

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.

Featured Study Operations

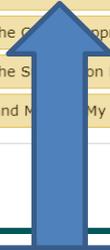
- Create a New Study
- Start a Submission Form for one of My Studies
- View the Approvals for one of My Studies
- View the Submission History for one of My Studies
- View and Manage My Studies

By the Numbers

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

Tasks

All Tasks	35
Study Tasks	33



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

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

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

Instructions: Select a study to work with, click to open it and start a Submission Form. You may use the search bar to find a specific study.

All Studies **Recently Used** Study Status

Search for RB Number, Title, Alias Search

All Draft IRB

54 result(s) found... 1 - 10

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

54 r... found... 1 - 10

Cancel Search

You can use the “Search” box to locate the study. Or you can just scroll down.

Once you locate the study, click on the “Select a Study” icon

This opens the study into the “Submissions” tab.

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			
Recruitment M			
Reportable Ev			

Click on “Start a New Submission” icon that corresponds to the “Change Request and Amendments”- blue arrow

- 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)

This will bring you to the Change Request and Amendments form. This is section "1.0 Amendments Verification". Depending on the study classification, this section might look different. Studies classified as exempt or ceded review will have additional questions in this section to determine if an amendment is needed. Answer these questions (if there are any) and follow what the resulting instructions tell you. If the instructions tell you that no amendment is needed, then just click on the "Back" button without saving and you're done.

If the system tells you that an amendment is needed, or if there are no additional questions (i.e. non-exempt study), then click on the "Save and Continue to Next Section" button to proceed (green arrow).

My Workspaces ▾ IRB Number: **H-31000**
Study Nickname: 2-18-2011-
PI: Administrator Study Assistant

Change Request and Amendments - (Version 10.0) 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 Amendments Verification

1.0 Amendments Verification

1.1 Study Information:

IRB Number:
H-31000

Study Title:
Testing

Principal Investigator:
Administrator

IRB Study Classification:
Exempt

This will bring you to section “2.0 Amendment Information”. Depending on the study classification, this section might look different. Complete question 2.3 “Amendment Description”. Make sure you click on “Save Section” every time you update this section; otherwise, you will lose your work.

Next, you need to answer 3 questions about whether 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.

My Workspaces IRB Number: **H-31000** Study Assistant **Change Request and Amendments - (Version 10.0)** Back

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

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

1.0 Amendments Verification

2.0 **Amendment Information**

2.2 Amendments to exempt research are only required when the change(s) could potentially impact the exempt determination or when the change could alter IRB determinations (e.g., changes to any of the following: funding, confidentiality, recruitment, use of PHI, and retention for extra use). For more information, click [here](#).

2.3 **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 has been approved by the IRB before creating a new "Change Request and Amendments" form (this form).**

Amendment Description:

Please summarize the proposed changes for this amendment below. Make sure to explain:

- Describe why each change proposed is necessary (scientific or operational rationale); and
- Identify the materials (INSPIR application, data collection forms, etc.) that are affected by the changes and describe the changes made (e.g., "application Section 16.2 Confidentiality was updated...." or "Focus Group Guide Version 1.0 was modified..."); and
- If the study has an exempt information sheet(s), outline the revisions made to the exempt information sheet(s) to reflect the changes, or explain why revisions to the information sheet(s) are not needed.

(Make sure you click on the "Save Section" button to save your answer)

The above amendment description becomes the cover sheet for the amendment outcome letter. A cover sheet *summarizes* the changes made to the study application and/or attached documents. IT IS RARELY SUFFICIENT to input your proposed changes in an amendment form and leave your underlying application or other materials untouched. Please indicate which materials require revisions:

1) Do these changes require revisions to the application? [NOTE: Nearly ALL amendments require amending the application to document the changes.]

Yes No

2) If your currently-approved Exempt Information Sheet(s) is attached in the Informed Consent section, do the changes in this amendment require revisions to this form? Or, do these changes require the addition of a new Exempt Information Sheet(s)? (Note: Please answer No if the final version of your Exempt Information Sheet(s) is attached in the Other Study Documents section and instead click on the "Save and Continue to Next Section" button to proceed to the next question if it requires revisions)

Yes No

3) Do these changes require revisions to any other study documents (protocol, survey, recruitment scripts, exempt information sheet, etc.) or the addition of new documents? Changes are expected to be reflected in all applicable parts of a submission.

Yes No

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



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 “3.1 Changes to the Application” visible.

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/BJMC - 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) | 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
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, Consent Form(s), or Study Document(s)".

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	TIB
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	<input type="checkbox"/>		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](#).

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 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 Consent Form" button.

Select or Revise Existing

Detach	Version	Sponsor Version	TBR
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 Attachment" button. If the document you wish to attach is not listed below, you can upload the document you wish to attach.

Select or Revise Existing

Detach	Version
No Document(s) have been attached to this form.	

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?

CONFIRM CANCEL

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

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.

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

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

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

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.							

1.0 General Information
2.0 Setup Department(s) Access
3.0 Grant Key Personnel access to the study
4.0 Review Path Determination
5.0 Required Training and Conflict of Interest
6.0 Funding Source
7.0 Study Summary
8.0 Navigation
9.0 Study Site
10.0 Purpose
11.0 Subjects
12.0 Design/P
13.0 Risks & B Justificati approval
14.

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).

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

My Workspaces IRB Number: H-31000 Study Application (Version 1.7) Back

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.							

1.0 General Information
 2.0 Setup Department(s) Access
 3.0 Grant Key Personnel access to the study
 4.0 Review Path Determination
 5.0 Required Training and Conflict of Interest
 6.0 Funding Source
 7.0 Study Summary
 8.0 Navigation Menu
 9.0 Study Site Information
 10.0 Purpose
 11.0 Subjects
 12.0 Design/Procedure
 13.0 Risks & Benefits & Justification for Approval
 14.0 Data & Safety Monitoring
 15.0 Consent Procedures
 16.0 Privacy and 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

Please note: this is just an example. Your screen will look different depending on the type of your study. And depending on the branching, you will see less or more sections on the left.

We recommend that you always visit the last section “Review For Completeness” to verify that the Study Application is complete

Click on any section on the left (orange arrow), to jump to that section and make your changes. Once you made all your changes to the application and you have saved all the changed sections and the Study Application is complete, keep clicking “Save and Continue to Next Section” (green arrow) until the system automatically takes you back to the “Change Request and Amendments form” page (next slide)

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).

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

Study Assistant

Change Request and Amendments - (Version 10.0) 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 Amendments Verification
2.0 Amendment Information
3.0 Changes to Study Application, Consent Form(s), or Study Docu ...

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

3.1 Changes to the Application

Use this section to amend the Study Application if this amendment requires a change to the Study application list. Then click on "Add Revision" to create a new version of the application. Once you click on "Attachments".

Deattach	Revise/Attach	Edit/View	Title
			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 2.0, you should have question “3.2 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](#)

3.2 Add/Modify a Consent Form

- To revise an existing consent form, click here (<https://www.umc.bu.edu/irb/files/2016/10/How-to-revise-an-existing-Consent-Form.pdf>) and follow the instructions on revising an existing consent form. You must submit revisions to existing consents as a revision - do not submit revisions as new consents. Failure to submit as a revision may result in the amendment being returned to you.
- To create/add a new consent form, click here (<https://www.umc.bu.edu/irb/files/2016/10/How-to-Add-a-New-Consent-Form.pdf>) and follow the instructions on adding/creating a new consent form.
- If the consent forms need to be stamped by our IRB, please submit all new or revised consent forms as CLEAN (no track changes/comments) Word documents.

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 2.0, you should have question “3.3 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](#)

3.3 Add/Modify a Study Attachment

- To revise an existing study document, click here (<https://www.bumc.bu.edu/irb/files/2016/10/How-to-revise-an-existing-Study-Document.pdf>) and follow the instructions on revising an existing study document. You must submit revisions to existing study documents as a revision - do not submit revisions as new study documents. Failure to submit as a revision may result in the amendment being returned to you.
- To add a new study document, click here (<https://www.bumc.bu.edu/irb/files/2016/10/How-to-Add-a-New-Study-Document.pdf>) and follow the instructions on adding a new study document.
- Please submit revised documents as CLEAN (no track changes/comments) Word documents. If a revised study document is provided in a non-editable format (such as a pdf), you must submit an additional document with each change to the document tracked in comparison to the already-approved version ("redlined") or a comprehensive "summary of changes" document must be attached.

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.							

?

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

- Section view of the Form
- Entire view of the Form
- 1.0 Amendments Verification
- 2.0 Amendment Information
- Changes to Study Application, Consent Form(s), or Study Document(s), or Study Docu ...

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

3.1 Changes to the Application

Use this section to amend the Study Application if this amendment requires a change to the Study Application. To revise the application, click on the grey button below to go to the application list. Then click on "Add Revision" to create a new version of the application. Once you are done modifying the application, attach it to this submission by clicking on "Save Attachments".

Detach	Revise/Attach	Edit/View	Title
(X)			Study Application (Version 1.7)

3.2 Add/Modify a Consent Form

- To revise an existing consent form, click here (<https://www.bumc.bu.edu/irb/files/2016/10/How-to-revise-an-existing-Consent-Form.pdf>) and follow the instructions on revising an existing consent form. You must submit revisions to existing consents as a revision - do not submit revisions as new consents. Failure to submit as a revision may result in the amendment being returned to you.
- To create/add a new consent form, click here (<https://www.bumc.bu.edu/irb/files/2016/10/How-to-Add-a-New-Consent-Form.pdf>) and follow the instructions on adding/creating a new consent form.
- If the consent form needs to be stamped by our IRB, please submit all new or revised consent forms as CLEAN (no track changes/comments) Word documents.

Select or Revise Existing Add a New Consent

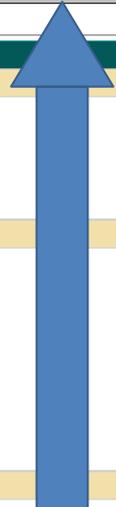
Detach	Version	Sponsor Version	Title	Category	Language	Expiration Date	Consent Outcome	View Document
(X)	1.0		Adult Consent Form Template	Adult Consent	English			1.11 MB

3.3 Add/Modify a Study Attachment

- To revise an existing study document, click here (<https://www.bumc.bu.edu/irb/files/2016/10/How-to-revise-an-existing-Study-Document.pdf>) and follow the instructions on revising an existing study document. You must submit revisions to existing study documents as a revision - do not submit revisions as new study documents. Failure to submit as a revision may result in the amendment being returned to you.
- To add a new study document, click here (<https://www.bumc.bu.edu/irb/files/2016/10/How-to-Add-a-New-Study-Document.pdf>) and follow the instructions on adding/creating a new study document.
- Please submit all revised documents as CLEAN (no track changes/comments) Word documents. If a revised study document is provided in a non-editable format (such as a pdf), your comparison to the already-approved version ("redlined") or a comprehensive "summary of changes" document must be attached.

Select or Revise Existing Add a New Document Add Multiple Documents

Detach	Version	Sponsor Version	Title	Category
(X)	1.0		Recruitment Materials _Adolescents	Recruitment/Advertising



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

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

The screenshot displays the IRB system interface. At the top, there is a header with 'My Workspaces', 'IRB Number: H-31000', 'Study Nickname: 2-18-2011-', 'PI: Administrator', 'Study Assistant', and 'Change Request and Amendments - (Version 10.0)'. On the right side of the header, there are buttons for 'Print Friendly' and 'Signoff and Submit'. Below the header, there is a navigation menu with 'Section view of the Form' and 'Entire view of the Form'. The main content area shows a green banner with the text 'Form has been Completed!' and 'Grant Key Personnel access to the study'. Below this banner, there are two buttons: 'Signoff and Submit' and 'Exit Form'. Three yellow callout boxes provide instructions: one pointing to 'Amendment Information' in the left sidebar, one pointing to the 'Signoff and Submit' button, and one pointing to the 'Exit Form' button.

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

Study Assistant

Change Request and Amendments - (Version 10.0) Back

Print Friendly Signoff and Submit

Section view of the Form Entire view of the Form

1.0 Amendments Verification
2.0 Amendment Information
3.0 Changes to Application Form(s), 0 Docu ...

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.