



Job Aid Title	eIRB File Management
Relevant Users	Principal Investigator (PI), Study Staff
Covered Topics	<ul style="list-style-type: none"> ○ eIRB File Management Overview ○ Important Tips for Naming Study Documents ○ Steps to Edit Study Documents

A. eIRB File Management Overview

- You can edit study documents in eIRB for the following three submission types:
 - **Study**
 - **Modification**
 - **Continuing Review and Modification**

! Note: You are not able to edit study documents for a Reportable New Information (RNI) or a 'Continuing Review' submission.
- Go to **Section 7.0 Attachments** of the eIRB submission to edit study documents.
- **eIRB does not allow users to delete documents in Section 7.0 Attachments.** Documents can only be added or replaced (revised). When appropriate, the IRB may advise you to rename the document as "do not use" or "no longer in use <old file name>." Use this workaround sparingly. Contact the IRB for assistance.
- **When revising existing study documents in eIRB, do not use the ADD button.** Replace the existing document by clicking on its name in section 7.0 Attachments, and then use the UPLOAD REVISION function. For the Investigator Study Plan, click on UPDATE next to its name and then UPLOAD REVISION.
See **section C 'Steps to Edit Study Documents'** below for detailed instructions.
[Or, watch a short tutorial here.](#)

TROUBLESHOOTING: If you are missing the buttons to add or update documents in Section 7.0 Attachments, try the following steps (in this order):

1. **Log out of eIRB and exit the browser. Log back in to eIRB. (This generally fixes permissions errors resulting from eIRB sessions timing out.)**
2. **Go to the main study (parent) and check that you are listed as Study Staff under Project Personnel.**
3. **Go to the main study (parent) and click on Edit Research Staff. Click OK at the bottom of the Edit Research Staff window.**
4. **Then, return to your submission (under Follow-on Submissions tab for continuing reviews, modification, or RNI).**

Try the above steps before contacting the IRB office. If you continue to have issues, contact the IRB office at 508-856-4261.



B. Important Tips for Naming Study Documents

- You control the names of the documents displayed in eIRB.
- Use a filename that describes the study specific document and version. The version in the filename should match the version listed within the document.
 - 'Good' filenames: ConsentNov2014; Sponsor protocol amendment 4
 - 'Bad' filenames: Investigator study plan template with instructions; Document 1
- **When you ADD a brand new document, leave the TITLE field blank** so that eIRB automatically uses the filename.
- **When using UPLOAD REVISION, erase the title field.** Otherwise, eIRB will continue to use the old (previous) document name. If you prefer, you can manually change the name in the TITLE field.
- The eIRB document name is displayed in eIRB and automatically merges into IRB correspondence letters. *Name the documents appropriately so the IRB letters will clearly reflect the document version that was reviewed and/or approved for the submission.*
- You can change the name of a document in eIRB without replacing it. Simply use the UPLOAD REVISION function in 7.0 Attachments and update the TITLE field. **See section C (steps 4 and 6) below for instructions.**

C. Steps to Edit Study Documents

The following steps will assist you in revising existing study documents in eIRB.

1. On the page for your submission, click **EDIT STUDY** or **EDIT CR/MODIFICATION** depending on your submission type.
2. Go to section **7.0 Attachments**.
You can quickly access 7.0 Attachments in the JUMP TO menu or you can click Continue through the sections. When editing a CR/MODIFICATION, you can quickly JUMP TO: OPEN STUDY FOR MODIFICATION and then JUMP TO: 7.0 Attachments.
3. If you are revising the Investigator Study Plan, click on **UPDATE** next to its name. See picture below.

If you are revising a document from the list of Other Documents, click on the **name of the document** (e.g., click on Informed Consent Form Version Dated 10.1.13). ***Do not click ADD when revising an existing document.*** See picture below.



7.0 Attachments

- Investigator Study Plan: Investigator Study Plan Version Dated 10.1.13.docx(0.01)
- Other Documents

Name	Category	Date Modified
Informed Consent Form Version Dated 10.1.13.docx(0.01)	Consent Document(s)	10/8/2013
Protocol Version Dated 8.1.13(0.01)	Sponsor Protocol	10/8/2013
HIPAA Authorization Version 1(0.01)	HIPAA	10/8/2013

Click **UPDATE** if you are revising the Investigator Study Plan

Click on the **name** of the document you are revising.

- Click on **UPLOAD REVISION** next to the attachment's name in the pop-up window to edit the attachment.

Add/Edit Attachments

* Attachment Name: Informed Consent Form Version Dated 10.1.13.docx(0.01) | History

* Attachment Category:

Name	Supporting Document
<input type="radio"/> Advertisements	yes
<input type="radio"/> Assent Document(s)	yes
<input checked="" type="radio"/> Consent Document(s)	yes
<input type="radio"/> Grant Application	no
<input type="radio"/> Investigator Brochure	yes
<input type="radio"/> Product Information-Devices	yes
<input type="radio"/> Sponsor Protocol	yes
<input type="radio"/> HIPAA	yes
<input type="radio"/> Other	yes
<input type="radio"/> Clear	

* Required

- If you are only revising the name of a document and not replacing the file, skip ahead to step 6.

Click on **BROWSE** in the 'Submit a Document' window to find and attach the revised file from your computer.

Submit a Document

Title: Informed Consent Form Version Dated 10.1.13 If not provided, the name of the file will be used

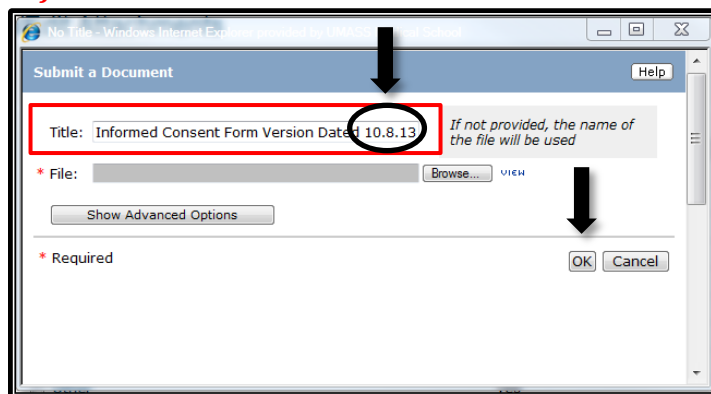
* File:

* Required

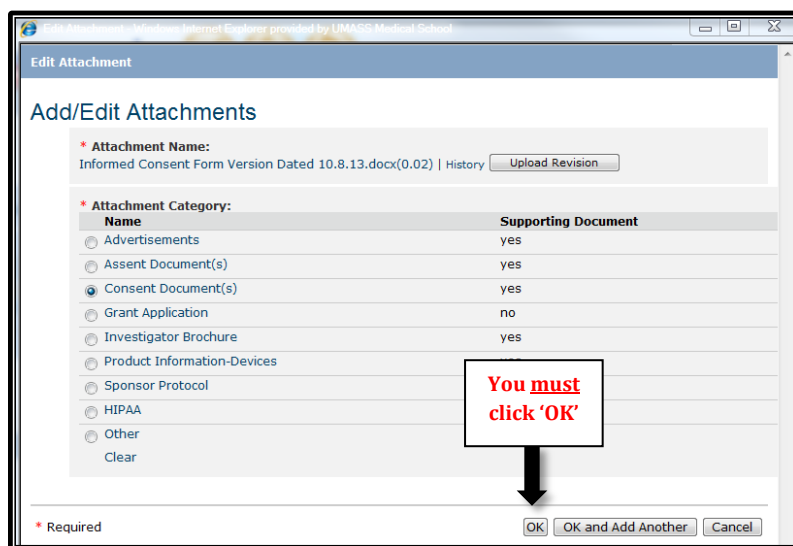


- Before clicking **OK** in the 'Submit a Document' window, remember to check the name of the document in the **TITLE** field. See **section B 'Important Tips for Naming Study Documents'** above for detailed instructions. When you are ready to submit the document, click **OK**.

In the picture below, we updated the **TITLE** field to reflect the new version date (Informed Consent Form Version Dated **10.8.13**). **You control the name of the document in eIRB via the TITLE field.**



- You will return to the 'Add/Edit Attachments' window. If needed, you can change the Attachment Category (e.g., advertisements, assent document(s), consent document(s)). Click **OK** at the bottom of the window.





8. You will then be returned to section 7.0 Attachments. Click **SAVE**. After saving, check the list in section 7.0 to ensure the documents attached. Please review to make sure all of your new and/or revised documents appear in this section. Then, click **EXIT**.

Save | Exit | Hide/Show Errors | Print...

<< Back
Save | Exit | Hide/Show Errors | Print... | Jump To: 7.0 Attachments

7.0 Attachments

1. **Investigator Study Plan:** Investigator Study Plan Version Dated 10.1.13.docx(0.01) Update
2. **Other Documents**

Add

Name	Category	Date Modified
Informed Consent Form Version Dated 10.8.13.docx(0.02)	Consent Document(s)	10/8/2013
Protocol Version Dated 8.1.13(0.01)	Sponsor Protocol	10/8/2013
HIPAA Authorization Version 1(0.01)	HIPAA	10/8/2013

You must click 'SAVE' and check the list of attachments in 7.0 before exiting!

!Note: If you find that a document 'disappears' or does not attach in section 7.0 after you have uploaded it, try uploading the document again. **Be sure to click SAVE and check the list of attachments before exiting! If you do not SAVE, you may lose the attachments after you exit.** If the document still does not appear in section 7.0, please contact the IRB office at x6-4261 for help.

!Note: By appropriately using the UPLOAD REVISION function, previously uploaded versions of the file will be stored in the document's **HISTORY** (see picture below).

Documents	Project Personnel	Follow-on submissions	Clarifications Requested	RNI	Full History
Category					Date Modified
Investigator Study Plan	INVESTIGATOR STUDY PLAN 12.30.14.docx - 0.01 History				1/14/2015 3:50 PM
Advertisements	Phone Screening Script Version 1.doc - 0.01 History				1/14/2015 4:13 PM
Consent Document(s)	Informed Consent Form V1 dated 1.14.15.doc - 0.04 History				1/14/2015 4:13 PM
HIPAA	HIPAA Authorization Form V1 dated 1.14.15.doc - 0.02 History				1/14/2015 4:13 PM

Resource History for Informed Consent Form V1 dated 1.14.15.doc

Title: Informed Consent Form V1 dated 1.14.15.doc
 File: Informed Consent Form V1 dated 1.14.15.doc
 Owner: Evelyn Foxtrot
 Author: Evelyn Foxtrot
 Content Type: Document
 Version: 0.04
 Description:

History:

Date	Version	Person	Action	Notes	Uploaded File
1/14/15 4:13 PM	0.04	Evelyn Foxtrot	File Uploaded & Edited		Informed Consent Form V1 dated 1.14.15.doc
1/14/15 3:52 PM	0.03	Evelyn Foxtrot	File Uploaded & Edited		Informed Consent Form V1 dated 1.2.15.doc
1/14/15 3:51 PM	0.02	Evelyn Foxtrot	File Uploaded & Edited		Informed Consent Form V1 dated 10.15.14.doc
1/14/15 3:50 PM	0.01	Evelyn Foxtrot	Created		Informed Consent Form.doc