



STUDY ASSISTANT

Study Management: Submissions

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Submissions

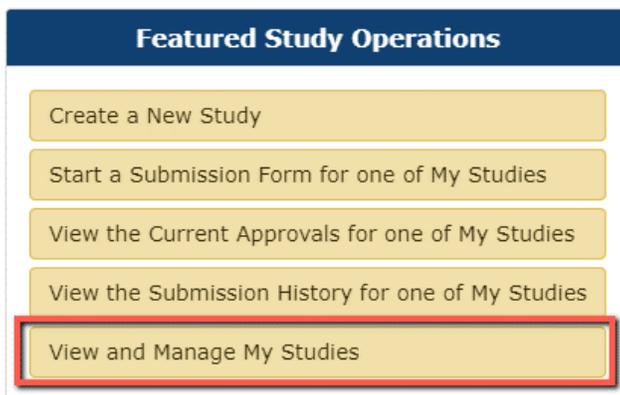
Introduction

A study record in iRIS™ is broken up into several sections: Submissions, Study Management, and—if using the Subject Management module—Subject Management. Each section allows you to access different portions of the study enabling proper tracking and maintenance of study information. The Submissions tab allows access to forms that you need to submit for review. You can also access and manage Informed Consents, Study Documents, previous submission forms, and review or generate study-related correspondence.

This manual will guide you through the process of accessing and completing submission forms for a study via the Submissions tab.

Accessing a Study

To locate your studies in iRIS™ open the View and Manage My Studies menu item found under “Study Assistant” in the navigation menu or click on the View and Manage My Studies button under the “Featured Study Operations” panel as shown below.



This will anchor you down the screen to the My Studies panel, which will display all studies that you have been assigned a role on, along with basic information about each study. Use the filters to narrow the list to the study you wish to open. By default, the studies will be listed in order from most recently accessed to last accessed. Using the search criteria at the top of the page may help locate for the desired study.

Once you have located the study in the list, click the  icon in the **Click to open Study Dashboard** column.

All Studies								Recently Used		Study Status		Search for RB Number, Title, Alias		Search	⚙	
All		Draft		IRB		IACUC										
57 result(s) found...															1 - 5 ▶	
Click to open Study Dashboard	Study Status	Review Board	RB Number	RB Expiration	Study Title	Principal Investigator	Actions									
					Study Alias		Applications	Documents	Forms	Hide	Exempt	Copy	Delete	Correspond		
	Pending - Submitted for Initial Review	IRB	Hello!		Copy of NIH - TD - 11345 - Influenza vaccine ANT62a31 elicits human cell r...	Investigator, John										
	Open	IRB	IRB-21-457	06/20/2022	NIH - TD - 11345 - Influenza vaccine ANT62a31 elicits human cell retraction...	Investigator, John										
	Pending - Submitted for Initial Review	IRB	IRB-21-484		Copy of NIH - TD - 11345 - Influenza vaccine ANT62a31 elicits human cell r...	Investigator, John										
	Draft	IRB	IRB-21-483		COVID 19 Complications in adults 55 and older	Investigator, John										
	Open	IRB	IRB-19-180	07/29/2021	Use of stem cells on subjects currently being treated for Diabetes Type 2	Investigator, John										
57 result(s) found...															1 - 5 ▶	

Submissions

When opening a study, the page will open to the Submissions tab. This tab contains links to various submission forms that can be created, completed, and submitted throughout the lifetime of the study. At the top of the page a header with study-specific details is displayed. The left portion of the page contains links to the Study Application, Informed Consent, Other Study Documents, and any form you may need to create and submit for review. The right side of the page contains a link to Submissions History, which will list out all forms that have been submitted for review on the study. Also listed is a link to Study Correspondence and an area for Outstanding Submissions.

The screenshot shows the top navigation bar with 'My Workspaces', 'IRB Number: IRB-21-476', 'PI: Investigator, John', 'Study Assistant', and 'Submissions'. Below this is a study information bar with 'Study Status: Pending - Submitted for Initial Review', 'IRB Number: IRB-21-476', and 'Study Title: Malaria in Juveniles'. The main content area is divided into 'Protocol Items' on the left and 'Outstanding Submission(s)' on the right. The 'Protocol Items' list includes 'Study Application', 'Informed Consents', 'Other Study Documents', and 'Contract Documents'. The 'Outstanding Submission(s)' table shows a submission with 'Ref Number: IRB-21-476-NEW-1.0' and 'Request Type: Initial Review Submission Form'.

The Header

Wherever you are within the study record, the top of the page will always display the study header. The header contains current information related to the study you are viewing, as displayed in the image below.

This close-up shows the navigation bar with 'My Workspaces', 'IRB Number: IRB-21-476', 'PI: Investigator, John', 'Study Assistant', and 'Submissions'. Below it is the study information bar with 'Study Status: Pending - Submitted for Initial Review', 'IRB Number: IRB-21-476', and 'Study Title: Malaria in Juveniles'.

Displayed at the top left of the header are the **Study Number, Alias, and PI**.

Below this is listed the current **Study Status**, the **RB Number**, **Study Title**, and the **RB Expiration Date** (depending on whether a date has been provided by the review board).

The information in the header will update as it is changed.

Protocol Items

The first section of the Submissions tab is called Protocol Items. This group contains links to the Study Application, Informed Consent, and Other Study Documents.

This close-up shows the 'Protocol Items' section with a list of links: 'Study Application', 'Informed Consents', 'Other Study Documents', and 'Contract Documents'.

Study Application

The link to the Study Application will open the Study Application page.

The screenshot shows the 'Study Application' page for study IRB-21-476. The page header includes 'My Workspaces', 'IRB Number: IRB-21-476', 'Study Assistant', and 'Study Application' with a 'Back' button. Below the header, the 'Study Status' is 'Pending - Submitted for Initial Review', 'IRB Number' is 'IRB-21-476', and 'Study Title' is 'Malaria in Juveniles'. A 'Compare Two Selected Versions' button is visible. Below this, it says '1 result(s) found...'. The main table has the following data:

<input type="checkbox"/>	Show Rev.	Edit/View	Application Type	Approved?	Approval Date	Created By	Date Created	Last Modified By	Last Date Modified	Create a Revised Application
<input type="checkbox"/>			IRB Application (Version 1.0)	No		John Investigator	06-23-2021 15:35	John Investigator	06-24-2021 15:36	

This page lists the Study Application that has been created for this study, along with any revisions of that application.

From here, you can view and edit the current application if it has not yet been submitted for review. You can also view approval information, compare versions, and revise the current application.

If your system is configured as such, you can add a new application type to the study. This functionality is available when the `system.use_study_app_add_new_type` property is set to Yes, available under System Administration > System Configuration > Study Application Setup.

This screenshot is similar to the previous one but includes an 'Add a New Application Type' button, which is highlighted with a red box. The rest of the page content, including the table and headers, is identical to the previous screenshot.

Compare Tool

If there is more than one version of the application, a folder icon will display in the **Show Rev.** column. Note that a version number is also listed in the **Application Type** column in parentheses after the name of the application.

To compare two versions of the Study Application, the checkboxes of each form must be selected. You can click the icon in the **Show Rev** column to view the application versions. Select two versions to compare and then click the **Compare Two Selected Versions** button.

Account: John Investigator
 Department: GHW - 7543 - General Hospital
 Path: Home > study mgmt.

Metrics Calendar Help My Profile Log out

My Workspaces IRB Number: **IRB-21-476** Study Assistant Study Application Back
 PI: Investigator, John

Study Status: Pending - Submitted for Initial Review IRB Number: IRB-21-476 Study Title: Malaria in Juveniles

Compare Two Selected Versions Delete Selected Version

1 result(s) found...

<input type="checkbox"/>	Show Rev.	Edit/View	Application Type	Approved?	Approval Date	Created By	Date Created	Last Modified By	Last Date Modified	Create a Revised Application
<input type="checkbox"/>			IRB Application (Version 1.1)	No		John Investigator	06-25-2021 08:00	John Investigator	06-25-2021 08:00	
<input type="checkbox"/>			IRB Application (Version 1.0)	No		John Investigator	06-23-2021 15:35	John Investigator	06-24-2021 15:36	

iRIS™ will analyze the two application forms using a comparison tool. This may take several moments, depending on the size of your Study Application. When the comparison process is complete, a new window will open displaying both selected versions of the application in a side-by-side view, with the older version listed in the left column and the newer version listed in the right column, as seen in the image below.

Print Close

IRB Application

Version: 1.0 John Investigator Version: 1.1 John Investigator

1.1 - Section 1 - General Information 1.1 - Please enter the full title of your study: Malaria in Juveniles	Section 1 - General Information 1.1 - Please enter the full title of your study: Malaria in Juveniles In South Africa
1.4 - Section 1 - General Information 1.4 - Is this Study using Subject Management? No	Section 1 - General Information 1.4 - Is this Study using Subject Management? No Yes
6.2 - Section 6 - Funding 6.2 - SPONSORS: Identify all sponsors and provide the funding details. If funding comes from a Subcontract, please list only the Prime Sponsor: External Sponsors: NOTE: It is no longer necessary to add the A or the P Number. iRIS now allows you to link the proposal to the study (see below)!	Section 6 - Funding 6.2 - SPONSORS: Identify all sponsors and provide the funding details. If funding comes from a Subcontract, please list only the Prime Sponsor: External Sponsors: NOTE: It is no longer necessary to add the A or the P Number. iRIS now allows you to link the proposal to the study (see below)!

View Details Sponsor Name Sponsor Type

No Sponsor has been added to this Study

View Details Sponsor Name Sponsor Type

No Sponsor has been added to this Study

3-M Pharmaceuticals **Pharmaceutical**

Sponsor Name: **3-M Pharmaceuticals**
 Sponsor Type: **Pharmaceutical**

Funding

ALL STUDIES **IF SPONSOR(S)**

Add funding source(s) below: Federal, Sponsor, or Other. Select "Original Development by Applicant(s)" above if there is no funding for the study.

Please provide contact information below for the IRB Fee billing purposes.
NOTE: * Denotes mandatory field.
 Contact Name: *
 Sean McMurray

This view will show you any differences in the newer version, by marking items either green or red. Green highlights indicate a new addition to the form and red highlights mark items that have been removed from the form.

This view will only show sections of the form that have changed. For example, if your Study Application is 15 sections long, but there are only differences found in 4 sections, only those 4 sections will display in the comparer view.

You can highlight sections by clicking on the section. Use the left and right navigation arrows at the bottom of the window to cycle through sections.

When you are finished viewing the differences in the Study Applications, click the **Close** button.

Revise Application

The current version of the Study Application cannot be modified if it has been submitted for review. When you click the icon in the **Edit/View** column, the application will open in a read-only format. If you need to make changes to the application, you must create a revision. Do this by clicking the icon in the **Create a Revised Application** column.

My Workspaces

IRB Number: **IRB-21-476**
 PI: Investigator, John

Study Assistant

Study Application

 Back

Study Status: Active

IRB Number : IRB-21-476

Study Title : Malaria in Juveniles

IRB Expiration Date: 06/24/2022

Compare Two Selected Versions

1 result(s) found...

	Show Rev.	Edit/View	Application Type	Approved?	Approval Date	Created By	Date Created	Last Modified By	Last Date Modified	Create a Revised Application
<input type="checkbox"/>			IRB Application (Version 1.1)	Yes	06/25/2021	John Investigator	06-25-2021 11:20	John Smith	06-25-2021 14:07	
<input type="checkbox"/>			IRB Application (Version 1.0)	Yes	06/25/2021	John Investigator	06-23-2021 15:35	IRB Reviewer	06-25-2021 08:11	

Note: The “Revise Application” icon will only be available for the most current approved version of the application.

When you create a revision, iRIS™ will increment the form version to the next available number. In this example case, the new version number is 1.2. An editable version of the application will then open for you to make changes. If your study is not in Draft mode, you will not be able to modify the current Key Personnel in section 2.0 of the application form’s Study Shell. You will need to submit an Amendment form to the review board for approval of any change in Key Personnel.

Also, note that when you create a revision to your Study Application from this area, you can make changes as needed. However, in order for those changes to be approved you will need to link your Study Application to a submission form and send it to the review board for approval. Without sending your application, the review board has no way to see that you have made changes that need to be approved. The revised version of the Study Application will be attachable to certain submission forms, like an Amendment. This is covered later in this document.

Any revision you create will populate in the table. The information in the **Approved** and **Approval Date** (as highlighted in the image below) columns reflects that the current version of the application has not yet been approved by the review board.

My Workspaces IRB Number: **IRB-21-476** Study Assistant Study Application Back
 PI: Investigator, John

Study Status: **Active** IRB Number: IRB-21-476 Study Title: Malaria in Juveniles
 IRB Expiration Date: 06/24/2022

1 result(s) found... Compare Two Selected Versions Delete Selected Version

<input type="checkbox"/>	Show Rev.	Edit/View	Application Type	Approved?	Approval Date	Created By	Date Created	Last Modified By	Last Date Modified	Create a Revised Application
<input type="checkbox"/>			IRB Application (Version 1.2)	No		John Investigator	07-08-2021 10:05	John Investigator	07-08-2021 10:06	
<input type="checkbox"/>			IRB Application (Version 1.1)	Yes	06/25/2021	John Investigator	06-25-2021 11:20	John Smith	06-25-2021 14:07	
<input type="checkbox"/>			IRB Application (Version 1.0)	Yes	06/25/2021	John Investigator	06-23-2021 15:35	IRB Reviewer	06-25-2021 08:11	

Delete Application

A version of the Study Application can only be deleted if it has not been submitted to a review board. In the example above, version 1.0 has been submitted and thus cannot be deleted. However, version 1.1 has not been submitted. You can delete this version of the application by clicking the checkbox next to the version and clicking the **Delete Selected Version** button. The system will ask you to confirm the deletion. Clicking **Confirm** will delete this version of the application from the study.

Note: It is advised that you do not delete applications as there is no way to restore the deleted information.

Also, if only one application exists for a study and it is deleted, the study will no longer have an application and you must create a new one.

Add Application

You will see a button to add an application to the study if you have initiated the study application process but did not save the form past the first three sections, or you deleted your Study Application from the study. You can click the **Add a New Application Type** button to create an application record for your study.

My Workspaces IRB Number: **IRB-21-473** Study Assistant Study Application Back
 PI: Investigator, John

Study Status: **Draft** IRB Number: IRB-21-473 Study Title: Malaria in Juveniles

0 result(s) found... Add a new Application

<input type="checkbox"/>	Show Rev.	Edit/View	Application Type	Approved?	Approval Date	Create a Revised Application
No application versions have been added to this study						

Informed Consent

The Informed Consent link on the main Submission screen will direct you to the study’s Informed Consent library, which stores any consent you have attached to submission forms or added through the library. If you hover over the Informed Consent link, a popup menu will appear that displays all the categories of consent documents that have been uploaded to the study. Clicking one of these links will open the Informed Consent library for only documents in the selected category.

Protocol Items

<input type="radio"/> Study Application
<input type="radio"/> Informed Consents ▶ Consent
<input type="radio"/> Other Study Documents ▶
<input type="radio"/> Contract Documents

The Informed Consent library stores any consent you have attached to submission forms or added through the library itself. When the review board approves a document, the approval information will update the document stored in the library. If your system is using Subject Management, you will also be able to update consent information for subjects on the study. The library is shown in the screenshot below.

The screenshot shows the 'Study Consent Dashboard' for study IRB-21-476, titled 'Malaria in Juveniles'. It includes a navigation bar with 'My Workspaces', 'Study Assistant', and 'Study Consent Dashboard'. Below the navigation bar, there are filter controls for 'Study Status' (Active), 'IRB Number', 'IRB Expiration Date', and 'Study Title'. A search and filter section includes 'Keep default values', 'Select Category', 'Version #', 'Approval Date', 'Show Hidden', 'Title', 'Consent Outcome', and 'Expiration Date'. Action buttons include 'Reset Filters', 'Filter Documents', 'Compare document versions', 'Add/Revise Consent', 'Delete Selected Document(s)', and 'Archive Selected Document(s)'. A table at the bottom shows 1 result(s) found, with columns for View History, Edit/View, Reference Number, Title, Version, Language, UnApproved Consent, Approved Consent, Consent Outcome, Approval Date, Expiration Date, Checked Out By, and Hide. The table contains one row for 'English Consent Form' with version 1.0 and expiration date 06/25/2021.

From this area you can revise existing consents, add new consent records, compare versions of consents, and print out approved copies of a consent document. The tabs of the library’s display table are detailed below. **All** – Displays all consent forms that have been uploaded throughout the life of the protocol.

Approved – Displays only those consents that have been approved by the review board.

Void – Displays all consents that have been voided either by the system or by the review board.

Archive – Displays all consents that were archived.

Removed from Use – This tab displays all consents that have been removed from use by the review board (not pictured above as this is a system configuration).

For more information on document and consent management, please see the Document Management guide.

Filters

At the top of the Informed Consent library page are several filters used to display specific consent forms on the study. The function of each of these filters is discussed below:

Keep default values – When checked this field preserves the most recent filter values, so when this page is revisited, the filters will be unchanged. If unchecked, the filter values reset each time the page is left and revisited.

Show Hidden – The default selection for this filter is set to “No”. This means that all the documents viewed on the page are “non-hidden”. Selecting “Yes” will refresh the page displaying both hidden and non-hidden consent documents.

Select Category – Provides the ability to filter by a Consent Category. The default selection is set to “All”, meaning all consents in all categories will display in the results.

Title – Type in all or part of a document title to include in the filter.

Version # – Type in a version number to include in the filter. The version number is exact case. For example, if you type in “1”, only documents that are version “1.x” will populate on the page.

Approval Date – Use this field to specify a date range for approval dates. You must enter a date into both fields. If you wish to filter by only one day, enter the same day in both date fields.

Consent Outcome – Use this drop-down list to filter by a review board document outcome.

Expiration Date – Use this field to specify a date range for expiration dates. You must enter a date into both fields. If you wish to filter by only one day, enter the same day in both date fields.

Compare Consent Versions

When there is more than one version of a consent form, a folder icon will appear in the table. When you click on the folder, any previous versions of the consent document will display below the most current version.

<input type="checkbox"/> Compare document versions <input type="checkbox"/> Add/Revise Consent <input type="checkbox"/> Delete Selected Document(s) <input type="checkbox"/> Archive Selected Document(s)												
All		Approved		Void		Archive						
1 result(s) found...												
<input type="checkbox"/>	View History	Edit/View	Title	Version	Language	UnApproved Consent	Approved Consent	Consent Outcome	Approval Date	Expiration Date	Checked Out By	Hide
			Category									
<input type="checkbox"/>			English Consent Form	1.2 06/25/2021	English							
<input type="checkbox"/>			English Consent Form	1.1 06/25/2021	English							
<input type="checkbox"/>			English Consent Form	1.0 06/25/2021	English							

This will allow you to view information related to older versions. You can view the previous versions' unapproved consents by clicking on the Word icon in the **UnApproved Consent** column, as seen in the image above.

You can also compare versions of the consent, by clicking the checkbox next to two versions of the same consent and then clicking on the **Compare Consent Versions** button at the top of the page.

Compare document versions Add/Revise Consent Delete Selected Document(s) Archive Selected Document(s)												
All Approved Void Archive												
1 result(s) found...												
<input type="checkbox"/>	View History	Edit/View	Title	Version	Language	UnApproved Consent	Approved Consent	Consent Outcome	Approval Date	Expiration Date	Checked Out By	Hide
			Category									
<input checked="" type="checkbox"/>			English Consent Form	1.2	English							
<input checked="" type="checkbox"/>			English Consent Form	1.1	English							
<input type="checkbox"/>			English Consent Form	1.0	English							

iRIS™ will analyze the two versions of the consent using a comparison tool. This may take several moments, depending on the size of your consent documents. When the comparison process is complete, a new window will open displaying both selected versions of the consent in a side-by-side view, with the older version listed in the left column and the newer version listed in the right column, as seen in the image below.

Document Version: 1.1
IRB - Review Board Consent Template
Synchronize scrollbars
IRB - Review Board Consent Template
Document Version: 1.2

New Consent

Consent for Subject 234
This study will require the Subject to:

- 1.

Details of Changes

Additions Into New Version
Deletions From Previous Version

New Consent - Consent for Subject 234
This study will require the Subject to:
1.

At the bottom of the window, a split view will display a combination of both versions, indicating where items have been modified. Differing items in the newer version are marked by either green or red highlights. Green highlights indicate a new addition to the consent document and red highlights mark items that have been removed from the document.

When you are finished viewing the differences between the two documents click the **Close** button.

Add a New Consent

You can add a new consent to the study by clicking **Add/Revise Consent** button. Once clicked, the following window will appear asking if you would like to revise an existing consent or upload a brand-new consent.

Please note that the **Add/Revise Consent** button is only available under the “Approved” and “All” tabs. Furthermore, if you add or revise a consent under the “Approved” tab, it will only appear in the “All” tab as it has not yet been reviewed and approved by the review board.

Study Consent Add Verification
X

Select Category: --none--

Version #:

Version Date: between

Consent Outcome: --none--

Title:

Search level: Top All

Expiration Date: between

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...

Create Revision	Title	Category	Version	Version Date	Consent Outcome	View Document
📄	English Consent Form	Consent	1.1	06/25/2021		📄 2.68 MB

Cancel Consent Add

Click on the **Upload a New Document Not on the List** button to upload a new consent. The following window will appear.

Study Consent Add:

* Consent Title:

* Select the consent to upload:

Please drop file/click here to upload

* Version Number: .0

* Version Date:

Category:

* Language:

Description:

Comments:

Please note that if you add a consent from Study Assistant outside of a submission form, it will not be reviewed by the review board.

Depending on your system settings you may or may not have the same options as shown in the window above. These fields are described as follows:

Consent Title – The title you would like to display for this consent document.

Select the consent to upload – Attach the consent document by dragging and dropping to this window. You can also click within the box to upload the file manually.

Version Number - Requires you to specify the version number of the new consent. This can be any character or number. Placed after the editable version number is a hard coded '0'. This is the iRIS™ version number for the consent. Any new document uploaded to the system will begin with the '0' affixed to your manually entered version number. Once a revision is made to the document, iRIS™ will change the '0' to '1'. It will continue to increment the numbers each time a revision is made.

Version Date – This required field is the date of the manually entered version number. This is typically the date that the consent document was uploaded to the system.

Category – This configurable drop-down list allows you to group documents into certain categories. The categories displayed here are configurable via System Administration.

Language – It is required that you select the Consent language from this dropdown list. The languages displayed here are configurable via System Administration.

Description – A description of the document.

Comments – Any comments regarding the consent document you feel necessary to add for the review board.

Once the above required fields are completed and the document has been uploaded, click the **Save Consent** button.

This will close the window and populate the new consent in the document library display table.

Editing a Consent

If you would like to make an edit to the consent form uploaded, click on the **Edit/View** icon as shown in the screen below.

All												
Approved												
Void												
Archive												
2 result(s) found...												
<input type="checkbox"/>	View History	Edit/View	Title	Version	Language	UnApproved Consent	Approved Consent	Consent Outcome	Approval Date	Expiration Date	Checked Out By	Hide
<input type="checkbox"/>			English Consent Form	1.2 06/25/2021	English							
<input type="checkbox"/>			Revised English Consent Form	1.0 07/08/2021	English							

Doing so will open the following screen, allowing you to edit the document information as well as download the document.

The screenshot shows a web application window titled "Study Consent Revision". The window contains the following elements:

- Consent Title:** Revised English Consent Form
- Version Number:** 1.0
- Version Date:** 07/08/2021
- Category:** Consent
- Language:** English
- Description:** This is a revised consent form.
- Comments:** N/A
- Download Consent:** A button labeled "Download".
- Check-out the Document to your workstation for editing:** A button labeled "Check-out Document...".
- Buttons at the bottom:** "Close, don't save any changes" and "Save Consent".
- View Document:** A button with a document icon in the top right corner.

Please note that there are system properties that control whether you can edit certain information. Therefore, some of the fields above may appear as read only.

You can also check-out the document by clicking the **Check-out Document** button. A confirmation window will appear confirming that you would like to check-out the document. Clicking **Confirm** downloads the file to your local drive and refreshes the window to show that the document is currently checked out.

Study Consent Revision
X

*** Consent Title:**

*** Version Number:** .1

*** Version Date:**

Category:

*** Language:**

Description:

Comments:

Download Consent:

This document is currently checked out by.. John Investigator at 06/25/2021 09:09:44 AM

Check-in when you are done editing upload the document back into iRIS.

Revert to the document stored in iRIS.

View Document

When downloading the document, depending on your Internet Browser, version, and settings, you may or may not be prompted with the file download information. The browser may ask if you would like to open or save the consent document. **Save** the document and be sure to save the document in a known location.

While the consent document is checked out, the **Checked Out By** display table column will populate with the appropriate user name and data of the check-out.

All	Approved	Void	Archive									
☑	View History	Edit/View	Title	Version	Language	UnApproved Consent	Approved Consent	Consent Outcome	Approval Date	Expiration Date	Checked Out By	Hide
			Category									
<input type="checkbox"/>			English Consent Form	1.2 06/25/2021	English							
<input type="checkbox"/>			Revised English Consent Form	1.0 07/08/2021	English						John Investigator at 07/08/2021 02:43:57 PM	

Once you are ready to check-in the modified consent, return to this window and click the **Check-in Document** button, as seen in the image below.

A small window will open allowing you to upload a document. Once you have successfully located and uploaded the edited consent document, click the **Save selected file** button to finalize the check-in.

The Consent document will be uploaded to the study and will appear as an icon next to the consent information, as shown below. Click the **Save Consent** button to create the consent record.

Study Consent Revision

* Consent Title: Revised English Consent Form

* Version Number: 1.0

* Version Date: 07/08/2021

Category: Consent

* Language: English

Description: This is a revised consent form.

Comments: N/A

Download Consent: Download

Check-out the Document to your workstation for editing: Check-out Document...

Close, don't save any changes Save Consent

View Document

The new consent record will populate in the document library display table.

Review Board Fields

The consent document display table contains several fields reserved for the review board: Consent Outcome, Approval Date, and Expiration Date. Information will populate in these columns the board reviews the consent.

In order for a consent document to be approved, it will need to be attached to a submission form and sent it to the board for review.

Delete Selected Consent(s)

You can delete Consents by selecting the checkbox next to the Consent record and clicking the **Delete Selected Consent(s)** button at the top right of the screen. If a Consent document has been submitted, it cannot be deleted from the study.

Accessing an Approved Consent

You can access Approved consents from the “Approved” or “All” tabs of document management. Within the Consent table are columns for the unapproved and approved versions of the Consent form. If the review board has not approved a Consent record, clicking on the icon in the **UnApproved Consent** column opens the consent document file in a new window.

All		Approved		Void		Archive						
2 result(s) found...												
	View History	Edit/View	Title Category	Version	Language	UnApproved Consent	Approved Consent	Consent Outcome	Approval Date	Expiration Date	Checked Out By	Hide
<input type="checkbox"/>			English Consent Form Consent	1.1 06/28/2021	English							

Once the review board approves the Consent, the unapproved copy of the consent will not be displayed in the column. Instead, the stamped, approved Consent will be available in the **Approved Consent** column. You can click the icon to open the approved Consent. This will open the approved Consent document file in a new window.

All		Approved		Void		Archive							
1 result(s) found...													
	View History	Edit/View	Reference Number	Title Category	Version	Language	UnApproved Consent	Approved Consent	Consent Outcome	Approval Date	Expiration Date	Checked Out By	Hide
<input type="checkbox"/>			IRB-20-336-NEW-1.0	Study Consent	1.0 09/21/2020	English			Approved	09/10/2020	09/09/2021		

Revise a Consent

If you would like to revise an existing Consent record, click on the **Add/Revise Consent** button to display the following window.

Study Consent Add Verification
X

Select Category: --none-- ▼

Version #: .

Version Date: between

Consent Outcome: --none-- ▼

Title:

Search level: Top All

Expiration Date: between

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...

	Title	Category	Version	Version Date	Consent Outcome	View Document	
	Study Consent		1.0	09/21/2020	Approved		65.65 KB

Cancel Consent Add

Please note that the **Add/Revise Consent** button is only available under the “All” and “Approved” tabs. If you revise a consent under the “Approved” tab, it will only appear in the “All” tab as it has not yet been reviewed and approved by the review board.

From this window, you can filter for which consent you would like to revise using the fields at the top of the screen. Once you have located the consent you wish to revise, click on the **Create Revision** icon and the following screen will appear with the details for the new consent revision.

Study Consent Revision
X

*** Consent Title:**

*** Version Number:** .1

*** Version Date:**

Category: --none--

*** Language:** English

Description:

Comments:

Download Consent:

Check-out the Document to your workstation for editing:

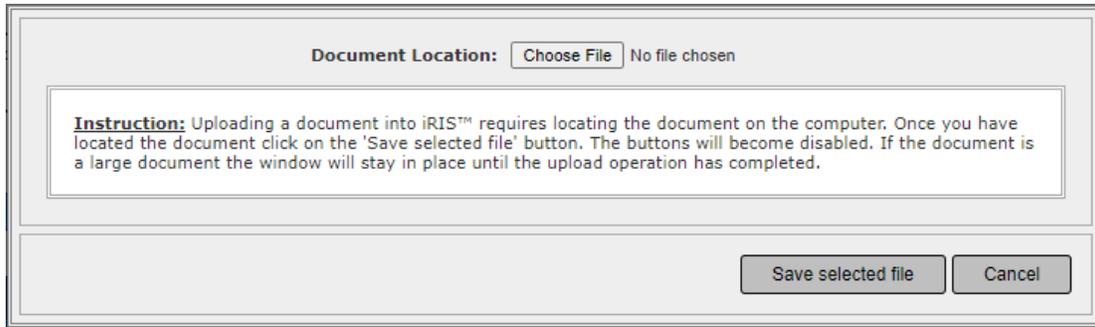
View Document

From this window you can check-out the document if you wish to edit the document. You can also download the document to your local computer without checking it out. After you make any changes to the document in Microsoft Word, you can return to the Informed Consent library to check in the changes. Click the icon in the **Edit/View** column for the consent record you wish to check-in.

All	Approved	Void	Archive										
2 result(s) found...													
	View History	Edit/View	Title	Version	Language	UnApproved Consent	Approved Consent	Consent Outcome	Approval Date	Expiration Date	Checked Out By	Hide	
<input type="checkbox"/>			English Consent Form										
<input type="checkbox"/>			Consent	1.2 06/25/2021	English								
<input type="checkbox"/>			Revised English Consent Form								John Investigator at 07/08/2021 02:43:57 PM		
			Consent	1.0 07/08/2021	English								

When the Informed Consent Document details window opens, you can click the **Check-in Document** button.

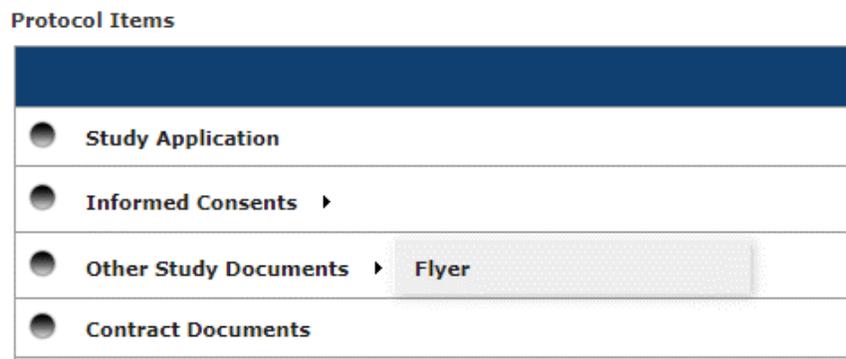
A window will open allowing you to upload the revised consent. Once you have located and uploaded a document, click the **Save selected file** button.



Click the **Save Consent** button to save the revised document to the study.

Other Study Documents

The **Other Study Documents** link from the main Submissions page will direct you to the Other Study Document library, which, similar to the Informed Consent library, stores all other documents you have attached to submission forms or manually added to the study.



If you hover over the Other Study Documents link, a popup menu will appear that displays all categories of documents that have been uploaded to the study. If you click a link in the menu, the Study Document library will open to display only documents in the selected category.

My Workspaces ▾

IRB Number: **IRB-20-336**
 PI: Smith, Betty

Study Assistant

Other Study Documents

◀ Back

Study Status: Active

IRB Number : IRB-20-336

Study Title : Serum Metal Ion Concentration after Insertion of Pediatric Flexible Nail

IRB Expiration Date: 07/14/2021

Keep default values:

Select a Category Type: All

Version #: .

Approval Date: between

Show Hidden: Yes No

Title:

Document Outcome: All

Expiration Date: between

Reset Filters

Filter Documents

Study document revision history list associated with this Study.

To view previous versions click on the folder .

Compare document versions
Add/Revise Document
Add Multiple Documents
Delete Selected Document(s)
Archive Selected Document(s)

Approved

All

Void

Archive

3 result(s) found...

<input type="checkbox"/>	View History	Edit	Version	Sponsor Version	Title	Document Outcome	Approval Date	Expiration Date	File	Stamped File	Checked Out By	Hide
<input type="checkbox"/>			1.0 06/25/2021		Recruitment Flyer Flyer				 1.15 KB			

The Study Document library stores any document you have attached to submission forms or added through the library itself. When the review board approves a document, the approval information will update the document stored in the library.

From this area you can revise, create, compare, and print study documents.

A new property has been added that allows the iRIS™ system administrator to prohibit documents that have been attached to a submission to be edited. The default setting of this property is “No”, if you want to change this and allow Researchers to edit documents, please contact your system administrator.

When this property is set to “No”, the Researcher will not be able to edit any study documents from the Study Management page. The documents will be available in read-only mode. The options to **Add/Revise Document**, **Add Multiple Documents**, **Delete Selected Document(s)**, and **Archive Selected Document(s)** will no longer be available as well, as shown in the screenshot below.

My Workspaces IRB Number: **IRB-20-336** Study Assistant Other Study Documents Back

PI: Smith, Betty

Study Status: **Active** IRB Number: IRB-20-336 Study Title: Serum Metal Ion Concentration after Insertion of Pediatric Flexible Nail

IRB Expiration Date: 07/14/2021

Keep default values:

Select a Category Type: All

Version #: . .

Approval Date: between

Show Hidden: Yes No

Title:

Document Outcome: All

Expiration Date: between

Reset Filters

Filter Documents

Study document revision history list associated with this Study.
To view previous versions click on the folder .

Compare document versions

Approved All Void Archive

3 result(s) found...

<input type="checkbox"/>	View History	Edit	Version	Sponsor Version	Title	Document Outcome	Approval Date	Expiration Date	File	Stamped File	Checked Out By	Hide
					Category							
<input type="checkbox"/>			1.0 06/25/2021		Recruitment Flyer Flyer				 9.57 KB			

When this property is set to “Yes”, the Researcher will be able to edit any study documents from the Study Management page and the options to **Add/Revise Document**, **Add Multiple Documents**, **Delete Selected Document(s)**, and **Archive Selected Document(s)** will now appear.

My Workspaces IRB Number: **IRB-20-336** Study Assistant Other Study Documents Back

PI: Smith, Betty

Study Status: **Active** IRB Number: IRB-20-336 Study Title: Serum Metal Ion Concentration after Insertion of Pediatric Flexible Nail

IRB Expiration Date: 07/14/2021

Keep default values:

Select a Category Type: All

Version #: . .

Approval Date: between

Show Hidden: Yes No

Title:

Document Outcome: All

Expiration Date: between

Reset Filters

Filter Documents

Study document revision history list associated with this Study.
To view previous versions click on the folder .

Compare document versions Add/Revise Document Add Multiple Documents Delete Selected Document(s) Archive Selected Document(s)

Approved All Void Archive

1 result(s) found...

<input type="checkbox"/>	View History	Edit	Version	Sponsor Version	Reference Number	Title	Document Outcome	Approval Date	Expiration Date	File	Stamped File	Checked Out By	Hide
						Category							
<input type="checkbox"/>			1.0 06/25/2021			Recruitment Flyer Flyer				 1.15 KB			

Filter Documents

Several filters are included at the top of this page to aid in finding a particular document or group of documents.

You can use any combination of the items described below to filter the results.

Study Status: Active	IRB Number : IRB-20-336	Study Title : Serum Metal Ion Concentration after Insertion of Pediatric Flexible Nail
	IRB Expiration Date: 07/14/2021	

Keep default values: <input type="checkbox"/>	Show Hidden: <input type="radio"/> Yes <input checked="" type="radio"/> No	<input type="button" value="Reset Filters"/>
Select a Category Type: All	Title: <input type="text"/>	<input type="button" value="Filter Documents"/>
Version #: <input type="text"/> . <input type="text"/>	Document Outcome: All	
Approval Date: <input type="text"/> between <input type="text"/>	Expiration Date: <input type="text"/> between <input type="text"/>	

Study document revision history list associated with this Study.
To view previous versions click on the folder .

The available filters are as follows:

Keep default values – When checked this field preserves the most recent filter values, so when this page is revisited, the filters will be unchanged. If unchecked, the filter values reset each time the page is left and revisited.

Show Hidden – The default selection for this filter is set to “No”. This means that all of the documents viewed on the page are “non-hidden”. Selecting “Yes” will refresh the page displaying both hidden and non-hidden study documents.

Select a Category Type – Provides the ability to filter by a document category. The default selection is set to “All”, meaning all documents in all categories will display in the results.

Title – Type in all or part of a document title to include in the filter.

Version # – Type in a version number to include in the filter. The version number is exact case. For example, if you type in “1”, only documents that are version “1.x” will populate on the page.

Approval Date – Use this field to specify a date range for approval dates. You must enter a date into both fields. If you wish to filter by only one day, enter the same day in both date fields.

Document Outcome – Use this drop-down list to filter by a review board document outcome.

Expiration Date – Use this field to specify a date range for expiration dates. You must enter a date into both fields. If you wish to filter by only one day, enter the same day in both date fields.

Compare Document Versions

When there is more than one version of a study document, a folder icon will appear in the table. When you click on the folder all previous versions of the document will display below the most current version.

Approved All Void Archive

2 result(s) found...

<input type="checkbox"/>	View History	Edit	Version	Sponsor Version	Title	Document Outcome	Approval Date	Expiration Date	File	Stamped File	Checked Out By	Hide
					Category							
<input type="checkbox"/>			1.3 06/25/2021		Recruitment Flyer Second Event Flyer				13.00 KB			
<input type="checkbox"/>			1.2 06/25/2021		Recruitment Flyer Second Event Flyer				13.00 KB			
<input type="checkbox"/>			1.0 06/25/2021		Recruitment Flyer Flyer				9.57 KB			

This will allow you to view information related to older versions. You can view the previous versions' unapproved documents by clicking on the Word icon in the **File** column, as seen in the image above.

You can also compare versions of the documents by clicking the checkbox next to two versions of the same document and then clicking on the **Compare document versions** button at the top of the page.

Approved All Void Archive

2 result(s) found...

<input type="checkbox"/>	View History	Edit	Version	Sponsor Version	Title	Document Outcome	Approval Date	Expiration Date	File	Stamped File	Checked Out By	Hide
					Category							
<input checked="" type="checkbox"/>			1.3 06/25/2021		Recruitment Flyer Second Event Flyer				13.00 KB			
<input checked="" type="checkbox"/>			1.2 06/25/2021		Recruitment Flyer Second Event Flyer				13.00 KB			
<input type="checkbox"/>			1.0 06/25/2021		Recruitment Flyer Flyer				9.57 KB			

iRIS™ will analyze the two files using a comparison tool. This may take several moments, depending on the size of your documents. When the comparison process is complete, a new window will open displaying both selected files in a side-by-side view, with the older version listed in the left column and the newer version listed in the right column, as seen in the image below.

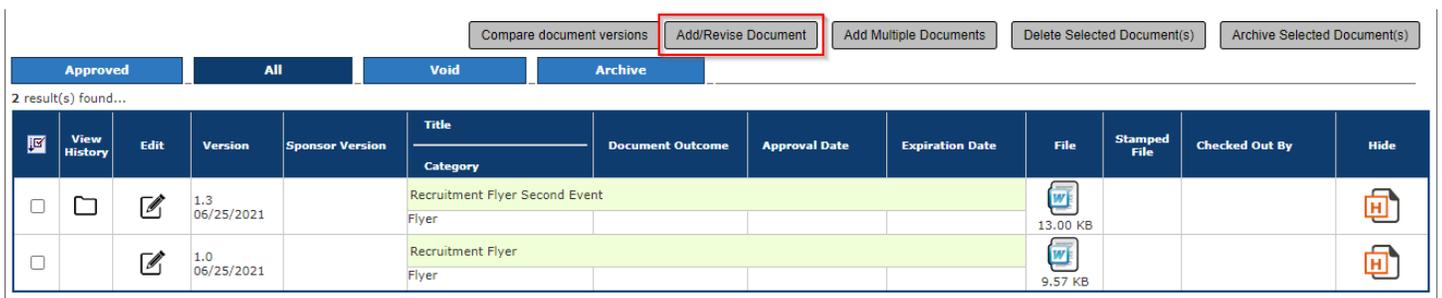


At the bottom of the window, a split view will display a combination of both versions, indicating where items have been modified. Differing items in the newer version are marked by either green or red highlights. Green highlights indicate a new addition to the document and red highlights mark items that have been removed from the document.

When you are finished viewing the difference between the two documents, click the **Close** button.

Add a New Document

You can add a new document to the study by clicking **Add/Revise Document** button.



Once clicked, the following window will appear asking if you would like to revise an existing document or upload a brand-new document.

Please note that the **Add/Revise Document** button is only available under the “Approved” and “All” tabs. Furthermore, if you add or revise a document under the “Approved” tab, it will only appear in the “All” tab as it has not yet been reviewed and approved by the review board.

Study Document Add Verification
X

Select Category: --none--

Version #: .

Version Date: ▼ between ▼

Document Outcome: --none--

Title:

Search level: Top All

Expiration Date: ▼ between ▼

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

2 result(s) found...

Create Revision	Title	Category	Version	Version Date	Document Outcome	Sponsor Version	View Document
	Recruitment Flyer Second Event	Flyer	1.3	06/25/2021			 13.00 KB
	Recruitment Flyer	Flyer	1.0	06/25/2021			 9.57 KB

Cancel Document Add

Click on the **Upload a New Document Not on the List** button to upload a new document. The following window will appear.

Please note that if you add a document from Study Assistant outside of a submission form, it will not be reviewed by the review board.

Depending on your system settings you may or may not have the same options as shown in the window above. These fields are described as follows:

Document Title – The title you would like to display for this document. If you did not enter the Document Title prior to uploading the document, the system will automatically apply the name of the document to the Document Title field.

Select the document to upload – Attach the document by dragging and dropping to this window. You can also click within the box to upload the file manually.

Version Number - Requires you to specify the version number of the new document. This can be any character or number. Placed after the editable version number is a hard coded '.0'. This is the iRIS™ version number. Any new document uploaded to the system will consist of the '.0' affixed to your manually entered version number. Once a revision is made to the document, iRIS™ will change the '.0' to '.1'. It will continue to increment the numbers each time a revision is made.

Version Date – This required field is the date of the manually entered version number. This is typically the date that the document was uploaded to the system. You may configure this field to auto-fill by turning on the *system.auto_fill_version_date* property.

Category – This configurable drop-down list allows you to group documents into certain categories. The categories displayed here are configurable via System Administration. This field may or may not be required based on the value of the *system.doc_category_required* property.

Description – A description of the document.

Comments – Any comments regarding the document you feel necessary to add for the review board.

Once the above required fields are completed and the document has been uploaded, click the **Save Document** button.

The screenshot shows a web form titled "Study Document Add" with a close button (X) in the top right corner. The form is organized into several sections:

- *Document Title:** A text input field containing "Recruitment Handbook".
- *Select the document to upload:** A dashed box containing a file preview for "Recruitment Handbook.docx" (12.4 KB) with a "Remove file" link below it.
- **Version Number:** A text input field with "1" and ".0" (with a dropdown arrow).
- Version Date:** A date input field showing "07/09/2021" with a calendar icon.
- Sponsor Version:** An empty text input field.
- * Category:** A dropdown menu currently set to "Other".
- Description:** A large empty text area.
- Comments:** A large empty text area.

At the bottom right of the form, there are two buttons: "Close, don't save any changes" and "Save Document". The "Save Document" button is highlighted with a red rectangular box.

This will close the window and populate the new record in the document library display table.

Approved All Void Archive

3 result(s) found...

<input type="checkbox"/>			Version	Sponsor Version	Title	Document Outcome	Approval Date	Expiration Date	File	Stamped File	Checked Out By	Hide
					Category							
<input type="checkbox"/>			1.3 06/25/2021		Recruitment Flyer Second Event Flyer				 13.00 KB			
<input type="checkbox"/>			1.0 06/25/2021		Recruitment Flyer Flyer				 9.57 KB			
<input type="checkbox"/>			1.0 07/09/2021		Recruitment Handbook Other				 9.98 KB			

Review Board Fields

The document library display table contains several fields reserved for the review board: Document Outcome, Approval Date, and Expiration Date. Information will populate in these columns as the board reviews the document.

Approved All Void Archive

3 result(s) found...

<input type="checkbox"/>			Version	Sponsor Version	Title	Document Outcome	Approval Date	Expiration Date	File	Stamped File	Checked Out By	Hide
					Category							
<input type="checkbox"/>			1.3 06/25/2021		Recruitment Flyer Second Event Flyer				 13.00 KB			
<input type="checkbox"/>			1.0 06/25/2021		Recruitment Flyer Flyer				 9.57 KB			
<input type="checkbox"/>			1.0 07/09/2021		Recruitment Handbook Other				 9.98 KB			

In order for a consent document to be approved, it will need to be attached to a submission form and sent to the board for review.

Add Multiple Documents

You can add multiple documents at once by clicking on the **Add Multiple Documents** button.

Approved All Void Archive

3 result(s) found...

<input type="checkbox"/>			Version	Sponsor Version	Title	Document Outcome	Approval Date	Expiration Date	File	Stamped File	Checked Out By	Hide
					Category							
<input type="checkbox"/>			1.3 06/25/2021		Recruitment Flyer Second Event Flyer				 13.00 KB			
<input type="checkbox"/>			1.0 06/25/2021		Recruitment Flyer Flyer				 9.57 KB			
<input type="checkbox"/>			1.0 07/09/2021		Recruitment Handbook Other				 9.98 KB			

When you click this button, a new window will open containing five rows for document uploads. Complete the following information for each row: Document Title (required), Version, Version Date, Category, and File Path. If you are not uploading five documents, just populate the necessary row(s) and click the **Save Record(s)** button.

Save Documents
Add New Record(s)

Document Title	Version	Version Date	Sponsor Version	Category	File path
Recruitment Flyer	1	06/25/2021		Flyer	Choose File Recruitment Flyer.docx
Recruitment Flyer Second Event	1	06/25/2021		Flyer	Choose File Recruitment Flyer (2).docx
				--none--	Choose File No file chosen
				--none--	Choose File No file chosen
				--none--	Choose File No file chosen
				--none--	Choose File No file chosen
				--none--	Choose File No file chosen
				--none--	Choose File No file chosen
				--none--	Choose File No file chosen
				--none--	Choose File No file chosen

If you have more than five documents to upload, you can click the **Add New Records** button and five additional rows will populate on the page.

Save Documents
Add New Record(s)

Document Title	Version	Version Date	Sponsor Version	Category	File path
Recruitment Flyer	1	06/25/2021		Flyer	Choose File Recruitment Flyer.docx
Recruitment Flyer Second Event	1	06/25/2021		Flyer	Choose File Recruitment Flyer (2).docx
				--none--	Choose File No file chosen
				--none--	Choose File No file chosen
				--none--	Choose File No file chosen
				--none--	Choose File No file chosen
				--none--	Choose File No file chosen
				--none--	Choose File No file chosen
				--none--	Choose File No file chosen
				--none--	Choose File No file chosen

You do not need to delete unused rows; the system will not upload anything that has not been entered in a row.

Delete Documents

You can delete documents by selecting the checkbox next to the document record and clicking the **Delete Selected Document(s)** button. Once a Study Document is submitted it cannot be deleted from the study.

Compare document versions Add/Revise Document Add Multiple Documents **Delete Selected Document(s)** Archive Selected Document(s)

Approved All Void Archive

3 result(s) found...

<input type="checkbox"/>	View History	Edit	Version	Sponsor Version	Title	Document Outcome	Approval Date	Expiration Date	File	Stamped File	Checked Out By	Hide
					Category							
<input type="checkbox"/>			1.3 06/25/2021		Recruitment Flyer Second Event Flyer				 13.00 KB			
<input type="checkbox"/>			1.0 06/25/2021		Recruitment Flyer Flyer				 9.57 KB			
<input checked="" type="checkbox"/>			1.0 07/09/2021		Recruitment Handbook Other				 9.98 KB			

Edit

You can view the details of any Other Study Document by clicking the icon in the **Edit** column. If the document has been submitted, you will not be able to make any edits to the record. You will need to create a revision of the document in order to do so.

Compare document versions Add/Revise Document Add Multiple Documents Delete Selected Document(s) Archive Selected Document(s)

Approved All Void Archive

3 result(s) found...

<input type="checkbox"/>	View History	Edit	Version	Sponsor Version	Title	Document Outcome	Approval Date	Expiration Date	File	Stamped File	Checked Out By	Hide
					Category							
<input type="checkbox"/>			1.3 06/25/2021		Recruitment Flyer Second Event Flyer				 13.00 KB			
<input type="checkbox"/>			1.0 06/25/2021		Recruitment Flyer Flyer				 9.57 KB			
<input type="checkbox"/>			1.0 07/09/2021		Recruitment Handbook Other				 9.98 KB			

When you open the details of the document, you can view the document by clicking the **View Document** icon. Depending on the status of the document, you may see a Word icon, a PDF icon, or an RTF icon as shown in the image below.

Study Document Revision: X

* Document Title:	<input type="text" value="Recruitment Flyer"/>	
Version Number:	<input type="text" value="1"/> .0	
Version Date:	<input type="text" value="06/25/2021"/> 	
Sponsor Version:	<input type="text"/>	
* Category:	<input type="text" value="Flyer"/>	
Description:	<input type="text"/>	
Comments:	<input type="text"/>	
Download Document:	<input type="button" value="Download"/>	
Check-out the Document to your workstation for editing:	<input type="button" value="Check-out Document..."/>	

You can also download a copy of the document by clicking on the **Download** button. This will download the document to your local machine in its native format.

Accessing Approved Documents

To access your approved documents, click on the **Approved** tab in document management. This will display all of your approved documents for your study.

My Workspaces IRB Number: **IRB-21-467** Study Assistant Other Study Documents Back

Study Status: **Active** IRB Number: IRB-21-467 Study Title: NIH - FD - 00001- Multi-Site safety of masks over 52 weeks in USA work environments

IRB Expiration Date: 06/19/2022

Keep default values: Show Hidden: Yes No Reset Filters

Select a Category Type: All Title: Document Outcome: All Filter Documents

Version #: Approval Date: between Expiration Date: between

Study document revision history list associated with this Study.
To view previous versions click on the folder

Compare document versions Add/Revise Document Archive Selected Document(s)

Approved All Void Archive

2 result(s) found...

<input type="checkbox"/>	View History	Edit	Version	Sponsor Version	Title	Document Outcome	Approval Date	Expiration Date	File	Stamped File	Checked Out By	Hide	
					Category								
<input type="checkbox"/>			1.0 06/20/2021	1.0	Investigator Brochure								
					Investigator brochure	Approved	06/20/2021			171.26 KB			
<input type="checkbox"/>			1.0 06/20/2021	1.0	IBC Document								
					Other	Approved	06/20/2021			50.66 KB			

The original copy of these approved documents will not be displayed in the **File** column as they are for unapproved documents. The approved document will be viewable via the icon in the **Stamped File** column. You can click the icon in this column to open the approved document. This will open the document in a new window, allowing you to print it for your records.

My Workspaces IRB Number: **IRB-21-467** Study Assistant Study Document Libraries Back

Study Status: **Active** IRB Number: IRB-21-467 Study Title: NIH - FD - 00001- Multi-Site safety of masks over 52 weeks in USA work environments

IRB Expiration Date: 06/19/2022

Study Documents Informed Consents Study Contracts Core Master Consent Template

Keep default values: Show Hidden: Yes No Reset Filters

Select a Category Type: All Title: Document Outcome: All Filter Documents

Version #: Approval Date: between Expiration Date: between

Study document revision history list associated with this Study.
To view previous versions click on the folder

Compare document versions Add/Revise Document Archive Selected Document(s)

Approved All Void Archive

2 result(s) found...

<input type="checkbox"/>	View History	Edit	Version	Sponsor Version	Reference Number	Title	Document Outcome	Approval Date	Expiration Date	File	Stamped File	Checked Out By	Hide
					Category								
<input type="checkbox"/>			1.0 06/20/2021	1.0	IBC-21-0113-NEW-1.0	Investigator Brochure							
					IRB-21-467-NEW-1.0	Investigator brochure	Approved	06/20/2021			171.26 KB		
<input type="checkbox"/>			1.0 06/20/2021	1.0	IBC-21-0113-NEW-1.0	IBC Document							
					IRB-21-467-NEW-1.0	Other	Approved	06/20/2021			50.66 KB		

Creating Revisions

If you would like to revise an existing document record, click the **Add/Revise Document** button in the “Approved” or “All” tabs. This will open the following window.

Study Document Add Verification
X

Select Category: --none--

Version #: .

Version Date: between

Document Outcome: --none--

Title:

Search level: Top All

Expiration Date: between

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

2 result(s) found...

Create Revision	Title	Category	Version	Version Date	Document Outcome	Sponsor Version	View Document
	Investigator Brochure	Investigator brochure	1.0	06/20/2021	Approved	1.0	 171.26 KB
	IBC Document	Other	1.0	06/20/2021	Approved	1.0	 50.66 KB

Cancel Document Add

From here you can use the filters at the top of the window to locate the document you want to revise. Once you have located the document, click on the icon in the **Create Revision** column and the following window will open.

Study Document Revision: [X]

* Document Title:	IBC Document
Version Number:	1 .1
Version Date:	06/20/2021 [Calendar Icon]
Sponsor Version:	1.0
* Category:	Other [Dropdown]
Description:	[Text Area]
Comments:	[Text Area]
Download Document:	Download
Check-out the Document to your workstation for editing:	Check-out Document...

[Close, don't save any changes] [Save Document]

From here you can edit the details of the document, download a copy of the document, and check the document out to edit on your desktop.

Study Document Revision: [X]

* Document Title:	IBC Document
Version Number:	1 .1
Version Date:	06/20/2021 [Calendar Icon]
Sponsor Version:	1.0
* Category:	Other [Dropdown]
Description:	[Text Area]
Comments:	[Text Area]
Download Document:	Download
This document is currently checked out by:	John Investigator at 06/25/2021
Check-in when you are done editing upload the document back into iRIS.	Check-in Document...
Revert to the document stored in iRIS.	Undo Check-out Document...

[Close, don't save any changes] [Save Document]

The system will indicate anytime a document is checked out.

Approved		All	Void	Archive									
2 result(s) found...													
<input type="checkbox"/>	View History	Edit	Version	Sponsor Version	Title	Document Outcome	Approval Date	Expiration Date	File	Stamped File	Checked Out By	Hide	
					Category								
<input type="checkbox"/>			1.1 06/20/2021	1.0	IBC Document						John Investigator 07/09/2021 10:44:38 AM		
					Other				13.00 KB				
<input type="checkbox"/>			1.0 06/20/2021	1.0	Investigator Brochure	Investigator brochure	Approved	06/20/2021					
										171.26 KB			

This document is currently checked out by. John Investigator at 06/25/2021

Check-in when you are done editing upload the document back into iRIS.

Revert to the document stored in iRIS.

If you are logged in as the user that has checked out the document, you will be able to **Check-in Document** or **Undo Check-out Document**.

To check-in the document after all desired changes have been applied, click the icon in the **Edit** column of the study document library display table.

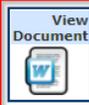
Approved		All	Void	Archive									
2 result(s) found...													
<input type="checkbox"/>	View History	Edit	Version	Sponsor Version	Title	Document Outcome	Approval Date	Expiration Date	File	Stamped File	Checked Out By	Hide	
					Category								
<input type="checkbox"/>			1.1 06/20/2021	1.0	IBC Document						John Investigator 07/09/2021 10:44:38 AM		
					Other				13.00 KB				
<input type="checkbox"/>			1.0 06/20/2021	1.0	Investigator Brochure	Investigator brochure	Approved	06/20/2021					
										171.26 KB			

When the Study Document details window opens, you can click the **Check-in Document** button.

A small window will open allowing you to upload the revised document. You will need to browse for the document on your computer by clicking on the **Browse** button. This will open another window allowing you to navigate the folders on your computer. Once you uploaded a document, click the **Save selected file** button.

The document will be uploaded and will appear as an icon next to the document information, as shown below. Click the **Save Document** button to save the revised document to the study.

Study Document Revision:



*Document Title:	<input type="text" value="IBC Document"/>
Version Number:	<input type="text" value="1"/> . <input type="text" value="1"/>
Version Date:	<input type="text" value="06/20/2021"/> 
Sponsor Version:	<input type="text" value="1.0"/>
* Category:	<input type="text" value="Other"/>
Description:	<div style="border: 1px solid gray; height: 30px;"></div>
Comments:	<div style="border: 1px solid gray; height: 30px;"></div>
Download Document:	<input type="button" value="Download"/>
Check-out the Document to your workstation for editing:	<input type="button" value="Check-out Document..."/>

Remember, the new revision will not appear under the “Approved” tab even if it was completed from that tab as it has not been approved or reviewed. Click on the “All” tab to see your revision.

View History	Edit	Version	Sponsor Version	Reference Number	Title Category	Document Outcome	Approval Date	Expiration Date	File	Stamped File	Checked Out By	Hide
<input type="checkbox"/>		1.1 06/20/2021	1.0		IBC Document Other				 13.00 KB			
<input type="checkbox"/>		1.0 06/20/2021	1.0	IBC-21-0113-NEW-1.0 IRB-21-467-NEW-1.0	Investigator Brochure Investigator brochure	Approved	06/20/2021		 171.26 KB			

Submission Forms

This area links to different submission forms that can be sent to a review board. The list of forms here will change depending on the forms setup in your system. You can create and submit a form any time by clicking on the link for the form.

The screenshot shows a navigation bar with 'Submissions', 'Study Management', and 'Subject Management'. Below it is a 'Current Approval Packet' button. The main content area is divided into two sections: 'Protocol Items' and 'Regulatory Forms'. The 'Regulatory Forms' section is highlighted with a red box and contains a sub-section 'Regulatory Submission Forms' with four items: 'Continuing Review Submission Form', 'Study Amendment Form', 'Study Closure Form', and 'Unanticipated Events Form'.

When you click on a form link from the main Submissions page you will be directed to a screen that lists any previously started or completed forms for the study. The header of the page contains buttons that allow you to **Copy Forms**, **Add a New Form**, **Compare Two Versions** or **Delete Selected Form(s)** (provided it has not been submitted for review).

The screenshot shows the 'Study Amendment Form' page. The header includes 'My Workspaces', 'IRB Number: IRB-21-476', 'Study Assistant', and 'Study Amendment Form' with a 'Back' button. Below the header, there are fields for 'Study Status: Active', 'IRB Number: IRB-21-476', 'Study Title: Malaria in Juveniles', and 'IRB Expiration Date: 06/24/2022'. Action buttons include 'Copy Form', 'Add a New Form', 'Compare Two Versions', and 'Delete Selected Form(s)'. An information icon and text state: 'List of records associated with form: Study Amendment Form. To view previous versions click on the folder icon [icon]'. Below this, it says '0 result(s) found...'. At the bottom, there is a table header with columns: Show Rev, Edit/View, Details, Apply to Multiple, Sub. Rounds, Track Location, Process Submission, Submission Date, Update Date, Update Number, UPDATE TYPE, and Created By. The table body contains the text 'No results found.'

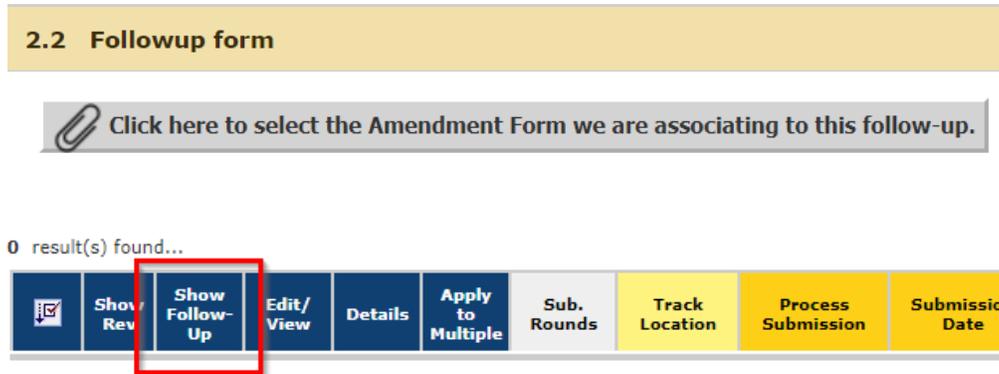
Submission Forms Display Table

The table below the buttons lists any form that has already been started. The columns of this table are described as follows:

The checkbox column can be used to copy, compare, and delete a form.

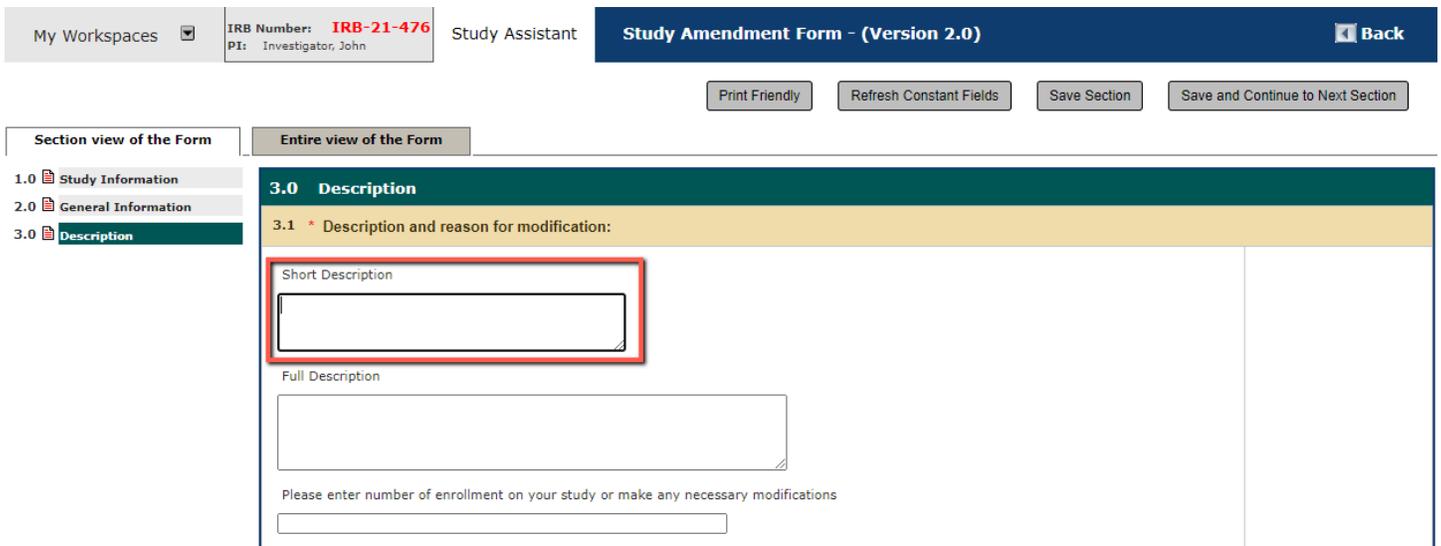
Show Rev – If a form has been revised for corrections, a folder will appear in this column. You can click on it to see the previous versions of the form. You will be able to open the previous submission, but it will be read only as that version has been submitted previously.

Show Follow-Up – If a form has been linked to another form as a follow-up form, it will show here. This column must be activated in System Form Designer in order to appear here.



Edit/View – Click on this icon to continue to work on a partially completed form or to view a form that has already been submitted.

Details – Hover over this icon to show the Short Description of the submission. The Short Description is a data value that acts as a basic summary for the submission form.



Study Status: Active	IRB Number : IRB-21-476	Study Title : Malaria in Juveniles
	IRB Expiration Date: 06/24/2022	

Copy Form Add a New Form Compare Two Versions Delete Selected Form(s)

i List of records associated with form: Study Amendment Form.
To view previous versions click on the folder icon .

1 result(s) found...

	Show Rev	Edit/View	Details	Apply to Multiple	Sub. Rounds	Track Location	Process Submission	Submission Date	Update Date	Update Number	UPDATE TYPE	Created By	
<input type="checkbox"/>								06/25/2021 10:57:05 AM PDT	06/25/2021	1	1111112	John Investigator	06/25/2021

Subject has Skin Cancer

Apply to Multiple – This icon allows you to add the form to another study. Clicking this icons opens the following page.

My Workspaces  IRB Number: **IRB-21-476** Study Assistant My Studies  Back

Display my studies by: Filter my studies by study status: Find by IRB Number:  Find

Most Recently Used: Find by Study Alias:  Find

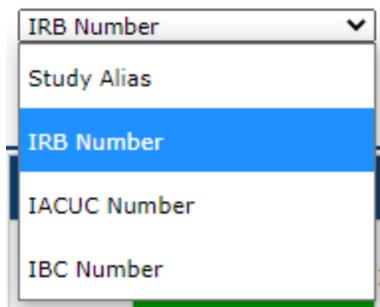
 Save a Copy of the selected form

Click to open	Study Status	IRB Number	IRB Expiration	Principal Investigator	Study Title / Study Alias
<input type="checkbox"/>	Active	IRB-21-467-0001	06/19/2022	Investigator, John	NIH - FD - 00001- Multi-Site safety of masks over 52 weeks in USA work environments NIH - FD - 0001
<input type="checkbox"/>	Open	IRB-19-180	07/29/2021	Investigator, John	Use of stem cells on subjects currently being treated for Diabetes Type 2 USCSD -13323
<input type="checkbox"/>	Active	IRB-20-336	07/14/2021	Smith, Betty	Serum Metal Ion Concentration after Insertion of Pediatric Flexible Nail Serum Metal Ion Concentration after Insertion of Pediatric Flexible Nail
<input type="checkbox"/>	Draft	IRB-21-473		Investigator, John	Malaria in Juveniles Malaria in Juveniles

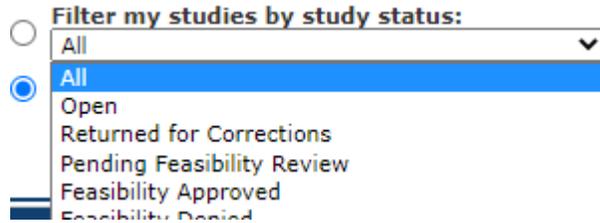
The filters shown in the page above are described as follows:

- **Display my studies by** – This drop-down will allow the user to filter by different search criteria as seen below in the example system setup. Again, your drop-down options may differ depending on your system configuration.

Display my studies by:



- **Filter my studies by study status** – This drop-down will allow the user to filter by different search criteria as seen below in the example system setup. Again, your drop-down options may differ depending on your system configuration.



- **Most Recently Used** – This will filter the studies so the most recently used forms display first.
- **Find by IRB Number** – Allows the user to search for a study using an IRB number.
- **Find by Alias** – This allows the user to search for a study using a specific set of words or by the known alias.

After selecting which study to attach the copy of the form to, click **Save a Copy of the selected form**.

My Workspaces ▾ IRB Number: **IRB-21-476** PI: Investigator, John Study Assistant **My Studies** Back

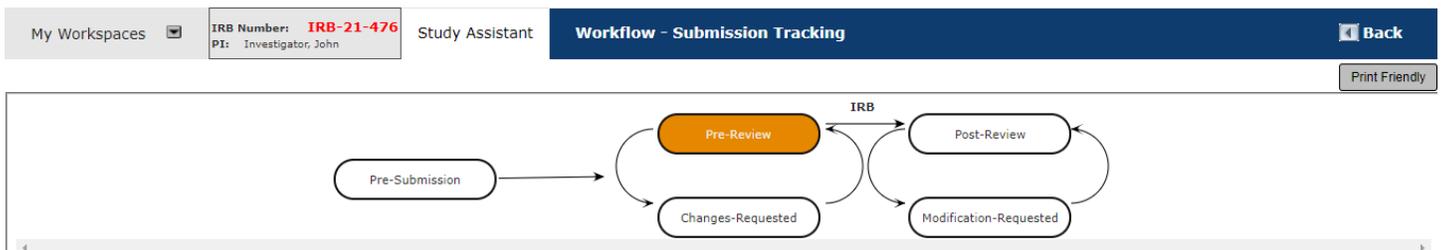
Display my studies by: IRB Number ▾ Filter my studies by study status: All (selected) Most Recently Used: Find by IRB Number: Find Find by Study Alias: Find

Save a Copy of the selected form

Click to open	Study Status	IRB Number	IRB Expiration	Principal Investigator	Study Title / Study Alias
<input checked="" type="checkbox"/>	Active	IRB-21-467-0001	06/19/2022	Investigator, John	NIH - FD - 00001- Multi-Site safety of masks over 52 weeks in USA work environments NIH - FD - 0001
<input type="checkbox"/>	Open	IRB-19-180	07/29/2021	Investigator, John	Use of stem cells on subjects currently being treated for Diabetes Type 2 USCSD -13323
<input type="checkbox"/>	Active	IRB-20-336	07/14/2021	Smith, Betty	Serum Metal Ion Concentration after Insertion of Pediatric Flexible Nail Serum Metal Ion Concentration after Insertion of Pediatric Flexible Nail

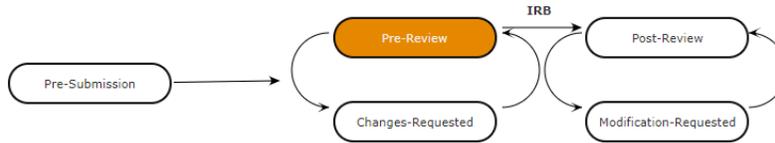
Sub. Rounds – Click this button to see the number of times this particular form has been sent back and forth for corrections.

Track Location - If a form has been submitted, this column will populate with the current status of the form. You can click on the text to view detailed information about the steps the form has taken since it was submitted.



Any steps that are still in process will be displayed and highlighted in a particular color. In this example, the form is located in the orange step. Details are displayed at the bottom of the Workflow detail diagram.

My Workspaces IRB Number: **IRB-21-476** PI: Investigator, John Study Assistant **Workflow - Submission Tracking** Back Print Friendly



Task Status	Task Action/Details	Task Name	Date Created	Date Completed	Total Time
<div style="display: flex; justify-content: space-between; align-items: center;"> Pre-Submission Retract Submission </div>					
Completed		Study Amendment Form is waiting to be submitted	06/25/2021 10:56 AM PDT	06/25/2021 10:57 AM PDT	0 Day(s) 0 Hour(s) 0 Minute(s)
Completed	View Signoff Routing List	Assign Department Personnel for Signoff	06/25/2021 10:56 AM PDT	06/25/2021 10:57 AM PDT	Day Hour Minute 0 0 0
Completed	View Signoff	John Investigator as Principal Investigator review and apply signoff, assigned by John Investigator	06/25/2021 10:56 AM PDT	06/25/2021 10:57 AM PDT	Day Hour Minute 0 0 0
Warning: Error Occurred	View Details	The following Study Personnel are not registered with up to date training records:	06/25/2021 10:57 AM PDT	06/25/2021 10:57 AM PDT	Day Hour Minute 0 0 0
<div style="display: flex; justify-content: space-between; align-items: center;"> IRB <div style="display: flex; gap: 10px;"> Submission Components Review Process: Not Assigned Review Outcome Outcome Letters </div> View Details </div>					
Received		IRB received the submission	06/25/2021 10:57 AM PDT		Day Hour Minute 0 0 6
Received		Jane Coordinator has been assigned as the analyst	06/25/2021 10:57 AM PDT		Day Hour Minute 0 0 6

The date that the process was received is displayed in the **Date Created** column.

Task Status	Task Action/Details	Task Name	Date Created	Date Completed	Total Time
<div style="display: flex; justify-content: space-between; align-items: center;"> Pre-Submission Retract Submission </div>					
Completed		Study Amendment Form is waiting to be submitted	06/25/2021 10:56 AM PDT	06/25/2021 10:56 AM PDT	Day Hour Minute 0 0 0
Completed	View Signoff Routing List	Assign Department Personnel for Signoff	06/25/2021 10:56 AM PDT	06/25/2021 10:57 AM PDT	Day Hour Minute 0 0 0
Completed	View Signoff	John Investigator as Principal Investigator review and apply signoff, assigned by John Investigator	06/25/2021 10:56 AM PDT	06/25/2021 10:57 AM PDT	Day Hour Minute 0 0 0
Warning: Error Occurred	View Details	The following Study Personnel are not registered with up to date training records:	06/25/2021 10:57 AM PDT	06/25/2021 10:57 AM PDT	Day Hour Minute 0 0 0

If details of a step can be viewed, an icon will be displayed under the **Task Action/Details** column. Select the icon to view the event details. The example used here is the routing signoff.

My Workspaces ▾ Study Assistant **Submission Routing Signoff** Back

Study Title: Malaria in Juveniles
 Submission Reference Number: IRB-21-476-AMD-1.0 Create PDF Packet

Submission Form(s):

Include in PDF Packet	Compare to Last Approved	View in Separate Window	Submission Component Name
<input checked="" type="checkbox"/>			
Submission Form(s)			
<input type="checkbox"/>		<input checked="" type="checkbox"/>	Study Amendment Form

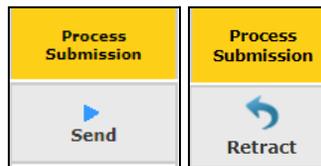
John Investigator as Principal Investigator
 Do you Approve or Deny this submission? Approve Deny Comments:

This form requires your electronic signature. Please enter your User ID & Password: ELECTRONIC SIGNATURE HAS BEEN APPLIED
 by John Investigator at 06/25/2021 10:57 AM PDT

The user can also view Submission Components, Review Process, Review Outcome, and Outcome letters from the review board once these steps are complete on the review board side.

IRB		Submission Components	Review Process	Review Outcome	Outcome Letters	06/25/2021 10:57 AM PDT	0 Day(s) 0 Hour(s) 6 Minute(s)
		View Details	Not Assigned				
Received		IRB received the submission				06/25/2021 10:57 AM PDT	Day Hour Minutes 0 0 6
Received		Jane Coordinator has been assigned as the analyst				06/25/2021 10:57 AM PDT	Day Hour Minutes 0 0 6

Process Submission – This column will populate with one of two buttons or will be empty depending on the status of the submission.



If the form has been filled out but not yet submitted into the workflow, a **Send** button will populate in the column, allowing you to send the form without opening it. If the form has been submitted into the workflow but has not been processed by the review board, a **Retract** button will populate in the column, allowing you to pull the form back to make any corrections. Otherwise this column will be blank.

Submission Date – Will display the date the form was submitted into the workflow.

Created By – Will display the name of the user who created the form record.

Date Created – Will display the date and time the form record was created.

Modified By – Will display the name of the user who last modified the form record.

Date Modified - Will display the date and time the form record was last modified.

Note: **Created By, Date Created, Modified By and Date Modified** can all be turned off in the System Form Designer. Other columns from the form can be turned on in their place. See the Form Designer manual for more details on displaying columns in the form table.

Form Creation Restriction Property

A new property has been added that restricts users from creating a submission form with an application data value when there is an existing submission form that is completed and has not exited the workflow. Contact your System Administrator for more information.

When this property is set to “No”, iRIS™ will function as before. When this property is set to “Yes”, the new restrictions will be implemented into the system.

When there is a submission form that has been started with the data value to attach a study application, users will not be able to start another submission until the first form has completed the workflow and has been fully processed.

The screenshot shows the 'Study Amendment Form - (Version 2.0)' interface. The left sidebar lists sections: 1.0 Study Information, 2.0 General Information, 3.0 Description, and 4.0 Revised Materials (selected). The main content area is titled '4.0 Revised Materials' and contains a section '4.1 * Revised material includes:'. Under this section, there is a checked checkbox for 'Application' and a note: 'NOTE: ALL applications submitted to the Review Board must be the newest version available. If you are given the option to convert your application to a newer version, you must do so before completing your submission.' Below the note is a table with columns: Deattach, Revise/Attach, Edit/View, and Title. The table contains one row: 'IRB Application (Version 1.1)'. Below the table are checkboxes for 'Protocol' and 'Other Study Documents'. Navigation buttons at the top include 'Print Friendly', 'Refresh Constant Fields', 'Save Section', and 'Save and Continue to Next Section'. A 'Back' button is in the top right.

Note: Users will not be able to start another submission even if there is no study application attached to the submission form. As long as the data vale exists in the form, uses will not be able to start a new submission form.

In the Study Management section on the study side, when users open the details of the form, in this case the Initial Submission Review Form, and the property is set to “Yes”, the option to **Add a New Application Type** or **Delete Selected Version** will not be available.

The screenshot shows the 'Study Application' details page. The top header includes 'My Workspaces', 'IRB Number: IRB-21-476', 'PI: Investigator, John', 'Study Assistant', and 'Study Application' with a 'Back' button. Below the header is a summary box with 'Study Status: Active', 'IRB Number: IRB-21-476', 'Study Title: Malaria in Juveniles', and 'IRB Expiration Date: 06/24/2022'. A 'Compare Two Selected Versions' button is on the right. Below the summary is a table with 1 result(s) found. The table has columns: Show Rev., Edit/View, Application Type, Approved?, Approval Date, Created By, Date Created, Last Modified By, Last Date Modified, and Create a Revised Application. The table contains one row: 'IRB Application (Version 1.1)' with 'No' in the 'Approved?' column and 'John Investigator' in the 'Created By' column.

When the property is set to “No”, the user will have the buttons to **Add a New Application Type** or **Delete Selected Version** will become available.

If the user tries to create a new submission form within the Study Workspace and there is an incomplete form with the Application Data Value present, the restriction will keep the user from starting another form with the application data value.

Submission Form List			
Study Status: Active	IRB Number: IRB-21-476	Study Title: Malaria in Juveniles	X
Regulatory Forms			
Regulatory Submission Forms	Version List	Start a new Submission	Edit Incomplete Submissions
Continuing Review Submission Form		Submission Types with Applications cannot be in progress concurrently	
Study Amendment Form		Submission Types with Applications cannot be in progress concurrently	
Study Closure Form			
Unanticipated Events Form			
Yearly Check-in Form			

Cancel

Users will receive a message stating that another form cannot be created until the form referenced has completed the workflow process.

My Workspaces IRB Number: **IRB-21-476** PI: Investigator, John Study Assistant **Study Amendment Form** Back

Study Status: **Active** IRB Number: IRB-21-476 Study Title: Malaria in Juveniles

IRB Expiration Date: 06/24/2022

[Compare Two Versions](#) [Delete Selected Form\(s\)](#)

List of records associated with form: Study Amendment Form.
To view previous versions click on the folder icon .

Unable to add a New Form until the following form(s) have completed board processing: Study Amendment Form (1.0)

2 result(s) found...

	Show Rev	Edit/View	Details	Apply to Multiple	Sub. Rounds	Track Location	Process Submission	Submission Date	Update Date	Update Number	UPDATE TYPE	Created By	Date Created
<input type="checkbox"/>									06/28/2021	2	1211112	John Investigator	06/25/2021 10:58:35 AM
<input type="checkbox"/>						In Process	Retract	06/25/2021 10:57:05 AM PDT	06/25/2021	1	1111112	John Investigator	06/25/2021 10:54:35 AM

Add a New Form

To start a new form, click the **Add New Form** button.

My Workspaces IRB Number: **IRB-21-476** PI: Investigator, John Study Assistant **Study Amendment Form** Back

Study Status: **Active** IRB Number: IRB-21-476 Study Title: Malaria in Juveniles

IRB Expiration Date: 06/24/2022

[Copy Form](#) [Add a New Form](#) [Compare Two Versions](#) [Delete Selected Form\(s\)](#)

List of records associated with form: Study Amendment Form.
To view previous versions click on the folder icon .

2 result(s) found...

	Show Rev	Edit/View	Details	Apply to Multiple	Sub. Rounds	Track Location	Process Submission	Submission Date	Update Date	Update Number	UPDATE TYPE	Created By	Date Create
<input type="checkbox"/>								06/25/2021 02:06:23 PM PDT	06/25/2021	3	1111112	John Investigator	06/25/2021 12:23:1
<input type="checkbox"/>								06/25/2021 12:07:58 PM PDT	06/25/2021	1	1111112	John Investigator	06/25/2021 12:06:0

The form will open in a new window. You can fill out the form, using the **Save and Continue** button at the top right of the page to navigate through the sections.

My Workspaces ▾ IRB Number: **IRB-21-476** Study Assistant **Study Amendment Form - (Version 2.0)** Back

PI: Investigator, John

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 **Study Information**
- 2.0 General Information
- 3.0 Description
- 4.0 Revised Materials

1.0 Study Modification Form

1.1 Study Number:
IRB-21-476

1.2 Sponsor:
3-M Pharmaceuticals(Pharmaceuticals)

1.3 Study Title:
Malaria in Juveniles

1.4 Principal Investigator:
John Investigator

1.5 Study Contact:
Betty Smith

When you are finished with the form, you will be presented with a section that will allow you to exit the form or signoff and submit, as seen in the image below. See details in the Add a Study manual for information on submitting a form.

My Workspaces ▾ Study Assistant **Submission Routing Signoff** Back

Save Signoff

Study Title: Malaria in Juveniles
Submission Reference Number: IRB-21-476-AMD-1.0 Create PDF Packet

Submission Form(s):	Include in PDF Packet	Compare to Last Approved	View in Separate Window	Submission Component Name
	<input checked="" type="checkbox"/>			
	<input type="checkbox"/>		<input checked="" type="checkbox"/>	Study Amendment Form

John Investigator as Principal Investigator
Do you Approve or Deny this submission? Approve Deny Comments: Click here to add comments.

This form requires your electronic signature.
Please enter your User ID & Password: User ID: Password:

Save Signoff

Submissions History

Submissions History contains every submission form sent for your study, so at any time you can view past submissions and track their progress.

This page is split up into three tabs:

My Workspaces IRB Number: **IRB-21-476** IRB Submissions Back

Study Status: **Active** IRB Number : IRB-21-476 Study Title : Malaria in Juveniles

IRB Expiration Date: 06/24/2022

Submissions | Study Management

Protocol Items

- Study Application
- Informed Consents ▶
- Other Study Documents ▶
- Contract Documents

● **Submissions History**

● Study Correspondence

Track Location	Ref Number	Request Type	Process Submission
There are no outstanding submissions.			

Submissions in Process- This tab displays all of the submissions in process, i.e., any form that has been submitted and has not been completed by the review board or returned for corrections. From this tab you can view the reference number, track the location of the submission, check the status, request the type, and view the details, review board, outcome letters, review process, meeting date, review outcome, and the date received.

My Workspaces IRB Number: **IRB-21-476** Study Assistant Submissions Back

Study Status: **Active** IRB Number : IRB-21-476 Study Title : Malaria in Juveniles

IRB Expiration Date: 06/24/2022

Submissions in Process | Completed Submissions | Submissions Returned with Changes Print Friendly

Reference Number	Track Location	Status	Request Type	Details	Review Board	View Outcome Letters	Review Process	Meeting Date	Review Outcome	Date Received
IRB-21-476-AMD-1.0			Study Amendment Form		IRB					06/25/2021 11:22:21 AM PDT

Completed Submissions- This tab displays all of the completed submissions, i.e., any form that the review board has completed processing. From here you can view the reference number, track the location of the submission, check the status, request the type, and view the details, review board, outcome letters, review process, meeting date, review outcome, and date received.

My Workspaces IRB Number: **IRB-21-476** Study Assistant Submissions Back

Study Status: **Active** IRB Number : IRB-21-476 Study Title : Malaria in Juveniles

IRB Expiration Date: 06/24/2022

Submissions in Process | **Completed Submissions** | Submissions Returned with Changes Print Friendly

Reference Number	Track Location	Status	Request Type	Details	Review Board	View Outcome Letters	Review Process	Meeting Date	Review Outcome	Date Received
IRB-21-476-NEW-1.0			Initial Review Submission Form		IRB		Process Administratively		Approved	06/25/2021 08:04:59 AM PDT

Submissions Returned with Changes – This tab lists the submissions that have been returned for corrections from the review board.

My Workspaces IRB Number: **IRB-21-476** Study Assistant **Submissions** Back

PI: Investigator, John

Study Status: **Active** IRB Number: IRB-21-476 Study Title: Malaria in Juveniles

IRB Expiration Date: 06/24/2022

Submissions in Process | Completed Submissions | **Submissions Returned with Changes**

Submissions Returned With Changes

Reference Number	Details	Track Location	Request Type	Review Board	View Outcome Letters	Review Process	Meeting Date	Review Outcome	Date Received
No Submissions are currently returned with changes requested									

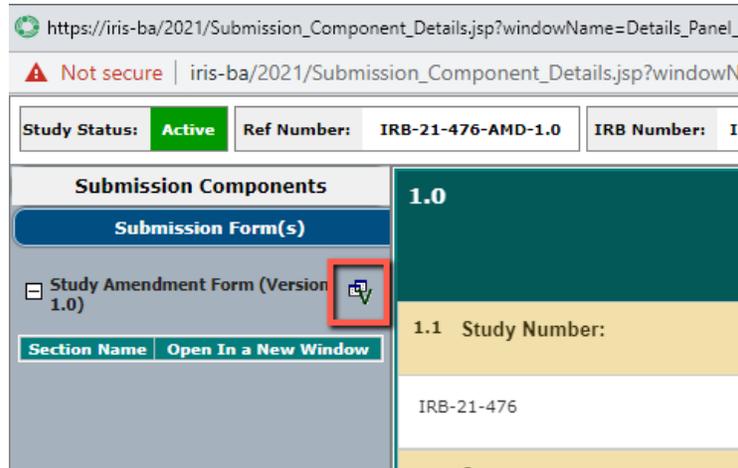
Within all three tabs, you can click to view more information in the Track Location, Request Type, and Details columns. These are described as follows:

Track Location- Click on the icon to view a step-by-step listing of the submission process (the Workflow – Submission Tracking page).

Request Type- Click on the link in this column to view the submission form.

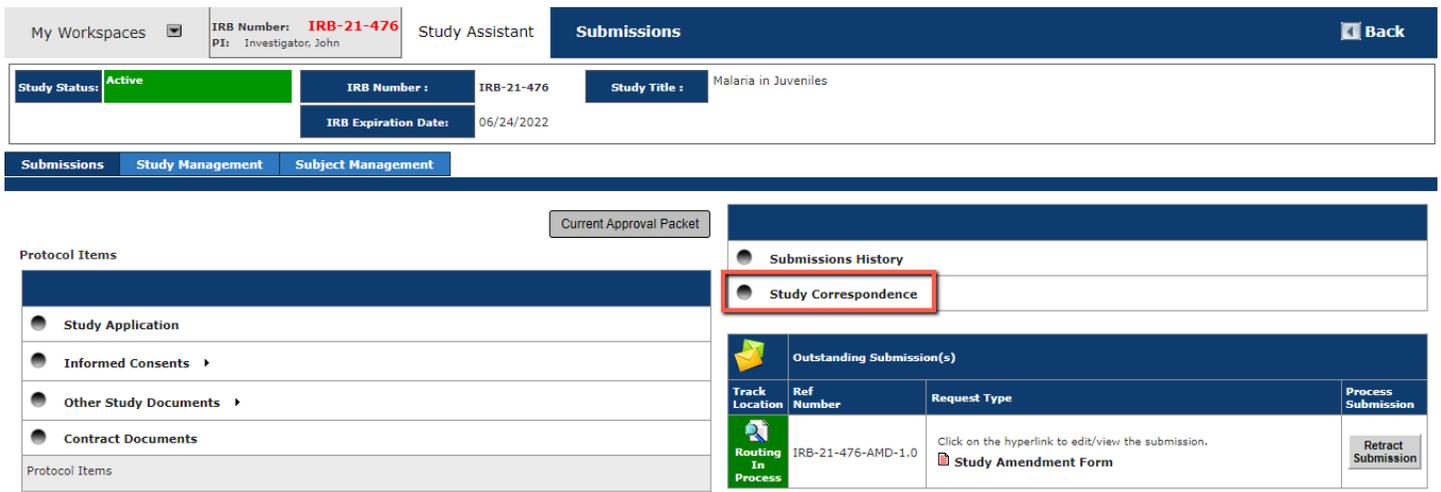
Details – Click the icon to view the forms and attachments associated with the submission. This will open the Submission Details Panel in a new window. Click on the **Submission Form(s)** button to view the submission’s contents as shown below.

From this screen, you can open any of the components of the submission by clicking on the icon as shown below. This will open the component in a new window.



Study Correspondence

This section, located on the main Submission screen, is used for any study related correspondence.



Clicking this link will open a page containing a list of any study-related correspondence that has been sent out at any point during the life of the study. The system will send out automatic notifications at certain points – “Principal Investigator signoff” notifications, “Review Response requested by the review board” notifications, “Submission signoff denied” notifications, “Continuing Review Due” notifications, etc. Whenever a study-related notification is generated and sent, a record of that notification will post to the Study Correspondence table.

My Workspaces ▾ IRB Number: **IRB-21-476** Study Assistant **Study Correspondence** Back

PI: Investigator, John

Study Status: **Active** IRB Number: IRB-21-476 Study Title: Malaria in Juveniles

IRB Expiration Date: 06/24/2022

[Print Friendly](#) [Add A New Correspondence](#) [Delete Selected Correspondence](#)

6 result(s) found...

<input type="checkbox"/>	View Message	Author	Subject
<input type="checkbox"/>		Post a Reply to this Topic / Forward this Topic	
<input type="checkbox"/>		John Smith	Posted: 06/25/2021 08:09 AM PDT Malaria in Juveniles NOTICE OF PREREVIEW ADMINISTRATIVE ASSIGNMENT
<input type="checkbox"/>		Post a Reply to this Topic / Forward this Topic	
<input type="checkbox"/>		John Investigator	Posted: 06/25/2021 08:09 AM PDT Malaria in Juveniles Study Notification for Signoff Removal
<input type="checkbox"/>		Post a Reply to this Topic / Forward this Topic	
<input type="checkbox"/>		John Smith	Posted: 06/25/2021 03:34 AM PDT Malaria in Juveniles Study Notification Reminder for Review and Signoff
<input type="checkbox"/>		Post a Reply to this Topic / Forward this Topic	
<input type="checkbox"/>		John Investigator	Posted: 06/24/2021 03:39 PM PDT Malaria in Juveniles iRIS System Notification: Approval required for IRB# IRB-21-476

This page also contains a list of any correspondence generated by users. If the review board generates correspondence and sends it to a user listed on the study, or if a person on the study team generates and sends correspondence to the review board, an outside recipient, or another study member, a record will post here.

The review board and the study share the Study Correspondence, meaning any correspondence generated is visible by both sides.

Note: If the study generates and sends a correspondence that does not include a recipient listed on the review board, that correspondence record will not be visible to the review board.

Add a New Correspondence

You can create and send correspondence as needed from this main Study Correspondence screen. To generate correspondence, click on the **Add a New Correspondence** button as shown below.

My Workspaces IRB Number: **IRB-21-476** Study Assistant Study Correspondence

PI: Investigator, John

Study Status: **Active** IRB Number: IRB-21-476 Study Title: Malaria in Juveniles

IRB Expiration Date: 06/24/2022

6 result(s) found...

<input type="checkbox"/>	View Message	Author	Subject
<input type="checkbox"/>		Post a Reply to this Topic / Forward this Topic	
<input type="checkbox"/>		John Smith	Posted: 06/25/2021 08:09 AM PDT Malaria in Juveniles NOTICE OF PREREVIEW ADMINISTRATIVE ASSIGNMENT
<input type="checkbox"/>		Post a Reply to this Topic / Forward this Topic	
<input type="checkbox"/>		John Investigator	Posted: 06/25/2021 08:09 AM PDT Malaria in Juveniles Study Notification for Signoff Removal
<input type="checkbox"/>		Post a Reply to this Topic / Forward this Topic	
<input type="checkbox"/>		John Smith	Posted: 06/25/2021 03:34 AM PDT Malaria in Juveniles Study Notification Reminder for Review and Signoff

A new page will open, containing a text editor and tools that you can use to generate your correspondence, as seen in the image below. (Note: * = required field)

My Workspaces IRB Number: **IRB-21-476** Study Assistant Study Correspondence

PI: Investigator, John

Study Status: **Active** IRB Number: IRB-21-476 Study Title: Malaria in Juveniles

IRB Expiration Date: 06/24/2022

Send Email

*Subject:

*Recipient(s):

Additional Recipient(s):

Reply To(s):

Additional Reply To(s):

Attachments

No Attachments have been added to this message

Total size of attachment(s) allowed: 50 MB

*Content

The process for creating a new correspondence from the above page is as follows:

1. Select the **Send Email** checkbox if you want an **Email** notification sent to the recipient(s). This checkbox is selected by default. If you do not want the correspondence to send as an email, make sure the checkbox is not selected.

2. Enter a **Subject** for the correspondence.
3. Assign **Recipients** to the correspondence. Clicking the Recipient(s) link will open a screen where you can select users from a list of Study Personnel.

My Workspaces		Study Assistant	Correspondence contact	Back
Save Changes				
Contacts	Role			
Study Personnel				
<input type="checkbox"/>	Principal Investigator	<input type="checkbox"/>	Investigator, John	
<input type="checkbox"/>	Additional Principal Investigator	<input type="checkbox"/>	Coordinator, Sean	
<input type="checkbox"/>	Co-Investigator	<input type="checkbox"/>	Jefferson, Tom	
<input type="checkbox"/>	Nurse	<input type="checkbox"/>	Jefferson, George	
<input type="checkbox"/>		<input type="checkbox"/>	Mossman, Nathan	
<input type="checkbox"/>	Study Author	<input type="checkbox"/>	Investigator, John	
<input type="checkbox"/>	Contact	<input type="checkbox"/>	Smith, Betty	
<input type="checkbox"/>	Department Administrator	<input type="checkbox"/>	Sykes, Jeff	
IRB Adverse Event				
<input type="checkbox"/>	Coordinator	<input type="checkbox"/>	Coordinator, OSF	
<input type="checkbox"/>		<input type="checkbox"/>	Ramirez, Yvette	
<input type="checkbox"/>		<input type="checkbox"/>	Smith, John	
<input type="checkbox"/>		<input type="checkbox"/>	Stewart, Andrew	
IRB Committee 1				
<input type="checkbox"/>	Coordinator	<input type="checkbox"/>	Analyst, John	
<input type="checkbox"/>		<input type="checkbox"/>	Carmichael, Bob	
<input type="checkbox"/>		<input type="checkbox"/>	Coordinator, Jane	
<input type="checkbox"/>		<input type="checkbox"/>	Coordinator, Jillian	
<input type="checkbox"/>		<input type="checkbox"/>	Coordinator, OSF	
<input type="checkbox"/>		<input type="checkbox"/>	Ramirez, Yvette	
<input type="checkbox"/>		<input type="checkbox"/>	Smith, John	

4. Add any **Additional Recipients** to which you would like a copy of the correspondence sent.

My Workspaces		Study Assistant	Correspondence Additional Contacts	Back
Add A New Contact Save And Return				
<input type="checkbox"/>	Name	E-mail Address		
No Additional Recipients have been added.				

Clicking the **Add A New Contact** on the main Study Correspondence screen will open a window where you can add the names and email addresses of the additional recipients.

My Workspaces		Study Assistant	Correspondence Additional Contacts	Back
Add A New Contact Remove Selected Contacts Save And Return				
<input type="checkbox"/>	Name	E-mail Address		
<input type="checkbox"/>	Jeff Carlisle	jcarisle@3m.com		

To add recipients to the list, click **Add A New Contact**. This will bring up the Name and E-mail Address fields, where you can enter the recipient’s contact information. If you need to remove a contact, check the box next to their name and click **Remove Selected Contacts**. When you are finished adding additional contacts, click **Save and Return** to return to the main Study Correspondence window.

5. Add **Reply To(s)** if necessary. This means that any user added here will receive a reply, if the original recipient replies to the email from their email inbox.
6. Add **Additional Reply To(s)** if necessary. This works the same as the **Reply To(s)**.
7. Add any **Attachments** you would like to include with the correspondence. Click **Add Attachment** to open a screen where you can upload a file to attach to your message.

Enter a Title and use the dotted box upload tool to locate the file on your computer. When you are finished adding the attachment, click **Save And Return**.

Once an attachment has been added, it will appear on the Study Correspondence screen. You can check the checkbox next to the attachment and click **Delete Attachment(s)** to remove it or click **Add Attachment** again to add additional attachments.

The total size of all attached files will also display here, and the maximum allowed by the system, which is configured in System Administration.

8. Enter the **Content** in the text editor.

Once you have completed the correspondence, click the **Save and Send Correspondence** button. If the **Send Email** checkbox is selected, an email will send to the recipients and will also be posted as “Un-opened Correspondence” on

their homepage. If **Send Email** is not selected, the recipients will only receive the correspondence in their “Un-opened Correspondence”. A record of the correspondence will post on their Study Correspondence page as well.

Saving a Draft Correspondence

If you have not completed your correspondence but would like to save it as a draft, click on the **Save Draft Correspondence** button. The correspondence content will be saved and will display as shown below.

	View Message	Author	Subject
<input type="checkbox"/>		Post a Reply to this Topic / Forward this Topic	
<input type="checkbox"/>		John Investigator	Saved as Draft: 06/25/2021 11:35 AM PDT Malaria in Juveniles Question on Study Title
		John Investigator	Posted: Delivery in Progress Malaria in Juveniles Question on Study Title

You can return to this page at any time to complete the draft and send the correspondence.

Viewing a Correspondence

Any correspondence added to the study will post on the screen. You can view the original correspondence by clicking on the icon in the **View Message** column.

<input type="checkbox"/>		Post a Reply to this Topic / Forward this Topic	
		John Investigator	Posted: 06/25/2021 11:33 AM PDT Malaria in Juveniles Question on Study Title

This will open a read-only copy of the correspondence. As it has been sent as an email, you are not able to modify it.

Study Status: Active	IRB Number : IRB-21-476	Study Title : Malaria in Juveniles
	IRB Expiration Date: 06/24/2022	

<p>Posted: 06/25/2021 11:33 AM PDT</p> <p><input checked="" type="checkbox"/> Send Email</p> <p>*Subject Question on Study Title</p> <p>* Recipient(s): John Investigator</p> <p>Additional Recipients(s): Jeff Carlisle</p> <p>Reply To(s):</p> <p>Additional Reply To(s):</p> <p>Attachments</p> <p> Sample Document.docx <i>Click Attachment Name to View</i></p> <p>Total size of attachment(s): 12.70 KB Total size of attachment(s) allowed: 50 MB</p>	<p>*Content</p> <p>Sent From: John Investigator Send To: John Investigator, Jeff Carlisle IRB Number: IRB-21-476 IRB Expiration: 06/24/2022 Study Alias: Malaria in Juveniles Title: Malaria in Juveniles Project Status: Active Principal Investigator: Investigator, John Message Content: Can you take a look at your title and the document attached? They Need to match.</p>
--	--

Replying To/Forwarding a Correspondence

You can reply to the original correspondence, or forward it to other recipients by clicking the text **Post a Reply to this Topic** or **Forward this Topic**.

<input type="checkbox"/>		Post a Reply to this Topic / Forward this Topic
	John Investigator	Posted: 06/25/2021 11:33 AM PDT Malaria in Juveniles Question on Study Title

Posting a reply will open a page similar to that when generating correspondence. The original message will populate in the **Content** area. You can add your reply then click the **Save & Send Correspondence** button.

My Workspaces ▾ IRB Number: **IRB-21-476** Study Assistant **Study Correspondence** Back

PI: Investigator, John

Study Status: Active **IRB Number :** IRB-21-476 **Study Title :** Malaria in Juveniles

IRB Expiration Date: 06/24/2022

Save Draft Correspondence Save & Send Correspondence

***Send Email**

***Subject**
Question on Study Title

***Recipient(s):**
Jeff Carlisle

Additional Recipient(s):
Jeff Carlisle

Reply To(s):

Additional Reply To(s):

Attachments

No Attachments have been added to this message

***Content**

Font Family 12

>>John Investigator wrote:
 Sent From: John Investigator
 Send To: John Investigator, Jeff Carlisle
 IRB Number: IRB-21-476
 IRB Expiration: 06/24/2022
 Study Alias: Malaria in Juveniles
 Title: Malaria in Juveniles
 Project Status: Active

Any replies will post in the Study Correspondence below the original.

<input type="checkbox"/>		Post a Reply to this Topic / Forward this Topic
	John Investigator	Posted: 06/25/2021 11:37 AM PDT Malaria in Juveniles Question on Study Title
	John Investigator	Posted: 06/25/2021 11:33 AM PDT Malaria in Juveniles Question on Study Title

Note that each correspondence generated is a record in the system. Any replies to correspondence are counted with the original correspondence and are not recognized as a separate record.

Forwarding correspondence is similar to replying. A new page will open, allowing you to add to the **Content** and select **Recipient(s)**. Just as replies, the system does not consider forwarded correspondence as new records.

Outstanding Submissions

Any submission form created for the study will at some time populate in the **Outstanding Submission(s)** table. Submissions are listed here if the form has been completed, but not yet sent. The submission will also populate if the

form has been sent but is still being routed to the review board (for example, if not all required signoffs have been collected).

My Workspaces IRB Number: **IRB-21-476** Study Assistant **Submissions** Back

PI: Investigator, John

Study Status: **Active** IRB Number: IRB-21-476 Study Title: Malaria in Juveniles

IRB Expiration Date: 06/24/2022

Submissions Study Management Subject Management

Current Approval Packet

Protocol Items

- Study Application
- Informed Consents
- Other Study Documents
- Contract Documents
- Reportable Event Form

Submissions History

Study Correspondence

Outstanding Submission(s)			
Track Location	Ref Number	Request Type	Process Submission
	IRB-21-476-AMD-1.0	Click on the hyperlink to edit/view the submission. Study Amendment Form	Retract Submission

Once the review board receives the submission and begins processing the form, the link in **Outstanding Submission(s)** will be removed. At this point, if you need to find information related to your form, you will need to go to **Submissions History** to find it. Any submission that is returned by the review board for corrections will also post to **Outstanding Submission(s)**. This allows the user to access the correction form, make necessary changes, and re-submit the form to the board.

At any time during the sign off process, or before the review board begins processing your submission, you can check on the status of the form and where it currently is located. If the form has been submitted, an icon will display in the **Track Location** column. You can click on this icon to open the Workflow – Submission Tracking page.

My Workspaces IRB Number: **IRB-21-476** Study Assistant **Workflow - Submission Tracking** Back

PI: Investigator, John

Print Friendly

```

    graph LR
      Pre-Submission --> Pre-Review
      Pre-Review --> Post-Review
      Pre-Review --> Changes-Requested
      Changes-Requested --> Pre-Review
      Post-Review --> Modification-Requested
      Modification-Requested --> Pre-Review
  
```

Task Status	Task Action/Details	Task Name	Date Created	Date Completed	Total Time
Pre-Submission	Retract Submission		06/25/2021 10:56 AM PDT	06/25/2021 11:22 AM PDT	0 Day(s) 0 Hour(s) 25 Minute(s)
IRB	View Details	Submission Components Review Process Review Outcome Outcome Letters	06/25/2021 11:22 AM PDT		0 Day(s) 0 Hour(s) 16 Minute(s)

The workflow will update as the submission moves forward in its processing. The screenshot above shows that the submission successfully passed required signoffs and is currently sitting in the IRB queue.

If users you have assigned have not completed their signatures, the Workflow would show that they are still in process. The Principal Investigator and the Study Contact would receive notifications from the system that a certain user has not completed signoff yet.

Outstanding Submission(s)			
Track Location	Ref Number	Request Type	Process Submission
	IRB-21-476-AMD-1.0	Click on the hyperlink to edit/view the submission.  Study Amendment Form	<input type="button" value="Retract Submission"/>

In the **Request Type** column, you can click on the link to open the form. If the form has not yet been submitted, you can make changes to the form; otherwise, the form will be read only.

The **Process Submission** column will contain buttons depending on the status of the submission. If the form has not been submitted, there will be a **Send Submission** button. If the form has been submitted, but has not been processed by the review board, you will be able to **Retract Submission**. This is helpful if a situation arises where you need to pull the form back to make revisions. If you retract the submission, you will be able to modify the form and its components, but you must also obtain the required signoffs again to submit it back to the review board.

Submitting a Continuing Review

When a study is up for Continuing Review, the system will begin to send notifications to the Principal Investigator and Study Contact. These notifications are configured under *Review Board Administration > Review Board Notification Setup > Continuing Review Notification Setup*.

Notifications can be setup for the Continuing Review depending on your system. Typically, notifications are sent 90, 60, and 30 days before the IRB Expiration Date.

Continuing Review Due Task

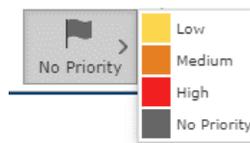
The Continuing Review Due task appears on your homepage. Any users noted as the Study Contact will receive a notification a certain number of days before the review due date, as specified in the notification setup.

This task will remain on the homepage until a Continuing Review form is submitted to the review board.

You can access the study that is up for Continuing Review by locating it in My Studies, or you can open the task from your homepage to link directly to the Continuing Review form.

All Tasks						
Outstanding		Completed				
All Tasks		Study Tasks		Task List : All		
				Filter By : --none--		
21 result(s) found...						1 - 5 ▶
Click to open	Task Type	Date Received	Description	Priority	Complete By	
<input type="checkbox"/>	Conflict of Interest Study Disclosure Questionnaire	07/19/2021 09:39 AM PDT	Notice to complete conflict of interest study disclosure questionnaire assigned to John Investigator	No Priority	⊗ [] []	
<input type="checkbox"/>	Conflict of Interest Study Disclosure Questionnaire	07/19/2021 08:10 AM PDT	Notice to complete conflict of interest study disclosure questionnaire assigned to John Investigator	No Priority	⊗ [] []	
<input type="checkbox"/>	Conflict of Interest Study Disclosure Questionnaire	07/19/2021 08:08 AM PDT	Notice to complete conflict of interest study disclosure questionnaire assigned to John Investigator	No Priority	⊗ [] []	
<input type="checkbox"/>	Continuing Review Due	07/16/2021 03:30 AM PDT	Pending Expiration Notice for 60 Day Continuing Review Notification with the expiration date of 09/14/2021	High	⊗ [] []	
<input type="checkbox"/>	Conflict of Interest Study Disclosure Questionnaire	07/12/2021 03:55 PM PDT	Notice to complete conflict of interest study disclosure questionnaire assigned to John Investigator	No Priority	⊗ 07/22/2021 []	

We have also added the ability to prioritize tasks as Low, Medium and High Priority. Users can click on the



Users can also set the **Complete By** date for a task. This will place an event on the system calendar that will link the user to the task.

Click the  icon to open the task. This will open the Continuing Review Form Selection screen, which will allow you to either select a form or go directly to the Study Management page for the study with the upcoming review due.

My Workspaces	IRB Number: IRB-19-135 PI: Investigator, John	Study Assistant	Continuing Review Form Selection	Back
Study Status: Open	IRB Number : IRB-19-135	Study Title : The Barrow 5-ALA Intraoperative Confocal Evaluation (BALANCE)trial		
	IRB Expiration Date: 07/09/2021			

[Continue](#)

No Action Required - Dismiss Task

Select a Form or go to the Study Management Page.

Continuing Review Submission Form

Go to the Study Management Page

Filling out the form

The form will navigate to a new page. You can fill out the form using the **Save and Continue** button at the top right of the page to navigate through the form sections.

My Workspaces	IRB Number: IRB-19-135 PI: Investigator, John	Study Assistant	Continuing Review Submission Form - (Version 1.0)	Back
---------------	---	-----------------	--	----------------------

[Print Friendly](#)
[Refresh Constant Fields](#)
[Save Section](#)
[Save and Continue to Next Section](#)
[Signoff and Submit](#)

Section view of the Form	Entire view of the Form
--------------------------	-------------------------

- 1.0 APPLICATION FOR CONTINUING REVIEW
- 2.0 Modifications
- 3.0 Deviations
- 4.0 Advertising / Recruitment
- 5.0 Attach any application revisions
- 6.0 Documents

1.0 APPLICATION FOR CONTINUING REVIEW	
1.1 PRINCIPAL INVESTIGATOR	
John Investigator	?
1.2 DATE	
06/25/2021	
1.3 Status of project	
<input checked="" type="checkbox"/> Continuing <input type="checkbox"/> Completed (Closure) <input type="checkbox"/> Terminated	

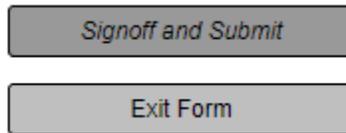
Once all sections are complete and the required documents are attached, the form is ready to send to the Review Board.

Submitting the Form

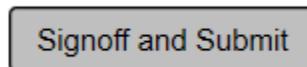
You will be presented with a section in the form notifying you that the form is complete. Depending on your role on the study and your system’s signoff requirements, you may see different buttons on this page.

The screenshot shows the top navigation bar with 'My Workspaces', 'IRB Numbers: IRB-19-135', 'PI: Investigator, John', 'Study Assistant', and 'Continuing Review Submission Form - (Version 1.0)'. There are 'Print Friendly' and 'Signoff and Submit' buttons in the top right. Below the navigation is a sidebar with sections: 1.0 APPLICATION FOR CONTINUING REVIEW, 2.0 Modifications, 3.0 Deviations, 4.0 Advertising / Recruitment, 5.0 Attach any application revisions, and 6.0 Documents. The main content area has a dark blue header with the text 'Form has been Completed!' and 'Grant Key Personnel access to the study'. At the bottom of the main area are two buttons: 'Signoff and Submit' and 'Exit Form'.

If you are not the Principal Investigator on this study and the form requires a PI signature, the buttons on this page will be **Exit Form** and **Notify PI to Signoff**.



If you are the Principal Investigator, or the form does not require a PI signoff, the **Notify PI to Signoff** button will be replaced with **Signoff and Submit**.



If your role on the study does not allow submission of forms, when you reach this page, you will only have the **Exit Form** button option. You will exit the form, and the Principal Investigator and Study Contact will be notified that a submission is waiting to be sent.



To initiate the signoff process, click the **Signoff and Submit** or **Notify PI to Signoff** button, depending on which is available to you. You may be prompted to route the form for additional signatures. You may choose this option if you

need to have other study personnel review the form before it reaches the review board or if you need department approval.

Make your selection and click the **Save and Continue** button, as seen in the image below.

Setup for Submission Routing and Signoff X

i This screen enables the collection of Key Personnel and Additional Personnel for Review and Signoff. The Check box "Checked" indicates the person is included in the signoff process. The Check box "Unchecked" indicates the person is not included in the signoff process. The Add Additional Personnel button is used to search from the user database and add them to the routing list. The order of the Additional Personnel is to create a review order for the assigned personnel. If personnel have 1. 2(sequential)

Select the Key Personnel for Submission Routing and Signoff:

Include in signoff	Approved	Name	Role
<input checked="" type="checkbox"/>	<input type="checkbox"/>	John Investigator	Principal Investigator

Select Additional Personnel for Submission Routing and Signoff: Add Additional Personnel to the Routing List

Include in signoff	Order	Approved	Name	Role
No additional personnel have been added to the signoff routing list.				

Cancel - Finalize later
Save - Signoff Routing List

If you opted to route for additional signatures, you will be brought to a page that will list Key Personnel that you can include in the signoff routing. If you chose not to route, you will immediately transition to a signoff page.

If the Principal Investigator signature is required on this form, that user will be pre-selected, and you will not be able to deselect the PI from the signoff process.

Select the check box next to the name(s) of any additional personnel you would like to include in the signoff process. Click the **Save and Continue** button when you are ready to proceed.

Select the Key Personnel for Submission Routing and Signoff:

Include in signoff	Approved	Name	Role
<input checked="" type="checkbox"/>		 John Investigator	Principal Investigator

The bottom table in the signoff process is for reviewers who need to approve the submission but are not listed as Key Personnel on the study.

Select Additional Personnel for Submission Routing and Signoff:

[Add Additional Personnel to the Routing List](#)

Include in signoff	Order	Approved	Name	Role
No additional personnel have been added to the signoff routing list.				

You can also add reviewers from iRIS™ by clicking the **Add Additional Personnel to the Routing List** button.

This will open a new page allowing you to search the database for a user. Use the **Last Name**, **First Name**, and **by Department** search filters to find the user you wish to add and then click the icon in the **Select User** column.

Add Additional Key personnel to the Routing Signoff List
X

Last Name: First Name:

by Department: All Departments ▼

Select	Name	Department	Email
No results found.			

The Additional Personnel will to be added to the signoff routing list upon clicking the "Save - Add to Routing List" button

Remove	Name	Role
No additional personnel have been added to the signoff routing list.		

The user you selected will be added to the list. Make sure you check the checkbox next to users you want to include in the signoff process. You can also set the **Order** in which the users will receive their signoff task. iRIS™ will default each user to the order of 1, which means they will all receive their task at the same time. Click the **Save and Continue** button to proceed.

Select Additional Personnel for Submission Routing and Signoff:

Include in signoff	Order	Approved	Name	Role
<input checked="" type="checkbox"/>	<input type="text" value="1"/>		Jeff Sykes	Department Chair ▼

The next page is a summary page, displaying all the users you selected for the signoff process. If you need to add any more signoffs, click the grey button to the left of the Key Study Personnel and Additional Personnel groups. This will open the corresponding page that will allow you to remove or add users to the signoff process.

When you are ready to initiate the signoffs, ensure you have selected “Yes” for the question **‘Please verify the list above represents the Finalize Personnel for review and signoff?’**, then click on the **Save – Start Signoff Routing** button. If you

are not ready to send signature tasks to the users, select **Go back to Make changes** before clicking **Save – Start Signoff Routing**. To cancel, click **Cancel – Finalize later**.

Setup for Submission Routing and Signoff
X

i This screen is for reviewing the signoff routing list. You must answer "Yes" or "No" to the finalization of the Personnel. Once the "Yes" selection is made the button "Save - Start Signoff Routing" becomes enabled to be clicked. Clicking the "Save - Start Signoff Routing" will start the routing list and then the submission board review(s). Clicking the "Go back to Make Changes" will place you back to editing the routing list. Clicking the "Cancel - Finalize later" will close this window. The submission process is incomplete, not eligible for submission, until the routing is complete.

Finalize List of Personnel for Submission Routing and Signoff:

Order	Approved	Name	Role
		John Investigator	Principal Investigator
1		Jeff Sykes	Department Chair

Please verify the list above represents the finalized Personnel for review and signoff? Yes No

Cancel - Finalize later
Go back to Make changes
Save - Start Signoff Routing

If you choose “Yes” and **Save – Start Signoff Routing** and you are assigned to sign off on the form, you will be brought to the Signoff Page. The button will turn gray when “Yes” is selected.

Please verify the list above represents the finalized Personnel for review and signoff? Yes No

Cancel - Finalize later
Go back to Make changes
Save - Start Signoff Routing

If you choose “Yes” and **Save and Continue** and you are NOT assigned to sign off on the form, you will be brought to the Workflow – Submission Tracking page and the users assigned to sign off will receive notifications from iRIS™ regarding their new assignments.

A user who is assigned to sign off on a submission form will receive a notification sent to the email address defined in their user account. They will also receive a *Submission Routing Signoff* task on their homepage. This task will remain on their homepage until the user opens the task and completes the sign off.

The screenshot shows the 'All Tasks' dashboard with tabs for 'Outstanding' and 'Completed'. A task list is displayed with 22 results found. The task 'Submission Routing Signoff' is highlighted. The task details are as follows:

Click to open	Task Type	Date Received	Description	Priority	Complete By
<input type="checkbox"/>	Submission Routing Signoff	07/20/2021 11:58 AM PDT	John Investigator as Principal Investigator review and apply signoff, assigned by John Investigator	No Priority	<input type="text"/>

When the task is opened, the Submission Routing Signoff Sheet will display. At the top of the page, the Study Title and Submission Reference Number will be listed. iRIS™ assigns a unique reference number to each form created in the system. The Reference Number displayed here is the number assigned to the submission form.

The screenshot shows the 'Submission Routing Signoff' form. At the top, it displays the Study Title: 'The Barrow 5-ALA Intraoperative Confocal Evaluation (BALANCE)trial' and the Submission Reference Number: 'IRB-19-135-CR-1.0'. Below this is a table of Submission Components:

Include in PDF Packet	Compare to Last Approved	View in Separate Window	Submission Component Name
<input checked="" type="checkbox"/>		<input type="checkbox"/>	
Submission Form(s)			
<input type="checkbox"/>		<input type="checkbox"/>	Continuing Review Submission Form
Document(s)			
Category : Application Documents			
<input type="checkbox"/>		<input type="checkbox"/>	F-033CVSample
<input type="checkbox"/>		<input type="checkbox"/>	Investigator Brochure

At the bottom, there is a section for the Principal Investigator: 'John Investigator as Principal Investigator'. It asks 'Do you Approve or Deny this submission?' with radio buttons for 'Approve' (selected) and 'Deny'. There is also a 'Comments' field with a 'Click here to add comments.' button. At the bottom right, there is a 'Save Signoff' button.

Also displayed on this page is the Submission Components table. This table contains a link to the Submission Form and if attached, the Study Application and any Consent and Other Study Document that has been associated to the form. These documents and forms comprise the packet that is being submitted to the review board for review.

My Workspaces ▾ Study Assistant **Submission Routing Signoff** Back

Save Signoff

Study Title: The Barrow 5-ALA Intraoperative Confocal Evaluation (BALANCE)trial
 Submission Reference Number: IRB-19-135-CR-1.0 Create PDF Packet

Include in PDF Packet	Compare to Last Approved	View in Separate Window	Submission Component Name
<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	Continuing Review Submission Form
Document(s)			
Category : Application Documents			
<input type="checkbox"/>		<input checked="" type="checkbox"/>	F-033CVSample
<input type="checkbox"/>		<input checked="" type="checkbox"/>	Investigator Brochure

John Investigator as Principal Investigator
 Do you Approve or Deny this submission? Approve Deny Comments: [Click here to add comments.](#)

This form requires your electronic signature.
 Please enter your User ID & Password: User ID:
 Password: Save Signoff

Below the Submission Components table, you will be able to enter your electronic signature. You must indicate whether you **Approve** or **Deny** the submission, enter your User ID and Password, and then click the **Save Signoff** button. Below the electronic signature portion of the page, you will be able to see any other Key Personnel listed for signoff. If any of the additional signoffs have completed their approval or denial of the form, that information will populate on this page.

John Investigator as Principal Investigator
 Do you Approve or Deny this submission? Approve Deny Comments: [Click here to add comments.](#)

This form requires your electronic signature.
 Please enter your User ID & Password: User ID:
 Password:

If you select **Approve**, iRIS™ will assign the next user in the list their user assignment task.

Task Status	Task Action/Details	Task Name	Date Created	Date Completed	Total Time
Pre-Submission		Retract Submission	06/25/2021 11:49 AM PDT		0 Day(s) 0 Hour(s) 7 Minute(s)
Completed		Continuing Review Submission Form is waiting to be submitted	06/25/2021 11:49 AM PDT	06/25/2021 11:50 AM PDT	Day Hour Minute 0 0 0
Received	Modify Signoff Routing List	Assign Department Personnel for Signoff	06/25/2021 11:50 AM PDT	06/25/2021 11:54 AM PDT	Day Hour Minutes 0 0 4
Completed	View Signoff	John Investigator as Principal Investigator review and apply signoff, assigned by John Investigator	06/25/2021 11:54 AM PDT	06/25/2021 11:56 AM PDT	Day Hour Minutes 0 0 6
Received	Pending Signoff	Jeff Sykes as Department Chair review and apply signoff, assigned by John Investigator	06/25/2021 11:56 AM PDT		Day Hour Minutes 0 0 6

If you select **Deny**, all other sign off tasks for that form will cancel, and the submission will be rejected.

If the signoff is denied, the Principal Investigator and Study Contact on the study will also receive a *Submission Signoff Denied* task. This will allow the PI to make any needed corrections and then re-submit the application.

The screenshot shows a task management interface with a dark blue header. The header contains 'All Tasks', 'Outstanding', and 'Completed' tabs. Below the header are three filter buttons: 'All Tasks', 'Study Tasks', and 'Project Tasks'. To the right, there are dropdown menus for 'Task List' (set to 'Submission Signoff Denied') and 'Filter By' (set to '--none--'). Below the filters, it says '10 result(s) found...' and '1 - 5'. The main content is a table with the following columns: 'Click to open', 'Task Type', 'Date Received', 'Description', 'Priority', and 'Complete By'. The table contains one row with the following data:

Click to open	Task Type	Date Received	Description	Priority	Complete By
<input type="checkbox"/>	Submission Signoff Denied	06/28/2021 08:42 AM PDT	Submission rejected	No Priority	<input type="text" value="07/14/2021"/>

Once all assigned users have completed their sign off tasks and they have indicated approval of the submission, the form will go to the review board’s submission queue for processing.

Responding to Corrections

The review board may return items to you for correction. When a submission is returned for corrections, the Principal Investigator and any Study Contacts listed on the study will receive a notification from iRIS™ alerting them of the request. They will also receive a task on the homepage called *Submission Correction*, or if a review board has met on your submission and returned it for corrections based on the review, the task will be called *Review Response*.

The screenshot below shows a *Submission Correction* task for Pre-Review Changes. This task will remain on your homepage until you respond to the corrections and re-submit the form to the review board. Click the icon in the **Open** column to open the Pre-Review Changes form.

All Tasks Outstanding Completed ⚙️

All Tasks Study Tasks Project Tasks Task List : All Filter By : --none--

11639 result(s) found... ◀ 6 - 10 ▶

	Click to open	Task Type	Date Received	Description	Priority	Complete By
<input type="checkbox"/>		Animal Schedule - Overdue Task	06/30/2021 04:06 AM PDT	Animal Schedule - Procedure: Maheen	High >	ⓧ <input type="text"/>
<input type="checkbox"/>		Conflict of Interest Study Disclosure Questionnaire	06/29/2021 12:07 PM PDT	Notice to complete conflict of interest study disclosure questionnaire assigned to Admin Admin admin, B.S. Brig. Gen.	High >	ⓧ <input type="text"/>
<input type="checkbox"/>		Submission Correction	06/28/2021 03:01 PM PDT	Dwight D. Eisenhower Army Medical Center (DDEAMC) Department of Clinical Investigation (DCI) returned the submission for corrections , assigned by Akshay Mandloi, M.S. BG	Medium >	ⓧ <input type="text"/>
<input type="checkbox"/>		Conflict of Interest Study Disclosure Questionnaire	06/28/2021 03:01 PM PDT	Notice to complete conflict of interest study disclosure questionnaire assigned to Admin Admin admin, B.S. Brig. Gen.	Low >	ⓧ <input type="text"/>
<input type="checkbox"/>		Submission Signoff Denied	06/28/2021 08:42 AM PDT	Submission rejected	No Priority >	ⓧ 07/14/2021

11639 result(s) found... ◀ 6 - 10 ▶

When you open the task a Pre-Review Correction or a Review Response form will open. This form works similar to other forms in the system, where you navigate through the form using the **Save and Continue** button.

Receiving Approval

When the review board approves your form, an Outcome Letter will be generated and sent to the study. If you have been listed as a recipient of this letter, a PDF copy will be emailed to you. A copy will also be accessible via the **Correspondence** button on your homepage.

The letter will be accessible to any study personnel with access to the Study Correspondence link within the Submissions tab.

Study Status: Active	IRB Number : IRB-21-476	Study Title : Malaria in Juveniles
	IRB Expiration Date: 06/24/2022	

Submissions Study Management

Current Approval Packet

Protocol Items

- Study Application
 - Informed Consents ▶
 - Other Study Documents ▶
 - Contract Documents
- Protocol Items
- Reportable Event Form

- Initial Review Submission Form

Regulatory Forms

- Regulatory Submission Forms
- Continuing Review Submission Form
 - Study Amendment Form
 - Study Closure Form
 - Unanticipated Events Form
 - Yearly Check-in Form

- Submissions History
- Study Correspondence

Outstanding Submission(s)			
Track Location	Ref Number	Request Type	Process Submission
There are no outstanding submissions.			

My Workspaces <input checked="" type="checkbox"/>	IRB Number: IRB-21-476 PI: Investigator, John	Study Assistant	Study Correspondence Back
Study Status: Active	IRB Number : IRB-21-476	Study Title : Malaria in Juveniles	
	IRB Expiration Date: 06/24/2022		

Print Friendly Add A New Correspondence Delete Selected Correspondence

10 result(s) found...

<input checked="" type="checkbox"/>	View Message	Author	Subject
<input type="checkbox"/>		Post a Reply to this Topic / Forward this Topic	
<input type="checkbox"/>		John Smith	Posted: Delivery in Progress Malaria in Juveniles Outcome Letter Notification

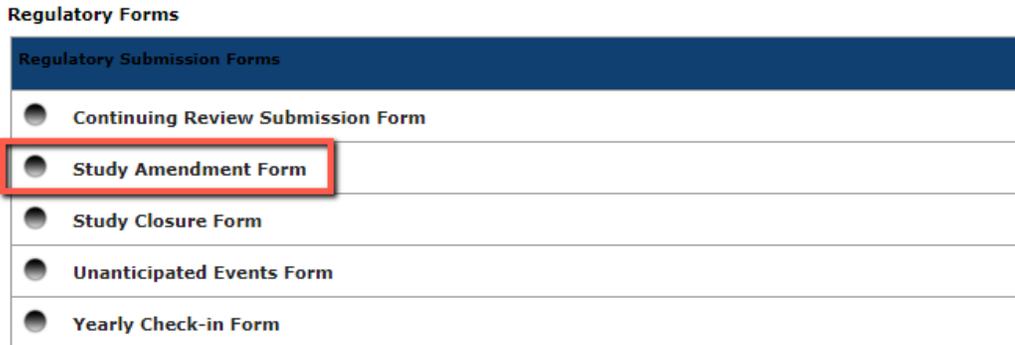
If the review board requests any further action, it will be addressed in the Outcome Letter.

Submitting an Amendment Form

At any point during the life of your study, you can complete a Modification or Change Request/Amendment form to submit changes to the review board for approval. Certain areas of the study require you to submit a change to the review board before that change can be applied to the study. Changing study personnel, drugs and devices are items that must be submitted as Amendment forms.

Accessing the Form

The Modification or Amendment Form will be located within the list of submission forms in the main Submissions tab. In this example, the form is called a Study Amendment form and is located within the Regulatory Forms group. Study forms can also be created from the Study Workspace.



When you click on the **Study Amendment Form** link, you will be directed to a page that lists all Amendments that have been created for this study. The components of this page are discussed in the “Submissions Forms” section of this document.

The image shows a screenshot of the 'Study Amendment Form' page. At the top, there is a dark blue header with the text 'Study Amendment Form' and a 'Back' button. Below the header, there is a form with the following details: 'Study Status: Active', 'IRB Number: IRB-21-476', 'PI: Investigator, John', 'Study Assistant', 'IRB Number: IRB-21-476', 'Study Title: Malaria in Juveniles', and 'IRB Expiration Date: 06/24/2022'. Below the form, there are four buttons: 'Copy Form', 'Add a New Form', 'Compare Two Versions', and 'Delete Selected Form(s)'. Below the buttons, there is an information icon and the text: 'List of records associated with form: Study Amendment Form. To view previous versions click on the folder icon'. Below this, there is a table with the following data:

1 result(s) found...													
	Show Rev	Edit/View	Details	Apply to Multiple	Sub. Rounds	Track Location	Process Submission	Submission Date	Update Date	Update Number	UPDATE TYPE	Created By	Date Created
<input type="checkbox"/>								06/25/2021 12:07:58 PM PDT	06/25/2021	1	1111112	John Investigator	06/25/2021 12:06:03 PM

To create a new amendment, click the **Add a New Form** button. This will open the form as it has been defined in the Forms Designer. You can fill out the form using the **Save and Continue** button to navigate through the sections.

Within this form you will be presented with different data values that will allow you to request changes to certain areas of your study.

My Workspaces

IRB Number: **IRB-21-476**
 PI: Investigator, John

Study Assistant

Study Amendment Form - (Version 2.0)
Back

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

Section view of the Form

Entire view of the Form

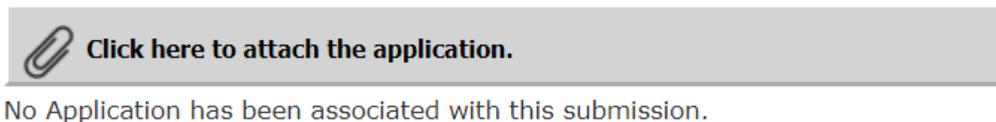
1.0 Study Information

1.0 Study Modification Form

1.1 Study Number:
IRB-21-476
1.2 Sponsor:
1.3 Study Title:
Malaria in Juveniles
1.4 Principal Investigator:
John Investigator
1.5 Study Contact:
Betty Smith

Modifying the Study Application

If you need to submit revisions to the Study Application, you will be presented with a link to attach the application to your Amendment, as seen in the image below. This data value functions similar to the value in the Initial Review Submission Form, but the application will not be pre-attached. Here you must click the link to access the application.



Once you click the link a window will open within your browser and the current version of the Study Application will be displayed.

Attaching Study Application
✕


Select the application that you would like to attach and then click Save Attachment

Save Attachment

Select	Show Rev.	Edit/View	Form Name	Approved	Create a Revised Application
<input type="radio"/>			IRB Application (Version 1.1)	No	

The current version of the Study Application cannot be modified if it has been submitted for review. When you click the icon in the **Edit/View** column, the application will open, but because it has been submitted you cannot modify it or add it to the Amendment form. You will need to create a revision of the application by clicking the icon in the **Create a Revised Application** button.

Note: this icon is only available in the most current version of the application.

The system will verify that you want to create a revision. Click **CONFIRM** to continue creating the revision. Click **CANCEL** to cancel the revision.

Confirm the adding a revision.

Are you sure you want to create a revision?

CONFIRM

CANCEL

If you clicked **CONFIRM**, the system will open the editable version of the application.

Note: If you need to modify the current Key Personnel in section 2.0, you will need to access the Personnel Change Request data value. You will not be able to change KSP in the revised version of the Study Application.

You can make any changes and click the **Back** button to return to the Amendment form.

The screenshot shows the top navigation bar with 'My Workspaces', 'IRB Number: IRB-21-476', 'PI: Investigator, John', 'Study Assistant', and 'IRB Application (Version 1.1)'. Below the navigation bar are buttons for 'Print Friendly', 'Assign User(s) to Sections', 'Save Section', and 'Save and Continue to Next Section'. The main content area is divided into 'Section view of Application' and 'Entire view of the Application'. The 'Entire view of the Application' section shows '1.0 General Information' with a text input field containing 'Malaria in Juveniles' and a label '* Please enter the full title of your study:'. Below this is another label '* Please enter the Study Number you would like to use to reference the study:'.

Once your changes are made, you will return to the Amendment form as shown above.

The revised application will be listed in the Application Attachment data value. If you need to detach the application, click the icon in the **Deattach** column. This will not delete this version of the application; it will simply remove the version from the form.

The screenshot shows the '5.0 Revised Materials' section. Below the header is a label '5.1 * Revised material includes:'. There are checkboxes for 'Application', 'Protocol', and 'Other Study Documents'. A note states: 'NOTE: ALL applications submitted to the Review Board must be the newest version available. If you are given the option to convert your application to a newer version, you must do so before completing your submission.' Below the note is a table with the following columns: 'Deattach', 'Revise/Attach', 'Edit/View', and 'Title'. The table contains one row with the title 'IRB Application (Version 1.2)'. The 'Deattach' column contains a circled 'X' icon, which is highlighted with a red box.

Deattach	Revise/Attach	Edit/View	Title
(X)			IRB Application (Version 1.2)

Requesting a Change in Key Personnel

If you need to request a change in the study personnel, you will be directed to the Personnel Change Request data value. This value looks and behaves similar to section 3.0 of the Study Application where you add personnel to the study.

1.3 Please identify KSP change you are requesting:

Assign key study personnel(KSP) Request to the study		Setup Key Study Personnel Request
If applicable, please add the new Principal Investigator for the study:		
If applicable, please select the new Research Staff personnel:		
A) Additional Investigators		
B) Research Staff		
C) Non-Study Personnel		
If applicable, please add any new Study Contact:		
<hr/> <p>The Study Contact(s) will receive all important system notifications along with the Principal Investigator. (Study Contacts are typically Study Coordinators or the Principal Investigator themselves).</p>		
If applicable, please add a new Faculty Advisor:		
<hr/>		
If applicable, please select any existing Personnel you wish to remove:		
<hr/>		

Here you will specify users you would like to add to the study by adding them to the appropriate group and selecting their role. Any user added to the study will have the ability to access the study in iRIS™ once the review board approves the personnel change.

If there is a change in the study’s KSP and the board approve the KSP change, a new version of the application will be created to reflect the newly updated KSP.

Note: This functionality is only available if the property `rb.use_revise_last_approved_app_on_change_personnel` within IRB Assistant > Review Board Administration > Board Configuration Options > Board Setup.

To add a new user to the study, click the **Setup Key Study Personnel Request** button.

3.0 Personnel Change Request or Procedures

Indicate **ONLY** personnel you are adding or deleting from the study.

Assign key study personnel(KSP) Request to the study Setup Key Study Personnel Request

If applicable, please add the new Principal Investigator for the study:

--	--	--

If applicable, please select the new Research Staff personnel:

A) Additional Investigators		
B) Research Staff		
C) Non-Study Personnel		

If applicable, please add any new Study Contact:

--	--	--

This opens a window allowing you to search the system user directory by First Name, Last Name, or Department. Enter all or part of the search criteria and click the **Find** button.

Setup Study Personnel X

<p>User Search</p> <p>Remove Personnel List</p>	<p>Last Name: <input type="text" value="mcm"/> First Name: <input type="text"/></p> <p>by Department: <input type="text" value="All Departments"/> ▼</p> <p>Search From: <input checked="" type="radio"/> Search Database <input type="radio"/> LDAP Directory</p> <p style="text-align: right;">Find User/Search Directory</p> <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr style="background-color: #003366; color: white;"> <th>Select</th> <th>Training?</th> <th>Name</th> <th>Department</th> <th>Email</th> </tr> </thead> <tbody> <tr> <td></td> <td></td> <td>McMurray, Sean</td> <td> Legal Department</td> <td>smcmurray@imedris.com</td> </tr> </tbody> </table>	Select	Training?	Name	Department	Email			McMurray, Sean	Legal Department	smcmurray@imedris.com
Select	Training?	Name	Department	Email							
		McMurray, Sean	Legal Department	smcmurray@imedris.com							

Selected Study Personnel:

Principal Investigator

Name	Role
No Personnel has been selected for this group.	

Additional Investigators

Name	Role
No Personnel has been selected for this group.	

Clear Key Study Personnel Close Setup of Study Personnel

To select a user to add, click the **Select** icon. Click on the **Close Setup of Study Personnel** button to complete your changes.

Assign key study personnel(KSP) Request to the study		Setup Key Study Personnel Request
If applicable, please add the new Principal Investigator for the study:		
If applicable, please select the new Research Staff personnel:		
A) Additional Investigators		
B) Research Staff		
<input type="checkbox"/> McMurray, Sean Lab Manager	 View Training Record	
C) Non-Study Personnel		
If applicable, please add any new Study Contact:		
The Study Contact(s) will receive all important system notifications along with the Principal Investigator. (Study Contacts are typically Study Coordinators or the Principal Investigator themselves).		
If applicable, please add a new Faculty Advisor:		
If applicable, please select any existing Personnel you wish to remove:		

You may or may not see the same role options as presented in this document, depending on your system configuration. Some of the roles available in this section include the following:

Principal Investigator – All studies in iRIS™ must be assigned a Principal Investigator (PI). Without a PI, the third section of the Study Shell cannot be completed, and the study will remain in Draft mode. Note that there may only be one PI per study. If additional PIs exist, add them to the “Additional Investigators” section.

Additional Investigators – Any non-PI investigators. There is no limit to the number of Additional Investigators that can be added to a study. Each user in this section is given a specific study role.

Research Support Staff – Any non-investigator study personnel. There is no limit to the number of Research Support Staff that can be added to a study. Each user in this section is given a specific study role.

Contact – User(s) on the study who will receive study related notifications from the system, such as Continuing Review notifications, Submission Correction notifications, Review Response notifications, etc. The Principal Investigator defaults as the study contact, but this is editable. Any number of contacts be defined for a given study.

If you added a user to the data value in error, you may remove the user by clicking on the Setup Key Study Personnel and clicking on the delete  icon next to the user's name.

The second option on the right-hand side, **Remove Personnel List**, will allow the user to select what users they would like to remove from the study as shown in the screenshot below.

Setup Study Personnel
X

User Search

Remove Personnel List

Create My Personnel Pool

Save Selections

<input checked="" type="checkbox"/>	Name	Role on the Study
<input type="checkbox"/>	John Investigator	Principal Investigator
<input type="checkbox"/>	Betty Smith	Contact
<input type="checkbox"/>	Tom Jefferson	Co-Investigator
<input type="checkbox"/>	John Investigator	Study Author
<input type="checkbox"/>	George Jefferson	Nurse
<input type="checkbox"/>	Nathan Mossman	Nurse
<input type="checkbox"/>	Sean Coordinator	Additional Principal Investigator

Selected Study Personnel:

Principal Investigator

	Name	Role
No Personnel has been selected for this group.		

Additional Investigators

	Name	Role
<input checked="" type="checkbox"/>	Sykes, Jeff	Co-Investigator

Research Support Staff

Selecting the checkbox(es) next to the user(s) and clicking **Save Selections** will add the user(s) to the Remove Personnel List.

If applicable, please select any existing Personnel you wish to remove:

Sykes, Jeff Department Administrator		
Jefferson, Tom Co-Investigator		
Smith, Betty Contact		

Any change in personnel will not take effect until the review board approves the request. This means that any user requested on the study will not have access to the study until the review board approves their role.

Modifying a Consent or Other Study Document

Any modifications to Consent forms or Other Study Documents will need to be submitted to the review board for approval. Within the Amendment form you will be presented with data values that will allow you to attach Consent forms and Other Study Documents. Using these data values, you can choose to add or revise any existing document on your study, or you can add a brand-new document. While the process is the same for both Consent forms and Other Study Documents, they are represented by two distinct data values in the System Form Designer.

As an example, the process of revising and adding Study Consent forms is described below. However, the same steps may be taken to add or revise Other Study Documents.

Shown below is the data value for making changes to the study’s attached consent forms.

Select or Revise Existing		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.								

Select or Revise Existing Consent or Other Study Document

If you would like to select an already revised Consent, Other Study Document or revise an existing document, click the **Select or Revise Existing** button.

Select or Revise Existing		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.								

A window will open within the browser that lists all documents that have been attached to the study. You can choose a document to attach by clicking the icon in the **Select** column.

Select Existing or Create Revised Study Consent

Select Category: --none-- ▾

Version #: ,

Version Date: between

Consent Outcome: --none-- ▾

Title:

Search level: Top All

Expiration Date: between

2 result(s) found...

Select	Show all Versions	Edit	Delete	Version	Version Date	Title	Language	Expiration Date	Consent Outcome	Checked Out By	View Document	Create Revision
						Category						
				1.2	06/25/2021	English Consent Form						
						Consent	English				2.68 MB	
				1.0	07/08/2021	Revised English Consent Form				John Investigator 07/08/2021 02:43:57 PM		(Read Only)
						Consent	English				5.60 KB	

If you have not yet modified the document, you can create a revision of that document from this area. Click the icon in the **Create Revision** column, as seen in the image below.

Select Existing or Create Revised Study Consent

Select Category: --none-- ▾

Version #: .

Version Date: ▾ between ▾

Consent Outcome: --none-- ▾

Title:

Search level: Top All

Expiration Date: ▾ between ▾

[Add a New Consent](#) [Filter Documents](#)

2 result(s) found...

Select	Show all Versions	Edit	Delete	Version	Version Date	Title	Language	Expiration Date	Consent Outcome	Checked Out By	View Document	Create Revision
						Category						
				1.2	06/25/2021	English Consent Form						
						Consent	English				2.68 MB	
				1.0	07/08/2021	Revised English Consent Form				John Investigator 07/08/2021 02:43:57 PM		(Read Only)
						Consent	English				5.60 KB	

The window will refresh and populate with details of the consent form you are revising, allowing you to change the general form details and check-out the revised form. To check-out the form, click the **Check-out Document** button.

Study Consent Revision

* Consent Title: English Consent Form

* Version Number: 1 .3

* Version Date: 06/25/2021

Category: Consent

* Language: English

Description:

Comments:

Download Consent: Download

Check-out the Document to your workstation for editing: Check-out Document...

View Document

Close, don't save any changes Save Consent

A window will open, confirming that you want to check-out the document. Click **Confirm**. The document should automatically download.

Note: each internet browser may function differently in the way it processes downloaded files.

Save the document in a safe and known location so that you can check it back into the system when complete.

Returning to the Study Consent Revision window will indicate that the consent is checked out. You will now have the ability to **Check-in Document** or **Undo Check-out Document**.

Download Consent:	<input type="button" value="Download"/>
This document is currently checked out by..	Sean Coordinator at 07/12/2021 09:25:47 AM
Check-in when you are done editing upload the document back into iRIS.	<input type="button" value="Check-in Document..."/>
Revert to the document stored in iRIS.	<input type="button" value="Undo Check-out Document..."/>

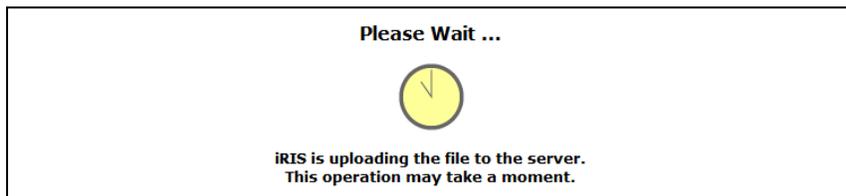
After you have made changes to the document in Microsoft Word, you can return to iRIS™ and check it back in by clicking the **Check-in Document** button.

A window will open, allowing you to browse your computer for the document you would like to upload. Click the **Save selected file** button once you specify the document location. If you do not want to upload the document, click the **Cancel** button.

Document Location: No file chosen

Instruction: Uploading a document into iRIS™ requires locating the document on the computer. Once you have located the document click on the 'Save selected file' button. The buttons will become disabled. If the document is a large document the window will stay in place until the upload operation has completed.

Depending on the file size, you may see a message from the system indicating iRIS™ is uploading the document.



You will then be returned to the Study Consent Revision window with the document successfully checked in and associated to the study. Click the **Save Consent** button to apply the changes.

Study Consent Revision
X

* Consent Title:	<input type="text" value="English Consent Form"/>	<div style="border: 1px solid gray; padding: 5px; width: 50px; margin: auto;">  </div>
* Version Number:	<input type="text" value="1"/> . <input type="text" value="3"/>	
* Version Date:	<input type="text" value="06/25/2021"/> 	
Category:	<input type="text" value="Consent"/>	
* Language:	<input type="text" value="English"/>	
Description:		
Comments:		
Download Consent:	<input type="button" value="Download"/>	
Check-out the Document to your workstation for editing:	<input type="button" value="Check-out Document..."/>	

Returning to the form, any consent documents that were selected will populate in the data value as shown below.

<input type="button" value="Select or Revise Existing"/>		<input type="button" value="Add a New Consent"/>						
Detach	Version	Title	Category	Language	Expiration Date	Consent Outcome	Checked Out	View Document
⊗	1.3	English Consent Form	Consent	English				 2.68 MB

Add a New Consent or Other Study Document

If you are requesting review of a brand-new document that has not been associated to the study, click the **Add a New Document** or the **Add a New Consent** button. Following this process, you will be able to add a document to the study and attach it to the form.

Modifying a Study Drug or Device

In order to make any changes to Study Drugs or Devices, you will need to add the changes to a form and submit it to the review board for approval. The process for revising or adding Drugs and Devices is the same. Modifying a Study Drug is used in this example.

Within the Amendment form you will be presented with a Drug or Device data value. This value will contain a list of current Study Drugs or Devices on the study.

+ Add new Drug to the Study				
Delete Drug	Edit	View Details	Trade Drug Name	IND Number
(X)		+	Trade Drug Name: Amoxicillin	

If you need to request a new drug or device on the study, click the **Add a New Drug to the Study** or **Add a New Device to the Study** button. This will take you through the steps of adding a drug or device to a study. If you need to request that a drug or device be removed from the study, locate the item in the list and click the icon in the **Delete** column. If you need to request changes to a current study drug or device, locate that item in the list and select the icon in the **Edit** column.

+ Add new Drug to the Study				
Delete Drug	Edit	View Details	Trade Drug Name	IND Number
(X)		+	Trade Drug Name: Amoxicillin	

When you choose to edit a Study Drug or Device the following window will open, containing the current information for the drug or device. You can make any necessary changes and click the **Save Drug Info** button to return to the form.

Study Drug Details:

Trade Drug Name: Amoxicillin

Dose Range:

Protocol Information: Drugs and Biological Products

Does your study involve INVESTIGATIONAL drugs, reagents, or chemicals?

Has this study been submitted to the Institutional Biosafety Committee (IBC) review? The IRB requires documentation of IBC approval before final approval of the study can be granted.

Yes
 No
 N/A

Investigational New Drug Application (IND)#

Is the drug provided free of charge?

Yes
 No
 N/A

What is the cost of the investigational drug to your institution?

All changes to the Study Drugs and Devices will not take effect until the review board approves the submission.

Signoff

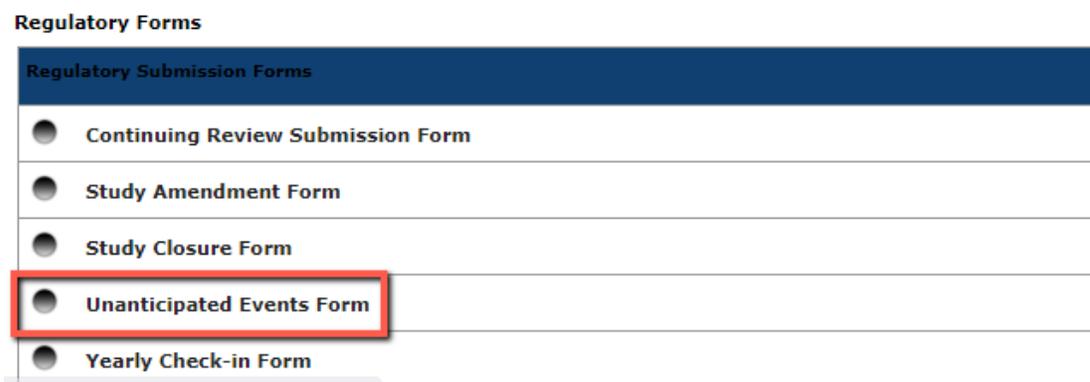
When the submission form is completed, you will receive information about sending the form into the workflow following the same steps listed in the “Submitting the Form” section for Continuing Review. Remember, your Amendment form may or may not contain all of the steps listed in these instructions.

Submitting an Adverse Event Form

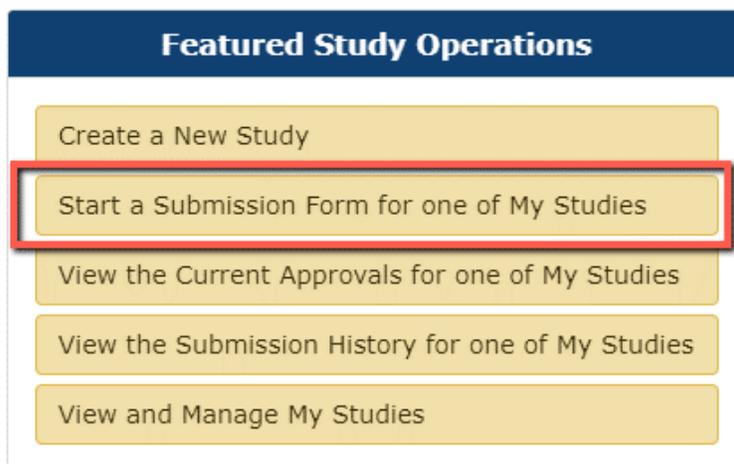
At any point during the life of your study, you can access an Adverse Event form to submit to the review board.

Accessing the Form

The Adverse Event form will be located within the list of submission forms in the Submissions tab. In this example, the form is called an **Unanticipated Events Form** and is located within the Regulatory Forms group



You may also start an Adverse Event Form from the Study Workspace by clicking on **Start a Submission Form for one of My Studies** as shown below.



When you click on the **Unanticipated Events Form** link, you will be directed to a page that lists all Adverse Events that have been created for this study.

My Workspaces IRB Number: **IRB-21-477** PI: Investigator, John Study Assistant **Unanticipated Events Form** Back

Study Status: **Active** IRB Number: IRB-21-477 Study Title: Malaria in Juveniles in South Africa
 IRB Expiration Date: 06/24/2022

List of records associated with form: Unanticipated Events Form.
 To view previous versions click on the folder icon .

1 result(s) found...

	Show Rev	Show Follow-Up	Edit/View	Details	Apply to Multiple	Sub. Rounds	Track Location	Process Submission	Submission Date	AE Report Type	Subject ID	AE Category	AE Attribution	AE
<input type="checkbox"/>										Follow-Up				

To create a new Adverse Event, click the **Add a New Form** button. Depending on your system settings, you may be presented with a list of subjects on the study. You can select a subject to which the Adverse Event will apply.

Note: this functionality will not be available if you do not have access to the Subject Management module.

My Workspaces IRB Number: **IRB-21-477** PI: Investigator, John Study Assistant **Subject Selection List** Back

Please select the subject this Form is associated with:

Select	On Study Status	(MRN) Last, First MI	Participant Number	Sex	Register Date	Date of Birth	Survival Status	Off Study Details
<input type="radio"/>	Eligible	Smith, John(554686)		M			Alive	
<input type="radio"/>	Other	(Subject is not tracked in IRIS)						

This will open the form as it has been defined in the Forms Designer.

You can fill out the form using the **Save and Continue** button at the top right of the page to navigate through the sections.

My Workspaces

IRB Number: **IRB-21-477**
 PI: Investigator, John

Study Assistant

Unanticipated Events Form - (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 Background
 2.0 **Type of Event**
 3.0 Initial or Follow-up

2.0 Type of Event (what type of event occurred?) (Choose only one)

PROTOCOL DEVIATION

Clear

Protocol deviations are unplanned or unforeseen changes in the implementation of an IRB-approved protocol. They generally refer to a modification of procedures that has already occurred for a single subject; they are not intended to modify the protocol. Protocol deviations DO NOT increase risks to subjects or affect the scientific validity of the study.

UNANTICIPATED PROBLEMS INVOLVING RISK TO SUBJECTS OR OTHERS (UPIRSO)

Clear

Unanticipated problems involving risk to subjects or others are events that meet ALL of the following criteria:
 1) Are unexpected given the research procedures and/or the characteristics of the subject population,
 2) Are definitely or probably related to participation in the research, AND
 3) Suggest that the research places subjects or others at a greater risk of harm than was previously known or recognized.

SERIOUS ADVERSE EVENT (SAE)

Clear

SAEs are internal events that include any of the following:
 Death
 Life-threatening experience
 Hospitalization (for a person not already hospitalized)
 Prolongation of hospitalization (for a person already hospitalized)
 Persistent of significant disability or incapacity
 Congenital anomaly and/or birth defects
 Any event that jeopardizes the subject and may require medical or surgical treatment to prevent one of the preceding outcomes.

Within this form you may be asked to indicate if the Adverse Event is an initial or follow up. If this is an initial report, you can select "Initial" and continue to complete the form, as seen in the image below.

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 Background
 2.0 Type of Event
 3.0 **Initial or Follow-up**

3.0 Initial or Follow-up

3.1 * Report Type:

Initial

Follow-Up

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 Background
- 2.0 Type of Event
- 3.0 Initial or Follow-up
- 4.0 Dates

4.0 Dates

4.1 * Date event occurred:

4.2 * Date Principal Investigator became aware of event:

4.3 * Indicate location where the event occurred below:

If this is a follow-up report, select **Follow-up Report** and then click the link in the image below to associate a previous Adverse Event form.

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 Background
- 2.0 Type of Event
- 3.0 Initial or Follow-up
- 4.0 Dates

3.0 Initial or Follow-up

3.1 * Report Type:

Initial

Follow-Up

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 Background
- 2.0 Type of Event
- 3.0 Initial or Follow-up
- 4.0 Follow-Up Description

4.0 Follow-Up Description

4.1 Select the associated report

[Click here to select the Unanticipated Events Form we are associating to this follow-up.](#)

4.2 Attach Follow-up Document(s)

A list of previously completed Adverse Events for the study will populate in a new page. You can select the Adverse Event to which you are sending a follow up, and then click the **Save Selected Event** button.

My Workspaces IRB Number: **IRB-19-180** Study Assistant **Unanticipated Events Form** [Back](#)

[Return back to the Form](#) [Save Selected Event](#)

List of records associated with form: Unanticipated Events Form.

1 result(s) found...

	Version	AE Report Type	Subject ID	AE Category	AE Attribution	AE Grade	Created By	Date Created	Last Modified By	Last Date Modified
<input type="radio"/>	1.0		15	Syndromes	Possible	1	John Investigator	07/12/2021 12:47:53 PM	John Investigator	07/12/2021 12:49:39 PM

Information related to the initial report will populate in a table below the data value. The rest of the Unanticipated Event form will populate based on the information completed in the Initial Report. You can save through the form, verify the information is correct, and change items as needed.

4.0 Follow-Up Description

4.1 Select the associated report

Click here to select the Unanticipated Events Form we are associating to this follow-up.

AE Report Type:	
Subject ID:	15
AE Category:	Syndromes
AE Attribution:	Possible
AE Grade:	1
Created By:	John Investigator
Date Created:	07/12/2021 12:47:53 PM
Modified By:	John Investigator
Date Modified:	07/12/2021 12:49:39 PM

Any Adverse Event that you create as a Follow-up Report will become associated to the Initial Report in the list of Adverse Event forms. You can expand the folder in the **Show Follow-up** column to view all Follow-up reports.

My Workspaces
IRB Numbers: **IRB-21-477**
PI: Investigator, John
Study Assistant

Unanticipated Events Form

Back

Study Status: Active

IRB Number : IRB-21-477

Study Title : Malaria in Juveniles in South Africa

IRB Expiration Date: 06/24/2022

Copy Form
Add a New Form
Compare Two Versions
Delete Selected Form(s)

i List of records associated with form: Unanticipated Events Form.
 To view previous versions click on the folder icon 📁.

1 result(s) found...

📁	Show Rev	Show Follow-Up	Edit/View	Details	Apply to Multiple	Sub. Rounds	Track Location	Process Submission	Submission Date	AE Report Type	Subject ID	AE Category	AE Attribution	AE Grade	Created By	I
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>							07/21/2021 10:40:24 AM PDT	Initial	41863				John Investigator	07/21/20
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>								Follow-Up					John Investigator	06/25/20

Signoff

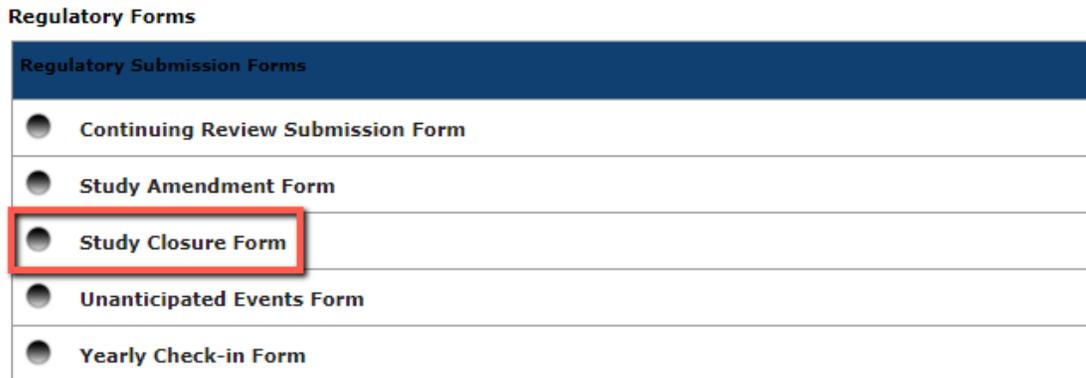
When the submission form is completed, you will receive information about sending the form into the workflow, following the same steps listed in the “Submitting the Form” section for Continuing Review.

Submitting a Study Closure Form

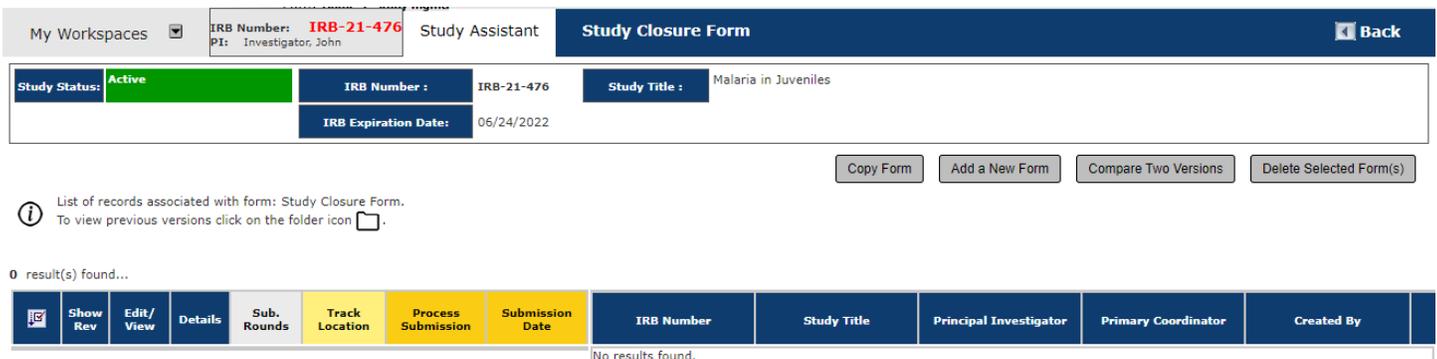
Once all study research has been completed and you are ready to inform the review board that your study is closed, you can submit a *Study Closure* form to the review board. Once the review board receives the form, they can close out the study in iRIS™.

Accessing the Form

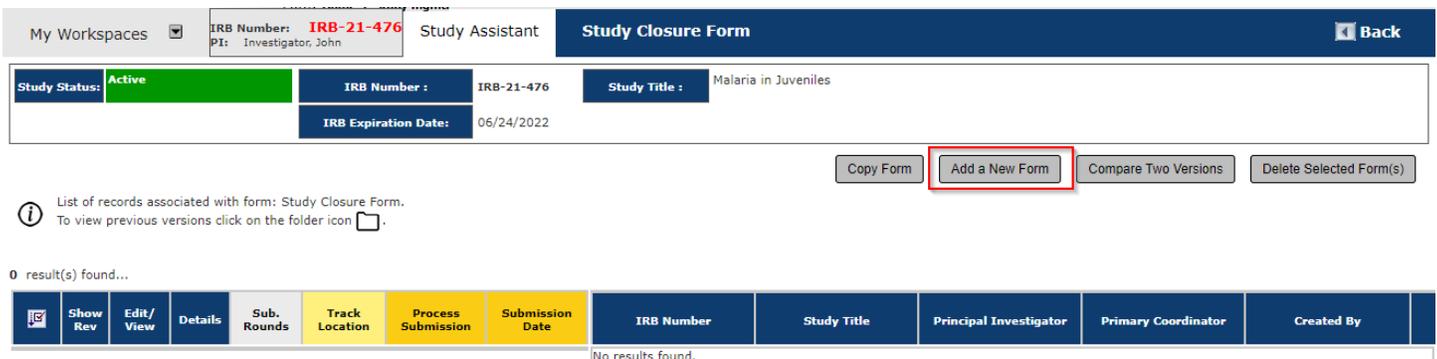
The *Study Closure* form will be located within the list of submission forms in the study’s Submissions tab. In this example, the form is called a **Study Closure** and is located within the Regulatory Forms group. However, your system may contain a different list of forms.



When you click on the **Study Closure** link, you will be directed to a page that lists all *Study Closure* forms that have been created for this study.



To create a new study closure, click the **Add a New Form** button.



This will open the form as it has been defined in the Forms Designer. You can fill out the form using the **Save and Continue** button to navigate through the sections.

The screenshot shows the 'Study Closure Form - (Version 1.0)' interface. At the top, there is a navigation bar with 'My Workspaces', 'IRB Number: IRB-21-476', 'PI: Investigator, John', 'Study Assistant', and a 'Back' button. Below this are buttons for 'Print Friendly', 'Refresh Constant Fields', 'Save Section', and 'Save and Continue to Next Section'. The main content area is divided into two tabs: 'Section view of the Form' and 'Entire view of the Form'. The 'Entire view of the Form' tab is active, showing a form titled '1.0 Institutional Review Board Study Closure Report'. The form contains the following sections:

- 1.1 IRB Number:** IRB-21-476
- 1.2 Study Title:** Malaria in Juveniles
- 1.3 Principal Investigator:** John Investigator
- 1.4 Study Coordinator:** Betty Smith
- 1.5 Date Submitted:** 07/12/2021
- 1.6 * Date of Closure:** (Empty field)
- 1.7 * Select the appropriate type of study closure.** (Empty field)

Signoff

When the submission form is completed, you will receive information about sending the form into the workflow, following the same steps listed in the “Submitting the Form” section for Continuing Review.

Close “Exempt” studies

A new ability to close “Exempt” studies from Study Assistant Workspace is now available.

This feature allows study personnel to close “Exempt” studies from the View My Studies section on the home screen. Users may check if a study is “Exempt” by going to the Study Summary page.

My Workspaces IRB Number: **IRB-21-477** Study Assistant **Study Summary** Back

PI: Investigator, John

Study Status: Active **IRB Number :** IRB-21-477 **Study Title :** Malaria in Juveniles in South Africa

IRB Expiration Date: 06/24/2022

Print Friendly Save Changes

Please Select the Type of Review Notification that Must be Sent: Email with Home Screen Task and Continuing Review

Committee of Record: --none--

IRB Initial Approval: 06/24/2022

Review Cycle: 12 Months

IRB Expiration Date: 06/24/2022

Last Continuing Review Approved:

Days Prior to IRB Expiration: 60 days prior exp

Continuing Review Due: 04/25/2022

Study Closure:

Temporary Closed: No

Temporary Closure Start:

Temporary Closure End:

Exempt: Yes

Subject Approved: 0

If the study is “Exempt” it may be closed directly from the Study Assistant home screen or study “Submissions” tab, as shown below.

My Workspaces IRB Number: **IRB-21-477** Study Assistant **Submissions** Back

PI: Investigator, John

Study Status: Active **IRB Number :** IRB-21-477 **Study Title :** Malaria in Juveniles in South Africa

IRB Expiration Date: 06/24/2022

Submissions **Study Management** **Subject Management**

Close Exempt Study Current Approval Packet

Protocol Items

- Study Application
- Informed Consents ▶
- Other Study Documents ▶
- Contract Documents

Protocol Items

Submissions History

● Study Correspondence

Outstanding Submission(s)

Track Location	Ref Number	Request Type	Process Submission
There are no outstanding submissions.			

All Studies Recently Used Study Status

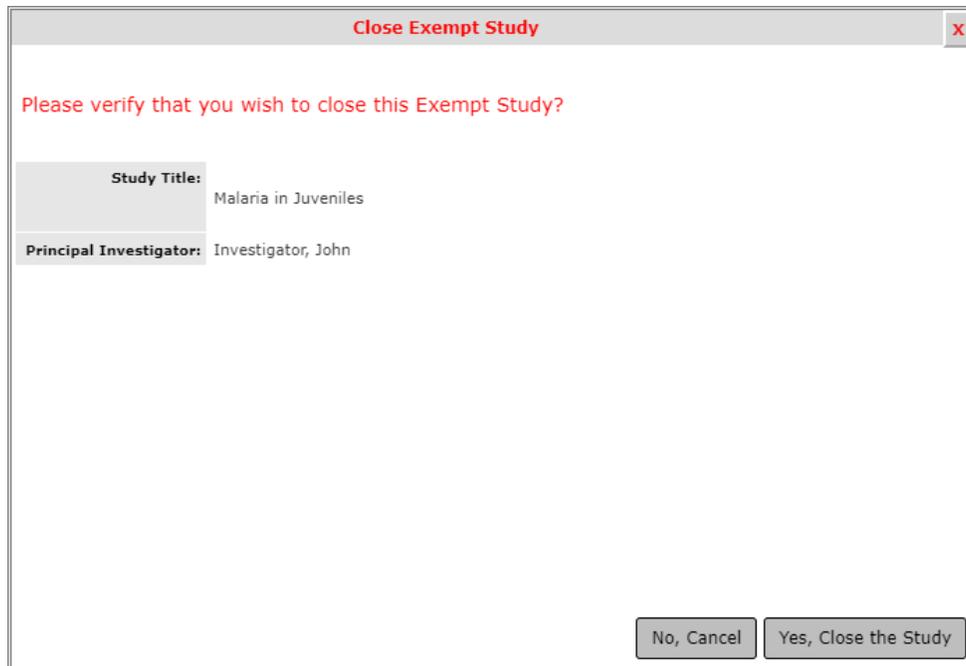
All **Draft** **IACUC** **IBC Board** ▼

57 result(s) found... ◀ 11 - 15 ▶

Click to open Study Dashboard	Study Status	Review Board	RB Number	RB Expiration	Study Title Study Alias	Principal Investigator	Actions
	Active	IRB	IRB-21-476	06/24/2022	Malaria in Juveniles Malaria in Juveniles	Investigator, John	Applications Documents Forms Hide Exempt Copy Delete Correspond
	Active	IRB	IRB-20-336	07/14/2021	Serum Metal Ion Concentration after Insertion of Pediatric Flexible Nail Serum Metal Ion Concentration after Insertion of Pediatric Flexible Nail	Smith, Betty	Applications Documents Forms Hide Exempt Copy Delete Correspond
	Open	IRB	IRB-21-478	06/28/2022	Malaria in Juveniles Malaria in Juveniles	Investigator, John	Applications Documents Forms Hide Close Exempt Copy Delete Correspond
	Open	IRB	IRB-21-479	06/29/2022	Malaria in Juveniles Malaria in Juveniles	Investigator, John	Applications Documents Forms Hide Exempt Copy Delete Correspond
	Draft	IRB	IRB-21-470		Copy of NIH - FD - 00001- Multi-Site safety of masks over 52 weeks in USA wo... NIH - FD - 0001	Investigator, John	Applications Documents Forms Hide Exempt Copy Delete Correspond

57 result(s) found... ◀ 11 - 15 ▶

Clicking one of these buttons will open a window confirming that the user would like to close the study.



If the user does not have access to close this study, the following error message will display.

Close Exempt Study x

Please verify that you wish to close this Exempt Study?

Study Title:	Malaria in Juveniles
Principal Investigator:	Smith, Jane

Your Privileges do not allow you change the Study status.
Contact your System Administrator to allow operation.

No, Cancel