

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.

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



This opens the “Submission form List” popup.

Submission Form List

Study Status: **Exempt** IRB Number: H-31000 Study Title: Testing

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

Cancel

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)

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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 Supervising 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 (Version 5.0)

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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.

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

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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

Section view of the Form Entire view of the Form

1.0 Amendment Information

Attach below the acknowledgment of responsibilities and the new responsibilities.

Select or Revise Existing Document

Detach	Version	Spouse

No Document(s) have been attached.

Please indicate the status of the study:

☐ 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

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

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	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	Materials handed out to subjects	1.0	07/19/2016		Approved and Stamped		135.39 KB
(Read Only)	testing stamp	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: [Text input field]
- *Select the document to upload: [Dashed box with text "Please drop file/click here to upload"]
- *Version Number: [Text input field with value "1"]
- Version Date: [Text input field with value "10/27/2023"]
- Sponsor Version: [Text input field]
- *Category: [Dropdown menu with value "--none--"]
- Description: [Text input field]
- Comments: [Text input field]

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

The background interface includes a top navigation bar with "My Workspaces", "Study", and "Internal Study Personnel Changes - (Version 6.0)". A sidebar on the left shows "Section view of the Form" and "Entire view of the Form". The main content area displays "Amendment Information" and a table with columns "Detach", "Version", "Sponsor Version", and "Title". Below the table, there is a section for "Please indicate the status of the study:" with three radio button options.

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)

Study Document Add:

*Document Title: Signed PI's Responsibilities document

*Select the document to upload:

Signed PI's Responsibilities.p
1.1 MB
Remove file

*Version Number: 1.0

Version Date: 11/06/2023

Sponsor Version:

*Category: Signed PI or Supervising PI Responsibilities

Description:

Comments:

Close, don't save any changes Save Document

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

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

The screenshot shows the 'Internal Study Personnel Changes - (Version 6.0)' form. A blue arrow points from the top navigation bar to the 'Attach below the acknowledgement' section. Another blue arrow points from the 'Please indicate the status of the study' section to the bottom of the slide.

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

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

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



 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 amendment 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 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	Checked Out	View Document
	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 outcome 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.

Select or Revise Existing Add a New Consent

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

javascriptApplication_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

Help

My Profile

Log out

My Workspaces

IRB Number

Study Alias

PI: Adminis

Section view of the Form

Entire

1.0 Amendment Information

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	English				
	<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	English				
<input checked="" type="checkbox"/>	<input type="checkbox"/>			1.1	12/10/2014			Non-Exempt Consent Form Template	English				
	<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				
	<input type="checkbox"/>			1.0	09/07/2016			testing 9-7-16	English				
<input checked="" type="checkbox"/>	<input type="checkbox"/>			1.0	06/27/2016			Adult Consent	English				
	<input type="checkbox"/>			1.0	06/27/2016			test consent	English				
	<input type="checkbox"/>			1.0	06/27/2016			Parental Permission (Consent)	English				
<input checked="" type="checkbox"/>	<input type="checkbox"/>			1.0	06/21/2016			test11234	English				
	<input type="checkbox"/>			1.0	06/21/2016			Assent	English				

consent form. If you wish to make changes.

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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 the 'Study Consent Revision' popup window. A blue arrow points to the 'Choose File' button. The popup contains 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:**
- *Category:** Adult Consent
- *Language:** English
- Description:**
- Comments:**

Buttons at the bottom of the popup: Close, don't save any changes, Save Consent, View Document.

Background interface elements include:

- Account: Administrator, Department: BMC/BUMC - MED - Institutional Review Board
- Path: Home > study mgmt. > form data list
- IRB Number: H-31000, Study Alias: 2-18-2011-PI: Administrator
- Section view of the Form: Amendment Information
- 1.5 You must attach any other changes to the consent form. If you wish to make additional changes.
- 1.7 Personnel to be added or removed

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 shows a web application interface for Boston Medical Center. A "Study Consent Revision" popup is open in the center. A blue arrow labeled "1" points to the "*Version Date:" field, which contains "11/06/2023". A green arrow labeled "2" points to the "Save Consent" button at the bottom right of the popup. The background interface includes a top navigation bar with "Help", "My Profile", and "Log out" buttons. The main content area shows a "Study Personnel Changes - (Version 6.0)" form with various fields like "Consent Title", "Select the consent to upload", "Version Number", "Sponsor Version", "Category", "Language", "Description", and "Comments".

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

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

Please indicate the type of amendment:

- ☒ Additional submission
- ☐ No additional submission
- ☐ No further corrections
- ☐ No consent has been obtained
- ☐ Additional submission

1.5 You must attach any other changes to the consent form.

- To revise an existing document.

Select the document to revise:

Detach Version

No Consent(s) have been attached.

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

Study Consent Revision

*Consent Title: Exempt Consent Form Template

*Select the consent to upload: Use File Adult Conse... Template.rtf

*Version Number: 1.2

*Version Date: 11/06/2023

Sponsor Version:

*Category: Adult Consent

*Language: English

Description:

Comments:

Close, don't save any changes Save Consent

Save Section Save and Continue to Next Section

Back

made in the consent form. If you wish to make additional changes.

ate consent

View Document

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

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)

Account: Administrator

Department: BMC/BUMC - MED - Institutional Review Board

My Workspaces

IRB Number

Study Alias

PI: Adminis

Section view of the Form

1.0 Amendment Information

1.5

1.7 Personnel to be added or removed

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
								Category					
<input checked="" type="checkbox"/>				1.0	10/14/2022			Adult Consent Form Template					
				1.1	06/26/2020			Adult Consent	English				
				1.0	08/23/2019			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				
<input checked="" type="checkbox"/>				1.1	12/10/2014			Non-Exempt Consent Form Template					
				1.1	12/10/2014			*Revision modified by the IRB					
				1.0	09/07/2016			Adult Consent	English				
				1.0	09/07/2016			testing 9-7-16					
				1.0	09/07/2016			Adult Consent	English			351.58 KB	
<input checked="" type="checkbox"/>				1.0	06/27/2016			test consent					
				1.0	06/27/2016			Parental Permission (Consent)	English			351.58 KB	
<input checked="" type="checkbox"/>				1.0	06/21/2016			test11234					
				1.0	06/21/2016			Assent	English			368.32 KB	

My Profile

Log out

Back

Save and Continue to Next Section

consent form. If you wish to make changes.

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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).



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)

The screenshot shows the 'Internal Study Personnel Changes - (Version 6.0)' form. The top navigation bar includes the Boston University Medical Campus logo, account information (Administrator, BMC/BUMC - MED - Institutional Review Board), and links for Help, My Profile, and Log out. The breadcrumb path is 'Home > study mgmt. > form data'. The left sidebar shows 'My Workspaces' and a list of sections: '1.0 Amendment Information' (selected) and '1.6 New Supervising Principal Investigator'. The main content area for section 1.6 contains instructions: '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.' and a prompt: '*Please describe the reasons for the 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).' Below the text is a rich text editor with a toolbar showing options like Bold, Italic, Underline, and Font Color. The text area contains the sentence 'The current Supervising PI has left the study.' A large blue arrow points down from the top of the form to the text area, and a large green arrow points right from the text area towards the right edge of the form, indicating the direction of the user's action.

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

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

My Workspaces

Study Assistant

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

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 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).

The current Supervising PI has left the study.

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.

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 of responsibilities and the new form

Select or Revise Existing Document

Detach Version Sponsor

No Document(s) have been attached

Please indicate the status of the study

☐ 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.")

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 I RB	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 I RB	Materials handed out to subjects	1.0	07/19/2016		Approved and Stamped		135.39 KB
(Read Only)	testing stamp *Added by the I RB	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 study management. A pop-up window titled "Study Document Add:" is open, displaying a form with the following fields:

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

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

The background interface includes a top navigation bar with "My Workspaces", "Study", and "Internal Study Personnel Changes - (Version 6.0)". On the left, there are tabs for "Section view of the Form" and "Entire view of the Form", and a sidebar with "1.0 Amendment Information". The main content area shows a table with columns "Detach", "Version", "Sponsor Version", and "Title", and a message "No Document(s) have been attached to this form". Below the table, there is a section titled "Please indicate the status of the study:" with three radio button options.

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 'Study Document Add' popup form. The background is a dark grey sidebar with 'My Workspaces' and 'Section view of the Form' (1.0 Amendment Information). The main content area shows 'Internal Study Personnel Changes - (Version 1.0)' with fields for IRB Number (H-31000), Study Alias (2-18-2011-), and PI (Administrator). The popup form has a title bar 'Study Document Add:' and a close button (X). It contains the following fields:

- *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 preview of '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'.0.
- Version Date:** A date input field containing '11/06/2023' with a calendar icon. 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 text area.
- Comments:** A large text area.

At the bottom of the popup are two buttons: 'Close, don't save any changes' and 'Save Document'. A grey arrow points to the 'Save Document' button.

Below the popup, the background form has a section 'Please indicate...' with radio button options:

- ☒ Additional subjects will be consented to this study.
- ☐ No additional subjects will be consented to this study.
- ☐ 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.

At the bottom of the page, a footer note states: '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 (blue arrow)
- Scroll down to the next section (green arrow).

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

? 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

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
	1.0		Signed PI Responsibilities document	Signed PI or Supervising PI Responsibilities			 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



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

30

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.

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

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

My Workspaces

Section view of the Form

1.0 Amendment Information

1.7 Personnel

Use the "Add" button to add new personnel. Existing personnel changes will be reflected in the list.

Assign

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:

Setup Study Personnel

User Search

Remove Personnel List

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.

The screenshot shows the 'Setup Study Personnel' window in the INSPIR system. A blue arrow points to the 'User Search' tab on the left. A green arrow labeled '1' points to the 'Last Name' input field. A yellow arrow labeled '2' points to the 'Find User/Search Directory' button. The window displays search criteria and a table for 'Selected Study Personnel'.

Setup Study Personnel

Account: Administrator
Department: BME/UMS
Path: Home

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

User Search (blue arrow)

Last Name: (green arrow 1) First Name:
by Department: All Departments (dropdown) Find User/Search Directory (yellow arrow 2)

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” pop-up.

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 shows a web application interface with a modal dialog titled "Setup Study Personnel" and a sub-header "Add Personnel Role". The dialog is for adding a role for "Khaled Khattar, BA".

Inside the dialog, there are five radio button options for roles:

- ☐ Principal Investigator
- ☒ Additional Investigators
- ☐ Research Support Staff
- ☐ Study Contact
- ☐ Supervising Principal Investigator

Below the radio buttons, there are two dropdown menus:

- The first dropdown is labeled "Co-Investigator" and has a blue arrow pointing to it.
- The second dropdown is labeled "--none--" and has a blue arrow pointing to it.

At the bottom of the dialog, there is a question: "Would you like to include as a Study Contact ?". It has two radio button options: "Yes" and "No". A yellow arrow points to the "Yes" option.

At the bottom right of the dialog, there are two buttons: "Cancel" and "Save". A red arrow points to the "Save" button.

The background of the application shows a sidebar with "Department", "Path: Home", "IRB Number: H-3", "Study Alias: 2-18-2", "PI: Administrator", and a "User Search" section. The main content area shows "Entire view of", "(Please remember)", "1.7 Personnel", "Use the 'Add existing Person' changes will", "Assign", "If applicable", "If applicable", "A) Addition", "B) Research Staff", and "If applicable, please add".

- 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.

Account: Administrator

Department: BMC/BIHMC MED Institutional Review Board

Path: Home

IRB Number: H-3

Study Alias: 2-18-2

PI: Administrator

Entire view of

(Please remember)

1.7 Personnel

Use the "Add Existing Personnel" button to add existing personnel. Any changes will be reflected in the list.

Assign

If applicable

If applicable

A) Addition

B) Research

Setup Study Personnel

User Search

Remove Personnel List

Create My Personnel Pool

Last Name: Khattar

First Name:

by Department: All Departments

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 Investigator

Name	Role
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 (green arrow)

Create My Personnel Pool

Last Name: Khattar First Name:

by Department: All Departments

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
Khattar, Khaled, BA	Co-Investigator

Clear Key Study Personnel Close Setup of Study Personnel

- 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/BIH/MSD - Institutional Review Board
Path: Home

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

Remove Personnel List

Create My Personnel Pool

	User Search	
<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
X Khattar, Khaled, BA	Co-Investigator

Save Selections

Clear Key Study Personnel Close Setup of Study Personnel

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).

Path: Home

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

Entire view of

(Please remember)

1.7 Personnel

Use the "Add Existing Personnel" button to add existing personnel. Any changes will be reflected in the list.

Assign

If applicable

If applicable

A) Addition

B) Research

If applicable

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).

Department: BMC/BUAC MED - Health Care Delivery Research

Path: Home > Study Setup > Study Personnel

IRB Number: H-3

Study Alias: 2-18-2

PI: Administrator

Entire view of study

(Please remember to save your changes)

1.7 Personnel

Use the "Add Existing Personnel" button to add existing personnel to the study. Any changes will be reflected in the "Study Personnel" table.

Assign Personnel

If applicable, select the role for each personnel.

If applicable, select the role for each personnel.

A) Additional Personnel

B) Research Personnel

If applicable, select the role for each personnel.

Setup Study Personnel

User Search

Remove Personnel List

Create My Personnel Pool

<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

Save Selections

Clear Key Study Personnel

Close Setup of Study Personnel

- 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)



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.
 - 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:

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

1

☐ 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.*

1

☐ 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 COAI offices. It is a violation of institutional policy to engage in human subjects research without complying with the institution's COI policy.

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
EXCEPTIONAL CARE, WITHOUT EXCEPTION.

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

? HelpMy ProfileLog out

My WorkspacesStudy AssistantInternal Study Personnel Changes - (Version 6.0)Back

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

Print FriendlyRefresh Constant FieldsSave SectionSave and Continue to Next Section

Section view of the FormEntire view of the Form

1.0Amendment Information

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, PhDAdministrative Assistant

1

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.

BOSTON UNIVERSITY MEDICAL CAMPUS 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 Signoff and Submit

Section view of the Form Entire view of the Form

1.0 Amendment Information

Form has been Completed!
Instruction of Form has Been Completed Screen

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.

Signoff and Submit

Signoff and Submit

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>