# iRIS

**Powered by iMedRIS**

## STUDY ASSISTANT

*Study Management: Submissions*

Software Version: 13.01

Manual Version: P1

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# Contents

# 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.
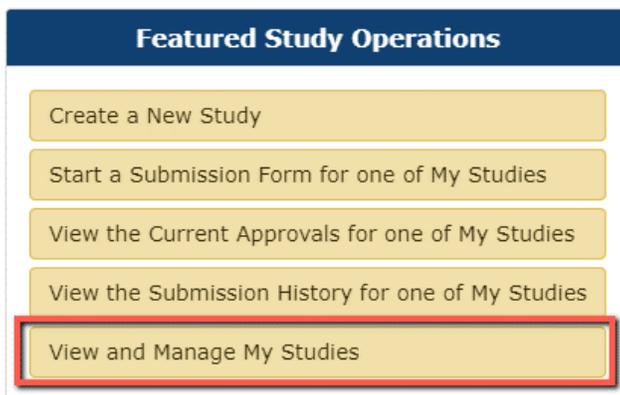


This will anchor you down the screen to the My Studies panel, which will display all studies that you have been assigned a role on, along with basic information about each study. Use the filters to narrow the list to the study you wish to open. By default, the studies will be listed in order from most 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.

## 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 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.



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.

## Study Application

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



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.



## 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.

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.



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.



*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.

| | Show Rev. | Edit/ View | Application Type | Approved? | Approval Date | Created By | Date Created | Last Modified By | Last Date Modified | Create a Revised Application |
|---|---|---|---|---|---|---|---|---|---|---|
| ☐ | 📂 | ✏ | IRB Application (Version 1.2) | No | | John Investigator | 07-08-2021 10:05 | John Investigator | 07-08-2021 10:06 | |
| ☐ | | ✏ | IRB Application (Version 1.1) | Yes | 06/25/2021 | John Investigator | 06-25-2021 11:20 | John Smith | 06-25-2021 14:07 | 📤 |
| ☐ | | ✏ | IRB Application (Version 1.0) | Yes | 06/25/2021 | John Investigator | 06-23-2021 15:35 | IRB Reviewer | 06-25-2021 08:11 | |

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 | Delete Selected Version

1 result(s) found...

## 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** PI: Investigator, John | Study Assistant | **Study Application** | ◀ **Back**

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

Add a new Application

0 result(s) found...

| | 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.

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.



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.

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.



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.



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.



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

*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.

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



*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.

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.



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.

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 |
| | | | English Consent Form | | | | | | | | | | |
| ☐ | 📁 | ✎ | Consent | 1.1 06/28/2021 | English | [W] | | | | | | | 🗂 |

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 |
| | | | | Study Consent | | | | | | | | | |
| ☐ | 📖 | | IRB-20-336-NEW-1.0 | | 1.0 09/21/2020 | English | | [PDF] | 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.

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.

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.



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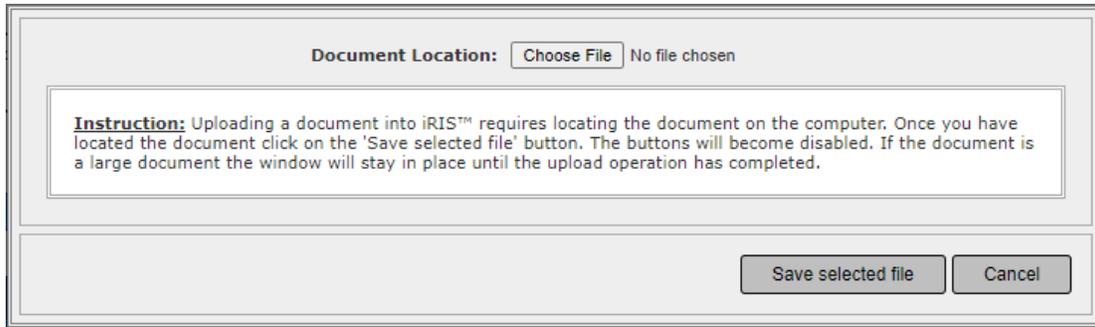
Click the **Save Consent** button to save the revised document to the study.

## 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.
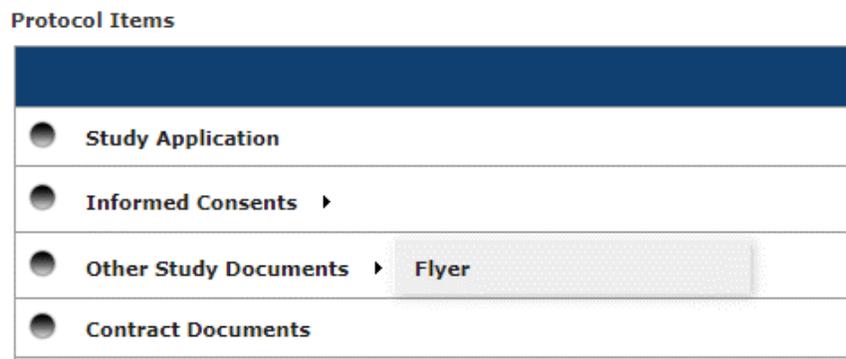


If you hover over the Other Study Documents link, a popup menu will appear that displays all categories of documents that have been uploaded to the study. If you click a link in the menu, the Study Document library will open to display only documents in the selected category.

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.

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.



### 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: ☐ | | Show Hidden: ○ Yes ● No | | Reset Filters |
| Select a Category Type: All ▾ | | Title | | Filter Documents |
| Version #: [ ] . [ ] | | Document Outcome: All ▾ | | |
| Approval Date: [ ] 🗓▾ between [ ] 🗓▾ | | Expiration Date: [ ] 🗓▾ between [ ] 🗓▾ | | |

> 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.

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.



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.
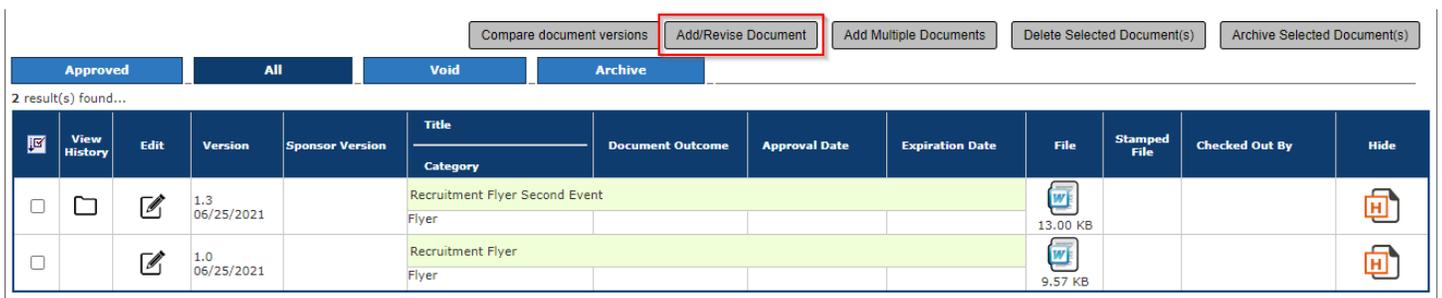


Once clicked, the following window will appear asking if you would like to revise an existing document or upload a brand-new document.

*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.*

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.



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

| | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 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...

| ☑ | View History | Edit | Version | Sponsor Version | Title / Category | Document Outcome | Approval Date | Expiration Date | File | Stamped File | Checked Out By | Hide |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| ☐ | 📁 | 🖊 | 1.3 06/25/2021 | | Recruitment Flyer Second Event / Flyer | | | | 📄 13.00 KB | | | H |
| ☐ | | 🖊 | 1.0 06/25/2021 | | Recruitment Flyer / Flyer | | | | 📄 9.57 KB | | | H |
| ☐ | | 🖊 | 1.0 07/09/2021 | | Recruitment Handbook / Other | | | | 📄 9.98 KB | | | H |

## 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.

| | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 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...

| ☑ | View History | Edit | Version | Sponsor Version | Title / Category | Document Outcome | Approval Date | Expiration Date | File | Stamped File | Checked Out By | Hide |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| ☐ | 📁 | 🖊 | 1.3 06/25/2021 | | Recruitment Flyer Second Event / Flyer | | | | 📄 13.00 KB | | | H |
| ☐ | | 🖊 | 1.0 06/25/2021 | | Recruitment Flyer / Flyer | | | | 📄 9.57 KB | | | H |
| ☐ | | 🖊 | 1.0 07/09/2021 | | Recruitment Handbook / Other | | | | 📄 9.98 KB | | | H |

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.

| | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 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...

| ☑ | View History | Edit | Version | Sponsor Version | Title / Category | Document Outcome | Approval Date | Expiration Date | File | Stamped File | Checked Out By | Hide |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| ☐ | 📁 | 🖊 | 1.3 06/25/2021 | | Recruitment Flyer Second Event / Flyer | | | | 📄 13.00 KB | | | H |
| ☐ | | 🖊 | 1.0 06/25/2021 | | Recruitment Flyer / Flyer | | | | 📄 9.57 KB | | | H |
| ☐ | | 🖊 | 1.0 07/09/2021 | | Recruitment Handbook / Other | | | | 📄 9.98 KB | | | H |

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.

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.



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...

| ☑ | View History | Edit | Version | Sponsor Version | Title / Category | Document Outcome | Approval Date | Expiration Date | File | Stamped File | Checked Out By | Hide |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| ☐ | 📁 | ✎ | 1.3 06/25/2021 | | Recruitment Flyer Second Event / Flyer | | | | 📄 13.00 KB | | | H |
| ☐ | | ✎ | 1.0 06/25/2021 | | Recruitment Flyer / Flyer | | | | 📄 9.57 KB | | | H |
| ☑ | | ✎ | 1.0 07/09/2021 | | Recruitment Handbook / Other | | | | 📄 9.98 KB | | | H |

## 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...

| ☑ | View History | Edit | Version | Sponsor Version | Title / Category | Document Outcome | Approval Date | Expiration Date | File | Stamped File | Checked Out By | Hide |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| ☐ | 📁 | ✎ | 1.3 06/25/2021 | | Recruitment Flyer Second Event / Flyer | | | | 📄 13.00 KB | | | H |
| ☐ | | ✎ | 1.0 06/25/2021 | | Recruitment Flyer / Flyer | | | | 📄 9.57 KB | | | H |
| ☐ | | ✎ | 1.0 07/09/2021 | | Recruitment Handbook / Other | | | | 📄 9.98 KB | | | H |

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.

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.

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.

## 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.



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.

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.

The system will indicate anytime a document is checked out.

| | View History | Edit | Version | Sponsor Version | Title / Category | Document Outcome | Approval Date | Expiration Date | File | Stamped File | Checked Out By | Hide |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| ☐ | 📁 | ✎ | 1.1 06/20/2021 | 1.0 | IBC Document / Other | | | | W 13.00 KB | | John Investigator 07/09/2021 10:44:38 AM | H |
| ☐ | | 📖 | 1.0 06/20/2021 | 1.0 | Investigator Brochure / Investigator brochure | Approved | 06/20/2021 | | PDF 171.26 KB | | | H |

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

Tabs: Approved | All | Void | Archive

2 result(s) found...

| | |
|---|---|
| **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... |

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.

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

Tabs: Approved | All | Void | Archive

2 result(s) found...

| | View History | Edit | Version | Sponsor Version | Title / Category | Document Outcome | Approval Date | Expiration Date | File | Stamped File | Checked Out By | Hide |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| ☐ | 📁 | ✎ | 1.1 06/20/2021 | 1.0 | IBC Document / Other | | | | W 13.00 KB | | John Investigator 07/09/2021 10:44:38 AM | H |
| ☐ | | 📖 | 1.0 06/20/2021 | 1.0 | Investigator Brochure / Investigator brochure | Approved | 06/20/2021 | | PDF 171.26 KB | | | H |

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.

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.



## 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.

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).



## 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.
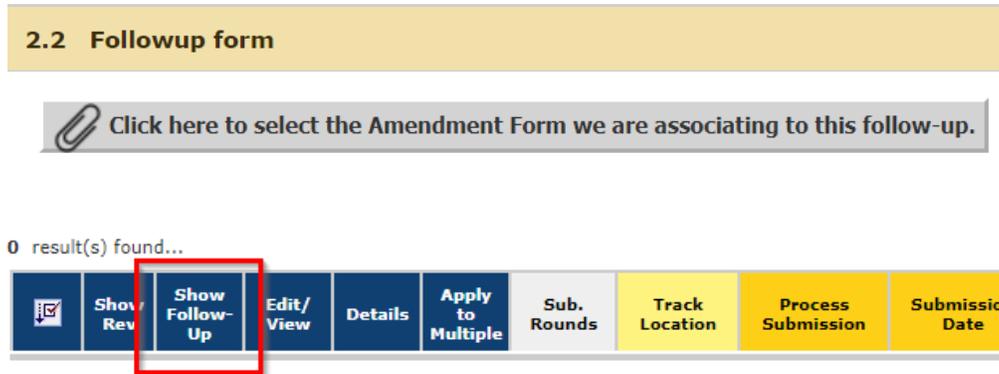


**Edit/View** – Click on this icon to continue to work on a partially completed form or to view a form that has already been submitted.

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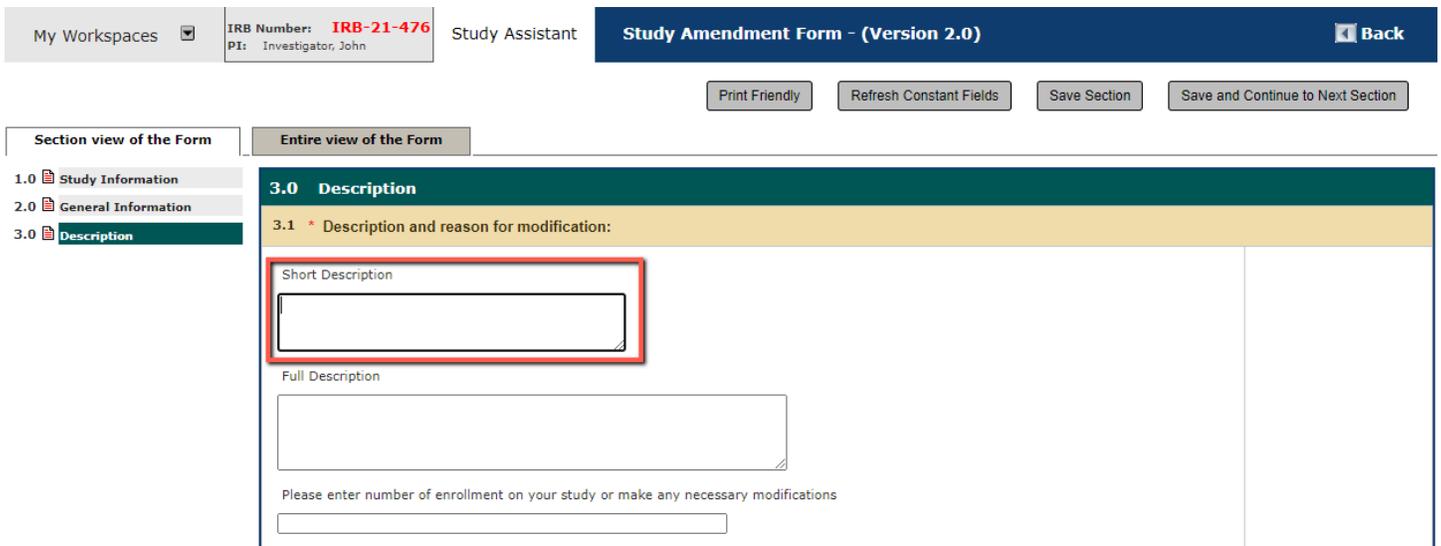
| Study Status: | Active | IRB Number : | IRB-21-476 | Study Title : | Malaria in Juveniles |
|---|---|---|---|---|---|
| | | IRB Expiration Date: | 06/24/2022 | | |

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

ⓘ  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 | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| ☐ | | 📖 | ⓘ | 📄 | 📋 | 🔵 In Process | ↩ Retract | 06/25/2021 10:57:05 AM PDT | 06/25/2021 | 1 | 1111112 | John Investigator | 06/25/20 |

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** PI: Investigator, John | Study Assistant | **My Studies** | | ◀ **Back** |
|---|---|---|---|---|---|

Display my studies by:          Filter my studies by study status:          Find by IRB Number: [_____] ➔ Find
[IRB Number ▼]          ○ All [▼]          Find by Study Alias: [_____] ➔ Find
                        ● Most Recently Used:

[Save a Copy of the selected form]

| Click to open | Study Status | IRB Number | IRB Expiration | Principal Investigator | Study Title/ Study Alias |
|---|---|---|---|---|---|
| ☐ | 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*<br>NIH - FD - 0001 |
| ☐ | Open | IRB-19-180 | 07/29/2021 | Investigator, John | *Use of stem cells on subjects currently being treated for Diabetes Type 2*<br>USCSD -13323 |
| ☐ | Active | IRB-20-336 | 07/14/2021 | Smith, Betty | *Serum Metal Ion Concentration after Insertion of Pediatric Flexible Nail*<br>Serum Metal Ion Concentration after Insertion of Pediatric Flexible Nail |
| ☐ | Draft | IRB-21-473 | | Investigator, John | *Malaria in Juveniles*<br>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:

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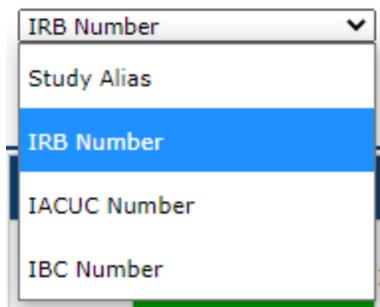
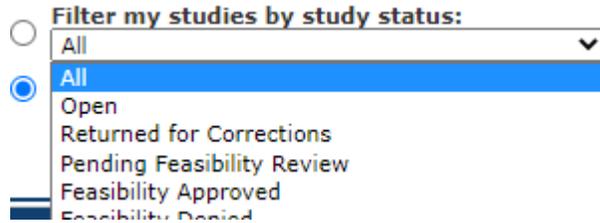- **Filter my studies by study status** – This drop-down will allow the user to filter by different search criteria as seen below in the example system setup. Again, your drop-down options may differ depending on your system configuration.



- **Most Recently Used** – This will filter the studies so the most recently used fomrs 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**.



**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.
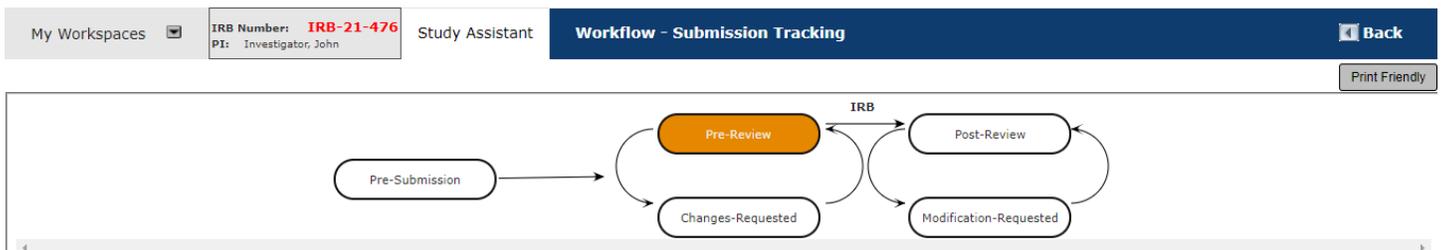


Any steps that are still in process will be displayed and highlighted in a particular color. In this example, the form is located in the orange step. Details are displayed at the bottom of the Workflow detail diagram.

| My Workspaces ▾ | IRB Number: **IRB-21-476** <br> PI: Investigator, John | Study Assistant | **Workflow – Submission Tracking** | ◀ Back |

Print Friendly

IRB

Pre-Submission → Pre-Review → Post-Review

Changes-Requested → Modification-Requested

| 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 10:57 AM PDT | **0** Day(s) **0** Hour(s) **0** Minute(s) |
| 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<br>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<br>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<br>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<br>0  0  0 |
| ⊟ **IRB** | Submission Components / Review Process / Review Outcome / Outcome Letters<br>View Details — Not Assigned | | 06/25/2021 10:57 AM PDT | | **0** Day(s) **0** Hour(s) **6** Minute(s) |
| Received | | IRB received the submission | 06/25/2021 10:57 AM PDT | | Day Hour Minutes<br>0  0  6 |
| Received | | Jane Coordinator has been assigned as the analyst | 06/25/2021 10:57 AM PDT | | Day Hour Minutes<br>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 |
|---|---|---|---|---|---|
| ⊟ **Pre-Submission** | | Retract Submission | 06/25/2021 10:56 AM PDT | 06/25/2021 10:57 AM PDT | **0** Day(s) **0** Hour(s) **0** Minute(s) |
| 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<br>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<br>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<br>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<br>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

| | **Include in PDF Packet** ☑ | **Compare to Last Approved** | **View in Separate Window** | **Submission Component Name** |
|---|---|---|---|---|
| **Submission Form(s):** | | | | |
| | **Submission Form(s)** | | | |
| | ☐ | | ↗ | **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** [View Details] | **Review Process** Not Assigned | **Review Outcome** | **Outcome Letters** | 06/25/2021 10:57 AM PDT | | **0 Day(s) 0 Hour(s) 6 Minute(s)** |
|---|---|---|---|---|---|---|---|
| Received | | IRB received the submission | | | 06/25/2021 10:57 AM PDT | | Day Hour Minutes<br>0   0   6 |
| Received | | Jane Coordinator has been assigned as the analyst | | | 06/25/2021 10:57 AM PDT | | Day Hour Minutes<br>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.
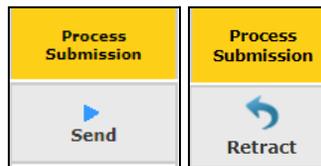


If the form has been filled out but not yet submitted into the workflow, a **Send** button will populate in the column, allowing you to send the form without opening it. If the form has been submitted into the workflow but has not been processed by the review board, a **Retract** button will populate 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.



*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.

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.



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

| | 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| ☐ | | ✎ | ⓘ | ⮊ | 📖 | | | | 06/28/2021 | 2 | 1211112 | John Investigator | 06/25/2021 10:58:35 AM |
| ☐ | | 📖 | ⓘ | ⮊ | 📖 | 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.

| | 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| ☐ | | 📖 | ⓘ | ⮊ | 📖 | ✓ | | 06/25/2021 02:06:23 PM PDT | 06/25/2021 | 3 | 1111112 | John Investigator | 06/25/2021 12:23:1 |
| ☐ | 📁 | 📖 | ⓘ | ⮊ | 📖 | ✓ | | 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**<br>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
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 |
|---|---|---|---|---|
| | **Submission Form(s)** | | | |
| | ☐ | | ↗ | **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** PI: Investigator, John | 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 | | | | Submissions History |
|---|---|---|---|---|
| ● Study Application | | | | ● Study Correspondence |
| ● Informed Consents ▸ | | | | |
| ● Other Study Documents ▸ | | | | |
| ● Contract Documents | | | | |

| 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** PI: Investigator, John | 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 | | | | | | | |
| | | | 🔄 | 📄 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** PI: Investigator, John | 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 | | | | | | | |
| | | | ✓ | 📄 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.

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.
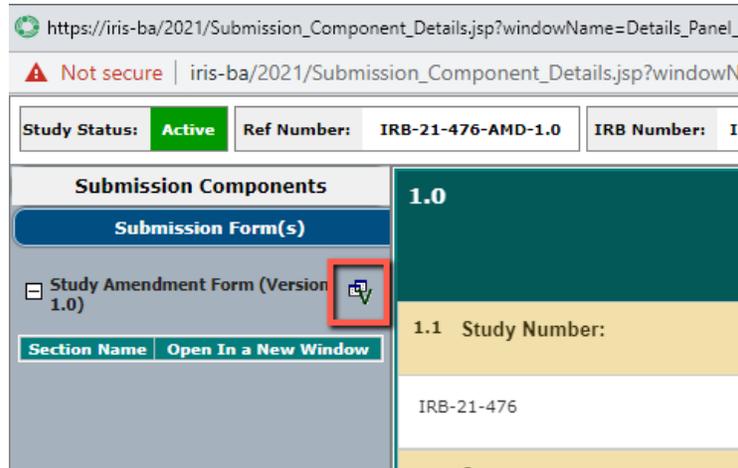
## Study Correspondence

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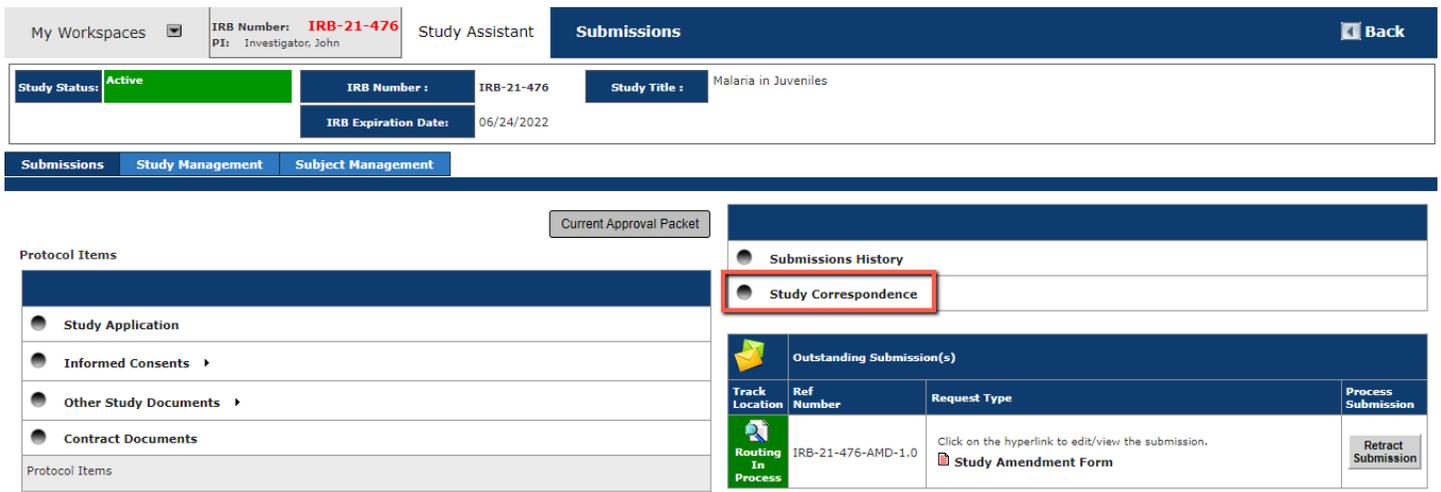


Clicking this link will open a page containing a list of any study-related correspondence that has been sent out at any point during the life of the study. The system will send out automatic notifications at certain points – "Principal Investigator signoff" notifications, "Review Response requested by 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**<br>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 ]

6 result(s) found...

| ☑ | View Message | Author | Subject |
|---|---|---|---|
| ☐ | 📨 | Post a Reply to this Topic / Forward this Topic | |
| | ✎ | John Smith | Posted: 06/25/2021 08:09 AM PDT |
| | | | Malaria in Juveniles<br>NOTICE OF PREREVIEW ADMINISTRATIVE ASSIGNMENT |
| ☐ | 📨 | Post a Reply to this Topic / Forward this Topic | |
| | ✎ | John Investigator | Posted: 06/25/2021 08:09 AM PDT |
| | | | Malaria in Juveniles<br>Study Notification for Signoff Removal |
| ☐ | 📨 | Post a Reply to this Topic / Forward this Topic | |
| | ✎ | John Smith | Posted: 06/25/2021 03:34 AM PDT |
| | | | Malaria in Juveniles<br>Study Notification Reminder for Review and Signoff |
| ☐ | 📨 | Post a Reply to this Topic / Forward this Topic | |
| | ✎ | John Investigator | Posted: 06/24/2021 03:39 PM PDT |
| | | | Malaria in Juveniles<br>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.

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)



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** | | ☑ | |
| | Principal Investigator | ☐ | Investigator, John |
| | Additional Principal Investigator | ☐ | Coordinator, Sean |
| | Co-Investigator | ☐ | Jefferson, Tom |
| | Nurse | ☐ | Jefferson, George |
| | | ☐ | Mossman, Nathan |
| | Study Author | ☐ | Investigator, John |
| | Contact | ☐ | Smith, Betty |
| | Department Administrator | ☐ | Sykes, Jeff |
| **IRB Adverse Event** | | ☑ | |
| | Coordinator | ☐ | Coordinator, OSF |
| | | ☐ | Ramirez, Yvette |
| | | ☐ | Smith, John |
| | | ☐ | Stewart, Andrew |
| **IRB Committee 1** | | ☑ | |
| | Coordinator | ☐ | Analyst, John |
| | | ☐ | Carmichael, Bob |
| | | ☐ | Coordinator, Jane |
| | | ☐ | Coordinator, Jillian |
| | | ☐ | Coordinator, OSF |
| | | ☐ | Ramirez, Yvette |
| | | ☐ | 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 |
|---|---|---|---|---|

| ☑ | 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 |
|---|---|---|---|---|

| ☑ | Name | E-mail Address |
|---|---|---|
| ☐ | Jeff Carlisle | jcarlisle@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.



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.



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.

## 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**.



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.



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



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).



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.



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.



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.

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



button to select the priority using the accompanying menu.
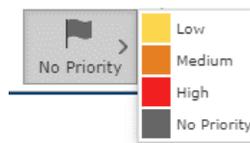


Users can also set the **Complete By** date for a task. This will place an event on the system calendar that will link the user to the task.

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**<br>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**<br>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    ⑦

**1.2 DATE**

06/25/2021

**1.3 Status of project**

☑ Continuing
☐ Completed (Closure)
☐ 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.

| My Workspaces ▾ | IRB Number: **IRB-19-135**<br>PI: Investigator, John | Study Assistant | **Continuing Review Submission Form - (Version 1.0)** | ◀ **Back** |

Print Friendly 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

## Form has been Completed!
Grant Key Personnel access to the study

Signoff and Submit

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**.

Signoff and Submit

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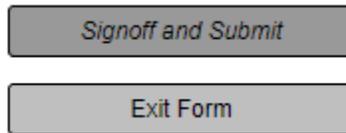
If you are the Principal Investigator, or the form does not require a PI signoff, the **Notify PI to Signoff** button will be replaced with **Signoff and Submit**.

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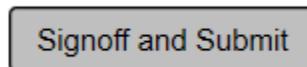
If your role on the study does not allow submission of forms, when you reach this page, you will only have the **Exit Form** button option. You will exit the form, and the Principal Investigator and Study Contact will be notified that a submission is waiting to be sent.

Exit Form

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.



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 |
|:---:|:---:|---|---|
| ☑ | | 👤ⁱ 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.

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.



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**.



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.



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.



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.



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.

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.



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.



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.

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 ▾ | **IRB Number:** **IRB-21-476**<br>**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...

| ☑ | View Message | Author | Subject |
|---|---|---|---|
| ☐ | ↩ | | Post a Reply to this Topic / Forward this Topic |
| | ✎ | John Smith | Posted: Delivery in Progress |
| | | | Malaria in Juveniles<br>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.
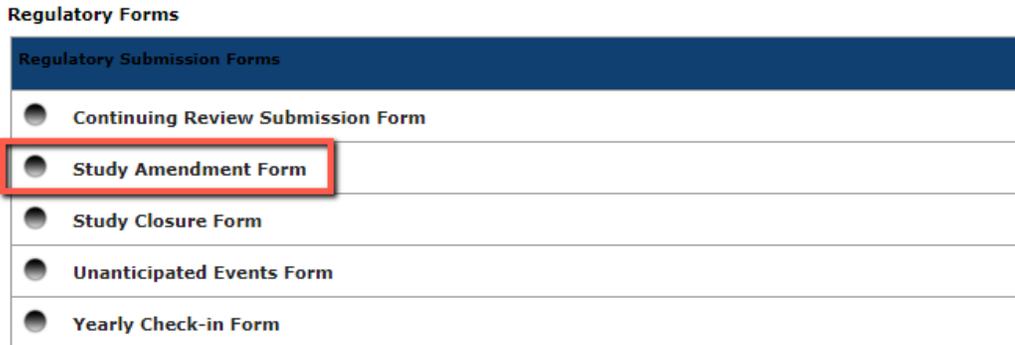


When you click on the **Study Amendment Form** link, you will be directed to a page that lists all Amendments that have been created for this study. The components of this page are discussed in the "Submissions Forms" section of this document.



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.

## 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.
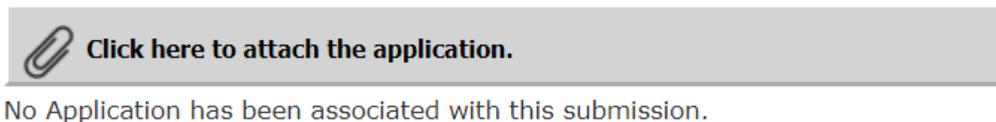


Once you click the link a window will open within your browser and the current version of the Study Application will be displayed.

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.



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.



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.



## 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.

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.

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.

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



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.

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



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.

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.

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.

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**.

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.



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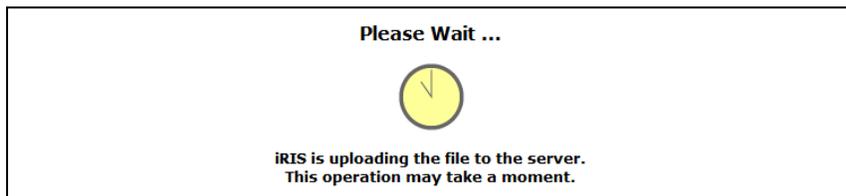


You will then be returned to the Study Consent Revision window with the document successfully checked in and associated to the study. Click the **Save Consent** button to apply the changes.

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



## 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.



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.



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.



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
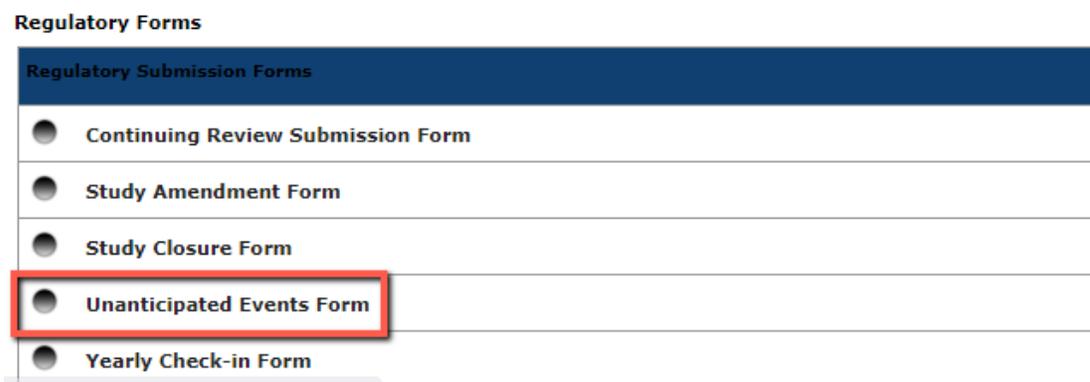


You may also start an Adverse Event Form from the Study Workspace by clicking on **Start a Submission Form for one of My Studies** as shown below.
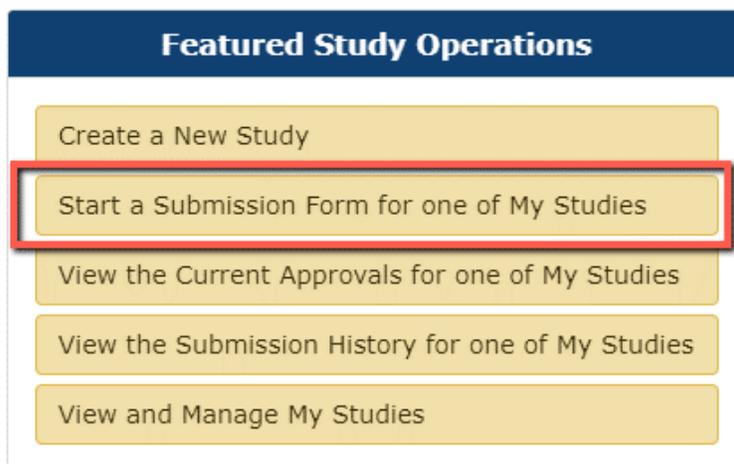


When you click on the **Unanticipated Events Form** link, you will be directed to a page that lists all Adverse Events that have been created for this study.

| My Workspaces ▼ | IRB Number: **IRB-21-477**<br>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) ]

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

1  result(s) found...

| ☑ | Show<br>Rev | Show<br>Follow-<br>Up | Edit/<br>View | Details | Apply<br>to<br>Multiple | Sub.<br>Rounds | Track<br>Location | Process<br>Submission | Submission<br>Date | AE Report Type | Subject ID | AE Category | AE Attribution | AE |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| ☐ | | | ✎ | | 📰 | 📇 | | | | 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**<br>PI: Investigator, John | Study Assistant | **Subject Selection List** | ◀ **Back** |
|---|---|---|---|---|

[ Save Selected Subject ]

Please select the subject this Form is associated with:

| Select | On Study<br>Status | (MRN)<br>Last, First MI | Participant Number | Sex | Register Date | Date of Birth | Survival Status | Off Study Details |
|---|---|---|---|---|---|---|---|---|
| ○ | **Eligible** | Smith, John(554686) | | M | | | Alive | |
| ○ | **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.

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
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** PI: Investigator, John | 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 |
|---|---|---|---|---|---|---|---|---|---|---|
| ○ | 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.



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.
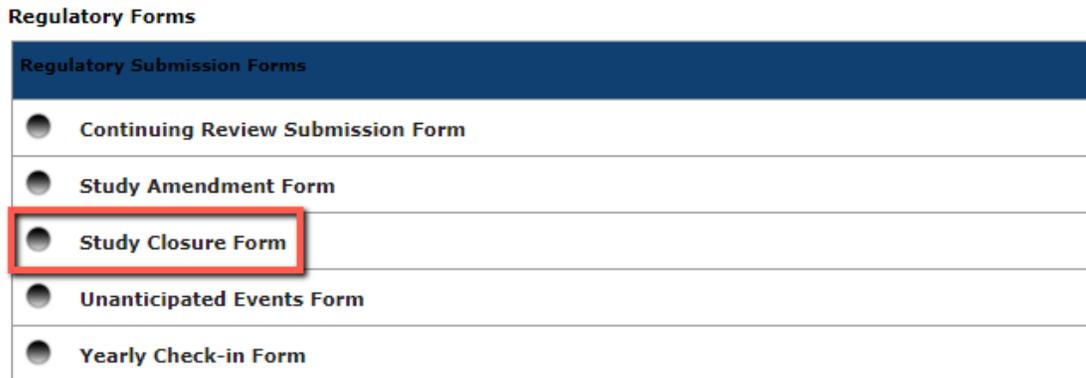


## Signoff

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.
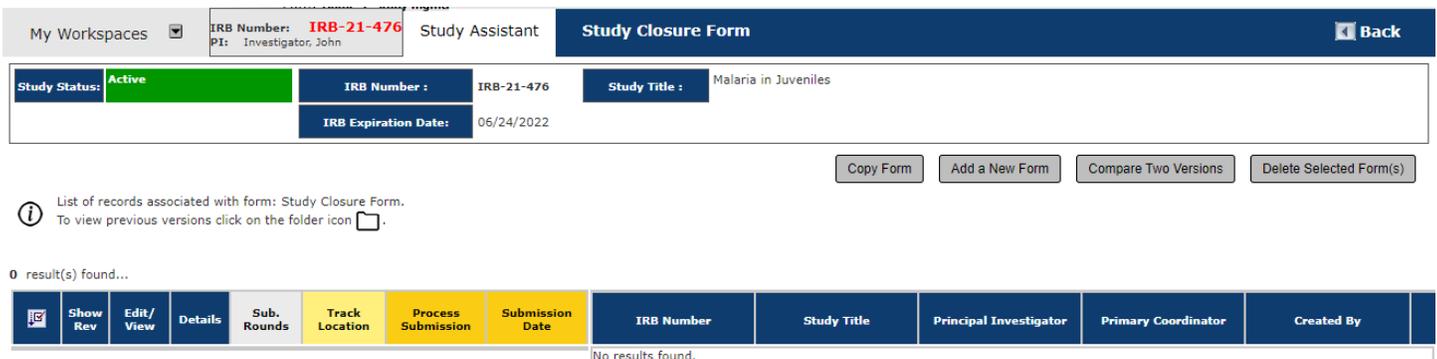
# Submitting a Study Closure Form

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™.
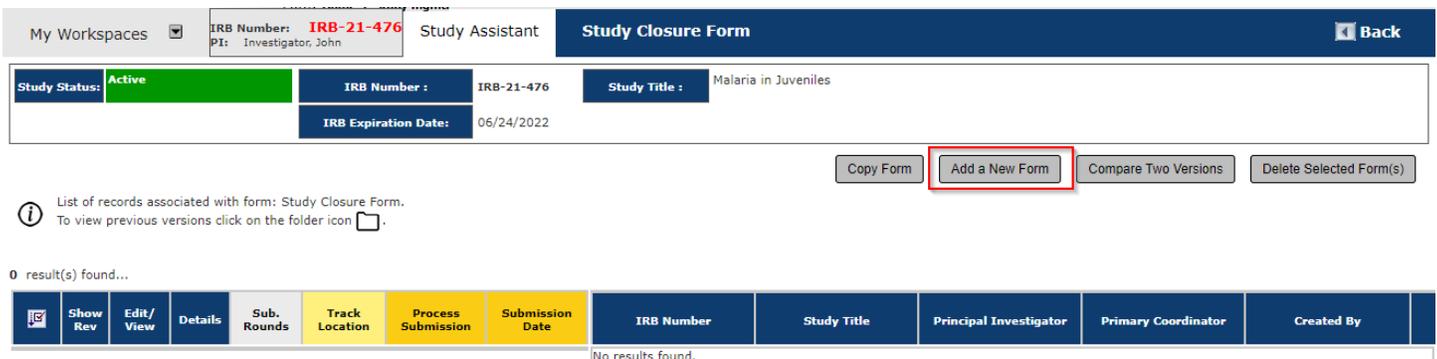
## Accessing the Form

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.

**Regulatory Forms**

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

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.

| My Workspaces ▼ | IRB Number: **IRB-21-476**<br>PI: Investigator, John | Study Assistant | **Study Closure 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 Closure Form.
To view previous versions click on the folder icon 📁.

0 result(s) found...

| ☑ | Show Rev | Edit/ View | Details | Sub. Rounds | Track Location | Process Submission | Submission Date | IRB Number | Study Title | Principal Investigator | Primary Coordinator | Created By |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | No results found. | | | | |

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

| My Workspaces ▼ | IRB Number: **IRB-21-476**<br>PI: Investigator, John | Study Assistant | **Study Closure 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 Closure Form.
To view previous versions click on the folder icon 📁.

0 result(s) found...

| ☑ | Show Rev | Edit/ View | Details | Sub. Rounds | Track Location | Process Submission | Submission Date | IRB Number | Study Title | Principal Investigator | Primary Coordinator | Created By |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | No results found. | | | | |

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.



## 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.

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

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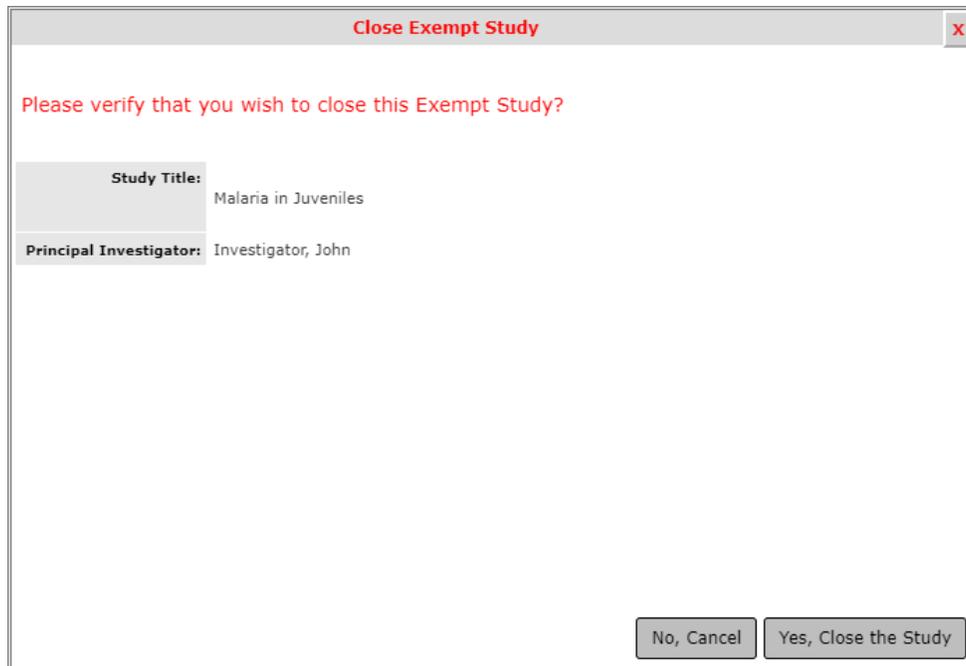


If the user does not have access to close this study, the following error message will display.

| **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 ]