

Quick Guide: Revise and/or Add Documents and Consent Forms to a Study

When to Use This Guide

Use this guide when you are submitting either of the following to the IRB:

- Revised versions of study documents or consent forms
- New documents or consent forms (e.g., no previous versions associated with the study)

Background

The April 2022 iRIS upgrade has impacted how users can revise and add documents and consent forms to a study. Previously, users could do this through the study dashboard, like this:

1

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Previously, this page included buttons for adding new documents

In the new version of iRIS, this is no longer an option:

Buttons for adding new documents no longer exist

Now, there are two ways to add new or revised consent forms and other study documents:

1. Through an IRB submission form (e.g., Initial review submission form, Modification Form, Continuing Review Form, Personnel Changes Form, etc.).
2. Through the Review Response Submission Form when stipulations have been sent to the study team.

Option 1: IRB Submission Forms

Documents and consent forms may be added or revised when submitting the following IRB submission forms: Continuing review, Modification, Personnel changes, and Protocol enrollment exception request.

New documents (not consent forms) may also be added (but not revised) when submitting the following IRB submission forms: Adverse event, Protocol violation/Incident report, and Reporting form.

The below example involves a modification form, but the steps are similar for other types of IRB submission forms.

In the submission form, there may be a question asking if any new or revised documents/consent forms will be attached, or if changes are being made to any documents/consent forms. If so, check the box for each kind of document you intend to add or revise; This will prompt the submission form to branch in a way that lets you attach new/revised forms.

Example:

The modifications require changes to: **(REQUIRED)**

- ☐ Study Application
- ☐ Consent Documents
- ☐ Other Study Documents
- ☐ None

Note: If this question is not on the submission form, don't worry! Not all IRB forms include a question like this.

The section for adding and/or revising documents and consent forms includes several buttons:

- **Select or Revise Existing:**
Use this when you need to revise an approved document or to upload a revised document
- **Add a New Document:**
Use this to add an entirely new document, *i.e.*, no version of this document has been previously associated with this study
- **Add Multiple Documents:**
Upload multiple entirely new documents simultaneously

1.20 NEW AND/OR REVISED DOCUMENTS AND CONSENT FORMS:

* Do you need to attach any revised consent forms: **(REQUIRED)**

☐ Yes ☐ No

Select or Revise Existing Add a New Consent

Detach	Version	Sponsor Version	Title	Category	Language	Expiration Date
No Consent(s) have been attached to this form.						

* Do you need to attach any new or revised Study Documents: **(REQUIRED)**

☐ Yes ☐ No

Select or Revise Existing Add a New Document Add Multiple Documents

Detach	Version	Sponsor Version	Title	Category	Expiration Date
No Document(s) have been attached to this form.					

Note: This is a screenshot from the Modification Form. This section may look slightly different, or there may be separate sections for Consent Forms and Other Documents, depending on which IRB submission form you use.

Add a New Document or Consent Form

To add a brand-new document or consent form, click **Add a New Document [or consent form]**.

A pop-up window will appear with a list of all the documents previously submitted for this study. This list is a prompt for you to make sure you are truly adding a never-before-submitted document rather than a new version of one of the listed documents.

Note: At the top of the window, there are search tools to help you find what you are looking for. This is helpful if there is a long list of documents associated with the study.

If a version of the document is not on the list, click **Upload a New Document Not on the List** and follow the instructions for uploading the new document.

New as of April 2022:

New Drag/Drop functionality allows you to drag and drop files from your local computer. Use this functionality when adding new or revised documents and consent forms or click "Click here to upload" to locate the file using the file explorer.

The screenshot shows the top navigation bar of the document management system. The button 'Add a New Document' is highlighted with a red rectangle. Other buttons include 'Select or Revise Existing' and 'Add Multiple Documents'.

The screenshot shows the 'Study Document Add Verification' window. It contains search filters and a table of existing documents. A red box highlights the table, and a text overlay reads: 'List of documents previously submitted for this study'.

Upload Revised Document	Title	Category	Version	Version Date	Download Document for Editing	Document Outcome	Sponsor Version	View Document
(Read Only)	Notice of Intent to Rely Letter	Notice of Intent to Rely on One UC IRB	0.0			Approved		185.31 KB
(Read Only)	Notice of Intent to Rely	Notice of Intent to Rely on One UC IRB						35.31 KB
(Read Only)	Protocol Appendix	Protocol						51.95 KB
(Read Only)	Notification of Agreement to Rely	Other						31.58 KB
(Read Only)	OHSU Memo RE: Non human subject research letter 04.18.2011	Letter from sponsor						51.71 KB
(Read Only)	10753 Example Physician Questionnaire	Other Document Type	1.0	02/07/2017		Approved		134.28 KB
(Read Only)	10753 Protocol V5.0 (12-03-2020)	Protocol	2.7	12/03/2020		Approved		382.51 KB

The screenshot shows the 'Upload a New Document Not on the List' button highlighted in red. It is part of the 'Study Document Add Verification' window. A red arrow points from the button to the 'Upload a New Document Not on the List' button.

The screenshot shows the 'Study Document Add' window. It contains fields for Version Number, Version Date, Sponsor Version, Category, Description, and Comments. A red box highlights the 'Please drop file/click here to upload' area.

If a version of the “new” document is already on the list, click **Cancel Document Add** and skip to the steps titled “Revise an Existing Document or Consent Form.”

Study Document Add Verification

If you already have the revised document on your computer, skip downloading the document for editing and proceed to uploading the revised document.

Select Category: --none-- Title: _____

Version #: _____ Search level: ☒ Top ☐ All

Version Date: _____ between _____ Expiration Date: _____ between _____

Document Outcome: --none--

Filter Documents

Upload a New Document Not on the List

These are the existing consent forms. If this is a revised version of one of these consent forms, click the 'Cancel Consent Add' button at the bottom of the window and use the 'Select or Revise Existing' button on the submission form instead. If this is a consent that has never been submitted before, click on the 'Upload a New Consent Not on the List' to upload a new consent to the study.

9 result(s) found...

Upload Revised Document	Title	Category	Version	Version Date	Download Document for Editing	Document Outcome	Sponsor Version	View Document
(Read Only)	Notice of Intent to Rely Letter	Notice of Intent to Rely on One UC IRB	0.0			Approved		185.31 KB
(Read Only)	Notice of Intent to Rely	Notice of Intent to Rely on One UC IRB	1.4	06/09/2011		Approved		35.31 KB
(Read Only)	Protocol Appendix	Protocol	1.0			Approved		51.95 KB
(Read Only)	Notification of Agreement to Rely	Other	1.0	04/27/2011				31.58 KB

Cancel Document Add → **Cancel Document Add**

To add multiple documents simultaneously, click **Add Multiple Documents**.

This will bring you to a screen where you can name, browse for, and upload several documents at once. Click **Save Documents** when done.

Select or Revise Existing Add a New Document **Add Multiple Documents**

Detach	Version	Sponsor Version	Title	Category	Expiration Date	Document Outcome
No Document(s) have been attached to this form.						

IRB Study Document Add Multiple:

Add New Record(s) Save Documents

Version	Version Date	Sponsor Version	Category	File path
0.0			--none--	Browse... No file selected.
0.0			--none--	Browse... No file selected.
0.0			--none--	Browse... No file selected.
0.0			--none--	Browse... No file selected.
0.0			--none--	Browse... No file selected.

Revise an Existing Document or Consent Form

Click **Select or Revise Existing**.

Select or Revise Existing Add a New Document Add Multiple Documents

Detach	Version	Sponsor Version	Title	Category	Expiration Date
No Document(s) have been attached to this form.					

Again, a pop-up window will appear with a list of all the documents previously submitted for this study.

If you already have the revised version on your computer, click the **Upload Revised Document** icon and follow the prompts for attaching the document.

Select Existing or Create Revised Study Document

If you already have the revised document on your computer, skip downloading the document for editing and proceed to uploading the revised document.

Select Category: --none-- Title: _____

Version #: _____ Search level: ☒ Top ☐ All

Version Date: _____ between _____ Expiration Date: _____ between _____

Document Outcome: --none--

Add a New Document Filter Documents

9 result(s) found...

Select	Show all versions	Edit	Delete	Version	Version Date	Sponsor Version	Download Document for Editing	Title	Expiration Date	Document Outcome	View Document	Upload Revised Document
<input type="checkbox"/>				0.0				Notice of Intent to Rely Letter				
<input type="checkbox"/>				1.4	06/09/2011			Notice of Intent to Rely				
<input type="checkbox"/>				1.0				Protocol Appendix		Approved		

Upload Revised Document

If you have not revised the document yet, click the **Download Document for Editing** button. This will download the most recently submitted version of the document so you can edit and save it to your computer. Once the revision is complete, return to this iRIS page and click the **Upload Revised Document** button to attach it.

Select	Show all Versions	Edit	Delete	Version	Version Date	Sponsor Version	Download Document for Editing	Title	Expiration Date	Document Outcome	View Document	Upload Revised Document
								Category				
								Notice of Intent to Rely Letter				
								Notice of Intent to Rely on One UC IRB		Approved	185.31 KB	
								Notice of Intent to Rely				
								Notice of Intent to Rely on One UC IRB		Approved	35.31 KB	
				1.0				Protocol Appendix				
								Protocol		Approved	51.95 KB	
				1.0	04/27/2011			Notification of Agreement to Rely				
								Other			31.58 KB	
				1.0	04/18/2011			OHSU Memo RE: Non human subject research letter 04.18.2011				
								Letter from sponsor		Approved	51.71 KB	

Option 2: Review Response Form

Documents and consent forms may also be added or revised via the Review Response Submission Form when responding to IRB stipulations.

The Review Response Submission Form is the screen where you respond to IRB stipulations.

Review Response Submission Form	
<p>You have received this form either during the administrative pre-review process or after formal review by the committee. This form allows you to respond to recommendations, stipulations, or other issues identified during this review process. Please review the interactive training module for help responding to stipulations.</p>	
Principal Investigator:	
Study Title:	
Study Alias:	
Study Number:	
The IRB Analyst assigned to this submission is:	
Stipulations and Comments	
<p>Please make the requested changes using the linked stipulations. Briefly explain the changes that were made in the text box, then click the 'Complete Action' button to change the status to complete.</p> <p>To ensure timely processing of this response, no additional changes should be included with this response.</p>	
<p>⚠ Stipulation 1 out of 1:</p> <p>Description:</p>	

First Method – Responding to Linked Stipulation:

Revise a document or consent form if the IRB has sent a stipulation asking for changes to it.

Stipulation 1 out of 1:									
<p>Description:</p> <p>Please remove questions about illegal substance use from the screening survey. This sensitive information should only be collected after participant has provided signed consent.</p>									
Links to components	<table border="1"> <thead> <tr> <th>Operation</th><th>Action Status</th><th>Component Name</th><th>Action</th></tr> </thead> <tbody> <tr> <td>Modify Existing Attachment</td><td>Action Not Complete</td><td>Study Document Screening Survey (Version 1.0)</td><td>Revise Existing</td></tr> </tbody> </table>	Operation	Action Status	Component Name	Action	Modify Existing Attachment	Action Not Complete	Study Document Screening Survey (Version 1.0)	Revise Existing
Operation	Action Status	Component Name	Action						
Modify Existing Attachment	Action Not Complete	Study Document Screening Survey (Version 1.0)	Revise Existing						

Add a new document or consent form if the IRB has sent a stipulation requesting that it be added.

Stipulation 1 out of 1:

Description:
Please add an assent form for 7-12 year old participants.

Links to Components (These are the items that are linked to this stipulation)	Operation	Action Status	Component Name	Action
	Add New Attachment	Action Not Complete	Please add the Study Consent	Add Consent

Second Method – Using the Revise/Attach button in the Submission Components Table

Scroll down to the **Submission Components** table.

Revise an existing document/consent by clicking the corresponding **Revise/Attach** icon.

A window will pop up to confirm that you want to make a revision. If you click “confirm,” an upload window will appear.

If you already have the revised version on your computer, click the **Browse** button and follow the prompts for attaching the document. Then click **Save**.

Submission Components

Submission Components:

These are the forms and documents that are part of this submission. If you don't see an attachment in the list, it hasn't been attached.

Compare	Include in PDF Packet	Compare to Last Approved	View in Separate Window	Unattach	Revise/Attach	Revisions	All Submission Components <small>(Previously Approved & Currently Attached)</small>
Submission Form(s)							
<input type="checkbox"/>	<input type="checkbox"/>						IRB - Review Response Submission Form - (Version 1.0)
<input type="checkbox"/>	<input type="checkbox"/>						Initial Review Submission Packet - (Version 1.0)
Application							
<input type="checkbox"/>	<input type="checkbox"/>						Study Application - (Version 1.1)
Consent Form(s)							
<input type="checkbox"/>	<input type="checkbox"/>						test (English) - (Version 1.0)
Document(s)							
Category : AE Summary Log							
<input type="checkbox"/>	<input type="checkbox"/>						Submission Components Omitting First Round Attachments - (Version 1.0)

Confirm the Revise.

Are you sure you want to revise this item from the submission? A new revision will be created as part of the submission.

CONFIRM

CANCEL

Study Consent Revision

*Consent Title:

*Version Number: .2

*Version Date:

Sponsor Version:

Category:

* Language:

* Reconsent Required: ☐ Yes ☒ No

Reconsent Reason:

Description:

Download Consent:

Select the document to upload: **Browse**

If you have not revised the document yet, click the **Download** button. This will download the most recently submitted version of the document so you can edit it and save it to your computer. Once the revision is complete, return to this iRIS page and click the **Browse** button to attach it.

Study Consent Revision

*Consent Title: tet

*Version Number: 1.2

*Version Date: 10/07/2021

Sponsor Version:

Category: --none--

*Language: English

*Reconsent Required: ☐ Yes ☒ No

Reconsent Reason:

Description:

Download Consent: **Download**

Select the document to upload: **Browse...** No file selected.

Download

Close, don't save any changes **Save Consent**

Third Method – Using the Add New Component button above the Submission Components table

Add a new document/consent by clicking the **Add New Component** button.

Indicate whether you are adding a consent form or other study document.

Click **Add a New Document**.

A pop-up window will appear with a list of all the documents previously submitted for this study. This list is a prompt for you to make sure you are truly adding a never-before-submitted document rather than a new version of one of the listed documents. If a version of the document is not on the list, click **Upload a New Document Not on the List** and follow the instructions for uploading the new document.

Submission Components

Submission Components:

These are the forms and documents that are part of this submission. If you don't see an attachment in the list, it hasn't been attached.

Add New Component Compare Item(s) Create PDF Packet

Compare	Include in PDF Packet	Compare to Last Approved	View in Separate Window	Unattach	Revise/Attach	Revisions	All Submission Components
							IRB - Review Response Submission Form - (Version 1.0)

Select an attachment type

Select the type of attachment you would like to add to this submission:
(Click on the radio button and it will transition you to next page)

☒ **Informed Consent**

☐ Other Study Document

Attach Study Document(s)

Hover over to display context help

Add Multiple Documents **Add a New Document** Attach

Show Rev.	Edit/View	Version	File	Stamped File	Title/Category	Last Modified By	Date Last Modified
Already Attached		1.0 06/30/2021	30.22 KB		PI Letter of Support Letter of Support		06/30/2021 11:54:27 AM

Study Document Add Verification

Filter Documents

Here are the documents for all categories:
Please click on the Create Revision icon to revise an existing document below or click on Upload a New Document Not on the List to upload a new document to the study.

Upload a New Document Not on the List

1 result(s) found...

Upload Revised Document	Title	Category	Version	Version Date	Download Document for Editing	Document Outcome	Sponsor Version	View Document
(Read Only)	PI Letter of Support_signed_CEK	Letter of Support	1.0	06/30/2021				30.22 KB