

# How to Create and Submit a “Change Request and Amendments” Form in INSPIR II

- You should not create a “Change Request and Amendments” form while another “Change Request and Amendments” form is still pending IRB review. The system will prevent you from submitting it.
- A Revision of a Study Document should be made (and attached) only in the “Change Request and Amendments” form and not in the Study Application.



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## My Work

This opens the study into the “Submissions” tab.

The screenshot shows the IRB submission interface. On the left, a table lists studies with columns for 'Select a Study', 'Study Status', and 'Review Board'. The 'Study Status' column includes options like 'Exempt - limited IRB review', 'Closed - Ceded Review', 'Draft', and 'Inactive - Administratively Closed'. A yellow callout box is overlaid on the 'Change Request and Amendments' row, containing the text: 'Click on “Start a New Submission” icon that corresponds to the “Change Request and Amendments” - blue arrow'. An orange arrow points to the 'Version List' icon (a document with a list) in the 'Change Request and Amendments' row. A blue arrow points to the 'Start a new Submission' icon (a document with a plus sign) in the same row. The background interface includes a 'Submission Form List' window with filters for 'Study Status', 'IRB Number', and 'Study Title', and a table of submission forms with columns for 'Available Forms', 'Version List', 'Start a new Submission', and 'Edit Incomplete Submissions'.

- NOTE: You should not create a new “Change Request and Amendments” submission form while another “Change Request and Amendments” form is still pending IRB review. To check if you already have one pending IRB review or one that is still in draft form and can be used instead of creating a new one, click on the “Version List” icon (orange arrow)



Next, you need to answer 3 questions about whether or not you will be making changes to the Study Application, adding or revising one or more consent forms, and/or adding or revising one or more study documents. If you answer “Yes” to any of these 3 questions, the appropriate section will be included in the next section. Complete these questions and then click on “Save and Continue to Next Section” (green arrow) to save and proceed.

Administrator

Print Friendly

Refresh Constant Fields

Save Section

Save and Continue to Next Section

Signoff and Submit

Section view of the Form

Entire view of the Form

1.0 Amendment Information

Changes to Study Application, Consent Form(s), or Study Docu ...

1.3

Note: This Change Request and Amendments form 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 instructions on how to submit the "Internal Study Personnel Changes" form, click on the (?) icon below.

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

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

NOTE: You cannot submit multiple "Change Request and Amendments" forms (this form) at the same time. If you already have another "Change Request and Amendment" form pending IRB review, you need to wait until it had been approved by the IRB before creating a new "Change Request and Amendments" forms (this form).

Amendment Description:

Please describe the amendment in detail below. Include an explanation for why these changes are necessary. If the risk/benefit ratio of the study is changing, but you are not changing the consent form, explain the reasons below. (Make sure you click on the "Save Section" button to save your answer)

test

This page becomes the cover sheet for the amendment report. If changes to the study application, consent form(s), or study attachments are indicated above, or if you are adding new documents, you need to address the appropriate section below before submitting this amendment to the IRB.

1) Do these changes require revisions to the application?

☒ Yes ☐ No

2) Do these changes require revisions to the consent form(s), or the addition of a new consent form(s)?

☒ Yes ☐ No

Do subjects need to be re-consented to be informed of these changes? Why or why not? Please explain. If re-consent is necessary, please explain your process and timeline for re-consenting current subjects.

test

3) Do these changes require revisions to any other study documents (protocol, survey, exempt information sheet, etc), or the addition of new documents?

☒ Yes ☐ No

?

1

2

3

6

If you wanted to make changes to the Study Application and therefore you have answered “Yes” to question # 1) in the previous section, you should have question “2.1 Changes to the Application” visible.

PI: Administrator

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 An amendment is any change or mo ...

2.0 Changes to Study Application, Consent Form(s), or Study Docu ...

2.1 Changes to the Application

Use this section to amend the Study Application if this amendment requires a change to the application. the grey button below to go to the application list. Then click on "Add Revision" to create a new version Attachments".

Click here to attach the application.

No Application has been associated with this submission.

To make changes to the Study Application, click on this grey bottom to create a revision of the Study Application and attach it.

If no changes will be made to the Study Application, you should not have this question. In this case, skip to page # 14.

The system will open the “Attaching Study Application” popup.

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

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

Study Change Request and Amendments - (Version 9.0)

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  
2.0 Changes to Study Application, Consent Form(s), or Study Document(s)

2.1 Changes to the Application

Use this section to amend the Study Application if this below to go to the application list. Then click on "Add Application".

Click here to attach the application.

No Application has been associated with this submission.

2.2 Add/Modify a Consent Form

- To revise an existing consent form, click on the revisions. Be sure to "check-in" the revised consent form.
- To create a new consent form, click on the "Add New Consent Form" button.

Select or Revise Existing

Detach	Version	Sponsor Version	TRB
No Consent(s) have been attached to this form.			

2.3 Add/Modify a Study Attachment

Attaching Study Application

Select the application that you would like to attach and then click Save Attachment

Save Attachment

Select	Show Rev.	Edit/View	Form Name	Approved	Create a Revised Application
Already Submitted			Study Application (Version 1.6)	Yes	Add Revision

Consent Outcome View Document

You will get a popup. Click on “Add Revision” to create a new revision and make changes to it.

Note: If you don't see “Add Revision” on the right, this means that a revision was already created, and you can use that one to make your changes. In that case, you would click on the “Edit/View” icon and skip to page # 10.



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

HelpMy ProfileLog out

Study Numbers: H-31000  
Study Alias: 2-18-2011  
Administrator

StudyChange Request and Amendments - (Version 9.0)Back

Print FriendlyRefresh Constant FieldsSave SectionSave and Continue to Next Section

Entire view of the Form

2.0 Changes to Study Application, Consent Form(s), or Study Document(s)

2.1 Changes to the Application

Use this section to amend the Study Application (if this is the case, click on the "Add" button below to go to the application list. Then click on "Add Application" to add a new application.)

Click here to attach the application.

No Application has been associated with this submission.

2.2 Add/Modify a Consent Form

To revise an existing consent form, click on the "Revisions" button. Be sure to "check-in" the revised consent form.

To create a new consent form, click on the "Add New Consent Form" button.

Select or Revise Existing

DetachVersionSponsor VersionTID

No Consent(s) have been attached to this form.

2.3 Add/Modify a Study Attachment

To upload a new document, click on the "Add New Document" button. If the document you wish to upload is already listed below, you can click on the "Attach" button to attach the document to the study.

Attaching Study Application

Select the application that you would like to attach and then click Save Attachment

Save Attachment

Select	Show Rev.	Edit/View	Form Name	Approved	Create a Revised Application
Already Submitted				Yes	

Confirm the adding a revision.

Are you sure you want to create a revision?

CONFIRMCANCEL

Consent OutcomeView Document

Click "Confirm" to proceed. The system will create a revision (read-write copy) of the Study Application and open it for editing.

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Note: Every few months or as needed, the IRB adds new questions to the Study Application and publishes it. The “Convert to the New Form Version” is the system’s way to bring your Study Application up to the most recent version.

The screenshot shows the Boston University Medical Campus Study Application interface. At the top, the header includes the university logo, account information (Administrator), and navigation links. The main content area displays the 'Study Application (Version 1.7)' form. A popup message titled 'New Form Version has been published' is centered on the screen. The popup contains an information icon, a message stating that a new version of the form has been published, and instructions to click the 'Convert to the New Form Version' button. A green arrow points from the bottom yellow callout to the 'Convert to New Form Version' button in the popup. A yellow callout on the left side of the screen provides instructions on how to handle the popup if it is not displayed.

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

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

Study Application (Version 1.7)

Print Friendly Convert to the New Form Version Save Section Save and Continue to Next Section

Section view of Application Entire view of the Application

1.0 General Information  
2.0 Information about your study::  
3.0 Information about the study you would like to use  
4.0 Information about the abbreviated version of the Study Application

16.0 Confidentiality  
17.0 HIPAA Compliance  
18.0 Cost/Payment  
19.0 Biological Sample Collection  
20.0 Drugs or Biological Agents  
21.0 Devices  
22.0 Retention of Samples or Data  
23.0 Study Attachments

**New Form Version has been published**

**i** A new version of the Study Application Form ( Study Application ) has been published.  
Please click on the Convert to the New Form Version button.  
New Sections and Questions may be present on this form so please click through each section to verify that the application is complete.

Convert to New Form Version

If you don't get this popup, then you are already in the newest form version.  
Please skip to page # 12.

If you do get this popup, then you will need to convert to the newly published Study Application form:

Click “Convert to New Form version” to close the popup (green arrow) and convert to the newly published Study Application form. Continue to the next page.

This page only applies if you need to convert to the newly published Study Application form.

Account: Administrator  
Department: BMC/BUHC - MED - Institutional Review Board  
Path: Home > study mgmt. > change request list > change request

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

My Workspaces

Study Application (Version 1.7)

Print Friendly Save Section Save and Continue to Next Section

Section view of Application Entire view of the Application

23.0 Study Attachments

23.1 Attach here any remaining study documents that you have not attached in previous sections.

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.							

The system will start converting to the new form section by section. If a section has a new question that is required, the system will stop there and hide all subsequent sections until you answer the new question. Don't worry, nothing is lost in these hidden sections!

1- Start clicking "Save and Continue to the Next Section" until all relevant sections reappear and you have answered all new questions (you can also make some or all your amendment's changes along the way).

23.0 Study Attachments

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

The system automatically takes you back to the “Change Request and Amendments form” page and attach the revised Study Application to the amendment’s submission components (assuming the Study Application was completed).

**BOSTON UNIVERSITY MEDICAL CAMPUS** **BOSTON MEDICAL CENTER**  
Account: Administrator  
Department: BMC/BUMC - MED - Institutional Review Board  
Path: Home > study mgmt. > change request list

My Workspaces ☒ IRB Number: **H-31000** Study **Change Request and Amendments - (Version 9.0)** [Back](#)

Study Alias: 2-18-2011- PI: Administrator

[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**

**2.0 Changes to Study Application, Consent Form(s), or Study Document(s)**

**2.1 Changes to the Application**

Use this section to amend the Study Application if this amendment requires a change to the application other than changes to the application list. Then click on "Add Revision" to create a new version of the application. Once you're done modifying the application, click on "Save" to save the application.

Deattach	Revise/Attach	Edit/View	Title
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Study Application (Version 1.7)

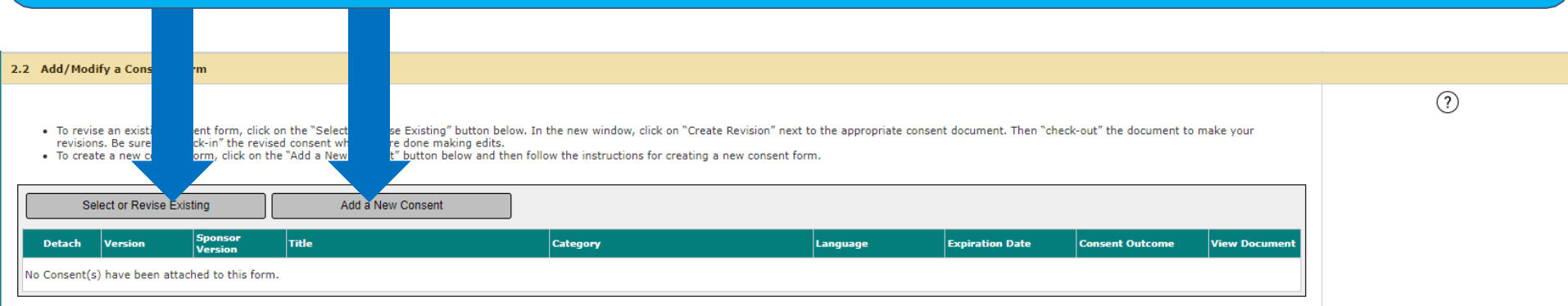
If the new revision of the Study Application was completed, it should now appear (be attached) here in the amendment. If you want to make more changes to the Study application, you can now access this version from this form by clicking on the “Edit/View” icon.

If you wanted to add a new consent form or revise one or more of the existing consent forms and therefore you have answered “Yes” to question # 2) in the previous section 1.0, you should have question “2.2 Add/Modify a Consent Form” visible.

If you need to make changes to the consent form(s), click on the “Select/Revise Existing” button. If you need to add a new consent form, click on the “Add a New Consent” button. Click on one of the links below for instructions on how to:

[-Revise a consent form](#)

[-Add a new consent Form](#)



2.2 Add/Modify a Consent Form

• To revise an existing consent form, click on the “Select/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 are done making edits.  
• To create a new consent form, click on the “Add a New Consent” button below and then follow the instructions for creating a new consent form.

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.								

?

If you are not adding or revising any study documents, you should not have this question. In this case, skip to the next page.

If you wanted to add a new study document or revise one or more of the existing documents and therefore you have answered “Yes” to question # 3 in the previous section 1.0, you should have question “2.3 Add/Modify a Study Attachment” visible.

If you need to make changes to the consent form(s), click on the “Select/Revise Existing” button. If you need to add a new consent form, click on the “Add a New Document” button. Click on one of the links below for instructions on how to:

[-Revise an existing document](#)

[-Add a new document](#)

**2.3 Add/Modify a Study Attachment**

To upload a new document or revise an existing one, click on the button below. If you need help (?) and follow the corresponding instructions/screenshots. Any newly uploaded/revise document needs to be attached (listed) here. If the document was uploaded but it's not listed below, you need to manually attach it here. To add a new document to this section, click on the "Select or Revise Existing" button below to go to the Study Documents list. Locate the document and click on the Plus sign icon to the left of the document you wish to amend.

Select or Revise ExistingAdd a New DocumentAdd Multiple Documents

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

?

If you are not adding or revising any study documents, you should not have this question. In this case, skip to the next page.





The system automatically takes you to the “Form has been Completed!” page .

The screenshot displays the IRB system interface. At the top, the header includes the Boston University Medical Campus logo, account information (Administrator, BMC/BUMC - MED - Institutional Review Board), and navigation links (Home > study mgmt. > change request list). The main content area shows a teal banner with the message "Form has been Completed!" and the subtext "Grant Key Personnel access to the study". Below this, there are two buttons: "Signoff and Submit" and "Exit Form". A yellow callout box on the left points to the "Amendment Information" link in the left sidebar, stating: "If you want to go back into the amendment, click on 'Amendment Information'". A yellow callout box on the right points to the "Signoff and Submit" button, stating: "Click on 'Signoff and Submit' or 'Notify PI for Signoff' if you're ready to submit to the IRB." A yellow callout box at the bottom points to the "Exit Form" button, stating: "Click on 'Exit Form' to exit this form and come back later."

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

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

Study Change Request and Amendments - (Version 9.0)

Print Friendly Signoff and Submit

Section view of the Form Entire view of the Form

1.0 Amendment Information  
Changes to Study  
2.0 Application Form(s)

**Form has been Completed!**  
Grant Key Personnel access to the study

Signoff and Submit  
Exit Form

If you want to go back into the amendment, click on “Amendment Information”.

Click on “Signoff and Submit” or “Notify PI for Signoff” if you’re ready to submit to the IRB.

Click on “Exit Form” to exit this form and come back later.