Quick Guide:
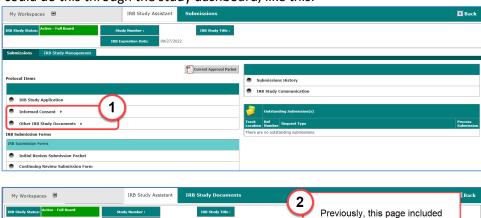# Revise and/or Add Documents and Consent Forms to a Study
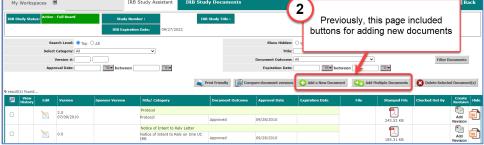
When to Use This Guide

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

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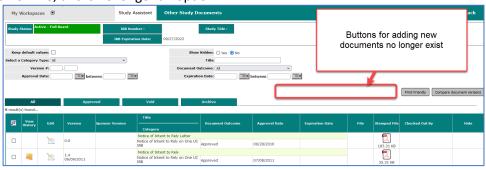- New documents or consent forms (e.g., no previous versions associated with the study)

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:

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

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.
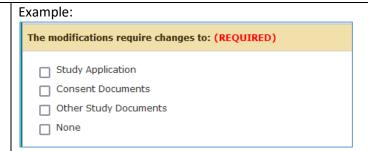
Option 1: IRB Submission Forms

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 | Expirati 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]**.

	Select or Revise Existing	Add a New Document	Add Multiple Documents	
Detach	**Version**	**Sponsor Version**	**Title**	**Category**	**Expiration D**

No Document(s) have been attached to this 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.

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

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.

Upload a New Document Not on the List

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			⬇			35.31 KB
(Read Only)	Protocol Append ix	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

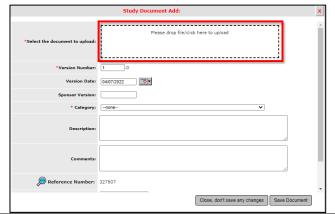**List of documents previously submitted for this study**

If a version of the document is <u>not</u> 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.

Filter Documents

Here are the documents for all categories.
Please click on the Create Revision icon to rev...
click on Upload a New Document Not on the L...

Upload a New Document Not on the List

Upload a New Document Not on the List

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 Append ix	Protocol	1.0		⬇	Approved		51.95 KB
(Read Only)	Notification of Agreement to Rely	Other	1.0	04/27/2011	⬇			31.58 KB

Study Document Add:

*Select the document to upload: Please drop file/click here to upload

*Version Number: 1 .0
Version Date: 04/07/2022
Sponsor Version:
* Category: --none--
Description:
Comments:
🔍 Reference Number: 327807

Close, don't save any changes   Save Document

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."	
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.	
Revise an Existing Document or Consent Form Click **Select or Revise Existing**.	
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.	

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.

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.

First Method – Responding to Linked Stipulation:

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

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

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**.

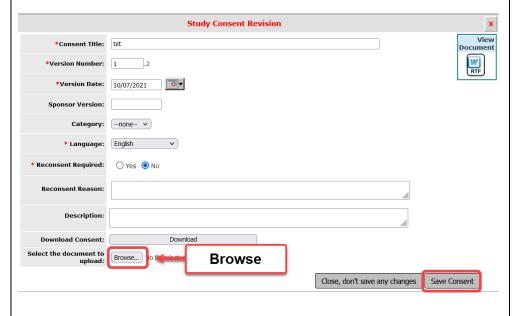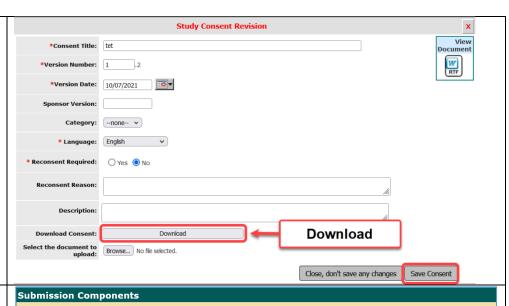|	
If you have not revised the document yet, click the **Download** button. This will download the most recently submitted version of the document so you can edit it and save it to your computer. Once the revision is complete, return to this iRIS page and click the **Browse** button to attach it.	**Study Consent Revision** [X] View Document [W] RTF *Consent Title: tet *Version Number: 1 .2 *Version Date: 10/07/2021 Sponsor Version: Category: --none-- v *Language: English v *Reconsent Required: ○ Yes ● No Reconsent Reason: Description: Download Consent: [Download] ← **Download** Select the document to upload: [Browse...] No file selected. [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 *Previous Rounds & Currently Attached*
---	---	---	---	---	---	---	---
							Submission Form(s)
☐	☐		📄				**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)** [X] ℹ 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
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Already Attached		✏	1.0 06/30/2021	[W] 30.22 KB		PI Letter of Support_ Letter of Support		06/30/2021 11:54:27 AM | **Study Document Add Verification** [X] [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
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(Read Only)	PI Letter of Support_signed_CEK	Letter of Support	1.0	06/30/2021	⬇			[W] 30.22 KB	