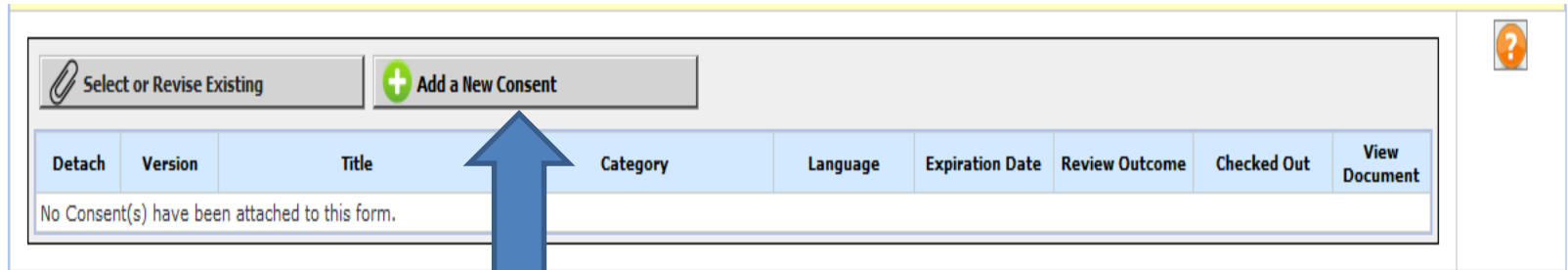


How to Add a New Consent Form

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 add/create a consent form.

Whether you started in the Initial Review Form, Amendment Form, or Submission Response Form, you will find a section similar to the table shown below where you can add a new consent form.



The screenshot shows a web interface with two buttons at the top: "Select or Revise Existing" (with a paperclip icon) and "Add a New Consent" (with a green plus icon). Below these buttons is a table with the following columns: Detach, Version, Title, Category, Language, Expiration Date, Review Outcome, Checked Out, and View Document. The table currently contains the text "No Consent(s) have been attached to this form." A blue arrow points from the "Add a New Consent" button down to the "Title" column header.

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

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

To revise an existing consent form, please refer to the instructions in the following link:
<http://www.bumc.bu.edu/irb/files/2016/10/How-to-revise-an-existing-Consent-Form.pdf>

1. Select one of the two options shown (instructions for these two options will follow):

- Option 1 – Select to download an RTF Word document of the Consent Form template with all the template languages included in it.
- Option 2 - Select to upload a consent form Word document that you already have, such as a revised consent form template that you have already downloaded or a Foreign language consent form.

The screenshot shows a window titled "Study Consent Add Selection Method:". It contains two radio button options:

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

At the bottom right of the window, there is a button labeled "Next Screen". A blue arrow labeled "2" points to this button. To the left of the window, there is a partial view of another window with buttons labeled "Detach" and "No Conse". To the right, there is a table with columns "Outcome", "Checked Out", and "View Document".

2. After selecting one of the options above, click on "Next Screen"

- If you selected option 1, proceed to page # 4 for instructions.
- If you selected option 2, proceed to page # 12 for instructions.

These are the instructions for option 1

Study Consent Add from Template:

Instructions

1. 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.
2. You can now edit this document using any standard word processing program such as MS Word and WordPerfect used on either a MAC or a standard PC. Make sure you save the document to your workstation in .rtf format.
3. Check the document into the iRIS system by clicking the **Check in Document** button. Use the **browse** button and find your document. Select your document, then select the **open** button. Select the **ok** button, then when back in the iRIS system, click the **Save Consent** link.

*** Please select the Consent Template:**

--none--
Consent Statement for Anonymous Survey/Interview Exempt Research
Research Assent Form for Children 12-17 Years of Age
Emergency Use Consent Form
Non-Exempt Consent Form Template

Download Template

1

2

You will see this popup. From the "Please select the Consent Template" drop down list,

1. Select one of the available templates.
2. Click on "Download Template" button.

Instructions for option 1 - continued

1. Click on the "X" to close this popup since you will not upload the document at this time.

2. Depending on your web browser, you will get a popup similar to this one. Click on the small arrow next to "Save" and then select "Save as"

Select or Revise Existing

Study Consent Add:

X

Save Consent

*Consent Title:

*Select the consent to upload:

 Browse...

*Version Number:

1 .0

*Version Date:

06/06/2014

Category:

--none--

*Language:

Description:

Comments:

Do you want to open or save Non-Exempt Consent Form Template.rtf (480 KB) from inspir-test.bu.edu?

Open

Save

Save

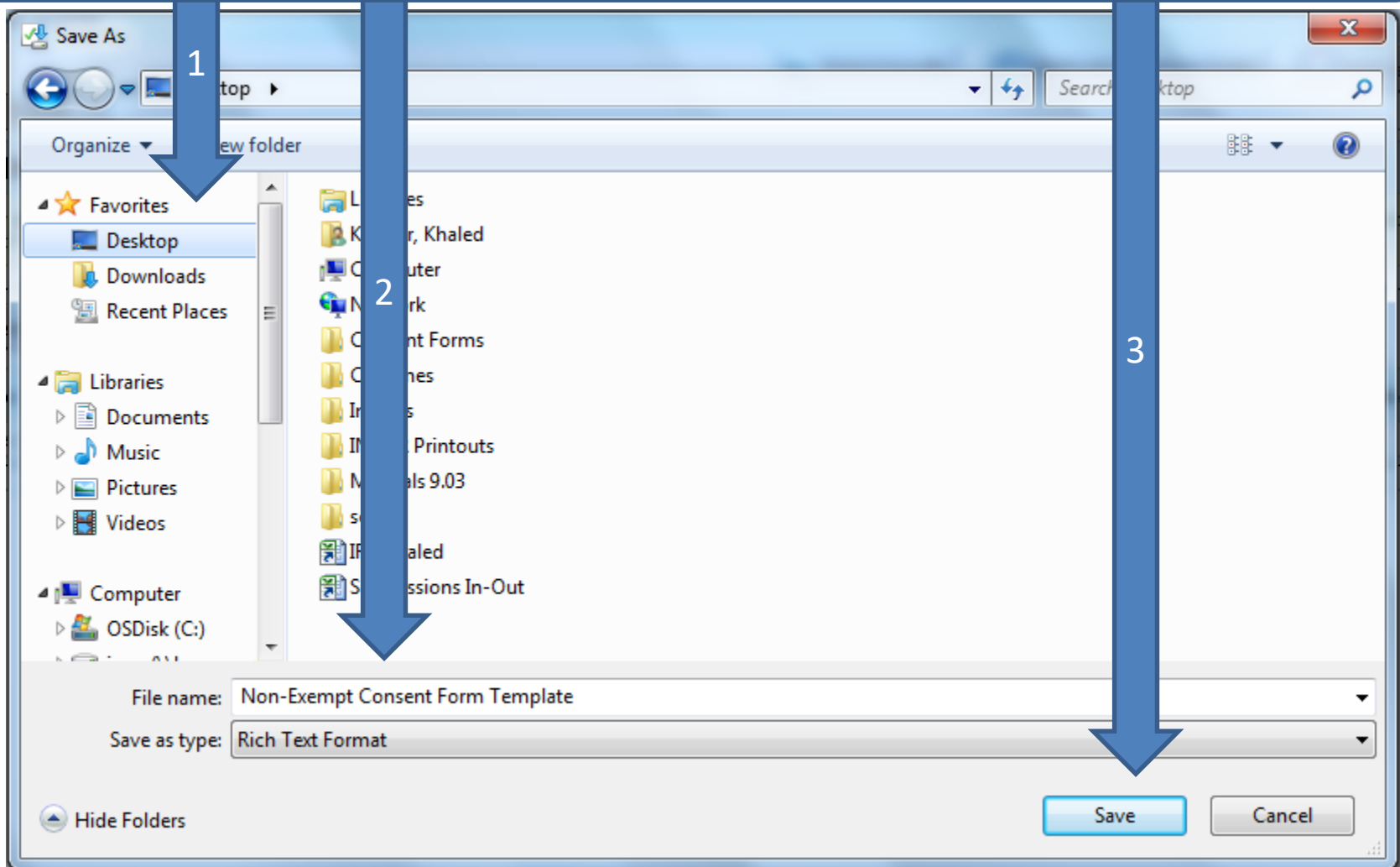
Save as

Save and open

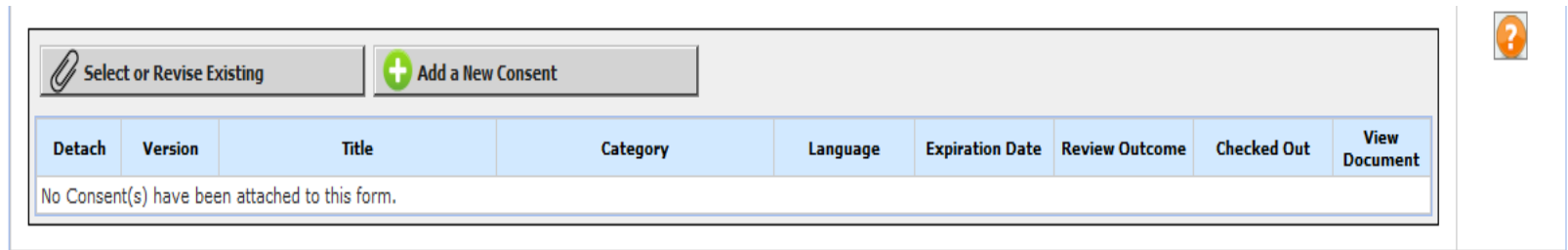
Instructions for option 1 - continued

Depending on your system, you will get a popup similar to this one. In Windows it's the "Save as" popup.

1. Click on "Desktop" to select it
2. Give the consent template a filename that you can remember
3. Click on "Save" to save it on your desktop.



Instructions for option 1 - continued



The screenshot shows a web interface for managing consents. At the top, there are two buttons: "Select or Revise Existing" (with a paperclip icon) and "Add a New Consent" (with a plus icon). Below these is a table with the following columns: Detach, Version, Title, Category, Language, Expiration Date, Review Outcome, Checked Out, and View Document. The table is currently empty, with the text "No Consent(s) have been attached to this form." displayed below it. A help icon (question mark) is visible in the top right corner.

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

The popup will close and the prompt at the bottom of the page will change similar to the one shown below. Click on "Open" to open the consent form that you have just saved on your desktop.

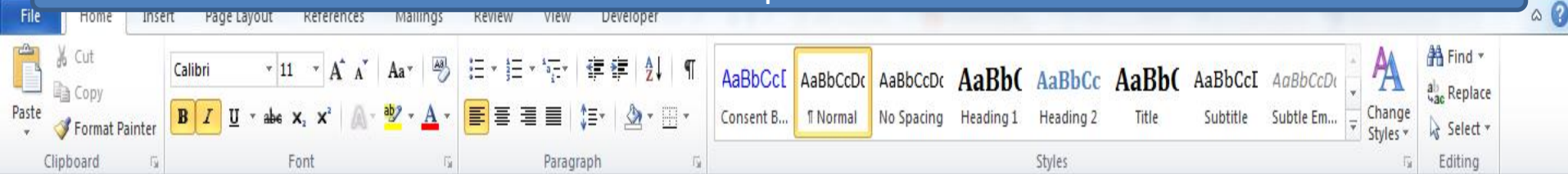


(Note to Mac users only)

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.

Instructions for option 1 - continued



BOSTON UNIVERSITY SCHOOLS OF MEDICINE,
PUBLIC HEALTH, DENTAL MEDICINE AND
THE BOSTON MEDICAL CENTER



RESEARCH CONSENT FORM

(Type your Research Consent Form Description/Title" here)

Title of Project:

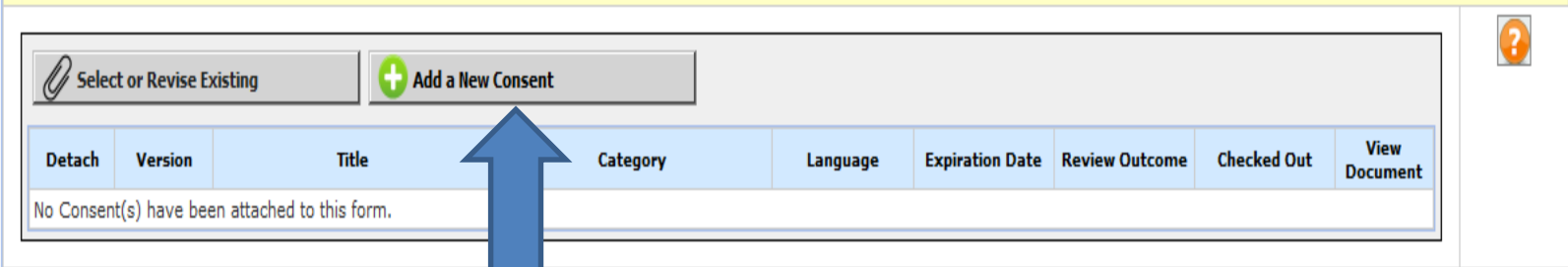
Principal Investigator:

This is a template for completing a research consent form.

The consent form template should save to your desktop and at the same time should open in Word. Start making your changes and don't forget to save your changes. Once this consent document is ready to be uploaded, proceed to the next page # 10 for instructions on how to upload this consent document.

Instructions for option # 1

Go back to where you started, to the screen where you can add a new consent form.



The screenshot shows a web interface with a table and two buttons. The table has the following columns: Detach, Version, Title, Category, Language, Expiration Date, Review Outcome, Checked Out, and View Document. Below the table, it says "No Consent(s) have been attached to this form." Above the table, there are two buttons: "Select or Revise Existing" (with a paperclip icon) and "Add a New Consent" (with a green plus icon). A blue arrow points from the "Add a New Consent" button in the screenshot above to the "Add a New Consent" button in the screenshot below.

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

Click again on the “Add a New Consent” button.

1. This time, select option # 2 to upload the revised consent form.

Study Consent Add Selection Method: X

1

Add an informed consent from the list of Informed Consent Template Documents?

Add an informed consent from an existing electronic document you already have?

Next Screen

2. Click on "Next Screen"

View Outcome	Checked Out	View Document

Instructions for options # 1 and # 2

Before uploading, make sure that 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.

The screenshot shows a 'Study Consent Add' dialog box with the following fields and values:

- *Consent Title:** Main Consent
- *Select the consent to upload:** Browse...
- *Version Number:** 1
- *Version Date:** 06/06/2014
- Category:** --none--
- * Language:** English
- Description:** (empty text area)
- Comments:** (empty text area)

A blue arrow points to the 'Browse...' button in the '*Select the consent to upload:' field.

After selecting Option 2, you will get this popup. Click on the "Browse" button.

Instructions for options # 1 and # 2 - continued

The screenshot shows a Windows Explorer window titled "Choose File to Upload" with the address bar set to "Desktop". The left sidebar shows "Favorites" with "Desktop" selected. The main pane displays a list of files, with "Main Consent" highlighted. A blue callout box with a white border contains the following text:

You will get a popup similar to this.

1. Navigate to where you saved the consent form you want to upload. In this example, it's the "Desktop"
2. Select the file you want to upload
3. Click on "Open"

Three blue arrows point from the callout box to the "Desktop" folder in the sidebar (labeled '1'), the "Main Consent" file in the main pane (labeled '2'), and the "Open" button at the bottom right (labeled '3'). The "Open" button is highlighted in blue. The "File name" field at the bottom shows "Main Consent" and the file type dropdown is set to "All Files".

Instructions for options # 1 and # 2 - continued

The screenshot shows a 'Study Consent Add' dialog box with the following fields and annotations:

- *Consent Title:** 'Main Consent' (Yellow arrow pointing to the text input field)
- *Select the consent to upload:** 'C:\Users\kkhattar\Desktop\Main Consent.rtf' (Green arrow pointing to the file path)
- *Version Number:** '1' (Text input field)
- *Version Date:** '06/06/2014' (Date input field with a calendar icon, Red arrow pointing to the date)
- Category:** '--none--' (Dropdown menu, Purple arrow pointing to the dropdown)
- * Language:** 'English' (Dropdown menu, Purple arrow pointing to the dropdown)
- Description:** (Empty text area)
- Comments:** (Empty text area)
- Save Consent:** (Button with a floppy disk icon, Blue arrow pointing to the button)

The system will bring you back to this popup. Note the name and path of the file to be uploaded (green arrow). Type in a title to your consent form (yellow arrow) and make sure the version date is current (red arrow). Also, select the appropriate category and language (purple arrows). Make all the necessary changes to this popup and then click on "Save Consent" (blue arrow).

Instructions for options # 1 and # 2 - continued

The consent form that you have just uploaded should appear on this list. You can verify that you have uploaded the right consent form by clicking on the “View Document” icon to open it (yellow arrow). You can remove any consent forms that you don’t want to submit to the IRB by clicking on the (X) icon next to it (red arrow).

Detach	Version	Title	Category	Language	Expiration Date	Review Outcome	Checked Out	Document
	1.0	Main Consent		English				 480.16 KB

You’re done adding the consent form. You can start over if you have additional Consent forms.