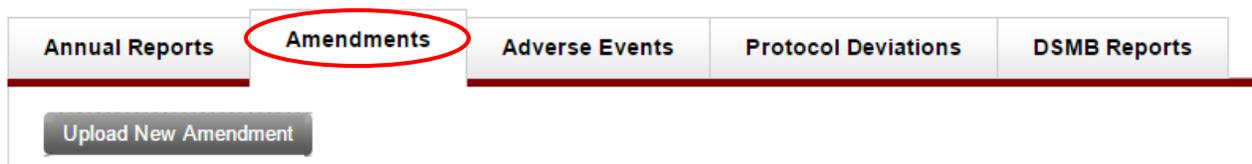


How to Submit an Amendment / Modification / Revision

From time to time, the PI may wish to modify a protocol. There are a variety of reasons for such modifications (scientific need, new risk information comes to light, protocol procedures don't work as intended, etc.). When a protocol is modified, the PI is required to submit the modification to the IRB for review. Such modifications may be called "amendments", "modifications" or "revisions" depending on the practice of the IRB. The regulations require that the IRB review and approve all such modifications, including modifications to exempt protocols (as the changes may affect the exempt status).

To submit an Amendment, logon to Mentor IRB. Under the IRB tab, click on My Protocols. All of your protocols should be listed. Click on the title of the protocol you want to revise, and the View Protocol screen will open.

At the bottom of the View Protocol screen there are a number of tabs: Annual Reports, Adverse Events, etc. (tabs may be labeled differently by your IRB based on the terminology that is customary at your institution). Make sure you are on the Amendments tab. Click on the gray Upload New Amendment button.



Upload a file by clicking on the "Choose File" button to navigate your computer, then click "Open" to select and upload the file.

Upload New Amendment

Protocol Title Test Protocol

Amendment **Choose File** No file chosen
Allowed Extensions: doc, docx, pdf, rtf

An email will automatically be sent to the IRB Chair and Administrator upon successful upload of your protocol amendment.
If you would like to send any message along in that email, please use the text box below.

Message

Save Cancel

Some IRBs will have defined a set of specific files to upload when submitting an amendment. For instance, there may be an upload button for Amendment Summary, Protocol Description – Track Changes, Protocol Description – Changes Accepted, etc. Upload the documents that are appropriate for your amendment. For instance, some amendments do not affect the approved consent form so there would be no need to upload a Consent Form file.

Some IRBs may also have defined a dropdown menu on the amendment submission form for indicating the type of amendment. If this menu appears, select the appropriate option.

Click "Save". An email will automatically be sent to the IRB Chair and Administrator upon successful upload of your protocol Amendment. If you would like to send a message along in that email, use the Message text box at the bottom of the page.

You must await formal approval of your amendment by the IRB before implementing the changes requested. Some amendments can be expedited approved by the chair if it is a minor change. Other amendments may require full board review.