interface with a modal window titled "Study Document Add:". The modal contains the following fields and elements:

- Document Title:** A text input field containing "Signed PI's Responsibilities document". A yellow arrow points to this field.
- Select the document to upload:** A dashed box containing a file thumbnail for "Signed PI's Responsibilities.p" (1.1 MB) with a "Remove file" link. A blue arrow points to the file name.
- Version Number:** A text input field containing "1" followed by ".0".
- Version Date:** A date picker showing "11/06/2023". A green arrow points to the date.
- Sponsor Version:** An empty text input field.
- Category:** A dropdown menu with "Signed PI or Supervising PI Responsibilities" selected. A red arrow points to the dropdown.
- Description:** A large empty text area.
- Comments:** A large empty text area.
- Buttons:** At the bottom right, there are two buttons: "Close, don't save any changes" and "Save Document". A grey arrow points to the "Save Document" button.

The background shows a navigation bar with "Help", "My Profile", and "Log out" buttons, and a breadcrumb trail: "Home > study mgmt. > form data list". The main content area is titled "Internal Study Personnel Changes - (Version)".

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)
- Scroll down to the next section (green arrow).

BOSTON UNIVERSITY MEDICAL CAMPUS | BOSTON MEDICAL CENTER | Account: Administrator | Department: BMC/BUMC - MED - Institutional Review Board | Path: Home > study mgmt. > form da

IRB Number: **H-31000** | Study Alias: 2-18-2011- | PI: Administrator

Internal Study Personnel Changes - (Version 6.0) | Back

Print Friendly | Refresh Constant Fields | Save Section | Save and Continue to Next Section

Section view of the Form | Entire view of the Form

1.0 Amendment Information

Attach the acknowledgement from the Supervising Principal Investigator. This may be a scan of a signed printout of Supervising Principal Investigator responsibilities (see PDF Document) or a pdf of an email listing these responsibilities and the new Supervising Principal Investigator responding and acknowledging them.

Select or Revise Existing | Add a New Document | Add Multiple Documents

Detach	Version	Sponsor Version	Category	Expiration Date	Document Outcome	View Document
(X)	1.0		Signed PI Responsibilities document			1.15 MB

(Please remember to add the new Supervising Principal Investigator's name in the section titled "If applicable, please add a Supervising Principal Investigator:" below)

1.7 Personnel to be added or removed

Use 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 person, scroll down to "Please select any existing Personnel you wish to remove:", and click on the "Select" 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.

Adding New Internal Investigators to a Study and/or Removing Existing Study Personnel from the Study



Section 1.7 “Personnel to be added or removed”, should be filled out in this form without exceptions.

- To fill out this section, click on “Setup Key Study Personnel Request” button (blue arrow).

The screenshot shows the top navigation bar with the Boston University Medical Campus logo, account information (Administrator, BMC/BUMC - MED - Institutional Review Board), and a path: Home > study mgmt. > form data list. A user profile dropdown shows 'My Profile' and a 'Log out' button. Below the navigation bar, there are buttons for 'My Workspaces', 'IRB Number: H-31000', 'Study Alias: 2-18-2011-', 'PI: Administrator', 'Study Assistant', and 'Internal Study Personnel Changes - (Version 6.0)'. There is also a 'Back' button. Below these are buttons for 'Print Friendly', 'Refresh Constant Fields', 'Save and Continue to Next Section', and 'Save and Continue to Next Section'. The main content area has two tabs: 'Section view of the Form' and 'Entire view of the Form'. Below the tabs is a section titled '1.0 Amendment Information' with a sub-section '1.7 Personnel to be added or removed'. A red note says: '(Please remember to add the new Supervising Principal Investigator's name in the section titled "If applicable, please add a Supervising Principal Investigator:" below)'. Below this is a text box with instructions: 'Use 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 person, scroll down to "Please select any existing Personnel you wish to remove:", and click on the "Select" button to select any personnel that you would like to remove from the KSP section of the application. Changes will only take effect if and when the IRB approves this amendment.' Below the text box is a section titled 'Assign key study personnel(KSP) Request to the study' with a 'Setup Key Study Personnel Request' button. Below this are three sections: 'If applicable, please add the new Principal Investigator for the study:', 'If applicable, please select the new Research Staff personnel:', and 'If applicable, please add any new Study Contact:'. The 'Research Staff' section has two rows: 'A) Additional Investigators' and 'B) Research Staff'. Below the 'Study Contact' section is a text box with instructions: 'The Study 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).'

This will open the “Setup Study Personnel” popup.

- If you are adding new study personnel to your study, proceed to the next slide.
- If you are only removing existing personnel from your study, skip the next instructions to slide # 38.

The screenshot shows a web application interface with a 'Setup Study Personnel' popup window. The background shows a sidebar with 'My Workspaces' and 'Amendment Information' sections. The main content area is partially visible, showing 'Section view of the Form' and 'Entire view' options. The popup window has a title bar with 'Setup Study Personnel' and a close button. It contains a search form with fields for 'Last Name', 'First Name', and 'Department' (set to 'All Departments'). A 'Find User/Search Directory' button is next to the department dropdown. Below the search form is a table with columns 'Select', 'Training', 'Name', 'Department', and 'Email'. The table is currently empty, displaying 'No results found.' Below the table is a section titled 'Selected Study Personnel:' with two sub-sections: 'Principal Investigator' and 'Additional Investigators'. Each sub-section has a table with columns 'Name' and 'Role'. Both sub-sections currently display 'No Personnel has been selected for this group.' At the bottom of the popup are two buttons: 'Clear Key Study Personnel' and 'Close Setup of Study Personnel'.

Account: Administrator
Department: BMS/UMS - MED - Translational Research
Path: Home

IRB Number: H-3
Study Alias: 2-18-2
PI: Administrator

My Workspaces

Section view of the Form

Entire view

1.0 Amendment Information

1.7 Personnel

Use the "Add Existing Personnel" button to add existing personnel. Changes will be reflected in the system.

Assign

If applicable, please add a new Study Contact:

If applicable, please add a new Faculty Advisor:

The Study 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).

Help My Profile Log out

Back

Save and Continue to Next Section

Request

?

Setup Study Personnel

User Search

Last Name: First Name:

by Department:

Find User/Search Directory

Select	Training	Name	Department	Email
No results found.				

Selected Study Personnel:

Principal Investigator

Name	Role
No Personnel has been selected for this group.	

Additional Investigators

Name	Role
No Personnel has been selected for this group.	

Clear Key Study Personnel Close Setup of Study Personnel

Note: If you are only removing existing personnel from your study, skip the next instructions to slide # 37.

Adding New Internal Investigators to a Study



Notes for adding New Investigators

- “Study Contact” is not a real study role. So, anyone that is listed as a Study Contact will also need to be listed under another study role such as “Additional Investigators” or “Research Staff”, if they are not already listed there.
- If the new investigator(s) that are being added will need to receive email notifications about the protocol and be assigned tasks in their INSPIR Home page, you will also have to give them the “Study Contact” Role.

Make sure you are in the “User Search” tab (blue arrow).

1- Enter the last name (green arrow)

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

Account: Administrator
Department: BUMC/UMC - MED - Institutional Review Board
Path: Home

IRB Number: H-3
Study Alias: 2-18-2
PI: Administrator

My Workspaces

Section view of the Form

Entire view of the Form

1.0 Amendment Information

1.7 Personnel

Use the "Add Existing Personnel" button to add existing personnel. Changes will be reflected in the "Selected Study Personnel" section.

Assign

If applicable, assign a role to the Principal Investigator.

If applicable, assign a role to the Additional Investigators.

A) Addition of Personnel

B) Researcher

Setup Study Personnel

User Search

Last Name: First Name:

by Department: All Departments

Find User/Search Directory

Select	Training	Name	Department	Email
No results found.				

Selected Study Personnel:

Principal Investigator

Name	Role
No Personnel has been selected for this group.	

Additional Investigators

Name	Role
No Personnel has been selected for this group.	

Clear Key Study Personnel Close Setup of Study Personnel

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>

If the person you are looking for has an INSPIR account, their name will show up like in the screenshot below (blue arrow)

1. First check that they are up-to-date with training by clicking on the training icon (green arrow). If they don't have the required IRB training, please do not add them.
2. Click on the "Select" icon (yellow arrow) to select this person.

Setup Study Personnel

User Search
Remove Personnel List

Last Name: K First Name:
by Department:
Find User/Search Directory

Select	Training	Name	Department	Email
		Khattar, Khaled, BA	Institutional Review Board	kkhattar@bu

Selected Study Personnel:

Principal Investigator

Name	Role
No Personnel has been selected for this group.	

Additional Investigators

Name	Role
No Personnel has been selected for this group.	

Clear Key Study Personnel Close Setup of Study Personnel

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>

This will open the “Add Personnel Role” popup.

1. Select their role on the study by clicking on one of the listed roles’ radio buttons (green arrow).
2. Some roles require that you select the user’s role subcategory from a drop-down menu- (blue arrow). Select the user’s role subcategory if applicable.
3. If you want this person to get study tasks and all study email notifications, select “Yes” (yellow arrow) for “Would you like to include as a Study Contact ?”, otherwise select “No”.
4. When you are done, click on the “Save” button (red arrow).

The screenshot displays the "Setup Study Personnel" application interface. A modal dialog box titled "Add Personnel Role" is open, showing the configuration for user "Khaled Khattar, BA". The dialog includes the following elements:

- Role Selection:** Radio buttons for "Principal Investigator", "Additional Investigators" (selected), "Research Support Staff", "Study Contact", and "Supervising Principal Investigator". A green arrow points to the "Additional Investigators" radio button.
- Subcategory Selection:** Two dropdown menus. The first is set to "Co-Investigator" and the second to "--none--". A blue arrow points to the "Co-Investigator" dropdown.
- Study Contact Question:** "Would you like to include as a Study Contact ?" with radio buttons for "Yes" and "No" (selected). A yellow arrow points to the "No" radio button.
- Buttons:** "Cancel" and "Save" buttons at the bottom right. A red arrow points to the "Save" button.

Background application details include: IRB Number: H-3, Study Alias: 2-18-2, PI: Administrator, and a "User Search" section with a "Remove Person" button. The user's email address "kkhattar@bu" is visible in the background.

This will take you back to the “Setup Study Personnel” popup.

- Note that the person just added is showing up in the appropriate section/role (green arrow).
- To add more personnel, repeat steps in slides 34 – 37.
- If you will be removing existing personnel from your study, proceed to the next slide.
- If you will not be removing any existing personnel from your study, skip the next instructions to slide # 42.

Setup Study Personnel

User Search

Remove Personnel List

Create My Personnel Pool

Last Name: First Name:

by Department: Find User/Search Directory

Select	Training	Name	Department	Email
<input type="checkbox"/>		Khattar, Khaled, BA	Institutional Review Board	kkhattar@bu

Selected Study Personnel:

Principal Investigator

Name	Role
No Personnel has been selected for this group.	

Additional Investigator

Name	Role
<input checked="" type="checkbox"/> Khattar, Khaled, BA	Co-Investigator

Clear Key Study Personnel Close Setup of Study Personnel

Note: If you will not be removing any existing personnel from your study, skip the next instructions to slide # 42.

Requesting the Removal of Existing Internal Investigators from the Study



While you still in the “Setup Study Personnel” popup:
1. Click on the “Remove Personnel List” tab (green arrow)

Setup Study Personnel

User Search
Remove Personnel List
Create My Personnel Pool

Last Name: Khattar First Name:

by Department: All Departments

Select	Training	Name	Department	Email
		Khattar, Khaled, BA	Institutional Review Board	kkhattar@bu

Selected Study Personnel:

Principal Investigator

Name	Role
No Personnel has been selected for this group.	

Additional Investigators

Name	Role
Khattar, Khaled, BA	Co-Investigator

- The “Setup Study Personnel” popup will refresh to list all personnel currently listed on your study:
1. Click on the check boxes to select the personnel you want to remove from your study (green arrow)
 2. When you’re done selecting all personnel that you want removed, click on the “Save Selections” button (yellow arrow).

Account: Administrator
Department: BMC/BUMC, MCO, Institutional Review Board
Path: Home

IRB Number: H-3
Study Alias: 2-18-2
PI: Administrator

Setup Study Personnel

User Search

Remove Personnel List

Create My Personnel Pool

<input type="checkbox"/>	Name	Role
<input type="checkbox"/>	Administrator	Principal Investigator
<input type="checkbox"/>	Khaled Khattar, BA	Study Contact
<input type="checkbox"/>	Administrator	Study Contact
<input type="checkbox"/>	Brandon Finn, BA, CIP, Senior IRB Analyst	Co-Investigator
<input type="checkbox"/>	Carolyn Swain, MPH, CIP, Senior IRB Analyst	Co-Investigator
<input type="checkbox"/>	Daly Franco, BA, CIP, Senior IRB Analyst	Co-Investigator
<input type="checkbox"/>	Emily Crowley, MPH	Co-Investigator
<input type="checkbox"/>	Mark Testerman, BS, CIP, Senior IRB Analyst II	Co-Investigator
<input checked="" type="checkbox"/>	Fanny Knox Ennever, PhD	Administrative Assistant

Selected Study Personnel:

Principal Investigator

Name	Role
No Personnel has been selected for this group.	

Additional Investigators

Name	Role
<input checked="" type="checkbox"/> Khattar, Khaled, BA	Co-Investigator

Clear Key Study Personnel Close Setup of Study Personnel

Save Selections

The “Setup Study Personnel” popup will refresh again:

- If you want to select more personnel to be removed repeat steps in [slide 40](#).
- To view the list of personnel that you selected to be removed, scroll down (green arrow)
- You will see all personnel that you selected to be removed under “Remove Personnel List” (yellow arrow).

Setup Study Personnel

User Search

Remove Personnel List

Create My Personnel Pool

Save Selections

<input checked="" type="checkbox"/>	Name	Role on the Study
<input type="checkbox"/>	Administrator	Principal Investigator
<input type="checkbox"/>	Khaled Khattar, BA	Study Contact
<input type="checkbox"/>	Administrator	Study Contact
<input type="checkbox"/>	Brandon Finn, BA, CIP, Senior IRB Analyst	Co-Investigator
<input type="checkbox"/>	Carolyn Swain, MPH, CIP, Senior IRB Analyst	Co-Investigator
<input type="checkbox"/>	Daly Franco, BA, CIP, Senior IRB Analyst	Co-Investigator
<input type="checkbox"/>	Emily Crowley, MPH	Co-Investigator
<input type="checkbox"/>	Mark Testerman, BS, CIP, Senior IRB Analyst II	Co-Investigator

Selected Study Personnel:

Faculty Advisor

Name	Role
No Personnel has been selected for this group.	

Remove Personnel List

Name	Role
<input checked="" type="checkbox"/> Ennever, Fanny Knox, PhD	Administrative Assistant

Clear Key Study Personnel

Close Setup of Study Personnel

If you are done selecting new personnel to be added and/or selecting existing personnel for removal from the study:

- You would click on “Close Setup of Study Personnel” button (yellow arrow).

The screenshot shows a software window titled "Setup Study Personnel". On the left, there are navigation options: "User Search", "Remove Personnel List", and "Create My Personnel Pool". The main area contains a table of personnel with columns for "Name" and "Role on the Study". Below the table are sections for "Selected Study Personnel" (Faculty Advisor) and "Remove Personnel List". At the bottom, there are two buttons: "Clear Key Study Personnel" and "Close Setup of Study Personnel". A yellow arrow points to the "Close Setup of Study Personnel" button.

<input checked="" type="checkbox"/>	Name	Role on the Study
<input type="checkbox"/>	Administrator	Principal Investigator
<input type="checkbox"/>	Khaled Khattar, BA	Study Contact
<input type="checkbox"/>	Administrator	Study Contact
<input type="checkbox"/>	Brandon Finn, BA, CIP, Senior IRB Analyst	Co-Investigator
<input type="checkbox"/>	Carolyn Swain, MPH, CIP, Senior IRB Analyst	Co-Investigator
<input type="checkbox"/>	Daly Franco, BA, CIP, Senior IRB Analyst	Co-Investigator
<input type="checkbox"/>	Emily Crowley, MPH	Co-Investigator
<input type="checkbox"/>	Mark Testerman, BS, CIP, Senior IRB Analyst II	Co-Investigator

Name	Role
No Personnel has been selected for this group.	

Name	Role
<input checked="" type="checkbox"/> Ennever, Fanny Knox, PhD	Administrative Assi

This should bring you back to the “Internal Study Personnel Changes” form.

- Notice that the personnel selected to be added to the study (if applicable), now appears in the appropriate section of this form (blue arrow)
- Notice that the personnel selected to be removed from the study (if applicable), now appears in the appropriate section of this form (yellow arrow).
- Scroll down to proceed (green arrow)

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

Account: Administrator
Department: BMC/BUMC - MED - Institutional Review Board
Path: Home > study mgmt. > form data list

? Help My Profile Log out

My Workspaces IRB Number: **H-31000** Study Alias: 2-18-2011- PI: Administrator Study Assistant **Internal Study Personnel Changes - (Version 6.0)** Back

Print Friendly Refresh Constant Fields Save Section Save and Continue to Next Section

Section view of the Form Entire view of the Form

1.0 Amendment Information

If applicable, please add the new Principal Investigator for the study:

If applicable, please select the new Research Staff personnel:

A) Additional Investigator

Khattar, Khaled, BA [View Training Record](#)
Co-Investigator

B) Research Staff

If applicable, please add any new Study Contact:

The Study 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 new Faculty Advisor:

If applicable, please select any existing Personnel you wish to remove:

Ennever, Fanny Knox, PhD Administrative Assistant

1.8 Training and Conflict of Interest (COI) Verification

Only if you are adding study personnel to your study, Section 1.8 will be displayed in this form and needs to be completed as explained in this slide. If you are not adding any Study Personnel, Section 1.8 will be hidden and in this case, you would skip this slide to the next.

- Basically, in Section 1.8 (if displayed), you will be attesting that you have verified that the personnel you are adding to this study have completed their required IRB training and submitted Conflict of Interest forms.
- You need to check both radio buttons before the system allows you to submit.
 1. Check the two radio buttons (blue arrows)

My Workspaces ▾ IRB Number: **H-31000**
Study Alias: 2-18-2011-
PI: Administrator Study Assistant Internal Study Personnel Changes - (Version 6.0) [Back](#)

[Print Friendly](#) [Refresh Constant Fields](#) [Save Section](#) [Save and Continue to Next Section](#)

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

1.0 [Amendment Information](#)

If applicable, please add any new Study Contact.

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The Study 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 new Faculty Advisor:

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If applicable, please select any existing Personnel you wish to remove:

Ennever, Fanny Knox, PhD	Administrative Assistant	
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1.8 Training and Conflict of Interest (COI) Verification

I have verified that all those added to this protocol are up to date with their human subjects training requirements and in their Good Clinical Practices (GCP) training if it is required.*

*(If someone listed above is not up to date with his/her training in human subjects or GCP (**if applicable**) do not add them to the study. Remove them from this list and resubmit when these requirements have been met. It is a violation of institutional policy for those who have not met the [institutional requirements](#) for human subjects or GCP training to engage in human subjects research.)

I have verified that (1) all those added to this study who are responsible for the design, conduct, or reporting of the study have submitted the required financial interest disclosure forms and that (2) any financial conflicts of interest that may have been identified have been resolved.**

**Required financial interest disclosure forms are submitted through [COI Smart](#) for [Boston Medical Center](#) and through the [Financial Interest Disclosure form](#) for [Boston University](#). Study personnel may be added as long as they have submitted as required and any [significant financial interests](#) that are [related to the research](#) have been resolved by the BMC or BU COI offices. It is a violation of institutional policy to engage in human subjects research without complying with the institution's COI policy.

javascript:Application_List();

Now it's time to save this form and submit it.

1. Click on "Save and Continue to Next Section" button (green arrow)

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

Account: Administrator
Department: BMC/BUMC - MED - Institutional Review Board
Path: Home > study mgmt. > form data list

Help My Profile Log out

My Workspaces IRB Number: **H-31000** Study Alias: 2-18-2011- PI: Administrator Study Assistant **Internal Study Personnel Changes - (Version 6.0)** Back

Print Friendly Refresh Constant Fields Save Section **Save and Continue to Next Section**

Section view of the Form Entire view of the Form

1.0 Amendment Information

If applicable, please add any new Study Contact:

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The Study 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 new Faculty Advisor:

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If applicable, please select any existing Personnel you wish to remove:

Ennever, Fanny Knox, PhD	Administrative Assistant	
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This will bring you to the “Form Has Been Completed” page.

1. Click on the “Notify PI to Signoff” or the “Signoff and Submit” button (whichever is available to you) to submit 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.

The screenshot shows the top navigation bar with the Boston University Medical Campus logo, account information (Administrator, BMC/BUMC - MED - Institutional Review Board), and navigation links (Home > study mgmt. > form data list). The main header area includes 'My Workspaces', 'Study Assistant', and the current page title 'Internal Study Personnel Changes - (Version 6.0)'. On the right, there are buttons for 'Print Friendly' and 'Signoff and Submit'. Below the header, there are tabs for 'Section view of the Form' and 'Entire view of the Form'. The main content area features a large green banner with the text 'Form has been Completed!' and 'Instruction of Form has Been Completed Screen'. A yellow arrow labeled '1' points to the 'Signoff and Submit' button in the top right. Another yellow arrow labeled '1' points to a 'Signoff and Submit' button located below the main content area.

After you click on the “Notify PI to Signoff” or the “Signoff and Submit” button , you will get a pop-up message saying that the PI has been notified about this signoff, or you’ll get the signoff page if you are the PI.

PI Signoff

- The PI will receive an email notification that there is a submission (in this case an “Internal Study Personnel Change Form”) awaiting their signoff
- The PI will also be able to locate this signoff “task” by going to their INSPIR homepage and looking under “All Tasks”
- For instructions on how to sign off as the PI, follow the instructions in the link below:

<https://www.bumc.bu.edu/irb/files/2016/10/How-to-sign-off-on-protocol-as-PI.pdf>