

How to Add a New Study Document

Note: To add/attach a study document, 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 a new study document in it (like the one shown in the next slide).

Also, please do not upload zip files or any files that the IRB will not be able to open without a special software.

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 study document in it, you will find a section similar to the table shown below where you can add a new study document.

Select or Revise Existing		Add a New Document			Add Multiple Documents			
Detach	Version	Sponsor Version	Title	Category	Expiration Date	Document Outcome	View Document	
No Document(s) have been attached to this form.								

If you haven't already done so, click on the grey "Add a New Document" button to open the "Add a New Document" page.

Note: If the study already have your study document uploaded/approved, you need to revise it and not add it as a new study document. To revise an existing study document, please refer to the instructions in the following link:

<https://www.bumc.bu.edu/irb/files/2016/10/How-to-revise-an-existing-Study-Document.pdf>

This opens the “Study Document Add Verification” pop-up.

Study Document Add Verification

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
Document Outcome: --none--

Title:
Search level: Top All
Expiration Date: between

Filter Documents

Upload a New Document Not on the List

Here are the documents for all categories.
Please click on the Create Revision icon to revise an existing document below or click on Upload a New Document Not on the List to upload a new document to the study.

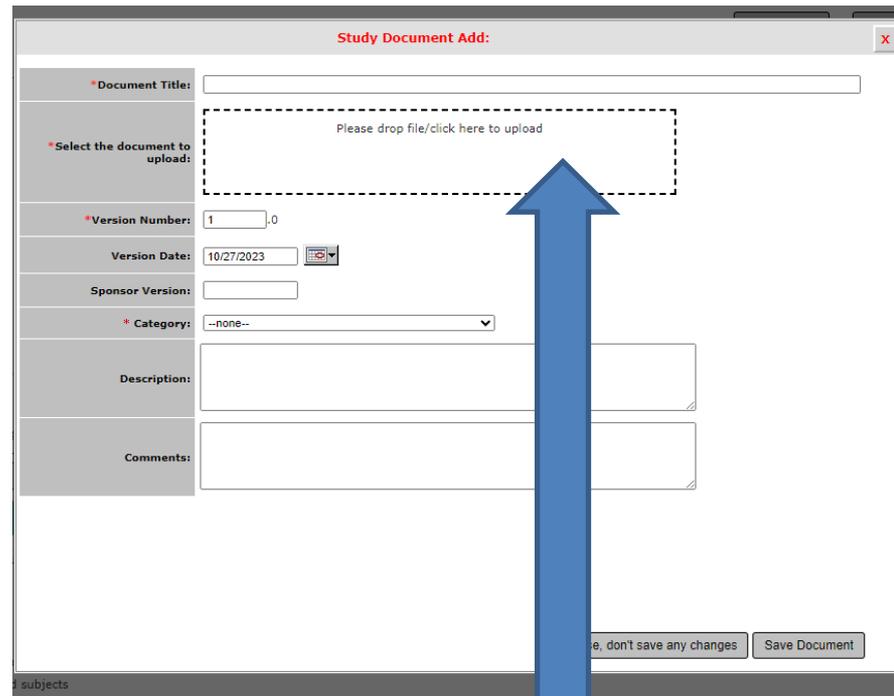
11 result(s) found...

Upload Revised Document	Title	Category	Version	Version Date	Download Document for Editing	Document Outcome	insor Version	View Document
(Read Only)	testing pptx	Flyer	1.2	04/23/2019				247.98 KB
(Read Only)	PI Responsibilities	Signed PI or Supervising PI Responsibilities	1.0	06/26/2020				419.36 KB
(Read Only)	Recruitment Materials Test	Flyer	1.0	12/03/2019				114.55 KB
(Read Only)	test	Not Defined	1.0	08/23/2019				11.30 KB
(Read Only)	Power Point to P DF Test *Added by the I RB	Flyer	1.0	09/05/2018		Approved and Stamped		636.49 KB
(Read Only)	test	FDA Document	1.0	08/27/2018				91.06 KB
(Read Only)	testing stamp	Other	1.1	07/19/2016				360.02 KB
(Read Only)	testing doc file *Added by the I RB	Materials handed out to subjects	1.0	07/19/2016		Approved and Stamped		135.39 KB
(Read Only)	testing stamp *Added by the I RB	Materials handed out to subjects	1.0	07/19/2016		Approved and Stamped		205.14 KB

Cancel Document Add

Click on “Upload a New Document Not on the List” button

This opens the “Study Document Add” pop-up.



The screenshot shows a web form titled "Study Document Add" with a close button (X) in the top right corner. The form is organized into several sections:

- *Document Title:** A text input field.
- *Select the document to upload:** A dashed rectangular box containing the text "Please drop file/click here to upload". A large blue arrow points to this box.
- *Version Number:** A text input field with "1" and ".0" visible.
- Version Date:** A date input field showing "10/27/2023" and a calendar icon.
- Sponsor Version:** A text input field.
- *Category:** A dropdown menu with "--none--" selected.
- Description:** A text area.
- Comments:** A text area.

At the bottom right of the form, there are two buttons: "Cancel, don't save any changes" and "Save Document".

You can either:

- Drag and drop your document in the “Select the Document to upload” box (skip the next slide and go to [slide #6](#)); Or
- Click inside this box and follow your system’s prompts to navigate to where you saved the document to upload it (see [slide #5](#)).

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

The screenshot shows a file explorer window titled "Study Document Add:". The window is open to the "Consent Forms" folder on the Desktop. The search bar contains the text "Signed". The file list is as follows:

Name	Status	Date modified
screen_shot	✓	4/29/2014 10:05 AM
screenshot 4-14-2014	✓	4/14/2014 8:42 AM
screenshot	✓	11/12/2013 12:42 PM
Shopping_Cart	✓	5/9/2014 11:16 AM
Signed Pls Responsibilities	✓	4/11/2016 2:19 PM
Siw...	✓	1/7/2015 11:29 AM
Siw...	✓	1/7/2015 11:26 AM
Spa...	✓	2/11/2013 11:23 AM
Study Personnel Request Screen Shot	✓	11/12/2014 9:54 AM
Sub...on_Review_Form_-_Institutional...	✓	12/4/2013 12:58 PM
tabl...CR Times 5 13	✓	5/28/2013 11:54 AM
tem...using builder	✓	4/2/2014 10:06 AM

The file "Signed Pls Responsibilities" is highlighted. A blue arrow points from the "Open" button at the bottom of the window to this file. Another blue arrow points from the "Open" button to the "Open" button. The "Open" button is highlighted with a blue border.

1. Navigate to the 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 Document Add:” popup.

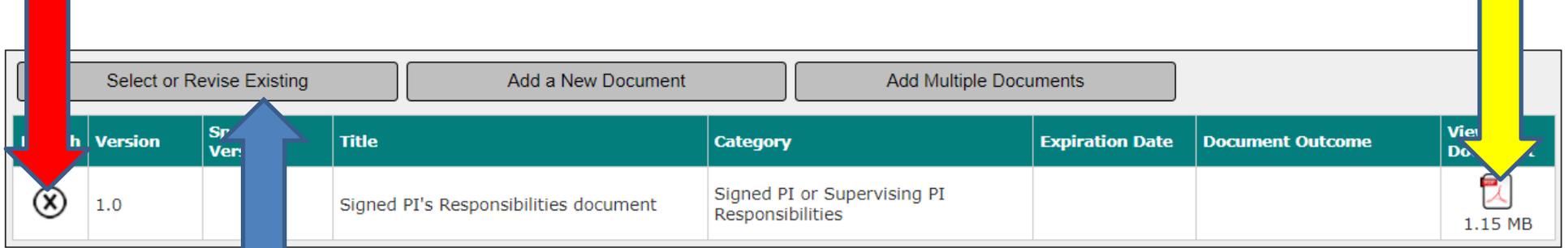
- Notice the uploaded document’s name is now appearing in the popup (blue arrow)
1. Type in a meaningful document title (yellow arrow)
 2. Change the “Version Date” to today’s date (green arrow)
 3. Select a document “Category” (red arrow)
 4. Click on the “Save Document” button (Grey arrow)

The screenshot shows a web form titled "Study Document Add:" with a close button (X) in the top right corner. The form contains the following fields and elements:

- *Document Title:** A text input field containing "Signed PI's Responsibilities document". A yellow arrow points to this field.
- *Select the document to upload:** A dashed box containing a file preview for "Signed PI's Responsibilities.p" (1.1 MB) with a "Remove file" link. A blue arrow points to the file name.
- *Version Number:** A text input field containing "1" followed by ".0".
- Version Date:** A date input field containing "11/06/2023" and a calendar icon. A green arrow points to the calendar icon.
- Sponsor Version:** An empty text input field.
- * Category:** A dropdown menu with "Signed PI or Supervising PI Responsibilities" selected. A red arrow points to the dropdown arrow.
- Description:** An empty text area.
- Comments:** An empty text area.
- Buttons:** At the bottom right, there are two buttons: "Close, don't save any changes" and "Save Document". A large grey arrow points to the "Save Document" button.

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

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



The screenshot shows a document management interface. At the top, there are three buttons: "Select or Revise Existing", "Add a New Document", and "Add Multiple Documents". Below these is a table with the following columns: "ID", "Version", "Sp. Ver.", "Title", "Category", "Expiration Date", "Document Outcome", and "View Document". A red arrow points to an "X" icon in the "ID" column of the first row. A blue arrow points to the "Sp. Ver." column of the first row. A yellow arrow points to a document icon in the "View Document" column of the first row. The first row contains the following data: ID: 1, Version: 1.0, Sp. Ver.: (empty), Title: Signed PI's Responsibilities document, Category: Signed PI or Supervising PI Responsibilities, Expiration Date: (empty), Document Outcome: (empty), View Document: 1.15 MB.

ID	Version	Sp. Ver.	Title	Category	Expiration Date	Document Outcome	View Document
1	1.0		Signed PI's Responsibilities document	Signed PI or Supervising PI Responsibilities			1.15 MB

To revise the document that you have just uploaded or to attach to this form a different existing document, 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-Study-Document.pdf>

You’re done adding the study document. You can start over if you have additional study documents.