

# 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.

## Notes:

- 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 (by following the instructions in these slides).
- 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.
- Before uploading your revised consent form document, make sure that you accept all changes if you have “Track Changes” on.

Detach	Version	Sponsor Version	Title	Category	Language	Expiration Date	Consent Outcome	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 open the “Select Existing or Create Revised Study Consent” popup.

The “Select Existing or Create Revised Study Consent” popup will open.

First you need to find the consent form that you want to revise. If you have many consent documents, you can use the filter fields to search for a specific document by selecting one or more filters then clicking on “Filter Documents”. Or you can just scroll down to find it. (yellow arrows)

**Select Existing or Create Revised Study Consent**

If you already have the revised document on your computer, skip downloading the document for editing and proceed to uploading the revised document.

Select Category:  Title:

Version #:  Search level:  Top  All

Version Date:  between  Expiration Date:  between

Consent Outcome:

20 result(s) found...



				1.2	08/01/2023		Adult Consent	Vietnamese			
				1.1	08/01/2023		ESS Validation Study - BMC Haitian Creole ICF Outpatient Clinic Setting				
				1.1	08/01/2023		Adult Consent	Haitian-Creole			
				1.1	08/01/2023		ESS Validation Study - BMC Spanish ICF Outpatient Clinic Setting				
				1.1	08/01/2023		Adult Consent	Spanish			
				1.1	08/01/2023		ESS Validation Study - BMC Vietnamese ICF Outpatient Clinic Setting				
				1.1	08/01/2023		Adult Consent	Vietnamese			
				1.1	08/01/2023		ESS Validation Study - Tufts MC Spanish ICF Outpatient Clinic Setting				
				1.1	08/01/2023		Adult Consent	Spanish			
				1.1	08/01/2023		ESS Validation Study - Tufts MC Vietnamese ICF Outpatient Clinic Setting				
				1.1	08/01/2023		Adult Consent	Vietnamese			
				1.1	08/01/2023		ESS Validation Study - BMC Chinese ICF Outpatient Clinic Setting				
				1.1	08/01/2023		Adult Consent	Chinese			
				1.2	08/01/2023		ESS Validation Study - Boston Medical Center Outpatient Clinic Setting Consent Form				
				1.2	08/01/2023		Adult Consent	English			
							ESS Validation Study - Boston Medical Center Operating Room Set				

If next to the consent form that you want to revise you see (X) icon (red arrow), that means a revision already exists that you can use. Click on edit/view to modify it (green arrow) and proceed to the next slide. If there is no (X), skip the next slides to slide # 6.

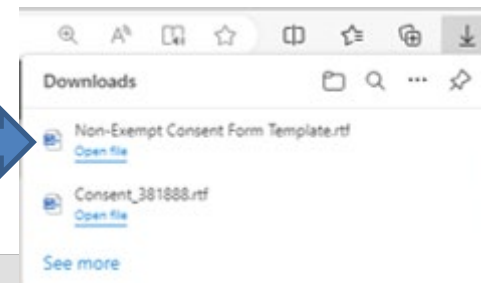
The “Study Consent Revision” popup will open.

- It is recommended that you download a copy of the latest revision of the consent form from INSPIR for editing. You can download it by clicking on “Download” icon (orange arrow) then proceed to the next slide.
- If you already have the revised consent form on your computer ready to be uploaded, click on “Choose File” and skip the next slides to slide # 11.

### Study Consent Revision X

<b>* Consent Title:</b>	<input type="text" value="ESS Validation Study - Boston Medical Center Outpatient Clinic Setting Consent Form"/>	
<b>* Version Number:</b>	<input type="text" value="1"/> .2	
<b>* Version Date:</b>	<input type="text" value="12/01/2022"/> 	
<b>Sponsor Version:</b>	<input type="text"/>	
<b>* Category:</b>	<input type="text" value="Adult Consent"/>	
<b>* Language:</b>	<input type="text" value="English"/>	
<b>Description:</b>	<input type="text"/>	
<b>Comments:</b>	<input type="text"/>	
<b>Download Consent:</b>	<input type="button" value="Download"/>	
<b>Select the document to upload:</b>	<input type="button" value="Choose File"/> No file chosen	


The selected consent document will download. Depending on your system and web browser, you will get the “Downloads” popup similar to this one. Click on the file to open it.



**Study Consent Revision**

<b>*Consent Title:</b>	ESS Validation Study - Boston Medical Center Outpatient Clinic Setting Consent Form
<b>*Version Number:</b>	1 .2
<b>*Version Date:</b>	12/01/2022
<b>Sponsor Version:</b>	
<b>* Category:</b>	Adult Consent
<b>* Language:</b>	English
<b>Description:</b>	
<b>Comments:</b>	
<b>Download Consent:</b>	<input type="button" value="Download"/>
<b>Select the document to upload:</b>	<input type="button" value="Choose File"/> No file chosen

**View Document**



Save the consent document to your computer then start making your changes. Don't forget to save it again when you're done editing. When you are ready to upload the revised consent form from your computer, come back here and click on “Choose File” and skip the next slides to slide # 11.

You are in the “Select Existing or Create Revised Study Consent” popup and you have located the consent document that you want to revise:

- It is recommended that you download a copy of the latest revision of the consent form from INSPIR for editing. You can download it by clicking on “Download Document for Editing” icon (orange arrow) then proceed to the next slide.
- If you already have the revised consent form on your computer ready to be uploaded, skip the next slides to slide # 9.

**Select Existing or Create Revised Study Consent**

If you already have the revised document on your computer, skip downloading the document for editing and proceed to uploading the revised document.

Select Category: --none--  
Version #: .  
Version Date:  between   
Consent Outcome: --none--

Title:   
Search level:  Top  All  
Expiration Date:  between

33 result(s) found...

				1.1	08/01/2023		Adult Consent	Haitian-Creole			
				1.1	08/01/2023		ESS Validation Study - BMC Spanish ICF Outpatient Clinic Setting	Adult Consent	Spanish		
				1.1	08/01/2023		ESS Validation Study - BMC Vietnamese ICF Outpatient Clinic Setting	Adult Consent	Vietnamese		
				1.1	08/01/2023		ESS Validation Study - Tufts MC Spanish ICF Outpatient Clinic Setting	Adult Consent	Spanish		
				1.1	08/01/2023		ESS Validation Study - Tufts MC Vietnamese ICF Outpatient Clinic Setting	Adult Consent	Vietnamese		
				1.1	08/01/2023		ESS Validation Study - BMC Chinese ICF Outpatient Clinic Setting	Adult Consent	Chinese		
				1.5	08/01/2023		ESS Validation Study - Boston Medical Center Operating Room Setting Consent Form	Adult Consent	English		
				1.0	02/10/2023		Translator Qualification Form	Not Defined	English	Approved	
				1.1	12/01/2022		ESS Validation Study - Boston Medical Center Outpatient Clinic Setting Consent Form	Adult Consent	English	Approved	
				1.0	03/28/2022		ESS Validation - Additional Signature Page for Short-Form Use			<b>*Added by the IRB</b>	

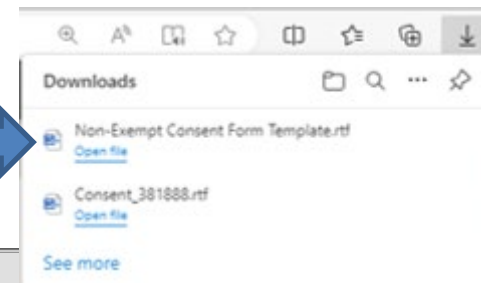
# (Note to Mac users only)

(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.

The selected consent document will download. Depending on your system and web browser, you will get the “Downloads” popup similar to this one. Click on the file to open it.



**Select Existing or Create Revised Study Consent**

If you already have the revised document on your computer, skip downloading the document for editing and proceed to uploading the revised document.

**Select Category:** --none--  
**Version #:** [ ] . [ ]  
**Version Date:** [ ] between [ ]  
**Consent Outcome:** --none--

**Title:** [ ]  
**Search level:**  Top  All  
**Expiration Date:** [ ] between [ ]

33 result(s) found...

							Adult Consent	Haitian-Creole		
				1.1	08/01/2023		ESS Validation Study - BMC Spanish ICF Outpatient Clinic Setting	Adult Consent	Spanish	
				1.1	08/01/2023		ESS Validation Study - BMC Vietnamese ICF Outpatient Clinic Setting	Adult Consent	Vietnamese	
				1.1	08/01/2023		ESS Validation Study - Tufts MC Spanish ICF Outpatient Clinic Setting	Adult Consent	Spanish	
				1.1	08/01/2023		ESS Validation Study - Tufts MC Vietnamese ICF Outpatient Clinic Setting	Adult Consent	Vietnamese	
				1.1	08/01/2023		ESS Validation Study - BMC Chinese ICF Outpatient Clinic Setting	Adult Consent	Chinese	
				1.5	08/01/2023		ESS Validation Study - Boston Medical Center Operating Room Setting Consent Form	Adult Consent	English	
				1.0	02/10/2023		Translator Qualification Form	Not Defined	English	

Save the consent document to your computer then start making your changes. Don't forget to save it again when you're done editing. Proceed to the next slide if you are ready to upload the revised consent document.



Once you have finished revising the consent document on your computer and it's ready to be uploaded, click on the "Upload Revised Document" icon (green arrow).

### Select Existing or Create Revised Study Consent

If you already have the revised document on your computer, skip downloading the document for editing and proceed to uploading the revised document.

Select Category:	--none--	Title:	
Version #:		Search level:	<input checked="" type="radio"/> Top <input type="radio"/> All
Version Date:	between	Expiration Date:	between
Consent Outcome:	--none--		

Add a New Consent      Filter Documents

33 result(s) found...

				1.1	08/01/2023		Adult Consent	Haitian-Creole				
							ESS Validation Study - BMC Spanish ICF Outpatient Clinic Setting					
				1.1	08/01/2023		Adult Consent	Spanish				
							ESS Validation Study - BMC Vietnamese ICF Outpatient Clinic Setting					
				1.1	08/01/2023		Adult Consent	Vietnamese				
							ESS Validation Study - Tufts MC Spanish ICF Outpatient Clinic Setting					
				1.1	08/01/2023		Adult Consent	Spanish				
							ESS Validation Study - Tufts MC Vietnamese ICF Outpatient Clinic Setting					
				1.1	08/01/2023		Adult Consent	Vietnamese				
							ESS Validation Study - BMC Chinese ICF Outpatient Clinic Setting					
				1.1	08/01/2023		Adult Consent	Chinese				
							ESS Validation Study - BMC Chinese ICF Outpatient Clinic Setting					
				1.5	08/01/2023		Adult Consent	English				
							ESS Validation Study - Boston Medical Center Operating Room Setting Consent Form					
				1.0	02/10/2023		Translator Qualification Form					
							Not Defined	English		Approved		
				1.1	12/01/2022		ESS Validation Study - Boston Medical Center Outpatient Clinic Setting Consent Form					
							Adult Consent	English		Approved		
				1.0	03/28/2022		ESS Validation - Additional Signature Page for Short-Form Use					
							*Added by the IRB					



The “Study Consent Revision” popup will open.

Notice that this revised consent document will now be given a new Version Number (the system will increment the version number by + .1) (yellow arrow)

**Study Consent Revision** x

\* Consent Title: ESS Validation Study - Boston Medical Center Outpatient Clinic Setting Cons...

\* Select the consent to upload: Choose File No file chosen

\* Version Number: .2

\* Version Date: 1/2022

Sponsor Version:

\* Category: t Consent

\* Language: ish

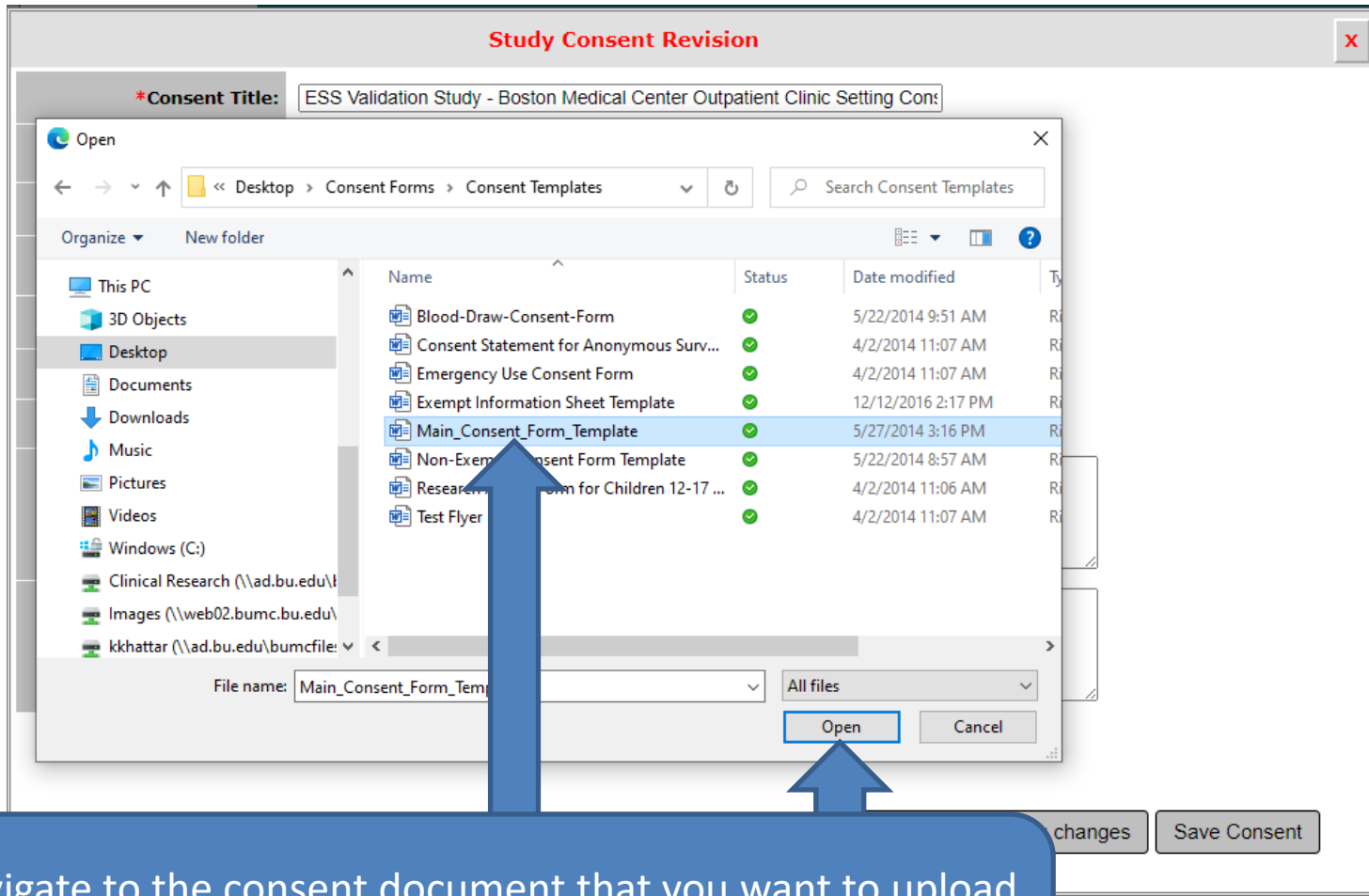
Description:

Comments:

Close, don't save any changes Save Consent

Click on the “Choose File” button to navigate on your computer to where you last saved your revised consent document to upload it (orange arrow)

This opens the “Open” pop-up or a different popup depending on the system that you are using.



1. Navigate to the consent document that you want to upload
2. Click on the document to highlight it
3. Click on “Open”

This will bring you back to the “Study Consent Revision:” popup.

- Notice the uploaded consent document’s name is now appearing in the popup (blue arrow)

1. Change the “Version Date” to today’s date (green arrow)
2. Click on the “Save Consent” button (Grey arrow)

The screenshot shows a 'Study Consent Revision' popup window. The form contains the following fields and controls:

- \*Consent Title:** Text input field containing 'ESS Validation Study - Boston Medical Center Outpatient Clinic Setting Cons'.
- \*Select the consent to upload:** A 'Choose File' button followed by the text 'Main\_Cons...\_Template.rtf'. A blue arrow points to this text.
- \*Version Number:** Text input field containing '1' followed by a '.2' suffix.
- \*Version Date:** Text input field containing '12/01/2022' and a calendar icon. A green arrow points to the calendar icon.
- Sponsor Version:** Empty text input field.
- \* Category:** Dropdown menu with 'Adult Consent' selected.
- \* Language:** Dropdown menu with 'English' selected.
- Description:** Large empty text area.
- Comments:** Large empty text area.
- Buttons:** 'Close, don't save any changes' and 'Save Consent' buttons at the bottom right. A grey arrow points to the 'Save Consent' button.

# This will bring you back to the “Select Existing or Create Revised Study Consent” popup.

- If you want to revise more consent documents, repeat slides 3 – 13
- If you are done revising consent documents, close this popup by clicking on the X icon (green arrow)



## Select Existing or Create Revised Study Consent



If you already have the revised document on your computer, skip downloading the document for editing and proceed to uploading the revised document.



**Select Category:** --none--    
**Version #:**  .    
**Version Date:**   between     
**Consent Outcome:** --none--    
**Title:**    
**Search level:**  Top  All   
**Expiration Date:**   between

33 result(s) found...

Select	Show all Versions	Edit	Delete	Version	Version Date	Sponsor Version	Download Document for Editing	Title	Language	Expiration Date	Consent Outcome	View Document	Upload Revised Consent	
								Category						
				1.2	12/01/2022			ESS Validation Study - Boston Medical Center Outpatient Clinic Setting Consent Form						
								Adult Consent	English			418.35 KB		
				1.4	08/01/2023			ESS Validation Study - Tufts Medical Center Operating Room Setting Consent Form						
								Adult Consent	English					
				1.2	08/01/2023			ESS Validation Study - Tufts Medical Center Outpatient Clinic Setting Consent Form						
								Adult Consent	English					
				1.1	08/01/2023			ESS Validation Study - Tufts MC Haitian Creole ICF Operating Room Setting						
								Adult Consent	Haitian-Creole					
				1.1	08/01/2023			ESS Validation Study - Tufts MC Spanish ICF Operating Room Setting						
								Adult Consent	Spanish					
				1.1	08/01/2023			ESS Validation Study - Tufts MC Vietnamese ICF Operating Room Setting						
								Adult Consent	Vietnamese					
				1.1	08/01/2023			ESS Validation Study - Tufts MC Chinese ICF Outpatient Clinic Setting						
								Adult Consent	Chinese					

This will bring you back to where you started in the form.

The revised consent document that you have just uploaded should appear on this table/list. You can verify that you have uploaded the right consent document by clicking on the “View Document” icon to open it (yellow arrow). You can detach (not common) from this submission any consent document that you don’t want to submit to the IRB by clicking on the (X) icon next to it (red arrow).

<input type="button" value="Select or Revise Existing"/>		<input type="button" value="Add a New Consent"/>						
	Version	Sponsor Version	Title	Category	Language	Expiration Date	Consent Outcome	View Document
	1.2		ESS Validation Study - Boston Medical Center Outpatient Clinic Setting Consent Form	Adult Consent	English			 418.35 KB

That’s it! You can start over if you have additional consent documents to revise.