

# IRIS TIPS

## How to Modify a Study

### OVERVIEW

**i** You can only request modifications if your study is active and approved by the IRB. To make changes to your approved study, please follow the instructions below.

1. Login to your iRIS account. Click **STUDY WORKSPACE**.

The screenshot shows the iRIS Study Assistant interface. On the left, there is a navigation menu with three main sections: 'Research Workspace', 'Administration Workspace', and 'System Administration'. The 'Study Assistant' menu item is highlighted in blue, and its dropdown menu is open, showing options like 'Study Workspace', 'Create a New Study', 'View My Studies', 'Start a Study Submission Form', 'My Current Approvals', 'Upcoming Renewals', 'Track Approvals', and 'Find a Study'. A red 'Tasks' button is visible to the right of the dropdown. Below the navigation menu, there is a 'Study Assistant' header with a search icon and a 'Find a Study' button. At the bottom, there is a red bar with 'All Tasks' and filters for 'Outstanding' and 'Completed'.

2. **SCROLL DOWN TO THE BOTTOM OF THE HOME PAGE** to **IRB STUDIES**, click on the **ALL** tab.

The screenshot shows the 'All Studies' page in iRIS. The page has a red header with 'All Studies', 'Recently Used', and 'Study Status' tabs. A search bar is on the right. Below the header, there are three tabs: 'All', 'Draft', and 'IRB'. The 'All' tab is selected and circled in blue. Below the tabs, it says '3 result(s) found...'. The main content is a table with columns: 'Click to open', 'Study Status', 'Review Board', 'IRB Number', 'IRB Expiration', 'Study Title', 'Principal Investigator', and 'Actions'. The table contains three rows of study data.

Click to open	Study Status	Review Board	IRB Number	IRB Expiration	Study Title	Principal Investigator	Actions
	Draft				afda	Aina, Sandee	History Items Forms Hide Copy Delete
	Draft				Testing the Scientific Review Committee	Teki, Rachel	History Items Forms Hide Copy Delete
	Pending - Submitted for Re-Review	IRB	IRB2020-319		TEST - Don't Play in Cool Waters: Mothers' Knowledge, Attitudes, and Practices regarding Child Nutrition in South...	Warren, Kristi	History Items Forms Hide Copy Delete

3. Search for the desired study row. On that row you will see several options under the **ACTIONS** column—select the **FORMS** icon.

All
Draft
IRB

4 result(s) found... 1 - 4

Click to open	Study Status	Review Board	RB Number	RB Expiration	Study Title	Principal Investigator	Actions					
					Abbreviated Study Title		History	Items	Forms	Hide	Copy	Delete
	Draft				asdfad	Aina, Sandee						
	Draft				Testing the Scientific Review Committee	Teki, Rachel						
	Draft				Copy of asdfad	Aina, Sandee						
	Pending - Submitted for Re-Review	IRB	IRB2020-319		TEST - Don't Play in Cool Waters: Mothers' Knowledge, Attitudes, and Prac...	Warren, Kristi						

4. When you click the **FORMS** icon you will now see a menu of forms pertaining to the study. Choose **IRB MODIFICATION REQUEST** and click on **START A NEW SUBMISSION**.

Submission Form List				
<b>Initial</b>		<b>Version List</b>	<b>Start a new Submission</b>	<b>Edit Incomplete Submissions</b>
Initial Review Submission Packet				
		<b>Version List</b>	<b>Start a new Submission</b>	<b>Edit Incomplete Submissions</b>
IRB Closure Form				
<b>IRB Modification Request</b>				
IRB Continuing Review Submission Form				

5. The modification form will open. Section 1.1 will draw in information from the original application. Fill out the form and provide a description of the modification and a justification for the change(s).

My Workspaces ▾    Abbreviated Study Title: afd    Study Assistant    **IRB Modification Request - (Version 1.0)** Back

Print Friendly    Refresh Constant Fields    Save Section    Save and Continue to Next Section

**Section view of the Form**    **Entire view of the Form**

1.0 **Modification Form - Human Subjects**

**1.2 Type of Modification**

Select all that apply:

- New Procedures
- Study Title Change
- Change in Study Personnel
- Change of Site
- Change in Enrollment
- Consent Change
- Recruitment Material
- Instruments (surveys, questionnaires, interviews, etc)
- Other

For each modification selected, complete the associated text box below explaining the change. At the end of the form, follow the instructions to create a revision of the actual application so the committee can see the proposed changes.

6. Update the application to include **ALL** of the proposed changes. Attach the application to the modification form by clicking on **CLICK HERE TO ATTACH THE APPLICATION**.

**Section view of the Form**    **Entire view of the Form**

1.0 **Modification Form - Human Subjects**

For each modification selected, complete the associated text box below explaining the change. At the end of the form, follow the instructions to create a revision of the actual application so the committee can see the proposed changes.

**1.12 Attach Revised Application**

Now that you have explained the modification, you will need to revise the application so the committee can see the proposed changes. Use the following step-by-step instructions to complete this process. You can also see step-by-step screenshots at this link: [\(add link to the Articulate training\)](#)

1. Click the gray button below labeled "Click here to attach the application"
2. A pop-up will appear with a table showing your currently approved application. On the right side, click the option to "Add Revision". On the second pop-up, click "OK" to create the revision.
3. This will take you to a new version of your application. You can now move through the application and make your proposed changes in the relevant sections. Just like the original application, it's very important to use the Save buttons to save the changes.
4. **DO NOT** make any changes to study personnel.
5. Once you make all the proposed changes, you should click the "Back" button to return to the Modification form, which will list the revised application. Now you can use the Save and Continue to Next Section button to complete the rest of the Modification form.

 Click here to attach the application.

No Application has been associated with this submission.

7. If the proposed changes include revisions to the instruments, consent forms and recruiting materials, attach them to Section 1.13.

**1.13 Documents**

Please use the table below to upload any necessary document(s).

+ Add a New Document    + Add Multiple Documents

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

+ Add a New Consent

Detach	Version	Title	Category	Language	Expiration Date	Consent Outcome	Checked Out	View Document
No Consent(s) have been attached to this form.								