


# How to Add a New Consent Form

Note: You don't usually start here, this would be a continuation or a part of an Initial Review submission, an Amendment, or a Continuing Review submission.

If you haven't already done so, click on the green button to take you to the "Attach Informed Consent Document" page.



 **Click here to attach a new informed consent.**

No informed consent has been associated with this submission.



Study Nickname: 3-16-2011  
PI: Khattar, Khaled

### Attach Informed Consent Documents

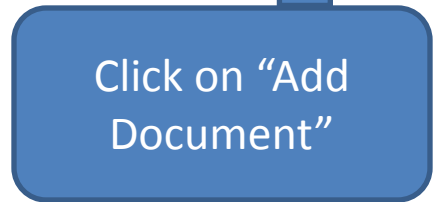
Back

*Click the checkbox to select/deselect the document(s).*  
Click the **Add New Document** button to add a new consent document.  
Click the **Add Revision** button to create a revised consent document.  
Click the **Delete Document** button to delete the selected consent documents.  
Click the **Save Attachments** to attach or unattach consent documents.

Add Document Save Attachments

<input type="checkbox"/>	Show Rev.	Edit/View	Version	UnApproved Consent	Approved Consent	Language	Review Outcome	Approval Date	Expiration Date	Checkout By	Create a Revised Document
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No inform consent document has been created for this study.



Study Nickname: 3-16-2011 Informed Consent Document Back  
PI: Khattar, Khaled

Study Status: **Draft** Study Title: Testing 3-16-2011  
Expiration Date:

- Add an informed consent from the list of Informed Consent Template Documents?
- Add an informed consent from an existing electronic document you already have?
- Add an informed consent from the list of Informed Consent Builder Templates?

Click here to upload Foreign language consent forms .

1- In most cases, you will use this option to create a consent form using the Consent Builder.

2- Click on "Next Screen"

Next Screen

\* Please select the Consent Template:

Provide the Consent Title if different from the template name:

\*Version Date:  

\* Version Number: .0

\* Language:

\* Reconsent Required:  Yes  No

Reconsent Reason:

Select the appropriate Consent template



**Instructions**

to the left side of the **Save Consent** CD template in review it.

2. Download the document to your workstation by clicking the **Download** button at the top right side of the screen. Your browser will then ask if you would like to save or open the file named "ConsentDocument.rtf". Click the **Save** option. This will download the file to your workstation.
3. Click the **Complete Checkout** button in your browser window.
4. You can now edit this document using



Study Nickname: 3-16-2011  
PI: Khattar, Khaled

### Informed Consent Document

Back

Study Status: **Draft** Study Title: Testing 3-16-2011

Expiration Date:

Fill out this screen and then click on "Save Consent"



Save Consent

\* Please select the Consent Template:

Non-Exempt Consent Form Template

Provide the Consent Title if different from the template name:

Main Consent

\*Version Date:

4/8/2011

\* Version Number:

1.0

\* Language:

English

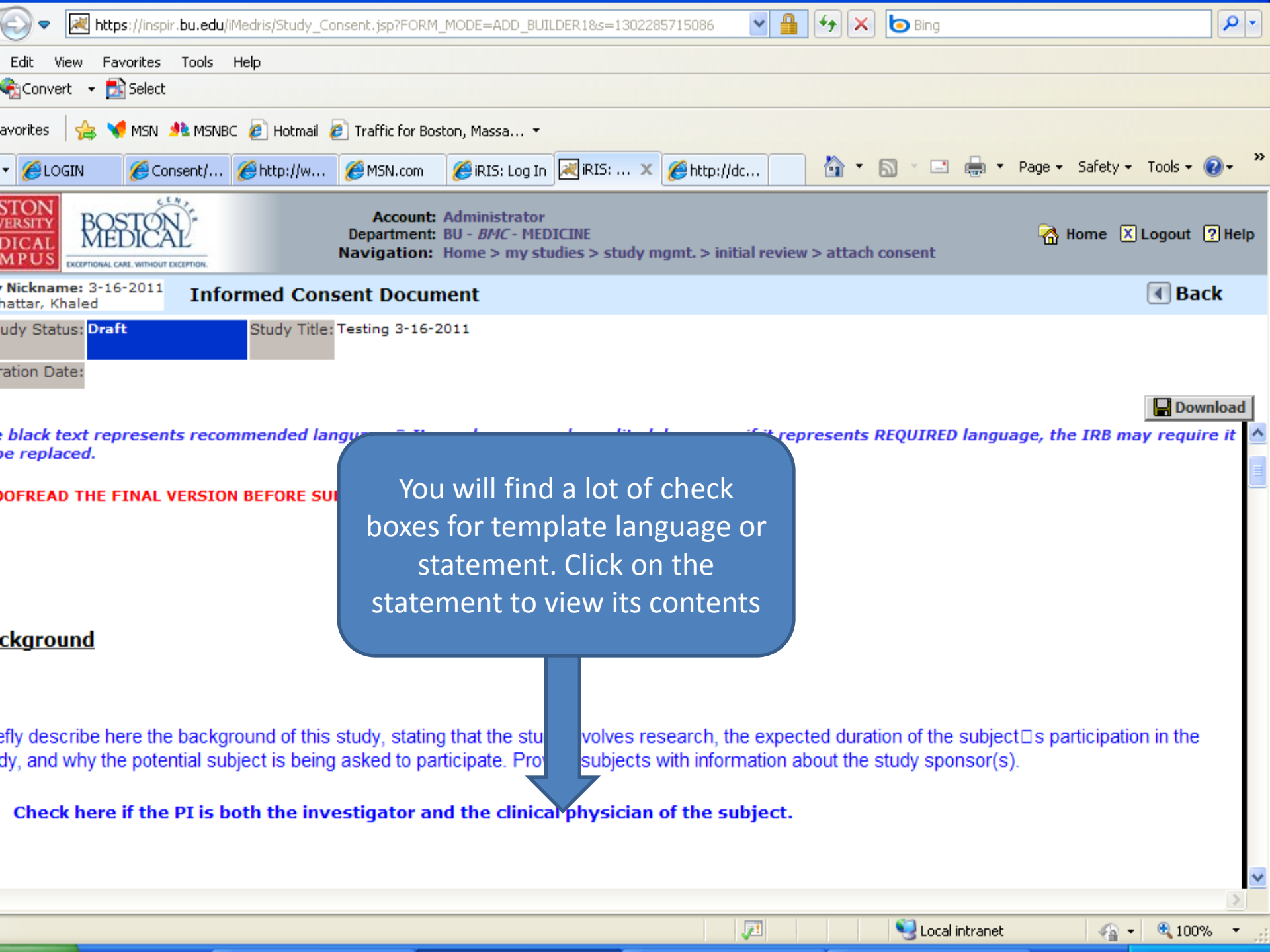
\* Reconsent Required:

Yes  No

Reconsent Reason:

#### Instructions

1. Complete the fields to the left side of the screen then click the **Save Consent** link. This will open the ICD template in your browser so you can review it.
2. Download the document to your workstation by clicking the **Download** button at the top right side of the screen. Your browser will then ask if you would like to save or open the file named "ConsentDocument.rtf". Click the **Save** option. This will download the file to your workstation.
3. Click the **Complete Checkout** button in your browser window.
4. You can now edit this document using



Account: Administrator  
Department: BU - BMC - MEDICINE

Home Logout Help

Navigation: Home > my studies > study mgmt. > initial review > attach consent

Nickname: 3-16-2011  
hattar, Khaled

### Informed Consent Document

Back

Study Status: **Draft** Study Title: Testing 3-16-2011

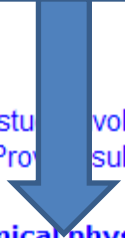
Expiration Date:

Download

*black text represents recommended language... if it represents REQUIRED language, the IRB may require it to be replaced.*

**DO NOT READ THE FINAL VERSION BEFORE SUBMITTING**

You will find a lot of check boxes for template language or statement. Click on the statement to view its contents



### Background

Effly describe here the background of this study, stating that the study involves research, the expected duration of the subject's participation in the study, and why the potential subject is being asked to participate. Provide subjects with information about the study sponsor(s).

**Check here if the PI is both the investigator and the clinical physician of the subject.**

**BOSTON UNIVERSITY MEDICAL CAMPUS**

**Study Nickname:** 3-  
**PI:** Khattar, Khaled

**Study Status:** D

**Expiration Date:**

*The black text needs to be replaced.*

**PROOFREAD THE**

**Background**

Briefly describe the study, and why

Check

**iRIS: Approved Language Check here if the PI is both the investigator and the clinical physician - Windows Intern...**

close print

Your doctor is acting as an investigator of this research study. As an investigator, your doctor is interested both in your clinical welfare and in the conduct of this study. Before enrolling in this study or at any time during this research, you may want to ask for a second opinion about your care from another doctor who is not an investigator in this study. You do not have to participate in any research study offered by your doctor.

Back

Download

Logout Help

Done Local intranet 100%

Click "Close" to close this window. And if you would like to include this language in your consent form click on the corresponding check box.

Study Nickname: 3-16-2011 Informed Consent Document Back  
PI: Khattar, Khaled

Study Status: Draft Study Title: Testing 3-16-2011

Expiration Date:

The black text represents recommended language. It may be removed or edited; however, if it represents REQUIRED language, the IRB may require it to be replaced.

PROOFREAD THE FINAL VERSION BEFORE SUBMITTING TO THE IRB.

Download

Scroll down and check the box for each language or statement that you want to be included in your consent form.

When you're done, click on "Download"

Background

Briefly describe here the background of this study, stating what the study involves, the expected duration of the subject's participation in the study, and why the potential subject is being asked to participate. Provide subjects with information about the study sponsor(s).

Check here if the PI is both the investigator and the clinical physician of the subject.

### Checkout the Study Informed Consent

**Instructions:**  
**Step 1:** If your browser blocks pop-ups, then after a while, return to your browser.

To help protect your security, Internet Explorer blocked some pictures from this page. To help protect your privacy, Outlook prevented automatic download of some pictures from the Internet. To help protect your privacy, Outlook prevented automatic download of some pictures from the Internet. Simply click on the bar and a small drop down list will appear.

**Step 2:** In a few moments, your browser will prompt you to save the file. This is not the actual File Download box, it is only a preview. To **Save** it to your workstation.

To do so, click **Save**. This will open up a window similar to the one shown below. Once you've selected where you will save the document, click **Save** as shown below. From here you can choose to open the document, or Close the Download Complete box to edit the document later.

**Step 3:** IT IS VERY IMPORTANT that after you've saved the file to your workstation and closed the Download Complete

**File Download**

Do you want to open or save this file?

Name: ConsentDocument.rtf  
Type: Rich Text Format, 541KB  
From: **inspir.bu.edu**

Open Save Cancel

While files from the Internet can be used to harm your computer. If you do not trust the source, do not open or save this file. [What's the risk?](#)

**File Download**

Do you want to open or save this file?

Name: stu...  
Type: Microsoft Word Document, 23.5KB  
From: 66.220.42.146

Open Save Cancel

While files from the Internet can be used to harm your computer. If you do not trust the source, do not open or save this file. [What's the risk?](#)

Complete Checkout

Cancel

You will get this popup screen. Click on "Save"

Home Insert Design Animations Slide Show Review View Developer Acrobat

Paste New Slide Delete Layout Reset Slides

Font Paragraph Drawing Editing

Clipboard Slides Font Paragraph Drawing Editing

Slides Outline

6

7

8

9

10

0% of System\_Download\_Servlet from inspir.bu.edu...

Save As

Save in: Docs

My Recent Documents

Desktop

My Documents

My Computer

My Network

File name: ConsentDocument.rtf

Save as type: Rich Text Format

Save Cancel

Click on the "Desktop" to save it there, or browse to where you want to save it. Then click on "Save" again.

Instructions: Step 1: If your browser blocks pop-ups, then after your browser.

To help protect your security, Internet Explorer blocked

Simply click on the bar and a small drop down list w

Step 2: In a few moments, your browser will prompt this is not the actual File Download box, it is only a to Save it to your workstation.

**Download complete**

Download Complete

ConsentDocument.rtf from inspir.bu.edu

Downloaded: 541KB in 1 sec

Download to: C:\Documents and ...\ConsentDocument.rtf

Transfer rate: 541KB/Sec

Close this dialog box when download completes

Open Open Folder Close

**File Download**

Do you want to open or save this file?

Name: study\_documents-dummys2.doc

Type: Microsoft Word Document, 23.5KB

From: 66.220.42.146

Open Save Cancel

While files from the Internet can be useful, some files can potentially harm your computer. If you do not trust the source, do not open or save this file. [What's the risk?](#)

To do so, click **Save**. This will open up a window similar to the one shown below that workstation you would like to save the document. Once you've selected where you will save the document, click **Save**. After this, the D as shown below. From here you can choose to open the document to edit it, open the or Close the Download Complete box to edit the document later.

Step 3: IT IS VERY IMPORTANT that after you've saved the file to your workstation a

Click on "Close" to close this popup.

Complete Checkout Cancel

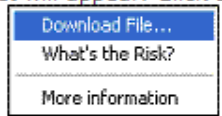
### Checkout the Study Informed Consent Back

**Instructions:**

**Step 1:** If your browser blocks pop-ups, then after a few moments a bar similar to the one shown below may appear in your browser.

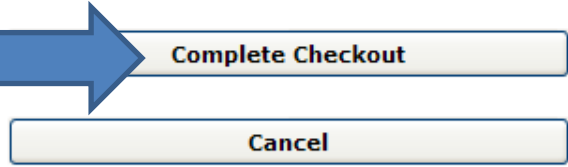
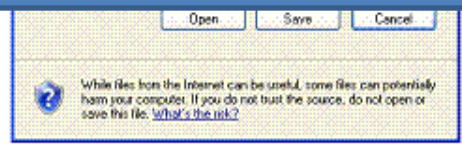


Simply click on the bar and a small drop down list will appear. Click **Download File** from the list of options.



**Step 2:** In a few moments, your browser will prompt you to either **Open** or **Save** the file (see example below). Note: this is not the actual File Download box, it is only a picture. In order to Check-out the document and edit it, you will need to **Save** it to...

Click on "Complete Checkout".



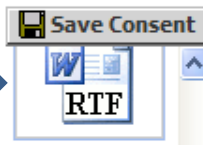
To do so, click **Save**. This will open up a window similar to the one shown below that allows you to choose where in your workstation you would like to save the document.

Once you've selected where you will save the document, click **Save**. After this, the Download Complete box will appear as shown below. From here you can choose to open the document to edit it, open the folder that contains the document, or Close the Download Complete box to edit the document later.

**Step 3:** IT IS VERY IMPORTANT that after you've saved the file to your workstation and closed the Download Complete

Note: This will indicate to everyone that you checked out this document for editing, and no one else can access it. If you changed your mind, you can always reverse this by clicking on "Undo Check-out Document"

A copy of the original Consent Form will appear here.



Reconsent Reason:

This document is currently checked out by.

Administrator at 04/08/2011 02:11 PM EDT

Check-in when you are done editing to upload the document back into iRIS.

Check-in Document...

Revert to the document stored in iRIS.

Undo Check-out Document...

Comments:

# (Note to Mac users only)

INSPIR II creates and downloads the consent form in Rich Text File (RTF) format. This RTF consent form needs to be opened on your Mac in Microsoft Word for the headers and footers to be included.

Macs by default open RTF files using “TextEdit” which strips the file of any advanced Word features. The only solution is to tell the system to “Open with” MS Word all RTF files by default. To do so, first click on the “Downloads” icon on your screen (at the bottom) and then select “open in Finder”. In the “Finder”, locate the RTF consent file and right-click on it (on a touchpad, click with two fingers). Select “Get Info” from the dropdown list. In the “get Info” popup, under “Open with”, select “Microsoft Word”, and then click on the “Change All...” button to set it as the default. Now when you open the RTF consent form, it should open in MS Word, and the headers and footers should be there.

Study Nickname: 3-16-2011 Informed Consent Document PI: Khattar, Khaled Back

Study Status: Draft Study Title: Testing 3-16-2011

Expiration Date:

\*Version Date: 04/08/2011

\*Version Number: 1 .0

\* Language: English

\* Reconsent Required: Yes No

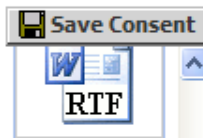
Reconsent Reason:

This document is currently checked out by. Administrator at 04/08/2011 02:13 PM EDT

Check-in when you are done editing to upload the document back into iRIS. Check-in Document...

Revert to the document stored in iRIS. Undo Check-out Document...

Comments



After you have finished editing the Consent Form, save it to your desktop. You need to come back to this screen to upload the finished consent form. You would click on "Check-in Document" to upload it and proceed.



**Upload Document - Windows Internet Explorer**

Document Location:

**Instruction:** Uploading a document into iRIS™ requires locating the document on the computer. Once you have located the document click on the 'Save selected file' button. The buttons will become disabled. If the document is a large document the window will stay in place until the upload operation has completed.

Save Consent

RTF

This document is currently checked out by: Administrator at 04/08/2011 02:13 PM EDT

Check-in when you are done editing to upload the document back into iRIS.

Revert to the document stored in iRIS.

After clicking "Check-in Document", you'll get this popup screen. Click on "Browse" to browse to where the Consent form is.

**Upload Document - Windows Internet Explorer**

Document Location: C:\Documents and Settings\khattar\Desktop\ConsentDocument.rtf

**Instruction:** Uploading a document into iRIS™ requires locating the document on the computer. Once you have located the document click on the 'Save selected file' button. The buttons will become disabled. If the document is a large document the window will stay in place until the upload operation has completed.

Administrator at 04/08/2011 02:13 PM EDT

Once you find the consent form, select it and click "Open". Then click on "Save selected file"

Save Consent  
RTF



Study Nickname: 3-16-2011  
PI: Khattar, Khaled

### Informed Consent Document

Back

Study Status: **Draft** Study Title: Testing 3-16-2011  
Expiration Date:

Consent Title: Main Consent

\*Version Date: 04/08/2011

\*Version Number: 1 .0

\* Language: English

\* Reconsent Required:  Yes  No

Reconsent Reason:

Check-in when you are done editing to upload the document back into iRIS.

Check-in Document...

Revert to the document stored in iRIS.

Undo Check-out Document...

Save Consent

Click on "Save Consent"



Account: Administrator  
 Department: BU - BMC - MEDICINE  
 Navigation: Home > my studies > study mgmt. > initial review

Home Logout Help

Study Nickname: 3-16-2011  
 PI: Khattar, Khaled

### Attach Informed Consent Documents

Back

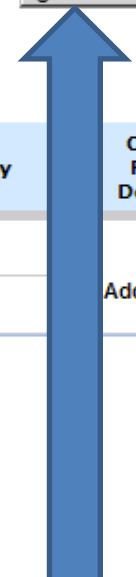
*Click the checkbox to select/deselect the document(s).*  
 Click the **Add New Document** button to add a new consent document.  
 Click the **Add Revision** button to create a revised consent document.  
 Click the **Delete Document** button to delete the selected consent documents.  
 Click the **Save Attachments** to attach or unattach consent documents.

Add Document Delete Document Save Attachments

<input type="checkbox"/>	Show Rev.	Edit/View	Version	UnApproved Consent	Approved Consent	Language	Review Outcome	Approval Date	Expiration Date	Checkout By	Create a Revised Document
<input type="checkbox"/>			1.0 04/08/2011			Main Consent English					 Add Revision



1- You can repeat these steps to add more consent forms. Once you're done you need to attach the consent form(s) to the submission by checking the text box adjacent to the selected consent form.



2- When done, click on "Save Attachments"