IRIS GUIDE

Revision Requests

Respond to revisions and corrections requested by the IRB or ORRC.

Office of Regulatory Research Compliance

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iRIS Guide
Revisions and Corrections

Notification for correction
When a submission is received by the ORRC, a Compliance Officer reviews the submission for completeness. In cases where the submission is incomplete, the ORRC may send an email through the iRIS to notify the research team of what changes are recommended to ensure that the , the ORRC ensures that that submission includes all necessary items prior

Notification for revision

Stipulations

Attaching documents

When you log into iRIS, go to the **Study Assistant Workspace**. You may switch workspaces by hovering over the **My Workspaces dropdown** under the iRIS logo. Whenever you want to manage your studies, be sure to use the Study Assistant Workspace. To review IRB submissions and perform other IRB-related activities go to the IRB Assistant workspace.

When you get to the Study Assistant Workspace, scroll down to the **Tasks** panel (The label may say All Tasks or Study Tasks). Ensure that the **Study Task tab** is selected so that you may see details on each task. Use the **RB Number column** to find the IRB number of the study you wish to work on. The **Task Type column** indicates the type of tasks that are awaiting an action from you. Once you have found the task that you wish to work on, open the task clicking on the icon in the **Click to open column**.

You will be sent to the **IRB - Review Response Form**, where you may respond to each stipulation. Scroll down the page to find the stipulations that you need to respond to. Depending on the stipulation, you may be asked to revise the application, revise a document that was previously submitted, add a new document, answer a specific question, or you may be given a recommendation that needs no response.

Below is an example of a requests that may be asked of you. For all stipulations, read the description of the stipulation to find out what is being asked of you.
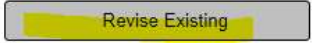
Revise the IRB Application or other Form

1. Read the edits that are being requested and click on the **Revise Existing button** in the **Actions column**.

2. A new, editable version of the IRB Application will be created. A link to the new version of the application will be listed in the Component Name column. Click on the link to open the application and make the necessary edits. When done, save the changes to return to the IRB - Review Response Form.

Revise a Document

1. Read the description to find out what document should be changed and what changes should be made to it. Update the document outside of iRIS.

2. A new version of the document will be created and listed in the Component Name column. Click on the link of the new version to upload the updated document.

3. The document window will open that includes details on the document. Scroll down to find a **Check-Out button**. Click on the button to check out the document, which saves the current version of the document to your computer so that you may revise. The Check-Out button will change into a Check-In button.

4. Once the required revision have been made to the document, click on the **Check-In button** to attach the updated document. Then click on the Save Consent button to complete the process.

Add a Document

1. Read the description to find out what document to add. Click on the Add Document button in the Action column.

2. Click on the Upload a New Document Not on the List button found on the right side of the window.

3. Add the document by dragging it into the space indicated or by clicking on the upload area and searching for the document. Ensure that a category is given to the document. A description can be given to the document to identify it from other similar documents. Once the upload is done, click on the **Save Document button**.

Add Additional Documents

1. For each stipulation, the system only allows one document to be added. However, if multiple documents need to be added for one stipulation, additional documents may be added in the Submission File section. Scroll to find the **Submission File section**. This section lists all documents and forms that have been attached to the study. Click on the Add New Component button to add a document.

2. Indicate if the document being added is an informed consent/assent document or another type of document.

   ○ Informed Consent
   ○ Other Study Document

3. Depending on the type of document click on the appropriate button to add a document.

4. Click on the Upload a New Document Not on the List button found on the right side of the window. Or the Choose File button for multiple documents.

5. Save the uploads.

For each stipulation, ensure that you indicate if you accept the stipulation or not. If you have accepted the stipulation and have edited or added an item, select the Complete Action option in the Actions column to indicate that the action has been completed. In the textbox, ensure that you explain how you addressed the stipulation or explain why you do not accept the stipulation. You may provide any other information related to the stipulation as well.

Links to Components	Operation	Action Status	Component Name	Action
(These are the items that are linked to this stipulation)	Modify Existing Attachment	Action Complete	✎ IRB Application (Version 1.1) 📖 IRB Application (Version 1.0) Section: General Information	Compare Application Version ● Complete Action ○ Incomplete Action

Do you accept this Stipulation?   ○ N/A ● Yes ○ No

Provide an explanation on how you addressed this Stipulation:

[text editor toolbar]

- Explain how you addressed the stipulation.
- Click on the Complete Action option to complete the action.
- Indicate if you accept the stipulation or not. If you do not accept the stipulation, explain why in this textbox.

Once all stipulations have been addressed, click on the Save and Continue to Next Section button located at the top-right of the page then Signoff on the submission.

Save Section   Save and Continue to Next Section