

How to Add a New Consent Form

Note: To add/create a consent form, you need to be in a submission form such as an Initial Review Submission Form, a Change Request & Amendments Form, a Review Response Submission Form, or any other type of form that has a section to add/create a consent form in it (like the one shown in the next slide).

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

| 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. | | | | | | | | | |

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

Note: If the study already have your consent form uploaded/approved, you need to revise it and not add it as a new consent form. 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 web form window titled "Study Consent Add Selection Method:". The window contains two radio button options. A blue arrow labeled "1" points to the top of the window. Two blue arrows labeled "Option 1" and "Option 2" point to the first and second radio buttons, respectively. A blue arrow labeled "2" points to the "Next Screen" button at the bottom right of the window.

1

Study Consent Add Selection Method: x

Option 1 Add an informed consent from the list of Informed Consent Template Documents?

Option 2 Add an informed consent from an existing electronic document you already have?

2

Next Screen

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

- If you selected option 1, proceed to slide # 4 for instructions.
- If you selected option 2, proceed to slide # 10 for instructions.


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

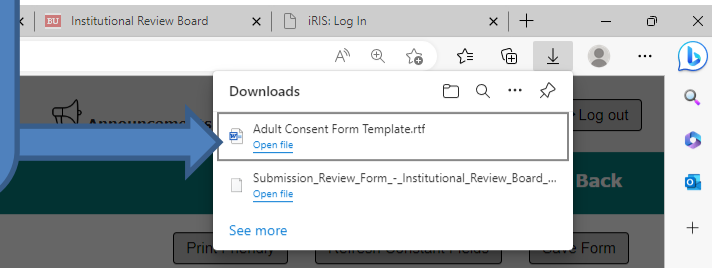
 Download Template



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.

1. The selected Consent template will download. Depending on your web browser, you will get the “Downloads” popup similar to this one. Click on the file to open it.

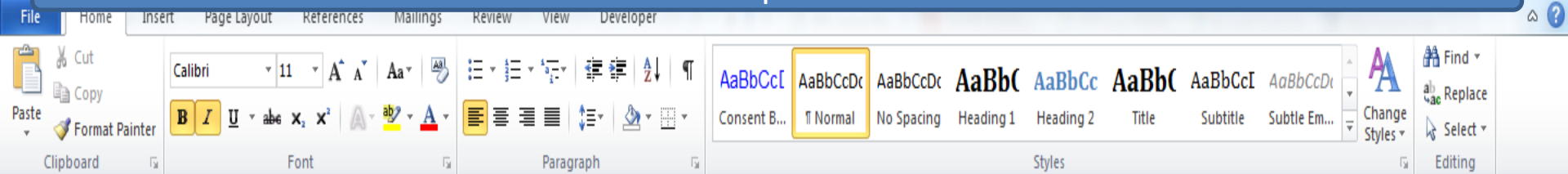
A screenshot of the 'Study Consent Add' popup form. The form has a title bar with a close button (X). It contains several fields: '*Consent Title:' (text input), '*Select the consent to upload:' (a dashed box with the text 'Please drop file/click here to upload'), '*Version Number:' (input with '1' and '.0'), '*Version Date:' (calendar icon and '03/24/2023'), 'Sponsor Version:' (text input), '*Category:' (dropdown menu with '--none--'), '*Language:' (dropdown menu with 'English'), 'Description:' (text area), and 'Comments:' (text area). At the bottom, there are two buttons: 'Close, don't save any changes' and 'Save Consent'. A blue arrow points from the text in the first block to the 'Open file' link in the Downloads popup. Another blue arrow points from the text in the second block to the 'Close, don't save any changes' button.

2. In INSPIR, you will also get the “Study Consent Add” popup. Close this popup since you will not upload the document at this time.

(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.



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 open in Word. Make sure you “save as” this file on your Desktop or somewhere you can find later. 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 slide # 8 for instructions on how to upload this consent document.

Instructions for option # 1

In INSPIR, go back to where you started, to the screen where you can add a new consent form.

| 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. | | | | | | | | |

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:

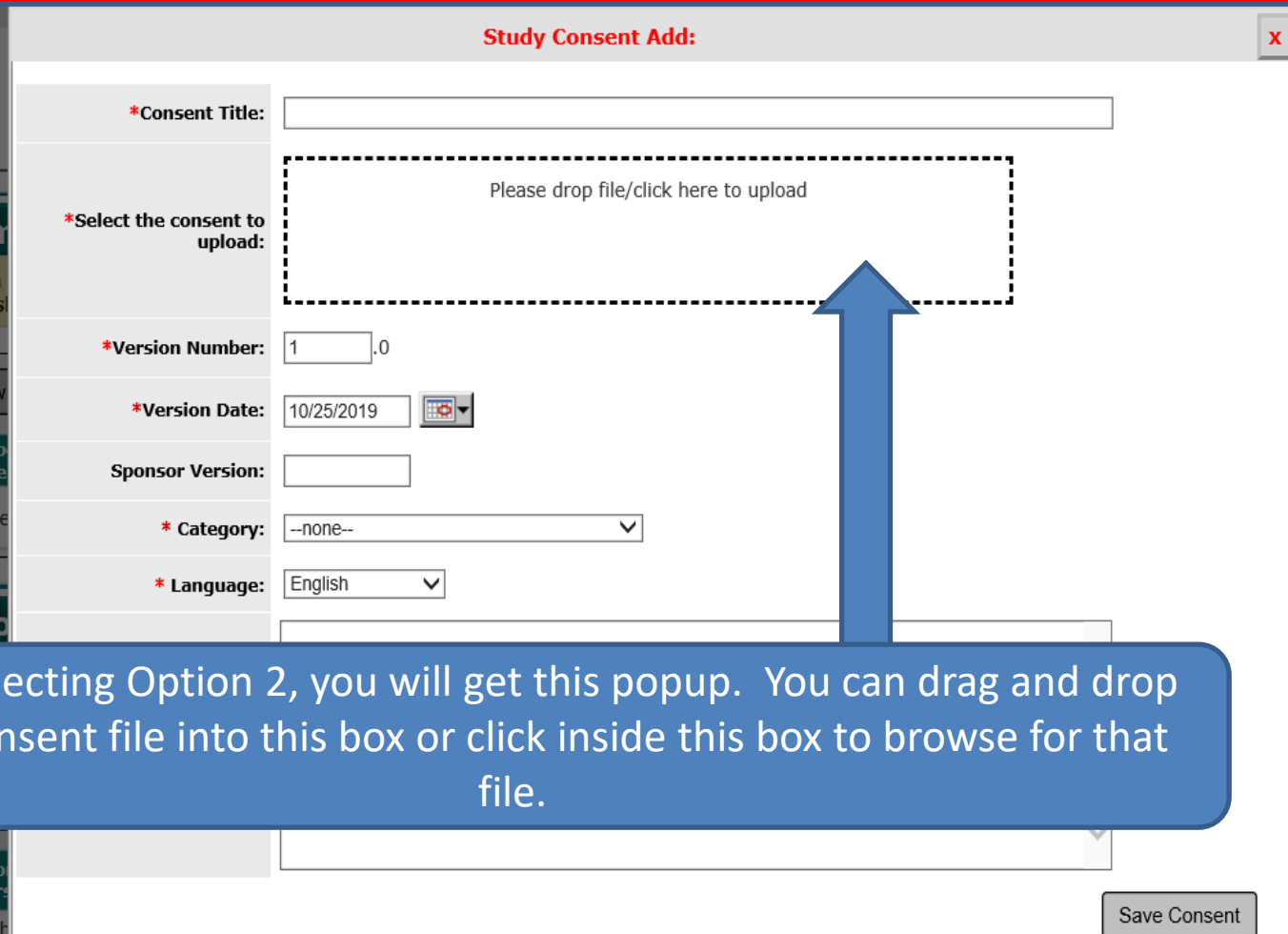
- Add an informed consent from the list of Informed Consent Template Documents?
- Add an informed consent from an existing electronic document you already have?

Next Screen

2. Click on "Next Screen"

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' popup window with the following fields:

- *Consent Title:**
- *Select the consent to upload:** A dashed box containing the text 'Please drop file/click here to upload'. A blue arrow points from a callout box below to this area.
- *Version Number:** .0
- *Version Date:**
- Sponsor Version:**
- * Category:**
- * Language:**

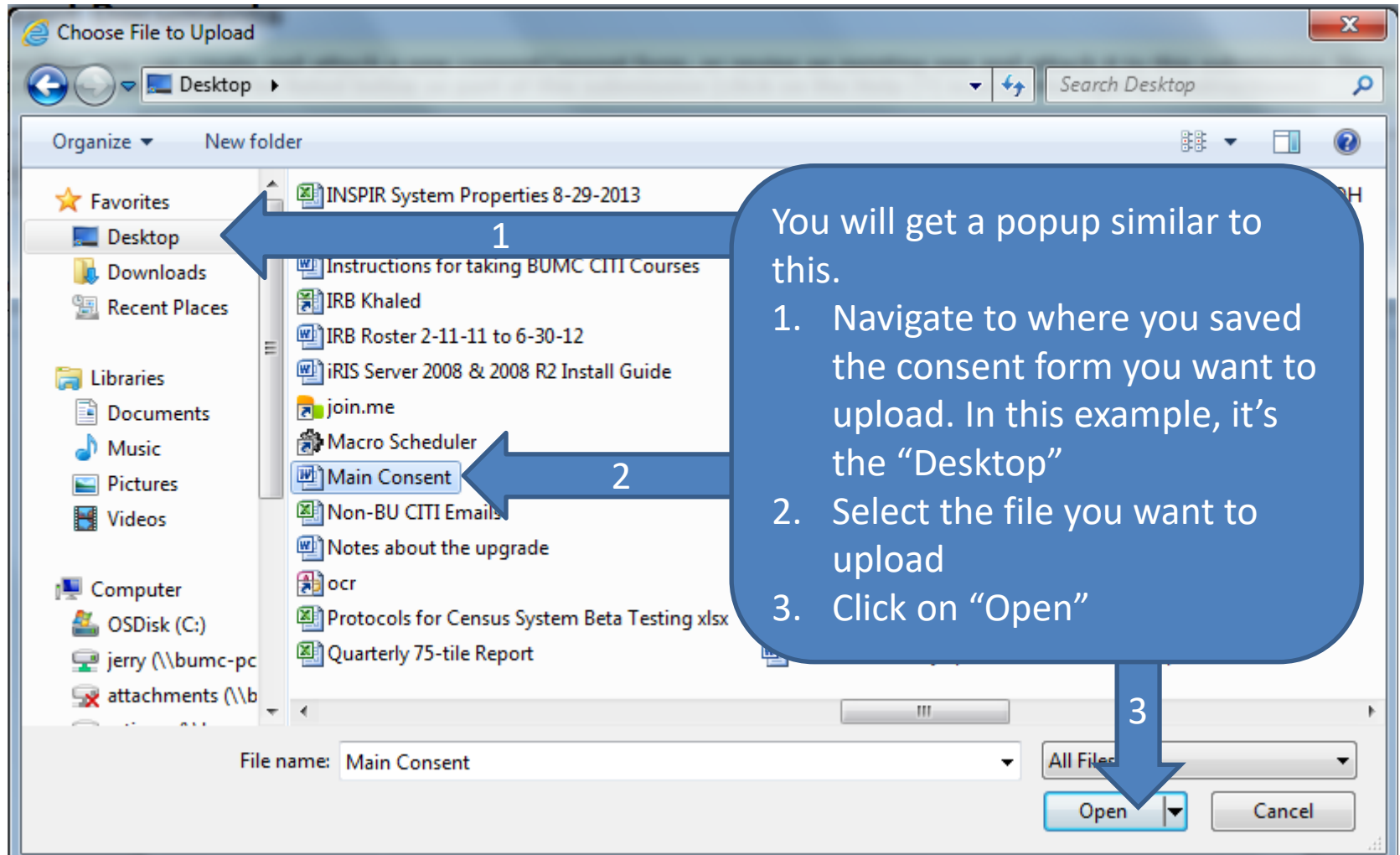
At the bottom right of the popup is a 'Save Consent' button.

After selecting Option 2, you will get this popup. You can drag and drop your consent file into this box or click inside this box to browse for that file.

Instructions for options # 1 and # 2 – continued

If you dragged and dropped the consent file into the box, go to the next slide.

If you clicked inside the box to browse, you will get this popup.



IRB Number: **H-36572**
Study Nickname: Expedited/F
PI: Administrator, --none--

Study Consent Add: X

*Consent Title:

*Select the consent to upload:

Adult Consent Form Template.rtf
0.8 MB
Remove file

*Version Number: .0

*Version Date:

Sponsor Version:

* Category:

* Language:


Description:

Comments:

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).

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

The consent form that you have just uploaded should appear on this table/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 detach (not common) from this submission any consent form that you don’t want to submit to the IRB by clicking on the (X) icon next to it (red arrow).

| Select or Revise Existing | | Add a New Consent | | | | | | |
|---------------------------|---------|-------------------|-------------------|---------------|----------|-----------------|-----------------|--|
| | Version | SP Ve | Title | Category | Language | Expiration Date | Consent Outcome | View Document |
| (X) | 1.0 | | Main Consent Form | Adult Consent | English | | |  290.69 KB |

To revise the consent form that you have just uploaded or to attach to this form a different existing consent form, click on “Select or Revise Existing” and follow the instructions in this link: <https://www.bumc.bu.edu/irb/files/2016/10/How-to-revise-an-existing-Consent-Form.pdf>

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