STUDY ASSISTANT

Study Management – Study Submissions

Version 10.03.02

Contents

Study Management – Study Submissions

Introduction

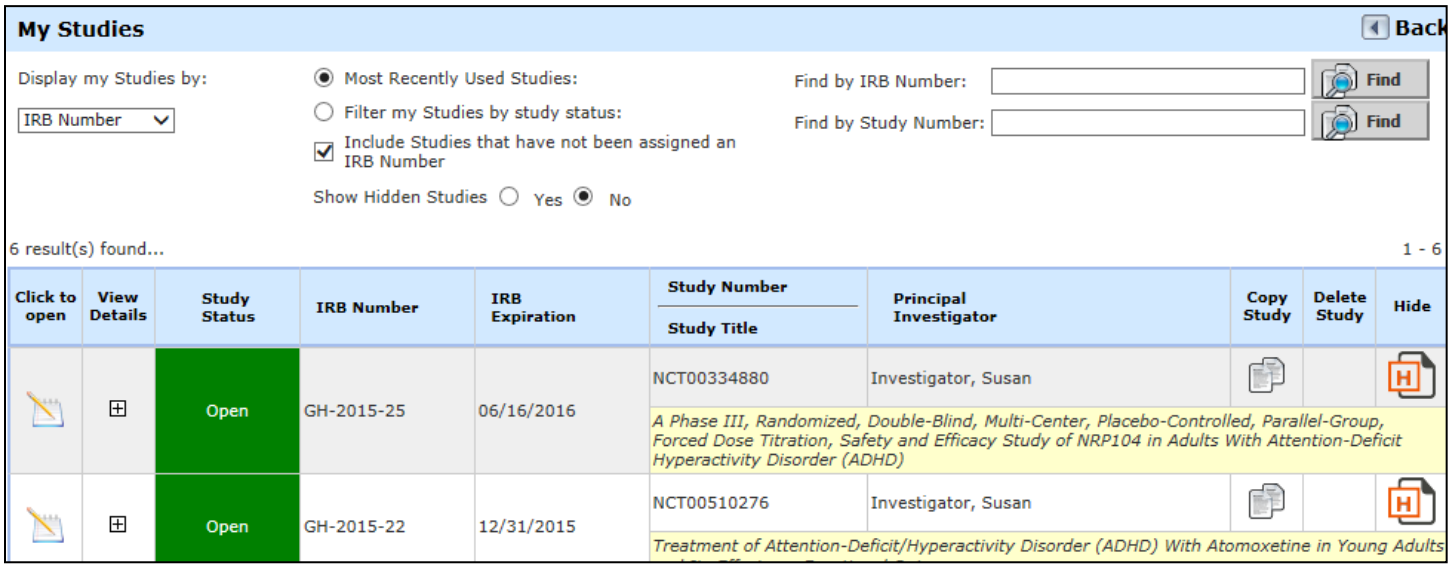
Within the study record, the study is broken up into sections, Submissions, Study Management, and, if using the Subject Management module, you will also have Subject Management. These tabs allow you to access different portions of the study so you can maintain study information in the system. This manual will take you through use of the Submissions tab, which 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.

Accessing a Study

To locate your study, click the My Studies link in the Study Assistant menu group on the homepage of your iRIS software.

The page that opens will display the studies you have a role on, along with basic information about each study. 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. You can consult the Study Assistant manual to learn more about navigating the My Studies screen.

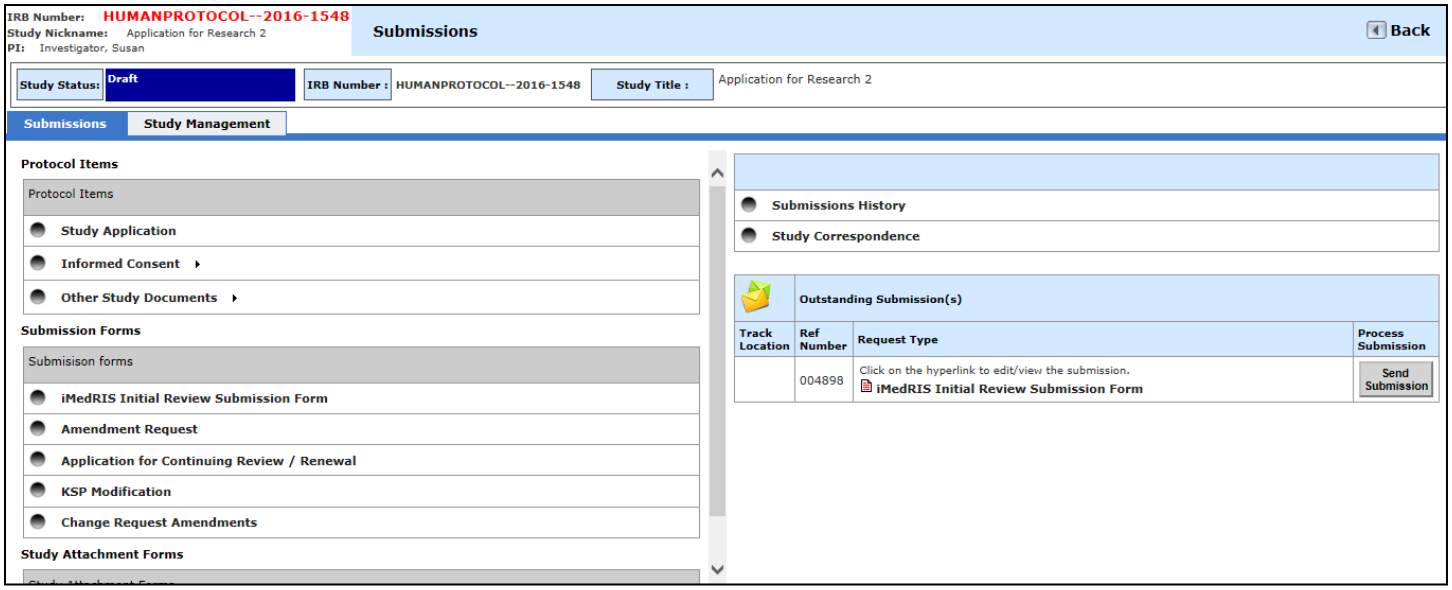
Once you have located the study in the list, click the  icon in the Click to Open column.



Submissions

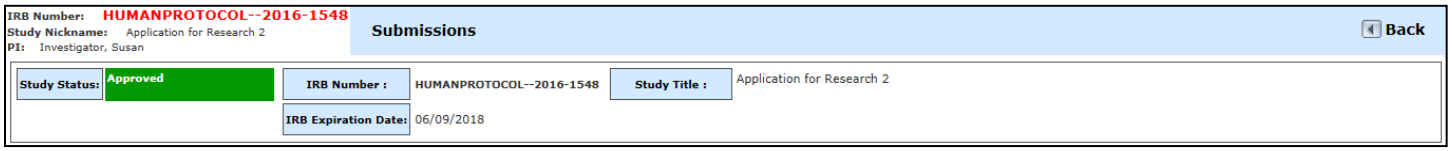
When you open a study in which the study application and submission form have been completed, the page will open to the Submissions tab. This tab contains links to various forms that can be created, completed, and submitted throughout the lifetime of the study. The top of the page lists a header with 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 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.



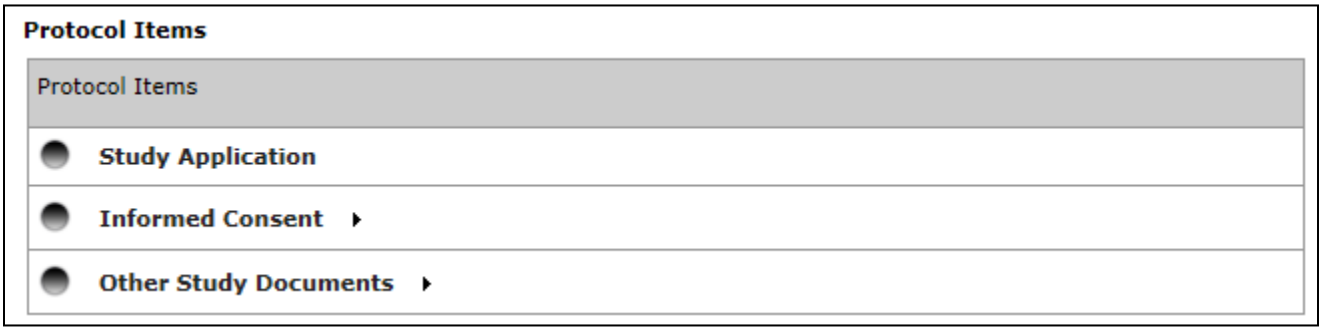
Displayed at the top left of the header are the Study Number/Nickname and PI.

Below this is listed the current Study Status, the IRB Number, Study Title, and the IRB Expiration Date, depending on whether or not 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 and view, revise and add Informed Consents or Other Study Documents.



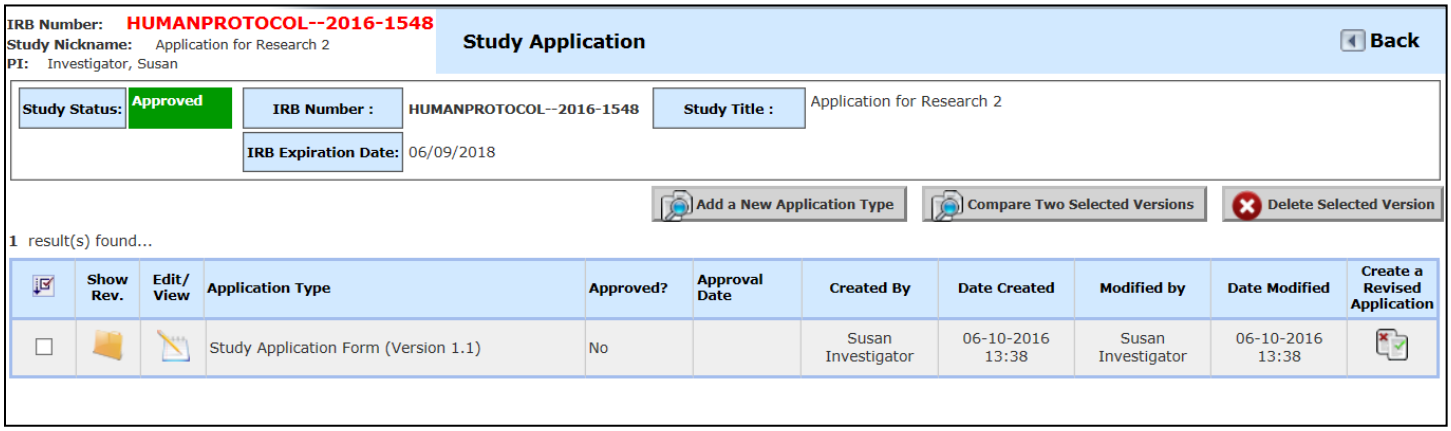
Study Application

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.

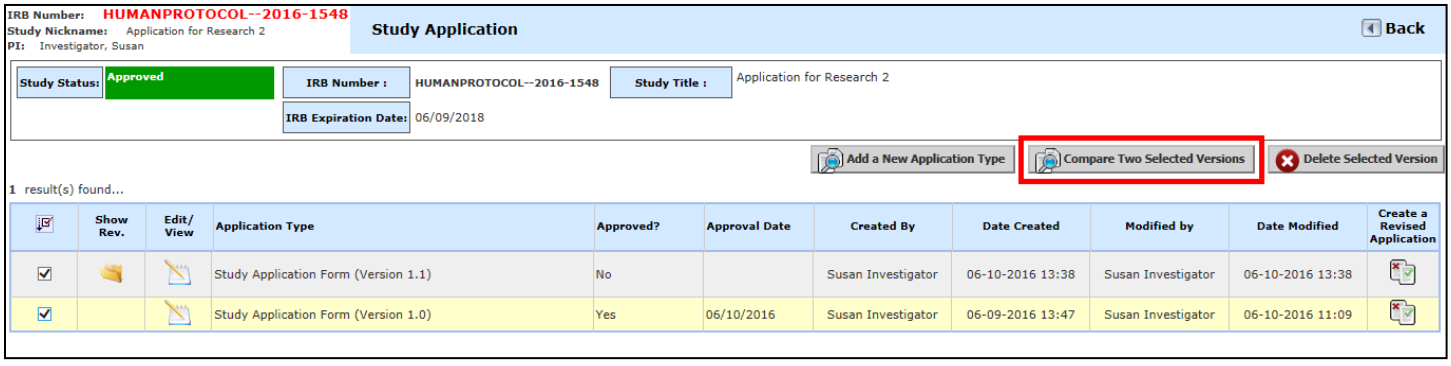
If your system is configured as such, you can add a new application type to the study. This functionality is available when the system.use_study_app_add_new_type property is set to Yes, available under System Administration > System Configuration > Study Application Setup.



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 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, and then click the **Compare Two Selected Versions** button.



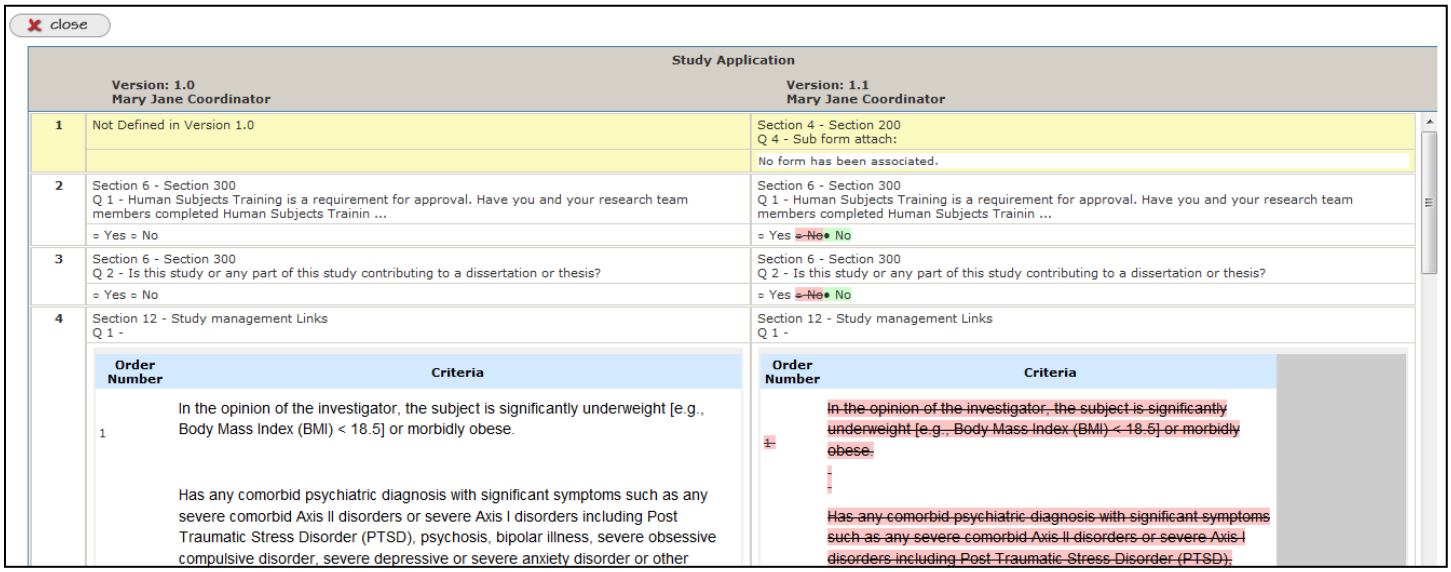
iRIS will run the two versions of the application through a comparer tool. This may take several moments, depending on the size of your Study Application. When the tool is complete, a new window will open, displaying both selected versions of the application in a side-by-side view, with the older version 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.

Click on sections to highlight them in yellow.

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



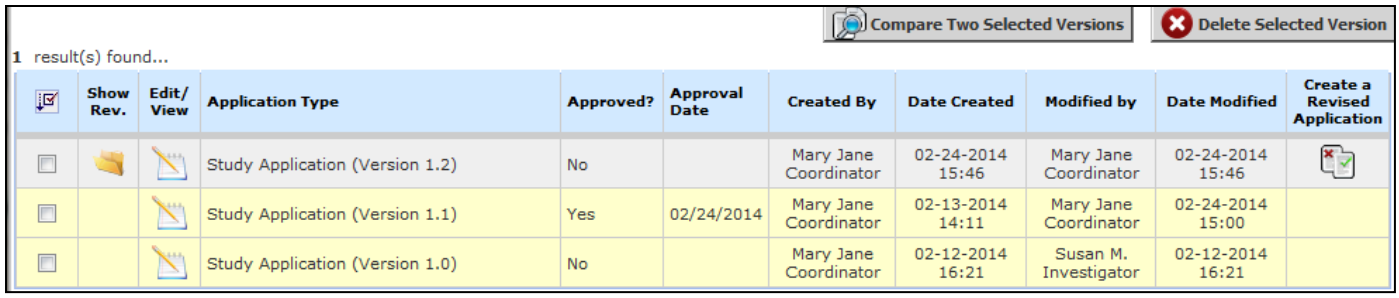
Revise Application

The current version of the Study Application cannot be modified if it has been submitted for review. When you click the  icon in the Edit/View column, the application will open, 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 column. The versions of the application which can be modified

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.

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. You can attach the revised version of the Study Application 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 columns does not reflect that the current version of the application is approved.



Delete Application

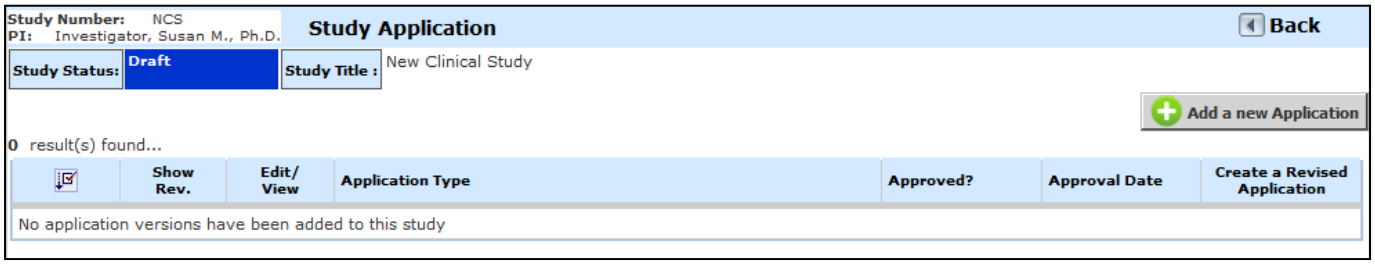
A version of the Study Application can only be deleted if you have not submitted that version. In the example above, version 1.0 and 1.1 have both been submitted, but 1.2 has not been submitted. You can delete this version of the application by clicking the checkbox next to the version and clicking the **Delete Selected Version** button. The system will ask you to confirm the deletion, and, if you click **OK**, 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.

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.

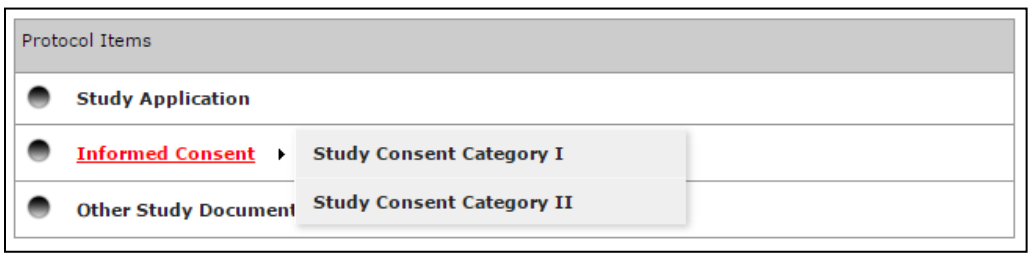
Add Application

The only time 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** button to create the application record for your study.



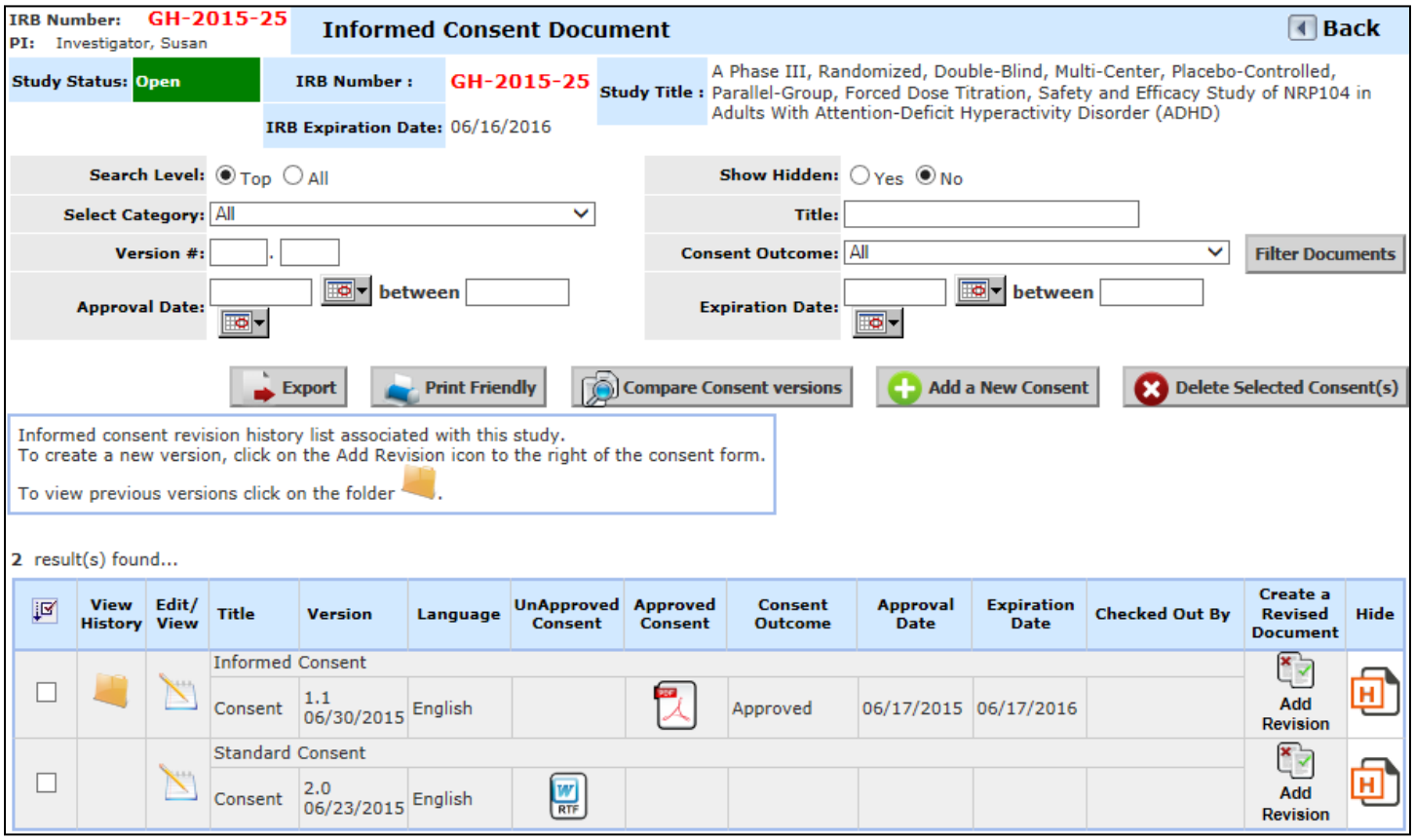
Informed Consent

The Informed Consent link, from the main Submissions screen, will direct you to the Informed Consent 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.



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.



Filters

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

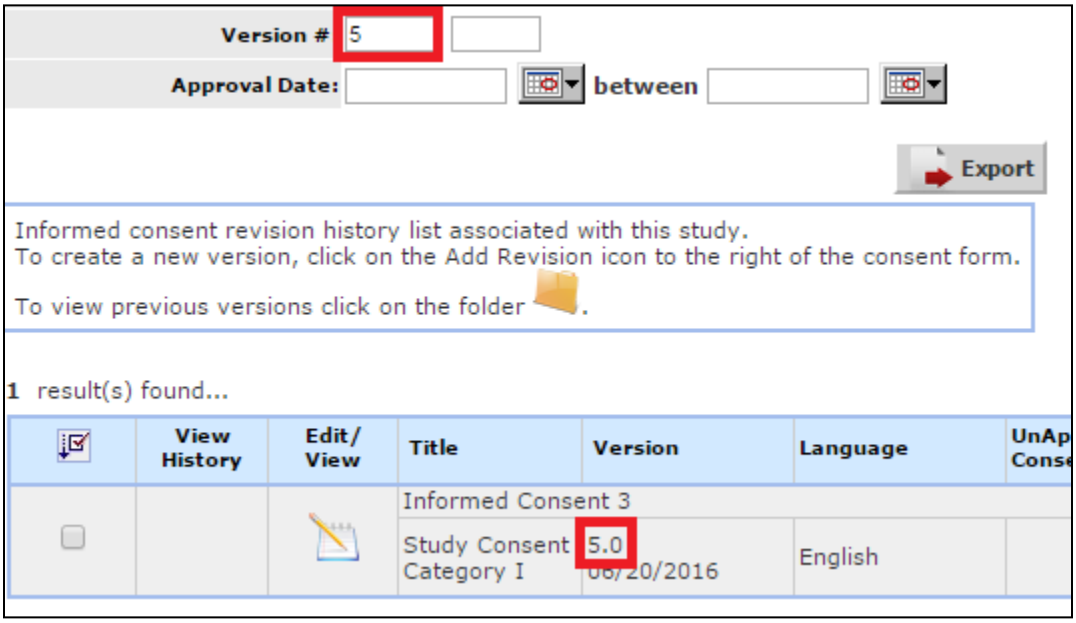
Search Level –The default selection for this filter is set to "Top." This means that when you use the search filters, the system will check only the top level, or latest version, of a document. If a document has revisions, only the latest version will be included in the search. If you would like to search 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. If you had selected a category before opening the library, that category will appear in this field and only consent documents in that category will appear in the search 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 "5," only documents that are version "5.x" will populate on the page; if you type in "1" in the second box (after the decimal), only documents that are version "x.1" 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.

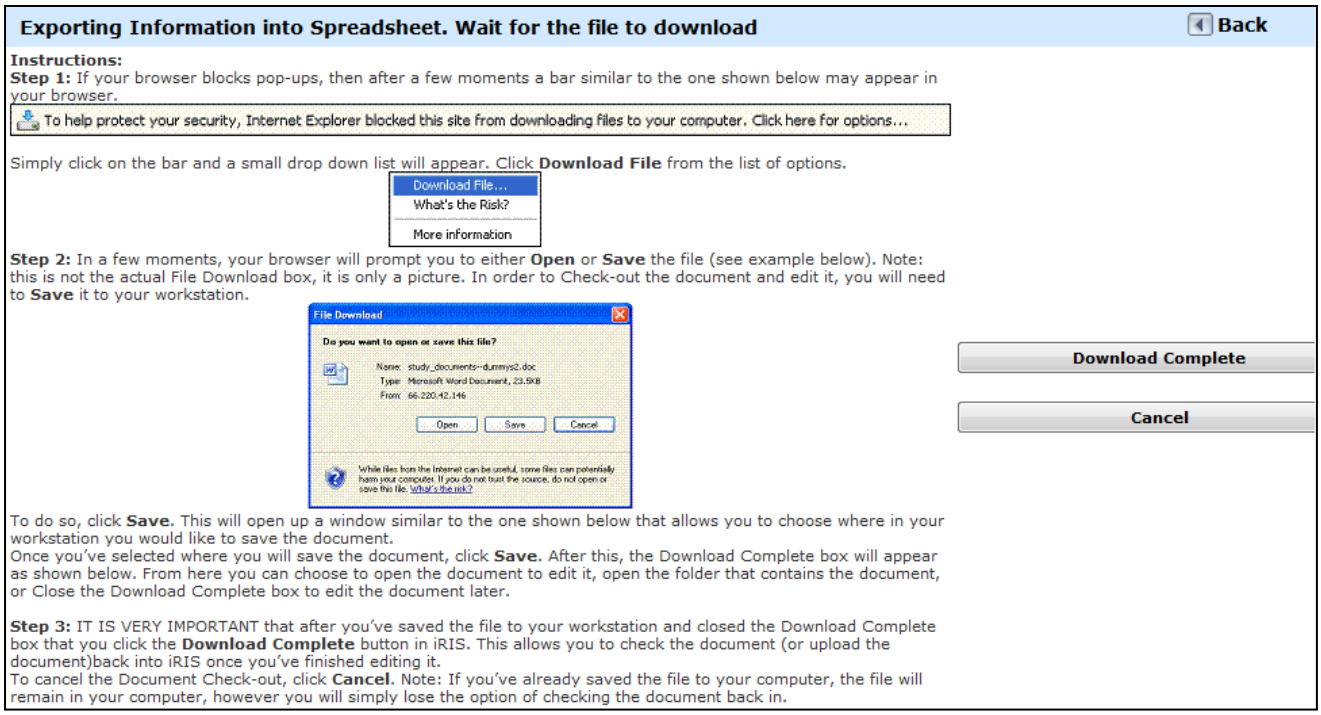
Consent Outcome – You can select a review board document outcome in this drop down list.

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.

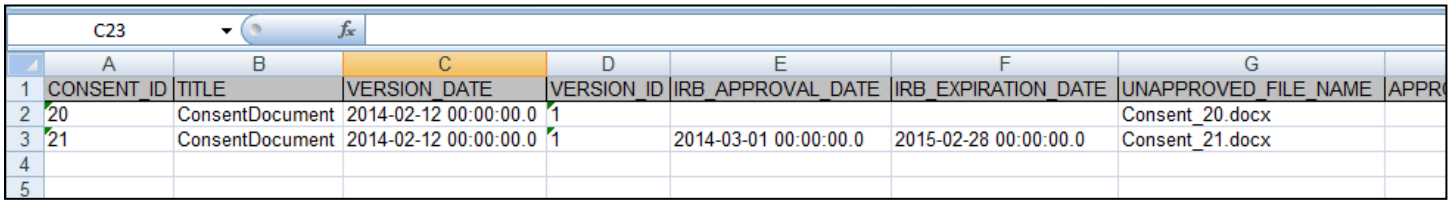
A new page will open and your Internet browser will download the spreadsheet. Internet Explorer is used in this example. Depending on your Internet settings, you may have a blocker installed that prevents you from downloading files without approval. Wait a few moments and the browser may prompt you with 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 will need to click **Export** again.



When you select to download the file, a popup window will ask you if you'd like to open or save the document. 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 can click the **Download Complete** button to return to the Informed Consent library.

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.



C23

	A	B	C	D	E	F	G
1	CONSENT_ID	TITLE	VERSION_DATE	VERSION_ID	IRB_APPROVAL_DATE	IRB_EXPIRATION_DATE	UNAPPROVED_FILE_NAME
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 print-friendly view.

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 as well as the consent records currently listed on the screen.

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.


close print

Informed Consent Document

Study Status:	Open
Principal Investigator:	**Investigator, Susan M., Ph.D.**
IRB Number:	**GH-14-016**
Study Title:	A Phase III, Randomized, Double-Blind, Multi-Center, Placebo-Controlled, Parallel-Group, Forced Dose Titration, Safety and Efficacy Study of NRP104 in Adults With Attention-Deficit Hyperactivity Disorder (ADHD)
Expiration Date:	02/28/2015

1 result(s) found

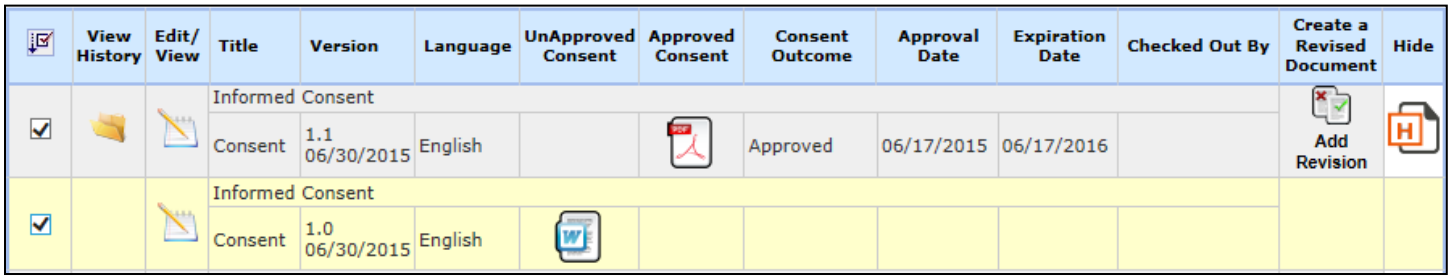
Title	Version	Language	UnApproved Consent	Approved Consent	Review Outcome	Approval Date	Expiration Date	Checkout By
ConsentDocument								
	1.1 02/12/2014	English			Approved	03/01/2014	02/28/2015	

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.

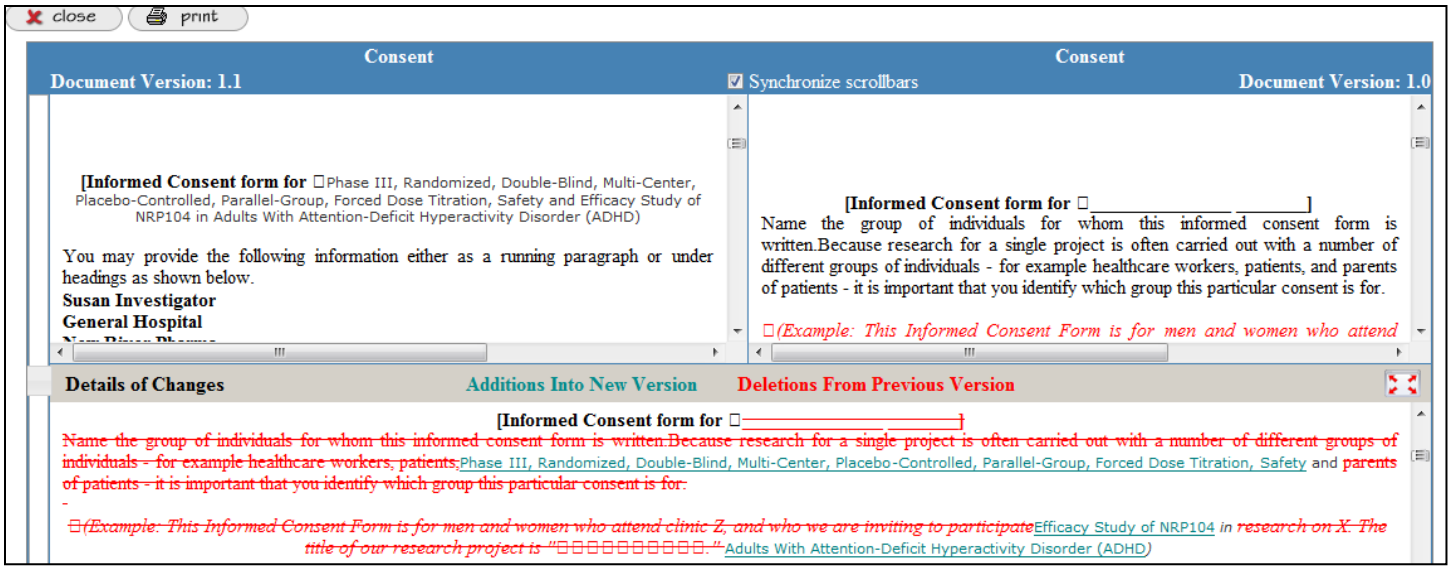


	View History	Edit/ View	Title	Version	Language	UnApproved Consent	Approved Consent	Consent Outcome	Approval Date	Expiration Date	Checked Out By	Create a Revised Document	Hide
☑			Informed Consent									Add Revision	
			Consent	1.1 06/30/2015	English			Approved	06/17/2015	06/17/2016			
☑			Informed Consent										
			Consent	1.0 06/30/2015	English								

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 document versions, click the **Close** button.



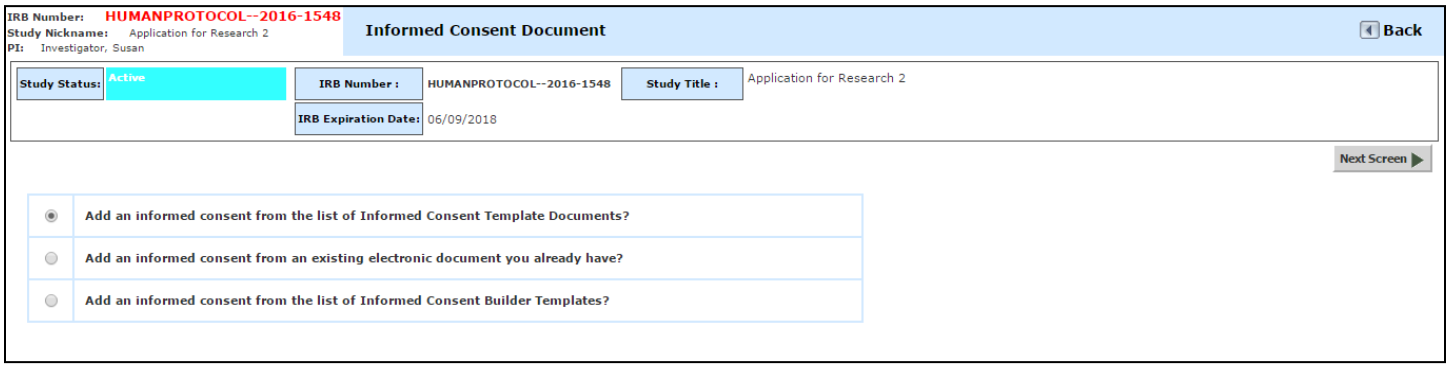
Add a New Consent

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

A new page will open, asking for input on how you will upload the consent document.

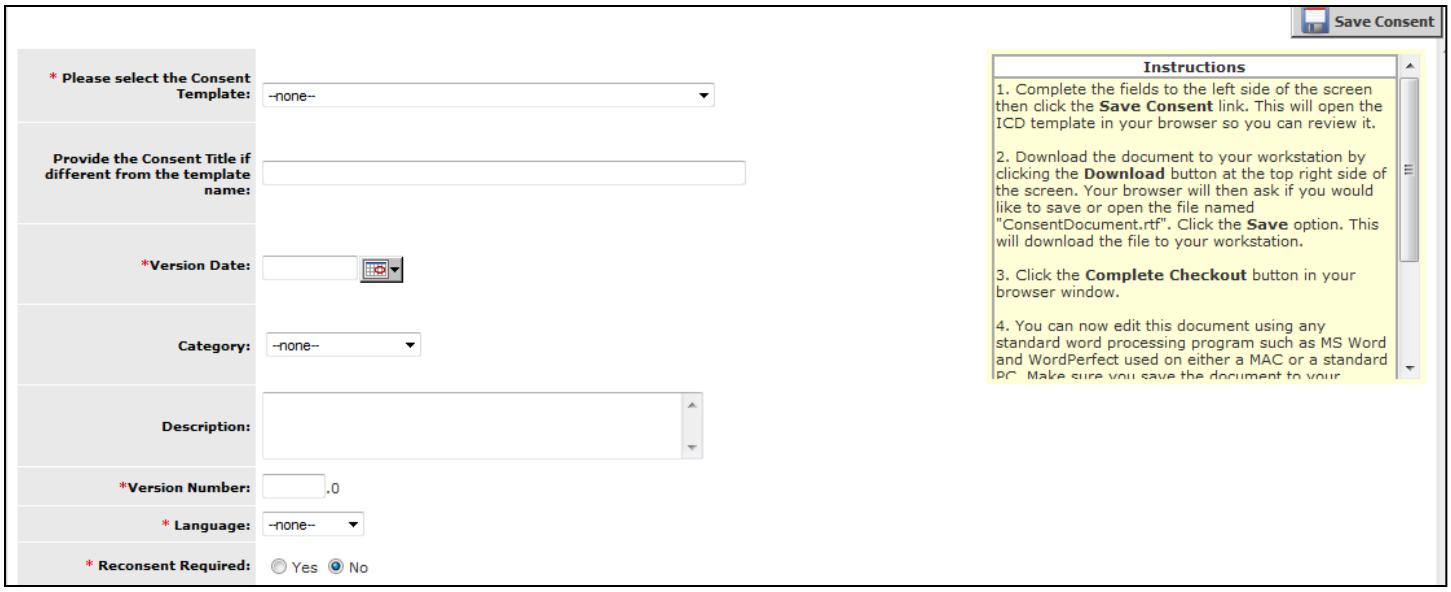
Depending on your system settings, you may or may not have the same options as described for adding an informed consent.

The available selections are described below. Choose the appropriate action, and 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 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.

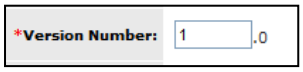


If you would like the name of the consent to appear differently than the given Consent Title, you can type in the name in the **Provide the Consent Title if different from the template name** field.

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.



Version Number – Specify the version of the document using any character or number. After the editable version number is a hard coded '.0'. This is the 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. Any time 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 – Select the consent language from this dropdown list.

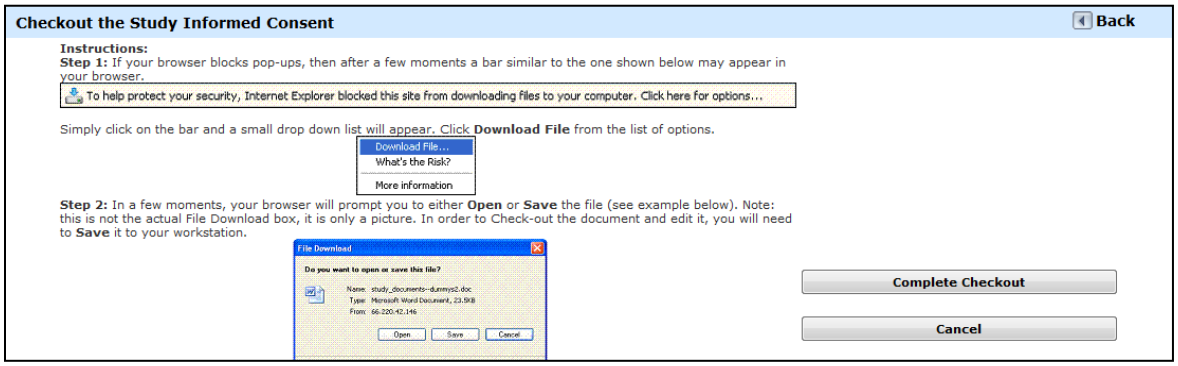
Reconsent Required – Indicate "Yes" if subjects on the study will need to be reconsented. Note that the appearance of this field and the Reconsent Reason field is controlled by the system.use_reconsent_on_consent system property, located under Study Consent Screen Setup properties. When this property is set to Yes, the reconsent fields will appear when uploading consent forms to studies that have already been submitted to the review board.

Reconsent Reason – You can add any reconsent reason to this field.

Comments – Add any comments regarding the consent document.

After entering the required information, click the **Save Consent** button.

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. Wait a few moments, and the browser may prompt you with a yellow bar at the top. Click the yellow bar, and then select Download File from the menu that appears. Do this before clicking the **Complete Checkout** button. If you click **Complete Checkout** before saving the file to your desktop, you will lose the document and will need to 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.

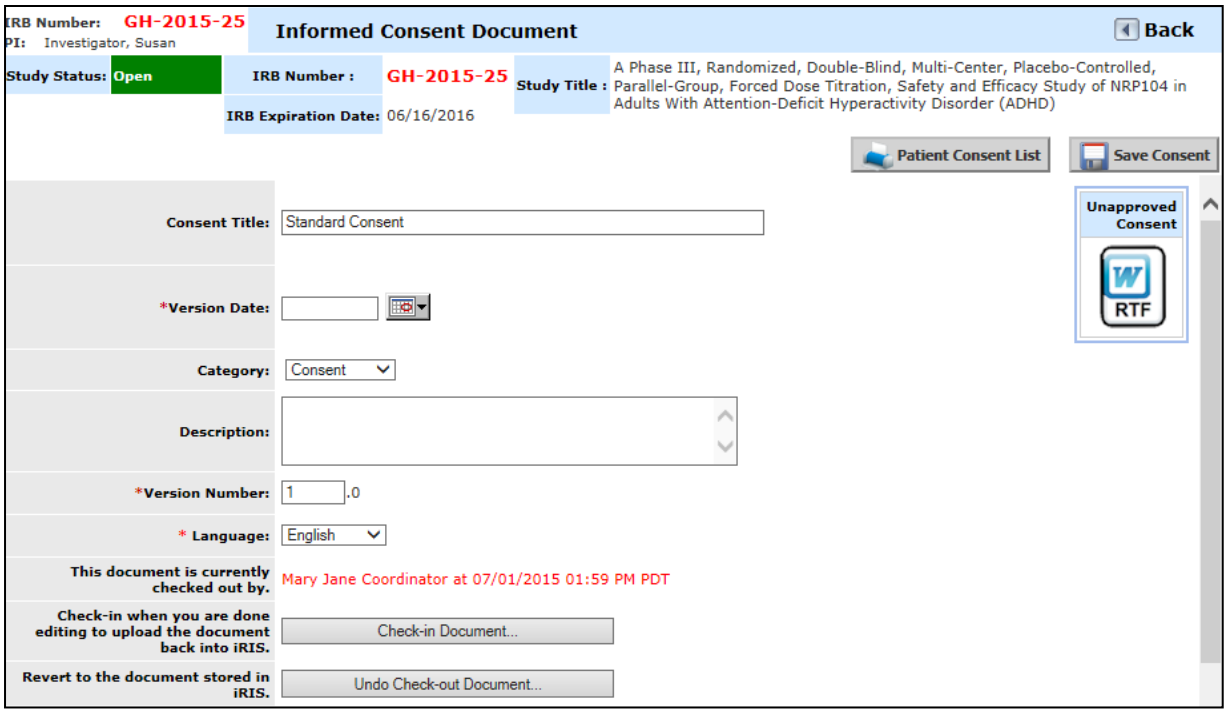
It is best to choose to **Save** the document, so you can be sure to save the document in a known location.

After saving the document, you can click the **Complete Checkout** button.

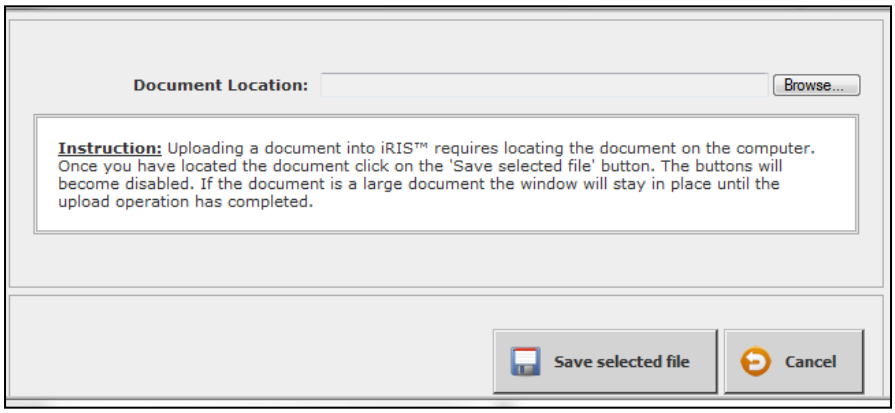
The system will return you to the previous page.

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.

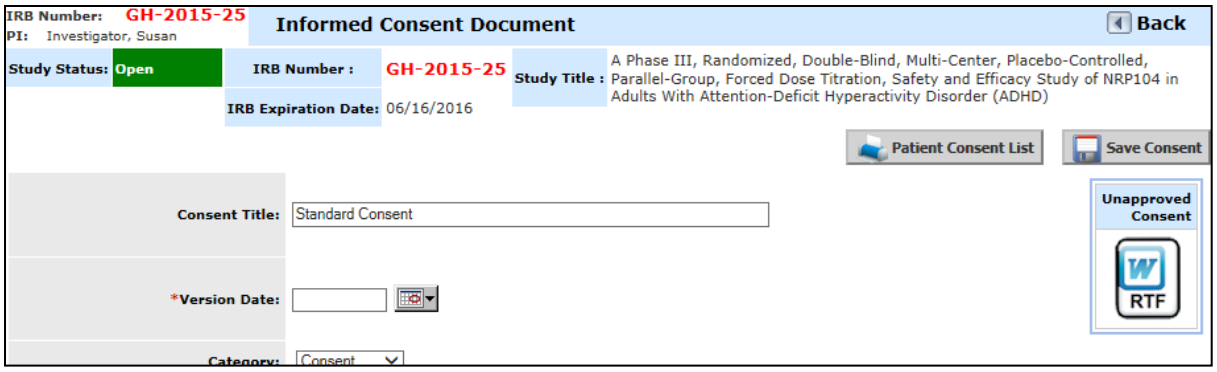
When you are ready to upload the modified consent, return to this page and click the **Check-in Document** button, as seen in the image below.



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 have 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.

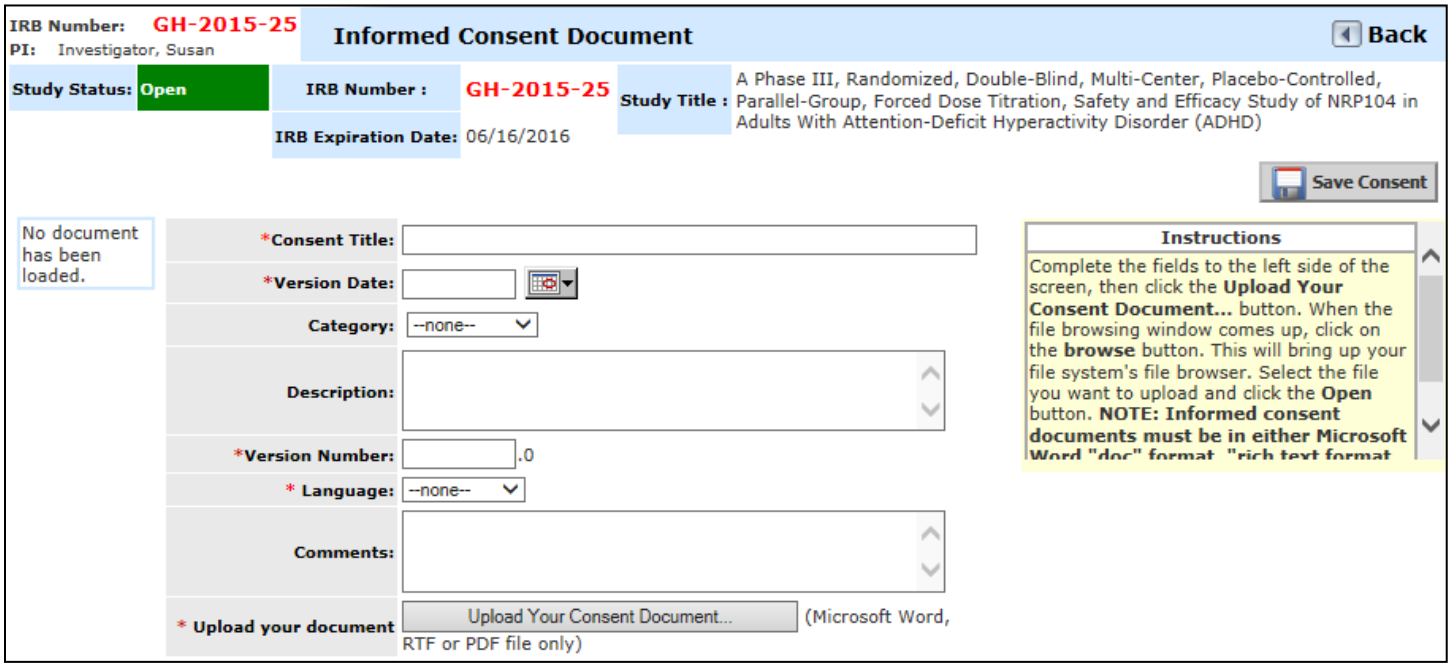


2. Add an informed consent from an existing document you already have?

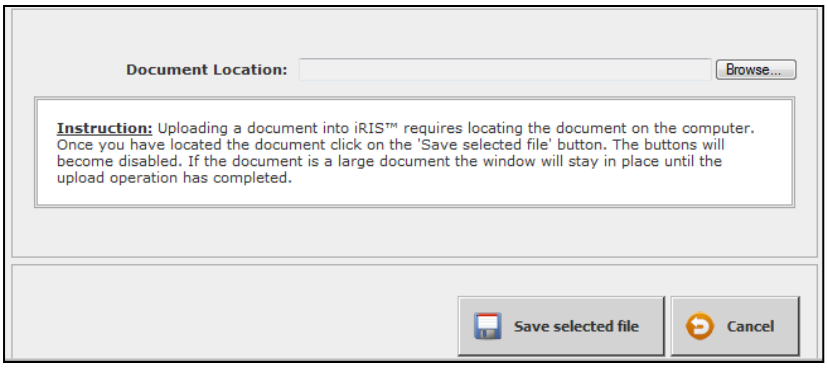
If you already have a consent document ready to upload, choose this option.

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

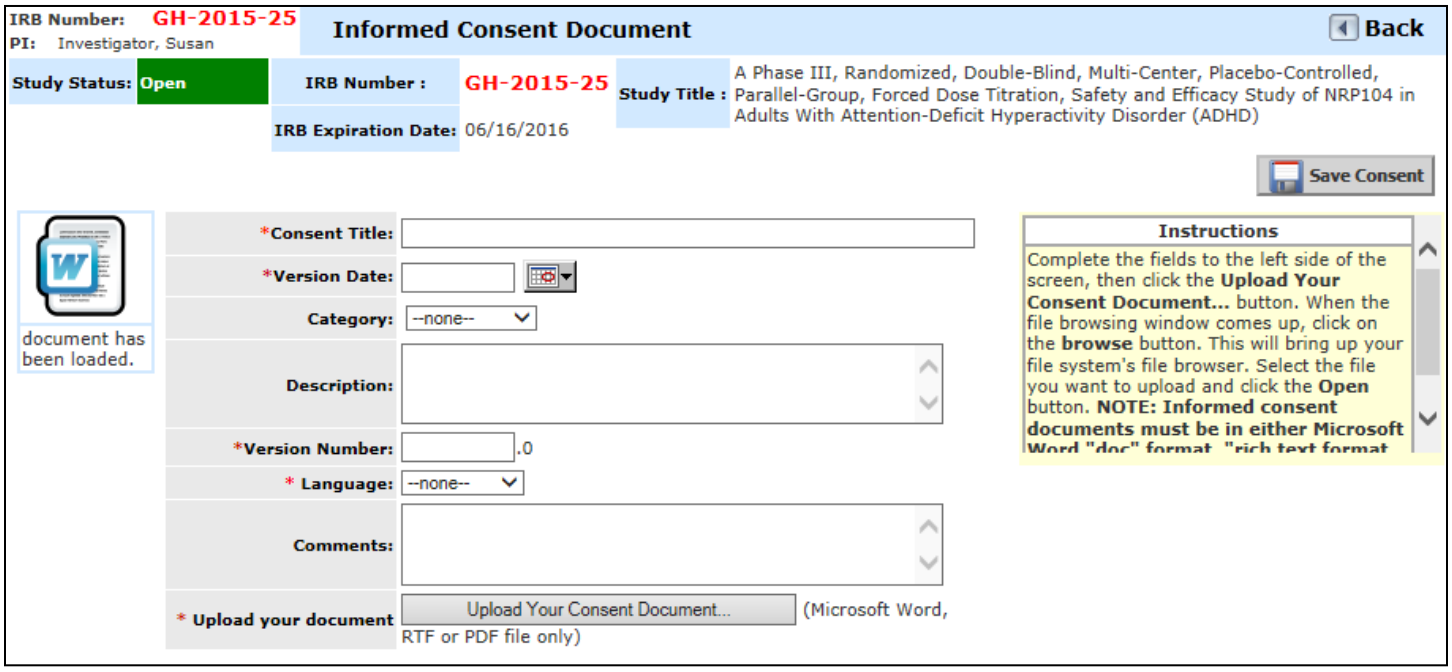
You can enter in the additional consent details. At the bottom of the page you can click the **Upload Your Consent Document** button to upload your consent.



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.

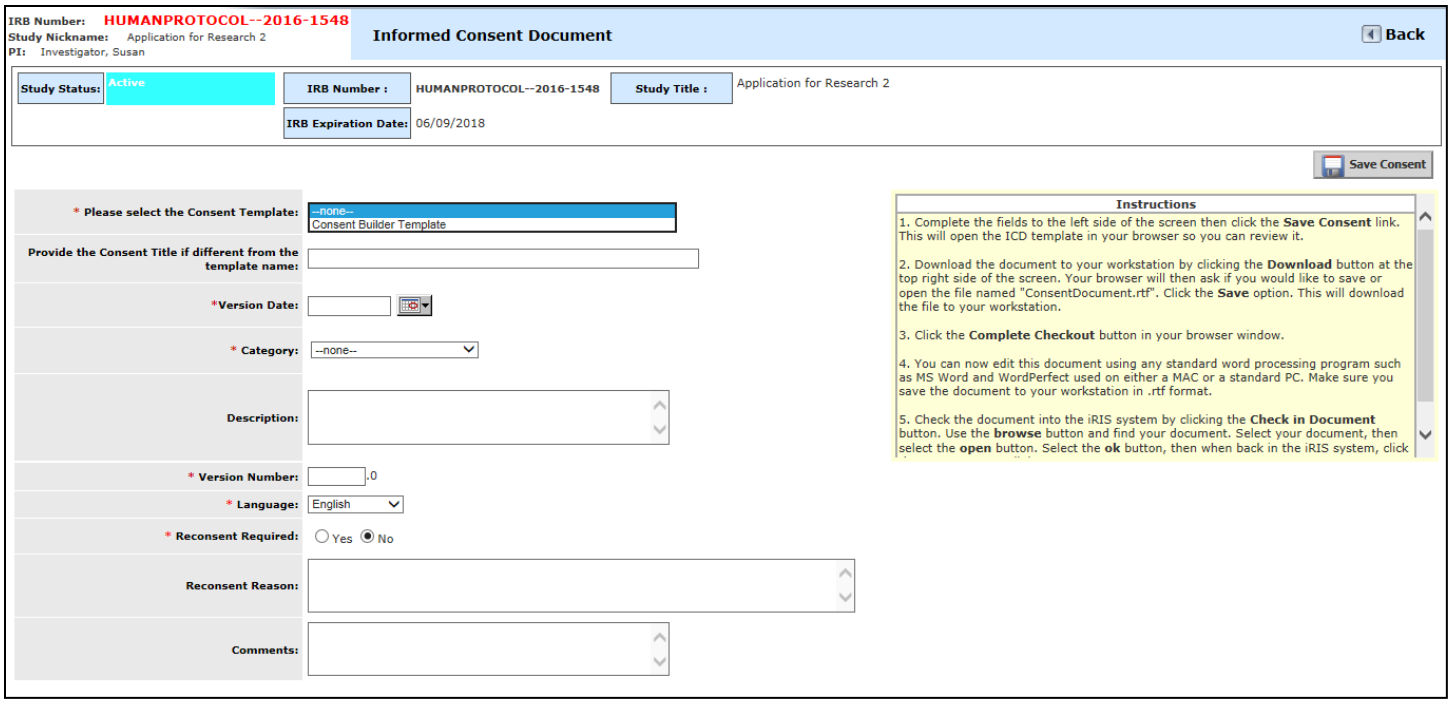


The consent document will be uploaded to the study and it will appear as an icon next to the consent information. Click the **Save Consent** button to create the consent record.

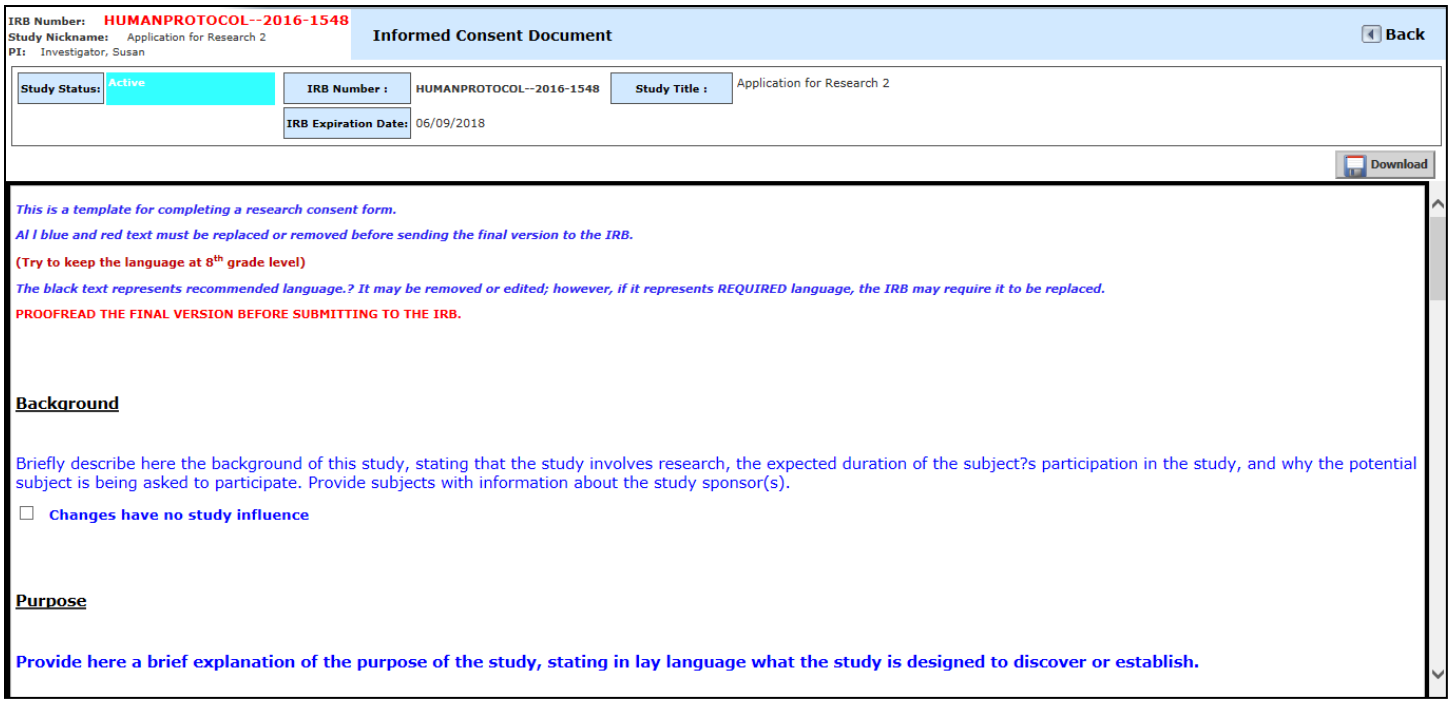


3. Add an informed consent from the list of Informed Consent Builder Templates?

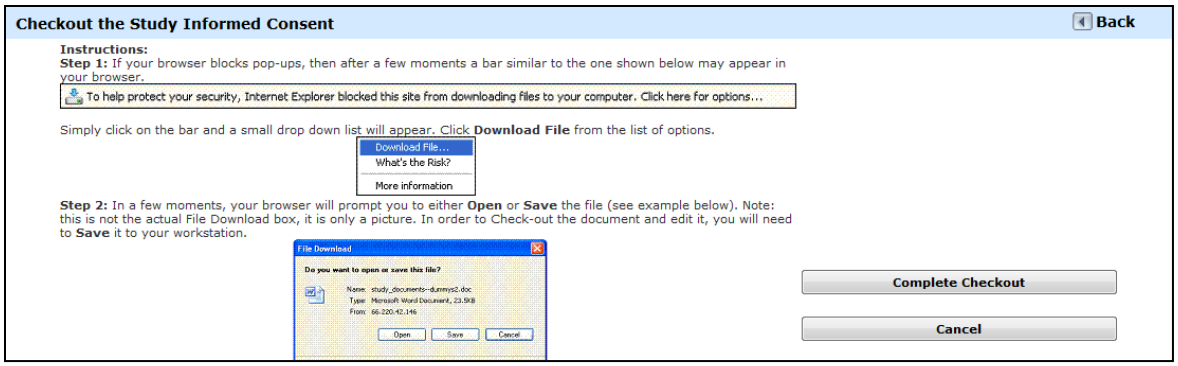
A consent builder template is a document that has been specifically designed to step you through the process of customizing your consent form. When you select this option, you will be prompted to select the consent builder template from a dropdown list.



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. Wait a few moments, and the browser may prompt you with a yellow bar at the top. Click the yellow bar, and then select Download File from the menu that appears. Do this before clicking the **Complete Checkout** button. If you click **Complete Checkout** before saving the file to your desktop, you will lose the document and will need to undo the checkout in order to restore the document.



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.

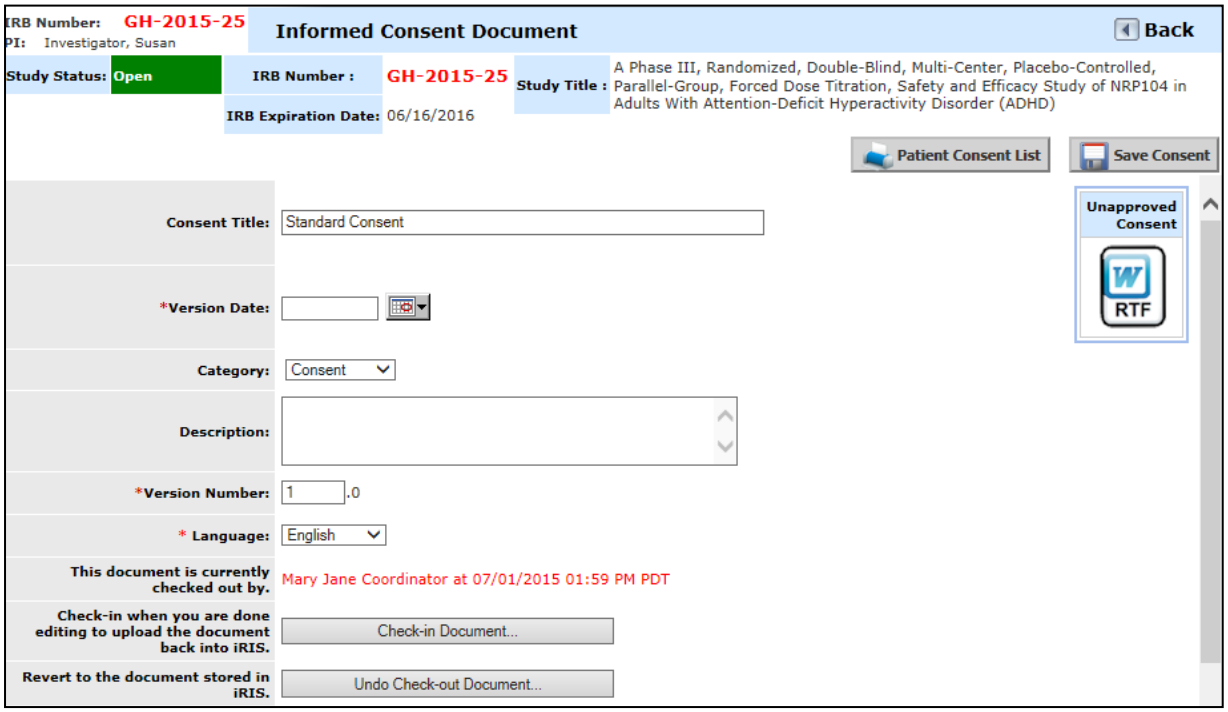
It is best to choose to **Save** the document, so you can be sure to save the document in a known location.

After saving the document, you can click the **Complete Checkout** button.

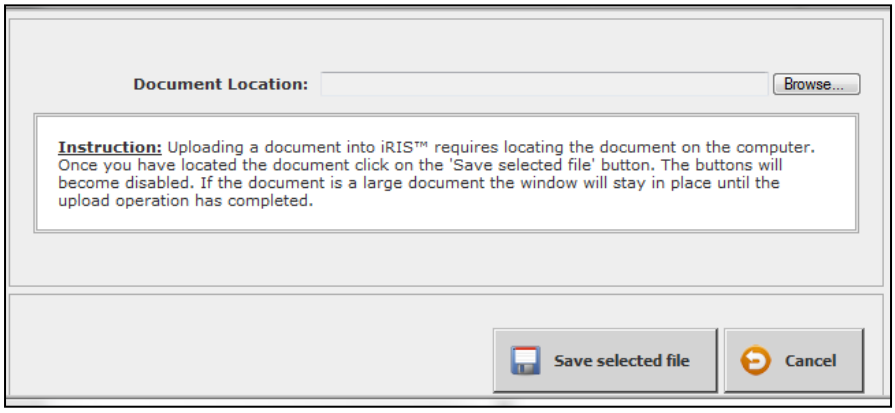
The system will return you to the previous page.

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.

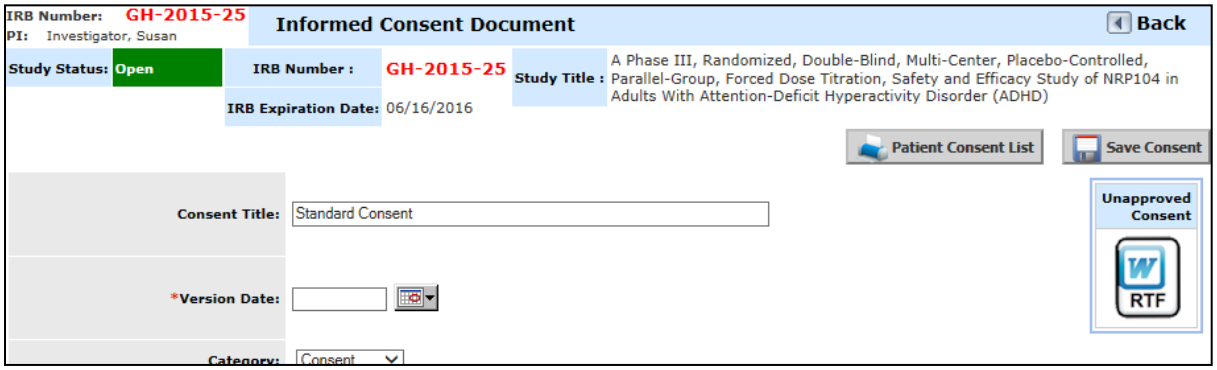
When you are ready to upload the modified consent, return to this page and click the **Check-in Document** button, as seen in the image below.



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.

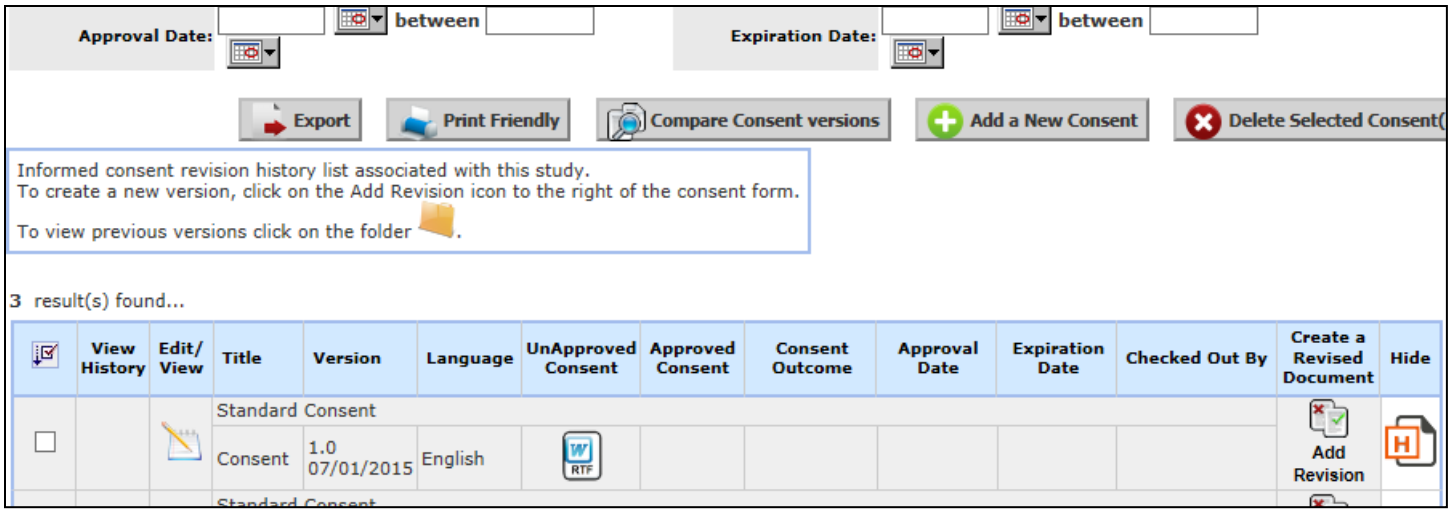


The consent document will be uploaded to the study and it will appear as an icon next to the consent information, as shown below. Click the **Save Consent** button to create the consent record.



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.



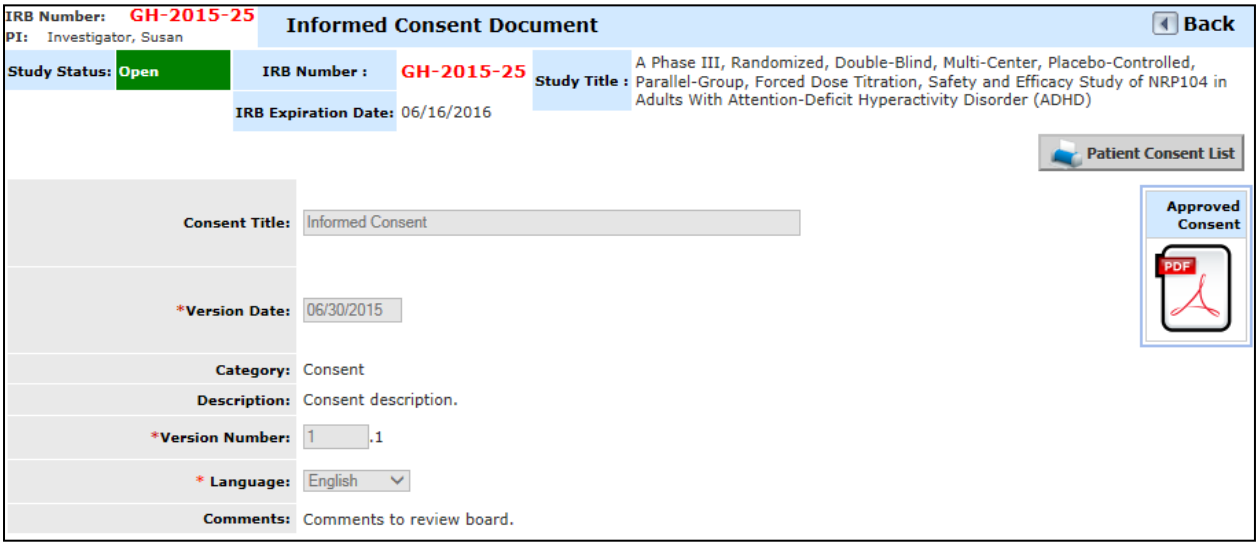
Delete Selected Consent(s)

You can delete consents by selecting the checkbox next to the consent record and clicking the **Delete Selected Consent(s)** button. 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. You will need to create a revision of the document in order to do so.

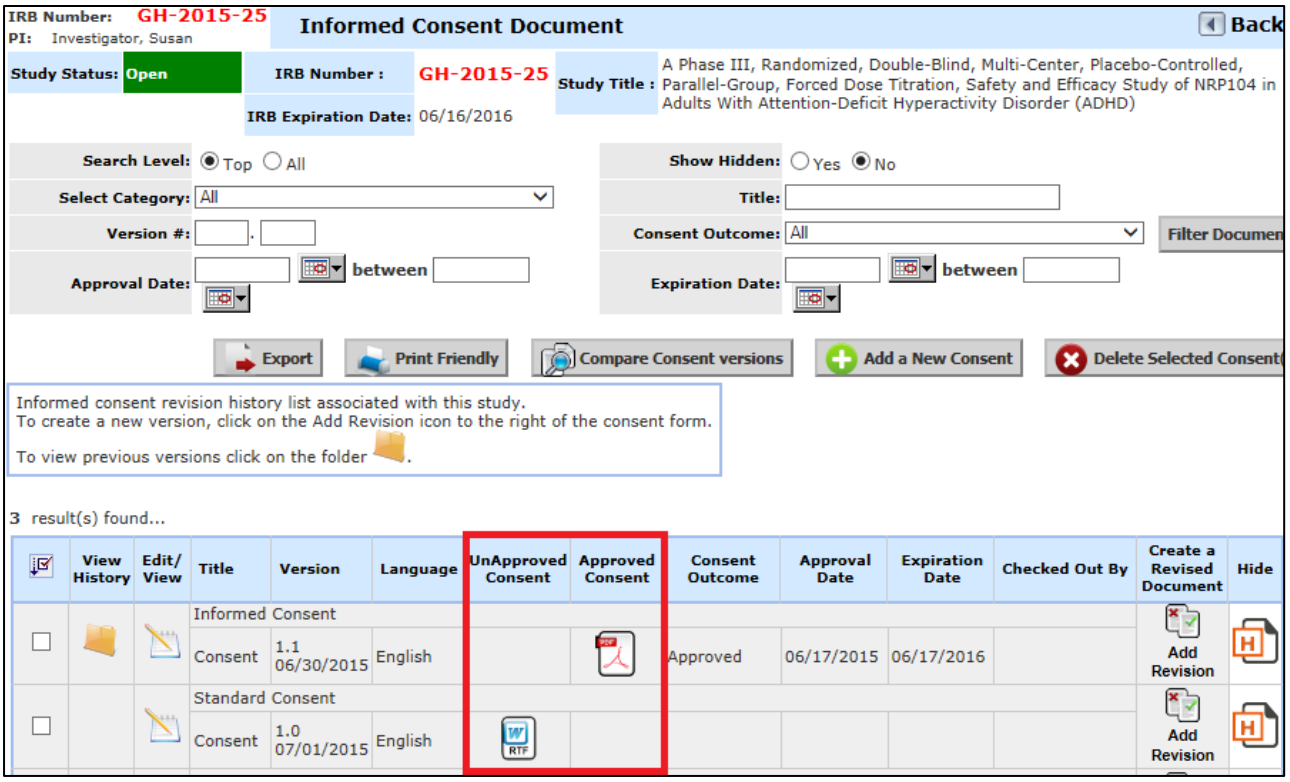
When you open the details of the consent, you can view the document by clicking the icon on the top right corner of the screen. Depending on the format of the document, you may see a Word icon, an RTF icon, or a PDF icon.



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 document icon in the UnApproved Consent column will open the consent document in a new window.

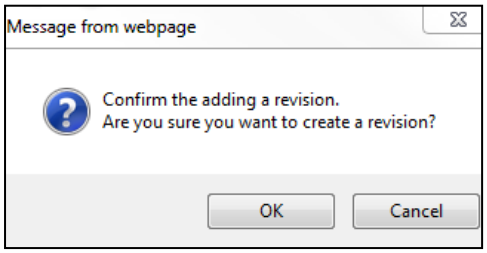
Once the review board approves the consent, the unapproved copy of the consent will not be displayed in the column. The stamped, approved consent will be available in the Approved Consent column. You can click the icon to open the approved consent in a new window, allowing you to print it for your records.



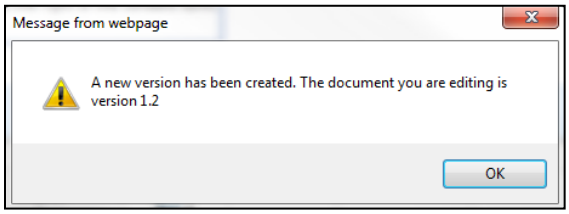
Revise a Consent

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

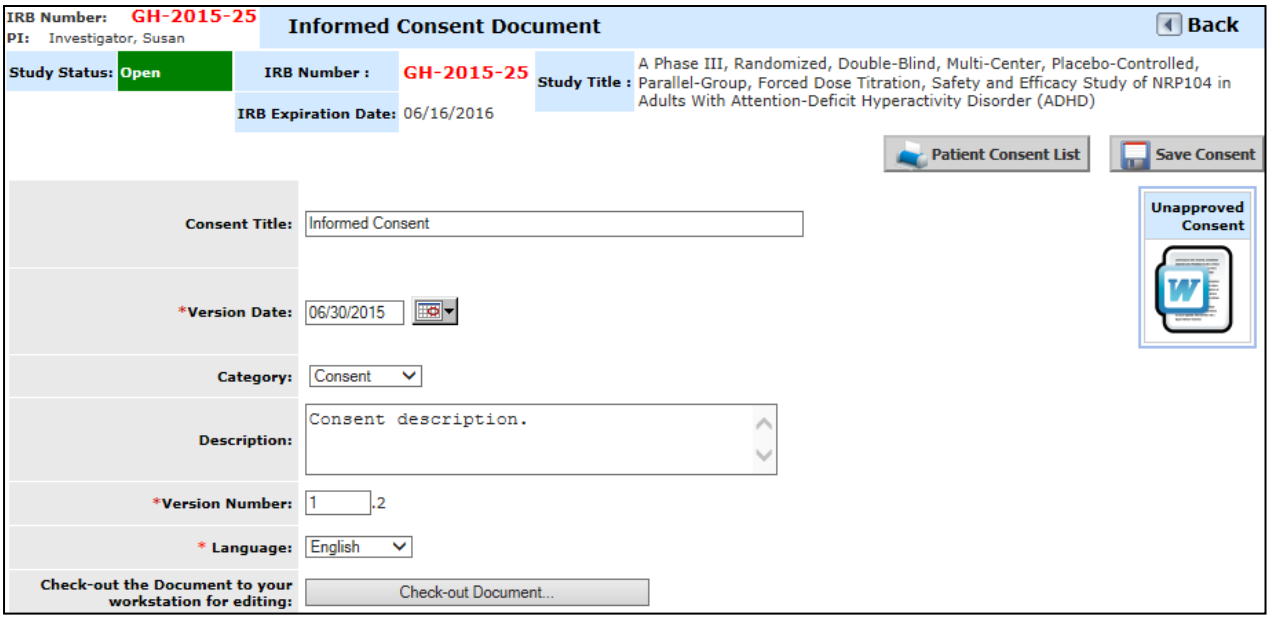
iRIS will ask for your confirmation to add the revision. Click **OK** to proceed with the revision, or click the **Cancel** button to return to the Informed Consent library page without creating a revision of the document.



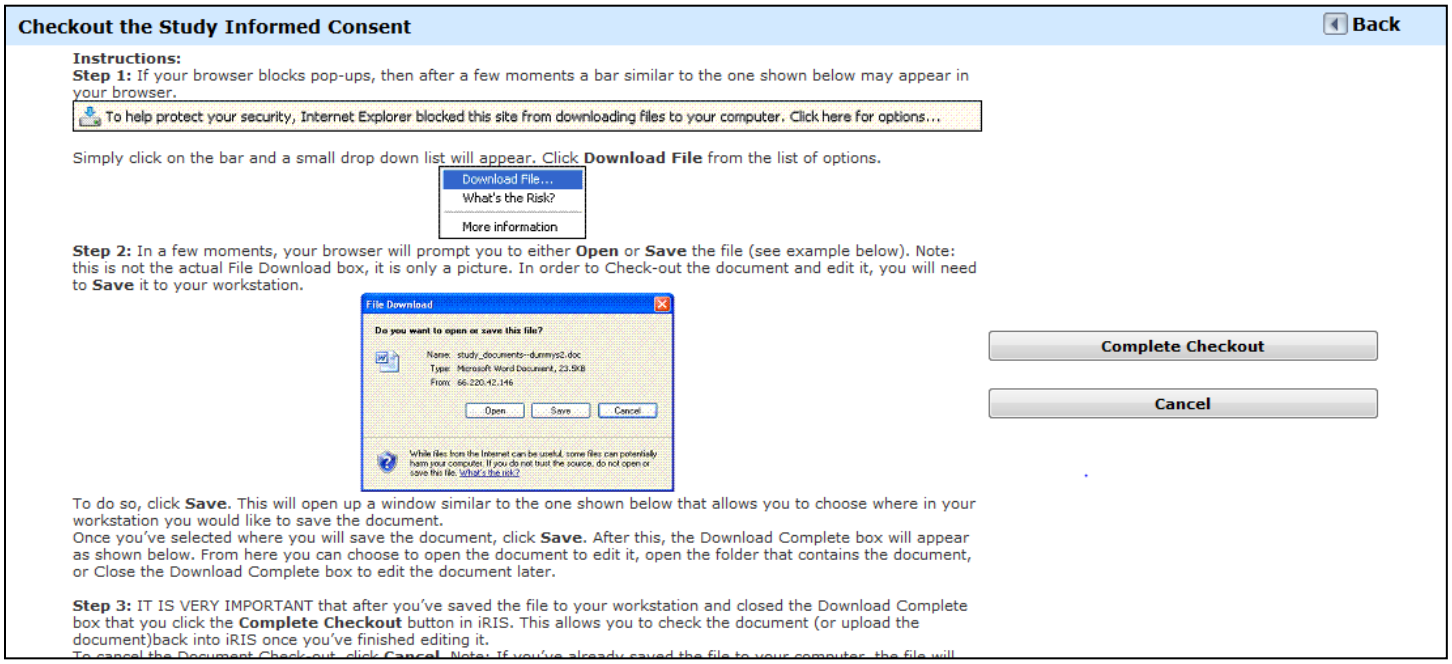
If you click the **OK** button, iRIS will confirm the revision and provide information about the version of the document you are editing. Click the **OK** button to proceed.



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



A new page will open and your Internet browser will download the consent document. Internet Explorer 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. Click the yellow bar, and then select Download File from the menu that appears. Do this before clicking the **Complete Checkout** button. If you click Complete Checkout before saving the file to your desktop, you will lose the document and will need to 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.

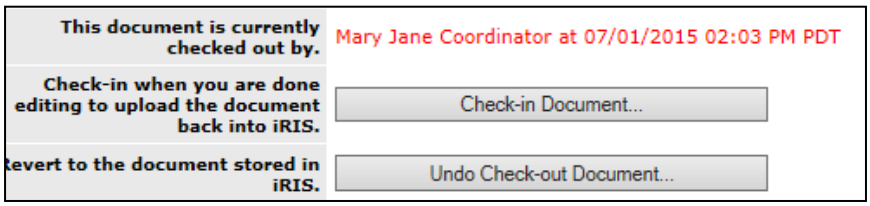
The browser asks if you would like to open or save the consent document.

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

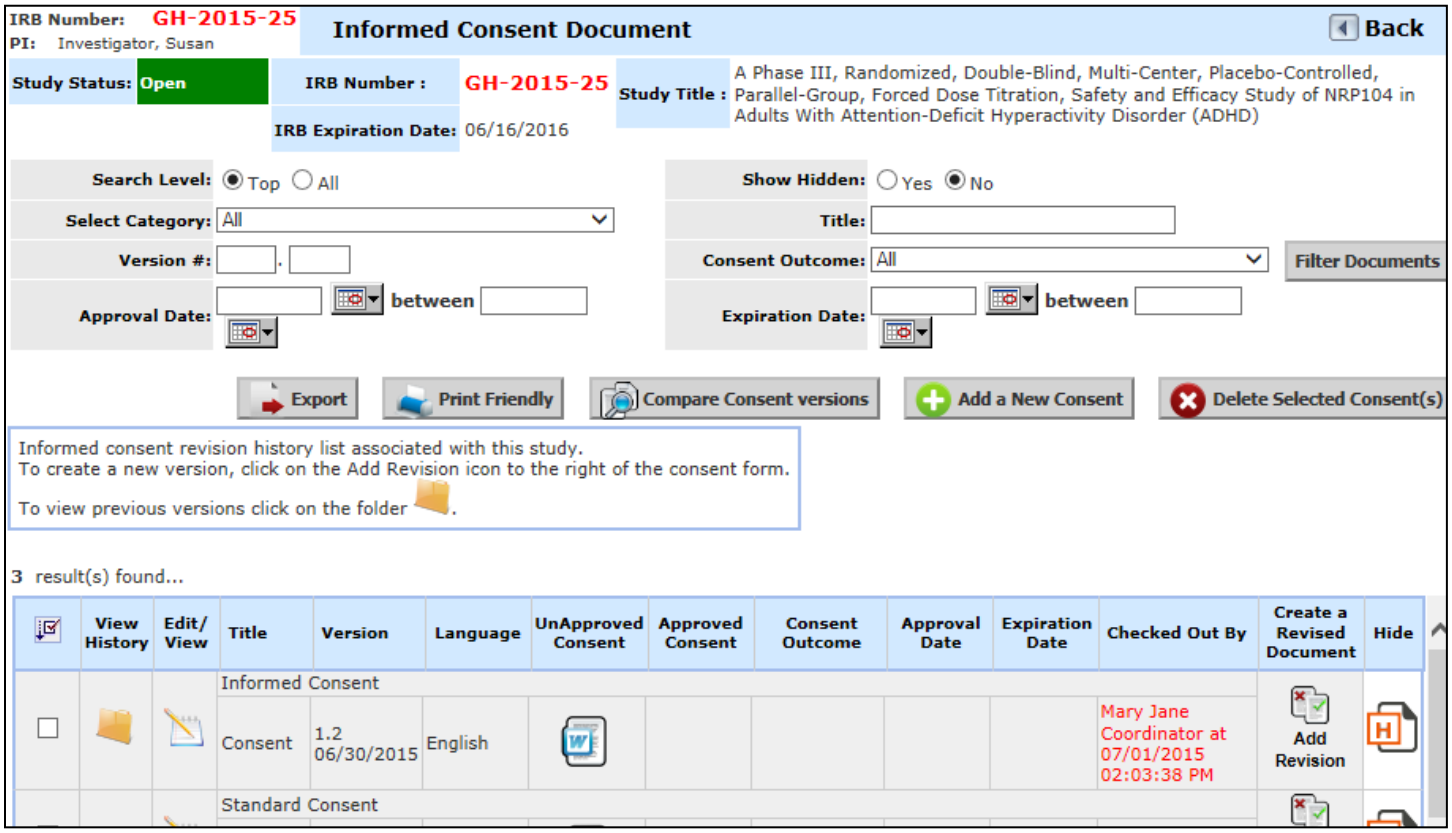
After saving the document, you can click the **Complete Checkout** button.

The system will return you to the previous page.

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.**

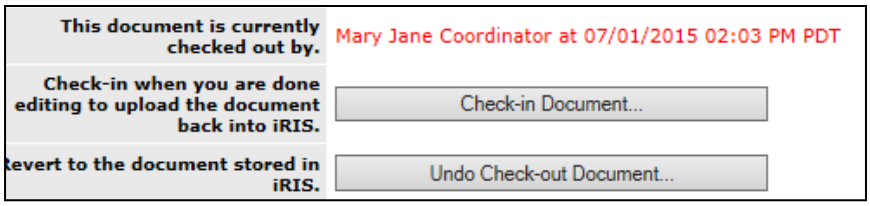


When you view the Informed Consent library, any document that is currently checked out will contain the checkout information in the Checked out By column.

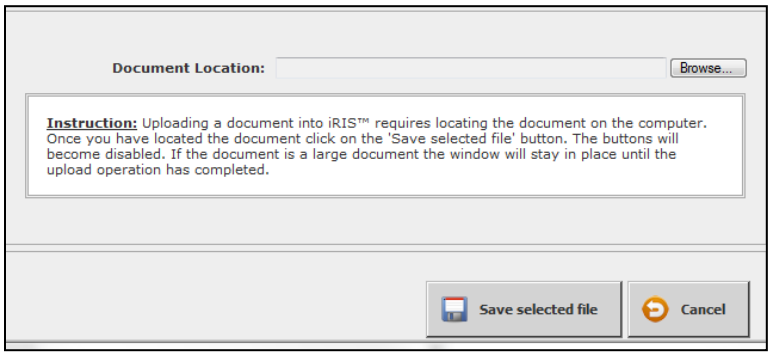


After you make any changes to the document in Microsoft Word, you can return to the Informed Consent library to check in the changes. Click the  icon in the Edit/View column.

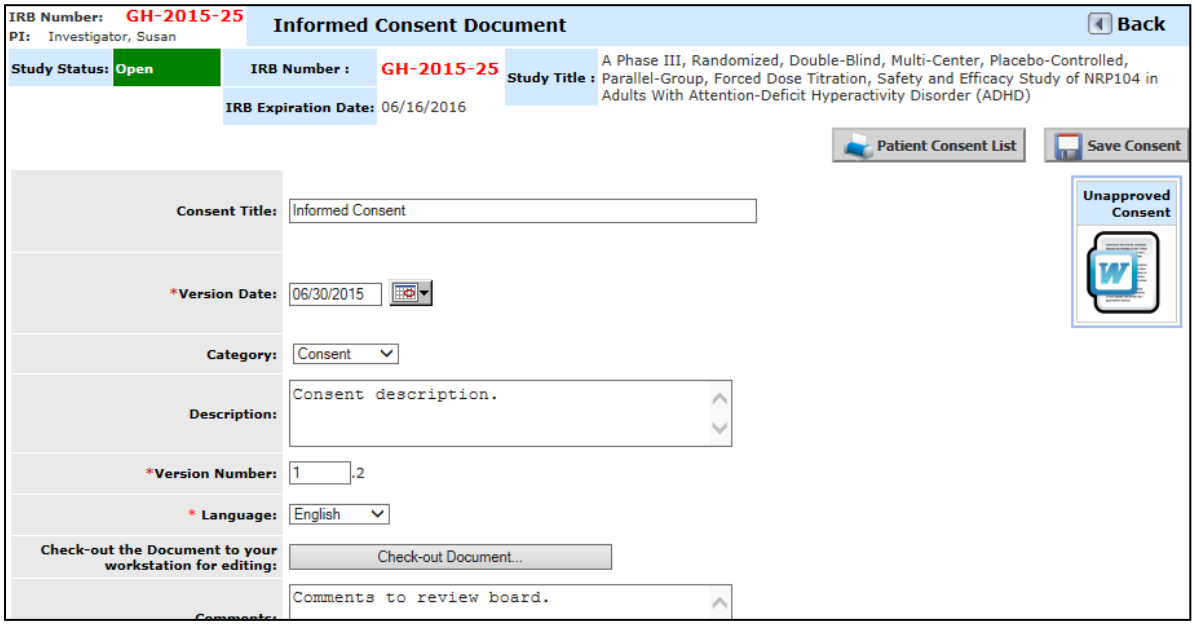
When the Informed Consent Document details page opens, you can click the **Check-in Document** button.



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 have 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.

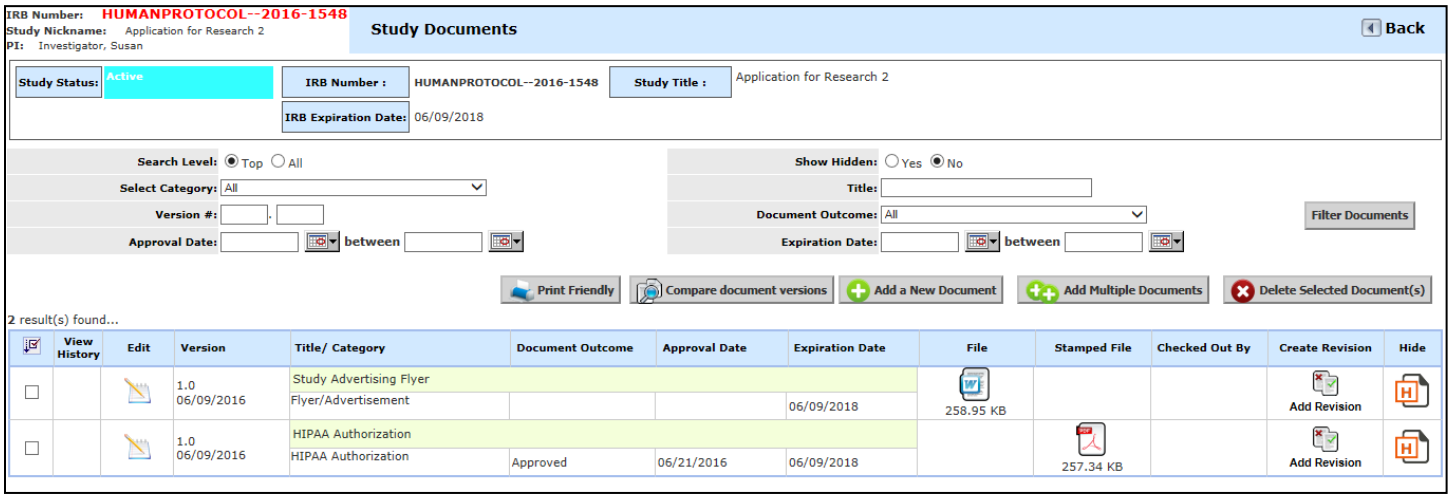


Other Study Documents

The Other Study Documents link, from the main Submissions screen, will direct you to the Study Documents 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.

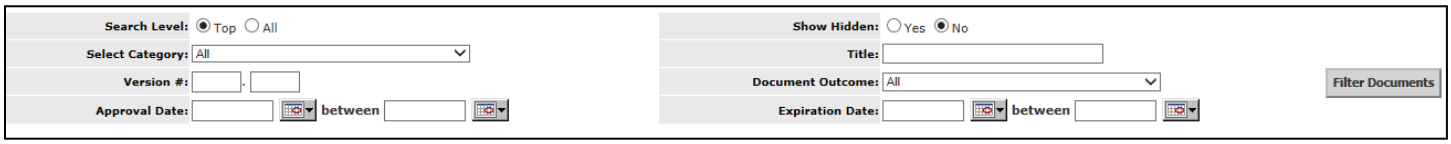
From this area, you can revise existing documents, add new documents, compare versions of documents, and print out approved copies of a document.



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 information in the different filters in order to obtain results.



The available filters are as follows:

Search Level –The default selection for this filter is set to “Top”. This means that 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, you can 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 that 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 the documents displayed 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.

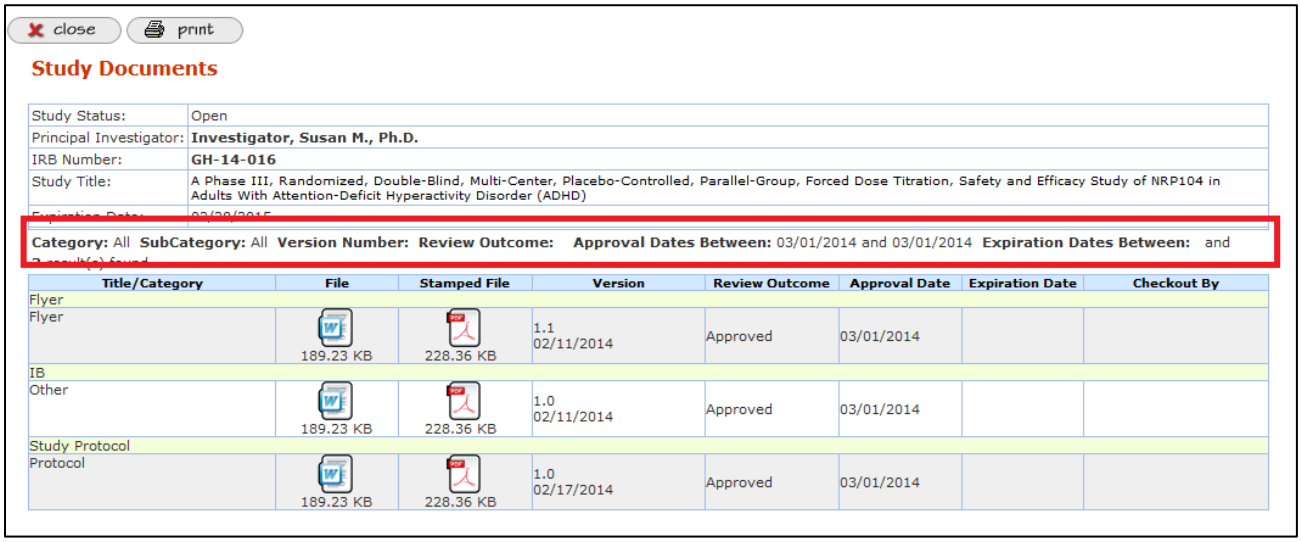
Print Friendly

You can 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: The Print Friendly view will display the filters in use, as shown in the screenshot below.


close print

Study Documents

Study Status:	Open
Principal Investigator:	**Investigator, Susan M., Ph.D.**
IRB Number:	**GH-14-016**
Study Title:	A Phase III, Randomized, Double-Blind, Multi-Center, Placebo-Controlled, Parallel-Group, Forced Dose Titration, Safety and Efficacy Study of NRP104 in Adults With Attention-Deficit Hyperactivity Disorder (ADHD)

Category: All **SubCategory:** All **Version Number:** **Review Outcome:** **Approval Dates Between:** 03/01/2014 and 03/01/2014 **Expiration Dates Between:** and

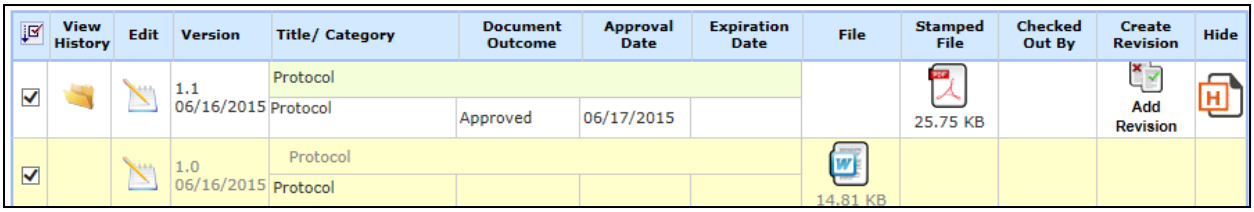
Title/Category	File	Stamped File	Version	Review Outcome	Approval Date	Expiration Date	Checkout By
Flyer							
Flyer	189.23 KB	228.36 KB	1.1 02/11/2014	Approved	03/01/2014		
IB							
Other	189.23 KB	228.36 KB	1.0 02/11/2014	Approved	03/01/2014		
Study Protocol							
Protocol	189.23 KB	228.36 KB	1.0 02/17/2014	Approved	03/01/2014		

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 view a previous version's unapproved document by clicking on the icon in the File column.

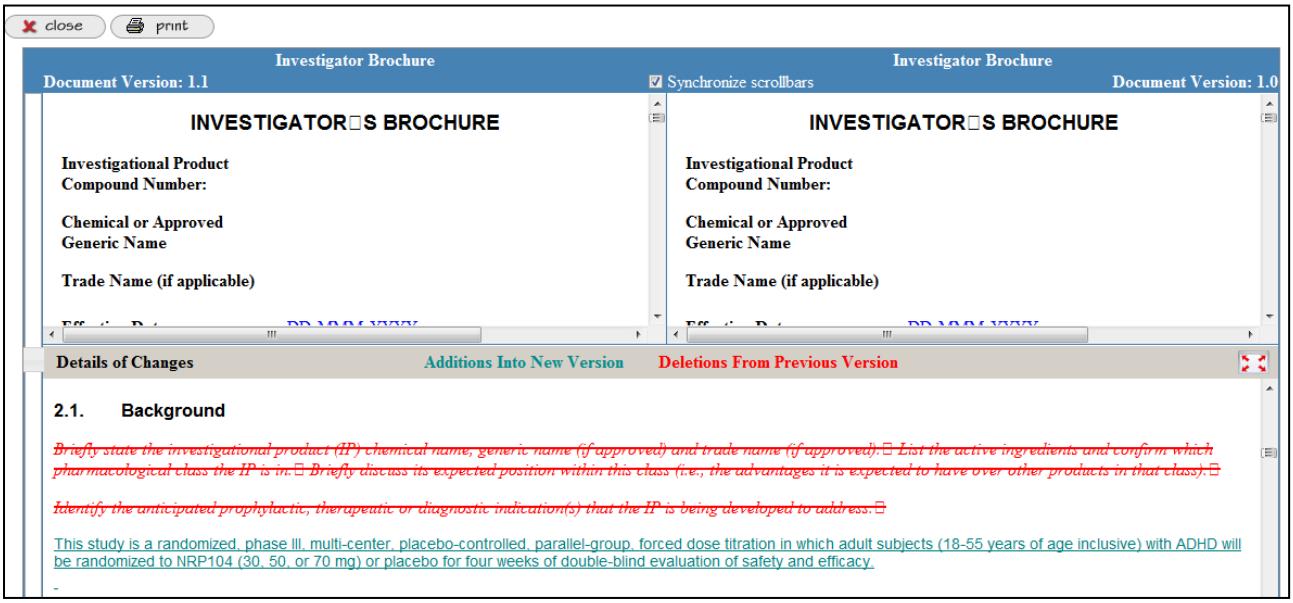
You can compare versions of the document by clicking the checkboxes next to two versions of the same document and then clicking on the **Compare document versions** button at the top of the page.



iRIS will 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. The newer version will be 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.

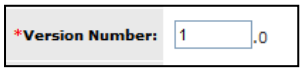
When you are finished viewing the differences, click the **Close** button.



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. First, specify the name of the document in the **Document Title** field.



Version Number – This field requires you to specify a number or character to be included in the document version number. 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

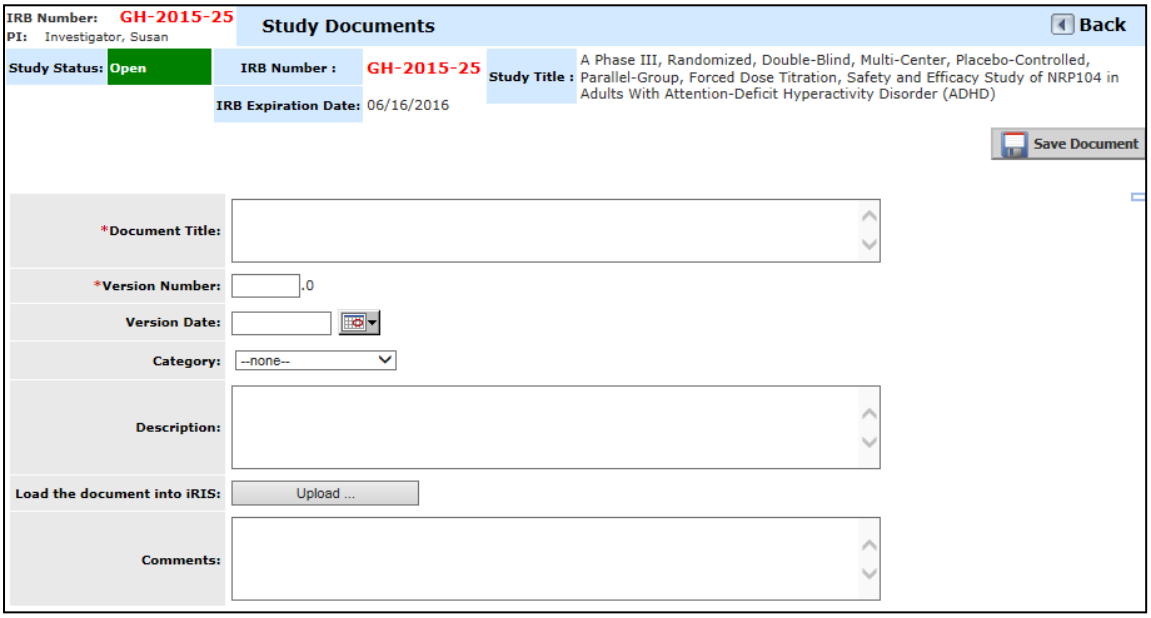
manually entered version number. Anytime a revision is made to the document through the system, iRIS will change the **.0** to **.1** and will continue to increment the numbers each time a revision is made. This is how the system tracks the number of revisions to the document in iRIS. You will always 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 autofilled for you 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.

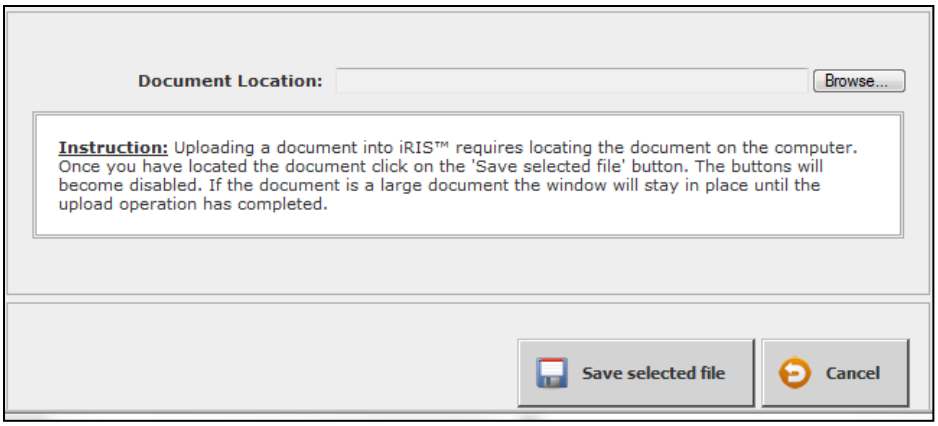
Description – A description of the document.

Comments – Any comments regarding the document that can be addressed to the review board.



Enter the required information, then click the **Upload** button to upload the document.

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 have associated a document, click the **Save selected file** button.

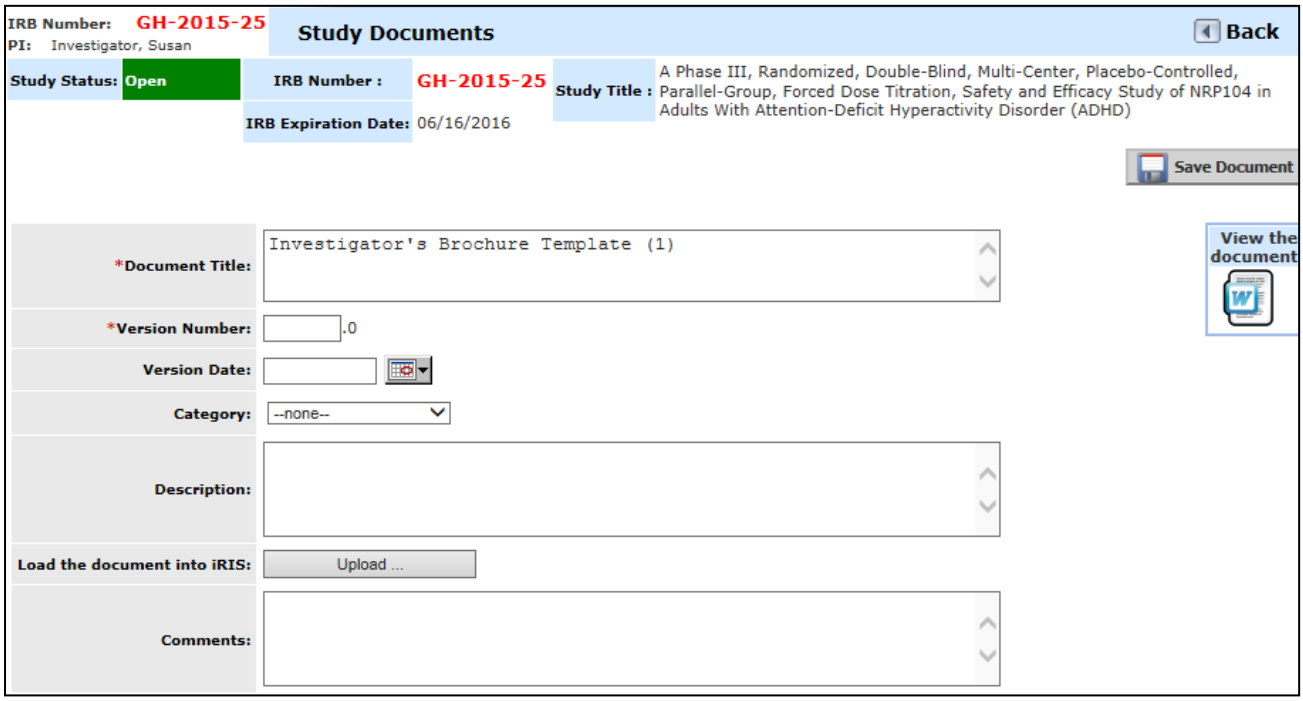


The system will return you to the previous page.

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 may automatically apply the name of the document to the Document Title field. This is controlled by the system.use_auto_populate_study_doc_title property, located under Study Document Screen Setup.

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, Document 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.

Note: when you add a new document record from this area, in order for the 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

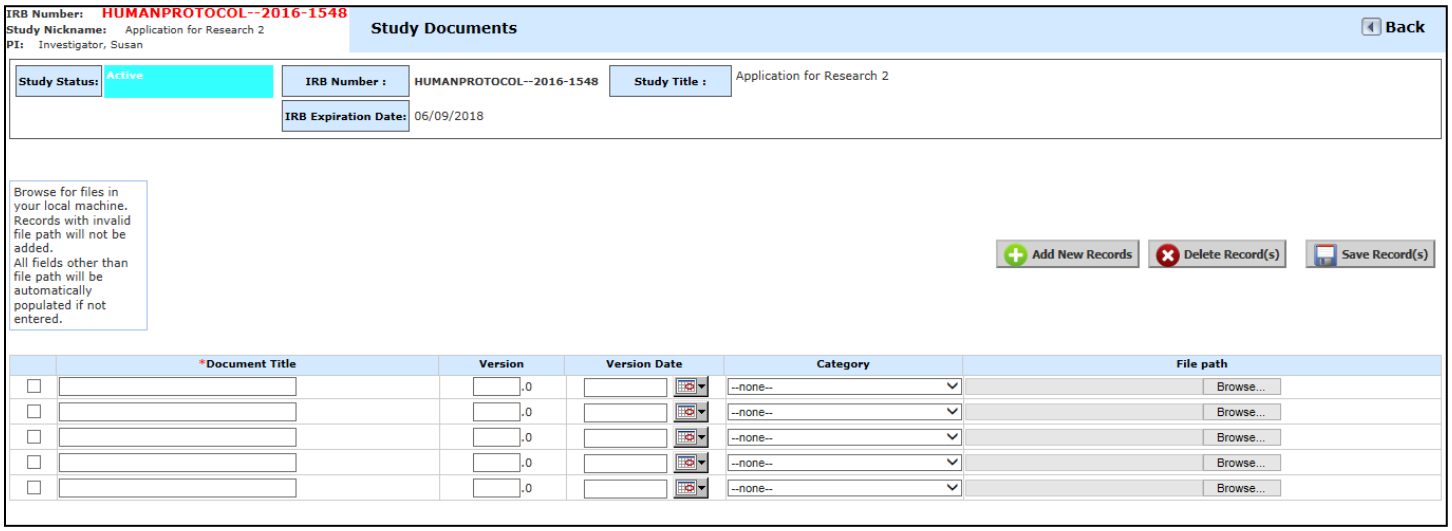
You can add multiple documents at once by clicking on the **Add Multiple Documents** button.

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.



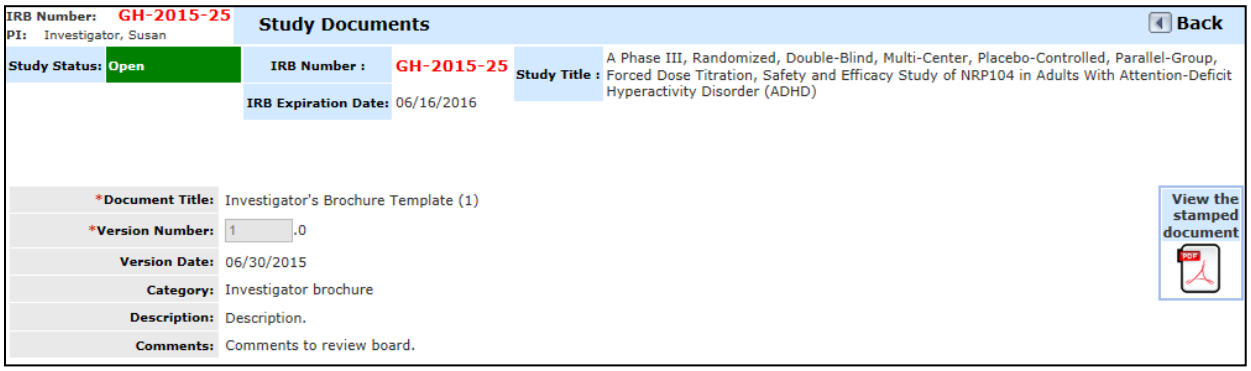
Delete Documents

You can delete documents from the main Study Documents library 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 a 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.

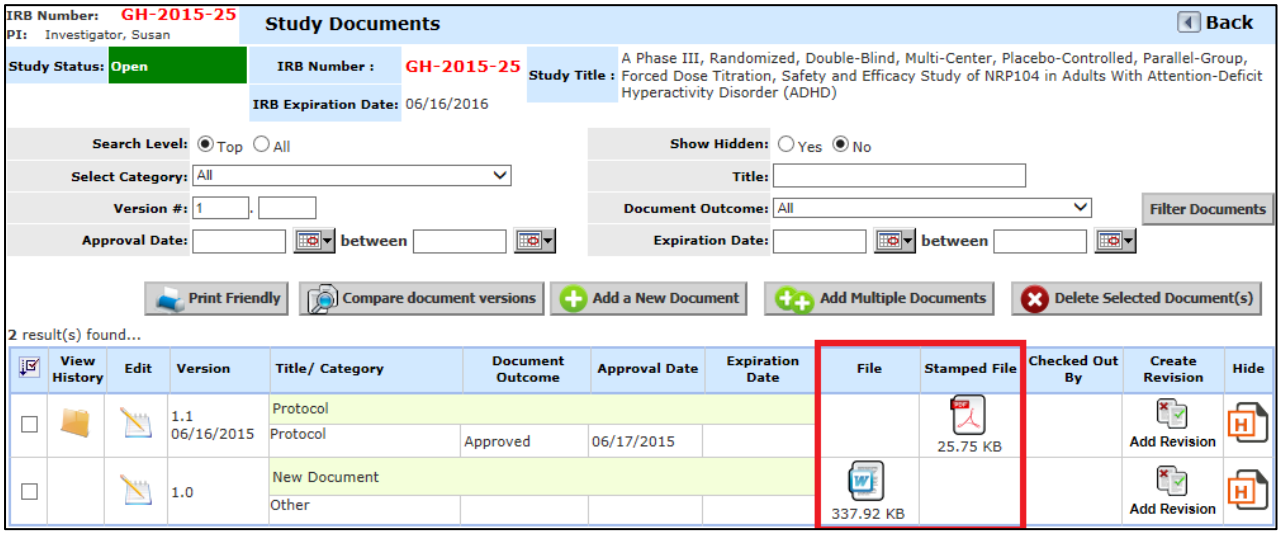
When you open the details of the document, you can view the document by clicking the document icon that appears on the right side of the screen. Depending on the status of the document, you may see a Word icon, an RTF icon, or a PDF icon, as shown in the image below.



Accessing Approved Documents

Within the table of documents, there will be columns for the un-approved and approved versions of the documents. If the review board has not approved a certain document, clicking on the document icon in the File column will open the document in a new window.

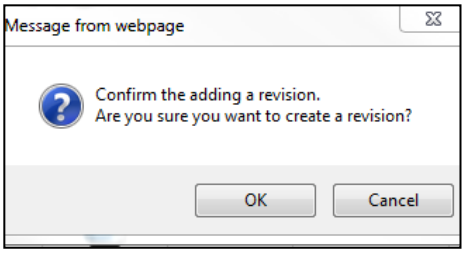
If the review board approves a document, the original copy will not be displayed in the File column. The approved document will be available in the Stamped File column. You can click the icon in this column to open the approved document in a new window, allowing you to print it for your records.



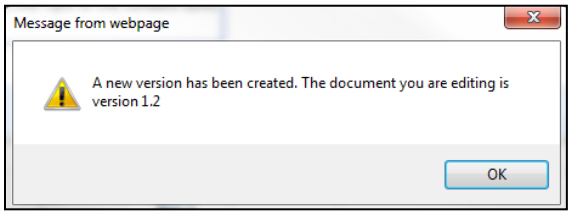
Creating Revisions

If you would like to revise an existing document record, click the icon in the **Create Revision** column.

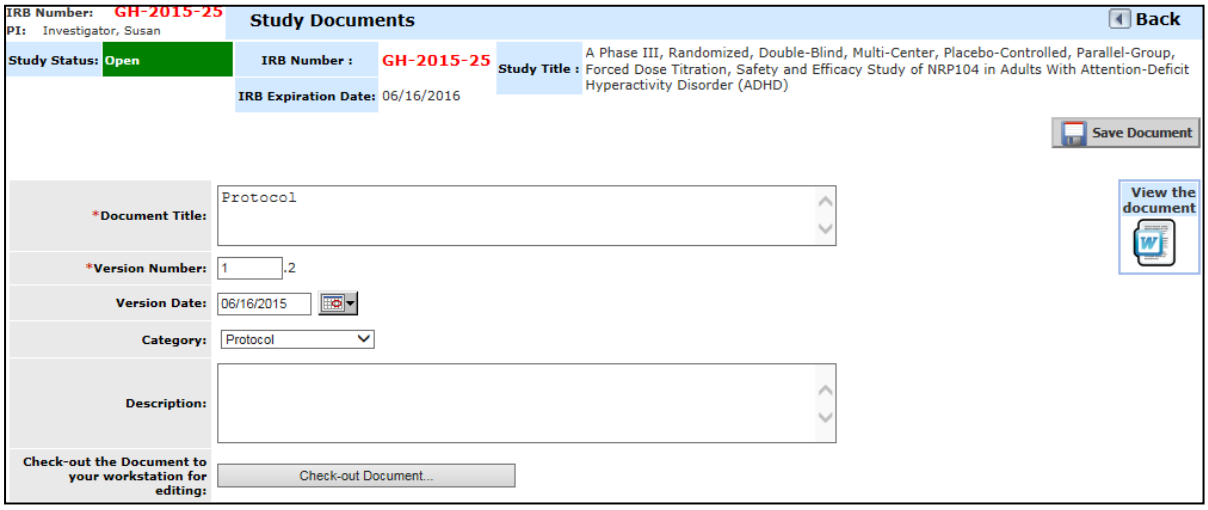
iRIS will ask for your confirmation to creating the revision. Click **OK** to proceed with the revision or click the **Cancel** button to return to the document library without creating a revision of the document.



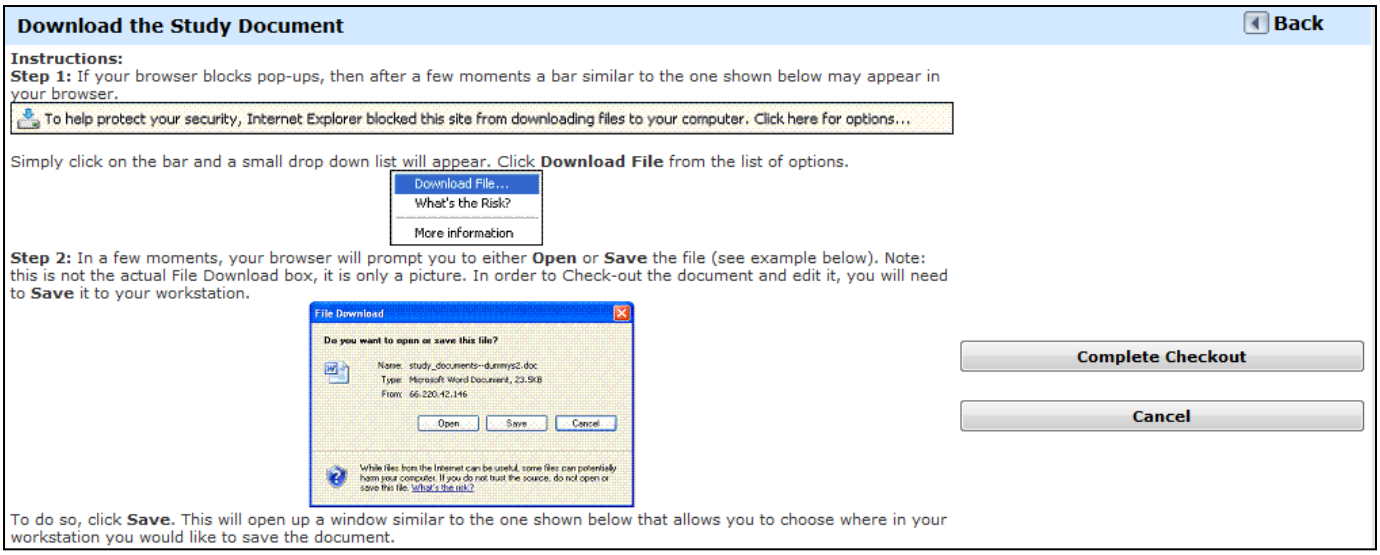
If you click the **OK** button, iRIS will confirm the revision and provide the information about the version of the document you are editing. Click the **OK** button to proceed.



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



A new page will open and your Internet browser will download the document. Internet Explorer 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. Click the yellow bar, and then select Download File from the menu that appears. Do this before clicking the **Complete Checkout** button. 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.

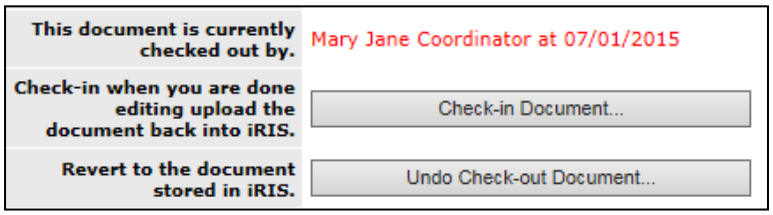
The browser will ask if you would like to open or save the document.

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

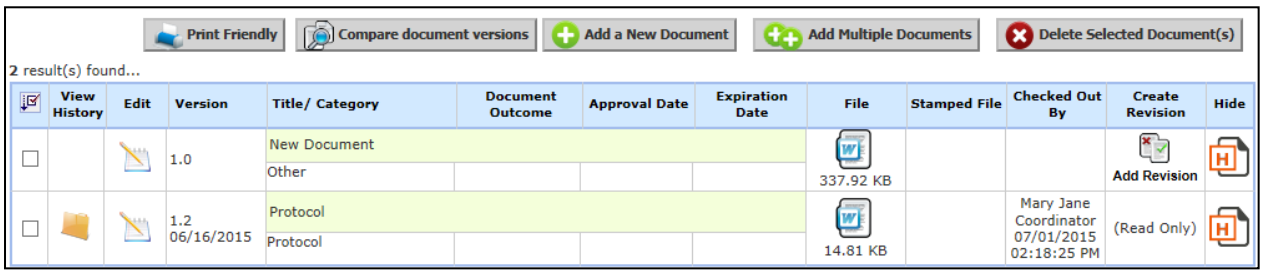
After saving the document, you can click the **Complete Checkout** button.

The system will return you to the previous page.

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.**

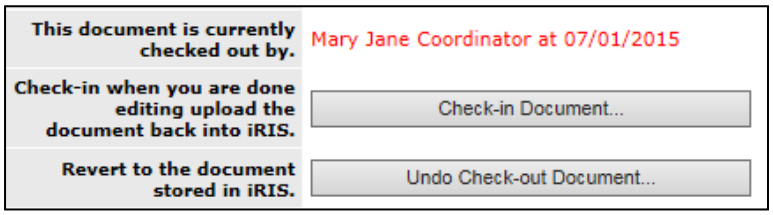


When you view the Study Document library, any document that is currently checked out will contain the checkout information in the **Checked Out By** column.

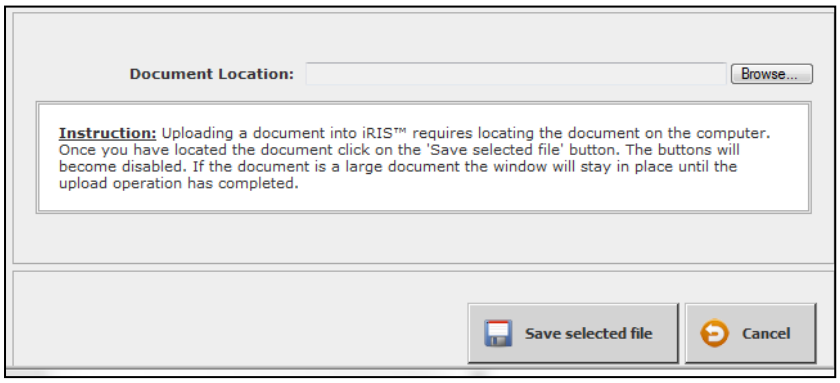


After you make any changes to the document in Microsoft Word, you can return to the Study Document library to check in the changes. Click the icon in the Edit column.

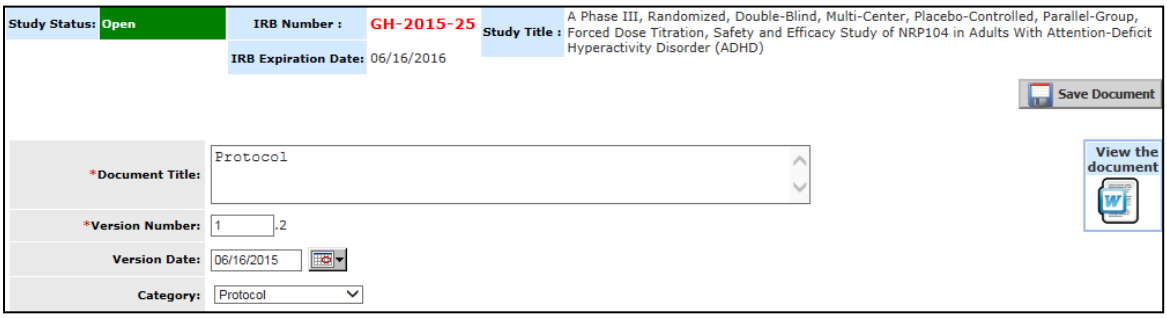
When the Study Document details page opens, you can click the **Check-in Document** button.



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 have associated a document, click the **Save selected file** button.

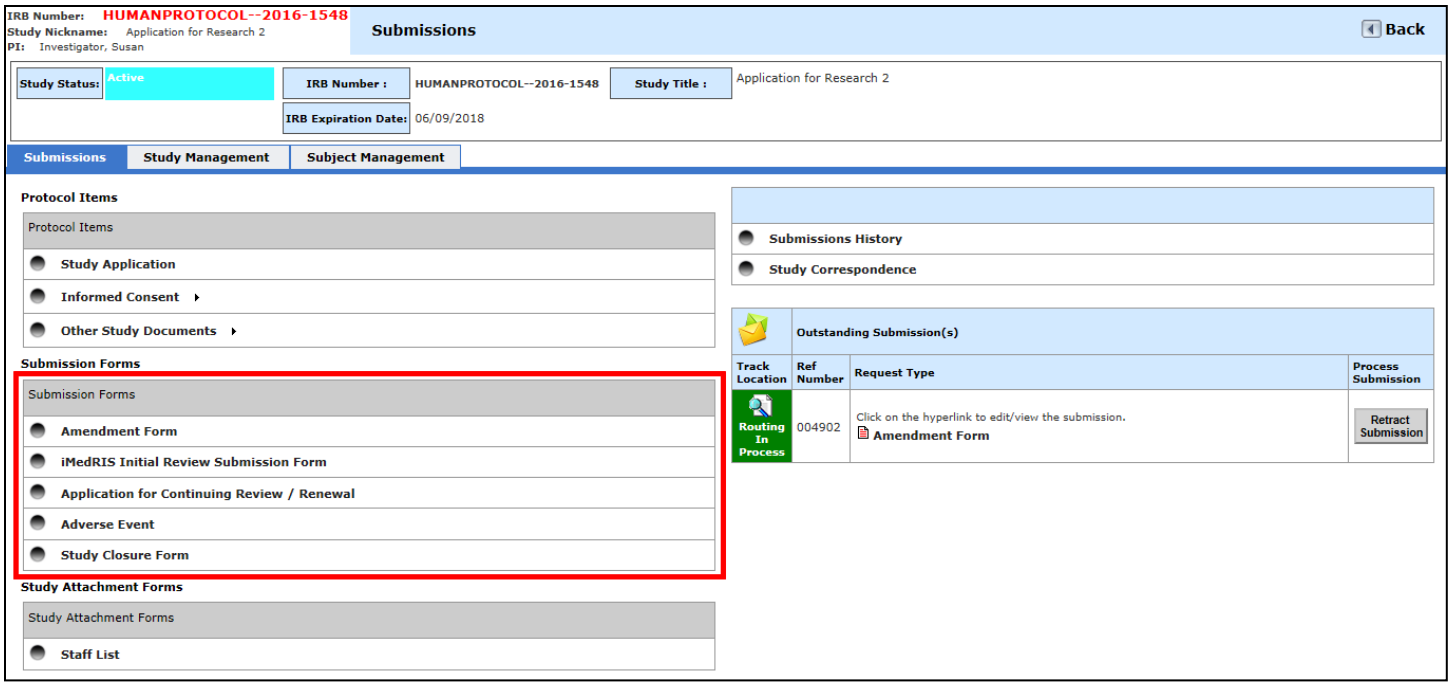


The revised document will be uploaded to the study. Click the **Save Document** button to save the revised document to the study.

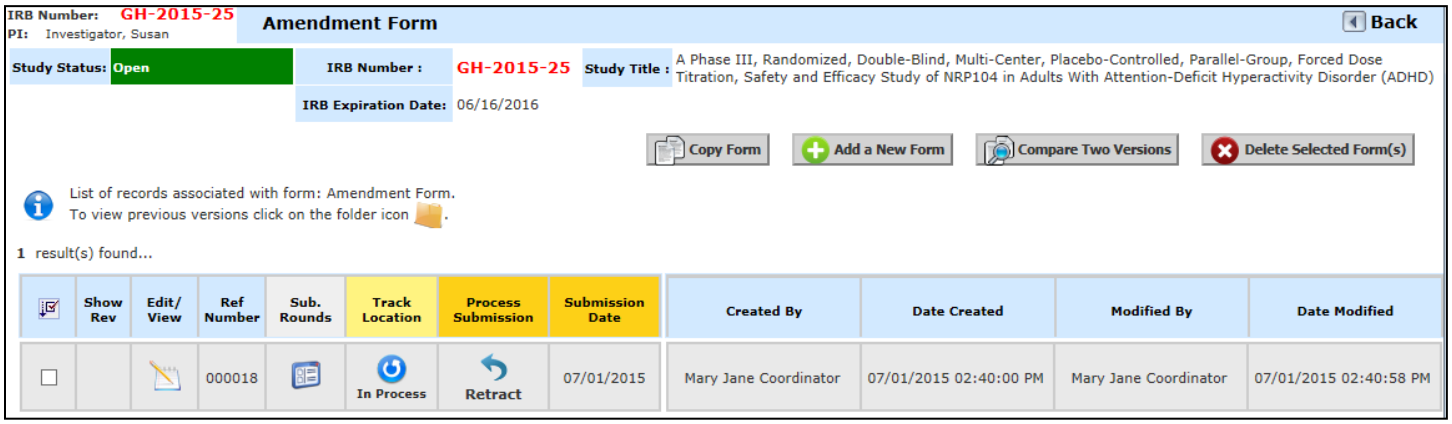


Submission Forms

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 set up 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 the form 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.

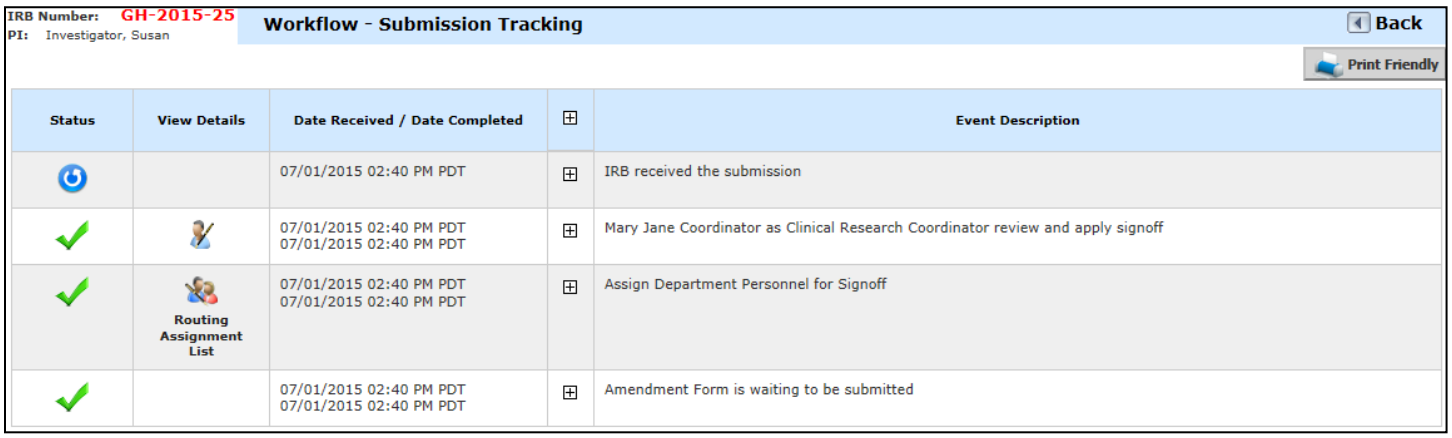
Show Rev – If a form has been revised for corrections, a folder will appear in this column. You can click on it to see the previous versions of the form. You will be able to open the previous submission, but it will be read-only, as that version has been submitted previously. You can also compare the differences between two versions of the same form by clicking the checkboxes and then click the **Compare Two Versions** button.

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.

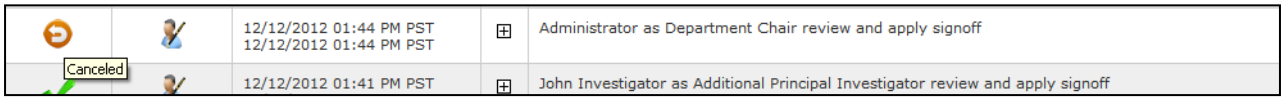
Ref Number – For every form that is submitted in iRIS, a unique number is assigned to that form, called the Reference Number. Each form that is submitted will get assigned a Reference Number. The presence of this field is set using the Use Reference Number flag in System Form Designer.

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

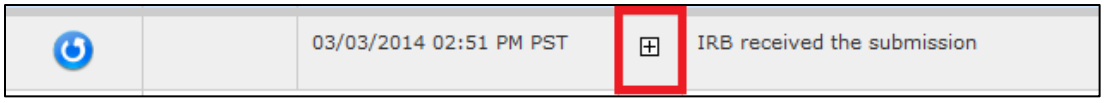
Track Location - If a form has been submitted, this column will populate with the current status of the form. You can click on the icon in this column to view detailed information about the steps the form has taken since it was submitted.



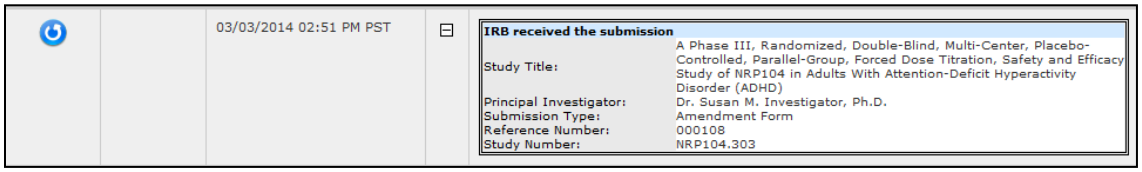
Any steps that are still in process will be displayed at the top of the list, with the status of **In Process** ( ). The steps that are completed will be displayed with the status of **Completed** ( ). Once a step has moved from In Process to Completed, the step will order by the date/time stamp. If any step was cancelled, the status will be cancelled and the Cancel icon will be displayed, as seen in the image below.



The time and date that the step occurred is displayed in the Date Received/Date Completed column. The Event Description will display the description of the event. Each item in this table can be expanded to show more details in the Event Description. This can be done by clicking the expand button:

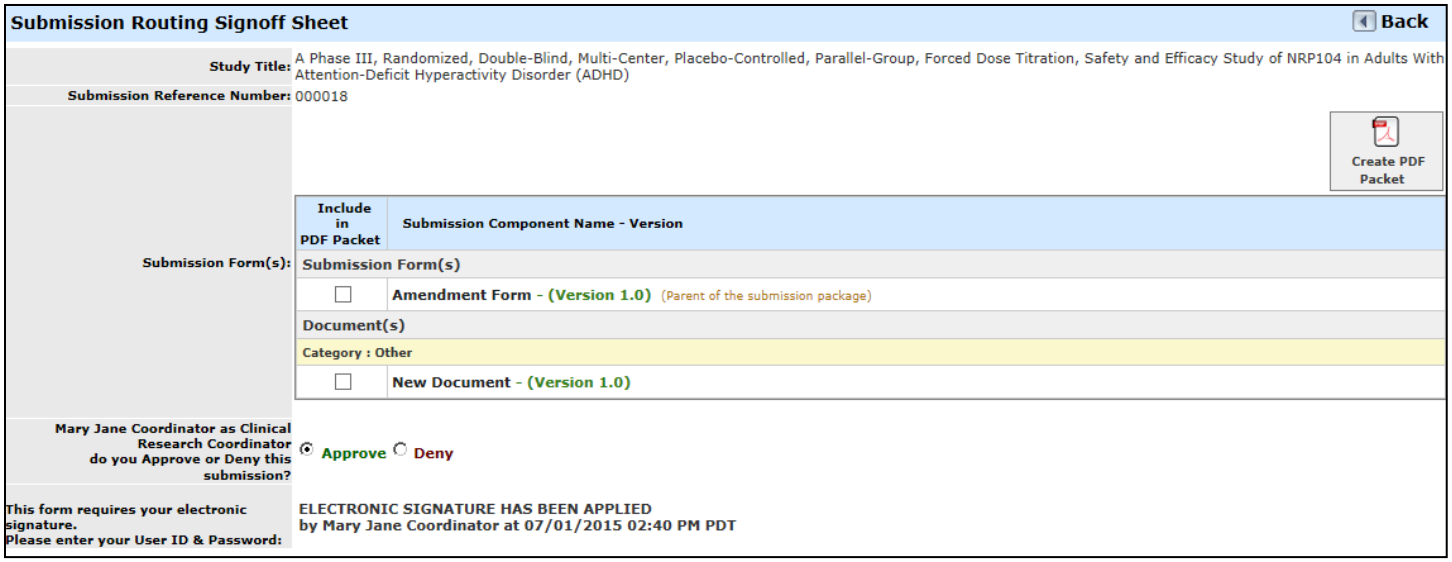


Clicking the expand icon will display detailed information regarding the event.



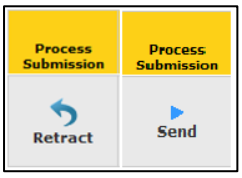
To minimize this view, simply click on the ⊟ icon.

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



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.

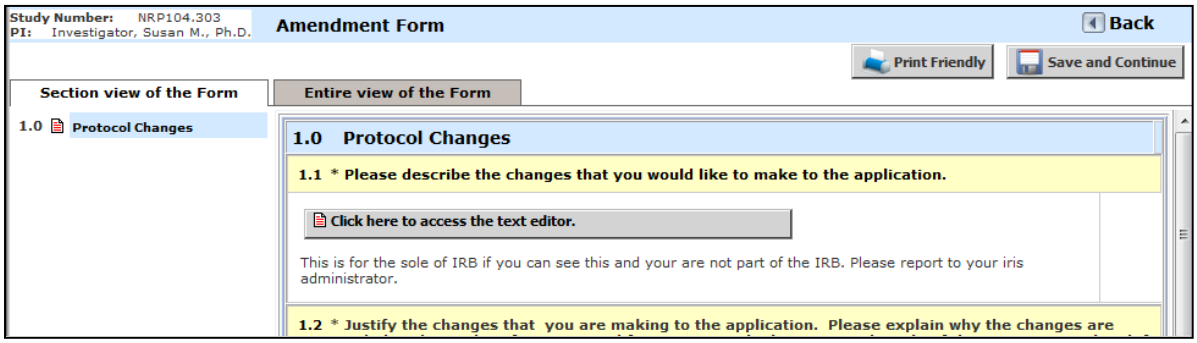
Modified By – Will display the name of the user who last modified the form record.

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

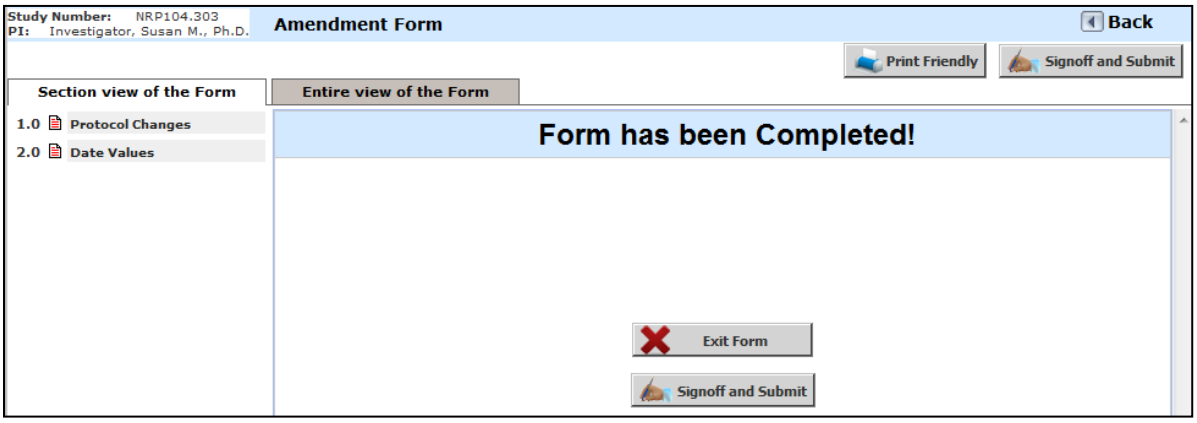
Note: Created By, Date Created, Modified By and Date Modified can all be turned off in the System Forms Designer. Other columns from the form can be turned on in their place. See the Forms Designer manual for more details on displaying columns in the form table.

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.

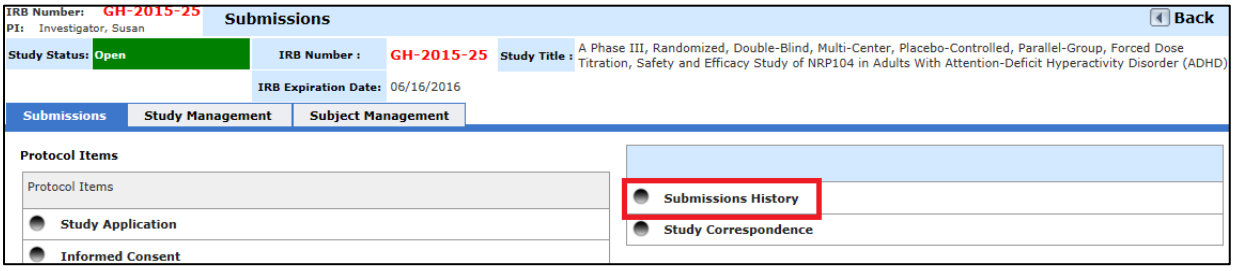


When you are finished with the form, you will be presented with a section that will allow you to exit the form or signoff and submit, as seen in the image below. See details in the Add a Study manual for information on submitting a form.



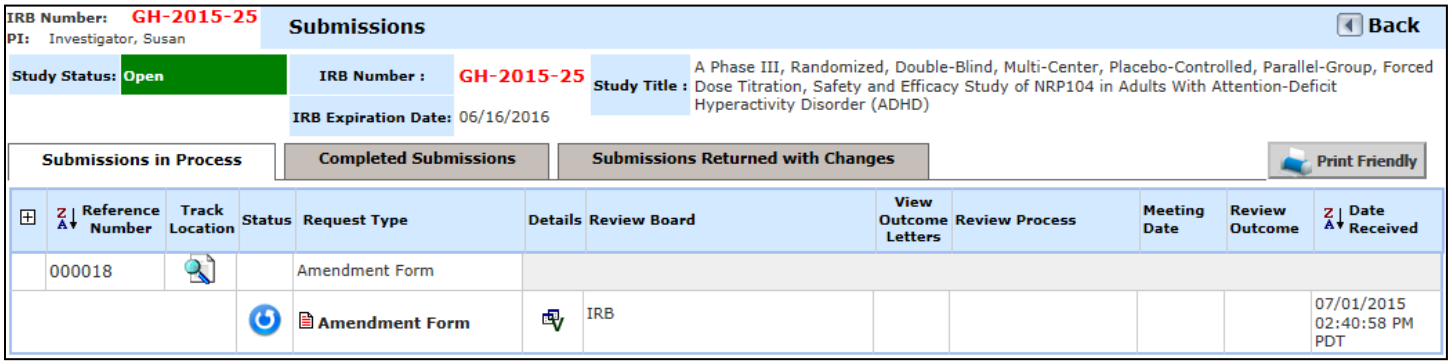
Submissions History

Submissions History contains a listing of every submission form that has been sent for your study, enabling you to look up past submissions and track their progress.



The list of submissions contains three tabs, Submissions in Process, Completed Submissions, and Submissions Returned with Changes.

Submissions in Process- This tab displays all of the submissions in process, which includes 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, view the request type, view the details of the submission, see the review board, and view outcome letters, the assigned review process, the meeting date, if any, the review outcome, and the date received.



Completed Submissions- This tab displays all the completed submissions, or any forms the review board has completed processing. From here you can view the reference number, track the location of the submission, check the status, view the request type, look at the details, see the review board, and view any outcome letters, the assigned review process, the meeting date, if any, the review outcome, and the date received.

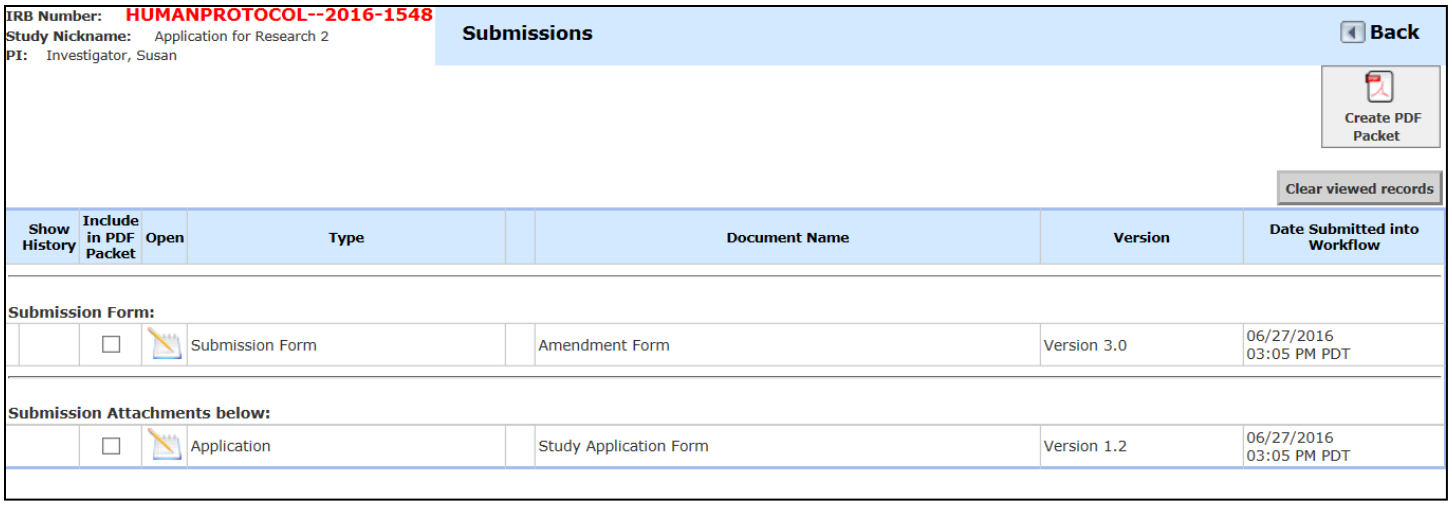
Submissions Returned with Changes – This tab lists the submissions that have been returned for corrections from the review board.

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

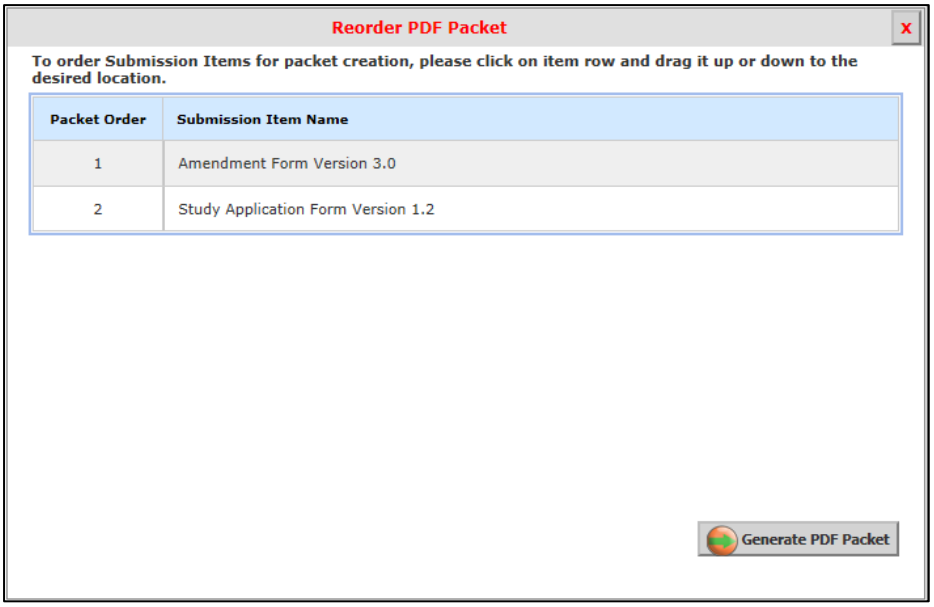
Track Location- Click on the icon to view a step-by-step listing of the submission process, the Workflow – Submission Tracking page.

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.



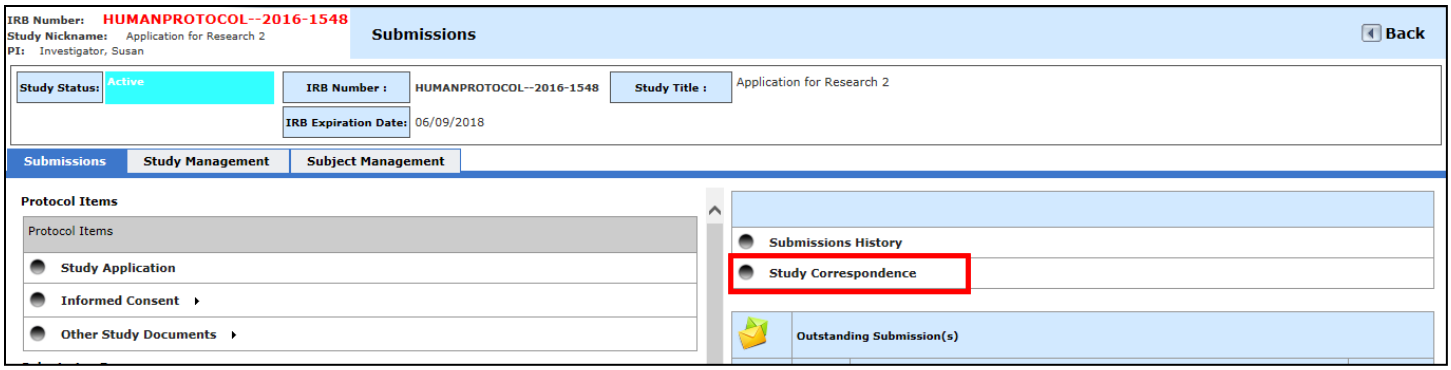
From this screen, you can open any of the components of the submission by clicking on the icon. You can also generate a PDF packet of the submission components from this screen. Check the boxes in the Include in PDF Packet column next to the components you wish to include, and click **Create PDF Packet**.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



When you are done reordering the submission items, click **Generate PDF Packet**. The PDF packet will open in a new window.

Study Correspondence

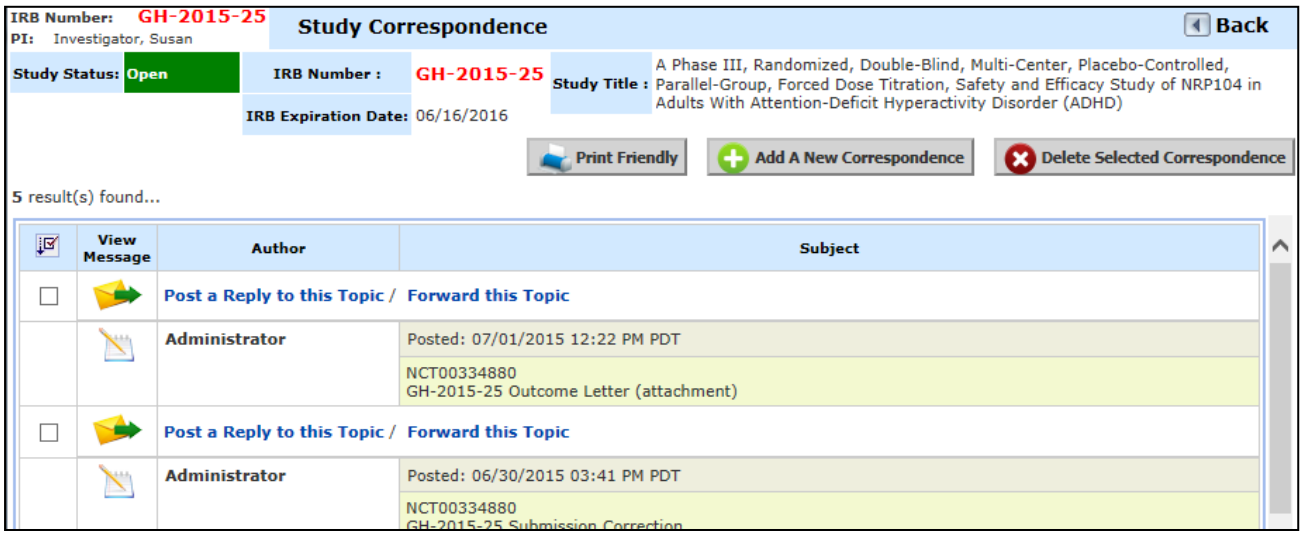
This section, located on the main Submissions screen, is used for any study-related correspondence.



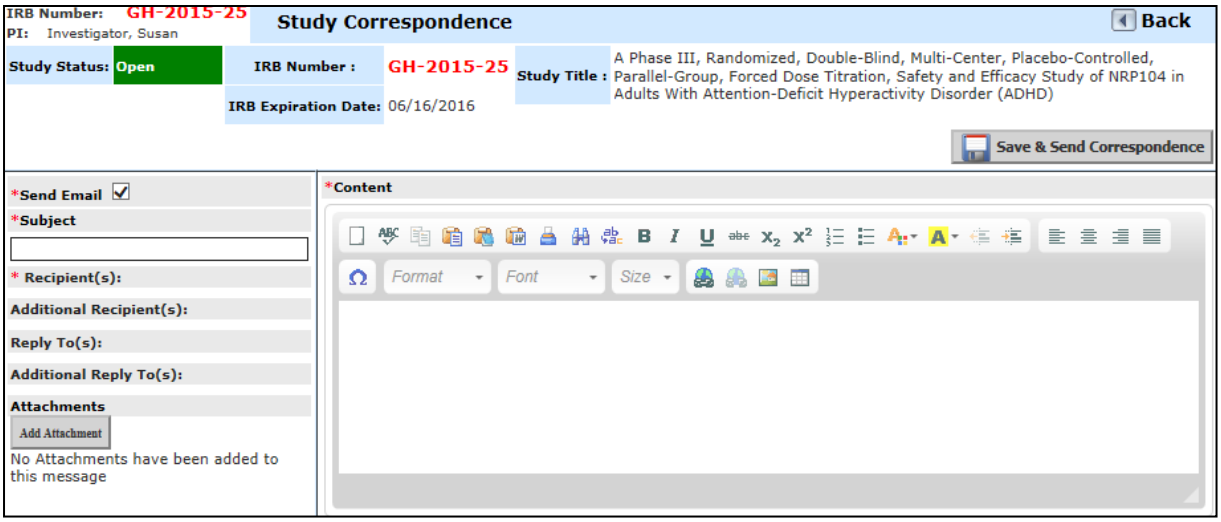
This area will contain a list of any study-related correspondence that has been sent throughout the life of the study. The system will send out automatic notifications at certain points, including Principal Investigator signoff notifications, Review Response requested by the review board notifications, Submission signoff denied notifications, Continuing Review Due notifications, etc. Whenever a study-related notification is generated and sent, a record of that notification will post to the Study Correspondence.

This area will also contain a list of any correspondence generated by users. If the review board generates correspondence via a submission or the study record, or if someone within the study team generates and sends correspondence, a record will post here.

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



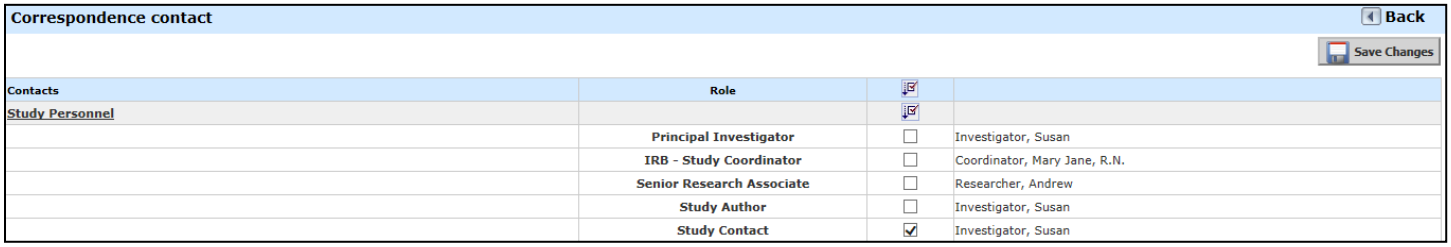
A new page will open, containing a text editor and tools you can use to generate your correspondence, as seen in the image below. (Note: *required field)



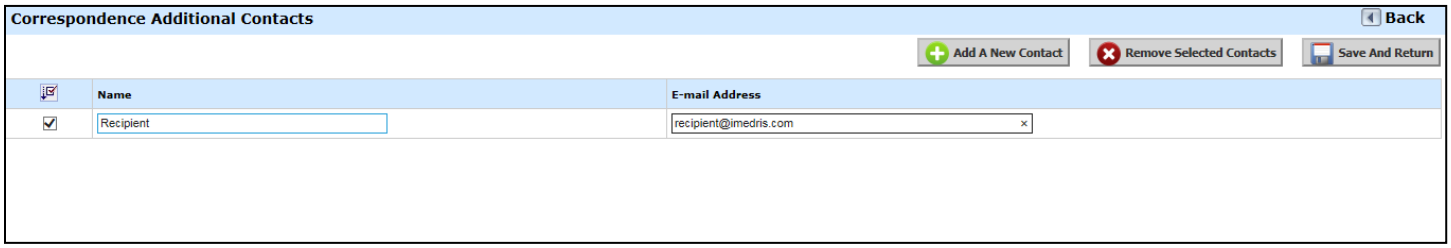
1. Select the checkbox if you want an **Email** notification sent to the recipient(s). This checkbox is selected by default. If you do not want the correspondence to send as an email, make sure the checkbox is not selected.

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 Additional Recipient(s) link will open a screen where you can add the names and email addresses of recipients.

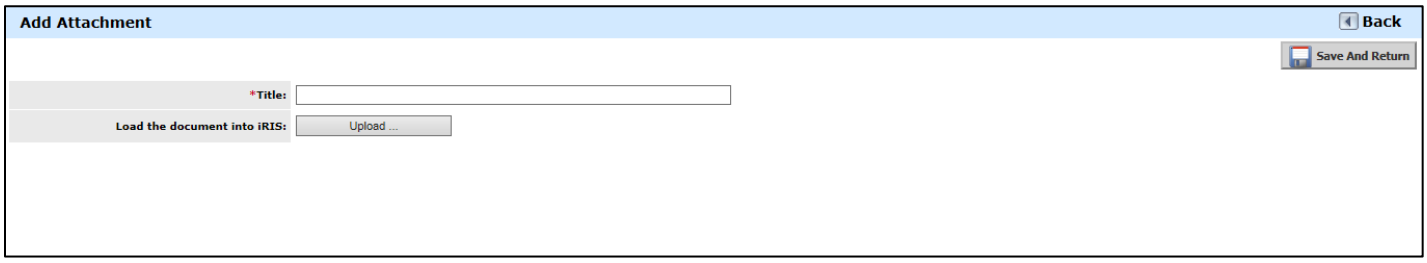


To add recipients to the list, click **Add A New Contact**. This will bring up the Name and E-mail Address fields, where you can enter the recipient's contact information. If you need to remove a contact, check the box next to their name and click **Remove Selected Contacts**. When you are finished adding 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. This process is the same as selecting recipients.

6. Add **Additional Reply To(s)** if necessary. This process is the same as entering additional recipients.

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.



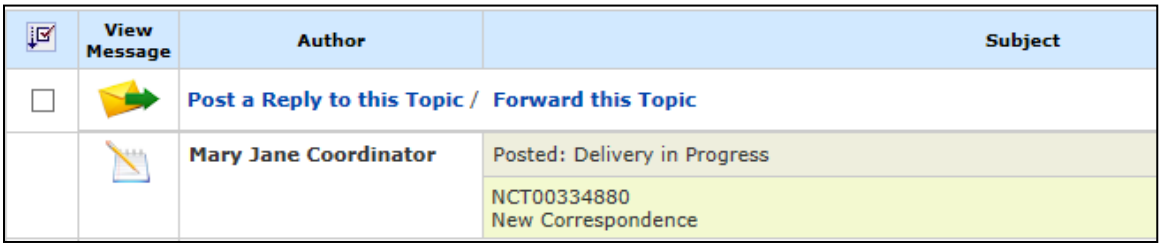
Enter a Title and click **Upload** to locate the file on your computer. When you are finished adding an attachment, click **Save And Return**.

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.

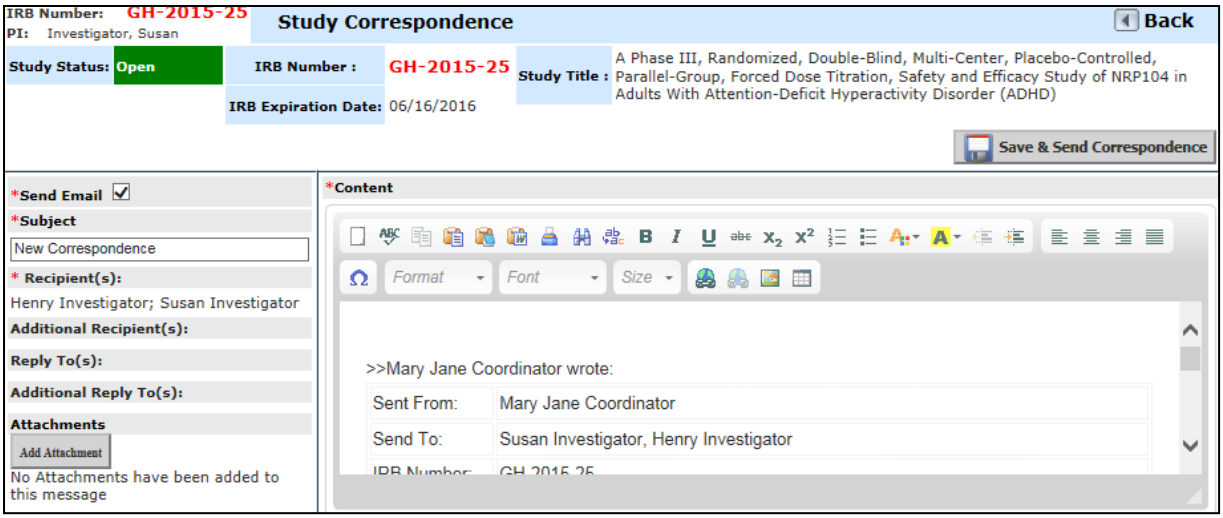
8. Enter the **Content** in the text editor.

Once you have completed the correspondence, click the **Save and Send Correspondence** button. If Send Email is not selected, the recipients will be able to view the correspondence under My Assistant > View 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 already been sent, you are not able to modify it. You can reply to the original correspondence or forward it to other recipients by clicking **Post a Reply to this Topic** or **Forward this Topic**.



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

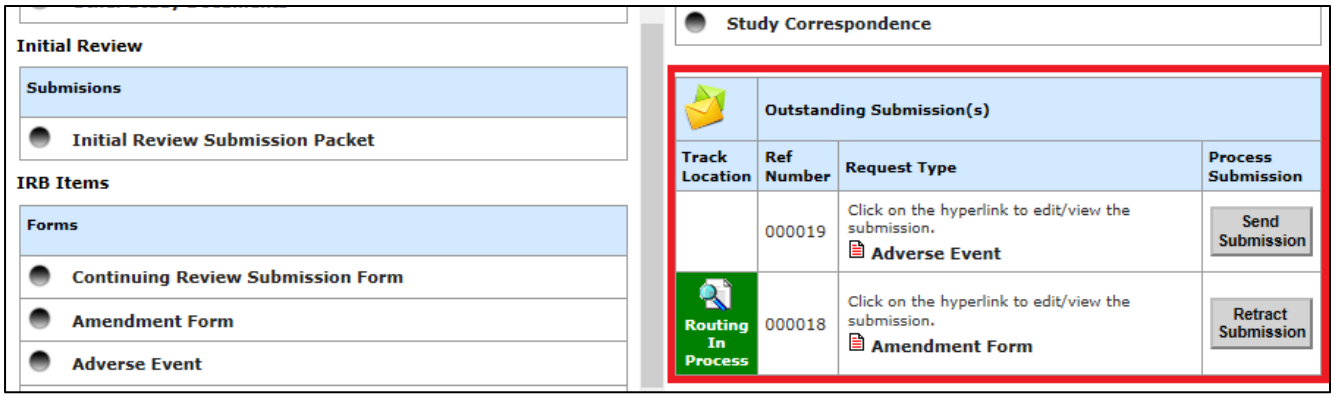


Any replies will post in the Study Correspondence below the original. Note that each correspondence generated is counted as one record in the system. Any replies are counted with the original correspondence and are not recognized as a separate correspondence record.

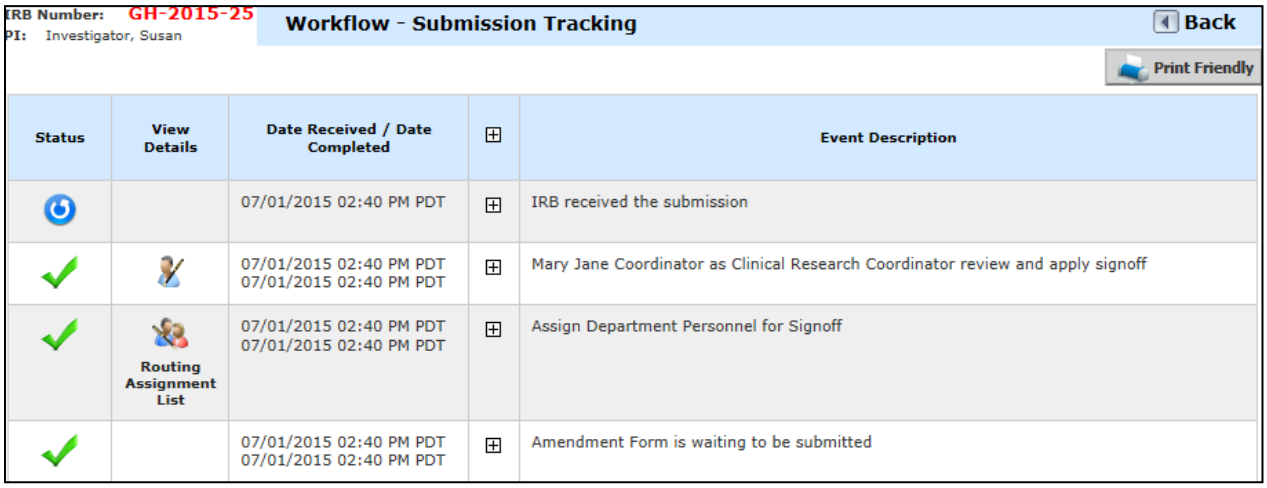
Forwarding a correspondence is similar to replying. A new page will open, allowing you to add to the Content and select Recipient(s). When you forward correspondence, the new message will be added to the same correspondence record on the main Study Correspondence screen.

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 assigns it a review process, 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 under Outstanding Submissions, allowing the user to access the correction form, make necessary changes, and re-submit the form to the board.

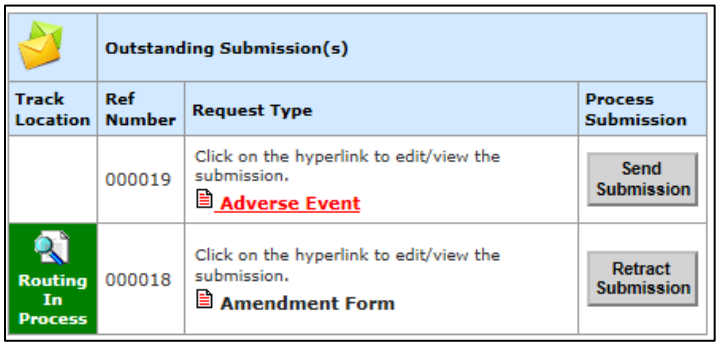


At any time during the signoff process, or before the review board begins processing your submission, you can check on the status of the form and where it currently is located. If the form has been submitted, an icon will display in the Track Location column. You can click on this icon to open the Workflow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



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.

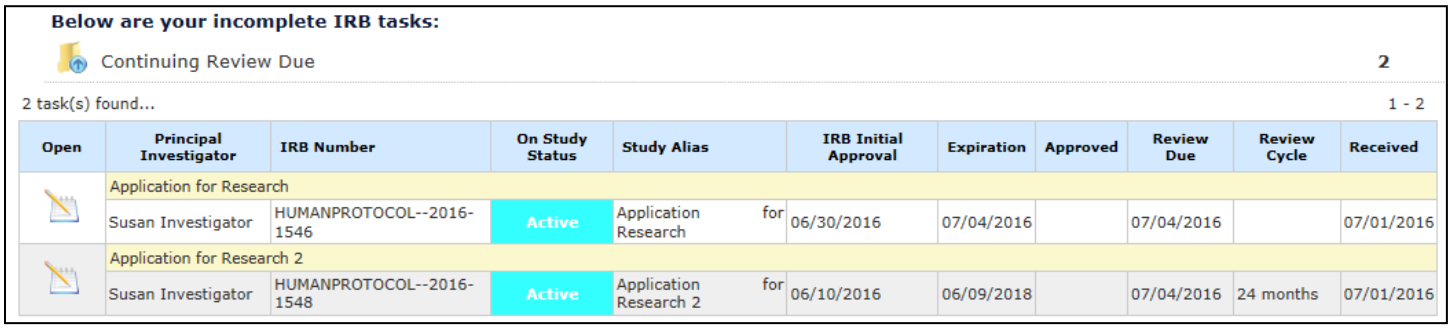
The **Process Submission** column will contain buttons depending on the status of the submission. If the form has not been submitted, there will be a **Send Submission** button. If the form has been submitted, but has not been processed by the review board, you will be able to **Retract Submission,** 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, system notifications can be configured to be sent to the Principal Investigator and the Study Contact. These notifications are configured under Review Board Administration > Review Board Notification Setup > Continuing Review Notification Setup.

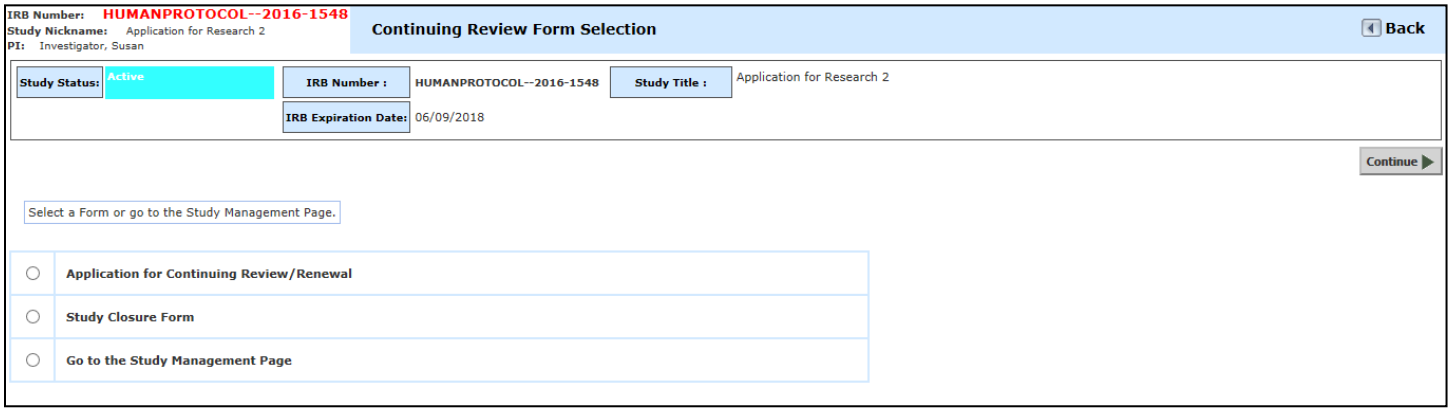
Continuing Review Due Task

The Continuing Review Due task appears on your homepage a certain number of days before the review due date, as specified in the notification setup.



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

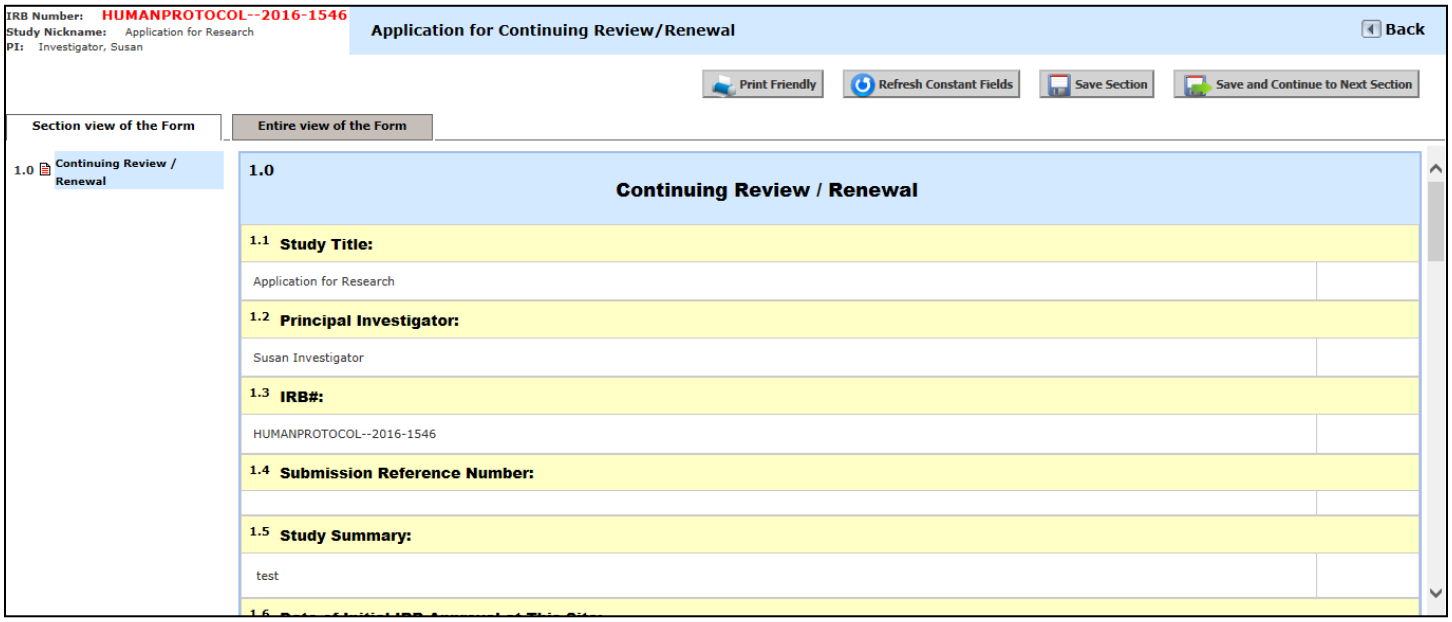
Click the icon to open the task. This will open the Continuing Review Form Selection screen, which will allow you to select a form or go directly to the Study Management page for the study with the upcoming review due.



Select a form from the list or select the Go to the Study Management Page option, and click **Continue**.

Filling out the Form

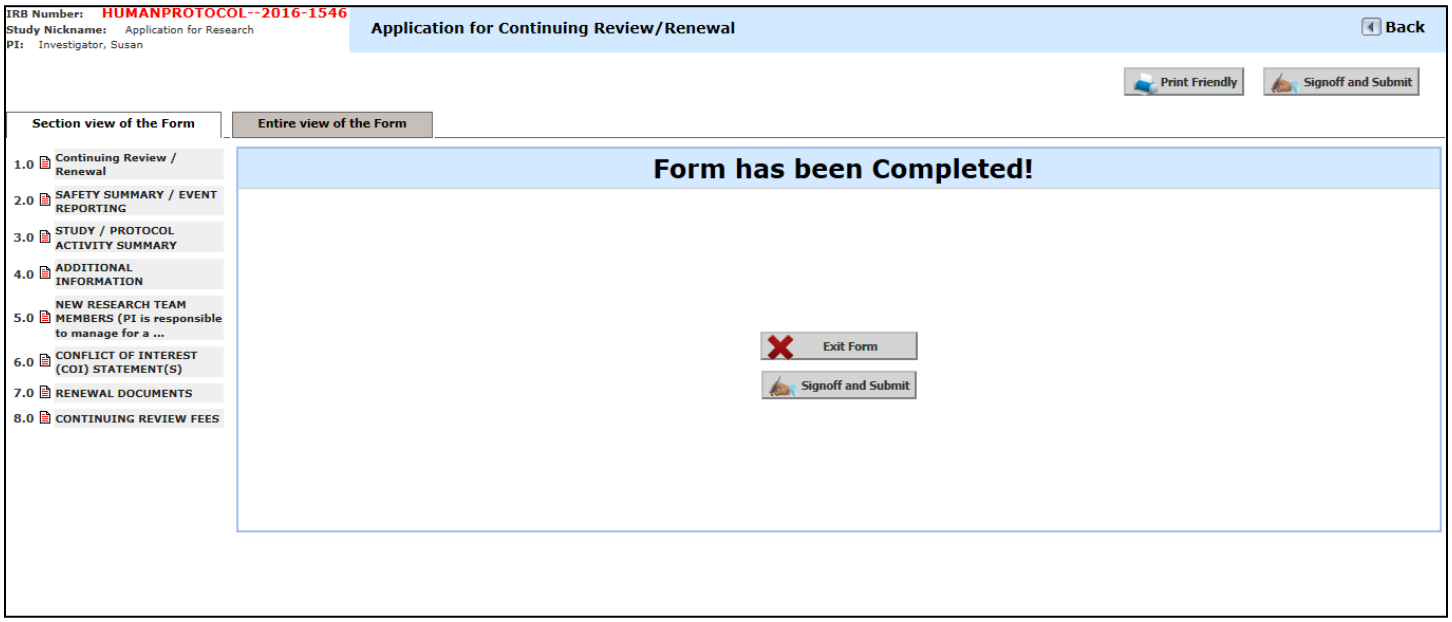
If you have selected a form from the list, the form will open. You can fill out the form using the **Save and Continue** button at the top right of the page to navigate through the sections.



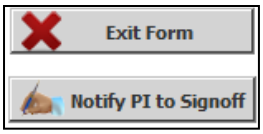
Once the form is complete and the required documents are attached, the form is ready to send to the review board.

Submitting the Form

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



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**.



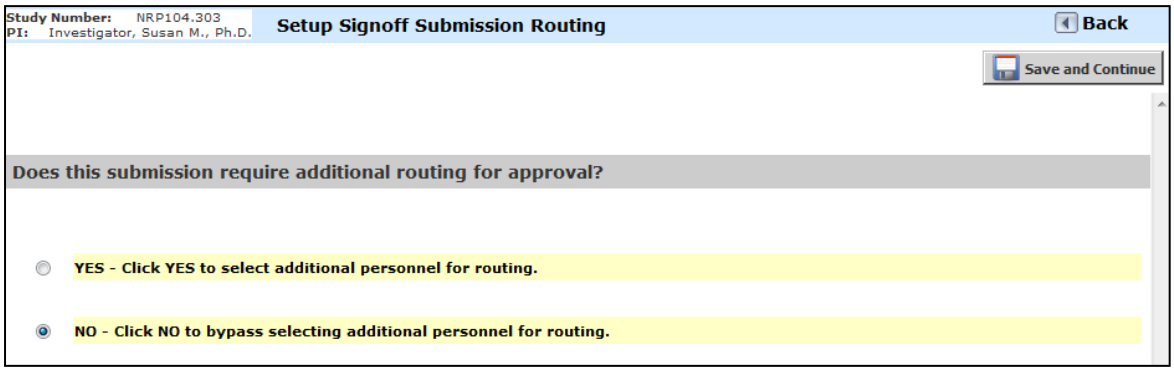
If you are the Principal Investigator, or the form does not require a PI signoff, the **Notify PI to Signoff** button will be replaced with **Signoff and Submit**.

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 or if you need departmental approval. Make your selection, and click the **Save and Continue** button, as seen in the image below.

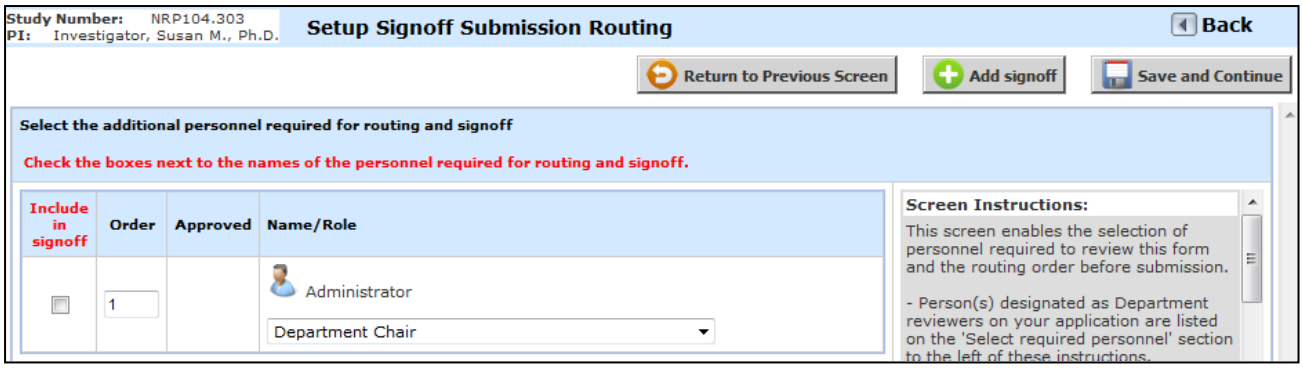


If you opted to route for additional signatures, you will be brought to a page that will list Key Personnel that you can include to signoff. If you chose not to route, you will immediately transition to a signoff page.

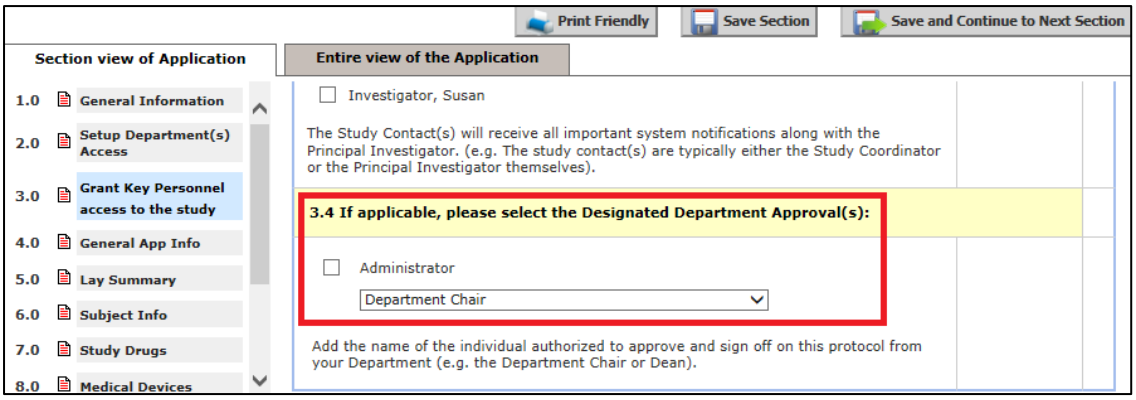
If the Principal Investigator's signature is required on this form, that user will be pre-selected and you will not be able to deselect the PI from the signoff process.

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

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

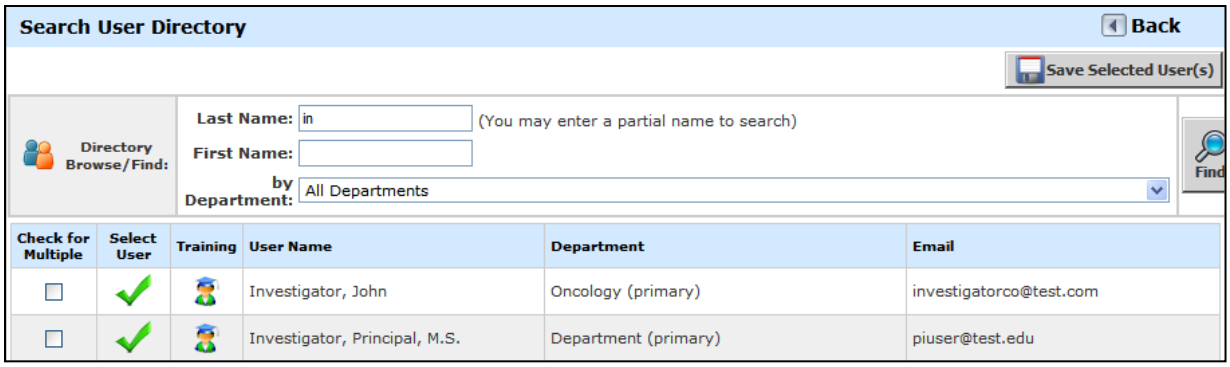


The user in the screenshot above was added in Designated Department Approvals, in the Grant Key Personnel section of the Study Application.

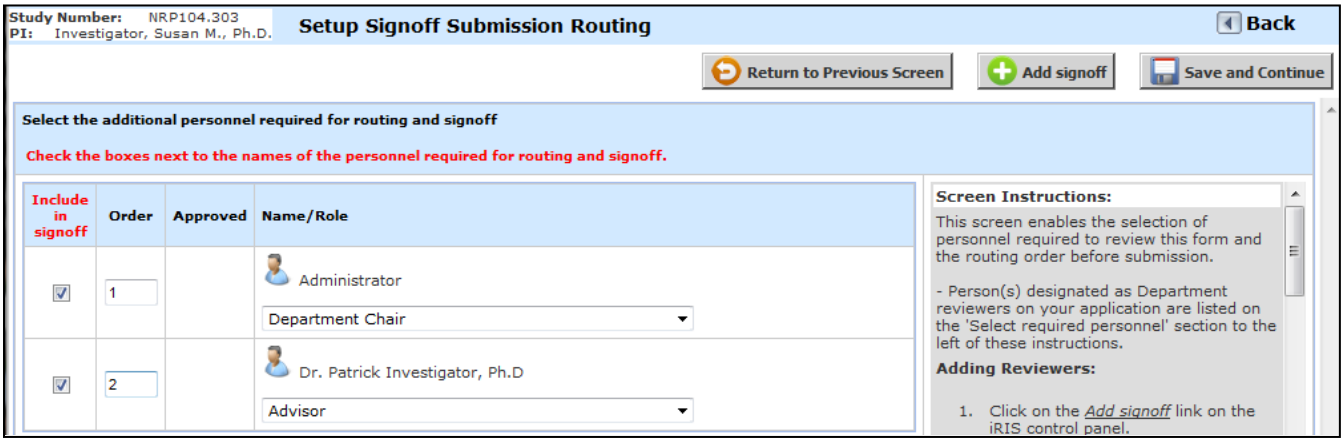


You can also add reviewers from iRIS by clicking the **Add Signoff** button.

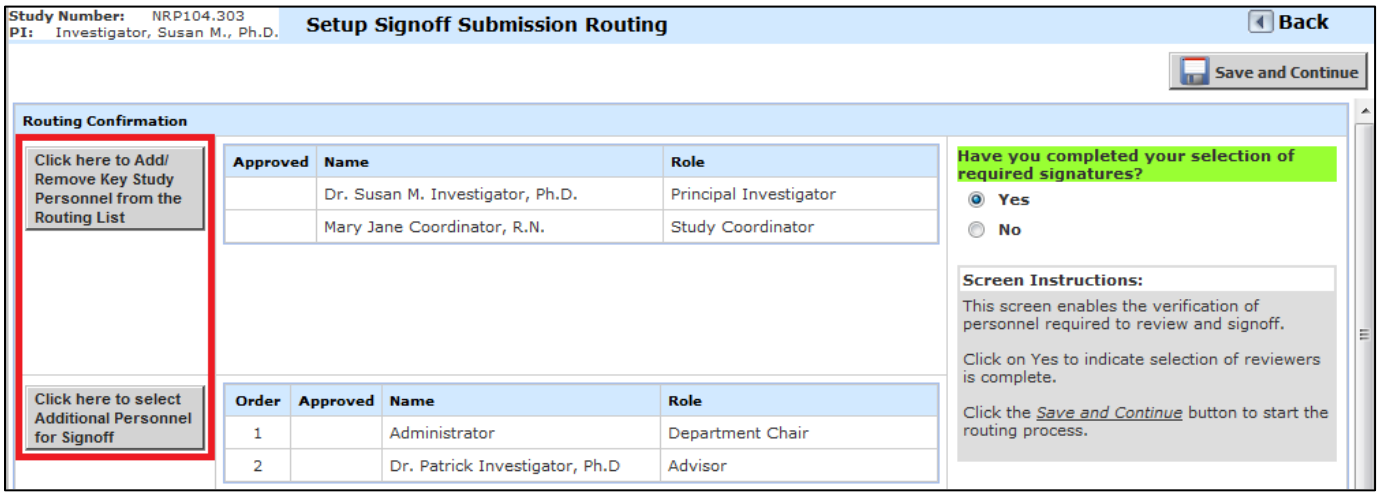
This will open a new page, allowing you to search the database for a user. Use the Last Name, First Name, and Department search filters to find the user you wish to add, and then click the ✔ icon in the Select User column. If you wish to add multiple users, check the boxes next to their records in the Check for Multiple column and click **Save Selected User(s)**.



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. If one reviewer should receive the task before another, you can change the order by entering different numbers in the Order boxes. Click the **Save and Continue** button to proceed.

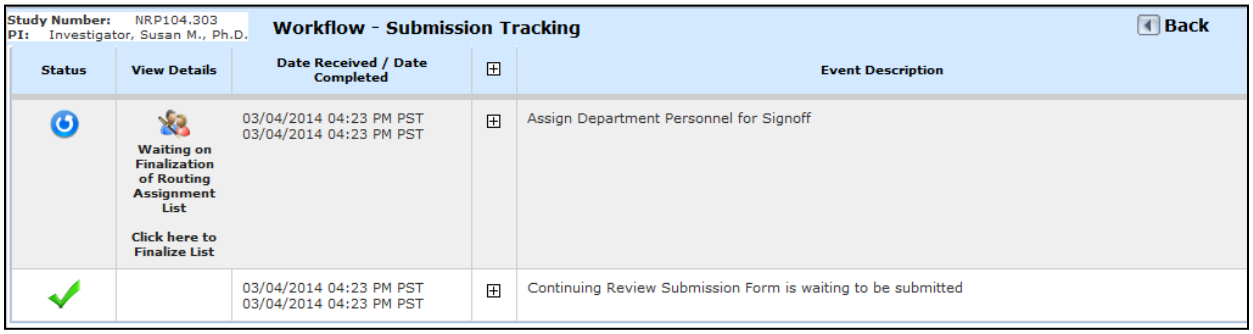


The next page is a summary page, displaying all the users you selected for the signoff process. If you need to add any more signoffs, click the gray button to the left of the Key Study Personnel and Additional Personnel groups. This will open the corresponding page that will allow you to remove or add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



When you are ready to initiate the signoffs, ensure you have selected Yes underneath the question "Have you completed your selection of required signatures?" (highlighted in green), then click on the **Save and Continue** button. If you are not ready to send signature tasks to the users, select No before clicking **Save and Continue.**

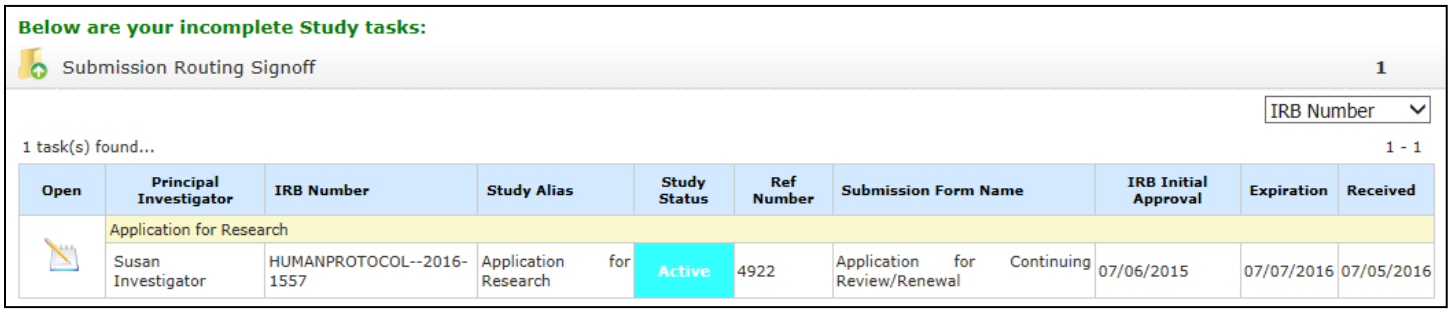
Selecting No and **Save and Continue** will bring you to the Workflow – Submission Tracking page. This page displays the steps your Study Application has taken from the time it was created until now. The Assign Department Personnel for Signoff record will appear under the Event Description column, as seen in the image below. You can click on the link in the View Details column to return to the Signoff Submission Routing pages.



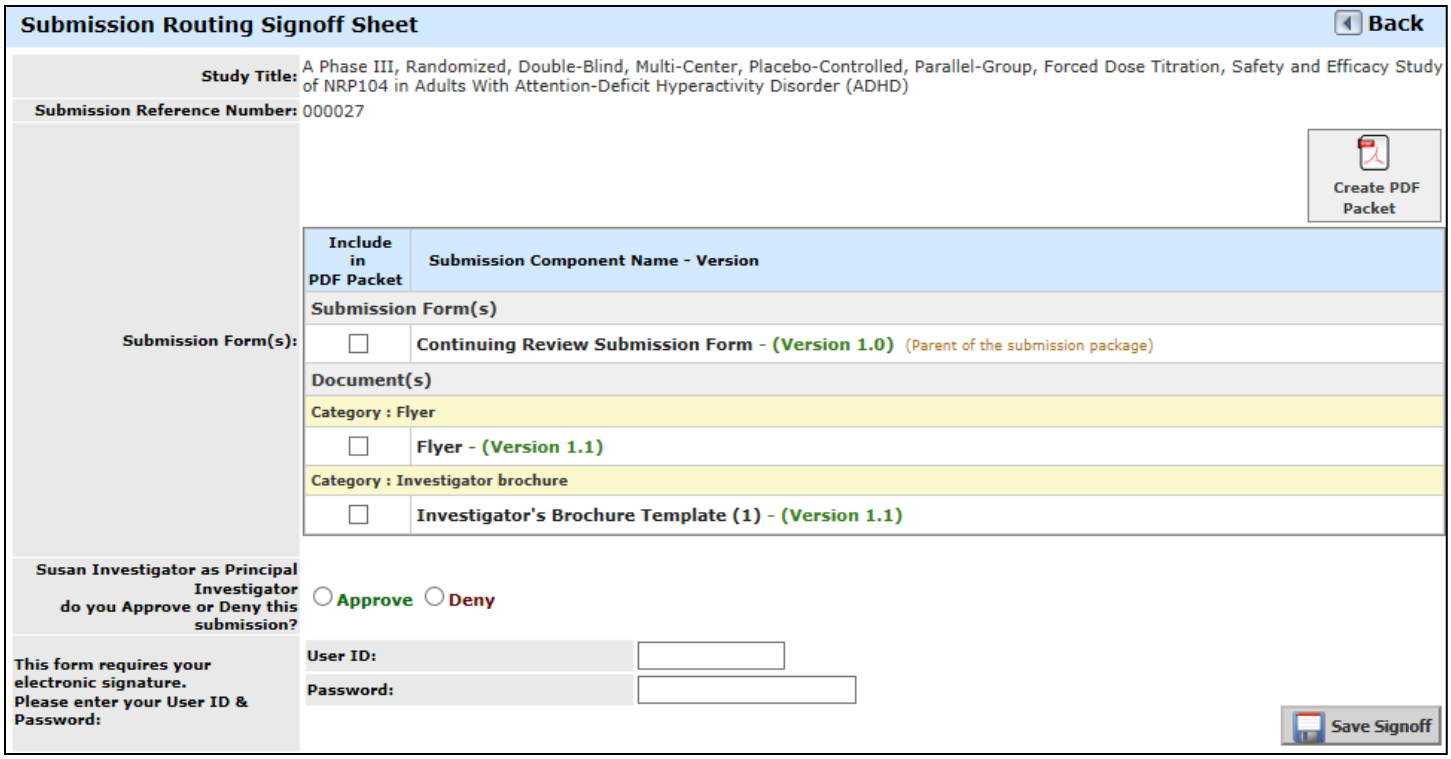
If you choose Yes and **Save and Continue** and you are assigned to sign off on the form, you will be brought to the Signoff Page.

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 signoff.

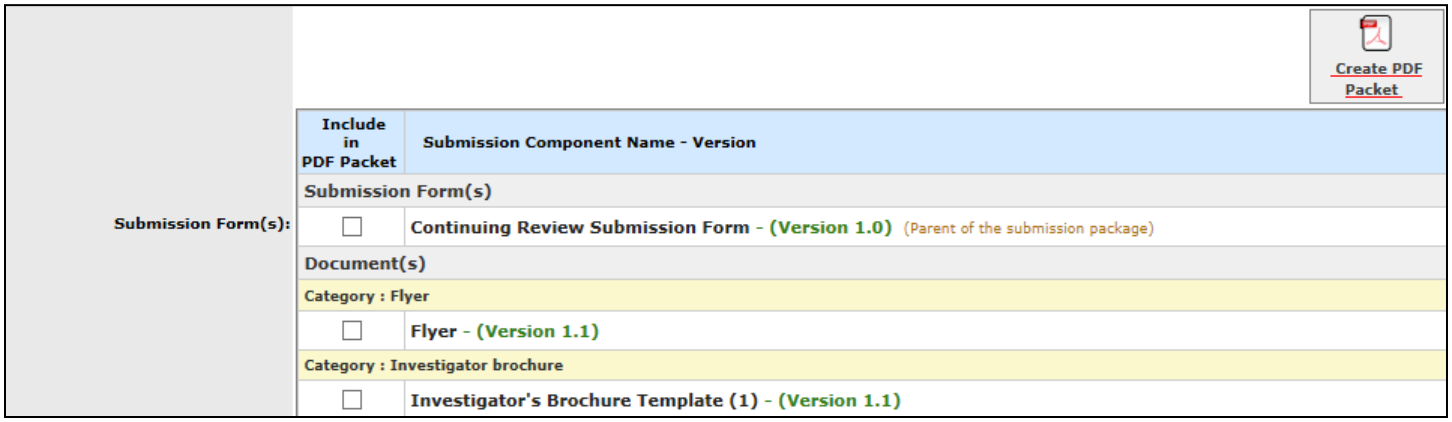


When the task is opened, the Submission Routing Signoff Sheet will display. At the top of the page, the Study Title and Submission Reference Number will be listed. iRIS assigns a unique reference number to each form created in the system. The reference number displayed here is the number assigned to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

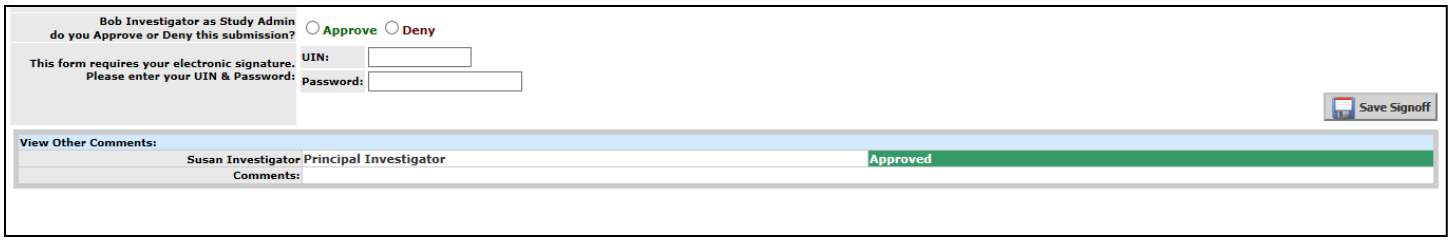


Also listed on this page are links to the Submission Components. This table contains a link to the Submission Form, and, if attached, the Study Application and any consent documents or other study documents that have been associated to the form. This is the package that is being submitted to the review board for review.

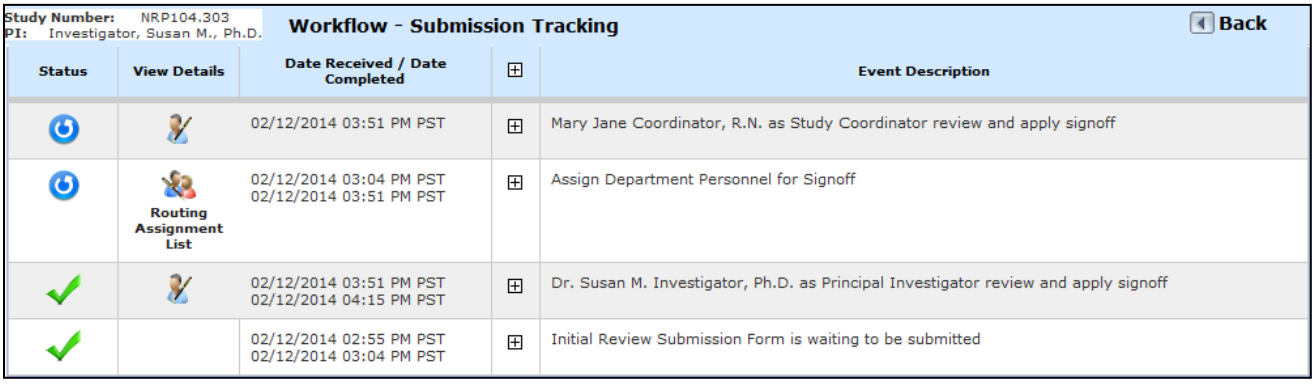
If a document can be printed, a check box will populate next to the document in the Include in PDF Packet column. You can select any of these items, and then click the **Create PDF Packet** button at the top of the table.



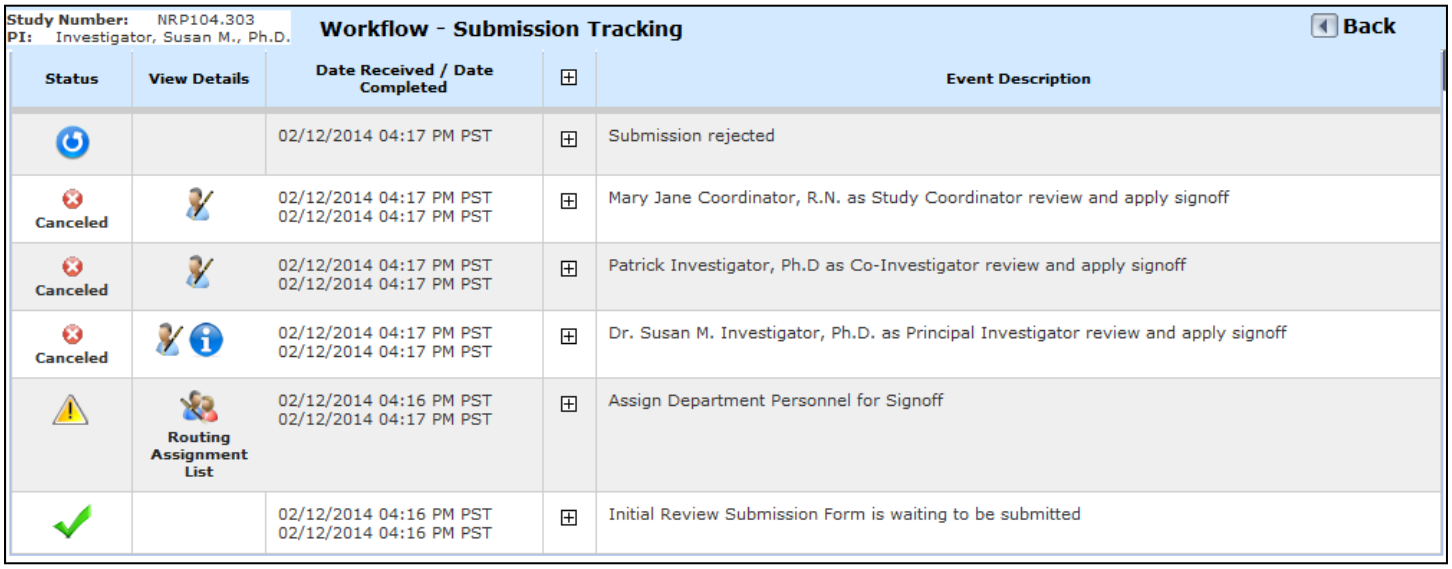
Below the Submission Components table, you will be able to enter your electronic signature. You must indicate whether you Approve or Deny the submission, enter your User ID and Password, and then click the **Save Signoff** button. Below the electronic signature portion of the page, you will be able to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



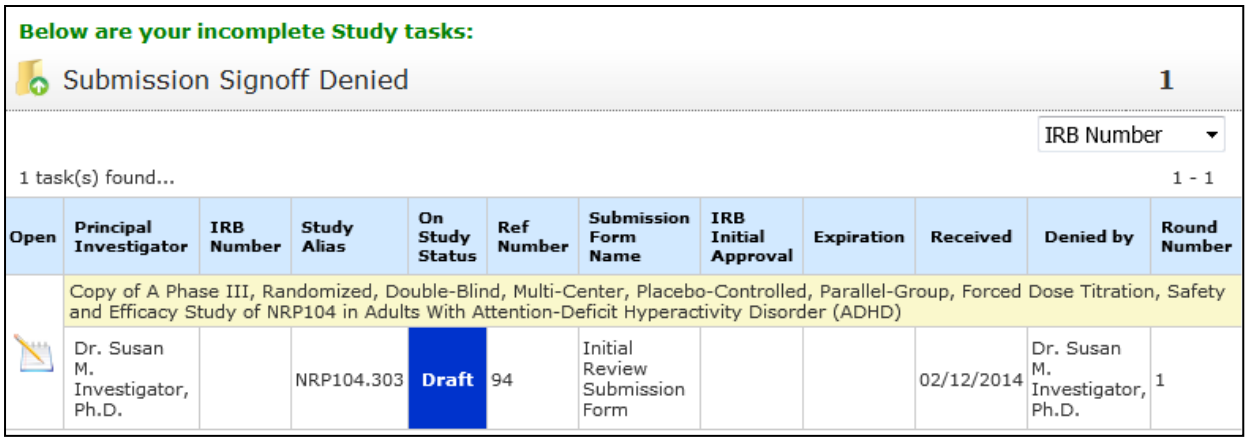
If you select Approve**,** iRIS will assign the next user in the list their user assignment task.



If you select Deny**,** any other signoff task will cancel.



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


Below are your incomplete Study tasks:

Submission Signoff Denied 1

IRB Number

1 task(s) found... 1 - 1

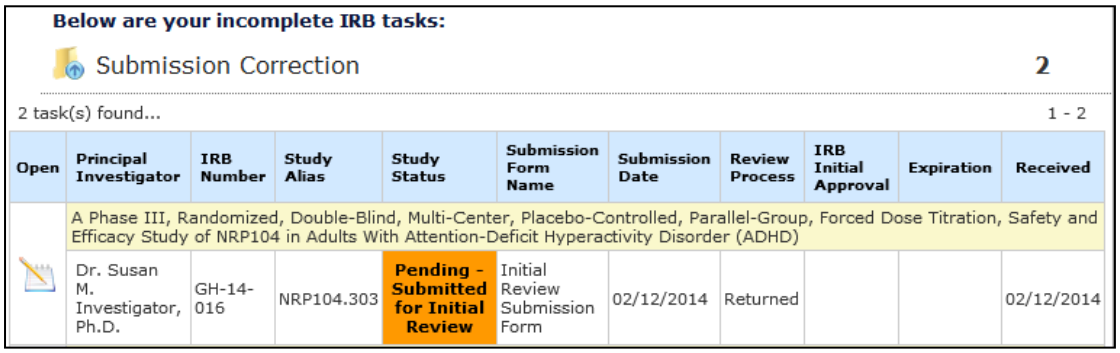
Open	Principal Investigator	IRB Number	Study Alias	On Study Status	Ref Number	Submission Form Name	IRB Initial Approval	Expiration	Received	Denied by	Round Number
	Copy of A Phase III, Randomized, Double-Blind, Multi-Center, Placebo-Controlled, Parallel-Group, Forced Dose Titration, Safety and Efficacy Study of NRP104 in Adults With Attention-Deficit Hyperactivity Disorder (ADHD)										
	Dr. Susan M. Investigator, Ph.D.		NRP104.303	Draft	94	Initial Review Submission Form			02/12/2014	Dr. Susan M. Investigator, Ph.D.	1

Once all assigned users have completed their signoff 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.


Below are your incomplete IRB tasks:

Submission Correction 2

2 task(s) found... 1 - 2

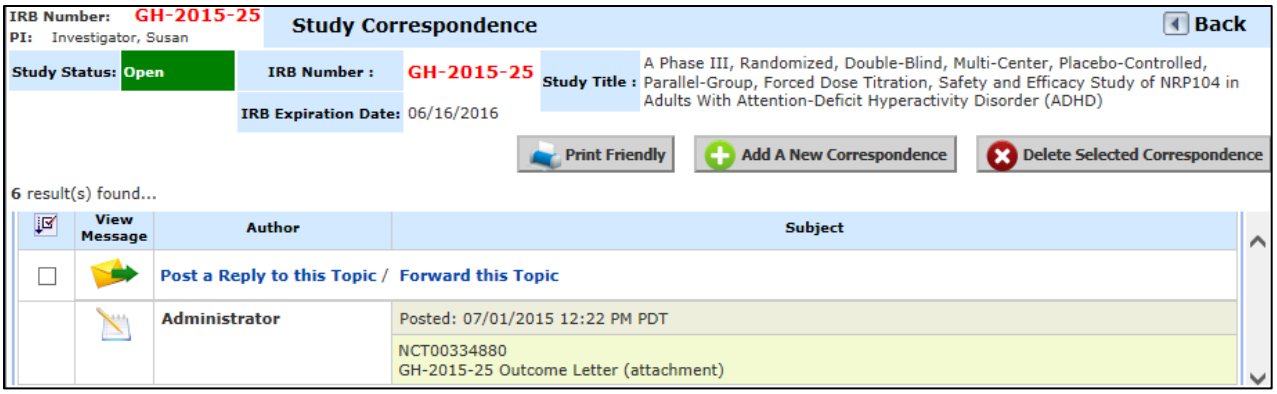
Open	Principal Investigator	IRB Number	Study Alias	Study Status	Submission Form Name	Submission Date	Review Process	IRB Initial Approval	Expiration	Received
	A Phase III, Randomized, Double-Blind, Multi-Center, Placebo-Controlled, Parallel-Group, Forced Dose Titration, Safety and Efficacy Study of NRP104 in Adults With Attention-Deficit Hyperactivity Disorder (ADHD)									
	Dr. Susan M. Investigator, Ph.D.	GH-14-016	NRP104.303	Pending - Submitted for Initial Review	Initial Review Submission Form	02/12/2014	Returned			02/12/2014

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 within your iRIS Correspondence.

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



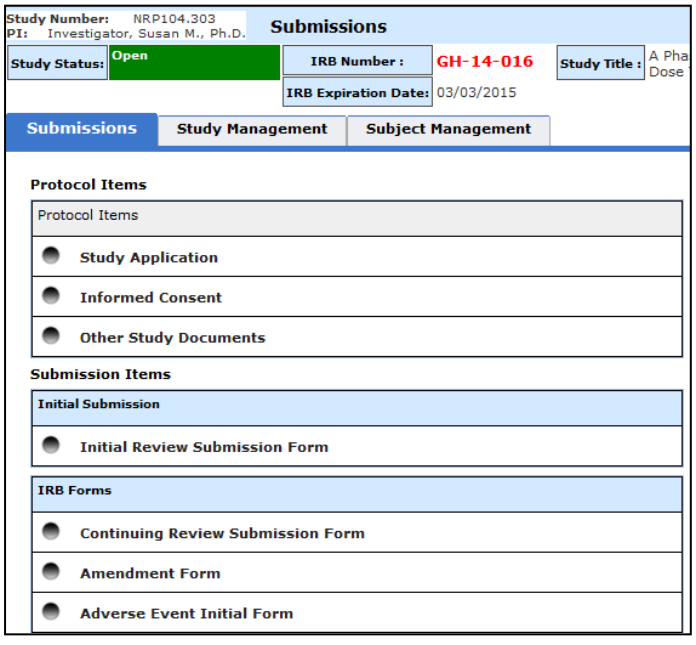
If the review board requests any further action, it will be addressed in the Outcome Letter.

Submitting an Amendment Form

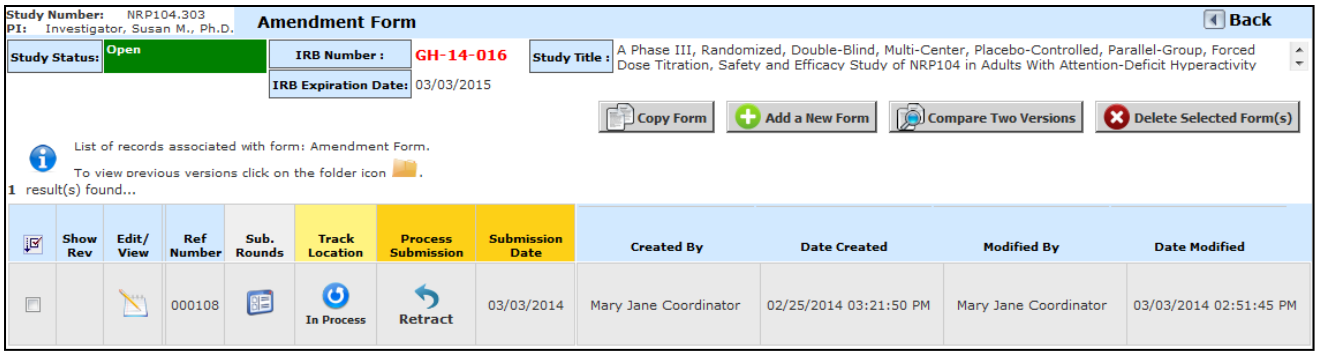
At any point during the life of your study, you can access a Modification or Change Request/Amendment form to submit changes for approval. Certain areas of the study require you to submit a change to the review board before that change can be applied to the study. Changing study personnel, drugs, and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

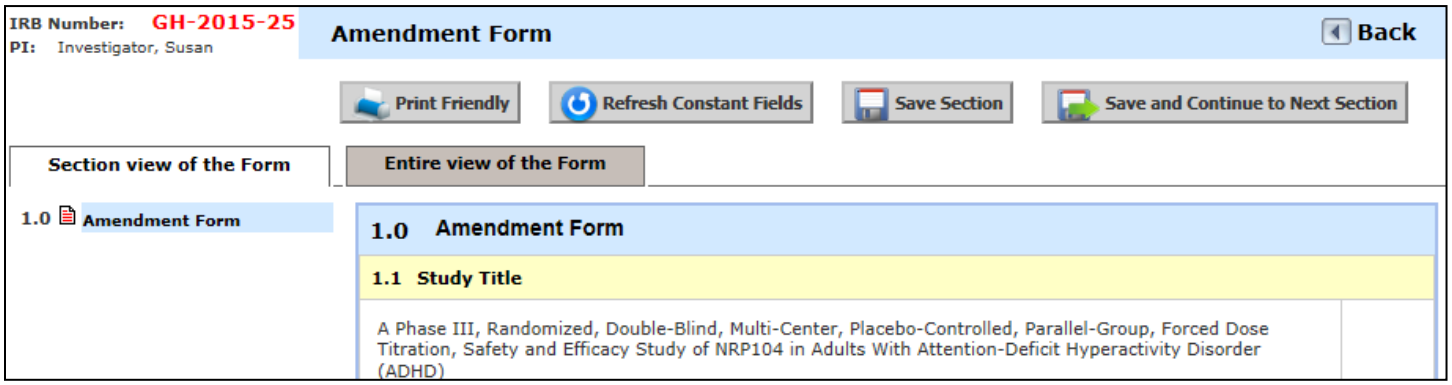


When you click on the link for the Amendment Form, you will be directed to a page that lists all amendments that have been created for this study. The items in this area are reviewed in the Submissions Forms section of this document.



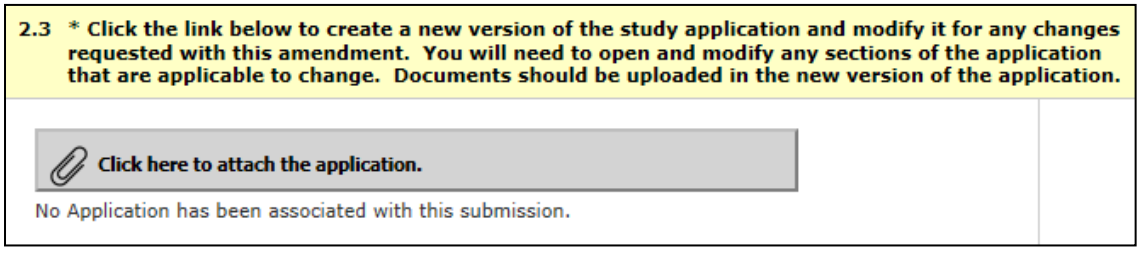
To create a new amendment, click the **Add a New Form** button. This will open the form as it has been defined in the Forms Designer. You can fill out the form using the **Save and Continue** button to navigate through the sections.

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



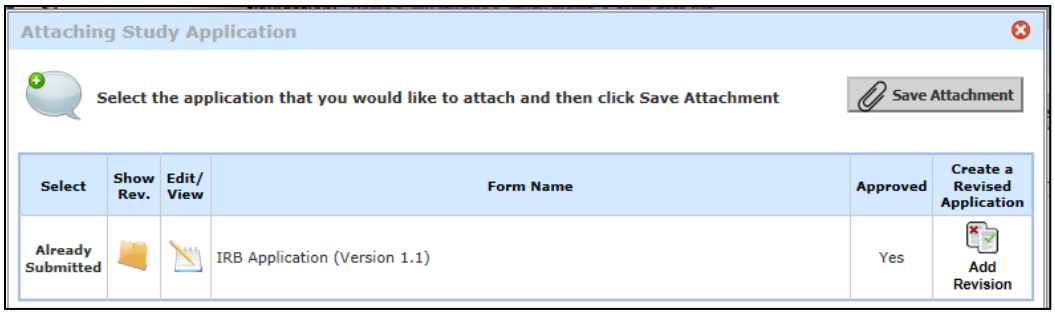
Modifying the Study Application

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

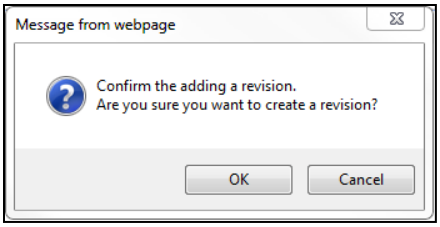


Once you click the link, a window will open within your browser and the current version of the Study Application will be displayed. The current version of the Study Application cannot be modified if it has been submitted for review. When you click the  icon in the Edit/View column, the application will open, but, because it has been submitted, you may not be able to add it to the Amendment form, depending on your system settings.

To create a revision, click the  icon in the Create a Revised Application column. Note: The versions of the application that can be revised are determined by system properties located under System Signoff and Submission Settings.



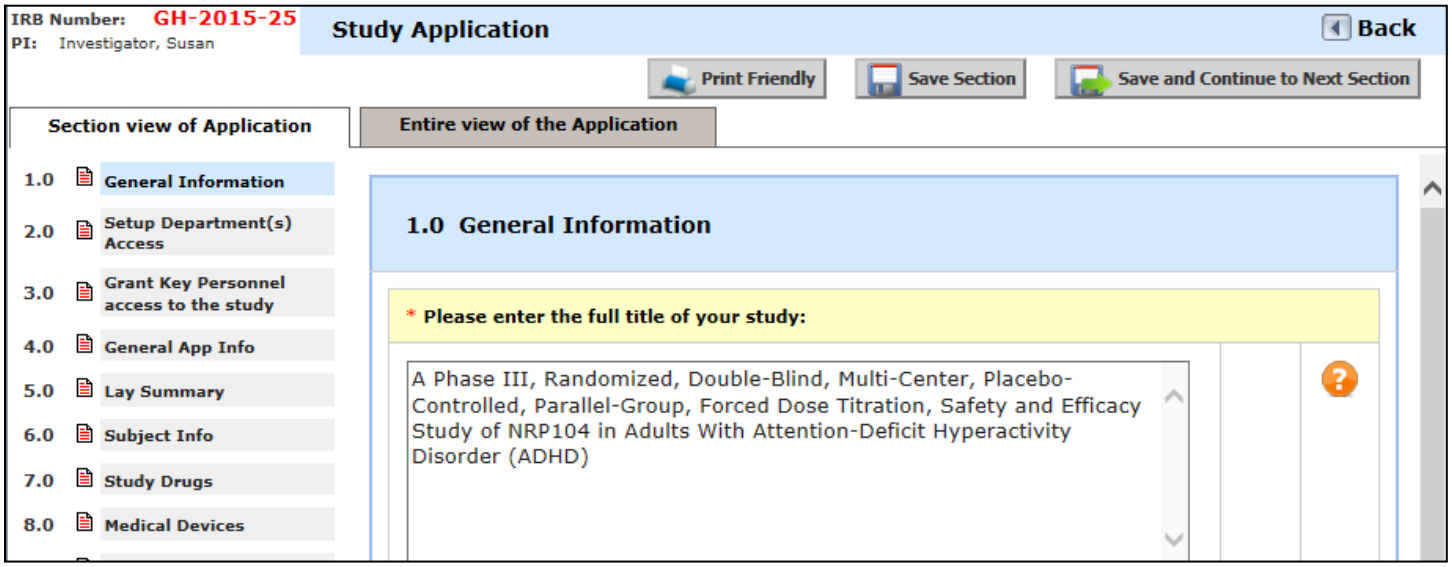
The system will verify that you want to create a revision. Click **OK** to confirm and continue creating the revision. Click **Cancel** to cancel the revision.



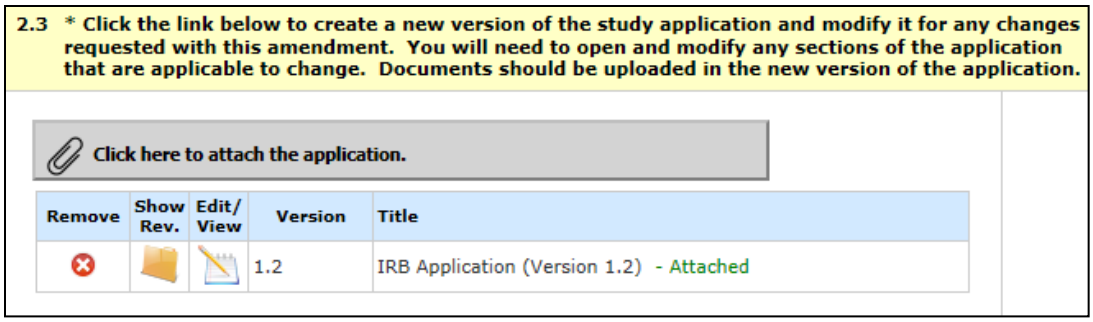
If you clicked **OK**, the system will open the editable version of the application.

Note: If you need to modify the current Key Personnel in section 3.0, you will need to access the Personnel Change Request data value. You will not be able to change KSP in the revised version of the Study Application.

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



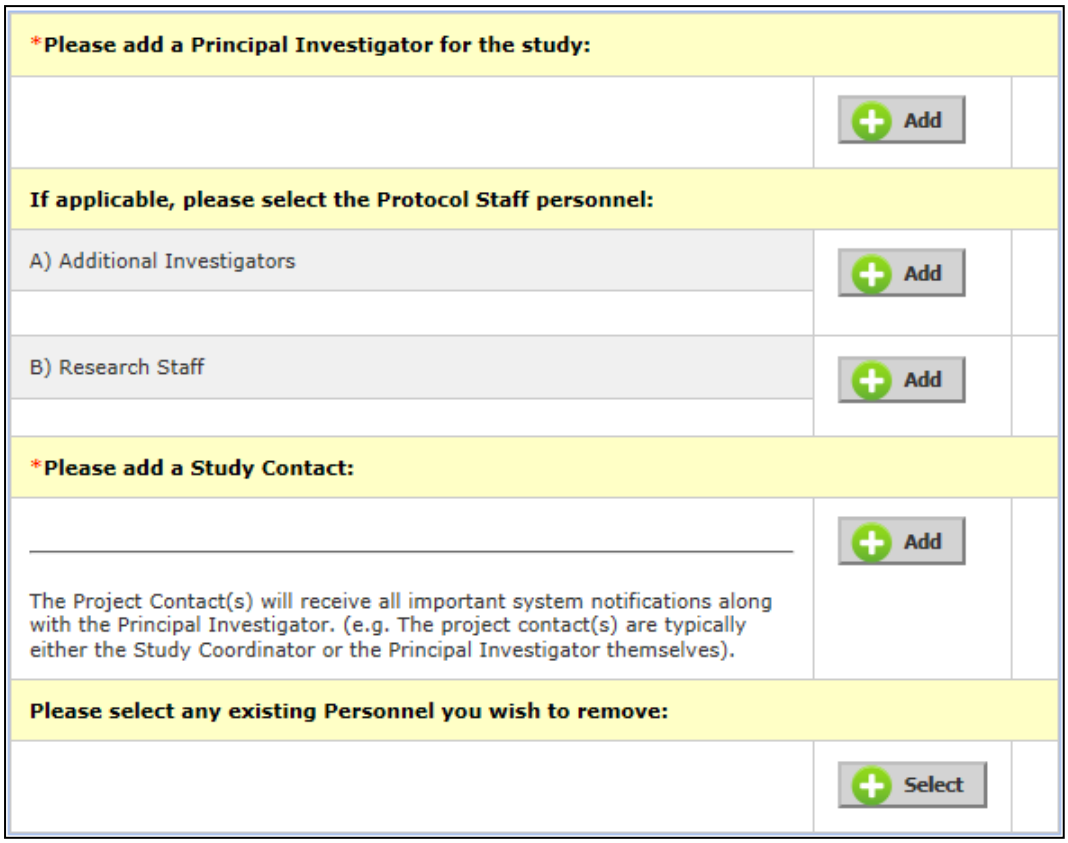
The revised application will be listed in the Application Attachment data value. If you need to detach the application, click the icon in the Remove column. This will not delete this version of the application; it will simply remove the version from the form.



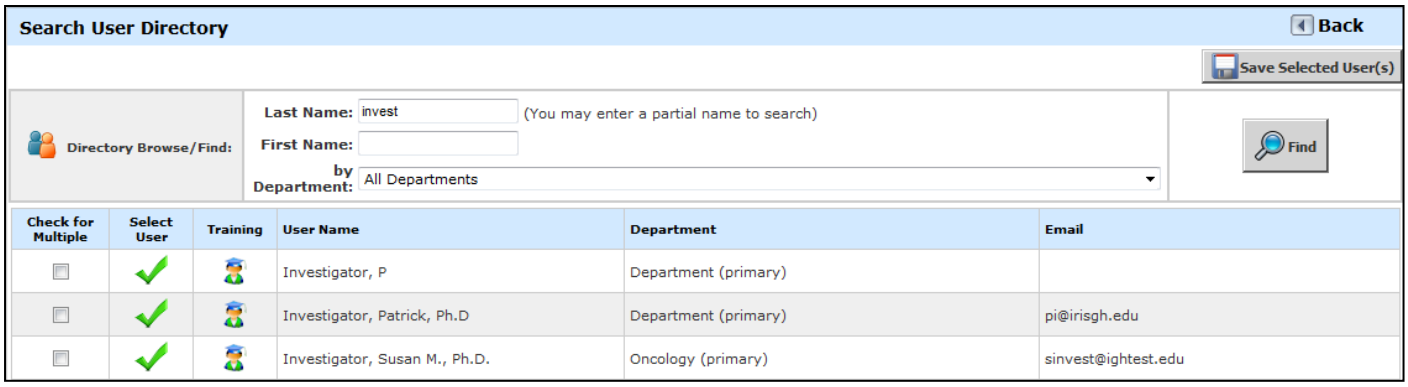
Requesting a Change in Key Personnel

If you need to request 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.

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 ✔ icon in the Select User column. 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.



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.

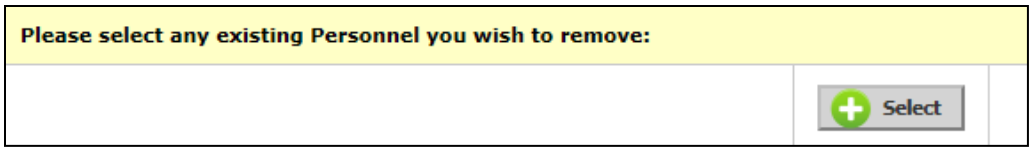
Additional Investigators – Any new investigator user for the study, aside from the Principal Investigator, can be listed here. You may have any number of Additional Investigators, and, after you add a user to this group, you will be able to specify their role.

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.

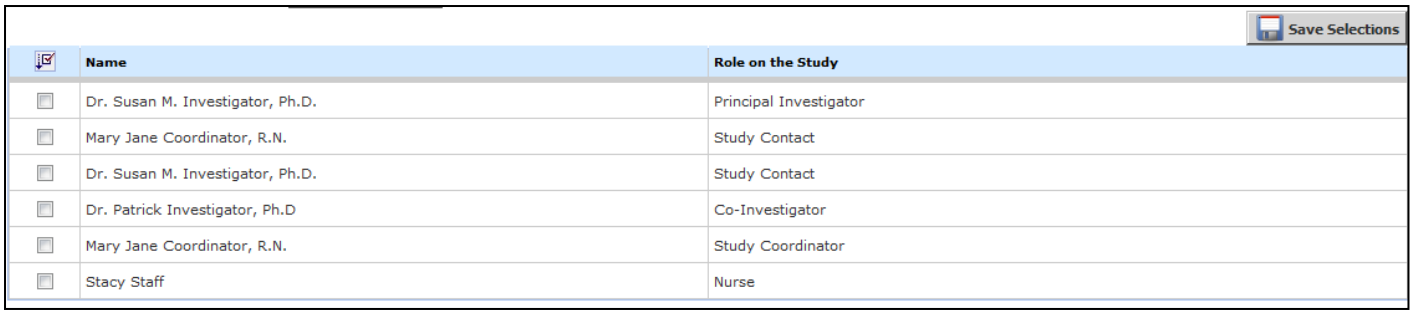
Study Contact – You may add additional Study Contacts as needed. A Study Contact is a user on the study who will receive study-related notifications from the system like Continuing Review notifications, Submission Correction notifications, and Review Response notifications. The Study Contact is usually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

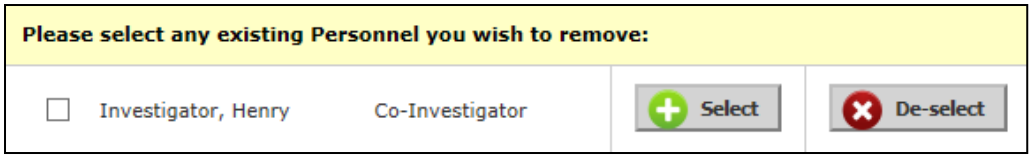
At the bottom of the Personnel Change Request is an area where you can request the removal of personnel from the study. Click the **Select** button in this group.



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, and then click the **Save Selections** button.



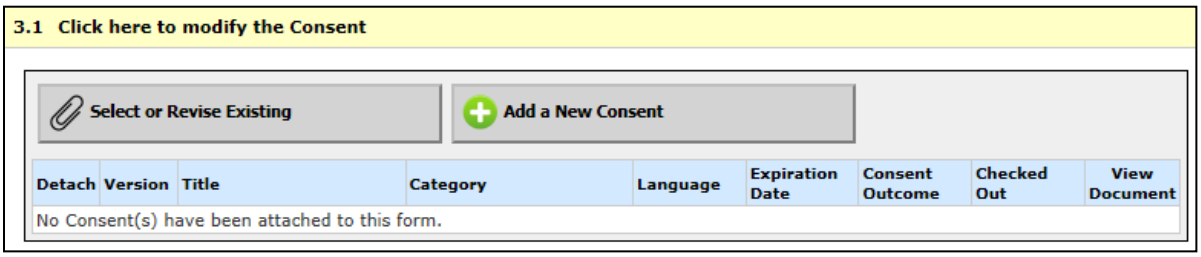
Any user you selected to be removed will be listed in this group. If you selected a user to remove in error, select the checkbox next to their name, and click the **De-select** button.



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.

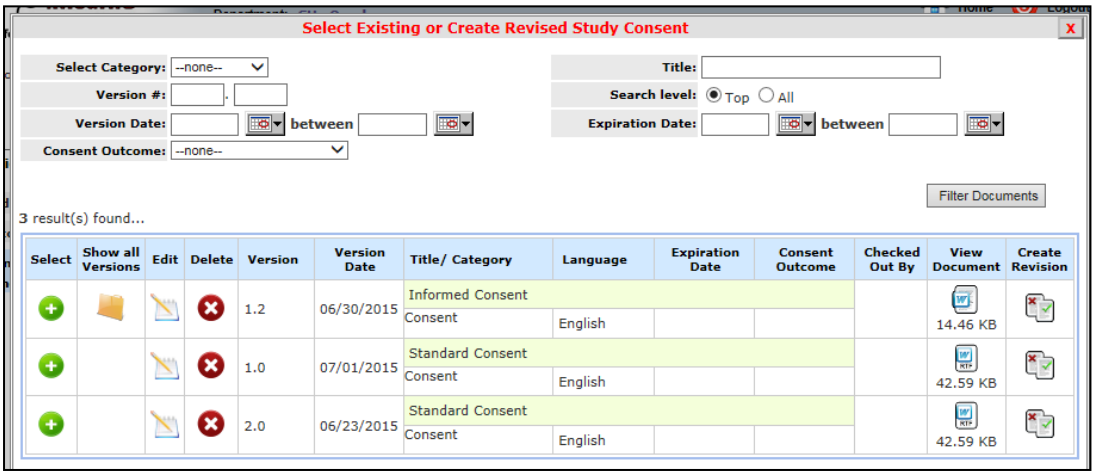


Select or Revise Existing Consent or Other Study Document

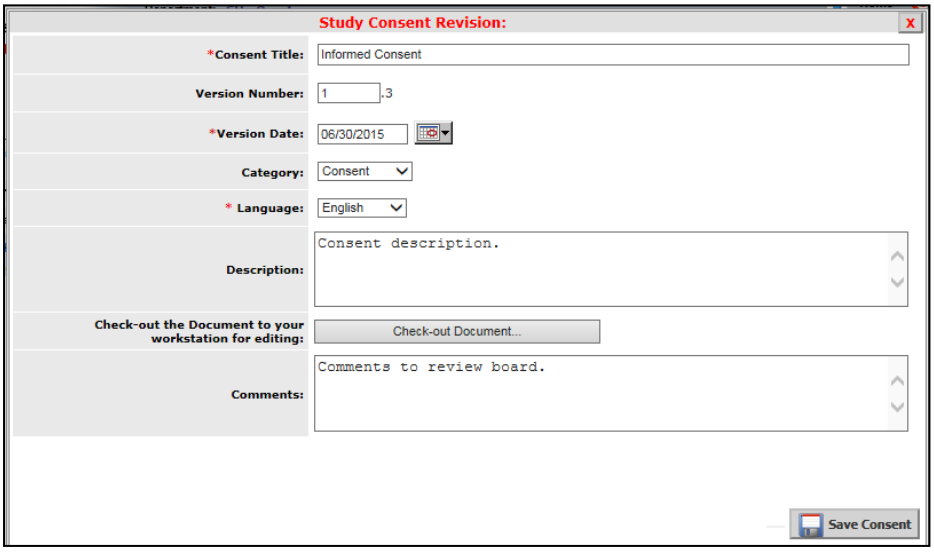
If you would like to select an already-revised consent or other study document or revise an existing document, click the **Select or Revise Existing** button.

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.

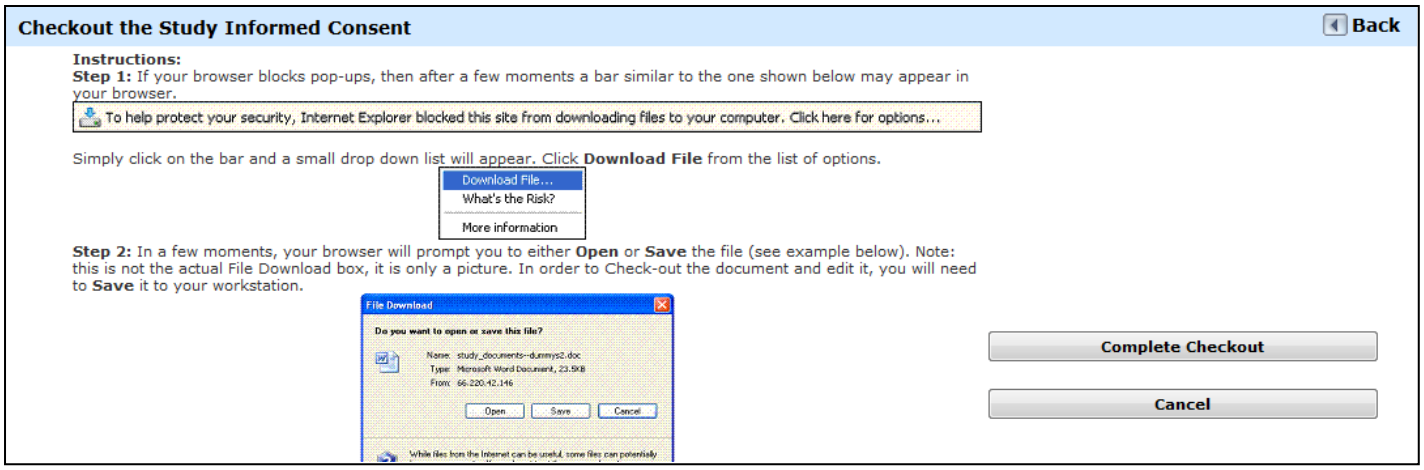
If you have not yet modified the document, you can create a revision of the document from this area. Click the icon in the Create Revision column, as seen in the image below.



The window will refresh and populate with details of the document you are revising, allowing you to change details and check out the revised document. Click the **Check-out Document** button.



A new page will open, and your Internet browser will download the document. Internet Explorer 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. Click the yellow bar, and then select Download File from the menu that appears. Do this before clicking the **Complete Checkout** button. If you click **Complete Checkout** before saving the file to your computer, you will lose the document and will need to undo the checkout in order to restore the document.



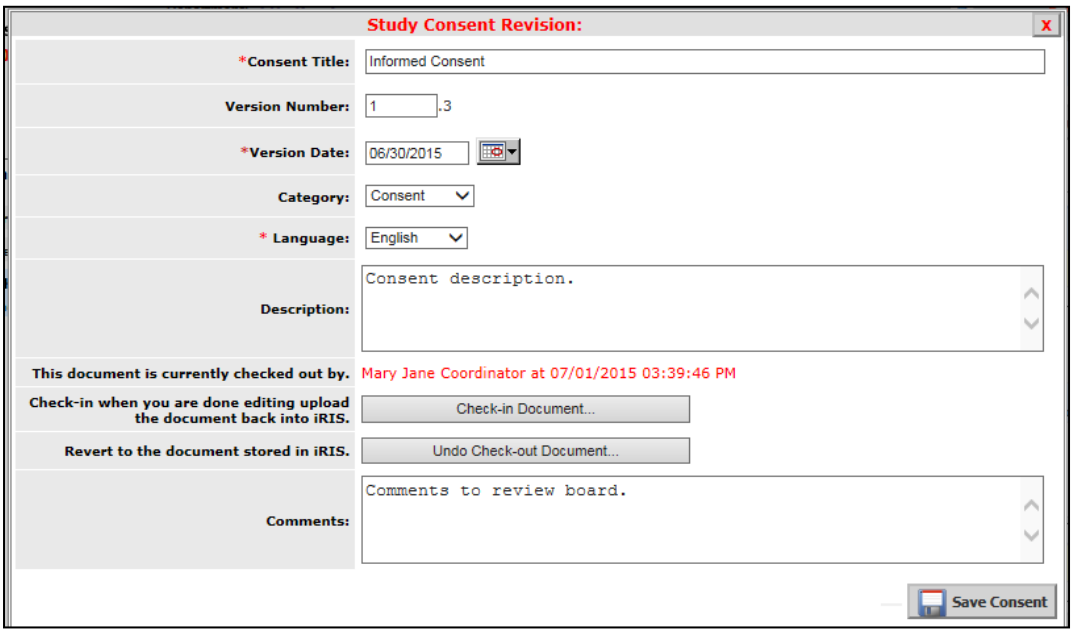
Depending on your Internet Browser, version, and settings, you may or may not be prompted with the file download information.

The browser asks if you would like to open or save the consent document.

It is best to choose to save the document so you can be sure to save the document in a known location on your computer.

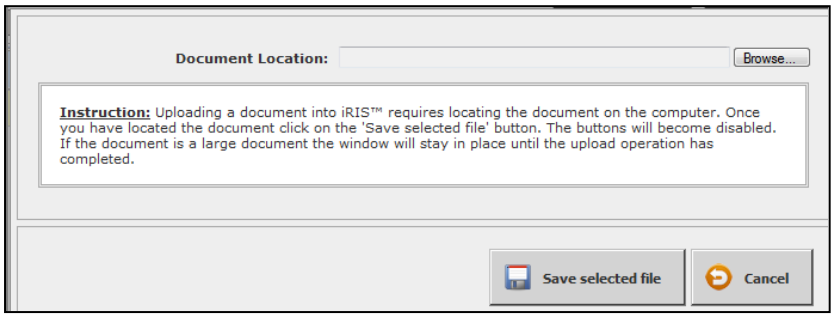
After saving the document, click the **Complete Checkout** button.

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**.

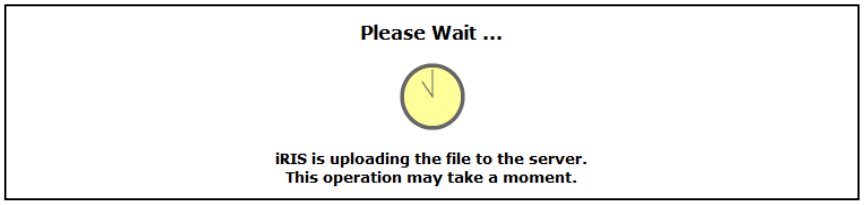


After you have made changes to the document in Microsoft Word, you can return to iRIS and check it back in by clicking the **Check-in Document** button.

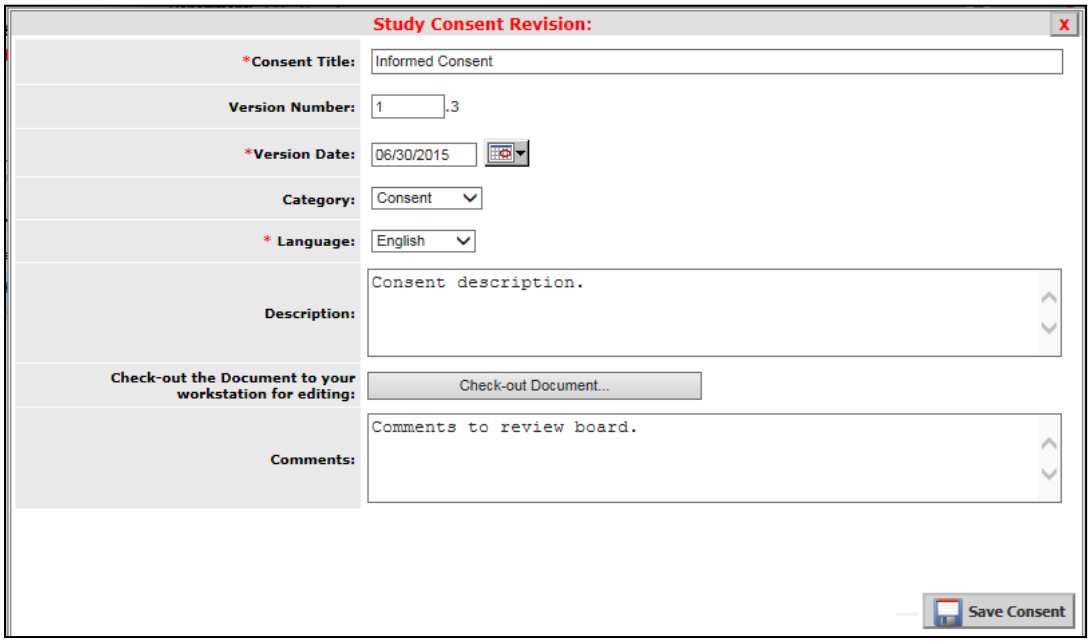
A window will open, allowing you to browse your computer for the consent document you would like to upload. Click the **Save selected file** button once you specify the document location. If you do not want to upload the document, click the **Cancel** button.



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.



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

Add a New Consent or Other Study Document

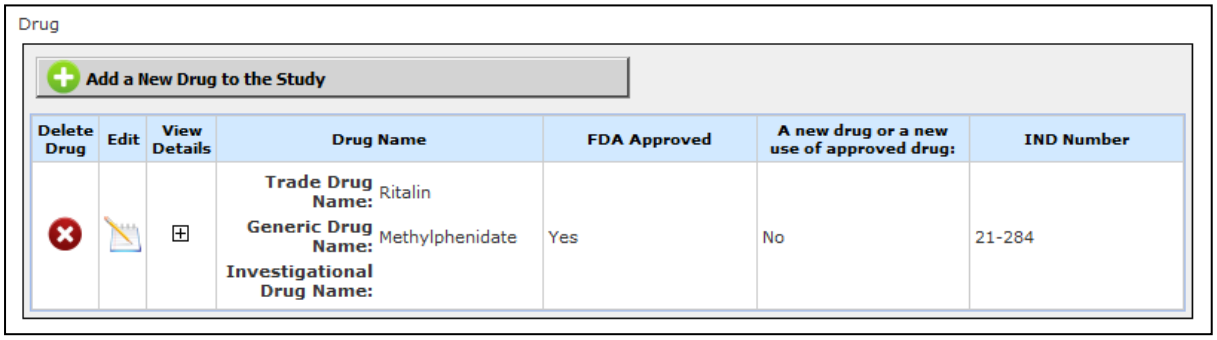
If you are requesting review of a brand new document that has not been associated to the study, click the **Add a New Consent** button. Following this process, you will be able to add a document to the study and attach it to the form.

Modifying a Study Drug or Device

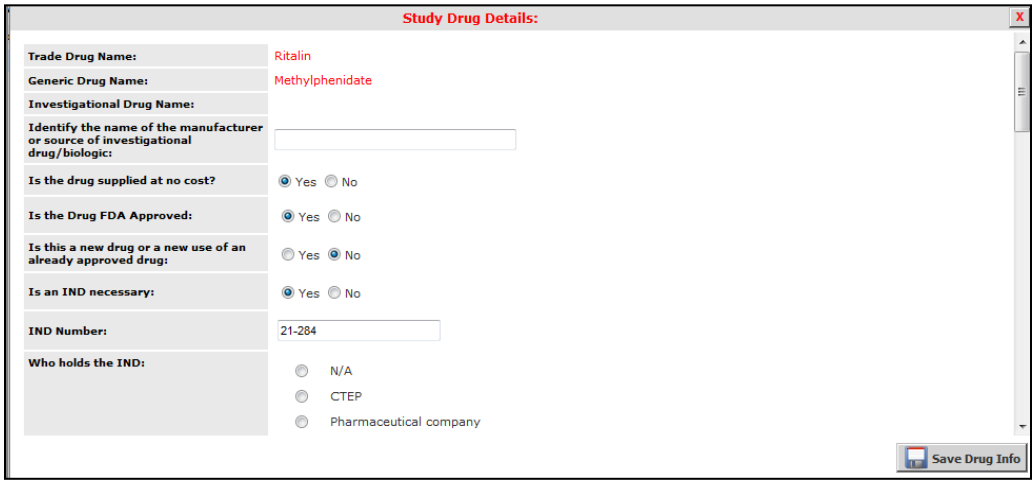
In order to make any changes to Study Drugs or Devices you will need to add the changes to a form and submit to the review board for approval. The process for making changes to or adding Drugs and Devices are the same. Modifying a Study Drug is used in this example.

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.



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/Device Info** button to return to the form.



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

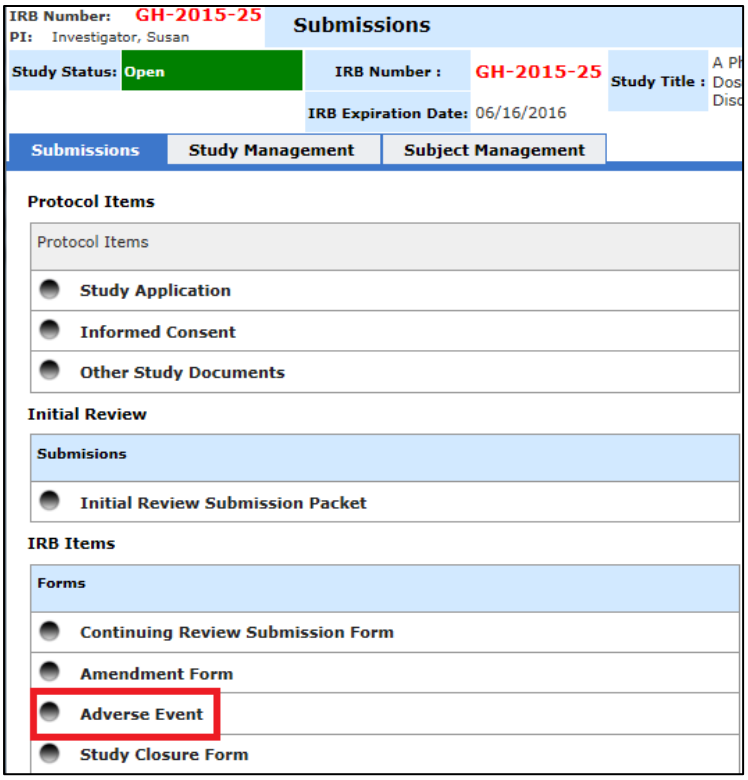
When the submission form is completed, you will receive information about sending the form into the workflow following the same steps listed in the Submitting the Form section for Continuing Review. Your Amendment form may or may not contain all the steps listed in these instructions.

Submitting an Adverse Event Form

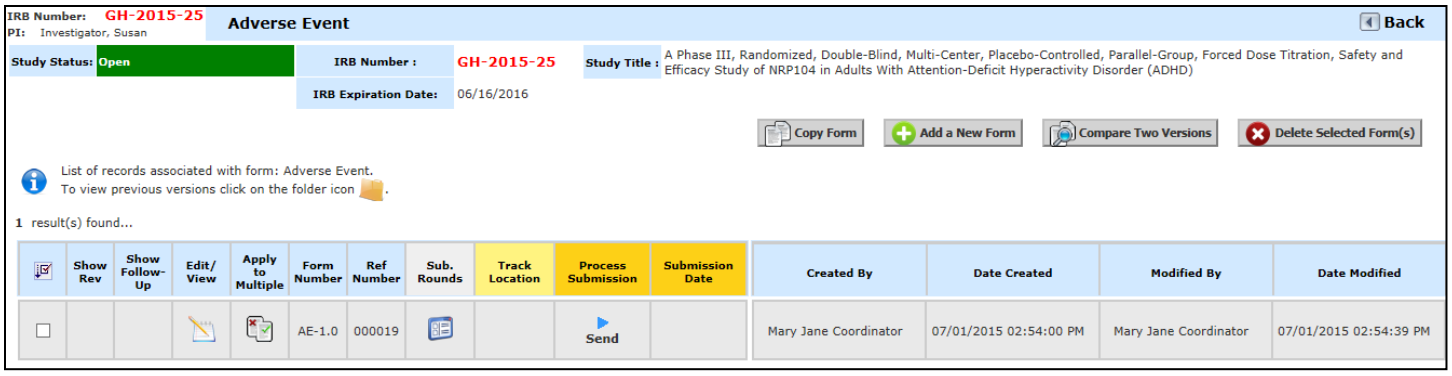
At any point during the life of your study, you can access an Adverse Event form to submit to the review board.

Accessing the Form

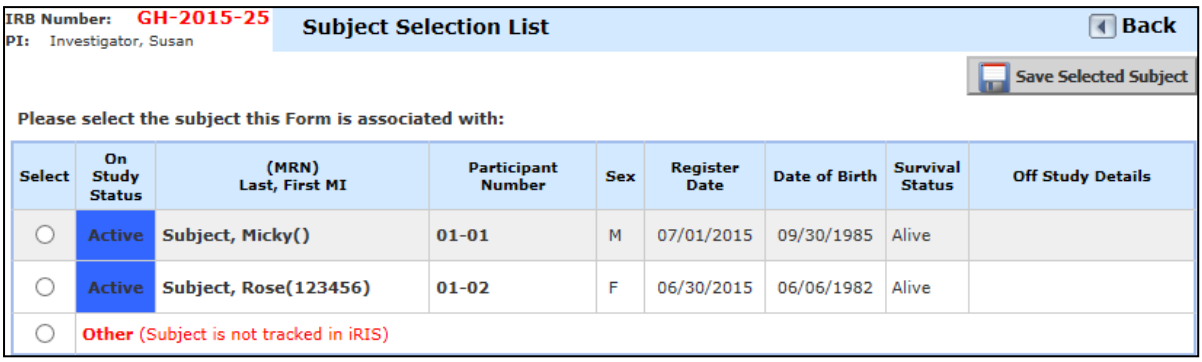
The Adverse Event form will be located within the list of submission forms in the Submissions tab. In this example, the form is called an **Adverse Event** form and is located within the IRB Forms group. However, your system may contain a different list of forms.



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

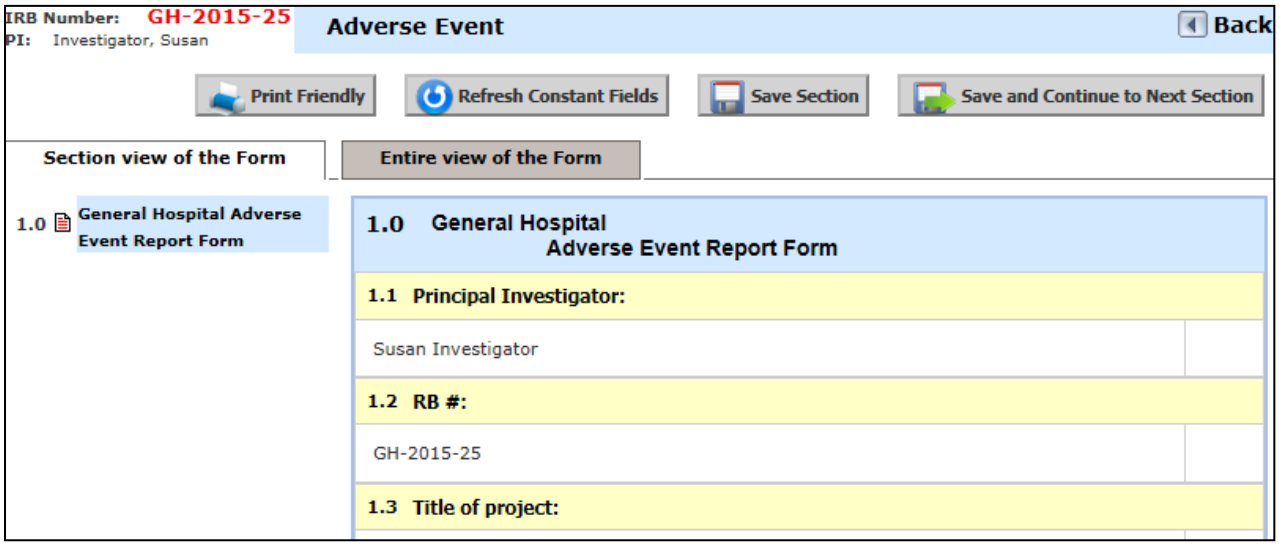


To create a new Adverse Event, click the **Add a New Form** button. Depending on your system settings, you may be presented with a list of subjects on the study. You can select a subject to which the Adverse Event is related. Note: This functionality will not be available if you do not have the Subject Management module.



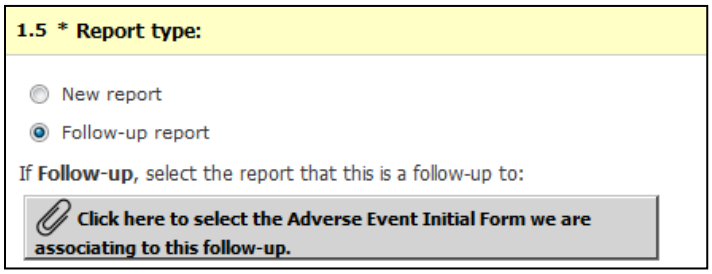
This will open the form as it has been defined in the Forms Designer.

After you select a subject, if applicable, you will be brought to the Adverse Event form. You can fill out the form using the **Save and Continue** button at the top right of the page to navigate through the sections.

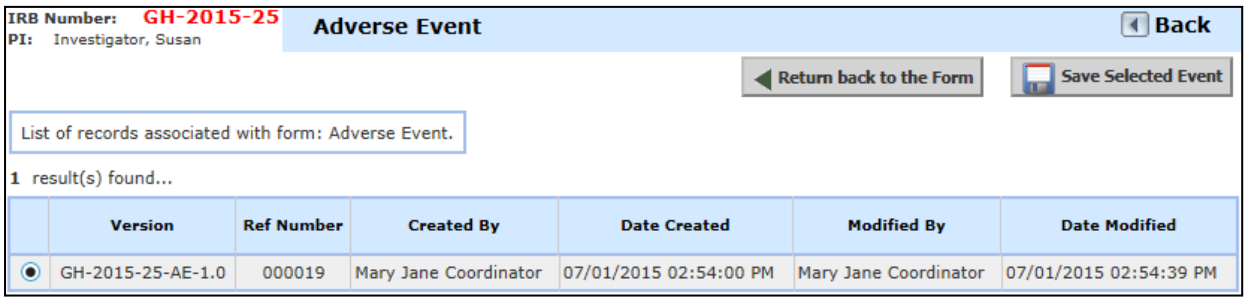


Within this form, you may be asked to indicate if the Adverse Event is an initial or follow up. If this is an initial report, you can select New Report and continue to complete the form, as seen in the image below.

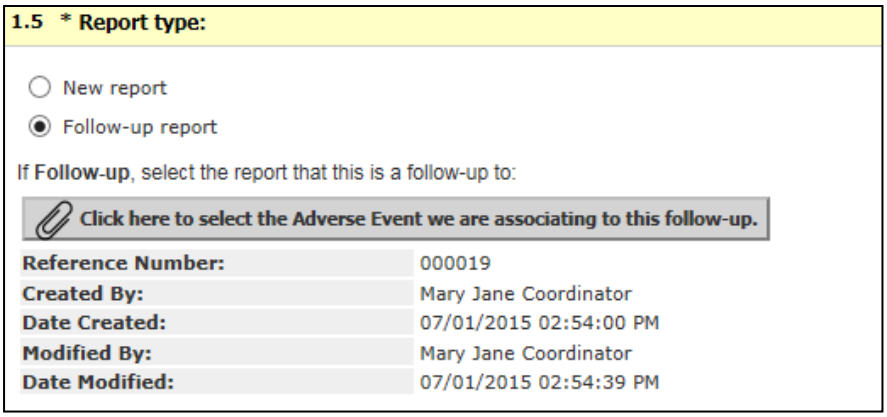
If this is a follow-up report, select **Follow-up Report** and then click the link in the image below to associate a previous Adverse Event form.



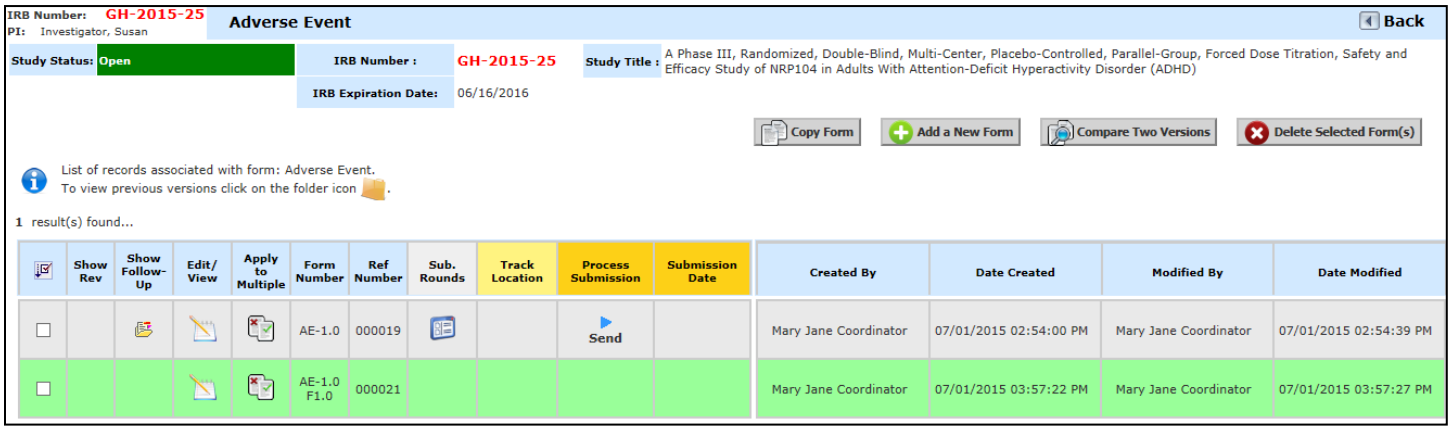
A list of previously completed Adverse Events for the study will populate in a new page. You can select the Adverse Event to which you are sending a follow up, and then click the **Save Selected Event** button.



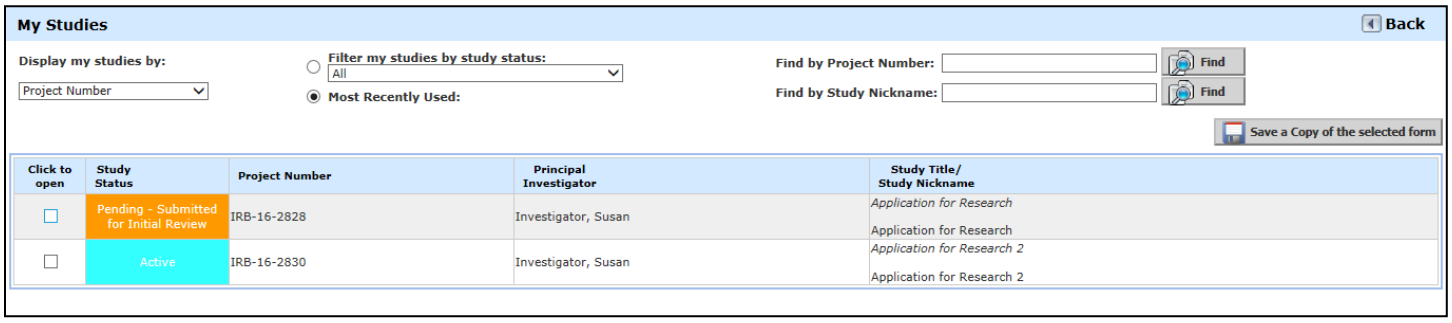
Information related to the initial report will populate in a table below the data value. The rest of the Adverse Event form will populate based on the information completed in the Initial Report. You can save through the form, verifying the information is correct, and change items as needed.



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 Follow-up reports.



In the above screenshot, you can see the Apply to Multiple column. This is used if you would like to associate the form to another study you are associated with. Click the icon to open the list of studies.



Check the box next to a study and click **Save a Copy of the selected form** to add the form to the study. You will need to open the study to submit the form.

Signoff

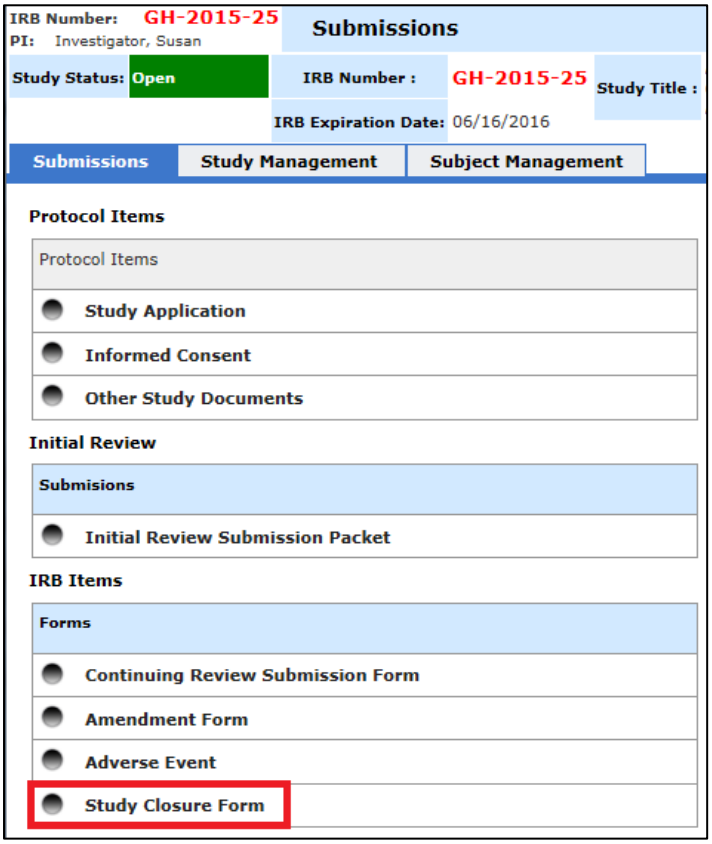
When the submission form is completed, you will receive information about sending the form into the workflow, following the same steps listed in the Submitting the Form section for Continuing Review.

Submitting a Study Closure Form

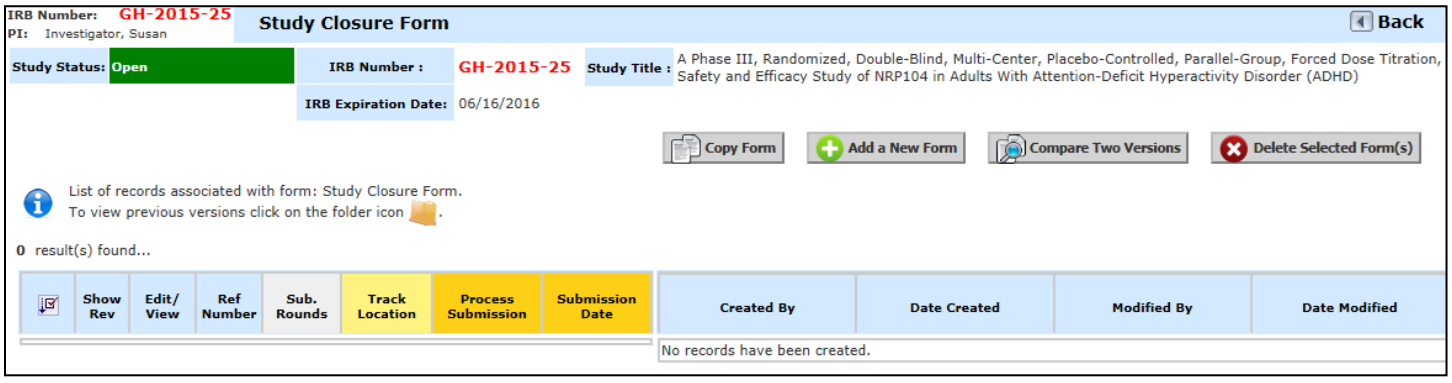
Once research has been complete and you are ready to inform the review board that your study is closed, you can access this type of form and submit it. Once the review board receives the form they can close out the study in iRIS.

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.

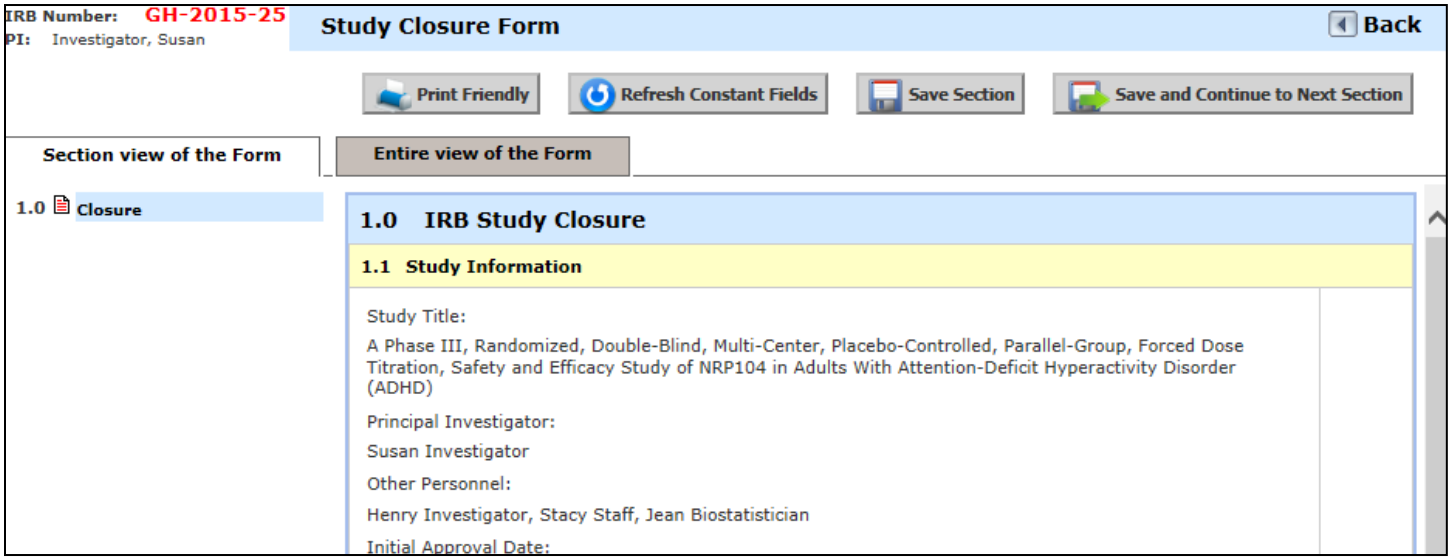


When you click on the link for the Study Closure, you will be directed to a page that lists all Study Closure forms that have been created for this study.



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.