



STUDY ASSISTANT

Study Management: Submissions

Software Version: 12.01

Manual Version: P-1

Manual Published: 12/08/2020

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Study Management

Introduction

Within the study record, the study is broken up into sections, Submissions, Study Management, and if using the Subject Management module, you will also have Subject Management. These tabs allow you to access different portions of the study, so you can maintain study information in the system. The Submissions tab allows you to access any forms that you need to submit for review. You can also access and manage Informed Consents and Other Study Documents, review past submission forms and review or generate study-related correspondence.

This manual will guide you through the process of accessing submission forms and submitting them as needed, accessing forms and revising them as needed and will also review accessing previous submissions, for updates on current processes.

Accessing a Study

To locate your study, open the View My Studies menu item found under Study Assistant.

The page that opens will display the studies you have a role on, along with basic information about each study. Use the filters to narrow the list to the study you need to open. iRIS will default this screen to show the most recently used study at the top of the list. You can use the search criteria at the top of the page to locate the study you are looking for.

Once you have located the study in the list, click the Open icon.

All Studies		Recently Used	Study Status	Change Filter	Search for RB Number, Title, Alias	Search	Settings
All	Draft	IRB	GateKeeper				
59 result(s) found... 1 - 10 ▶							
Click to open Study Dashboard	Study Status	Review Board	RB Number	RB Expiration	Study Title Alias	Principal Investigator	Actions
	Draft				<i>Effects of dopamine and antihistamine medication on smokers</i> SA	admin, Admin Admin, R.N. Brig. Gen.	History Items Forms Hide Copy Delete Corr
	Active	IRB	IRB-18-2383		<i>Study on Caffeine and its effects on physical performance</i> 5310	Ack, Abby, MSN Ph.D.	History Items Forms Hide Close Exempt Copy Delete Corr
	Pending - Submitted for Initial Review	IRB	IRB-19-5491		<i>Medical History - Abuse of alcohol and effects of pain medication -Advil</i> 725-5	Pope, Ann , B.S.	History Items Forms Hide Copy Delete Corr

Submissions

When you open a study, the page will open to the Submissions tab. This tab contains links to various forms that can be created, completed and submitted throughout the lifetime of the study. The top of the page lists a header with study-specific details. 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

Submission History, which will list out all forms submitted for review on the study. Also listed is a link to Study Correspondence and an area for Outstanding Submissions.

The screenshot shows the top navigation bar with 'My Workspaces', 'IRB Number: IRB-19-5430', 'Alias: sun exposure', 'PI: Anderson, Douglas Stuart, Dr.', 'Study Assistant', and 'Submissions'. Below this is a sub-header with 'Study Status: Pending - Submitted for Initial Review', 'IRB Number: IRB-19-5430', and 'Study Title: Effects of sun exposure in water and out of water'. The main content area is divided into 'Protocol Items' on the left and 'Submissions History' and 'Outstanding Submission(s)' on the right. The 'Outstanding Submission(s)' table shows one entry with 'Ref Number: 021477' and 'Request Type: Initial Review Submission Form Real'.

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 in, as displayed in the image below.

This close-up shows the header information: 'My Workspaces', 'IRB Number: IRB-19-5430', 'Alias: sun exposure', 'PI: Anderson, Douglas Stuart, Dr.', 'Study Assistant', 'Submissions', and a 'Back' button. Below this is a row with 'Study Status: Pending - Submitted for Initial Review', 'IRB Number: IRB-19-5430', and 'Study Title: Effects of sun exposure in water and out of water'.

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

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

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

Protocol Items

Within the Submissions tab, the first group on the page is called Protocol Items. Within this group is a link to the Study Application, Informed Consent, and Other Study Documents. This area allows you to view and revise the Study Application, view, revise and add Informed Consents, Other Study Documents and Contract Documents.

The screenshot shows the 'Protocol Items' section with a list of items: 'Study Application', 'Informed Consent', 'Other Study Documents', and 'Contract Documents'. Each item has a radio button and a right-pointing arrow.

Study Application

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

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

From here, you can view the current application and make edits, if the current version has not 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.

The screenshot shows the 'Study Application' page for IRB-19-5430. The study title is 'Effects of sun exposure in water and out of water'. The status is 'Pending - Submitted for Initial Review'. A table lists one application: 'MAIN IRB APP 6 (Version 1.1)' with a status of 'No' for approval, created by 'Abby Ack' on 07-29-2019 12:00. The 'Show Rev.' column contains a folder icon.

IRB Number	Alias	PI	Study Assistant	Study Application	Back				
IRB-19-5430	sun exposure	Anderson, Douglas Stuart, Dr.	Study Assistant	Study Application	Back				
Study Status: Pending - Submitted for Initial Review									
IRB Number :		IRB-19-5430		Study Title : Effects of sun exposure in water and out of water					
1 result(s) found...									
IRB Number	Alias	PI	Study Assistant	Study Application	Back				
Show Rev.	Edit/View	Application Type	Approved?	Approval Date	Created By	Date Created	Modified by	Date Modified	Create a Revised Application
		MAIN IRB APP 6 (Version 1.1)	No		Abby Ack	07-29-2019 12:00	Abby Ack	07-29-2019 12:01	

Compare Tool

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

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

The screenshot shows the 'Study Application' page with two versions of 'MAIN IRB APP 6'. The first is Version 1.1 (created 07-29-2019 12:00) and the second is Version 1.0 (created 07-22-2019 12:06). The 'Show Rev.' column for Version 1.1 contains a folder icon. The 'Compare Two Selected Versions' button is highlighted with a red box.

IRB Number	Alias	PI	Study Assistant	Study Application	Back				
IRB-19-5430	sun exposure	Anderson, Douglas Stuart, Dr.	Study Assistant	Study Application	Back				
Study Status: Pending - Submitted for Initial Review									
IRB Number :		IRB-19-5430		Study Title : Effects of sun exposure in water and out of water					
1 result(s) found...									
IRB Number	Alias	PI	Study Assistant	Study Application	Back				
Show Rev.	Edit/View	Application Type	Approved?	Approval Date	Created By	Date Created	Modified by	Date Modified	Create a Revised Application
		MAIN IRB APP 6 (Version 1.1)	No		Abby Ack	07-29-2019 12:00	Abby Ack	07-29-2019 12:01	
		MAIN IRB APP 6 (Version 1.0)	No		Admin Admin admin	07-22-2019 12:06	Abby Ack	07-29-2019 11:51	

iRIS will run the two versions of the application through a comparer tool. This may take several moments, depending on the size of your Study Application. When the tool 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 you sections within the form that have changed, so if your Study Application is fifteen sections long, but there are only differences found in four sections, only those four sections will display in the comparer view.

You can highlight sections by clicking on the section and highlight them in yellow.

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

Version: 1.0 Abby Ack		MAIN IRB APP 6		Version: 1.1 Abby Ack	
1.1 -	Section 1 - General Information 1.1 - Please enter the full title of your protocol: Effects of sun exposure in water and out of water	Section 1 - General Information 1.1 - Please enter the full title of your protocol: Effects of sun exposure in water and out of water	-	Section 1 - General Information 1.1 - Please enter the full title of your protocol: Effects of sun exposure in water and out of water	- examine effect of melanin levels in skin
1.3 -	Section 1 - General Information 1.3 - Please identify the Study Phase? --none--	Section 1 - General Information 1.3 - Please identify the Study Phase? --none--		Section 1 - General Information 1.3 - Please identify the Study Phase? --none--	
1.5 -	Section 1 - General Information 1.5 - Please identify the Research Type? --none--	Section 1 - General Information 1.5 - Please identify the Research Type? --none--		Section 1 - General Information 1.5 - Please identify the Research Type? --none--	Research Type 1
1.6 -	Section 1 - General Information 1.6 - Please identify the Study Classification? --none--	Section 1 - General Information 1.6 - Please identify the Study Classification? --none--		Section 1 - General Information 1.6 - Please identify the Study Classification? --none--	Dermatology
1.8 -	Section 1 - General Information 1.8 - Is this Study using Subject Management? No	Section 1 - General Information 1.8 - Is this Study using Subject Management? No		Section 1 - General Information 1.8 - Is this Study using Subject Management? No	Yes
3.1 -	Section 3 - Give people access the study 3.1 - Please Add a Principal Investigator For The Study: Douglas Stuart Anderson, Dr.	Section 3 - Give people access the study 3.1 - Please Add a Principal Investigator For The Study: Douglas Stuart Anderson, Dr.		Section 3 - Give people access the study 3.1 - Please Add a Principal Investigator For The Study: Douglas Stuart Anderson, Dr.	

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 but because it has been submitted you cannot modify it. If you do need to make changes to the application, click the icon in the **Create a Revised Application** button.

Note: The Revise Application icon will only be available for the most current approved version of the application. The option will only be available to create just one Revised Application

When you create a revision, iRIS will increment the form to the next available number. In this case, it is 1.2. Then, the editable version of the application will 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. You will need to submit an Amendment form to the review board for approval of any change in Key Personnel.

Also, note: 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 associate 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, which is covered later in this document.

Any revision you create will be listed in the table. Because the form was revised, but it has not yet been reviewed by the review board, the information in the **Approved** and **Approval Date** (as highlighted in the image below) columns do not reflect that the current version of the application is approved.

My Workspaces IRB Number: **IRB-19-5430** Study Assistant **Study Application** Back

Alias: sun exposure
PI: Anderson, Douglas Stuart, Dr.

Study Status: **Pending - Submitted for Initial Review** IRB Number: IRB-19-5430 Study Title: Effects of sun exposure in water and out of water

Add a New Application Type Compare Two Selected Versions Delete Selected Version

1 result(s) found...

<input type="checkbox"/>	Show Rev.	Edit/View	Application Type	Approved?	Approval Date	Created By	Date Created	Modified by	Date Modified	Create a Revised Application
<input type="checkbox"/>			MAIN IRB APP 6 (Version 1.1)	No		Abby Ack	07-29-2019 12:00	Abby Ack	07-29-2019 12:03	
<input type="checkbox"/>			MAIN IRB APP 6 (Version 1.0)	Yes	07/29/2019	Admin Admin admin	07-22-2019 12:06	Abby Ack	07-29-2019 11:51	

Delete Application

A version of the Study Application can only be deleted if you have not submitted that version. In the example above, version 1.0 has been submitted however, 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 and if you click **Confirm**, the version of the application will be deleted from the study.

It is advised that you do not delete an application because you will not be able to restore that version of the application.

Also, if the only version of the application is version 1.0 and you delete it, you will delete your entire application from the study and will need to add a new one.

Add Application

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

My Workspaces IRB Number: **IRB-2017-2040** Study Assistant **Study Application** Back

Alias: Amendment
PI: Hayes, Amber

Study Status: **Draft** IRB Number: IRB-2017-2040 Study Title: Amending to add a key personnel

Add a New Application Type Add a new Application

0 result(s) found...

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

Informed Consent

The Informed Consent link, from the main Submission screen, will direct you to the 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 for consent documents that have been uploaded to the study. If you click a link in the menu, the Informed Consent library will open to display only documents in the selected category.

Protocol Items

- Study Application
- Informed Consent ▶ Study Consent Category I
- Other Study Documents ▶
- Contract Documents

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

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.

My Workspaces

IRB Number: **IRB-19-5430**
 Alias: sun exposure
 PI: Anderson, Douglas Stuart, Dr.

Study Assistant
Informed Consent Document
Back

Study Status: Pending - Submitted for Initial Review
IRB Number: IRB-19-5430
Study Title: Effects of sun exposure in water and out of water

Search Level: Top All

Select Category: All

Version #: -

Approval Date: between

Show Hidden: Yes No

Title:

Consent Outcome: All

Expiration Date: between

Filter Documents

Export
Print Friendly
Compare Consent versions
Add a New Consent
Delete Selected Consent(s) ?

Informed consent revision history list associated with this study.
 To create a new version, click on the Add Revision icon to the right of the consent form.
 To view previous versions click on the folder icon.

1 result(s) found...

View History	Edit/View	Title/Category	Version	Sponsor Version	Language	UnApproved Consent	Approved Consent	Consent Outcome	Approval Date	Expiration Date	Checked Out By	Create a Revised Document	Hide
		IRB - Review Board Consent Template	1.0		English								

Filters

At the top of the page, you can use several filters to display specific consent forms on the study.

Search Level –The default selection for this filter is set to “Top”. This means when you use the search filters, the system will check only the top level, or latest version, of a document. If a document has revisions, only the latest version will be included in the search. If you would like to search all versions of a document set the selection to “All”.

Show Hidden – The default selection for this filter is set to “No”. This means that all the documents viewed on the page are only the non-hidden documents. When you select “Yes”, the page will refresh and will display all documents for the study.

Select Category – This provides the ability to choose a Consent Category in the search. 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.

Note: The version number is exact case. If you type in ‘1’ only documents that are version ‘1.x’ will populate on the page.

The screenshot shows the 'Study Assistant' interface with the following elements:

- My Workspaces** (dropdown menu)
- IRB Number:** IRB-19-5430
- Alias:** sun exposure
- PI:** Anderson, Douglas Stuart, Dr.
- Study Assistant** (header)
- Info** (button)
- Study Status:** Pending - Submitted for Initial Review (dropdown menu)
- IRB Number :** IRB-19-5430
- Search Level:** Top All
- Select Category:** All (dropdown menu)
- Version #:** 1 (highlighted with a red box)
- Approval Date:** [] between [] (date range selector)

Approval Date – You can specify a date range for approval dates. You must enter a date into both fields. If you want just one day, put the same day in both date fields.

Consent Outcome – You can select a review board document outcome in this drop-down list.

Expiration Date - You can specify a date range for expiration dates. You must enter a date into both fields. If you want just one day, put the same day in both date fields.

Export

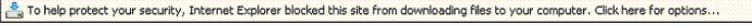
You can export a list of the consent forms to an Excel spreadsheet. Click the **Export** button on the top of the page.

A new page will open, and your Internet browser will download the spreadsheet. Internet Explorer Version 9 is used in this example. Depending on your Internet settings, you may have a blocker installed that prevents you from downloading files without approval. Wait a few moments and the browser may prompt you with a yellow bar at the top, as seen in the image below. Click the yellow bar then select Download File from the menu that appears. Do this before clicking the **Download Complete** button. If you click **Download Complete** before saving the file to your desktop you will lose the spreadsheet and need to click **Export** again.

Study Assistant **Exporting Information into Spreadsheet. Wait for the file to download** Back

INSTRUCTIONS

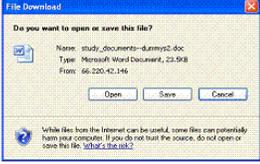
Step 1:
If your browser blocks pop - ups, then after a few moments a bar similar to the one shown below may appear in your browser.

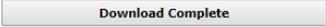


Simply click on the bar and a small drop down list will appear. Click **Download File** from the list of options.



Step 2:
In a few moments, your browser will prompt you to either **Open** or **Save** the file (see example below).
Note: this is not the actual File Download box, it is only a picture. In order to Check - out the document and edit it, you will need to **Save** it to your workstation.






To do so, click **Save**. This will open up a window similar to the one shown below that allows you to choose where in your workstation you would like to save the document.

Once you've selected where you will save the document, click **Save**. After this, the Download Complete box will appear as shown below. From here you can choose to open the document to edit it, open the folder that contains the document, or Close the Download Complete box to edit the document later.

Step 3:
IT IS VERY IMPORTANT that after you've saved the file to your workstation and closed the Download Complete box that you click the **Download Complete** button in iRIS. This allows you to check the document (or upload the document) back into iRIS once you've finished editing it.
To cancel the Document Check - Out, click **Cancel**. Note: If you've already saved the file to your computer, the file will remain in your computer, however you will simply lose the option of checking the document back in.

When you select to download the file a popup window will ask you if you'd like to open or save the document. You can do either, however we recommend that you save the spreadsheet before opening. You will want to make sure you save the document to a location on your computer that you will remember.

Once you save the document to a location on your computer, you need to click on the **Download Complete** button within the browser. If you did not want to check out the document click the **Cancel** button. This will return you to the previous page.



You will return to the Informed Consent library. The spreadsheet you downloaded will display a list of consents with detail related to the columns stored in the consent table. There will be one record for each consent version in the Informed Consent library.

	A	B	C	D	E	F	G	
	CONSENT_ID	TITLE	VERSION_DATE	VERSION_ID	IRB_APPROVAL_DATE	IRB_EXPIRATION_DATE	UNAPPROVED_FILE_NAME	APPR
2	20	ConsentDocument	2014-02-12 00:00:00.0	1			Consent_20.docx	
3	21	ConsentDocument	2014-02-12 00:00:00.0	1	2014-03-01 00:00:00.0	2015-02-28 00:00:00.0	Consent_21.docx	
4								
5								

Print Friendly

You can also view the consents on the page in a printer friendly view, if you would like to print out a list of the consents.

Click the **Print Friendly** button at the top of the page. A new window will open, displaying basic study information, at the top of the page. The page will also list out any consent records on the study, along with basic consent information.

You can click the **Print** button to send this page to your printer or click the **Close** button to close the window.

Note: When you Export a consent form, each version of the consent is displayed. When you choose the Print Friendly view, only the latest version of a consent record will display and not each individual version of a consent record.

<input type="button" value="Print"/> <input type="button" value="Close"/>									
Informed Consent Document									
Study Status:	Pending - Submitted for Initial Review								
Principal Investigator :	Anderson, Douglas Stuart, Dr.								
Study Title:	Effects of sun exposure in water and out of water								
1 result(s) found									
Title/Category	Version	Sponsor Version	Language	UnApproved Consent	Approved Consent	Review Outcome	Approval Date	Expiration Date	Checkout By
IRB - Review Board Consent Template									
Study Consent Category I	1.0		English						
	07/29/2019								

Compare Consent Versions

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

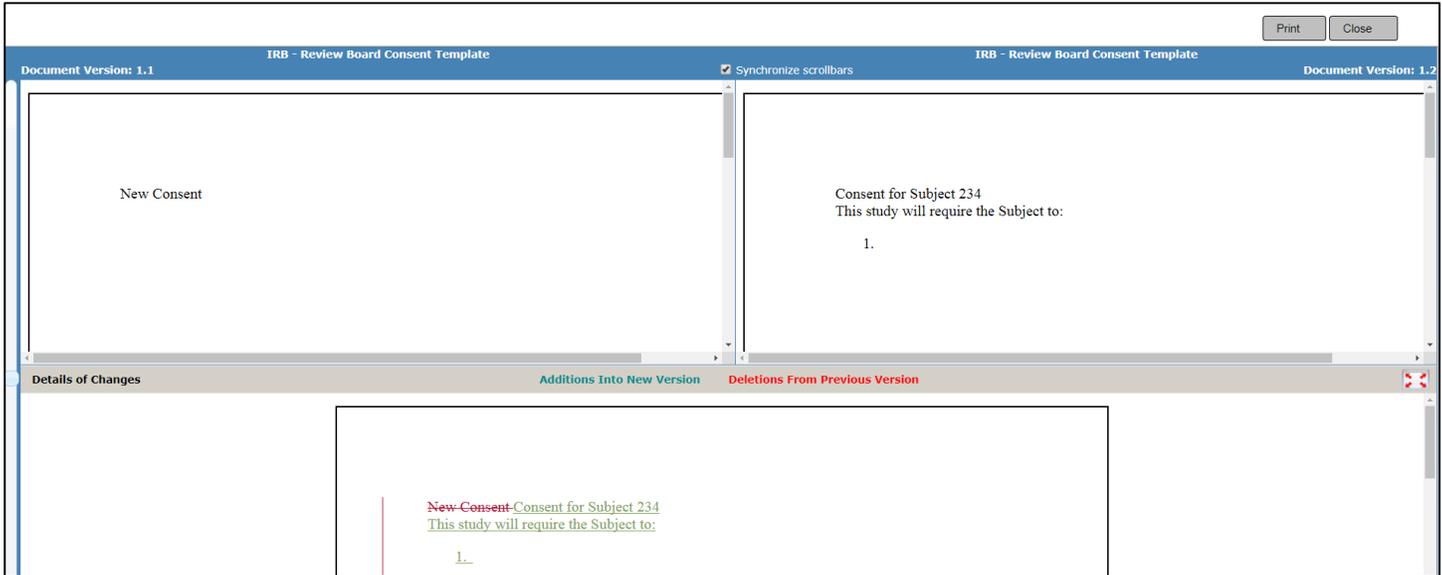
This will allow you to view information related to older versions. You can even view the previous versions’ unapproved consent by clicking on the Word icon in the **UnApproved Consent** column, as seen in the image above.

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.

1 result(s) found...														
<input type="checkbox"/>	View History	Edit/View	Title/Category	Version	Sponsor Version	Language	UnApproved Consent	Approved Consent	Consent Outcome	Approval Date	Expiration Date	Checked Out By	Create a Revised Document	Hide
<input checked="" type="checkbox"/>			IRB - Review Board Consent Template	1.2		English								
			Study Consent Category I	07/29/2019										
<input checked="" type="checkbox"/>			IRB - Review Board Consent Template	1.1		English								
			Study Consent Category I	07/29/2019										
<input type="checkbox"/>			IRB - Review Board Consent Template	1.0		English								
			Study Consent Category I	07/29/2019										

iRIS will run the two versions of the consent through a comparer tool. This may take several moments, depending on the size of your consent documents. When the tool is complete a new window will open displaying both selected versions of the consent in a side-by-side view, with the newer version listed in the left column and the older version listed in the right column. At the bottom of the window a split view will display a combination of both versions, indicating where items have been modified. The screenshot below shows you any differences in the newer version by marking items either Green or Red. 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 in the Informed Consent, click the **Close** button.



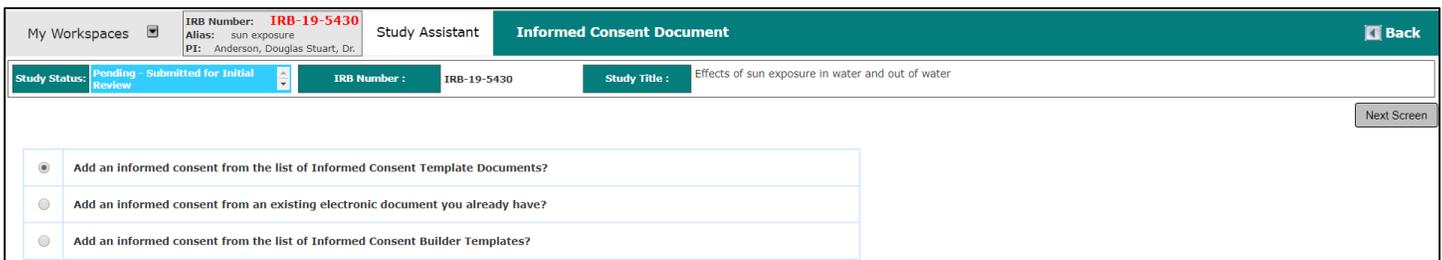
Add a New Consent

You can add a new consent to the study by clicking **Add a New Consent** button.

A new page will open within the window asking for input on how you will upload the Consent document.

Depending on your system settings you may or may not have the same options as described for adding an Informed Consent.

Each possible selection is described below. Choose the appropriate action then click the **Next Screen** button.



1. Add an informed consent from the list of Informed Consent Template Documents?

Review boards may make consent templates available for you to download, modify, and then upload to the study. If you would like to download a copy and use the review board’s consent template, choose this option. Selecting this option will present you with the ability to select the desired template from a dropdown list. Select the template. After selecting the template, you are able to specify additional details.

The screenshot shows the 'Informed Consent Document' form in the iRIS system. At the top, it displays 'My Workspaces', 'IRB Number: IRB-19-5430', 'Study Assistant', and 'Informed Consent Document'. Below this, there are tabs for 'Study Status: Pending - Submitted for Initial Review', 'IRB Number: IRB-19-5430', and 'Study Title: Effects of sun exposure in water and out of water'. A 'Save Consent' button is located in the top right corner. The main form area contains several fields:

- * Please select the Consent Template:** A dropdown menu currently set to '--none--'.
- Provide the Consent Title if different from the template name:** A text input field.
- *Version Date:** A date input field with a calendar icon.
- Category:** A dropdown menu currently set to '--none--'.
- Description:** A text area.
- *Version Number:** A text input field containing '1' followed by a hard-coded '.0'.
- Sponsor Version:** A text input field.
- * Language:** A dropdown menu set to 'English'.
- * Reconsent Required:** Radio buttons for 'Yes' and 'No', with 'No' selected.
- Reconsent Reason:** A text area.
- Comments:** A text area.

 An 'Instructions' box on the right side of the form provides the following steps:

- Complete the fields to the left side of the screen then click the **Save Consent** link. This will open the ICD template in your browser so you can review it.
- Download the document to your workstation by clicking the **Download** button at the top right side of the screen. Your browser will then ask if you would like to save or open the file named "ConsentDocument.rtf". Click the **Save** option. This will download the file to your workstation.
- Click the **Complete Checkout** button in your browser window.
- You can now edit this document using any standard word processing program such as MS Word and WordPerfect used on either a MAC or a standard PC. Make sure you save the document to your workstation in .rtf format.
- Check the document into the iRIS system by clicking the **Check in Document** button. Use the **browse** button and find your document. Select your document, then select the **open** button. Select the **ok** button, then when back in the iRIS system, click the **Save Consent** link.

If you would like the name of the consent to appear differently than the given Consent Title, you can type in the name in the **Provide the Consent Title if different from the template name** field.

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

Category – This configurable drop-down list allows you to group documents into certain categories.

Description – A description of the document.

A close-up of the ***Version Number** field. It consists of a text input box containing the number '1', followed by a hard-coded '.0'.

Version Number - Requires you to specify what number you wish this version of the document, to be on. This can be any character or number. After the editable version number is a hard coded '.0'. This is iRIS version number for the Consent document. Any new document you upload to the system will begin with the '.0' affixed to your manually entered version number. Anytime a revision is made to the document through the system, iRIS will change the '.0' to '.1' and will continue to increment the numbers each time a revision is made. This is how the system tracks the number of revisions to the document in iRIS. You will always be able to revise your manually entered version number, but you are unable to revise the iRIS version number.

Language – It is required that you select the Consent language from this dropdown list.

Reconsent Required – Indicate “Yes” if subjects on the study will need to be re-consented.

Reconsent Reason – You can add any re-consent reason to this field.

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

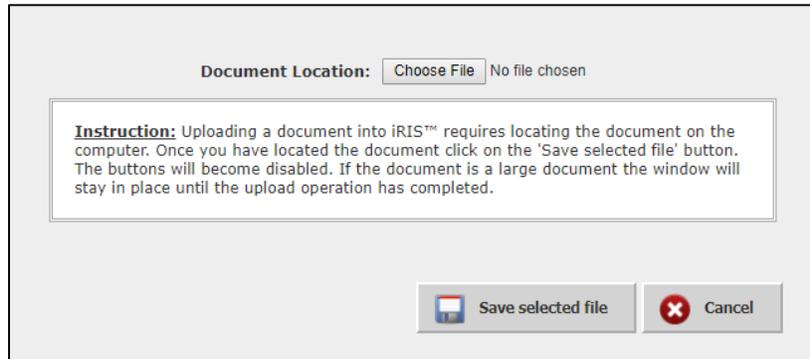
Enter the required information including the document itself then click the **Save Consent** button. The study will update with information regarding the informed consent you chose. The system will wait for you to open the consent form in Microsoft Word, for any edits.

You can also check-out the document. If you click Complete Checkout before saving the file to your desktop you will lose the document and will need to click undo the checkout in order to restore the document.

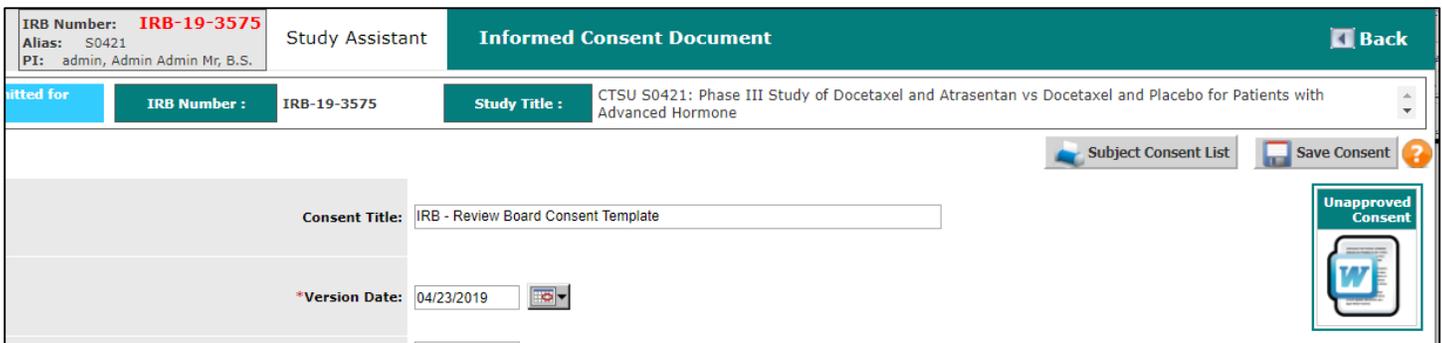
Depending on your Internet Browser, version and settings, you may or may not be prompted with the file download information. The browser asks if you would like to open or save the consent document. **Save** the document and be sure to save the document in a known location. The system will return you to the previous page.

When you are ready to upload the modified consent, return to this page and click the **Check-in Document** button, as seen in the image below.

A small window will open allowing you to upload a 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 so you can locate your Consent document. Once you associated a document, click the **Save selected file** button.



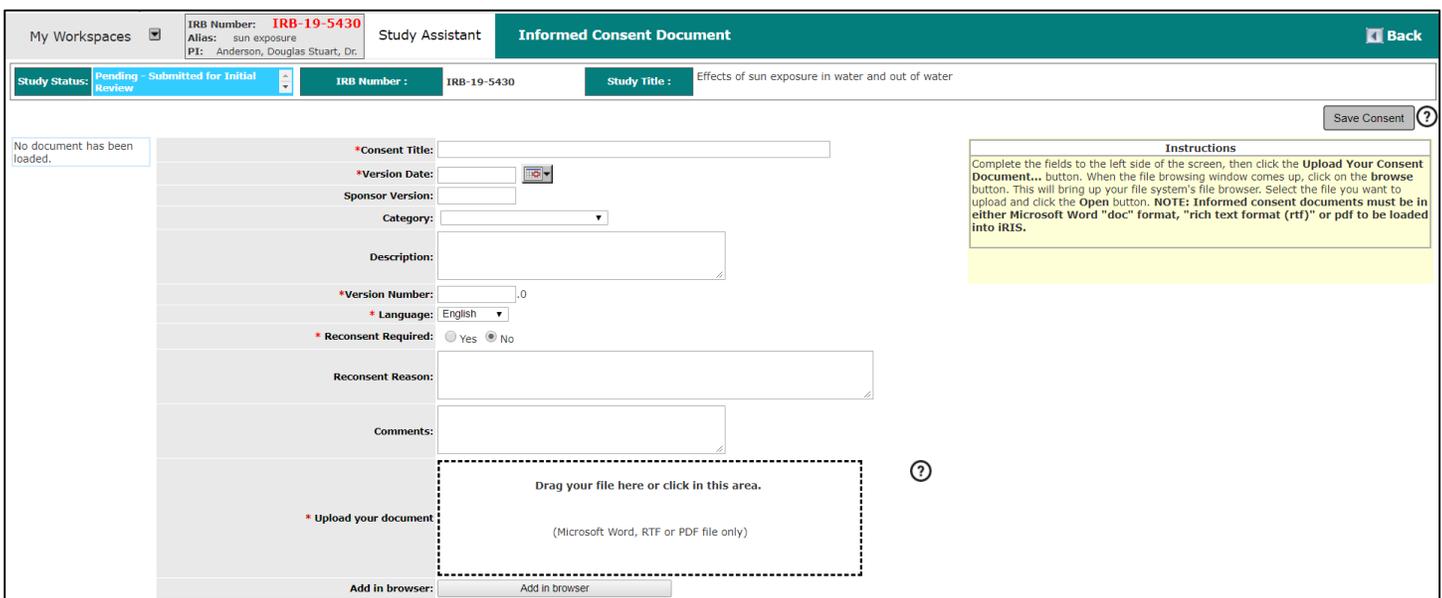
The Consent document will be uploaded to the study and it will appear as an icon next to the consent information, as shown below. Click the **Save Consent** button to create the consent record.



2. Add an informed consent from an existing electronic document you already have?

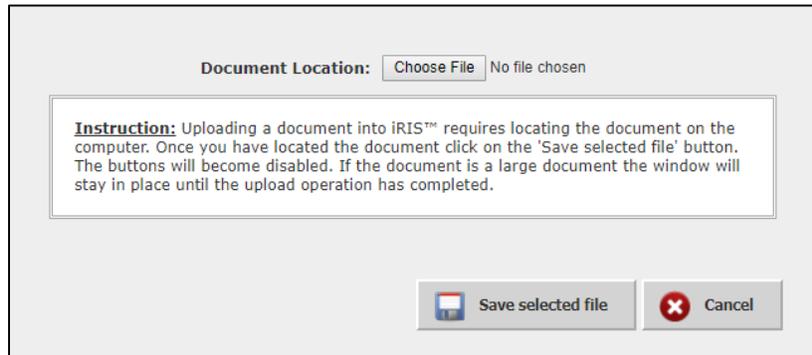
If you already have a consent document ready to upload, choose this option.

A new page will open within the browser. Here you will specify the name of the document in the **Consent Title** field.

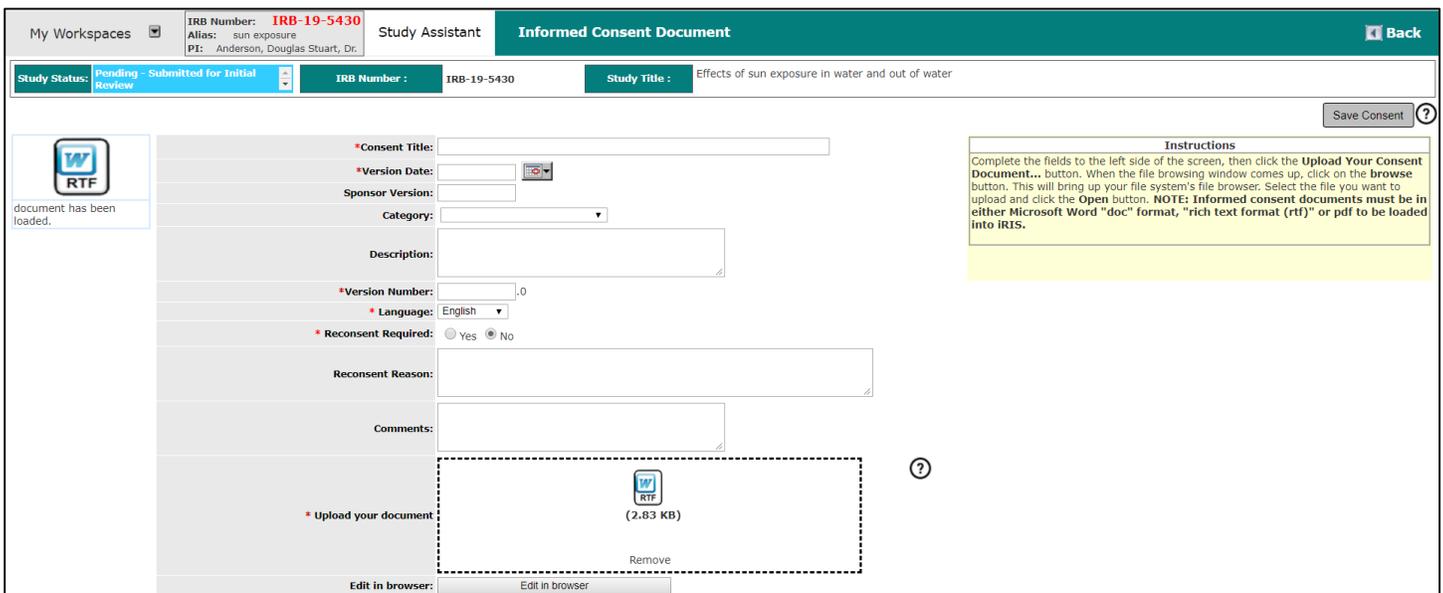


You can enter in the additional consent details. At the bottom of the page you can click the **Upload Your Document** box or you can drag and drop the document into the dotted lined box to upload your consent.

If you click into the box, a small window will open allowing you to upload a 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 so you can locate your Consent document. Once you associated a document, click the **Save selected file** button, as shown in the image below.



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



3. Add an informed consent from the list of Informed Consent Builder Templates?

A consent builder template is a document that has been specifically designed to step you through the process of customizing your consent form. When you select this option, you will be prompted to select the consent builder template from a dropdown list.

Instructions

1. Complete the fields to the left side of the screen then click the **Save Consent** link. This will open the ICD template in your browser so you can review it.
2. Download the document to your workstation by clicking the **Download** button at the top right side of the screen. Your browser will then ask if you would like to save or open the file named "ConsentDocument.rtf". Click the **Save** option. This will download the file to your workstation.
3. Click the **Complete Checkout** button in your browser window.
4. You can now edit this document using any standard word processing program such as MS Word and WordPerfect used on either a MAC or a standard PC. Make sure you save the document to your workstation in .rtf format.
5. Check the document into the IRIS system by clicking the **Check in Document** button. Use the **browse** button and find your document. Select your document, then select the **open** button. Select the **ok** button, then when back in the IRIS system, click the **Save Consent** link.

Once you have selected the template, fill out the fields on the screen as described above, and then click **Save Consent**. A screen will open with a preview of the template. Click **Download** to continue.

A new page will open, and your Internet browser will download the consent document. Depending on your Internet settings, you may have a blocker installed that prevents you from downloading files without approval.

Depending on your browser, version, and settings, you may or may not be prompted with the file download information. The browser asks if you would like to open or save the consent document.

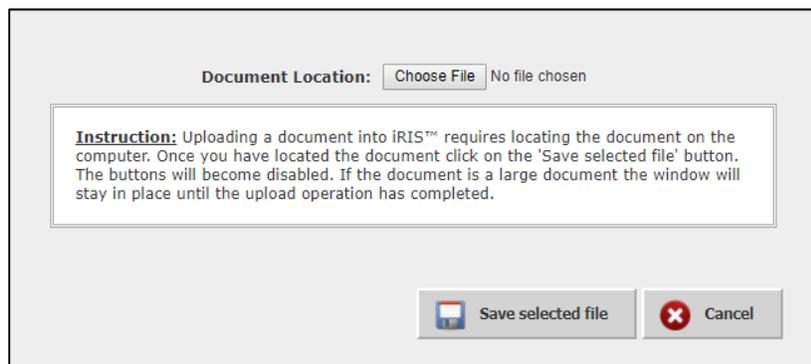
It is best to choose to **Save** the document, so you can be sure to save the document in a known location.

The system will return you to the previous page.

The study will update with information regarding the informed consent you chose. The system will wait for you to open the consent form in Microsoft Word, for any edits.

When you are ready to upload the modified consent, return to this page and click the **Check-in Document** button.

A small window will open, allowing you to upload a 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 so you can locate your Consent document. Once you associated a document, click the **Save selected file** button.



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

Informed Consent Document
← Back

430 **Study Title :** Effects of sun exposure in water and out of water

Consent Title:

***Version Date:**

Sponsor Version:

Unapproved Consent

Any consent record you add will be displayed on the page in the table of consents on the study. Included with the consent record are fields reserved for the review board, Review Outcome, Approval Date, and Expiration Date. This information will populate when the review board gives the consent form an outcome. There is also a column called Checked Out By. This column only populates if the consent is checked out for edits.

When you add a new consent record from this area, in order for the new consent to be approved you will need to associate the document to a submission form and send it to the board for approval. Consent forms can be added here and later attached to a submission form.

3 result(s) found...

<input type="checkbox"/>	View History	Edit/View	Title/Category	Version	Sponsor Version	Language	UnApproved Consent	Approved Consent	Consent Outcome	Approval Date	Expiration Date	Checked Out By	Create a Revised Document	Hide
<input type="checkbox"/>			IRB - Review Board Consent Template											
<input type="checkbox"/>			Study Consent Category I	1.2 07/29/2019		English								
<input type="checkbox"/>			Consent Document	1.0 07/26/2019		English						Abby Ack at 07/29/2019 01:00:55 PM		
<input type="checkbox"/>			Standard Consent	2.0 07/29/2019		English								

Delete Selected Consent(s)

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

Edit/View

You can view the details of any Consent by clicking the icon in the **Edit/View** column. If the consent has been submitted, you will not be able to make any edits. Sections will be grayed out like the image below. You will need to create a revision of the document in order to do so.

My Workspaces | IRB Number: **IRB-19-5430** | Study Assistant | Informed Consent Document | Back

Study Status: Pending - Submitted for Initial Review | IRB Number: IRB-19-5430 | Study Title: Effects of sun exposure in water and out of water

Consent List ?

Unapproved Consent
W
RTF

Consent Title: IRB - Review Board Consent Template

*Version Date: 07/29/2019

Sponsor Version:

Category: Study Consent Category I

Description:

*Version Number: 1 .1

* Language: English

* Reconsent Required: Yes No

Reconsent Reason:

Comments:

When you open the details of the consent, you can view the document by clicking the icon on the top right corner of the screen. Depending on the status of the document you may see a Word icon, an RFT icon, or a PDF icon.

My Workspaces | IRB Number: **IRB-19-5430** | Study Assistant | Informed Consent Document | Back

Study Status: Pending - Submitted for Initial Review | IRB Number: IRB-19-5430 | Study Title: Effects of sun exposure in water and out of water

Consent List ? | Save Consent ?

Unapproved Consent
W
RTF

Consent Title: Standard Consent

*Version Date: 07/29/2019

Sponsor Version:

Category:

Description:

*Version Number: 2 .0

* Language: English

* Reconsent Required: Yes No

Reconsent Reason:

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

Edit in browser: Edit in browser

Comments:

Accessing an Approved Consent

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 can access the copy of the consent. This will open the Consent document in a new window.

Once the review board approves the Consent, the unapproved copy of the consent will not be displayed in the column. 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 in a new window allowing you to print it for your records.

My Workspaces IRB Number: **IRB-19-5554** Study Assistant **Informed Consent Document** Back

Study Status: **Pending - Submitted for Initial Review** IRB Number: IRB-19-5554 Study Title: Human study on melanin pigments and sun exposure

Search Level: Top All
 Select Category: All
 Version #: -
 Approval Date: between

Show Hidden: Yes No
 Title:
 Consent Outcome: All
 Expiration Date: between

Filter Documents

Export Print Friendly Compare Consent versions Add a New Consent Delete Selected Consent(s) ?

Informed consent revision history list associated with this study.
 To create a new version, click on the Add Revision icon to the right of the consent form.
 To view previous versions click on the folder icon.

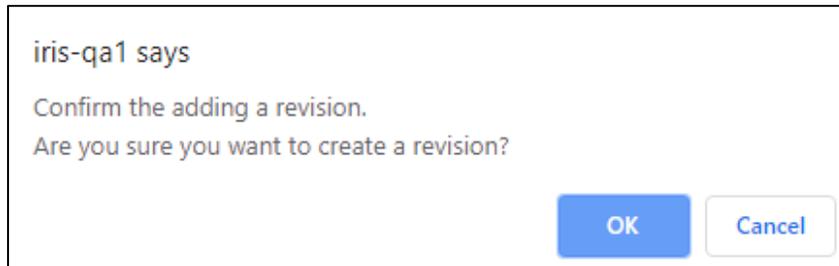
5 result(s) found...

	View History	Edit/View	Title/Category	Version	Sponsor Version	Language	UnApproved Consent	Approved Consent	Consent Outcome	Approval Date	Expiration Date	Checked Out By	Create a Revised Document	Hide
<input type="checkbox"/>			IRB - Review Board Consent Template	1.0 07/30/2019		English								
<input type="checkbox"/>			Consent Document	1.0 07/30/2019		English			Approved	07/30/2019	07/30/2019			

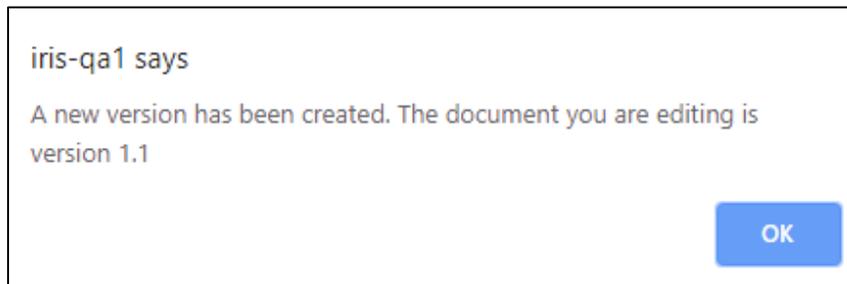
Revise a Consent

If you would like to revise an existing Consent record, click the icon in the **Create a Revised Document** column.

iRIS will ask for your confirmation to creating the revision. Click **OK** to proceed with the revision or click the **Cancel** button to return to the Informed Consent library page without creating a revision of the document.



If you click the **OK** button, iRIS will confirm the revision and provide the information about the version of the document you are editing. Click the **OK** button to proceed.



The window will refresh again and populate with details of the document you are revising, allowing you to change details and checkout the revised document.

The screenshot shows the 'Informed Consent Document' form. At the top, it displays 'My Workspaces', 'IRB Number: IRB-19-5430', 'Study Assistant', and a 'Back' button. Below this, there are tabs for 'Study Status' (Pending - Submitted for Initial Review) and 'IRB Number' (IRB-19-5430). The 'Study Title' is 'Effects of sun exposure in water and out of water'. The form contains several input fields: 'Consent Title' (Standard Consent), '*Version Date' (07/29/2019), 'Sponsor Version', 'Category', 'Description', '*Version Number' (2.1), '*Language' (English), and '*Reconsent Required' (Yes/No). There are also buttons for 'Check-out Document...', 'Edit in browser', and 'Save Consent'. A 'Consent List' button is also visible.

Check-out the document if you want to edit the document or you can also click **Edit in browser** to edit the form within the browser.

Whenever a document is checked out, the system will indicate the document is checked out. 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**.

This document is currently checked out by. Abby Ack at 07/29/2019 01:56 PM PDT

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

Revert to the document stored in iRIS. Undo Check-out Document...

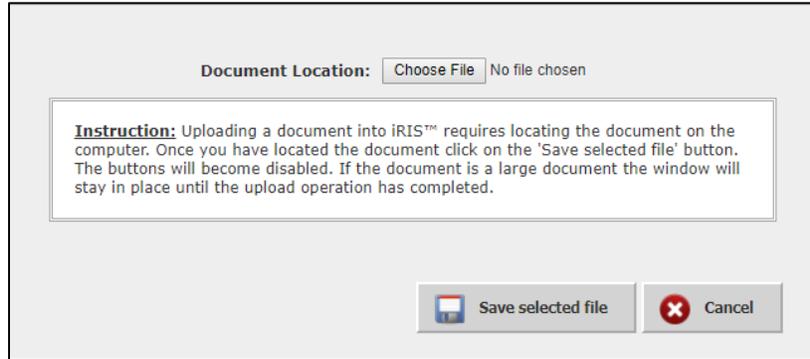
When you view the Informed Consent library, any document that is currently checked out will contain the checkout information, in the **Checkout by** column.

View History	Edit/View	Title/Category	Version	Sponsor Version	Language	UnApproved Consent	Approved Consent	Consent Outcome	Approval Date	Expiration Date	Checked Out By	Create a Revised Document	Hide
		Standard Consent	1.1 07/15/2019		English								
		Standard Consent	2.1 07/29/2019		English						Abby Ack at 07/29/2019 01:56:26 PM		

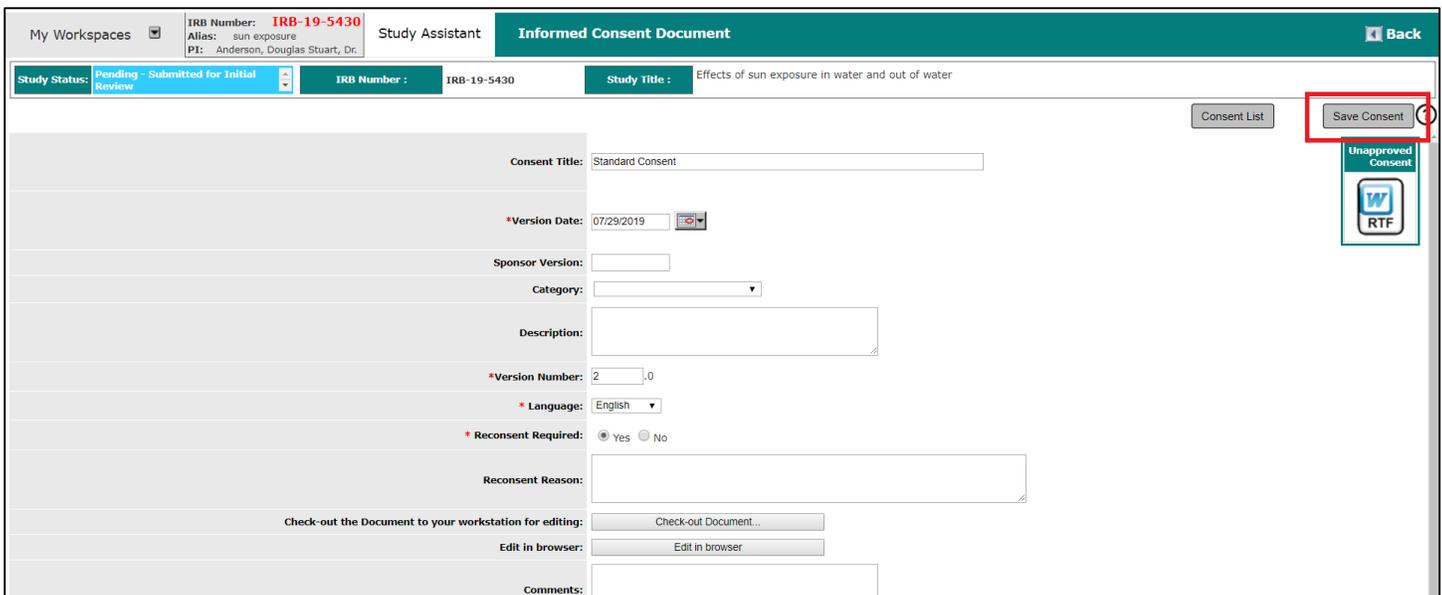
After you make any changes to the document in Microsoft Word, you can return to the Informed Consent library to check in the changes. Click the icon in the **Edit/View** column.

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

A window will open allowing you to upload the revised Consent. 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 so you can locate your Consent document. Once you associated a document, click the **Save selected file** button.

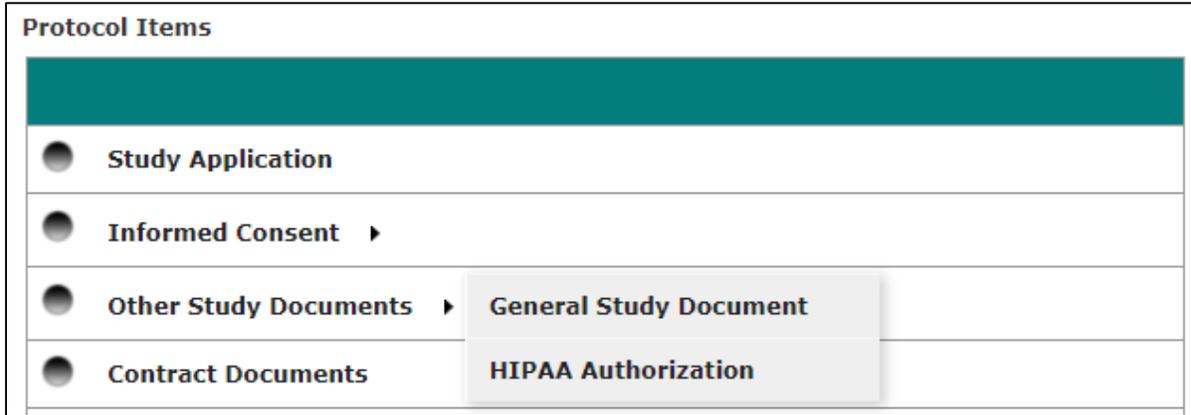


The Consent document will be uploaded to the study and it will appear as an icon next to the consent information, as shown below. Click the **Save Consent** button to save the revised document to the study.



Other Study Documents

The **Other Study Documents** link from the main Submissions page will direct you to the Other Study Document library, which stores any document you have attached to submission forms or added through the library. If you hover over the Other Study Documents link, a popup menu will appear that displays all the categories for 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 existing document, add new documents, compare versions of documents and print out approved copies of a document.

A new property has been added that allows the system administrator to prohibit documents attached to a submission to be edited. This property controls whether Researchers are able to edit documents from the Study Management Document List. The default setting is set to “No”, if you want to change the function and allow Researchers to edit documents, 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 a New Document**, **Add Multiple Documents**, and **Delete Selected Document(s)**, will no longer be available as well.

My Workspaces IRB Number: **IRB-19-5430** Study Assistant **Study Documents** [Back](#)

Alias: sun exposure
PI: Anderson, Douglas Stuart, Dr.

Study Status: **Pending - Submitted for Initial Review** IRB Number: IRB-19-5430 Study Title: Effects of sun exposure in water and out of water

Search Level: Top All Show Hidden: Yes No

Select Category: All Title:

Version #: . Document Outcome: All [Filter Documents](#)

Approval Date: between Expiration Date: between

[Print Friendly](#) [Compare document versions](#)

1 result(s) found...

<input type="checkbox"/>	View History	Edit	Version	Title/ Category	Document Outcome	Approval Date	Expiration Date	File	Stamped File	Checked Out By	Create Revision	Hide
<input type="checkbox"/>			1.0 07/30/2019	Survey for people under 55 years old Survey				 5.56 KB			(Read Only)	

When this property is set to “Yes”, the Researcher will be able to edit any study documents from the Study Management page. Under the “Create Revision” tab, the option to Add Revision is no available. The options to **Add a New Document**, **Add Multiple Documents**, and **Delete Selected Document(s)**, now is available as well.

Filter Documents

At the top of the page are different filters you can use to find a particular document or group of documents.

You can enter a combination of different filter items to display results.

The available filters are as follows:

Search Level –The default selection for this filter is set to “Top”. This means when you use the search filters, the system will check only the top level, or latest version, of a document. If a document has revisions, only the latest version will be included in the search. If you would like to search all versions of a document set the selection to “All”.

Select Category – You can choose a document category from the drop-down menu. If you had selected a category before opening the library, that category will appear in this field, and only documents in this category will appear in the results.

Version # - Type in a version number to include in the filter.

Note: The version number is exact case. If you type in ‘5’ only documents that are version ‘5.x’ will populate on the page.

Approval Date – You can specify a date range for approval dates. You must enter a date into both fields. If you want just one day, put the same day in both date fields.

Show Hidden – The default selection for this filter is set to “No”. This means that all the documents viewed on the page are only the non-hidden documents. When you select “Yes”, the page will refresh and will display all documents for the study.

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

Document Outcome – You can select a review board document outcome in this drop-down list.

Expiration Date - You can specify a date range for expiration dates. You must enter a date into both fields. If you want just one day, put the same day in both date fields.

Printer Friendly

You can also view the documents on the page in a printer friendly view if you would like to print out a list of the documents.

Click the **Print Friendly** button at the top of the page. A new window will open, displaying basic study information at the top of the page. The page will also list out any document records on the study, along with basic document information.

You can click the **Print** button to send this page to your printer or click the **Close** button to close the window.

Note: If you had set filter criteria prior to clicking the Printer Friendly button, the filters will carry forward to this view. The Print Friendly view will display the filters in use, as shown in the screenshot below.

Study Documents

Study Status: Pending - Submitted for Initial Review
 Principal Investigator : admin, Admin Admin, R.N. Brig. Gen.
 Study Title: Human study on melanin pigments and sun exposure

Category: All SubCategory: All Version Number: Review Outcome: Approval Dates Between: and Expiration Dates Between: and
 1 result(s) found

Title/Category	File	Stamped File	Version	Document Outcome	Approval Date	Expiration Date	Checked Out By
HIPPA HIPAA Authorization	 18.16 KB		2.0 07/30/2019				

Compare Document Versions

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

This will allow you to view information related to older versions. You can even view the previous versions’ unapproved document by clicking on the Word icon in the **File** column.

You can also compare versions of the document 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.

2 result(s) found...

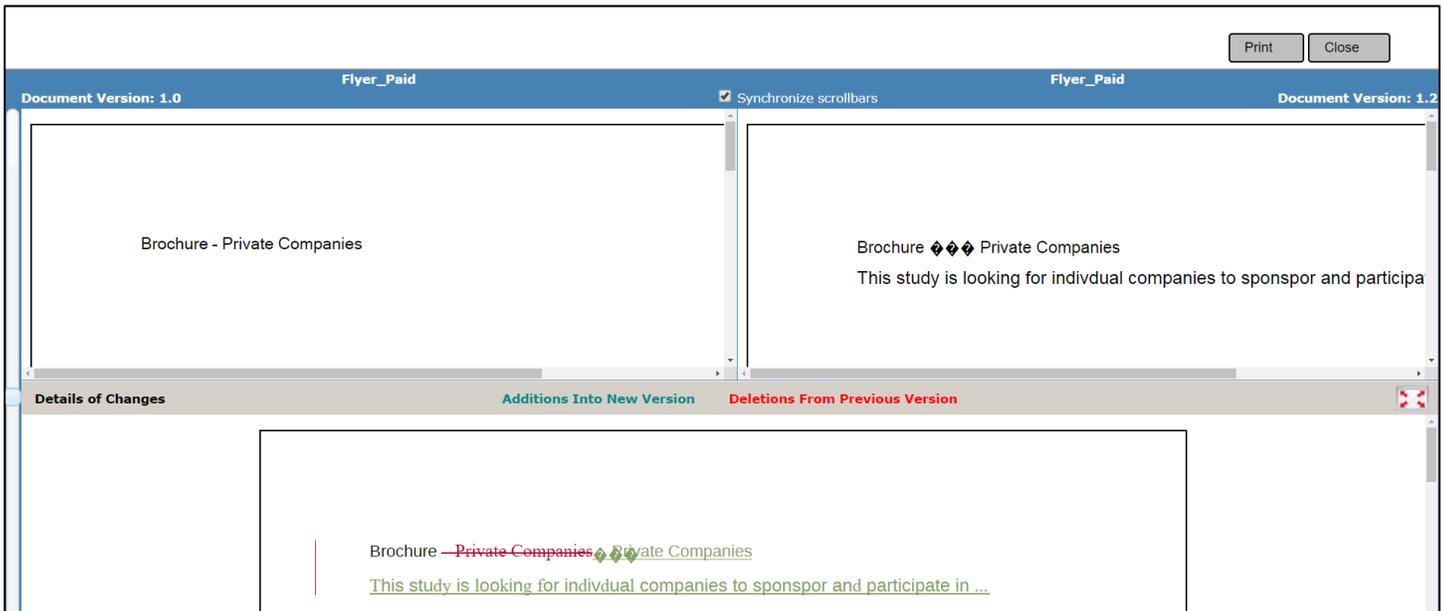
<input type="checkbox"/>	View History	Edit	Version	Title/ Category	Document Outcome	Approval Date	Expiration Date	File	Stamped File	Checked Out By	Create Revision	Hide
<input checked="" type="checkbox"/>			1.1 07/30/2019	Flyer_Paid Flyer/Advertisement				 11.95 KB			 Add Revision	
<input checked="" type="checkbox"/>			1.0 07/30/2019	Flyer_Paid Flyer/Advertisement				 11.95 KB				
<input type="checkbox"/>			2.0 07/30/2019	HIPPA HIPAA Authorization				 4.02 KB			 Add Revision	

iRIS will run the two versions of the document through a comparer tool. This may take several moments, depending on the size of your documents. When the tool is complete, a new window will open displaying both selected versions of the

document in a side-by-side view, with the newer version listed in the left column and the older version listed in the right column. At the bottom of the window a split view will display a combination of both versions, indicating where items have been modified.

This bottom 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 document, and Red highlights mark items that have been removed from the document.

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



Add a New Document

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

A new page will open within the browser. Here you will specify the name of the document, in the **Document Title** field.

***Version Number:** .0

Version Number - Requires you to specify what number you wish this version of the document, to be on. This can be any character or number. After the editable version number is a hard coded **.0**. This is the iRIS version number for the document. Any new document you upload to the system will begin with the **.0** affixed to your manually entered version number. Anytime a revision is made to the document through the system, iRIS will change the **.0** to **.1** and will continue to increment the numbers each time a revision is made. This is how the system tracks the number of revisions to the document in iRIS. You will always be able to revise your manually entered version number, but you are unable to revise the iRIS version number.

Version Date – This is the date of the manually entered version number. This is typically the date the document was uploaded to the system. You can choose whether or not to have this field auto filled for you are using the system.auto_fill_version_date property, located under Study Document Screen Setup.

Category – This configurable drop-down list allows you to select a category for the document. This question may or may not be required, based on the system.doc_category_required property.

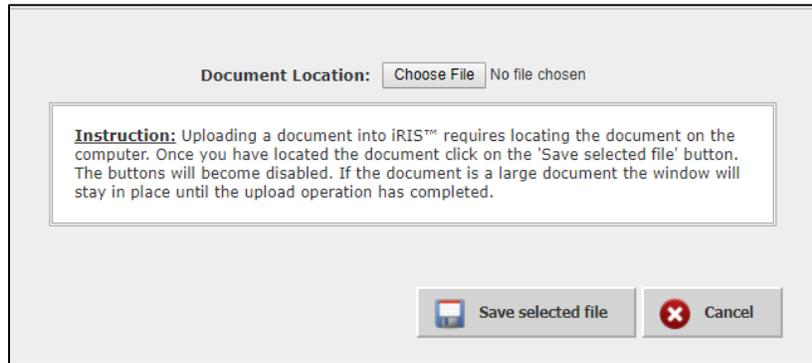
Description – A description of the document.

Comments – Any comments regarding the document you feel necessary, to add for the reviewing board to see.

The screenshot shows the 'Study Documents' section of the iRIS Study Assistant. At the top, there is a header with 'My Workspaces', 'IRB Number: IRB-19-5555', 'Alias: correlation', 'PI: admin, Admin Admin, R.N. Brig. Gen.', 'Study Assistant', and 'Study Documents'. A 'Back' button is in the top right. Below the header, a summary bar shows 'Study Status: Draft', 'IRB Number: IRB-19-5555', and 'Study Title: Human study on melanin pigment and sun exposure correlation'. A 'Save Document' button is in the top right of the form area. The main form contains several fields: '* Document Title' (text input), '* Version Number' (text input with '.0' suffix), 'Version Date' (calendar icon and '07/30/2019'), '* Category' (dropdown menu with '--none--'), 'Description' (text area), 'Load the document into iRIS:' (dotted box with 'Drag your file here or click in this area.' and a help icon), 'Add in browser:' (button), and 'Comments:' (text area).

Enter the required information including the document itself then click the dotted box or drag and drop your document into the box to upload the document.

If you click the box, a small window will open allowing you to upload a 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 so you can locate your document. Once you associated a document, click the **Save selected file** button.



The system will return you to the previous page.

The document will be uploaded to the study, and it will appear as an icon next to the document information, as shown below.

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.

Click the **Save Document** button to create the record.

Any document record you add will be displayed on the page in the table of Other Study Documents on the study. Included with the document record are fields reserved for the review board, Review Outcome, Approval Date, and Expiration Date. This information will populate when the review board gives the Other Study Document an outcome. There is also a column called **Checked Out By**. This column only populates if the document is checked out for edits.

3 result(s) found...												
	View History	Edit	Version	Title/ Category	Document Outcome	Approval Date	Expiration Date	File	Stamped File	Checked Out By	Create Revision	Hide
			2.0 07/30/2019	HIPPA HIPAA Authorization				4.02 KB		Abby Ack 07/30/2019 10:50:13 AM	(Read Only)	
			1.2	Flyer_Paid								

Note: When you add a new document record from this area, in order for the new document to be approved you will need to associate your document, to a submission form and send it to the review board for approval. Without sending your document, the review board has no way to see there is a new document for review. Other Study Documents can be added here and later attached to a submission form, like an Amendment, which is covered later in this document.

Add Multiple Documents

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

When you click this button, a new page will open containing five rows for document uploads. Depending on the number of documents you are adding, you can populate the information in each row: Document Title (required), Version, Version Date, Category, and File Path.

Add the information for the number of documents you are uploading. 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 can also delete records from the upload, by selecting the checkbox next to the record and clicking the **Delete Record(s)** button. 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 Documents(s)** button. Once a Study Document is submitted it cannot be deleted from the study.

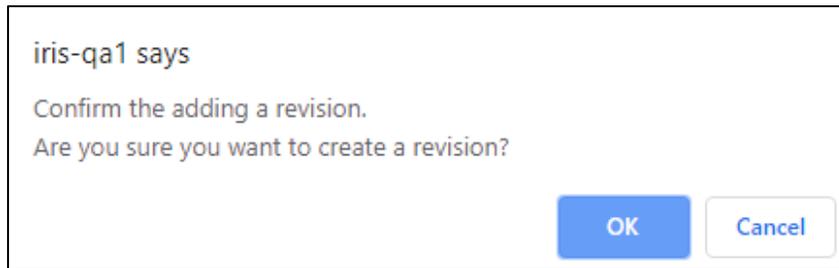
Edit

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.

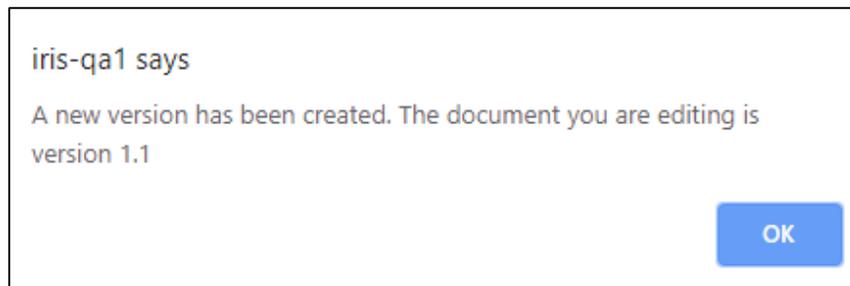
When you open the details of the document, you can view the document by clicking the View the Stamped Document icon. Depending on the status of the document, you may see a Word icon, an RFT icon, or a PDF icon, as shown in the image below.

You can also edit the document within the browser. Layouts might be differ, depending on the browser being used.

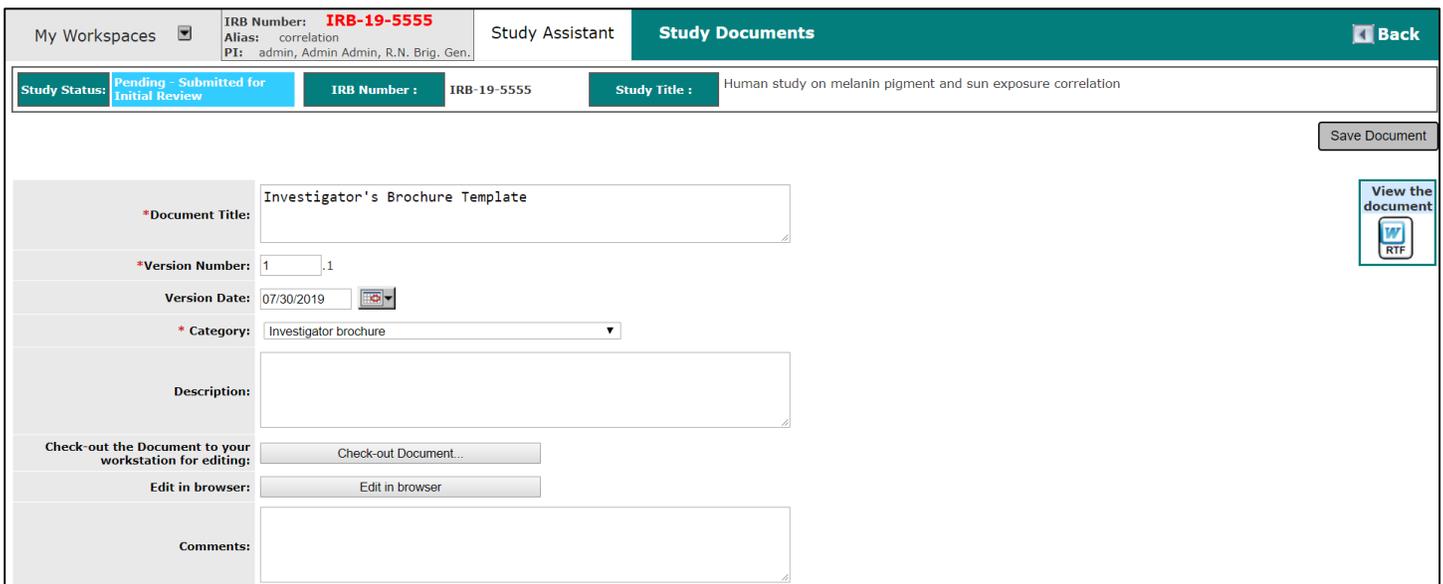
iRIS will ask for your confirmation to creating the revision. Click **OK** to proceed with the revision or click the **Cancel** button to return to Other Study Document library page, without creating a revision of the document.



If you click the **OK** button, iRIS will confirm the revision and provide the information about the version of the document you are editing. Click the **OK** button to proceed.



The window will refresh again and populate with details of the document you are revising, allowing you to change details and checkout the revised document. Click the **Check-out Document** button, as seen in the image below.



Depending on your Internet Browser, version and settings, you may or may not be prompted with the file download information.

Save the document in a secure and known location so that you can check it back in. The system will refresh and will look similar to the screen below.

My Workspaces ▾

IRB Number: **IRB-19-5555**
 Alias: correlation
 PI: admin, Admin Admin, R.N. Brig. Gen.

Study Assistant

Study Documents

⏪ Back

Study Status: Pending - Submitted for Initial Review

IRB Number : IRB-19-5555

Study Title : Human study on melanin pigment and sun exposure correlation

***Document Title:**

***Version Number:** .

Version Date:

*** Category:**

Description:

This document is currently checked out by. Abby Ack at 07/30/2019

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

Revert to the document stored in iRIS.

Comments:

View the document

Whenever a document is checked out, the system will indicate the document is checked out. 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**.

This document is currently checked out by.

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

Revert to the document stored in iRIS.

Abby Ack at 07/30/2019

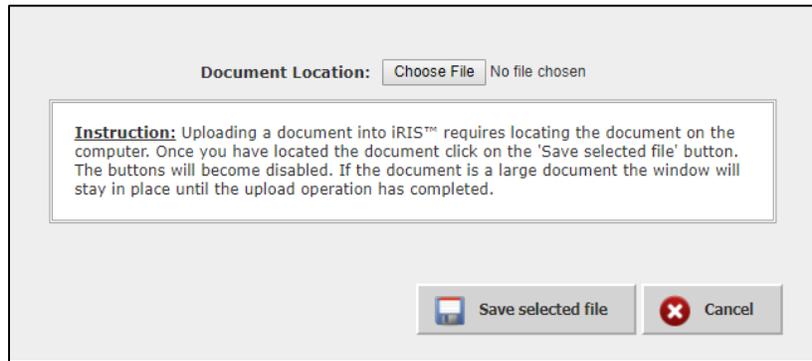
When you view the Other Study Document library any document that is currently checked out will contain the checkout information in the **Checked Out By** column.

3 result(s) found...												
<input type="checkbox"/>	View History	Edit	Version	Title/ Category	Document Outcome	Approval Date	Expiration Date	File	Stamped File	Checked Out By	Create Revision	Hide
<input type="checkbox"/>			1.0 07/30/2019	Flyer_Paid Flyer/Advertisement	Approved	07/30/2019	07/30/2019		 30.51 KB		Add Revision	
<input type="checkbox"/>			2.0 07/30/2019	HIPPA HIPAA Authorization				 4.02 KB			Add Revision	
<input type="checkbox"/>			1.1 07/30/2019	Investigator's Brochure Template Investigator brochure				 4.02 KB		Abby Ack 07/30/2019 11:05:18 AM	(Read Only)	

After you make any changes to the document in Microsoft Word, you can return to the Other Study Document library to check in the changes. Click the icon in the **Edit** column.

When the Study Document details page 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, so you can locate your document. Once you associated a document, click the **Save selected file** button.

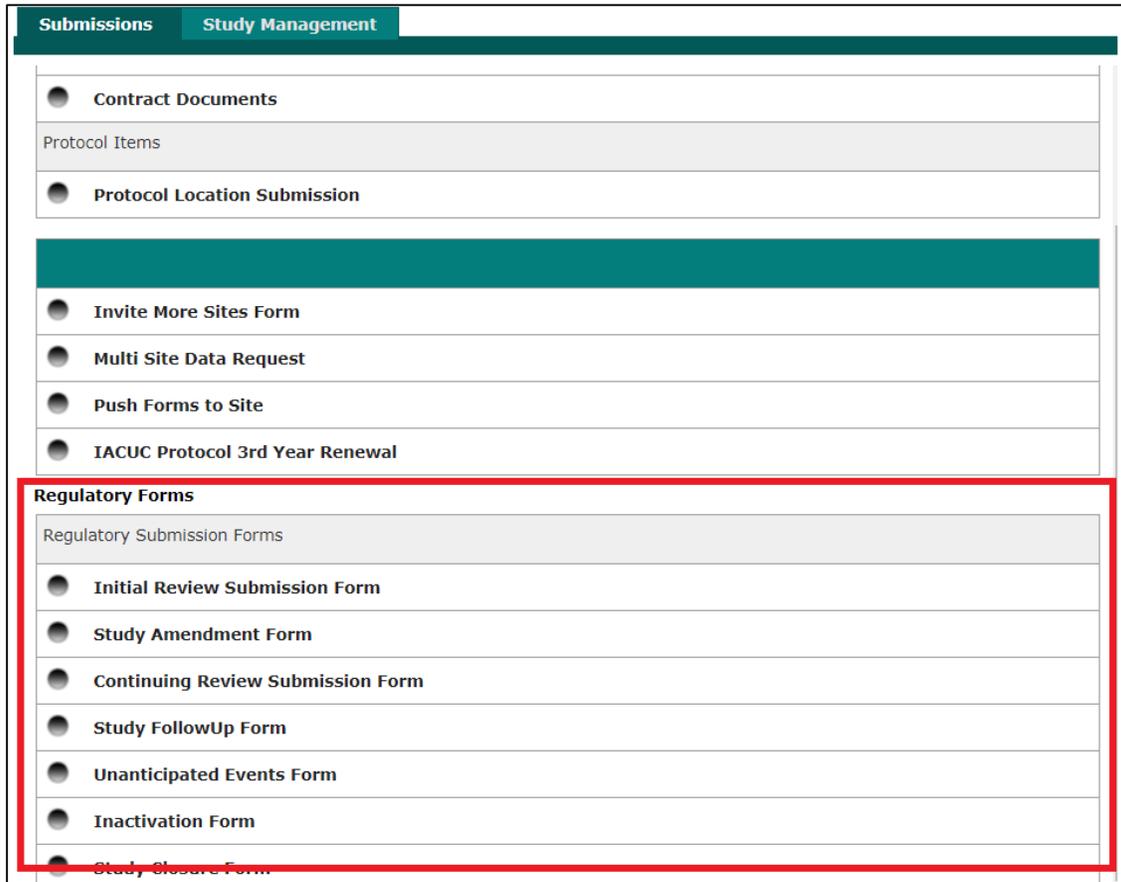


The document will be uploaded to the study and it will appear as icon next to the document information, as shown below. Click the **Save Document** button to save the revised document to the study.

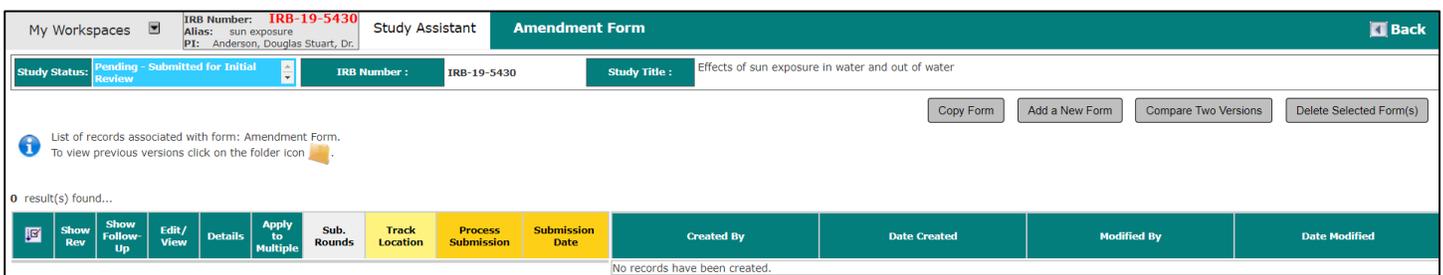
My Workspaces	IRB Number: IRB-19-5555 Alias: correlation PI: admin, Admin Admin, R.N. Brig. Gen.	Study Assistant	Study Documents	Back
Study Status: Pending - Submitted for Initial Review	IRB Number : IRB-19-5555	Study Title :	Human study on melanin pigment and sun exposure correlation	
				Save Document
*Document Title:	Investigator's Brochure Template			
*Version Number:	1 .1			
Version Date:	07/30/2019			
* Category:	Investigator brochure			
Description:				
Check-out the Document to your workstation for editing:	Check-out Document...			
Edit in browser:	Edit in browser			
Comments:				
				View the document RTF

Submission Forms

This area links to different submission forms that can be sent to a review board as needed. 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 allows you to **Copy Forms, Add a New Form, Compare Two Versions** or **Delete Selected Form(s)**, (provided it has not been submitted for review).



The table below the buttons lists any form already started.

The Checkbox column is used to copy, compare and delete a form. Click the checkbox next to the form(s) to delete, then click the **Delete Selected Form(s)** button.

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. You can also compare the differences between two versions of the same form by clicking the checkboxes and then click the **Compare Two Versions** button.

Show Follow-Up – If a form has been linked to another form as a follow-up form, it will show here. There must be a previous version of the form to associate the current form you are filling out to, as a follow-up form. You must have it turned on in the Systems Form Designer to be able to see this column.

2.2 Followup form

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

3 result(s) found...

	Show Rev	Show Follow-Up	Edit/View	Details	Apply to Multiple	Sub. Rounds	Track Location	Process Submission	Submission Date	Created By	Date Created	Modified By	Date Modified
<input type="checkbox"/>										Abby Ack	07/29/2019 04:12:02 PM	Abby Ack	07/29/2019 04:12:08 PM
<input type="checkbox"/>										Admin Admin admin	07/30/2019 11:10:36 AM	Admin Admin admin	07/30/2019 11:12:20 AM

Edit/View – Click on this icon to continue to work on a form you have already started but have not completed yet, or to view a form that has been submitted previously.

Details – Click over hover over this icon to show the Submission Summary.

When the user fills out the data value “Submission Summary”, it will act as a summary for the submission, but also as an identifier that will show up under “Details”.

My Workspaces |
 Study Numbers: **CHR-19-1277** |
 Study Alias: magnification in water |
 PI: Adams, Lisa |
 Study Assistant |
 Adverse Event Reporting 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

- 1.0 Adverse Event Reporting Form
- 2.0 Internal (on-site) Adverse Event
- 3.0 Significant New Findings
- 4.0 Late Submissions

Entire view of the Form

1.9 For initial reports only, is this AE being reported within the required reporting window:

Yes

No

N/A - This is a follow-up report

1.10 Submission Summary

Submission Summary

subject has skin cancer

My Workspaces Study Assistant Adverse Event Reporting Form

Study Number: CHR-19-1277 Study Title: Effects of Sun Exposures in water and out of water - magnification process

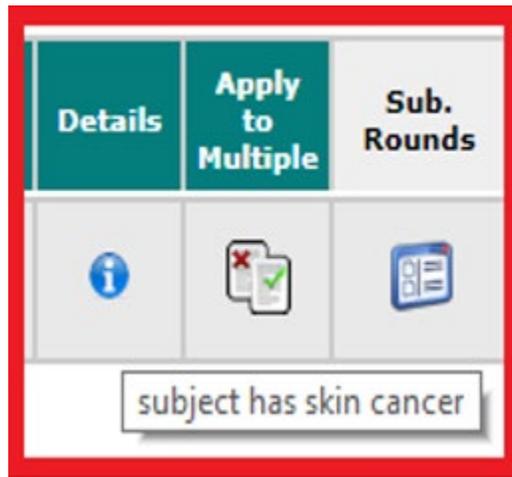
Copy Form Add a New Form Compare Two Versions Delete Selected Form(s)

List of records associated with form: Adverse Event Reporting Form. To view previous versions click on the folder icon.

1 result(s) found...

Study Status	Study Number	Study Title	AE Date	Participant ID	Created By	Date Created	Modified By	Date Modified
Pending - Submitted for Initial Review	CHR-19-1277	Effects of Sun E...			Sean McMurray	08/05/2019 11:23:25 AM	Sean McMurray	08/05/2019 11:24:32 AM

When the user hovers the mouse over the  icon, the content collected in the data value from the form will appear in a small pop-up.



Apply to Multiple – An icon will appear when a form has been created. This allows you to add the form to another study.

By clicking on the icon, it will take you to another screen where the user will be able to attach a copy of the form to the another study.

My Workspaces Study Assistant My Studies

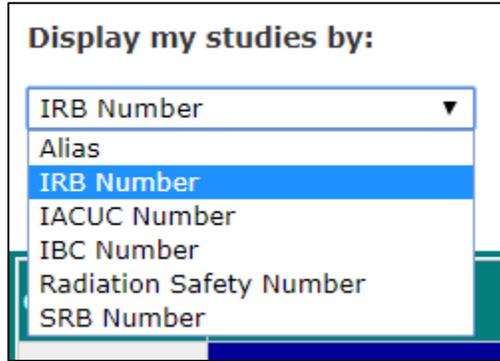
IRB Number: IRB-19-5430 Alias: sun exposure PI: Anderson, Douglas Stuart, Dr.

Display my studies by: IRB Number Filter my studies by study status: All Most Recently Used Find by IRB Number: Find Find by Alias: Find Save a Copy of the selected form

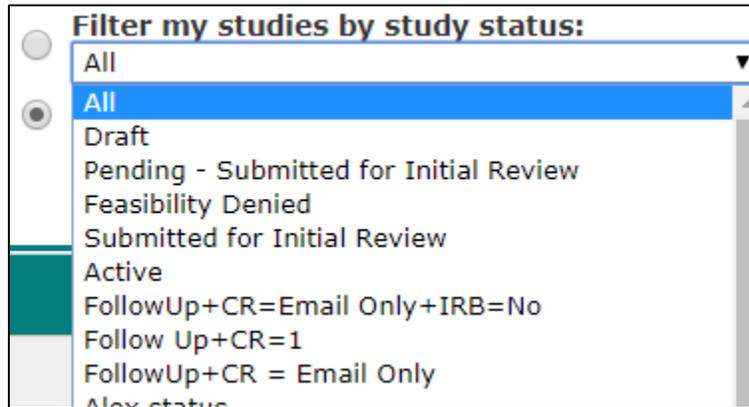
Click to open	Study Status	IRB Number	IRB Expiration	Principal Investigator	Study Title/ Alias
<input type="checkbox"/>	Draft			admin, Admin Admin, R.N. Brig. Gen.	Study on post-natal women and the effects of different vitamins on body restoration post-natal women
<input type="checkbox"/>	Active	IRB-18-2383		Ack, Abby, MSN Ph.D.	Medical Record study: Diabetes and Exercise
<input type="checkbox"/>	Pending - Submitted for Initial Review	IRB-19-5491		Pope, Ann, B.S.	Diabetes and Exercise Effects of Caffeine on smokers Caffeine on smokers

Users can also choose to filter the results by using the search bars and drop-down menus above.

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, the options might look different depending on your institution.



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, the options might look different depending on your institution.



Most Recently Used – This will filter the studies to the most recently used at the top.

Find by IRB Number – is allows the user to search for a study using the IRB number.

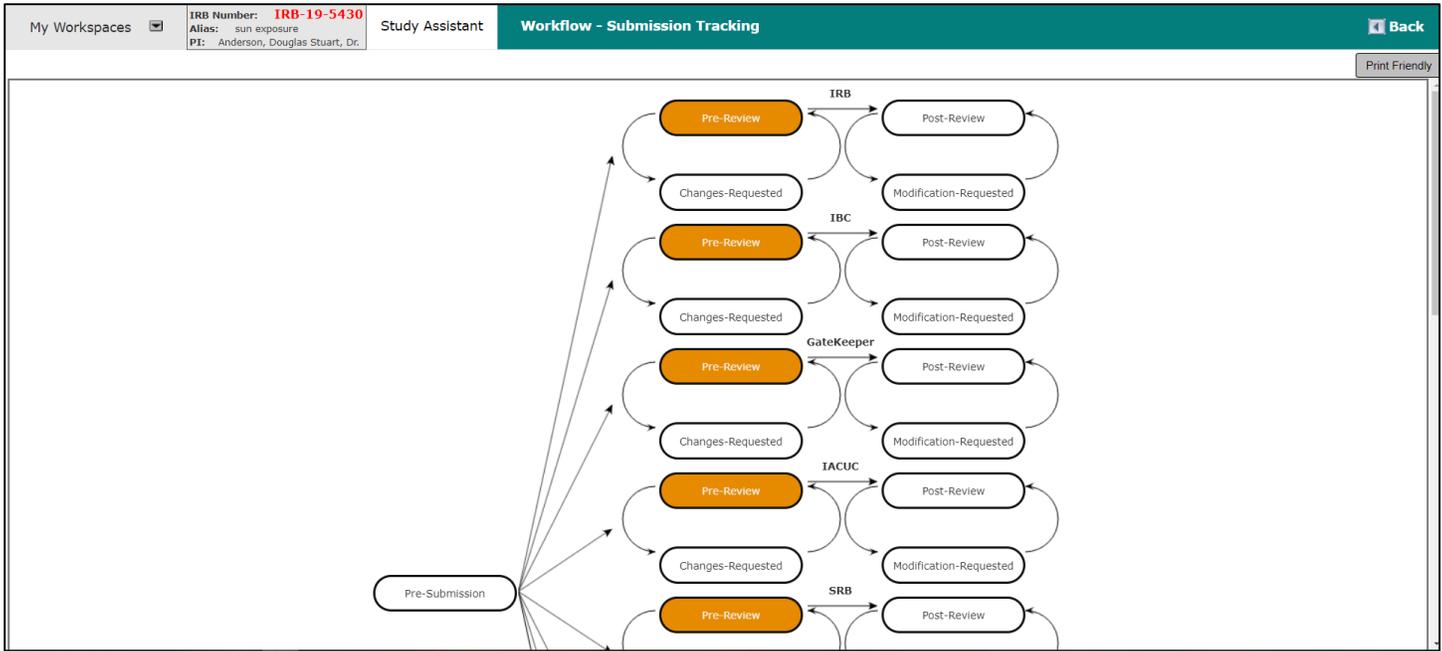
Find by Alias – This allows the user to search for a study using a specific set of words or by the known alias.

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

Click to open	Study Status	IRB Number	IRB Expiration	Principal Investigator	Study Title/ Alias
<input type="checkbox"/>	Draft			admin, Admin Admin, R.N. Brig. Gen.	Study on post-natal women and the effects of different vitamins on body restoration post-natal women
<input type="checkbox"/>	Active	IRB-18-2383		Ack, Abby, MSN Ph.D.	Medical Record study: Diabetes and Exercise
<input type="checkbox"/>	Pending - Submitted for Initial Review	IRB-19-5491		Pope, Ann , B.S.	Diabetes and Exercise Effects of Caffeine on smokers Caffeine on smokers

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 where the steps are orange. Details are at the bottom of the Workflow detail diagram.

Task Status	Task Action/Details	Task Name	Date Created	Date Completed	Total Time
<div style="text-align: center;"> </div>					
<div style="background-color: #ffffcc;"> Pre-Submission Retract Submission </div>					
Completed		Amendment Form is waiting to be submitted	07/29/2019 02:11 PM PDT	07/29/2019 02:11 PM PDT	0 Day(s) 0 Hour(s) 0 Minute(s)
Completed	View Signoff Routing List	Assign Department Personnel for Signoff	07/29/2019 02:11 PM PDT	07/29/2019 02:12 PM PDT	0 Day(s) 0 Hour(s) 0 Minute(s)
Completed	View Signoff	Douglas Stuart Anderson, Dr. as Principal Investigator review and apply signoff, assigned by Abby Ack, MSN Ph.D.	07/29/2019 02:12 PM PDT	07/29/2019 02:12 PM PDT	0 Day(s) 0 Hour(s) 0 Minute(s)
Completed	View Signoff	Abby Ack, MSN Ph.D. as IRB - Nurse review and apply signoff, assigned by Abby Ack, MSN Ph.D.	07/29/2019 02:12 PM PDT	07/29/2019 02:12 PM PDT	0 Day(s) 0 Hour(s) 0 Minute(s)
Completed		Send Email with Submission Forms	07/29/2019 02:12 PM PDT	07/29/2019 02:12 PM PDT	0 Day(s) 0 Hour(s) 0 Minute(s)
Error		The following Study Personnel are not registered with up to date training records:	07/29/2019 02:12 PM PDT	07/29/2019 02:12 PM PDT	0 Day(s) 0 Hour(s) 0 Minute(s)
<div style="background-color: #ffffcc;"> IRB </div>					
Received		IRB received the submission	07/29/2019 02:12 PM PDT		0 Day(s) 0 Hour(s) 2 Minute(s)
<div style="background-color: #ffffcc;"> IBC </div>					
<div style="background-color: #ffffcc;"> GateKeeper </div>					

The date 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			07/29/2019 02:11 PM PDT	07/29/2019 02:12 PM PDT	0 Day(s) 0 Hour(s) 0 Minute(s)
Completed		Amendment Form is waiting to be submitted	07/29/2019 02:11 PM PDT	07/29/2019 02:11 PM PDT	Day Hour Minute 0 0 0
Completed	View Signoff Routing List	Assign Department Personnel for Signoff	07/29/2019 02:11 PM PDT	07/29/2019 02:12 PM PDT	Day Hour Minute 0 0 0
Completed	View Signoff	Douglas Stuart Anderson, Dr. as Principal Investigator review and apply signoff, assigned by Abby Ack, MSN Ph.D.	07/29/2019 02:12 PM PDT	07/29/2019 02:12 PM PDT	Day Hour Minute 0 0 0
Completed	View Signoff	Abby Ack, MSN Ph.D. as IRB - Nurse review and apply signoff, assigned by Abby Ack, MSN Ph.D.	07/29/2019 02:12 PM PDT	07/29/2019 02:12 PM PDT	Day Hour Minute 0 0 0
Completed		Send Email with Submission Forms	07/29/2019 02:12 PM PDT	07/29/2019 02:12 PM PDT	Day Hour Minute 0 0 0
Error		The following Study Personnel are not registered with up to date training records:	07/29/2019 02:12 PM PDT	07/29/2019 02:12 PM PDT	Day Hour Minute 0 0 0

If details of a step can be viewed, an icon will be displayed under the **View 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: Effects of sun exposure in water and out of water
Submission Reference Number: 021497

Printable Version

Submission Form(s):	Include in PDF Packet	Compare to Last Approved	View in Separate Window	Submission Component Name - Version
	<input type="checkbox"/>		<input type="checkbox"/>	Amendment Form - (Version 1.0)

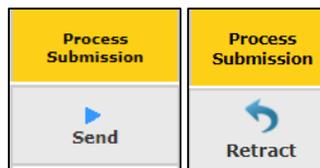
Abby Ack, MSN Ph.D. as IRB - Nurse do you Approve or Deny this submission? Approve Deny Comments:

ELECTRONIC SIGNATURE HAS BEEN APPLIED by Abby Ack, MSN Ph.D. at 07/29/2019 02:12 PM PDT

View Other Comments:
Douglas Stuart Anderson, Dr. Principal Investigator Approved

Comments:

Process Submission – This column will populate with one of two buttons or will display empty, based 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 Forms Designer. Other columns from the form can be turned on in their place. See the Forms Designer manual for more details on displaying columns in the form table.

A new property has been that restricts users to create another submission form with an application data value at a time, when there is an existing submission form that has not exited the workflow and is completed. 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 submission 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 the users clicks into 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.

Show Rev.	Edit/View	Application Type	Approved?	Application Status	Approval Date	Created By	Date Created	Modified by	Date Modified	Create a Revised Application
<input type="checkbox"/>		MAIN IRB APP (Version 1.0)	No	null		Admin Admin admin	08-06-2019 12:01	Admin Admin admin	08-06-2019 12:09	<input type="button" value="Create a Revised Application"/>

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.

My Workspaces ▼ Alias: sleep and growth PI: Investigator, Jane jr., M.D. Brig. Gen. Study Assistant **Study Application** Back

Study Status: **Draft** Study Title : Correlation between number of hours of sleep and physical growth

Add a New Application Type Compare Two Selected Versions Delete Selected Version

1 result(s) found...

<input type="checkbox"/>	Show Rev.	Edit/View	Application Type	Approved?	Application Status	Approval Date	Created By	Date Created	Modified by	Date Modified	Create a Revised Application
<input type="checkbox"/>			MAIN IRB APP (Version 1.0)	No	null		Admin Admin admin	08-06-2019 12:01	Admin Admin admin	08-06-2019 12:09	

Users will also not be able to add a form from the home screen under the Actions Tab.

All Studies Recently Used Study Status

Search for RB Number, Title, Alias Search ⚙️

All Draft IRB IACUC ▼

2679 result(s) found... 1 - 10 ▶

Click to open Study Dashboard	Study Status	Review Board	RB Number	RB Expiration	Study Title Alias	Principal Investigator	Actions
	Draft				Correlation between number of hours of sleep and physical growth sleep and growth	Investigator, Jane jr., M.D. Brig. Gen.	↓ History 📍 Items 📄 Forms 👁️ Hide 📄 Copy 🗑️ Delete ✉️ Corr

When the user click on the **Forms** button and the property is set to “Yes”, all submission forms with the application data value will be unavailable for use, as long as there is a submission that has not yet been completed and exited the workflow.

Submission Form List			
	Version List	Start a new Submission	Edit Incomplete Submissions
Adverse Event Form		Submission Types with Applications cannot be in progress concurrently	
Appendix D: Controlled Substances			
Appendix E: Radiation Use in a Non-Clinical Area			
Submission Invitation		Submission Types with Applications cannot be in progress concurrently	

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

My Workspaces Study Assistant **Amendment Form** [Back](#)

Alias: sleep and growth
 PI: Investigator, Jane jr., M.D. Brig. Gen.

Study Status: Draft **Study Title :** Correlation between number of hours of sleep and physical growth

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

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

Unable to add a New form until the following form(s) have completed board processing: Initial Review Submission Form Real (1.0)

0 result(s) found...

	Show Rev	Show Follow-Up	Edit/View	Details	Apply to Multiple	Sub. Rounds	Track Location	Process Submission	Submission Date	Created By	Date Created	Modified By	Date Modified
--	----------	----------------	-----------	---------	-------------------	-------------	----------------	--------------------	-----------------	------------	--------------	-------------	---------------

No records have been created.

Add a New Form

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

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.

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.

Submissions History

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

This section can be viewed three ways:

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

My Workspaces		IRB Number: IRB-19-5430 Alias: sun exposure PI: Anderson, Douglas Stuart, Dr.	Study Assistant	Submissions							Back	
Study Status: Pending - Submitted for Initial Review		IRB Number: IRB-19-5430		Study Title: Effects of sun exposure in water and out of water								
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		
021502			Amendment Form		Third IRB					07/29/2019 02:45:54 PM PDT		

Completed Submissions- This tab displays all the completed submissions, any form 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, look at the details, the review board, view the outcome letters, review the process, the meeting date, the review outcome, and the date received.

My Workspaces		IRB Number: IRB-19-5430 Alias: sun exposure PI: Anderson, Douglas Stuart, Dr.	Study Assistant	Submissions							Back	
Study Status: Pending - Submitted for Initial Review		IRB Number: IRB-19-5430		Study Title: Effects of sun exposure in water and out of water								
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		
021477			Initial Review Submission Form Real		IRB		Process Administratively			07/29/2019 11:53:36 AM PDT		

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

My Workspaces		IRB Number: IRB-19-5430 Alias: sun exposure PI: Anderson, Douglas Stuart, Dr.	Study Assistant	Submissions							Back	
Study Status: Pending - Submitted for Initial Review		IRB Number: IRB-19-5430		Study Title: Effects of sun exposure in water and out of water								
Submissions in Process		Completed Submissions		Submissions Returned with Changes								Print Friendly
Submissions Returned With Changes												
Reference Number	Details	Track Location	Request Type	Review Board	View Outcome Letters	Review Process	Meeting Date	Review Outcome	Date Received			
No Submissions are currently returned with changes requested												

Within all three tabs, you can click to view more information in the Track Location, Request Type, and Details columns.

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.

My Workspaces		IRB Number: IRB-19-5430 Alias: sun exposure PI: Anderson, Douglas Stuart, Dr.		Study Assistant		Submissions		Back	
Create PDF Packet Clear viewed records									
Show History	Include in PDF Packet	Open	Type	Document Name		Version	Date Submitted into Workflow		
Submission Form:									
<input type="checkbox"/>	<input type="checkbox"/>		Submission Form	Initial Review Submission Form Real		Version 1.0	07/29/2019 11:53 AM PDT		
Submission Attachments below:									
<input type="checkbox"/>	<input type="checkbox"/>		Application	MAIN IRB APP 6		Version 1.0	07/29/2019 11:53 AM PDT		

From this screen, you can open any of the components of the submission by clicking on the icon. You can also generate a PDF packet of the submission components from this screen. Check the boxes in the Include in PDF Packet column next to the components you wish to include and click **Create PDF Packet**. This will open the Reorder PDF Packet window, where you can drag the submission items to change their order in the list using the blue arrow that appears when you hover your mouse over the Packet Order.

Reorder PDF Packet

To order Submission Items for packet creation, please click on item row and drag it up or down to the desired location.

Packet Order		Submission Item Name
1		Initial Review Submission Form Real Version 1.0
2		MAIN IRB APP 6 Version 1.0

Generate PDF Packet

Study Correspondence

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

My Workspaces		IRB Number: IRB-19-5430 Alias: sun exposure PI: Anderson, Douglas Stuart, Dr.		Study Assistant		Submissions		Back	
Study Status: Pending - Submitted for Initial Review		IRB Number: IRB-19-5430		Study Title: Effects of sun exposure in water and out of water					
Submissions		Study Management		Current Approval Packet					
Protocol Items						<input type="radio"/> Submissions History <input checked="" type="radio"/> Study Correspondence			

This area will contain a list of any study related correspondence that has been sent out at any point of 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 notification is generated and sent related to the study a record of that notification will post to the Study Correspondence.

The screenshot shows the 'Study Correspondence' page for study IRB-19-5430. The page header includes 'My Workspaces', 'Study Assistant', and 'Study Correspondence'. The study status is 'Pending - Submitted for Initial Review'. The study title is 'Effects of sun exposure in water and out of water'. There are three buttons: 'Print Friendly', 'Add A New Correspondence', and 'Delete Selected Correspondence'. Below the header, it says '3 result(s) found...'. A table lists three messages:

View Message	Author	Subject
Post a Reply to this Topic / Forward this Topic	Abby Ack	Posted: Delivery in Progress sun exposure IRB-19-5430 PI Signoff Notification/1102dev
Post a Reply to this Topic / Forward this Topic	Admin Admin. admin	Posted: Delivery in Progress sun exposure Prereview Administrative Notification (1102 testing)
Post a Reply to this Topic / Forward this Topic	Abby Ack	Posted: Delivery in Progress sun exposure IRB-19-5430 PI Signoff Notification/1102dev

This area will also contain a list of any correspondence generated by users. If the review board generates a correspondence and sends it to someone listed on the study, if someone within the study team generates and sends a correspondence to someone within the study, to the review board or to an outside recipient, a record will post here.

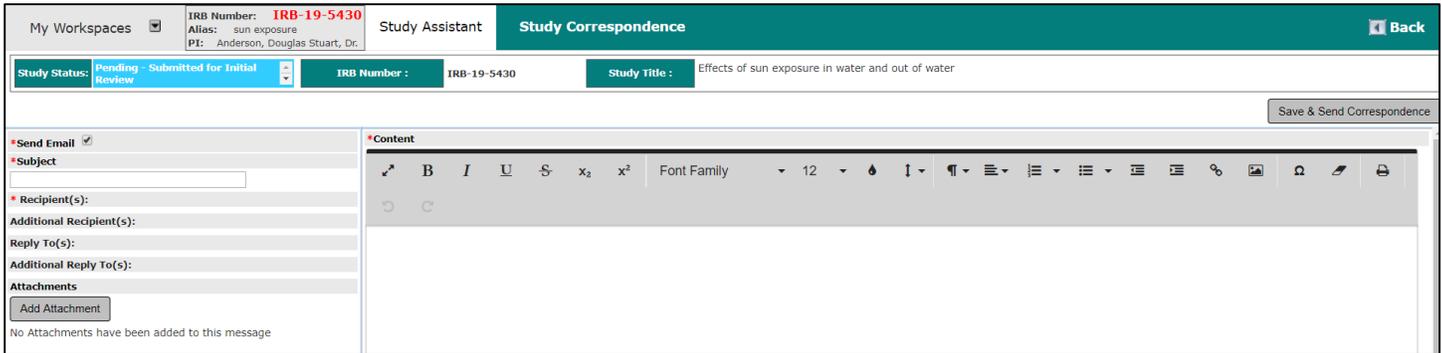
The review board and the study share the Study Correspondence, meaning any correspondence generated is visible by both sides.

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

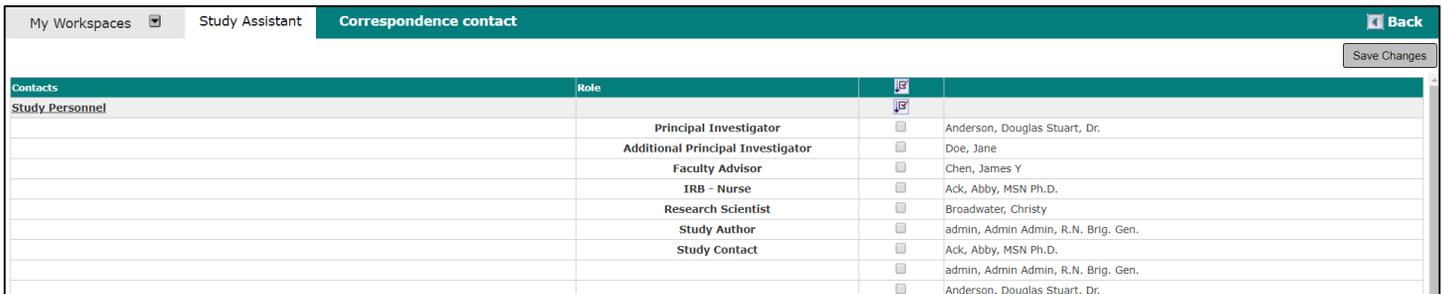
You can create and send correspondence as needed from this screen. To generate correspondence, click on the **Add a New Correspondence** button.

This screenshot is identical to the one above, but the 'Add A New Correspondence' button is highlighted with a red rectangle to draw attention to it.

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



1. Select the 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 bring up a screen where you can select from among the Study Personnel, with the Study Contact checked by default.



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



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



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)** and allows you to add any additional users, who should receive a reply.
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 click **Upload** to locate the file on your computer. When you are finished adding an 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.



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 in their Un-opened Correspondence on their homepage. If the Send Email is not selected, the recipients will only have the correspondence in their Un-opened Correspondence and a record of the correspondence will post in Study 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. 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**.

	View Message	Author	Subject
		Post a Reply to this Topic / Forward this Topic	
		Abby Ack	Posted: Delivery in Progress sun exposure IRB-19-5430 PI Signoff Notification/1102dev

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

Study Status: Pending - Submitted for Initial Review **IRB Number:** IRB-19-5430 **Study Title:** Effects of sun exposure in water and out of water

[Save & Send Correspondence](#)

***Send Email**

***Subject**
IRB-19-5430 PI Signoff Notification/1102dev

***Recipient(s):**
Douglas Stuart Anderson, Dr.; Admin Admin admin, R.N. Brig. Ge n.; Douglas Stuart Anderson, Dr.

Additional Recipient(s):

Reply To(s):

Additional Reply To(s):

Attachments
[Add Attachment](#)

No Attachments have been added to this message

***Content**

>>Abby Ack wrote:
Study Principal Investigator Signoff Notification

Please do not respond to this message. These messages are automatically generated from the IRIS system.

TO: Douglas Stuart Anderson, Dr.

Other Study Personnel: Jane Doe, Abby Ack, MSN Ph.D., Christy Broadwater

Reference Number: 021497

Protocol Number (if available): IRB-19-5430

Go here to view : [Click Here](#)

Any replies will post in the Study Correspondence below the original. Note that each correspondence generated is a record in the system, (at the top of the table reads 1 result found). Any replies to a correspondence are counted with the original correspondence and is not recognized as a separate correspondence.

	View Message	Author	Subject
		Post a Reply to this Topic / Forward this Topic	
		John Investigator	Posted: Delivery in Progress S0421 Prereview Administrative Notification (10032 testing)
		Admin Admin. admin	Posted: 05/01/2019 09:31 AM PDT S0421 Prereview Administrative Notification (10032 testing)

Forwarding a correspondence is similar to replying. A new page will open, allowing you to add to the **Content** and you can select **Recipient(s)**. When you forward a correspondence, a new record will not list in Study Correspondence, as the Reply does.

Outstanding Submissions

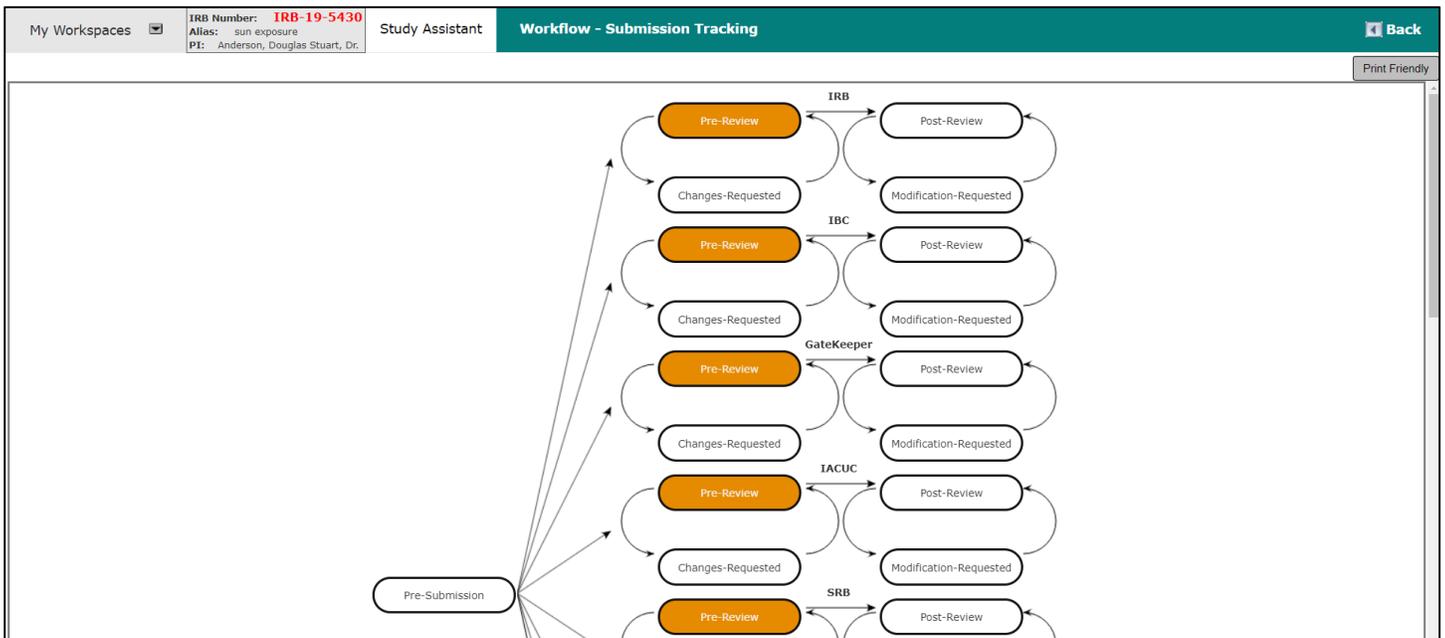
Any submission form created for the study will populate in the Outstanding Submission(s) table at some point. Submissions are listed here if the form has been completed, but not yet sent. The submission will also populate if the form has been sent, but is still being routed to the review board, (example, not all required signoffs have been collected). When the review board receives the submission and begins processing the form, the link in Outstanding

Submissions will be removed. At this point, if you need to find information related to your form, you would go to Submissions History to find it. Any submission that is returned by the review board for corrections will also post here, allowing the user to access the correction form, to make necessary changes and re-submit the form to the board.

The screenshot shows the 'Submissions' page for a study with IRB Number IRB-19-5430. The study title is 'Effects of sun exposure in water and out of water'. The submission status is 'Pending - Submitted for Initial Review'. On the left, there are sections for 'Protocol Items' and 'Current Approval Packet'. The 'Outstanding Submission(s)' table is highlighted with a red border and contains the following data:

Track Location	Ref Number	Request Type	Process Submission
	021497	Click on the hyperlink to edit/view the submission. Amendment Form	Send Submission
Routing In Process	021502	Click on the hyperlink to edit/view the submission. Amendment Form	Retract Submission

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.



This will open the same Workflow – Submission Tracking screen you may have seen earlier after completing a signoff task. 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 also receive notifications from the system, to alert them that a certain user has not completed signoff yet.

 Outstanding Submission(s)			
Track Location	Ref Number	Request Type	Process Submission
	021497	Click on the hyperlink to edit/view the submission.  Amendment Form	<div style="border: 1px solid gray; padding: 2px; text-align: center;">Send Submission</div>
 Routing In Process	021502	Click on the hyperlink to edit/view the submission.  Amendment Form	<div style="border: 1px solid gray; padding: 2px; text-align: center;">Retract Submission</div>

In the **Request Type** column, you can click on the link to open the form. If the form has not been submitted yet, 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**, 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 send it back through for required signoffs again.

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 and any users noted as the Study Contact will receive a notification a certain number of days before the review due date, as specified in the notification setup.

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

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

All Tasks				
Outstanding		Completed		
All Tasks	Study Tasks	Project Tasks		
Task List: Continuing Review Due				
30 result(s) found... 1 - 10				
	Click to open	Task Type	Received	Description
<input type="checkbox"/>		Continuing Review Due	05/03/2019 10:31 AM PDT	Pending Expiration Notice for Email and Home Screen Task Notification IRB-19-4651 1102Dev - Day IRB-19-4651 with the expiration date of 05/04/2019
<input type="checkbox"/>		Continuing Review Due	05/03/2019 10:23 AM PDT	Pending Expiration Notice for TEST 1102Dev- Continuing Review Notification IRB-19-4637 - 1 day with the expiration date of 05/04/2019

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

My Workspaces | IRB Number: **IRB-19-4651** | Study Assistant | Continuing Review Form Selection | Back

Study Status: FollowUp+ CR=2 | IRB Number: IRB-19-4651 | Study Title: Continue Review

Continue

No Action Required - Dismiss Task

Select a Form or go to the Study Management Page.

Continuing Review Submission Form

IRB Change Request

Filling out the form

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-19-4651** | Study Assistant | Continuing Review Submission Form - (Version 1.0) | Back

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

Section view of the Form | Entire view of the Form

1.0 Renewal Information

1.1 Submission Summary

Submission Summary

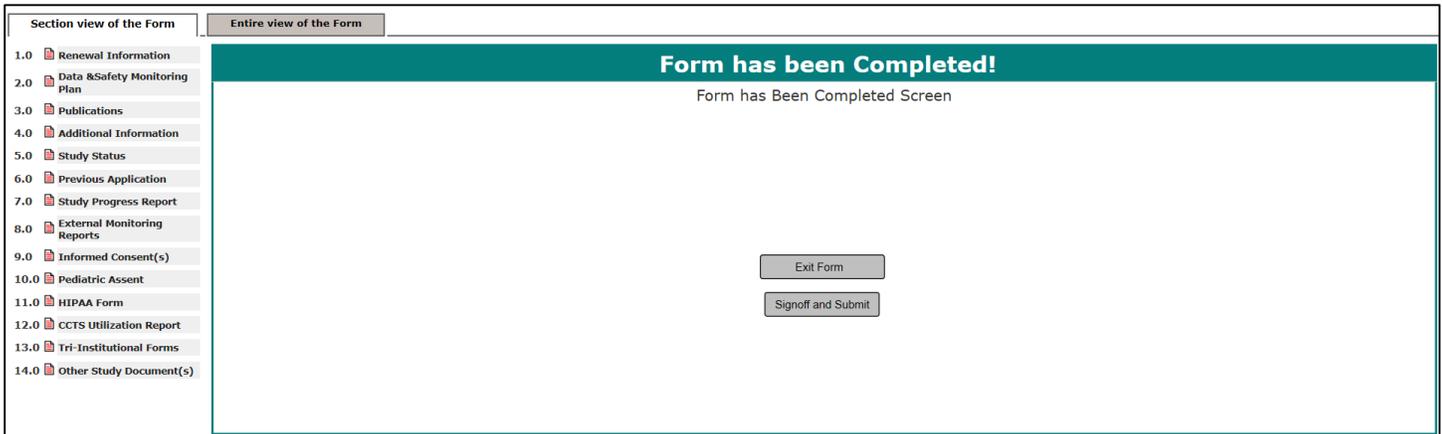
1.2 Study Information

Study Title:

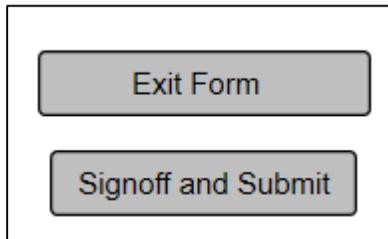
Once the form is complete and the required document are attached, the form is ready to send to the Review Board.

Submitting the Form

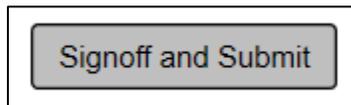
You will be presented with a section in the form, notifying you that the form is complete. Depending on your role on the study, and your systems signoff requirements you may see different buttons on this page.



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



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



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



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

You may choose to route for additional signatures, if you need to have other personnel on the study review the form, before it reaches the review board and if you need department approval. Make your selection and click the **Save and Continue** button, as seen in the image below.

Setup for Submission Routing and Signoff

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

Select the Key Personnel for Submission Routing and Signoff:

Include in signoff	Approved	Name	Role
<input checked="" type="checkbox"/>		Admin Admin admin, R.N. Brig. Gen.	Principal Investigator

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

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

Cancel - Finalize later
Save - Signoff Routing List

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

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

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

Select the Key Personnel for Submission Routing and Signoff:

Include in signoff	Approved	Name	Role
<input checked="" type="checkbox"/>		Admin Admin admin, R.N. Brig. Gen.	Principal Investigator

The bottom table in the signoff process is for reviewers who need to approve the submission, but they 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, by Department** search filters to find the user you wish to add and then click the icon in the **Select User** column.

Add Additional Key personnel to the Routing Signoff List

Last Name: First Name: Find User/Search Directory

by Department:

Select	Name	Department	Email
Your search criteria returned 0 results.			
The Additional Personnel will to be added to the signoff routing list upon clicking the "Save - Add to Routing List" button			
Remove	Name	Role	
No additional personnel have been added to the signoff routing list.			

Cancel - Adding Personnel Save - Add to Routing List

The user you selected will add 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. You can change this by changing the order, if one reviewer should receive the task before another. Click the **Save and Continue** button to proceed.

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

Include in signoff	Order	Approved	Name	Role
<input checked="" type="checkbox"/>	<input type="text" value="1"/>		Joe T Board	--none-- <input type="text"/>
<input checked="" type="checkbox"/>	<input type="text" value="2"/>		John Philip Capitanio	--none-- <input type="text"/>

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

Setup for Submission Routing and Signoff

This screen is for reviewing the signoff routing list. You must answer "Yes" or "No" to the finalization of the Personnel. Once the "Yes" selection is made the button "Save - Start Signoff Routing" becomes enabled to be clicked. Clicking the "Save - Start Signoff Routing" will start the routing list and then the submission board review(s). Clicking the "Go back to Make Changes" will place you back to editing the routing list. Clicking the "Cancel - Finalize later" will close this window. The submission process is incomplete.

Finalize List of Personnel for Submission Routing and Signoff:

Order	Approved	Name	Role
		Admin Admin admin, R.N. Brig. Gen.	Principal Investigator
1		Joe T Board	Additional personnel
2		John Philip Capitanio	Study Chairman

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

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

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

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 stored in their user account information. They will also receive a Submission Routing Signoff task on their homepage. This task will remain on their homepage until the user opens the task and completes the sign off.

The screenshot shows the 'All Tasks' dashboard with tabs for 'Outstanding' and 'Completed'. A task list is displayed with columns for 'Click to open', 'Task Type', 'Received', and 'Description'. The task 'Submission Routing Signoff' is highlighted, with a received date of 07/29/2019 03:47 PM PDT and a description: 'Admin Admin admin, R.N. Brig. Gen. as Principal Investigator review and apply signoff, assigned by Admin A admin, R.N. Brig. Gen.'

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

The screenshot shows the 'Submission Form(s)' section with a list of documents: 'Subject 214 (English) - (Version 1.0)', 'Standard Consent (1) - (Version 1.0)', and 'Brochure_College - (Version 1.0)'. Below the list, there are radio buttons for 'Approve' and 'Deny', a 'Comments' field, and a 'Save Signoff' button.

Also listed on this page is a link to the Submission Components. 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. This is the package that is being submitted to the review board for review.

If a document can be printed, a check box will populate next to the document in the **Print** column. You can select any of these items then click the **Print Selected Item(s)** button at the top of the table.

The screenshot shows a table with columns: 'Include in Last Approved', 'Compare to Last Approved', 'View in Separate Window', and 'Submission Component Name - Version'. A red box highlights the 'Continuing Review Submission Form - (Version 1.0)' row. Below it, there are rows for 'Application - (Version 1.0)', 'Consent Form(s)', and 'Document(s)' including 'Standard Consent (1) - (Version 1.0)' and 'Brochure_College - (Version 1.0)'.

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 been completed their approval or denial information will populate on this page.

<p>Admin Admin admin, R.N. Brig. Gen. as Principal Investigator do you Approve or Deny this submission?</p> <p>This form requires your electronic signature. Please enter your User ID & Password:</p>	<p><input type="radio"/> Approve <input type="radio"/> Deny</p> <p>Comments: <input type="text" value="Click here to add comments."/></p> <p>User ID: <input type="text"/></p> <p>Password: <input type="text"/></p>
--	---

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
<input type="checkbox"/> Pre-Submission Retract Submission			07/29/2019 03:33 PM PDT	07/29/2019 03:56 PM PDT	0 Day(s) 0 Hour(s) 22 Minute(s)
Completed		Continuing Review Submission Form is waiting to be submitted	07/29/2019 03:33 PM PDT	07/29/2019 03:56 PM PDT	Day Hour Minute 0 0 22
Completed		Submission rejected	07/29/2019 03:54 PM PDT	07/29/2019 03:55 PM PDT	Day Hour Minute 0 0 1
Completed		Continuing Review Submission Form has been retracted by Admin Admin admin, R.N. Brig. Gen.	07/29/2019 03:55 PM PDT	07/29/2019 03:55 PM PDT	Day Hour Minute 0 0 0
Completed	<input type="button" value="View Signoff Routing List"/>	Assign Department Personnel for Signoff	07/29/2019 03:56 PM PDT	07/29/2019 03:56 PM PDT	Day Hour Minute 0 0 0
Completed	<input type="button" value="View Signoff"/>	Admin Admin admin, R.N. Brig. Gen. as Principal Investigator review and apply signoff, assigned by Admin A admin, R.N. Brig. Gen.	07/29/2019 03:56 PM PDT	07/29/2019 03:56 PM PDT	Day Hour Minute 0 0 0

If you select **Deny** any other sign off task will cancel, and the submission will be rejected.

<input type="button" value="Pre-Submission"/>					
Task Status	Task Action/Details	Task Name	Date Created	Date Completed	Total Time
<input type="checkbox"/> Pre-Submission Retract Submission			07/29/2019 03:33 PM PDT		0 Day(s) 0 Hour(s) 21 Minute(s)
Completed		Continuing Review Submission Form is waiting to be submitted	07/29/2019 03:33 PM PDT	07/29/2019 03:34 PM PDT	Day Hour Minute 0 0 1
Error	<input type="button" value="View Signoff Routing List"/>	Assign Department Personnel for Signoff	07/29/2019 03:34 PM PDT	07/29/2019 03:54 PM PDT	Day Hour Minutes 0 0 20
Error	<input type="button" value="View Signoff"/>	Admin Admin admin, R.N. Brig. Gen. as Principal Investigator review and apply signoff, assigned by Admin A admin, R.N. Brig. Gen.	07/29/2019 03:47 PM PDT	07/29/2019 03:54 PM PDT	Day Hour Minutes 0 0 7
Received		Submission rejected	07/29/2019 03:54 PM PDT		Day Hour Minute 0 0 0

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

The screenshot shows the 'All Tasks' section of the iRIS interface. The 'Outstanding' tab is selected. The 'Task List' dropdown is set to 'All'. Below the navigation tabs, it indicates '8854 result(s) found...'. The table below has the following data:

	Click to open	Task Type	Received	Description
<input type="checkbox"/>		Submission Signoff Denied	07/29/2019 03:57 PM PDT	Submission rejected

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 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 task for Pre-Review Changes, called a Submission Correction. 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 Corrections form.

The screenshot shows the 'All Tasks' section of the iRIS interface. The 'Outstanding' tab is selected. The 'Task List' dropdown is set to 'Submission Correction'. Below the navigation tabs, it indicates '129 result(s) found...'. The table below has the following data:

	Click to open	Task Type	Received	Description
<input type="checkbox"/>		Submission Correction	07/26/2019 11:25 AM PDT	IBC returned the submission for corrections , assigned by Admin A admin, R.N. Brig. Gen.
<input type="checkbox"/>		Submission Correction	07/26/2019 10:09 AM PDT	IRB returned the submission for corrections , assigned by Akshay M.S. Brjaodier General

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 in 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.

My Workspaces IRB Number: **IRB-19-5430** Study Assistant Study Correspondence Back

IRB Alias: sun exposure
PI: Anderson, Douglas Stuart, Dr.

Study Status: Pending - Submitted for Initial Review IRB Number: IRB-19-5430 Study Title: Effects of sun exposure in water and out of water

5 result(s) found...

Print Friendly Add A New Correspondence Delete Selected Correspondence

View Message	Author	Subject
	Admin Admin. admin	Posted: Delivery in Progress sun exposure IRB meeting outcome - protocol IRB-19-5430 Effects of sun exposure in water and out of water

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 access a Modification or Change Request/Amendment form to submit changes 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 in the form.

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 an Amendment form and is located within the IRB Forms group. However, your system may contain a different list of forms.

Submissions **Study Management**

Current Approval Packet

Protocol Items

- Study Application
- Other Study Documents ▶
- Contract Documents

- 2-Initial Review Submission Summary and Attachments
- 8-Site Submission Invitation
- Amendment Form
- Adverse Event Form
- ...

When you click on the link for Amendment Form you will be directed to a page that lists all Amendments that have been created for this study. The items within this area are reviewed in the Submissions Forms section of this document.

My Workspaces		IRB Number: IRB-19-5430	Study Assistant	Amendment Form		Back																																							
Study Status:	Pending - Submitted for Initial Review	IRB Number :	IRB-19-5430	Study Title :	Effects of sun exposure in water and out of water																																								
<p>List of records associated with form: Amendment Form. To view previous versions click on the folder icon.</p> <p>Copy Form Add a New Form Compare Two Versions Delete Selected Form(s)</p> <p>2 result(s) found...</p> <table border="1"> <thead> <tr> <th>Show Recv</th> <th>Show Follow-Up</th> <th>Edit/View</th> <th>Details</th> <th>Apply to Multiple</th> <th>Sub. Rounds</th> <th>Track Location</th> <th>Process Submission</th> <th>Submission Date</th> <th>Created By</th> <th>Date Created</th> <th>Modified By</th> <th>Date Modified</th> </tr> </thead> <tbody> <tr> <td><input type="checkbox"/></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td>In Process</td> <td>07/29/2019 02:45:51 PM PDT</td> <td>Abby Ack</td> <td>07/29/2019 02:44:06 PM</td> <td>Admin Admin admin</td> <td>07/29/2019 04:06:25 PM</td> </tr> <tr> <td><input type="checkbox"/></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td>Abby Ack</td> <td>07/29/2019 02:11:35 PM</td> <td>Douglas Stuart Anderson</td> <td>07/29/2019 02:12:31 PM</td> </tr> </tbody> </table>							Show Recv	Show Follow-Up	Edit/View	Details	Apply to Multiple	Sub. Rounds	Track Location	Process Submission	Submission Date	Created By	Date Created	Modified By	Date Modified	<input type="checkbox"/>							In Process	07/29/2019 02:45:51 PM PDT	Abby Ack	07/29/2019 02:44:06 PM	Admin Admin admin	07/29/2019 04:06:25 PM	<input type="checkbox"/>									Abby Ack	07/29/2019 02:11:35 PM	Douglas Stuart Anderson	07/29/2019 02:12:31 PM
Show Recv	Show Follow-Up	Edit/View	Details	Apply to Multiple	Sub. Rounds	Track Location	Process Submission	Submission Date	Created By	Date Created	Modified By	Date Modified																																	
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<input type="checkbox"/>									Abby Ack	07/29/2019 02:11:35 PM	Douglas Stuart Anderson	07/29/2019 02:12:31 PM																																	

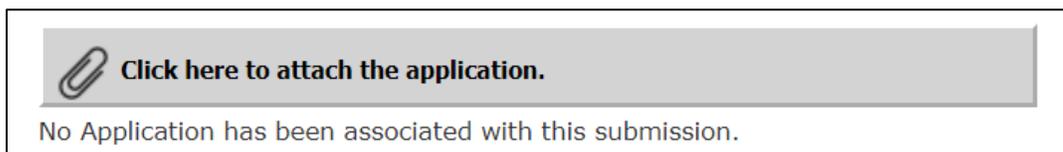
To create a new amendment, click the **Add a New Form** button. This will open the form as it has been defined in the Forms Designer. You can fill out the form using the **Save and Continue** button to navigate through the sections.

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

My Workspaces		IRB Number: IRB-19-5430	Study Assistant	Amendment Form - (Version 3.0)		Back								
<p>Print Friendly Save Section Save and Continue to Next Section</p> <p>Section view of the Form Entire view of the Form</p> <p>1.0 Protocol Changes</p> <p>1.0 Protocol Changes</p> <p>1.1 Submission Summary</p> <p>Submission Summary</p> <p><input type="text"/></p> <p>1.2 Select User to Route this Form to:</p> <p><input type="button" value="Add Selected User"/></p> <p>No Users have been selected.</p> <p>1.3 Populate Data Collection</p> <p>Please choose Institutions to Populate Tables with</p> <p>Select the Institution(s) you wish to share the form.</p> <table border="1"> <thead> <tr> <th>Select</th> <th>Institution Name/ Site</th> <th>Principal Investigator</th> <th>Status on Study</th> </tr> </thead> <tbody> <tr> <td colspan="4">No Institution(s) have been added to this form</td> </tr> </tbody> </table> <p>1.4 Attach Site App</p>							Select	Institution Name/ Site	Principal Investigator	Status on Study	No Institution(s) have been added to this form			
Select	Institution Name/ Site	Principal Investigator	Status on Study											
No Institution(s) have been added to this form														

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, 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 and click the icon in the **Create a Revised Application** button. Note: this icon is only available in the most current version of the application.

Attaching Study Application ✕


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

Save Attachment

Select	Show Rev.	Edit/View	Form Name	Approved	Create a Revised Application
<input type="radio"/>			MAIN IRB APP (Version 1.0)	Yes	 Add Revision

The system will verify that you want to create a revision. Click **OK** to confirm and continue creating the revision. Click **Cancel** to cancel the revision.

Confirm the adding a revision.

Are you sure you want to create a revision?

CONFIRM

CANCEL

If you clicked **OK**, 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 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.

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

Unattach	Revise/ Attach	Edit/ View	Title
			MAIN IRB APP (Version 1.1)

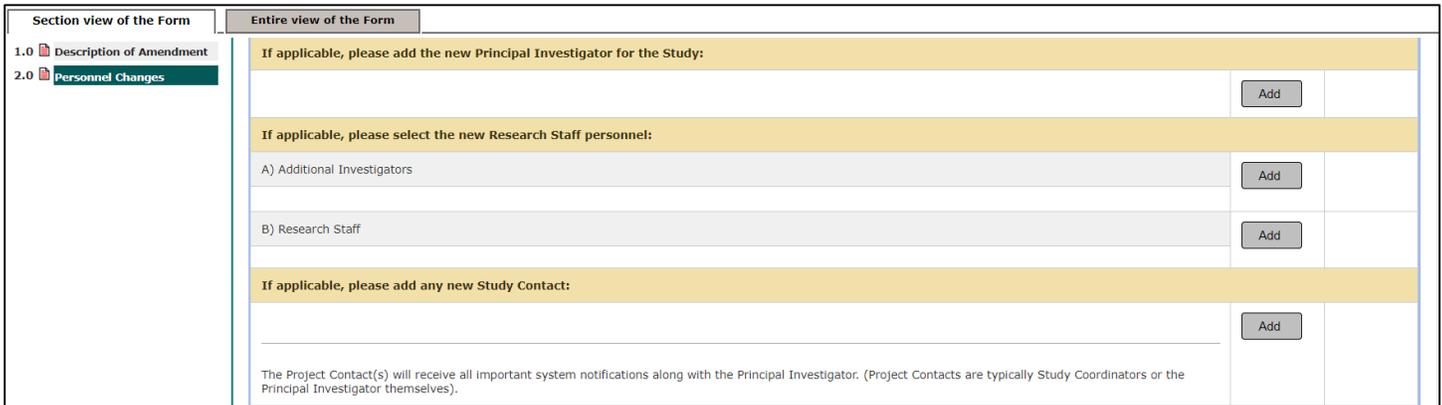
Requesting a Change in Key Personnel

If you need to request additional or removal study personnel, you will be directed to the Personnel Change Request data value. This value looks similar to section 2.0 of the Study Application where you add personnel to the study. This value will allow you to 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 but not until the review board approves the change in personnel.

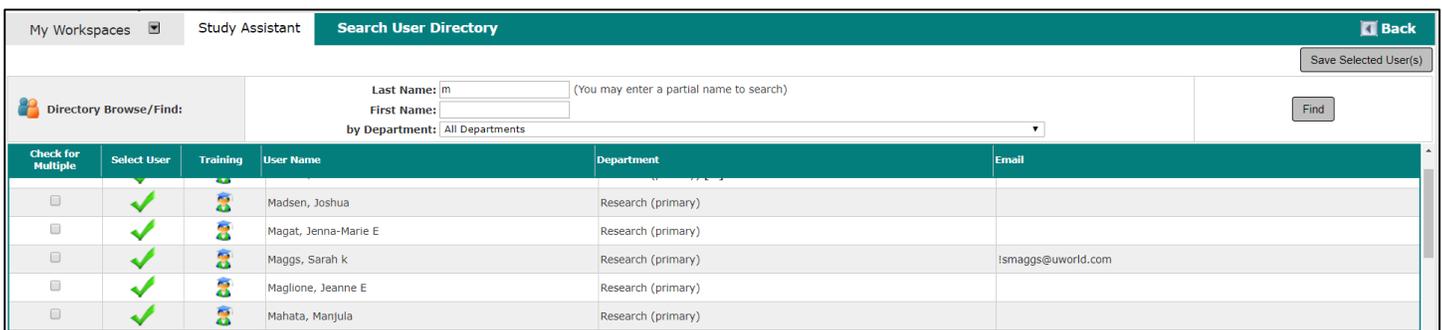
If there is a change in the study’s KSP and the board approve the KSP change, a new version of the application will be created to reflect the newly updated KSP.

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 user to any role, click the **Add** button next to the corresponding role.



This allows you to search the user directory by First name, Last name, or Department. Enter all or part of the criteria you know and click the **Find** button. To select a user to add, click the **Select User** icon. This selects the user and brings you back to the form. You can select more than one user by checking the boxes next to the users and then click the **Save Selected User(s)** button.



Check for Multiple	Select User	Training	User Name	Department	Email
<input type="checkbox"/>	<input checked="" type="checkbox"/>		Madsen, Joshua	Research (primary)	
<input type="checkbox"/>	<input checked="" type="checkbox"/>		Magat, Jenna-Marie E	Research (primary)	
<input type="checkbox"/>	<input checked="" type="checkbox"/>		Maggs, Sarah k	Research (primary)	ismaggs@uworld.com
<input type="checkbox"/>	<input checked="" type="checkbox"/>		Maglione, Jeanne E	Research (primary)	
<input type="checkbox"/>	<input checked="" type="checkbox"/>		Mahata, Manjula	Research (primary)	

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 – You can only have one Principal Investigator listed on the study. If you are requesting a change in PIs add the desired PI to the form and when the review board approves the change, the system will change out the PI. If additional PIs are needed on the study you may add them in the Additional Investigator’s section, if available.

Additional Investigators – Any new investigator user for the study, aside from the Principal Investigator, can be listed here. You may have any number of Additional Investigator’s and after you add a user to this group you will be able to specify their role.

Research Support Staff – This section is for any non-investigator users; you need to add to the study. You may have any number of research support staff listed here and after you add a user to this group, you will be able to specify which role they have.

Study Contact – You may add additional Study Contacts as needed. A Study Contact is a user on the study who will receive study related notifications from the system like Continuing Review notifications, Submission Correction

notifications, Review Response notifications, etc. The Study Contact is usually also another role on the study, like a Research Coordinator, PI, etc.

If you added a user to the data value in error, you can remove the request by selecting the checkbox next to their name and then clicking the **Remove** button in that same group.

At the bottom of the Personnel Change Request is an area where you can request the removal of personnel from the study. Click the **Select** button in this group.

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

A new page will open that lists the current personnel on the study. Select the user(s) you would like to remove from the study then click the **Save Selection** button.

My Workspaces | IRB Number: **IRB-19-5430** | Study Assistant | Select Personnel to Remove from Study | Back

Study Status: Pending - Submitted for Initial Review | IRB Number: IRB-19-5430 | Study Title: Effects of sun exposure in water and out of water

<input type="checkbox"/>	Name	Role on the Study
<input type="checkbox"/>	Douglas Stuart Anderson, Dr.	Principal Investigator
<input type="checkbox"/>	Abby Ack, MSN Ph.D.	Study Contact
<input type="checkbox"/>	Admin Admin admin, R.N. Brig. Gen.	Study Contact
<input type="checkbox"/>	Douglas Stuart Anderson, Dr.	Study Contact
<input type="checkbox"/>	Admin Admin admin, R.N. Brig. Gen.	Study Author
<input type="checkbox"/>	James Y Chen	Faculty Advisor
<input type="checkbox"/>	Abby Ack, MSN Ph.D.	IRB - Nurse
<input type="checkbox"/>	Jane Doe	Additional Principal Investigator
<input type="checkbox"/>	Christy Broadwater	Research Scientist

Any user you selected to be removed will be listed in this group. If you selected a user to remove in error, select the checkbox next to their name and click the **De-select** button.

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

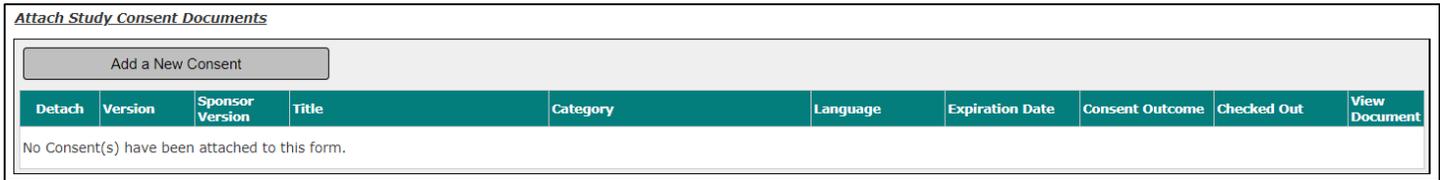
Doe, Jane Additional Principal Investigator
 admin, Admin Admin, R.N. Brig. Gen. Study Contact

Any change in personnel will not take effect on the study 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. The process is the same for both Consent forms and Other Study Documents, but they are two separate data values in the system forms designer. The process for revising and adding

new documents is described below using the Consent form as an example. However, the process is the same for adding Other Study Documents.

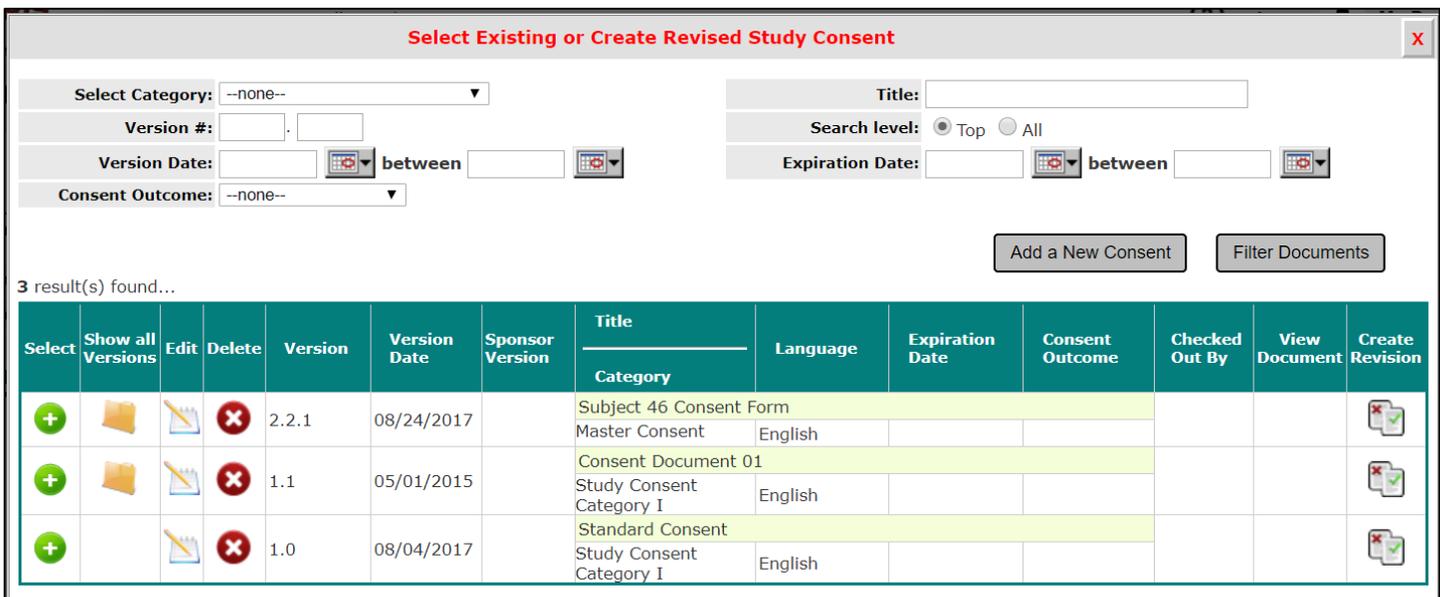


Select or Revise Existing Consent or Other Study Document

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.

A window will open within the browser that lists existing documents. This table lists details about the documents on 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 document you are revising, allowing you to change details and checkout the revised document. 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: different internet browsers might function differently in the way they process downloaded files.

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

You will return to the Study Consent Revision page. The page will indicate the document is checked out and you will have the ability to **Check-in Document** or **Undo Check-out Document**.

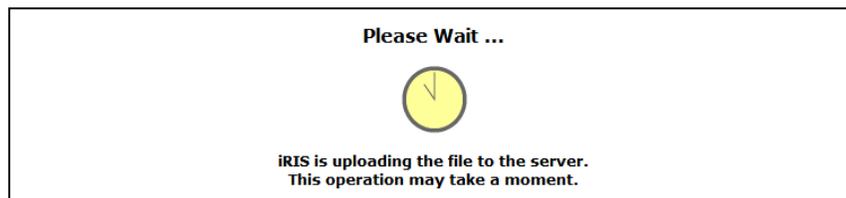
After you have made changes to the document in Microsoft Word, you can return to iRIS and check it back in by clicking the **Check-in Document** button.

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

Document Location: No file chosen

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

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



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

Study Consent Revision: X

* Consent Title:

Version Number: _2

* Version Date:

Sponsor Version:

Category: ▼

* Language: ▼

* Reconsent Required: Yes No

* Reconsent Reason:

Description:

Check-out the Document to your workstation for editing:

You will return to the form, and any consent document you selected will display in the table.

Select or Revise Existing		Add a New Consent							
Detach	Version	Sponsor Version	Title	Category	Language	Expiration Date	Consent Outcome	Checked Out	View Document
✘	2.2.1		Subject 46 Consent Form	Master Consent	English				
✘	1.2		Consent Document 01	Study Consent Category I	English				

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 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 to the review board for approval. The process for making changes to or adding Drugs and Devices are 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 select the icon in the **Delete** column. If you need to request changes to a current study drug or device, locate that item in the list and select the icon in the **Edit** column.

+ Add a New Drug to the Study						
Delete Drug	Edit	View Details	Trade Drug Name	Is the Drug FDA Approved	Is this a new drug or a new use of an already approved drug	IND Number
			Trade Drug Name: Laxiom	No	No	

When you select to edit an item the Study Drug or Study Device details window will open, containing the current information for the drug or device. You can make any necessary edits and click the **Save Drug Info** button to return to the form.

Study Drug Details:

Trade Drug Name: Laxiom

* Identify the name of the manufacturer or source of Investigational drug/biologic:

Is the drug supplied at no cost? Yes No

Is the Drug FDA Approved: Yes No

Is this a new drug or a new use of an already approved drug: Yes No

Is an IND necessary: Yes No

Who holds the IND:

- N/A
- Pharmaceutical company
- PI
- Outside PI

Provide details:

If FDA Approved and an IND is not required, Please provide a rationale for exemption:

Any additional drugs or devices, changes to drugs or devices or requests to remove drugs or devices from the study will not take effect until the review board approves the submission.

Signoff

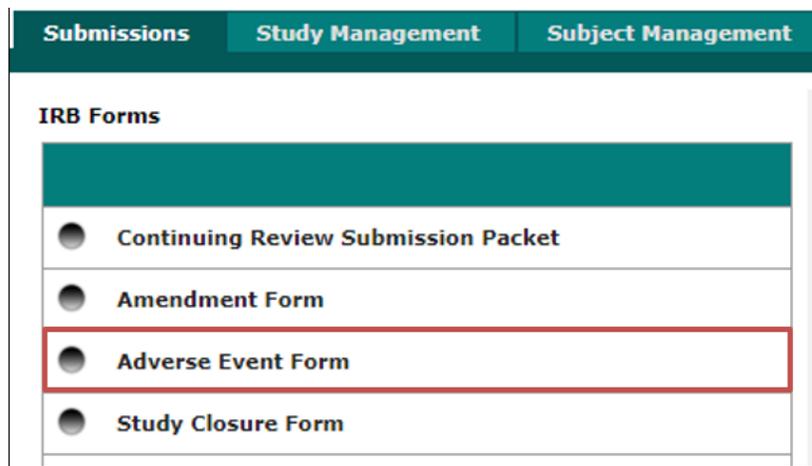
When the submission form is completed you will receive information about sending the form into the workflow following the same steps listed in the Submitting the Form section for Continuing Review. Remember, your Amendment form may or may not contain all the steps listed in these instructions.

Submitting an Adverse Event Form

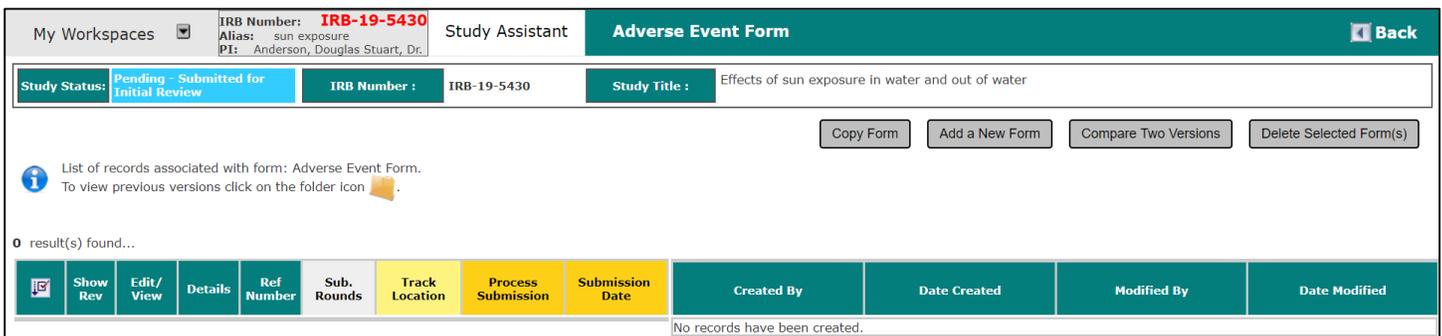
At any point during the life of your study, you can access an Adverse Event form to submit to the review board.

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 **Adverse Event Initial Form** and is located within the IRB Forms group. However, your system may contain a different list of forms.



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



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

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

After you select a subject, if applicable, you will be brought to the Adverse Event 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 **New Report** and continue to complete the form, as seen in the image 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.

1.5 Type of Report:

Initial Report
 Follow Up to report filed on date noted below:

Date initial report was filed:

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

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: **PRO-14-1222**

Alias: Subjects Study

PI: admin, Admin Admin, R.N. Brig. Gen.

Study Assistant

Adverse Event Form

Back

Return back to the Form
Save Selected Event

List of records associated with form: Adverse Event Form.

1 result(s) found...

Version	Ref Number	Created By	Date Created	Modified By	Date Modified	
<input type="radio"/>	1.0	021549	Admin Admin admin	07/30/2019 09:13:54 AM	Admin Admin admin	07/30/2019 09:25:41 AM

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

1.5 Type of Report:

Initial Report
 Follow Up to report filed on date noted below:

Date initial report was filed:

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

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 and Follow-up reports.

1 result(s) found...

	Show Rev	Show Follow-Up	Edit/View	Details	Ref Number	Sub. Rounds	Track Location	Process Submission	Submission Date	Created By	Date Created	Modified By	Date Modified
					021549				07/30/2019 09:27:28 AM PDT	Admin Admin admin	07/30/2019 09:13:54 AM	Admin Admin admin	07/30/2019 09:27:29 AM
										Admin Admin admin	07/30/2019 09:30:04 AM	Admin Admin admin	07/30/2019 09:30:12 AM
										Admin Admin admin	07/30/2019 09:28:37 AM	Admin Admin admin	07/30/2019 09:28:37 AM

Signoff

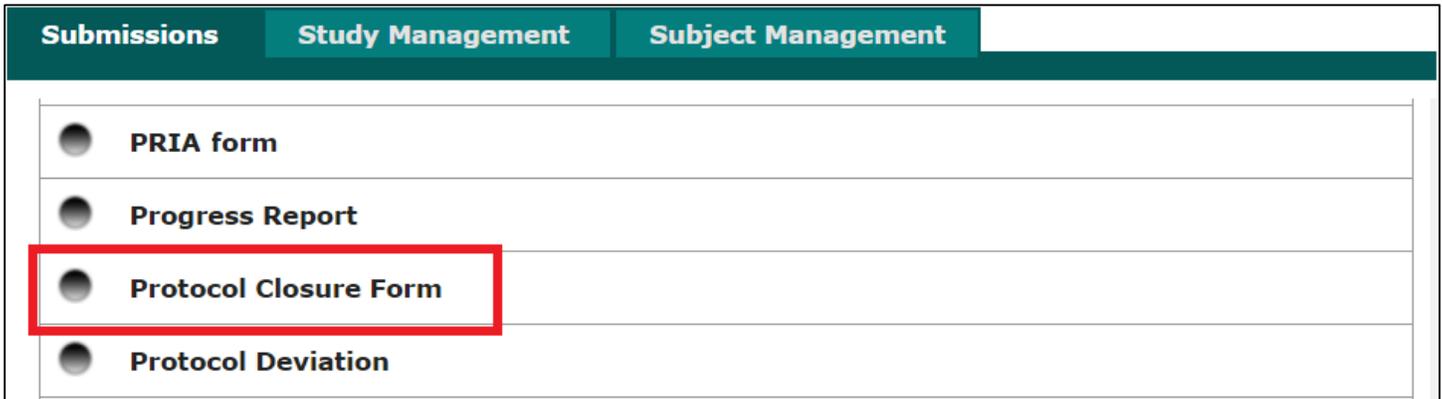
When the submission form is completed, you will receive information about sending the form into the workflow, following the same steps listed in the Submitting the Form section for Continuing Review.

Submitting a Study Closure Form

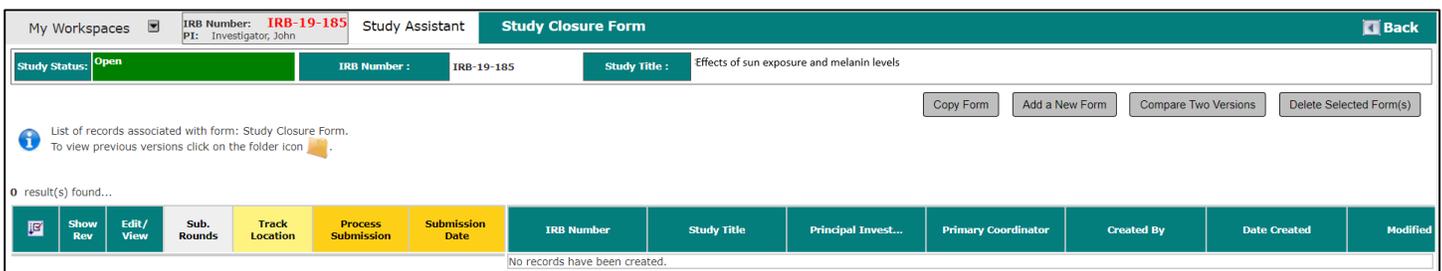
Once research has been complete and you are ready to inform the review board that your study is closed, you can access this type of form and submit it. Once the review board receives the form they can close out the study in iRIS.

Accessing the Form

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

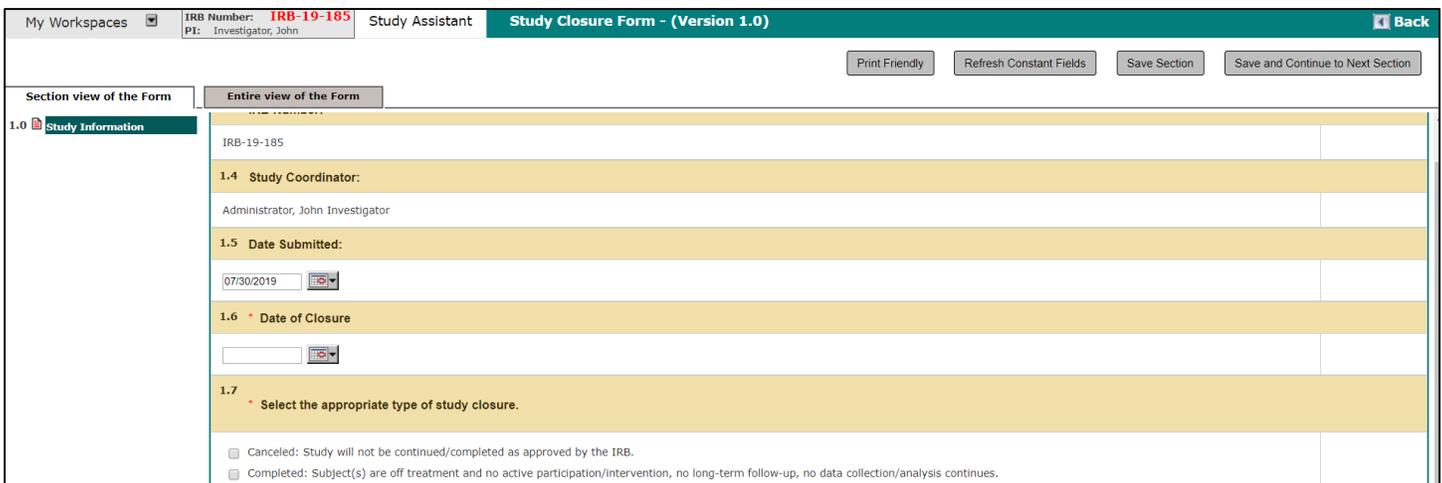


When you click on the link for the Study Closure, you will be directed to a page that lists all Study Closure forms that have been created for this study.



To create a new Study Closure, click the **Add a New Form** button.

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



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 property allows study personnel to close “Exempt” studies from the View My Studies section on the home screen. Users are able to check by going to the Study Summary page.

My Workspaces | IRB Number: **DT-IRB-18-03** | Protocol Assistant | **Protocol Summary** | Back

Protocol Status: **Open** | IRB Number: DT-IRB-18-03 | Protocol Title: Patient presenting with facial abscess and aggressive osteolysis with prominent periosteal reaction of the mandible

IRB Expiration Date: 09/28/2018

Print Friendly | Save Changes

IRB Number:	DT-IRB-18-03	Is Ceded From:	No
IRB of Record:	Yes		
Committee of Record:	—none—		
IRB Initial Approval:	03/29/2018		
Review Cycle:	6 Months		
IRB Expiration Date:	09/28/2018		
Continuing Review Due:			
Protocol Follow-up:			
Temporary Closed:	No		
Risk Assigned:			
Exempt:	Yes		
Subject Approved:	125		

Study personnel then have the option to close the study from the home page under “View my Studies” or by clicking into the study and by pressing the button, **Close Exempt Study**.

My Workspaces | IRB Number: **DT-IRB-18-03** | Protocol Assistant | **Submissions** | Back

Protocol Status: **Open** | IRB Number: DT-IRB-18-03 | Protocol Title: Patient presenting with facial abscess and aggressive osteolysis with prominent periosteal reaction of the mandible

IRB Expiration Date: 09/28/2018

Submissions | Protocol Management | Subject Management

Close Exempt Study | Current Approval Packet

Protocol Items

- Protocol Application
- Informed Consent
- Other Protocol Documents
- Contract Documents

Regulatory Forms

Regulatory Submission Forms

Submissions History

Protocol Correspondence

Outstanding Submission(s)

Track Location	Ref Number	Request Type	Process Submission
Routing In Process	000151	Click on the hyperlink to edit/view the submission. Unanticipated Events Form	In Process

The screenshot shows the 'IRB Studies' interface. At the top, there are tabs for 'All', 'Draft', 'IRB', and 'IACUC'. A search bar is located on the right. Below the tabs, it says '58 result(s) found...'. The main area contains a table with columns: 'Click to open Protocol Dashboard', 'Protocol Status', 'Review Board', 'RB Number', 'RB Expiration', 'Protocol Title / Study Number', 'Principal Investigator', and 'Actions'. The first row shows a study with status 'Open', review board 'IRB', RB Number 'DT-IRB-18-03', RB Expiration '09/28/2018', Protocol Title 'Patient presenting with facial abscess and aggressive osteolysis with promi...', and Principal Investigator 'Doe, Jane B.S.'. The 'Actions' column for this study includes buttons for 'History', 'Items', 'Forms', 'Hide', 'Close Exempt' (highlighted with a red box), 'Copy', 'Delete', and 'Corr'.

A window will pop up, confirming that the user would like to close the study.

The dialog box is titled 'Close Exempt Protocol'. It contains the text 'Please verify that you wish to close this Exempt Protocol?'. Below this, it displays the 'Protocol Title: Patient presenting with facial abscess and aggressive osteolysis with prominent periosteal reaction of the mandible' and 'Principal Investigator: Investigator, John'. At the bottom right, there are two buttons: 'No, Cancel' and 'Yes, Close the Protocol'.

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

The dialog box is titled 'Close Exempt Protocol'. It contains the text 'Please verify that you wish to close this Exempt Protocol?'. Below this, it displays the 'Protocol Title: Patient presenting with facial abscess and aggressive osteolysis with prominent periosteal reaction of the mandible' and 'Principal Investigator: Administrator'. A red error message follows: 'Your Privileges do not allow you change the Protocol status. Contact your System Administrator to allow operation.'. At the bottom right, there is a 'No, Cancel' button.