

Quick Start Guide - Submitting an Amendment in iRIS

Log in and open your study

- Log in to iRIS
- From your Study Dashboard, select Change Request and Amendments

Protocol Items	
<input type="radio"/>	Study Application
<input type="radio"/>	Informed Consents ▶
<input type="radio"/>	Other Study Documents ▶
<input type="radio"/>	Contract Documents
<input type="radio"/>	Administrative Update / Check-in
<input type="radio"/>	Adverse Event Form
<input type="radio"/>	Change requests and Amendments
<input type="radio"/>	Continuing Review Form
<input type="radio"/>	Inactivation Form
<input type="radio"/>	IND Safety Report Initial Form
<input type="radio"/>	Initial Review Submission Form
<input type="radio"/>	Other Study Document Submission Form
<input type="radio"/>	PROTOCOL DEVIATION
<input type="radio"/>	Study Closure Form

Create a New Amendment

- Once you click the link, determine the Update Number then click **Add a New Form**.

Study Status: **Draft** | IRB Number: IRB #000 | Study Title: Test

Buttons: Copy Form | **Add a New Form** | Compare Two Versions

List of records associated with form: Change requests and Amendments.
To view previous versions click on the folder icon.

1 result(s) found...

Show Rev	Edr/View	Details	Ref Number	Sub. Rounds	Track Location	Process Submission	Submission Date	Update Date	Update N...	Created By	Date Created	Last Modified By	Last Date
<input type="checkbox"/>			007240				12/15/2025 09:23:15 AM PST	12/15/2025		Marie Carmina Reyes Pineda	12/15/2025 09:21:34 AM	Marie Carmina Reyes Pineda	12/15/2025 09:23:15 AM

Complete the amendment application

- Fill out all required sections of the amendment form. Be clear and specific about what is changing and why.

If your change affects the Main Study Application

Some changes require you to update the existing study application in iRIS.

Check "Yes" if your amendment includes changes such

- Adding a new subject population
- Changing the target enrollment
- Revising inclusion/exclusion criteria
- Updating study procedures, risks, or recruitment methods
- Any modification that alters previously approved content

Revision/Amendment Description

* Provide a detailed explanation of any changes being made that will affect the subjects pa

Click here to access the text editor.

Revised Application, if applicable

IF THE STUDY WAS ORIGINALLY ENTERED IN iRIS, are changes to the application required

If the study was not originally entered in iRIS, please check "NO" and continue to the next

If "YES", attach a revised copy of the application below.

Yes No

Attach new version of the IRB application (if applicable):

Click here to attach the application.

No Application has been associated with this submission.

as:

After checking “Yes”:

- Click the paper clip to access the current application.
- Create a revised application to make the necessary edits
- Click “Save Attachment” to upload the revised version of the study application.

Select	Show Rev.	Edit/View	Form Name	Approved	Create a Revised Application
Already Submitted			Study Application Form (cIRB)- Local Context Review (Version 1.0)	No	 Add Revision

Final Steps Before Submission

Before submitting your amendment:

- Confirm the amendment form is complete
- Ensure all revised documents are attached
- Verify that updated sections of the main application have been saved
- Review for consistency across all materials

When ready, click Submit to IRB

If you're unsure about any step, reach out to the IRB office. Early questions prevent delays later.