Log In

NIH National Institutes of Health
Turning Discovery Into Health

User ID:

Password:

Log In

System/Browser Requirements

Any issue? Please submit a request to nihirbsupport@nih.gov

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General Information:

This document is to help study staff users correctly version their documents within the IRIS system. The versioning will allow for both study staff and IRB staff quickly access the currently approved documents for their study. First, we will cover document submissions when the action is being submitted to the IRB for the first time. Secondly, we will show how to revise a document that was sent back to the study staff as part of a stipulation or pre-review.

Initial Action Submission (when first submitting an initial review/amendment/CR/ETC):

Uploading a document for the first time:
These instructions are for uploading a document THAT HAS NEVER BEEN UPLOADED INTO IRIS. For example, the addition of a consent for a new cohort or PFH Form for a new investigator. To upload these documents, we will use the Add A Document Feature.

Click on the Add a New Consent or Add a New Document button

This will open the upload window. Click browse to select the document for your computer. Enter the Version number, Version Date and select a Category from the Drop-Down Menu. Once the information is entered, click Save Document
You can now see the document listed on the Attachments Table. To un-attach, click the red X.

To Attach a Previously Attached document:

To add a new version of a previously submitted (IN ANY SUBMISSION) document, do the following steps. Select the “Select or Revise Existing” button
This will open the document pick list of documents. You can filter the documents shown by version number, category, title or date. When you find the document, click the “Create Revision” button to the far right of the document row.

This will open the study Document Revision Screen. Click Check-Out Document. Note: The system automatically creates a new version number (ie 1.1 becomes 1.2).
On the next screen, click “Complete Checkout”.

Click the “Check-In Document” Button
This will open the window to upload the new version from your computer. Click on the “Browse” button to select the file. Then click the “Save selected File” button.
You can now update the document information such as Name and Version Date. Once complete, click the “Save Document” button.

The newly revised document is now attached to this submission and is viewable on the table.
Document Versioning in Response to Stipulations:

There are two ways the analysts can send back Stipulations to the study staff. The first is linking the document in question and the second is a non-linked stipulation.

Linked Stipulation:

Revising a document that was submitted
These are identified by the Red Action Not complete box as part of the stipulation. First we will cover revising a document based on a stipulation.

Click on the Revise Existing button. Click OK to create a revision.

This will open the window to the Document Revision Screen. Click Check-Out Document. Note: The system automatically creates a new version number (ie 1.1 becomes 1.2).
On the next screen, click “Complete Checkout”.

Click the “Check-In Document” Button
This will open the window to upload the new version from your computer. Click on the "Browse" button to select the file. Then click the "Save selected File" button.
You can now update the document information such as Name and Version Date. Once complete, click the “Save Document” button.

The newly revised document is now attached to this submission and you can see it in the stipulation.

To complete the action, click the complete action radial button. This will mark the action as completed. Answer the stipulation in the box provided.
This will also update the table at the end of the submission response form with the newly updated document.

Add a document

To add a document to a linked stipulation, do the following:

Click on the Add Document button under the stipulation.
This will bring up the add document screen. Select Add a New Document.

This will open the Study Document Add screen. Click browse to select the file from your computer. Enter the Version Number, Version Date and Category. When finished Select Save Document.
The document is now added to the Submission and the Action is automatically marked as Complete. Enter a Response in the explanation box to complete the stipulation.

Remove a document

To remove a document from a linked stipulation, do the following:

Click on the Remove button with the action.
Confirm that you wish to remove the component by clicking OK.

The document has now been removed from the submission. The system automatically marks as complete. Enter an explanation in the box provided.
Non-Linked Stipulations:

Revise a document

To revise a document, when it is not linked to a stipulation, do the following:

Determine document to be reviewed from the stipulation. Scroll to the bottom of the form to the list of the submission components. Find the document in question and click the Revise/Attach button next to the document. Click Ok to create a revision.

This will open the window to the Document Revision Screen. Click Check-Out Document. Note: The system automatically creates a new version number (ie 1.1 becomes 1.2).
On the next screen, click “Complete Checkout”.

Click the “Check-In Document” Button

This will open the window to upload the new version from your computer. Click on the “Browse” button to select the file. Then click the “Save selected File” button.
You can now update the document information such as Name and Version Date. Once complete, click the “Save Document” button.

The document is now attached the submission in the submission component Section. The newest version is on top and older revisions can be viewed by clicking the folder icon.
Add a document

To add a document to an un-linked stipulation:

**NOTE: THIS IS FOR A DOCUMENT THAT WAS NOT PREVIOUSLY SUBMITTED**

Scroll to the table at the bottom of the Submission Response Form and select Add New Component:

Select the document type.
This will open the Add Document Screen. Note: Add Multiple is only available under the Other Study Document Category.

The Add Document Screen will then open. Enter the document details, click upload to add the document.

The upload window will open for you to select the document from your computer. Click browse then save selected file.
Click the Save Document button in the upper right-hand corner.

This will bring you back to the Attach Study Documents Screen. The new document is already selected from the list. Click Attach to attach it to the submission. **NOTE: IF YOU DO NOT DO THIS STEP THE DOCUMENT WILL NOT APPEAR.**

The document is now attached to the submission and is viewable on the Attachment table. Enter a response to the stipulation to close the stipulation.
Remove a document:

**ONLY THE IRB CAN REMOVE A DOCUMENT WITHOUT LINKING IT TO A STIPULATION.**