

Revising and Uploading Documents for a Modification

(v. 05-15-24)

IMPORTANT

- A [modification request form](#) is to be included with a modification submission.
- **Personnel Changes DO NOT require a modification request form UNLESS you are changing the study PI in which case, a mod request form is required.**
- **Include tracked changes** versions of revised documents for review by the IRB, making sure to add the word “Tracked” to the document titles as applicable. The tracked changes version allows the reviewer to see the changes made to the document and act as placeholders during review.
- Include the **date** of the document in the document title.
- Update the version date in the footer for any document you are modifying.
- All documents, except for SPONSOR provided documents (e.g. PROTOCOL, IB, MOP etc.) must be submitted as Word documents for editing purposes.
- Keep **your own Word copies** of IRB approved documents to be used for future modifications when applicable.

STUDY TEAM INSTRUCTIONS:

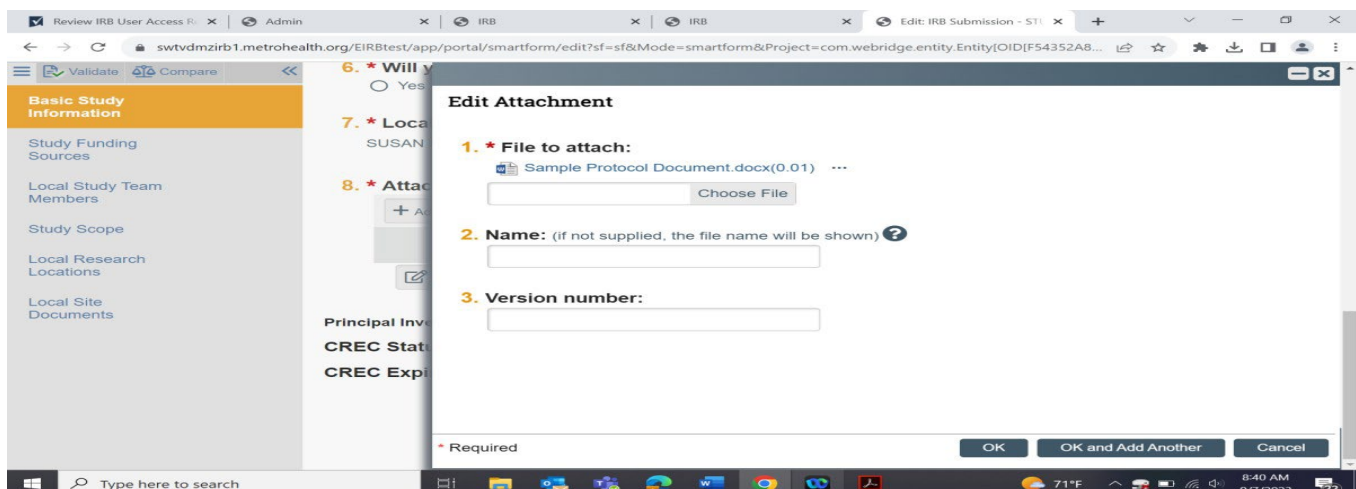
1) After you have made the applicable revisions to the documents and are ready to upload and submit to the IRB, find the section of the eIRB application where the document is located. As an example, see image below showing the PROTOCOL.

2) Next to the document name, click “Update.” Note: If there are not previous tracked change copies of your document, then upload your tracked changes document using the “Add” button.

8. * Attach the protocol: ?



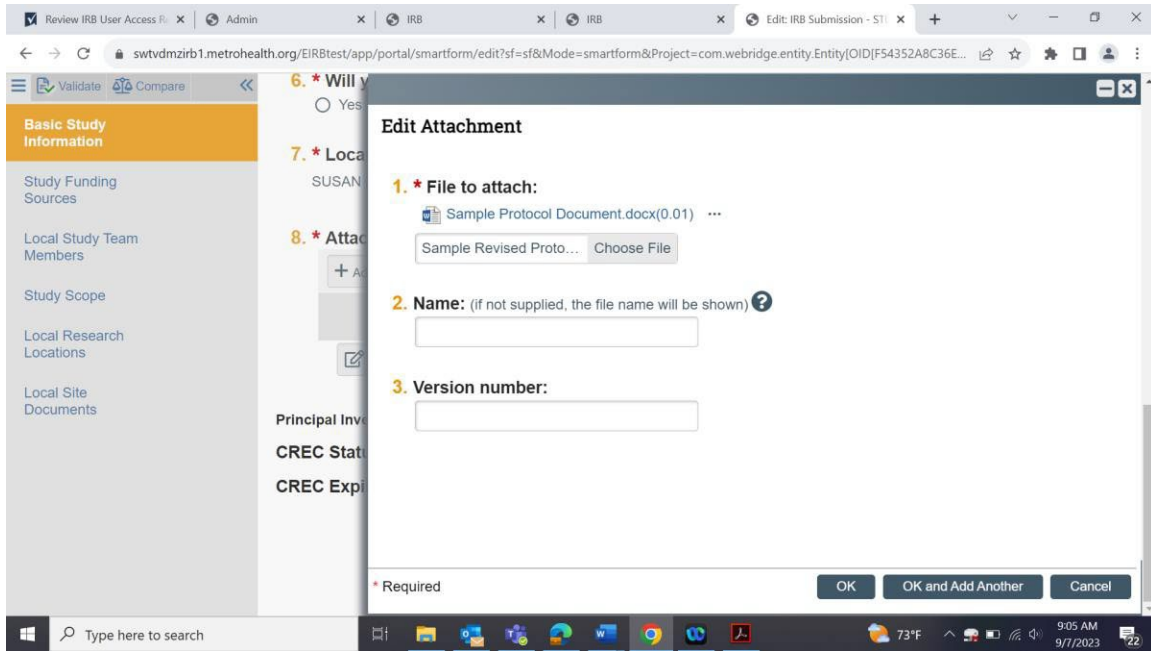
3) In the window that opens, click “Choose File” in section 1 to select the document that you would like to replace the document currently attached to the eIRB application.



4) After uploading your document of choice, you may click “OK.” Alternatively, you may click “OK and Add Another” to begin adding additional revised documents to this section of the eIRB application. **The remaining sections in the window should be completed as follows:**

- **Section 2:** Add a **display name for the document AND the date of revision in the title** (e.g., a name that you or your sponsor need to appear on the IRB approval letter_DATE).
- **Section 3:** By default, the version number will auto-populate as 0.01, 0.02, etc. each time a revised version of the document is uploaded.

E.g., Protocol_04-23-24_tracked; Adult Consent_04-23-24-tracked; Flyer_04-23-24.



5) The revised document will now be saved and replace the older version.

8. * Attach the protocol: ?

Document	Category	Date Modified	Document History
 Sample Revised Protocol Document.docx(0.01)	IRB Protocol	9/7/2023	History

Note: Any older versions of the document may be seen by clicking “History” to the right of the document. A new tab will open with all previous versions of the document that have been attached to the application to date (see below).

How Upload newer versions of documents on top of (stacked) the older version.

Click “update” next to the older version. The latest version of that document will present at the front. (and the older version will only be able to be accessed by hitting “history”)

The screenshot shows the 'Attach the protocol' step of the IRB submission form. A table lists the attached documents:

Document	Category	Date Modified	Document History
IRB20-00148_Generated.Snapshot.html(0.01)	Other		History

Below the table, the 'Principal Investigator Training' section shows 'CREC Status: Certified' and 'CREC Expiration Date: 8/8/2026'. At the bottom right, there are buttons for 'Exit', 'Save', and 'Continue'.

The 'Edit Attachment' dialog box is open, showing the following fields:

- 1. * File to attach: IRB20-00148_Generated.Snapshot.html(0.01) ...
- 2. Name: (if not supplied, the file name will be shown) File Example 4.29.24
- 3. Version number: 2

Buttons at the bottom include 'OK', 'OK and Add Another', and 'Cancel'.

The 'Resource History' page for 'Sample Revised Protocol Document.docx' shows the following details:

Title: Sample Revised Protocol Document.docx
File: Sample Revised Protocol Document.docx
Owner: System Administrator
Author:
Content Type: Document
Version: 0.02
Description:

History:

Compare	Date	Version	Person	Action	Notes	Uploaded File
<input type="checkbox"/>	9/7/2023 9:58 AM	0.02	System Administrator	File Uploaded & Edited		Sample Revised Protocol Document.docx
<input type="checkbox"/>	9/7/2023 9:58 AM	0.01	System Administrator	Created		Sample Protocol Document.docx

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Buttons: Compare, OK