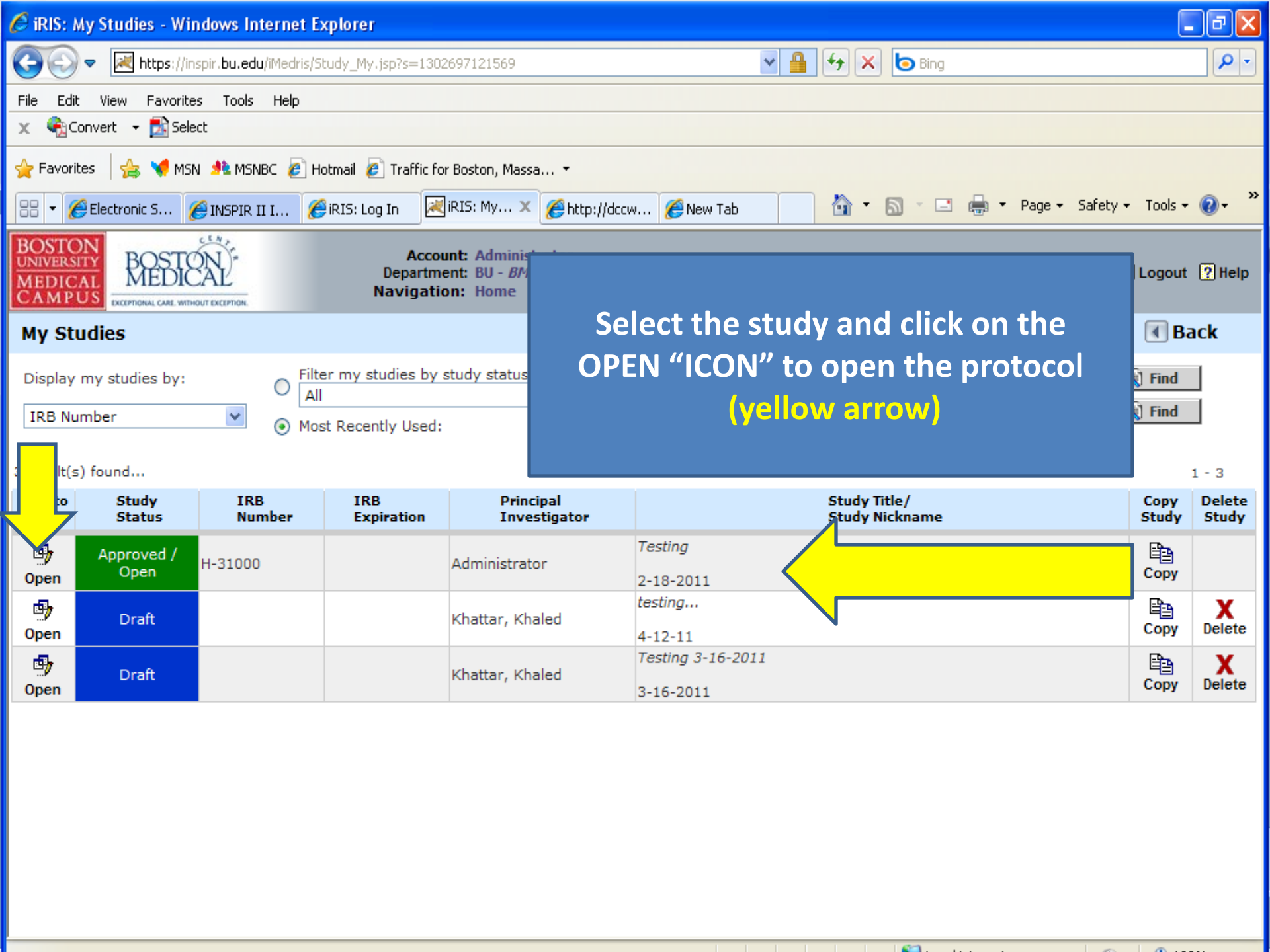


# How to Create and Submit an Amendment in INSPIR II



Account: Administrator  
Department: BU - BM  
Navigation: Home

Logout Help

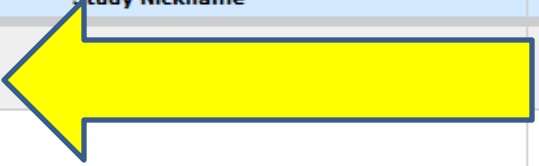
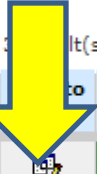
### My Studies

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

1 result(s) found...

	Study Status	IRB Number	IRB Expiration	Principal Investigator	Study Title/ Study Nickname	Copy Study	Delete Study
Open	Approved / Open	H-31000		Administrator	Testing 2-18-2011	Copy	
Open	Draft			Khattar, Khaled	testing... 4-12-11	Copy	Delete
Open	Draft			Khattar, Khaled	Testing 3-16-2011 3-16-2011	Copy	Delete

Select the study and click on the OPEN "ICON" to open the protocol (yellow arrow)



This opens the STUDY MANAGEMENT page for the protocol.

From here you can

- Make sure that there are NO current “Change Request & Amendments” form or “Continuing Review Submission Form” pending
- Create an Amendment.

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

Account: Administrator  
Department: BU - BMC - MEDICINE  
Navigation: Home > my studies

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

Study Status: **Approved / Open** Study Title: Testing  
Expiration Date:

**Submissions**

Submissions | Study Management

**Protocol Items**

- Application
- Informed Consent
- Other Study Documents
- Miscellaneous
- Study Correspondence
- Submissions History
- Study Notebook
- Forms
- Recruitment Materials

**Submission Forms**

- Adverse Event Form
- Change Request & Amendments
- Continuing Review Submission Form
- Final/Closure Report Form
- Initial Review Submission Form
- Internal Study Personnel Changes
- Protocol Deviation/Violation Form
- Protocol Exception Form

**Outstanding Submission(s)**



Track Location	Ref Number	Request Type	Process Submission
	318115	Click on the hyperlink to edit/view the submission. Internal Study Personnel Changes	Send Submission

**Annotations:**

- A yellow arrow points from the text box to the "Outstanding Submission(s)" table.
- A red arrow points to the "Submissions History" link in the "Protocol Items" list.

a. There are no pending amendments or PRs in “Outstanding Submissions” (yellow arrow). Also, click on “Submission History” (red arrow) to see if there are any amendments or PRs pending (in IRB office) - “Internal Study Personnel Changes” forms are allowed.

If you have determined there are no amendments or progress reports in Outstanding Submissions or in Submission History – then you can go ahead and create an amendment by clicking on Change Request & Amendments form [green arrow] from the Column titled SUBMISSION FORMS (red arrow)

Account: Administrator  
 Department: BU - BMC - MEDICINE  
 Navigation: Home > my studies

Home Logout Help

IRB Number: **H-31000** Study Nickname: 2-18-2011 Submissions [Back](#)

PI: Administrator

Study Status: **Approved / Open** Study Title: Testing

Expiration Date:

Submissions

Study Management

**Protocol Items**

- Application
- Informed Consent
- Other Study Documents
- Miscellaneous
- Study Correspondence
- Submissions History
- Study Notebook
- Forms
- Recruitment Materials

**Submission Forms**

- Adverse Event Form
- Change Request & Amendments
- Continuing Review Submission Form
- Final/Closure Form
- Initial Review Submission Form
- Internal Study Personnel Changes
- Protocol Deviation Violation Form
- Protocol Exception Form

**Outstanding Submission(s)**

Track Location	Ref Number	Request Type	Process Submission
	318115	Click on the hyperlink to edit/view the submission. Internal Study Personnel Changes	<input type="button" value="Send Submission"/>



Click on the "Add a New Form" button . (red arrow)  
This will create a new Change Request & Amendments form.

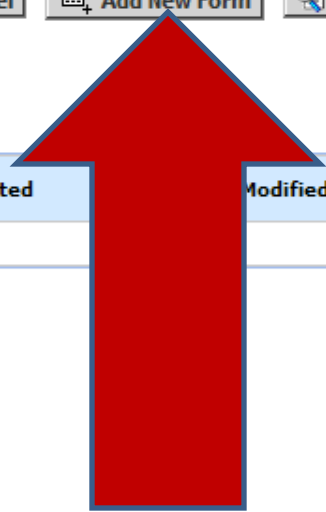
Study Status: **Approved / Open** Study Title: Testing  
Expiration Date:

Export to Excel Add New Form Compare Two Versions Delete Selected Form(s)

List of records associated with form: Change Request & Amendments.  
To view previous versions click on the folder icon.

0 result(s) found...

<input checked="" type="checkbox"/>	Show Rev	Edit/View	Created By	Date Created	Modified By	Date Modified
No records have been created.						



This will bring you to the Change Request & Amendments form.

Complete Section 1.1 and then use the scroll bar (red arrow) to scroll down to the next section of the form.

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

Account: Administrator  
Department: BU - BMC - MEDICINE  
Navigation: Home > my studies > study mgmt. > change request list

Home Logout Help

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

## Change Request & Amendments

Back

Printer Friendly Save and Continue to the Next Section

Section view of the Form Entire view of the Form

1.0 Amendment Information

### 1.0 Amendment Information

**1.1 Note: This Amendment cannot be used to add/remove study personnel from "3.0 internal Study Personnel" section. To add/remove personnel from section 3.0, you need to submit the "Internal Study Personnel Changes" form instead. For more information click [here](#).**


Other than changes to the "3.0 Internal Study Personnel" section, this amendment can be used to make changes to the study application, consent form(s), and study documents.

Amendment Reason:  
--none--

Does this amendment change the risk/benefit ratio?  
 Yes  No

(Please note that amendments which change a protocol's risk/benefit ratio almost always require a change in the consent form).

Briefly (<300 words) describe the amendment and indicate which portions of the protocol and/or consent form you will be modifying. If the risk/benefit ratio is changing but you are not changing the consent form, indicate the reasons below.





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

## Change Request & Amendments

[Back](#)[Printer Friendly](#)[Save and Continue to the Next Section](#)

### Section view of the Form

### Entire view of the Form

#### 1.0 Amendment Information

#### 1.2 Changes to the Application

Use this section to amend the application if this amendment requires a change in personnel, consent forms, or study attachments. To amend the application, click on "Add Revision" to create a new version of the application. Or, to attach an existing revision to this submission, click on "Save Attachments".

[Click here to attach the application.](#)

No Application has been associated with this submission.

#### 1.3 Add/Modify a Consent Form

Skip this section if you do not need to add a new consent form to the study or if you don't need to make any changes to an existing one. Else, click on the link below to go to the Consent Forms list. In the Consent Forms list, click on Create Form to create a new consent form; to add a revised one, click on Add a Revision; to attach an existing revision to this submission, check the little Check box on the left and then click on Save Attachment.

[Click here to attach a new informed consent.](#)

No informed consent has been associated with this submission.

#### 1.4 Add/Modify a Study Attachment

[Click here to attach any study document.](#)

No electronic document has been associated.

If there are changes to be made to the study application, click on this green bottom to create a revision of the application and attach it.

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

Back

*Click the checkbox to select the application(s) to attach.*  
Click the **Save Attachments** to attach or unattach forms.  
Click the **Delete Revision** button to delete the selected application.

Save Attachments

	Show Rev.	Edit/View	Form Name	Create a Revised Application
			Study Application (Version 1.0)	Add Revision

Click on "Add Revision" to create a new revision and make changes to it

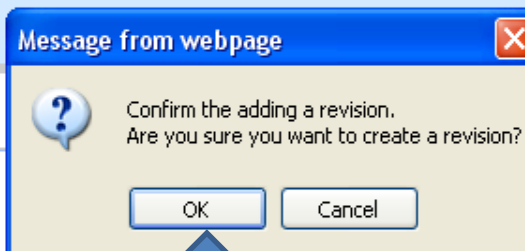
IRB Number: **H-31000** Study Nickname: 2-18-2011  
PI: Administrator

## Attach Study Application

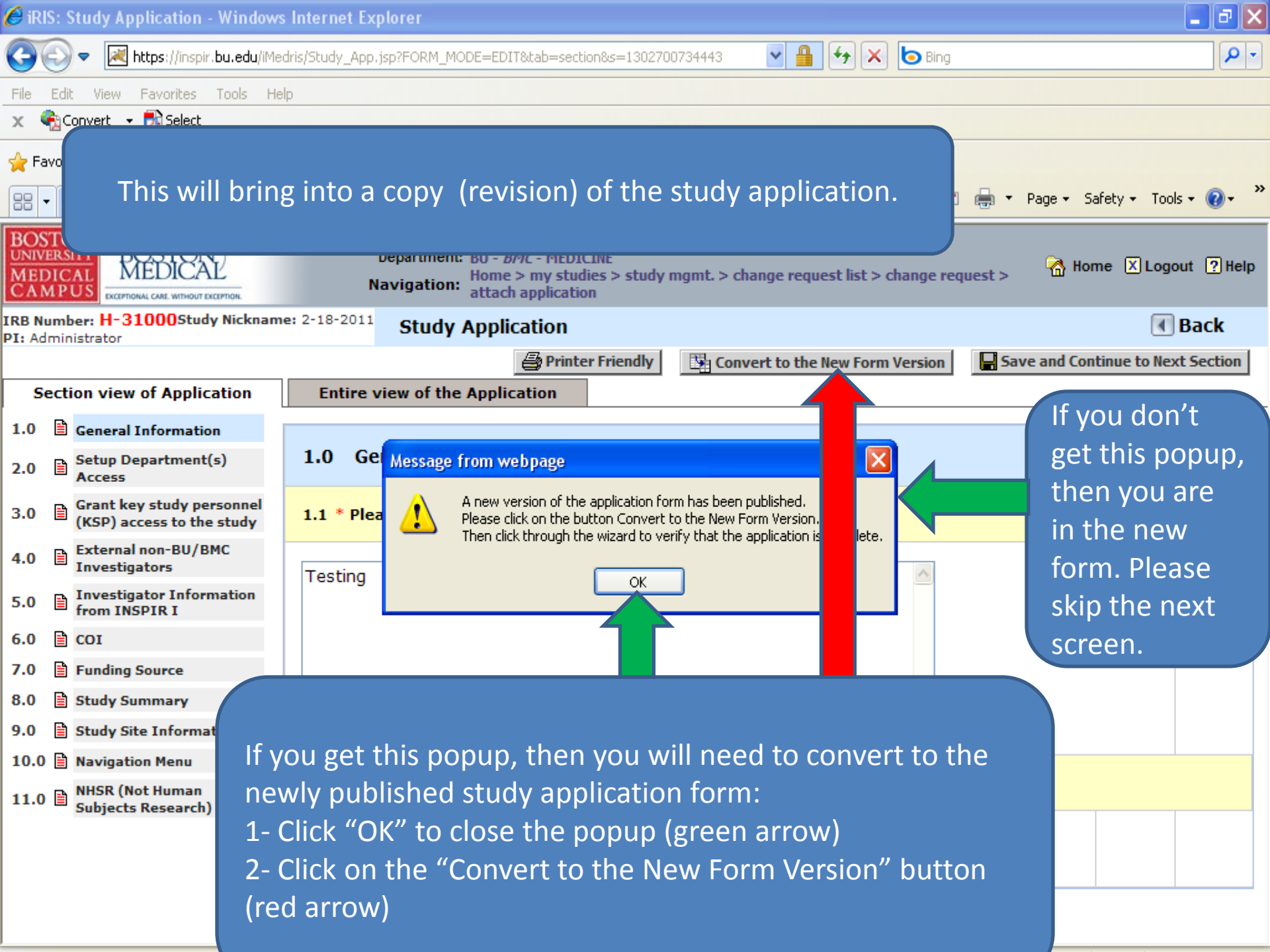
[Back](#)

*Click the checkbox to select the application(s) to attach.*  
Click the **Save Attachments** to attach or unattach forms.  
Click the **Delete Revision** button to delete the selected application.

<input type="checkbox"/>	Show Rev.	Edit/View		Create a Revised Application
			Study Application (Version 1.0)	<input type="button" value="Add Revision"/>



Click "OK" to proceed.




This will bring into a copy (revision) of the study application.

If you don't get this popup, then you are in the new form. Please skip the next screen.

If you get this popup, then you will need to convert to the newly published study application form:  
1- Click "OK" to close the popup (green arrow)  
2- Click on the "Convert to the New Form Version" button (red arrow)

**Message from webpage**

 A new version of the application form has been published. Please click on the button Convert to the New Form Version. Then click through the wizard to verify that the application is complete.

- Section view of Application
- 1.0 General Information
- 2.0 Setup Department(s) Access
- 3.0 Grant key study personnel (KSP) access to the study

Entire view of the Application

1.0 General Information

1.1 \* Please enter the full title of your study (Spell out acronyms):

Testing

1.2 \* Please enter the Study Nickname you would like to use

2-18-2011

\* This field allows you to enter an abbreviated version of the Study Title

When converted, the system will hide all sections except the first three. Don't worry, nothing is lost!

Start clicking "Save and Continue to the Next Section" until all sections reappear and you have made all your changes along the way. Once the application is complete, the system will automatically take you back to the "Attach Study Application" page (next slide)



Account: Administrator  
Department: BU - BMC - MEDICINE  
Navigation: Home > my studies > study mgmt. > change request list > change request

Home Logout Help

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

## Attach Study Application

Back

Click the **checkbox** to select the application(s) to attach.  
Click the **Save Attachments** to attach or unattach forms.  
Click the **Delete Revision** button to delete the selected application.

Delete Version

Save Attachments

<input type="checkbox"/>	Show Rev.	Edit/View	Form Name	Create Revision Application
<input checked="" type="checkbox"/>			Study Application (Version 1.1)	

1- Make sure this check box is checked

2- Click "Save Attachment" to attach this new revision of the study application to the amendment

Section view of the Form

Entire view of the Form

1.0 Amendment Information

1.2 Changes to the Application

Use this section to amend the application if this amendment requires a change to the application other than changes to study personnel, consent forms, or study attachments. To amend the application, click on the link below to go to the application list. Then click on "Add Revision" to create a new version of the application. Once you're done modifying the application, attach it to this submission by clicking on "Save Attachments".

Click here to attach the application.

Show Rev.	Edit/View	Version	Title
		1.1	Study Application (Version 1.1)

Note the new revision attached here in the amendment.

1.3 Add/Modify a Consent Form

Skip this section if you do not need to add a new consent form to the study or if you don't need to make any changes to an existing one. Else, click on the link below to go to the Consent Forms list. In the Consent Forms list, click on Create Form to create a new consent form; to add a revised one, click on Add a Revision; to attach an existing revision to this submission, check the little Check box on the left and then click on Save Attachment.

Click here to attach a new informed consent.

No informed consent has been associated with this submission.

Scroll down here to complete the rest of the form

1.4 Add/Modify a Study Attachment



## Change Request &amp; Amendments

[Back](#)[Printer Friendly](#)[Save and Continue to the Next Section](#)

## Section view of the Form

## Entire view of the Form

1.0 [Amendment Information](#)

Then click on "Add Revision" to create a new version of the application. Once you're done modifying the application, attach it to this submission by clicking on "Save Attachments".

[Click here to attach the application.](#)

Show Rev.	Edit/View	Version	Title
		1.1	Study Application (Version 1.1)

## 1.3 Add/Modify a Consent Form

Skip this section if you do not need to add a new consent form to the study or to modify an existing one. Else, click on the link below to go to the Consent Forms list. To create a new consent form; to add a revised one, click on Add a Revision; check the little Check box on the left and then click on Save Attachment.

[Click here to attach a new informed consent.](#)

No informed consent has been associated with this submission.

## 1.4 Add/Modify a Study Attachment

[Click here to attach any study document.](#)

No electronic document has been associated.

If you need to add or make changes to the consent form(s), click on this button. Click on one of the links below for instructions on how to:

- [Add a new consent Form](#)
- [Revise a consent form](#)



Account: Administrator  
Department: BU - BMC - MEDICINE  
Navigation: Home > my studies > study mgmt. > change request list

Home Logout Help

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

### Change Request & Amendments

Back

Printer Friendly

Save and Continue to the Next Section

If you need to add or make changes to a Study Document, click on this button. Click on one of the links below for instructions on how to:

- [-Add a new document](#)
- [-Revise an existing document](#)

When you're done with the amendment, click on "Save and continue to the next section" to close this form and/or send it to the PI for sign off.

Click here to attach any informed consent.

No informed consent has been associated with this submission.

#### 1.4 Add/Modify a Study Attachment

Click here to attach any study document.

No electronic document has been associated.