



How to revise an existing Consent Form

Note: You need to be in a submission form such as an Initial Review Submission Form, a Change Request & Amendments Form, or a Review Response Submission Form to revise an existing consent form.

Step 1 – Creating a revision of the existing consent form and Checking it out (downloading it) to your desktop

Note: If you want to modify an existing consent form, do not add it as a new consent form. Instead, make a revision of the existing consent form .

If this consent form will require a stamp from the IRB, you need to make sure that the consent form you upload is in RTF or Microsoft Word format

 **Select or Revise Existing**  **Add a New Consent**

| Detach | Version | Title | Category | Language | Expiration Date | Review Outcome | Checked Out | View Document |
|--|---------|-------|----------|----------|-----------------|----------------|-------------|---------------|
| No Consent(s) have been attached to this form. | | | | | | | | |

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

Note: If there are multiple versions of the same consent form, make sure that you are in the most recent version of the consent form before you add a revision.

| Select Existing or Create Revised Study Consent | | | | | | | | | | | | |
|---|-------------------|------|--------|---------|--------------|---|----------|-----------------|----------------|----------------|---------------|-----------------|
| 8 result(s) found... | | | | | | | | | | | | |
| Select | Show all Versions | Edit | Delete | Version | Version Date | Title/Category | Language | Expiration Date | Review Outcome | Checked Out By | View Document | Create Revision |
| | | | | 1.0 | 06/11/2013 | test 6-11-2013 | English | | | | 1.14 MB | |
| | | | | 1.0 | 08/08/2013 | test 8-8-2013 | English | | | | 480.16 KB | |
| | | | | 2.0 | 11/21/2011 | test3 | English | | Approved | | 328.56 KB | |
| | | | | 1.0 | 11/27/2012 | testing | English | | | | 371.37 KB | |
| | | | | 1.0 | 06/11/2013 | testing 2 6-11-2013 | English | | | | 475.76 KB | |
| | | | | 1.2 | 07/30/2012 | testing 7-30-12 builder <i>*Revision modified by the IRB</i> | English | | Approved | | 330.72 KB | |

If next to the consent form that you want to revise you see (X) icon (red arrow), that means a revision already exists. Click on edit/view to modify it (green arrow).

Otherwise, click on the "Create Revision" icon to create a revision of the existing consent form (blue arrow).

1 -Change the Version Date

Study Consent Revision. [X]

*Consent Title: [text box]

Version Number: [text box] .1

*Version Date: 11/21/2011 [calendar icon]

Category: --none-- [dropdown]

* Language: English [dropdown]

Description: [text area]

Check-out the Document to your workstation for editing: [Check-out Document... button]

Comments: [text area]

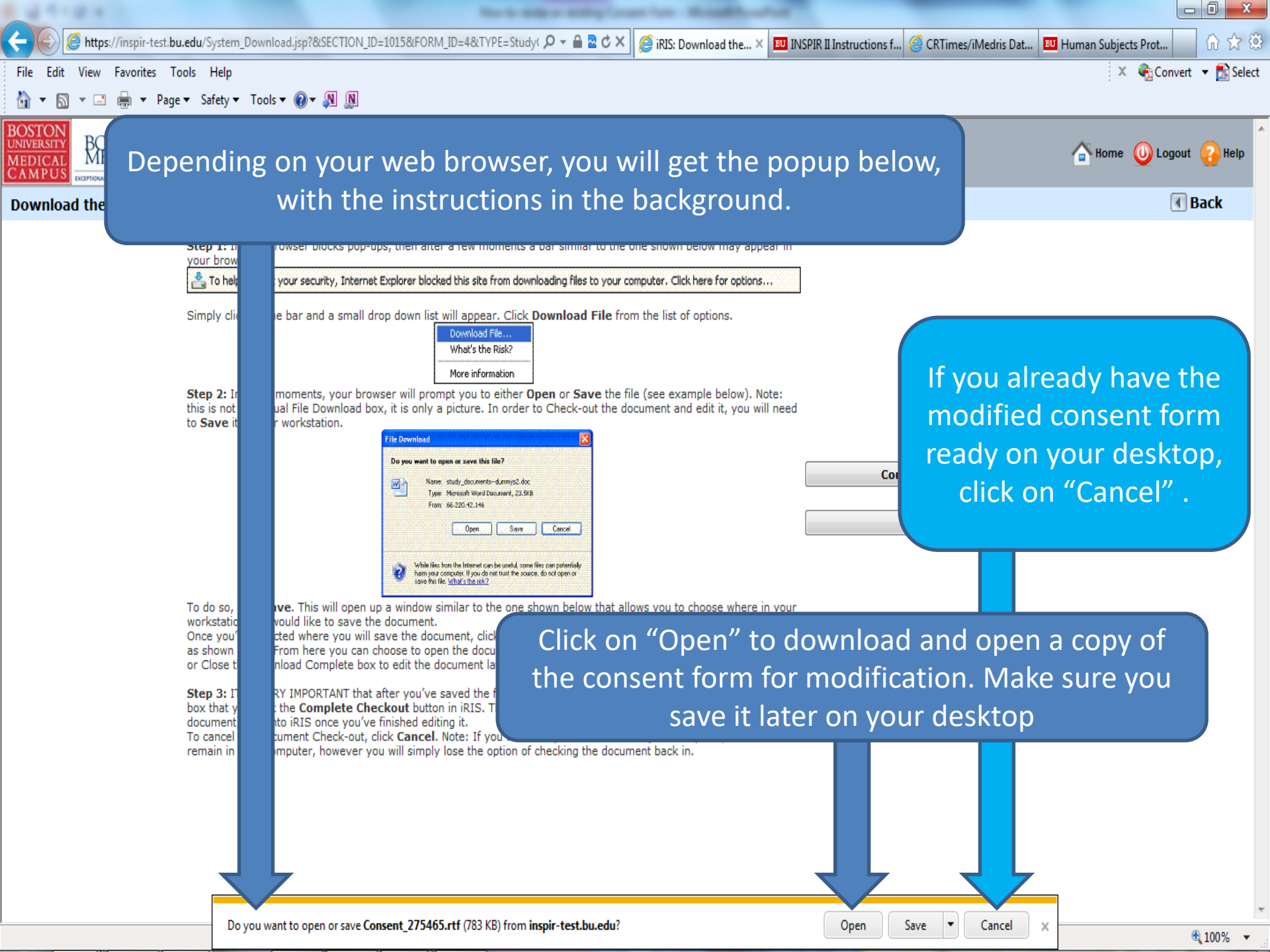
[Save Consent button]

2- Click on "Check-out Document" to download a copy of the current consent form to your desktop to modify it.

Select or Revise Existing Consent

| Detach | Version |
|-------------------------------------|---------|
| No Consent(s) have been checked out | |

| | |
|-------------|---------------|
| Checked Out | View Document |
|-------------|---------------|



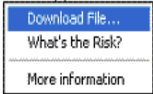
Depending on your web browser, you will get the popup below, with the instructions in the background.

If you already have the modified consent form ready on your desktop, click on "Cancel".

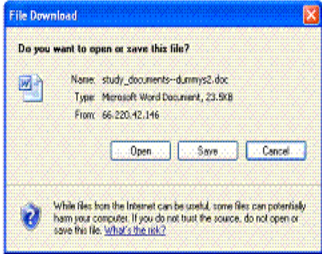
Click on "Open" to download and open a copy of the consent form for modification. Make sure you save it later on your desktop

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. To help protect your security, Internet Explorer blocked this site from downloading files to your computer. Click here for options...

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

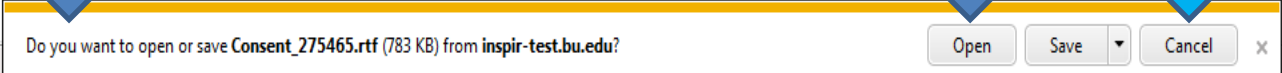


Step 2: In a few moments, your browser will prompt you to either **Open** or **Save** the file (see example below). Note: this is not a usual File Download box, it is only a picture. In order to Check-out the document and edit it, you will need to **Save** it to your workstation.



To do so, you must **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 **Open**. From here you can choose to open the document in your browser or Close the browser. To edit the document, click on 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, you click on the **Complete Checkout** button in iRIS. To check-out the document to iRIS once you've finished editing it. To cancel the document Check-out, click **Cancel**. Note: If you do not check-out the document on your computer, however you will simply lose the option of checking the document back in.



(Note to Mac users only)

(Windows users please skip this screen)

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.

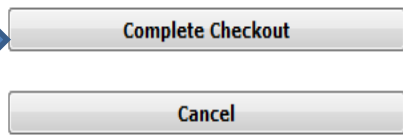
Macs by default open RTF files using “TextEdit” which strips the file of any advanced Word features. The only solution is to tell the system to “Open with” MS Word all RTF files by default. To do so, first click on the “Downloads” icon on your screen (at the bottom) and then select “Open in Finder”. 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.

Whether you downloaded the document for revision or canceled the download because you already have this document ready, you will still need to come back to this page and click on "Complete Checkout"

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



Click on "Complete Checkout". Don't forget to click this button to indicate that you have the document, and for the system to allow you to check it in (upload it) later. This step is crucial.



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 box that you click the **Complete Checkout** button in iRIS. This allows you to check the document (or upload the document) back into iRIS once you've finished editing it.
To cancel the Document Check-out, click **Cancel**. Note: If you've already saved the file to your computer, the file will remain in your computer, however you will simply lose the option of checking the document back in.

Make sure this date is current.

The screenshot shows a web-based form for editing a consent document. The form fields include:

- *Consent Title:** test3
- Version Number:** 2 (with a small '1' next to it)
- *Version Date:** 04/04/2014 (with a calendar icon)
- Category:** --none--
- * Language:** English
- Description:** (empty text area)

Below the form, there is a status bar indicating the document is checked out by Administrator at 04/04/2014 01:23:45 PM. At the bottom of the form, there are three buttons: "Check-in Document...", "Undo Check-out Document...", and "Save Consent".

Callout boxes provide instructions:

- A blue arrow points from the "Make sure this date is current." box to the "Version Date" field.
- A large blue box on the right contains the text: "If you have the consent form document ready, click on 'Check-in Document' to upload the modified document and skip to slide # 16 to continue." A blue arrow points from this box to the "Check-in Document..." button.
- A blue arrow points from the bottom of the "Save Consent" button to the bottom callout box.

If you have the consent form document ready, click on "Check-in Document" to upload the modified document and skip to slide # 16 to continue.

In most cases, you will not be ready to upload the consent form right away. In this case, you can close out of this screen and come back later when you're ready. To do so, click on "Save Consent" and proceed to the slide.


This will bring you back to this screen.
Click on the "X" icon to close this window.



| Select Existing or Create Revised Study Consent | | | | | | | | | | | | |
|---|-------------------|------|--------|---------|--------------|------------------------------------|----------|-----------------|----------------|--|---------------|-----------------|
| Select | Show all Versions | Edit | Delete | Version | Version Date | Title/Category | Language | Expiration Date | Review Outcome | Checked Out By | View Document | Create Revision |
| | | | | 1.0 | 04/02/2014 | Consent using 2nd option - builder | English | | | | 482.90 KB | |
| | | | | 1.0 | 04/02/2014 | Consent using builder | English | | | | 476.69 KB | |
| | | | | 1.0 | 06/11/2013 | test 6-11-2013 | English | | | | 1.14 MB | |
| | | | | 1.0 | 08/08/2013 | test 8-8-2013 | English | | | | 480.16 KB | |
| | | | | 2.1 | 04/04/2014 | test3 | English | | | Administrator 04/04/2014 01:23:45 PM | 783.21 KB | (Read Only) |
| | | | | 1.0 | 11/27/2012 | testing | English | | | | 371.37 KB | |


Se
Detach
No Cons

This should close the popup window and bring you back to where you started. The consent form will be added but it will show up as “Checked out” (orange arrow) and there is nothing under “View Document” (red arrow)

| Detach | Version | Title | Category | Language | Expiration Date | Review Outcome | Checked Out | View Document |
|---|---------|-------|----------|----------|-----------------|----------------|--|---------------|
|  | 2.1 | test3 | | English | | | Administrator 04/04/2014 01:22:13 PM | |

Step 2 – Checking in (uploading)
the revised consent form
document from your desktop

Before uploading, make sure that the revised copy of the consent form that you want to upload is clean (i.e. Track changes had been all accepted, there are no comments on the right margin, Headers and Footers are there, etc...). In other words, it should look the way you want the final consent form to look minus the approval stamp which will be applied later when it is approved by the IRB.

| Select or Revise Existing | | + Add a New Consent | | | | | | |
|---|---------|---------------------|----------|----------|-----------------|----------------|--|---------------|
| Detach | Version | Title | Category | Language | Expiration Date | Review Outcome | Checked Out | View Document |
|  | 2.1 | test3 | | English | | | Administrator 04/04/2014 01:22:13 PM | |

























This is where you would come back to when you're ready to upload the updated consent form.

At this point you should have opened the document from your Desktop (or wherever you saved it), and made all your changes. Once you have finished modifying the document and it is saved, you come back to this screen to upload it.

When you are ready to upload the consent form, you would click on the "Select or Revise Existing" button (blue arrow).

Select Existing or Create Revised Study Consent

12 result(s) found...

| Select | Show all Versions | Edit | Delete | Version | Version Date | Title/Category | Language | Expiration Date | Review Outcome | Checked Out By | View Document | Create Revision |
|---|---|---|---|---------|--------------|------------------------------------|----------|-----------------|----------------|--|---|---|
| | |  | | 1.0 | 04/02/2014 | Consent using 2nd option - builder | English | | | |  482.90 KB |  |
| | |  | | 1.0 | 04/02/2014 | Consent using builder | English | | | |  476.69 KB |  |
|  | |  |  | 1.0 | 06/11/2013 | test 6-11-2013 | English | | | |  1.14 MB |  |
|  | |  |  | 1.0 | 08/08/2013 | test 8-8-2013 | English | | | |  480.16 KB |  |
| |  |  | | 2.1 | 04/04/2014 | test3 | English | | | Administrator 04/04/2014 01:23:45 PM |  783.21 KB | (Read Only) |
|  | |  |  | 1.0 | 11/27/2012 | testing | English | | | |  371.37 KB |  |

This will bring you to this screen. Locate in this list the consent form that you want to upload (it should say that it is checked out by you), and then click on the "Edit" icon next to it.

Study Consent Revision:

*Consent Title: test3

Version Number: 2 .1

*Version Date: 04/04/2014

Category: --none--

* Language: English

Description:

This document is currently checked out by.

Administrator at 04/04/2014 01:23:45 PM

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

Check-in Document...

Revert to the document stored in iRIS.

Undo Check-out Document...

Save Consent

Select or Revise E

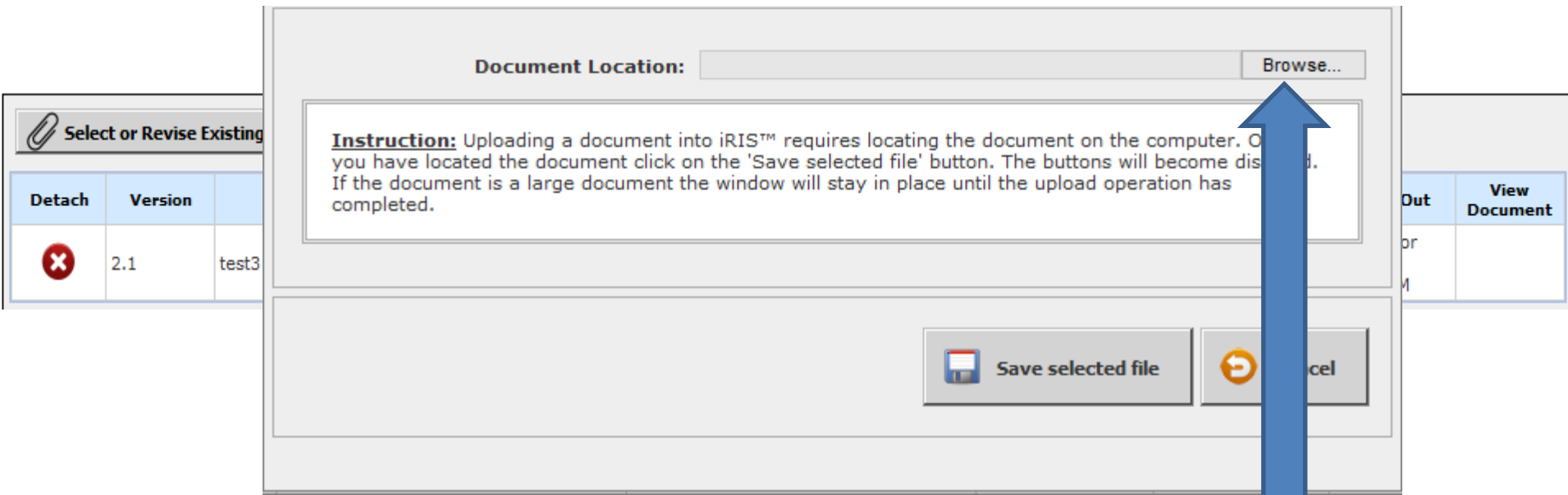
| Detach | Version |
|---|---------|
|  | 2.1 |

| Checked Out | View Document |
|----------------------------------|---------------|
| Administrator /2014 :13 PM | |

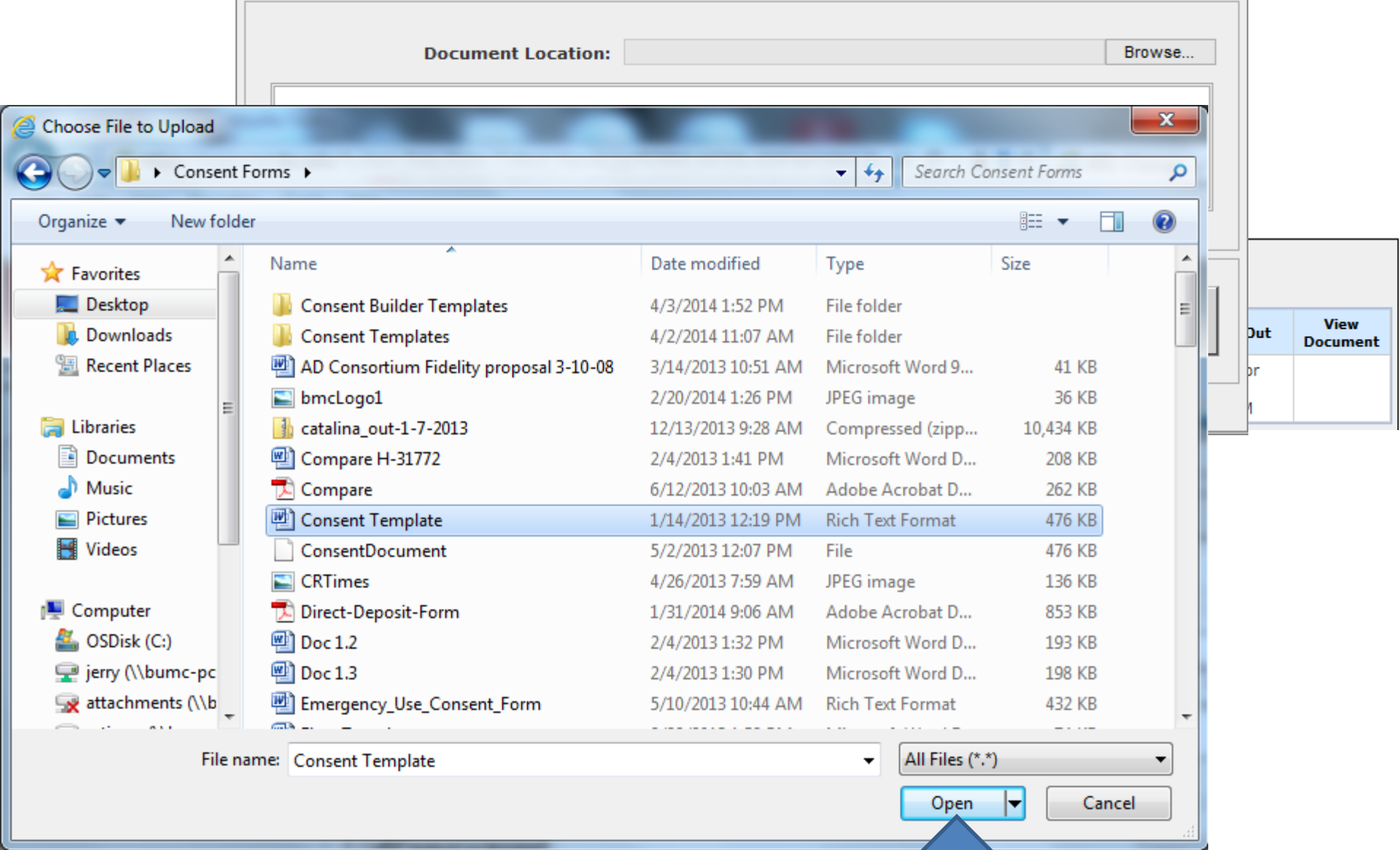
Click on "Check-in Document" to upload the modified document.



Before uploading, make sure that the revised copy of the consent form that you want to upload is clean (i.e. Track changes had been all accepted, there are no comments on the right margin, Headers and Footers are there, etc...). In other words, it should look the way you want the final consent form to look minus the approval stamp which will be applied later when it is approved by the IRB.



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




Depending on your system, you will get a popup similar to this one. Click on "Desktop" (if that's where you saved the document), then locate the document itself and click on it to highlight it. Then click on the "Open" button.

Document Location: C:\Users\kkhattar\Desktop\Consent Forms\Consent Template.rtf Browse...

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 selected file Cancel

Select or Revise Existing


| Detach | Version | |
|--|---------|----|
|  | 2.1 | te |

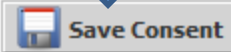
| Out | View Document |
|-------------------|---------------|
| rator 14 PM | |

This will bring you back to this screen. Note that the “Document Location” had been updated to point to the document on your desktop. Click on “Save selected file” to upload the consent form document .

This will bring you to this screen. Make any final changes (like version number, version date, category, or language) before clicking on the “Save Consent” button.

Study Consent Revision: [X]

| | |
|--|--|
| *Consent Title: | test3 |
| Version Number: | 2 |
| *Version Date: | 04/04/2014  |
| Category: | --none-- ▾ |
| * Language: | English ▾ |
| Description: | <input type="text"/> |
| Check-out the Document to your workstation for editing: | <input type="button" value="Check-out Document..."/> |
| Comments: | <input type="text"/> |



Make sure this date is current.

This will bring you back to this screen. If you would like to revise more consent documents, repeat/start over from here with the instructions from page 4.

If you're done . Then click on the "X" icon to close this screen.







Select Existing or Create Revised Study Consent



12 result(s) found...

| Select | Show all Versions | Edit | Delete | Version | Version Date | Title/Category | Language | Expiration Date | Review Outcome | Checked Out By | View Document | Create Revision |
|--------|-------------------|------|--------|---------|--------------|------------------------------------|----------|-----------------|----------------|----------------|---------------|-----------------|
| | | | | 1.0 | 04/02/2014 | Consent using 2nd option - builder | English | | | | 482.90 KB | |
| | | | | 1.0 | 04/02/2014 | Consent using builder | English | | | | 476.69 KB | |
| | | | | 1.0 | 06/11/2013 | test 6-11-2013 | English | | | | 1.14 MB | |
| | | | | 1.0 | 08/08/2013 | test 8-8-2013 | English | | | | 480.16 KB | |
| | | | | 2.1 | 04/04/2014 | test3 | English | | | | 475.29 KB | |
| | | | | 1.0 | 11/27/2012 | testing | English | | | | 371.37 KB | |

This will bring you back to where you started. Note that it no longer states that it is checked out by anyone (orange arrow), and now the new consent form document appears under “View Document” (red arrow).

|  Select or Revise Existing | |  Add a New Consent | | | | | | |
|---|---------|---|----------|----------|-----------------|----------------|-------------|--|
| Detach | Version | Title | Category | Language | Expiration Date | Review Outcome | Checked Out | View Document |
|  | 2.1 | test3 | | English | | | |  475.29 KB |