iRIS
Integrated Research
Information System

STUDY ASSISTANT

Adding a New Study & Submitting to the Review Board

Version 10.03

Contents

Add a New Study

Introduction

The basics of adding a study begin creating a Study Shell and filling out the Study Application. Once the Study Shell, Study Application and supporting documents are attached, submit your new study to an IRB for pre-review. Depending on how your system is setup, your new application may first be submitted to other review boards, such as an SRB or Radiation Safety committee before being reviewed by the IRB.

This manual will guide you through the process of adding a new study to the system and submitting that study to the IRB. This manual will also show user's how to respond to any corrections requested by the IRB.

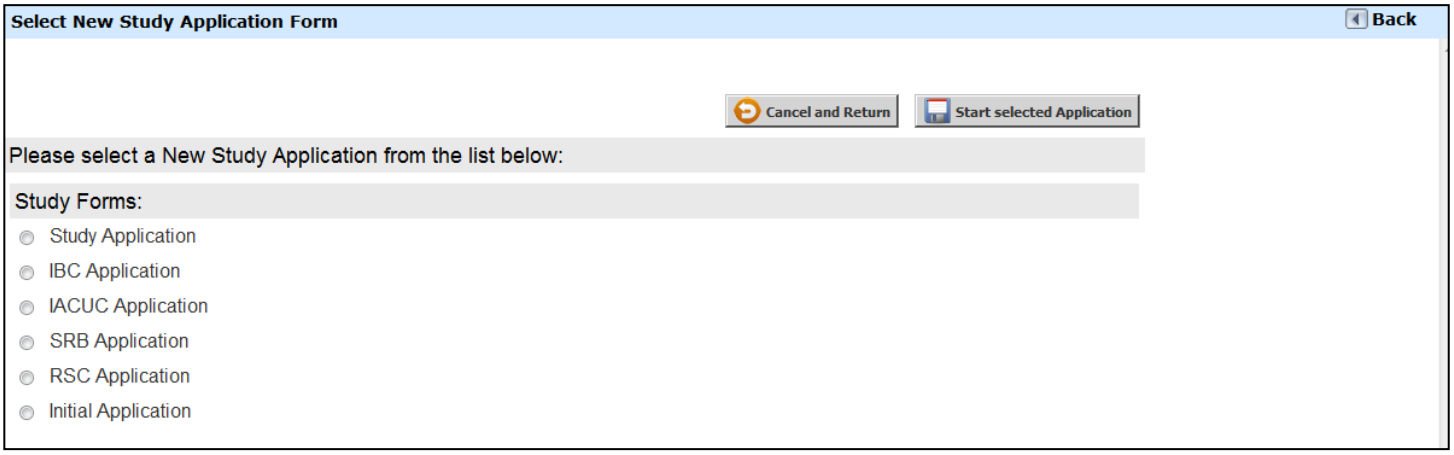
Add a Study

To begin, click the **Add a New Study** button in the Study Assistant menu group on the homepage of your iRIS software.

Selecting an Application

If your system has more than one application type available, you will be directed to a page that lists each application out, allowing you to select the application you need to complete. The number of applications available here depends on the number of modules being used.

Select the desired application, then click the **Start selected Application** button. If you do not need to create a new study at this time, click the **Cancel and Return** button to return to your iRIS homepage.

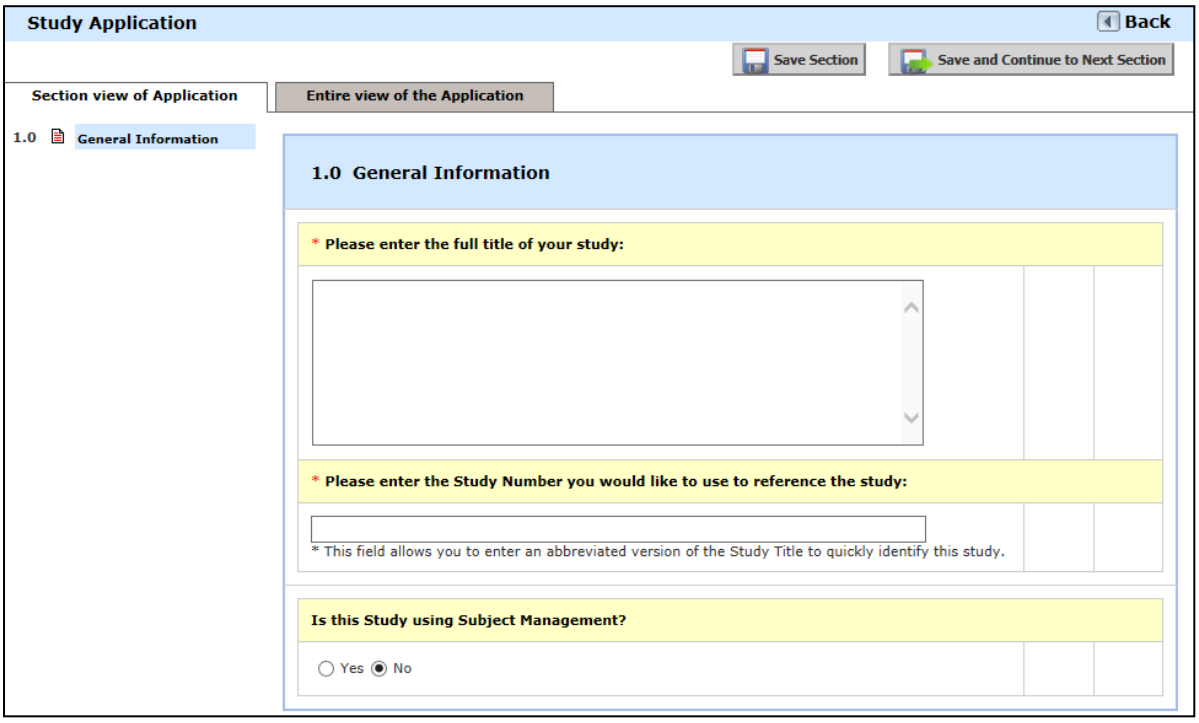


Selecting an application brings you to the first of three sections of the application, known as the Study Shell. After the first three initial screens of this application are complete, a new study record is created in the system. You can exit the application at any time. Some of the fields in the application are required. In order to progress to the next section of the application, data must be entered into these required fields. Note that you may return to the application and edit these fields any time before submitting the form. After an application has been submitted, it can be viewed but cannot be edited.

1.0 General Information

The first of the Study Shell screens is the General Information screen. This section will capture the Study Title and Study Number.

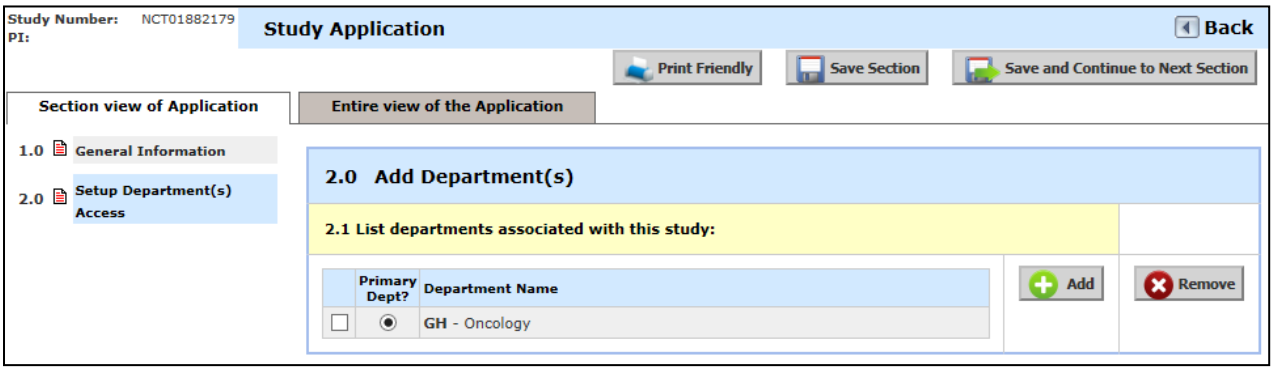
If your system is using the Subject Management module, you will also be asked whether or not this study is going to be using Subject Management. If you indicate "Yes" you will have the ability to add subjects once the IRB approves your study.



Click **Save and Continue to the Next Section** button in the upper right corner of the screen after the Study Title and Study Number have been added to this section as shown in the above image. You can also click the **Save Section** button to save your work, but not continue to the next section.

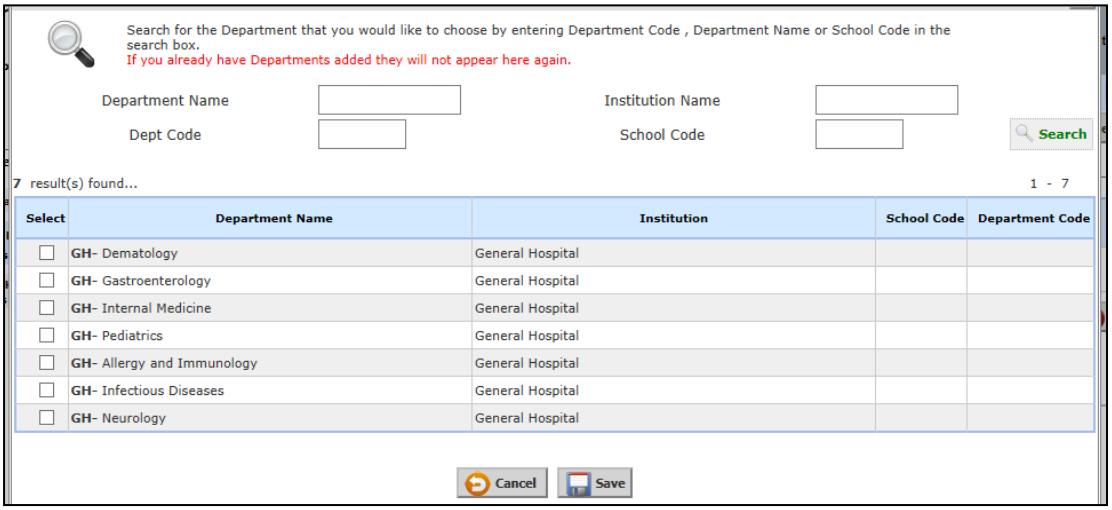
2.0 Add Department(s)

The second section of the Study Shell screens involves the setting up of departments that will have access to this study. You want to select any department the study is involved with and note that the study will be linked to the department for report purposes. Department Administrators will be able to pull data from the study into certain reports based on the Department(s) associated to the study.



The system will pull in your primary department as the potential primary department for the study. You can associate additional departments by clicking on the **Add** button.

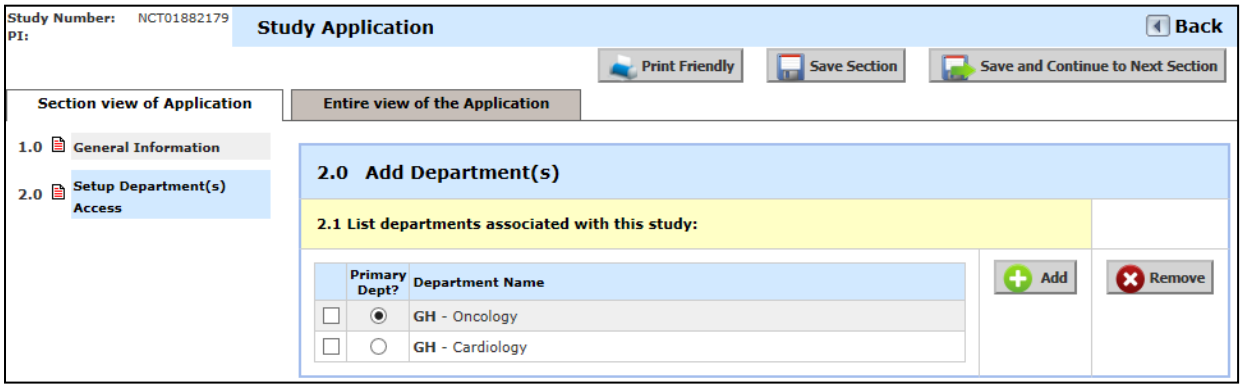
The departments will display in a pop up within your window, as seen in the image below. Click the check box next to the desired department(s) and click the **Add** button when you are ready to add the selected departments to the study. You can also search for a particular department by entering all or part of the Department Name, Institution Name, Department Code and/or School Code and clicking the **Search** button.



If you do not need to add additional Departments, click the **Cancel** button to close the pop up.

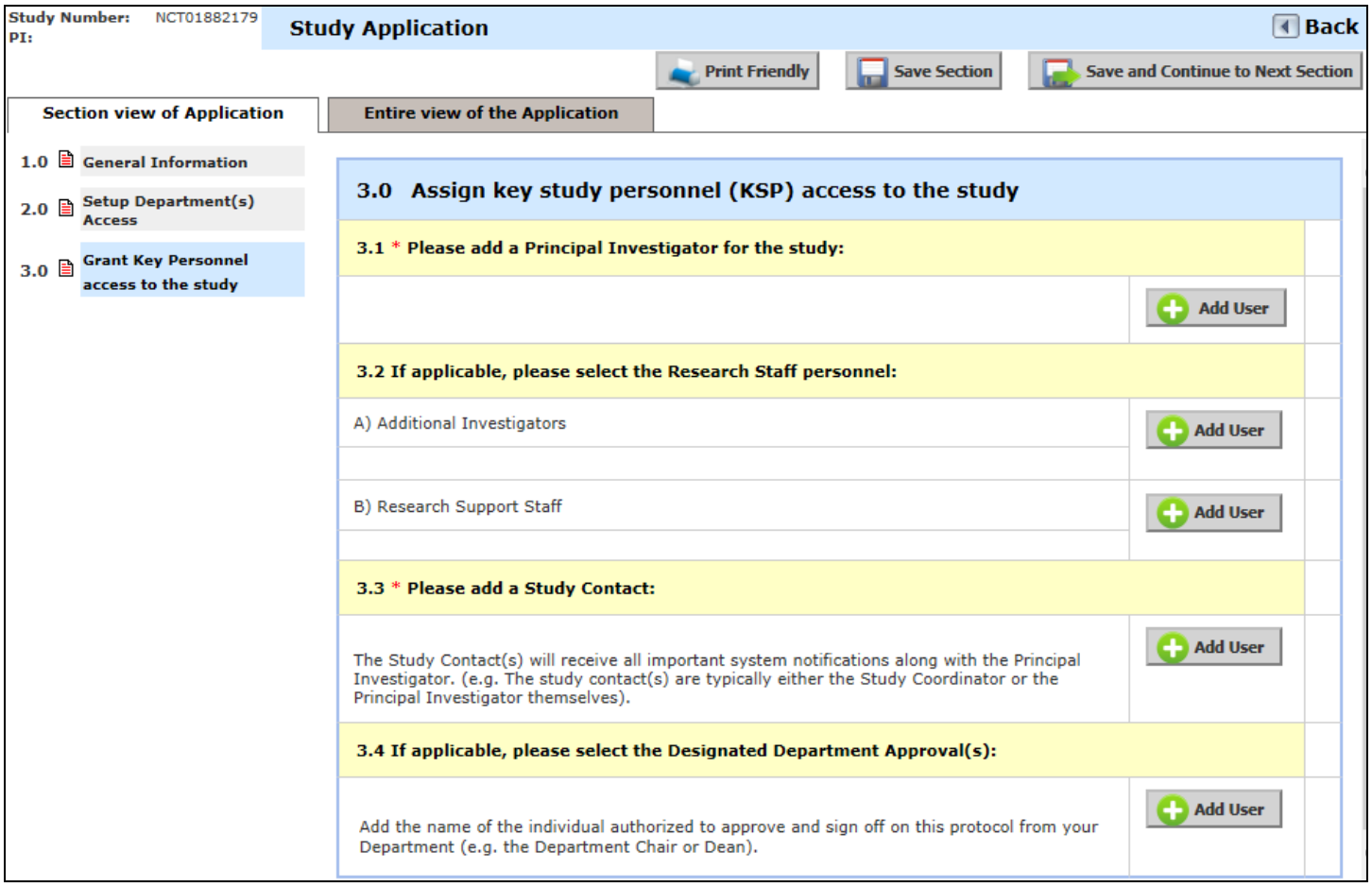
Any added department(s) will now show in the department table. To remove a department, click the **checkbox** next to the appropriate department name then click the **Remove** button. You can change the primary department, if necessary. To do this, click the radio button for the department under the Primary Dept. column. Only one primary department can be selected at one time.

After adding the necessary departments, click the **Save and Continue to the Next Section** button, as seen in the image below.



3.0 Assign key study personnel (KSP) access to the study

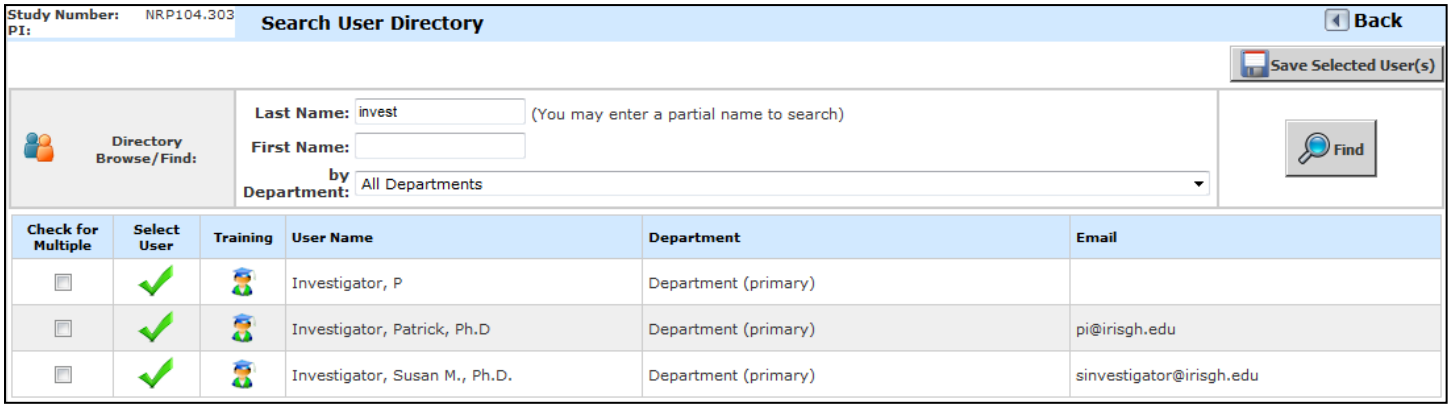
The third section of the Study Shell Screens involves assigning Key Study Personnel (KSP) to the study. The page will list the different roles available to assign a user to. Your system may or may not display all the roles, depending on how your system is configured.



Any user added to the study will have the ability to access the study in iRIS.

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

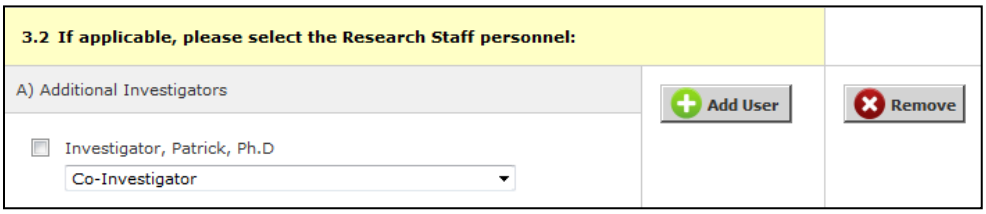
This allows you to search the user directory by First name, Last name, or Department. Enter all or part of the criteria and click the **Find** button, as seen in the image below. To select a user to add, click the **Select User** icon. This selects the user and brings you back to section 3.0 of the application. To select more than one user, check the boxes next to the corresponding users and click the **Select User(s)** button.



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

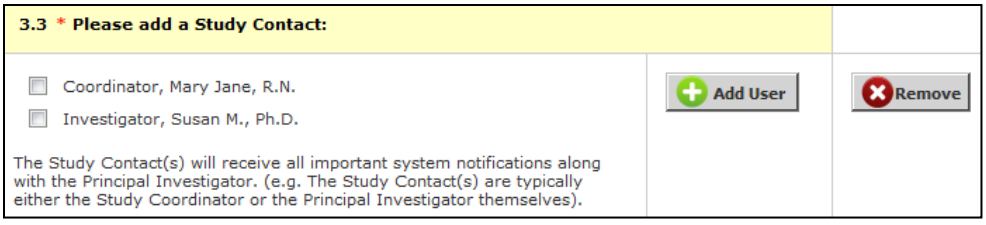
Principal Investigator – All study records must have a Principal Investigator. If you do not add a PI to this screen, you will not be able to progress to the next section. Also note that you can only have one Principal Investigator listed on the study. If additional PIs are needed on the study, you may add them in the Additional Investigator's section, if available.

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



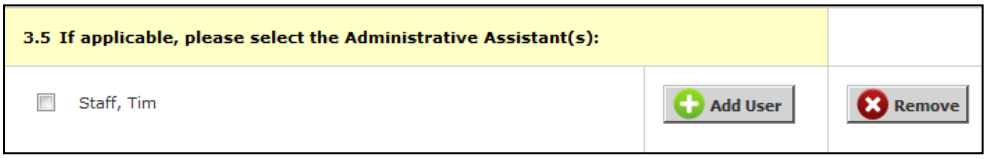
Research Support Staff – This section is for any non-investigator users you need to list on the study. You may have any number of research support staff listed here and after you add a user to this group, you will be able to specify which role they have.

Study Contact – The user you add as the Principal Investigator will default to the 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, such as Continuing Review notifications, Submission Correction notifications, Review Response notifications, etc. The Study Contact is usually also another role on the study, like a Research Coordinator, PI, etc.



Designated Department Approvals – You can add a user to Designated Department Approvals if you need to route your application to a department reviewer before the IRB will accept your submission. You can have any number of users listed here. At the end of your application process, you will have the ability to select this user for submission routing. More will be discussed later.

Administrative Assistants – If you would like to allow an administrative assistant access to the study for data entry purposes, you can add them here. You can have any number of users listed. These users typically have limited access to the study and will not be considered KSP in the education check and will not be included in the submission signoff process.



You can remove any user from the study by clicking the checkbox next to their name, and then clicking the **Remove** button in that same group. If you need to remove the PI, you will have to select a new user to take the PI's place because a study record cannot be created without this information.

After all of the necessary users have been associated to the study, click the **Save and Continue to the Next Section** button.

Custom Application Sections

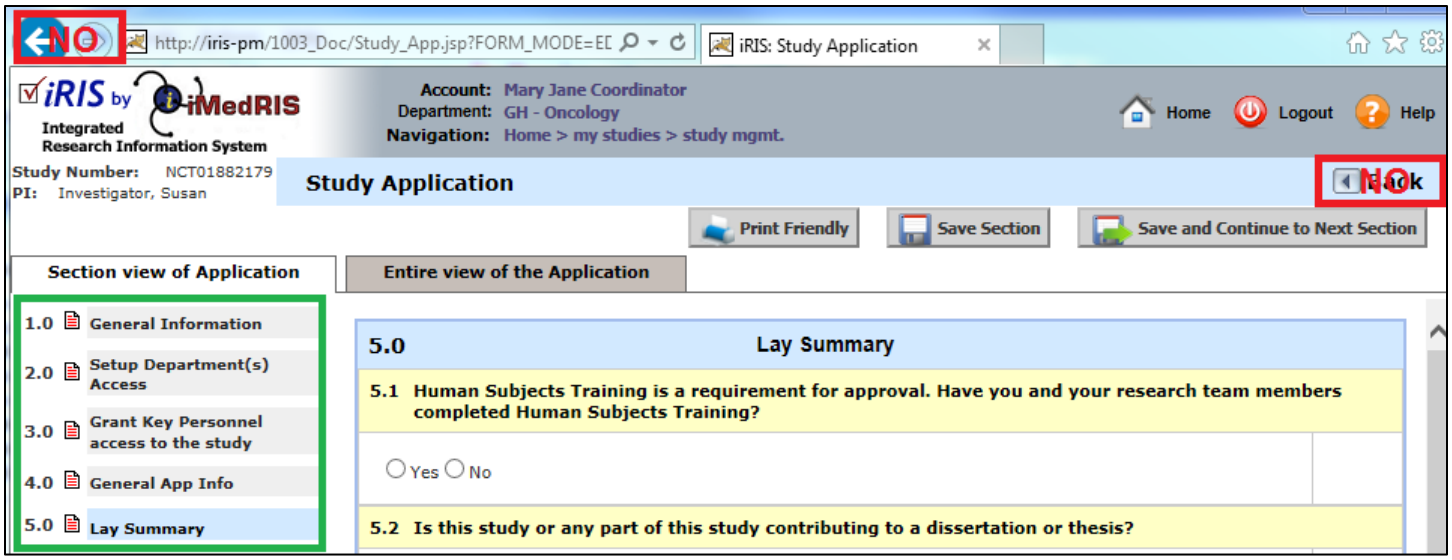
The sections in the application following the initial three sections are customized based on the configuration of your Study Application.

When you complete a section, click the **Save and Continue to Next Section** button. If a required field is left blank and you try to save and continue you will get an error message alerting you to the missing field. Correct the missing field to save and continue.

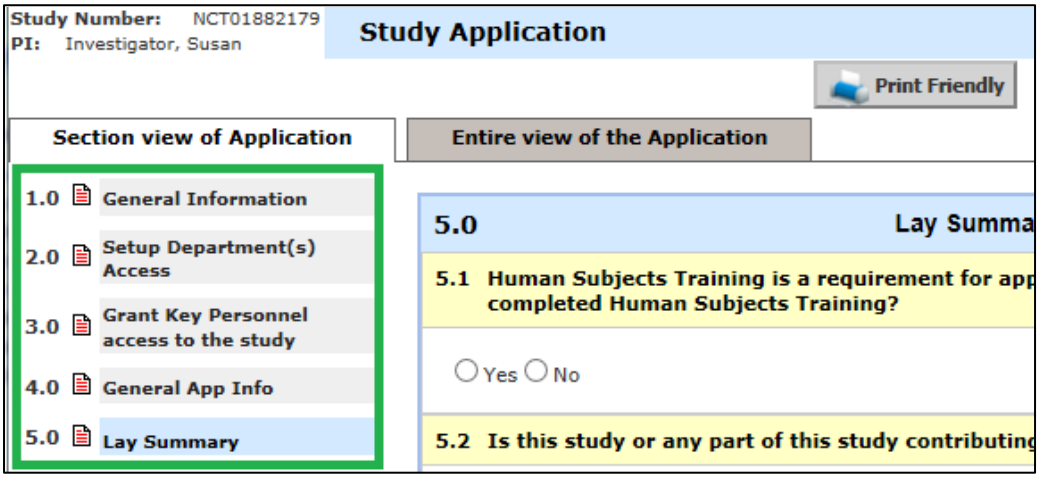
Throughout the application you may be asked to provide details for different aspects of the Study. Unique data values that capture this information are detailed below. These data values are defined in the form in the System Forms Designer by your System Administrator and may or may not be present in your form.

Notes regarding forms navigation

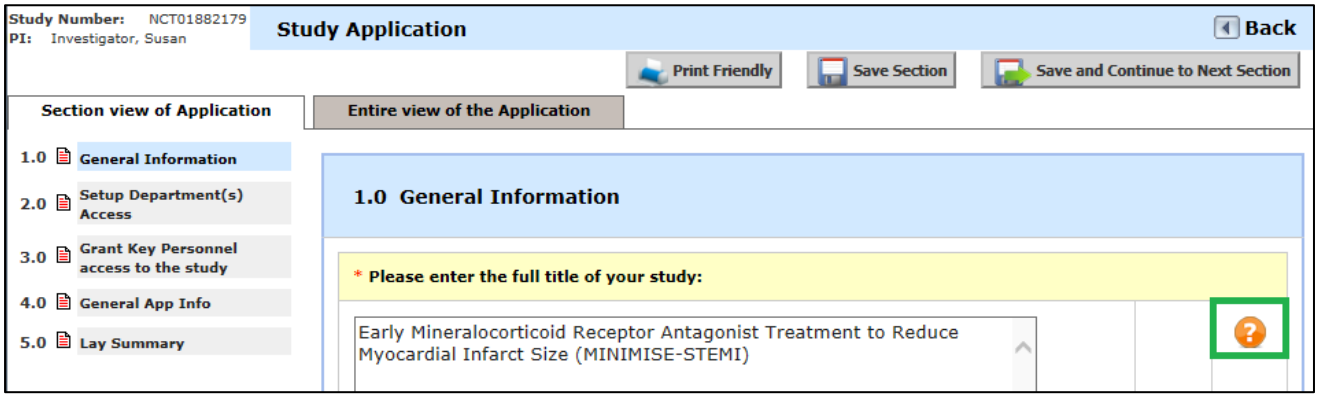
Back Button: When constructing the Study Application, it is important to remember that if you need to return to the previous section, DO NOT hit the Back button on your Internet Browser. To properly navigate to the previous section, click on the link for that section in the navigation pane.



Navigation Pane: On the left side of the screen, a navigation pane builds as you progress through the application. Click on the link of a section at any time to move to that section. The section you are in will appear blue, while the other sections will appear gray.



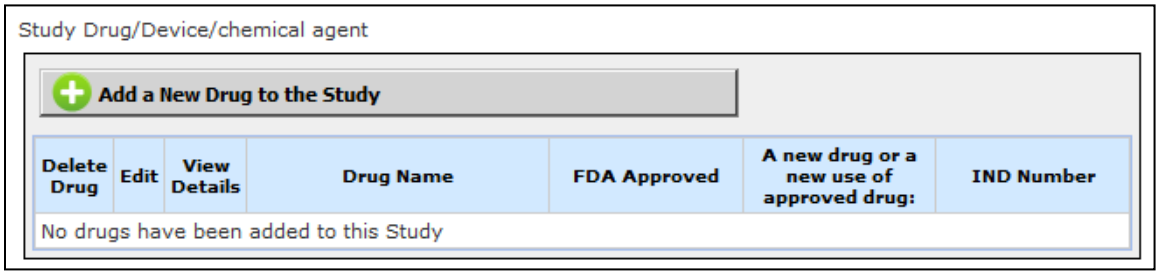
Help Icons: Some of the sections will contain help icons. Click on the icon to open a window, this will list available information about a certain question.



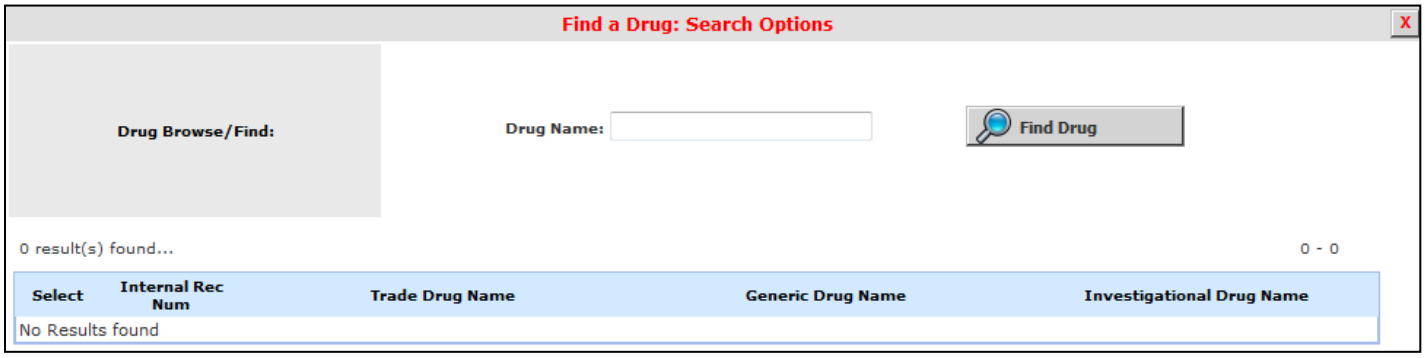
Study Drugs

The Study Drug data value will allow you to search the iRIS database for a study drug to add to your study. You can have any number of drugs on the study. Follow the process described below to add each record.

Begin by clicking on the **Add a New Drug to the Study** button, as seen in the image below.

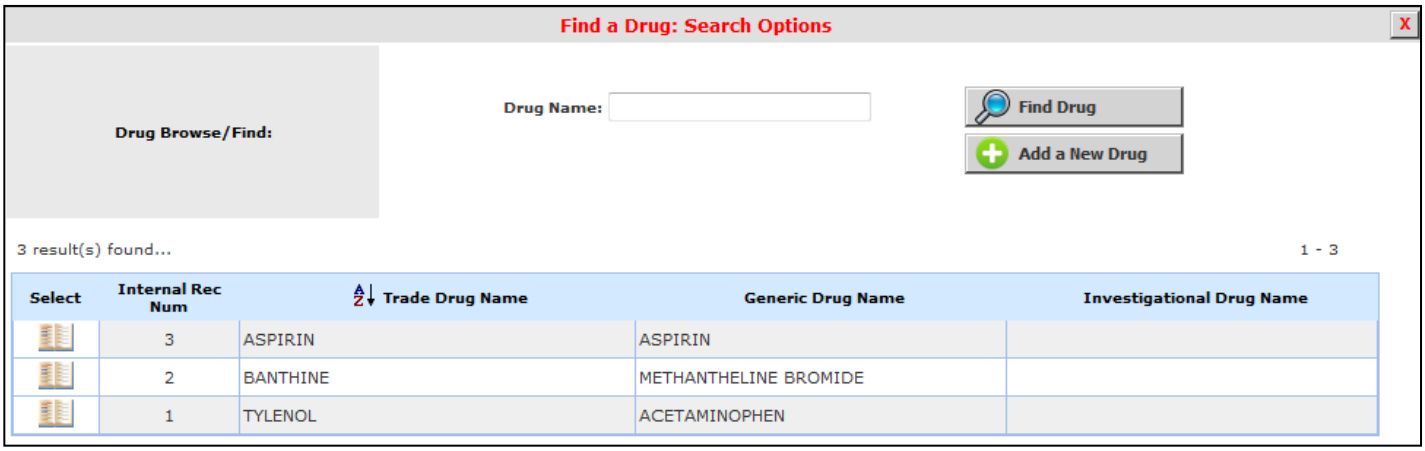


A popup window will open within your browser, as seen in the image below, allowing you to search the system for the drug you would like to add to the study. You can enter in all or part of the Drug Name or leave that field blank and click the **Find Drug** button to return all drugs in the system.

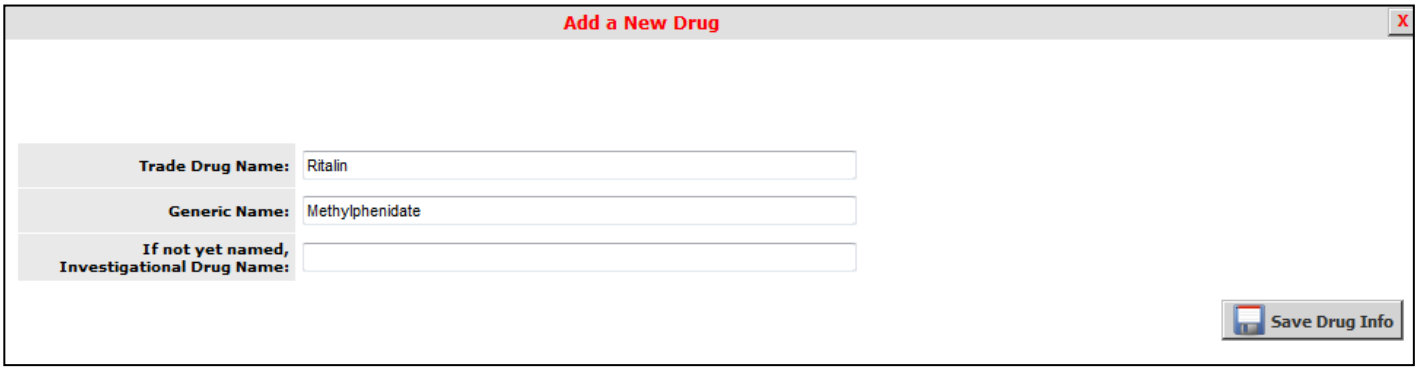


Once your search returns results, you can choose the drug you need to add by clicking on the icon in the **Select** column, as seen in the image below.

If the drug you need to add to the study is not in the list, you can add a drug to the master list by clicking on the **Add a New Drug** button.



After you choose to add a new drug, the window will update, allowing you to specify the Trade Drug Name, Generic Name and/or Investigational Drug Name. You can enter the name for one or all of the fields. When you are finished, click the **Save Drug Info** button.

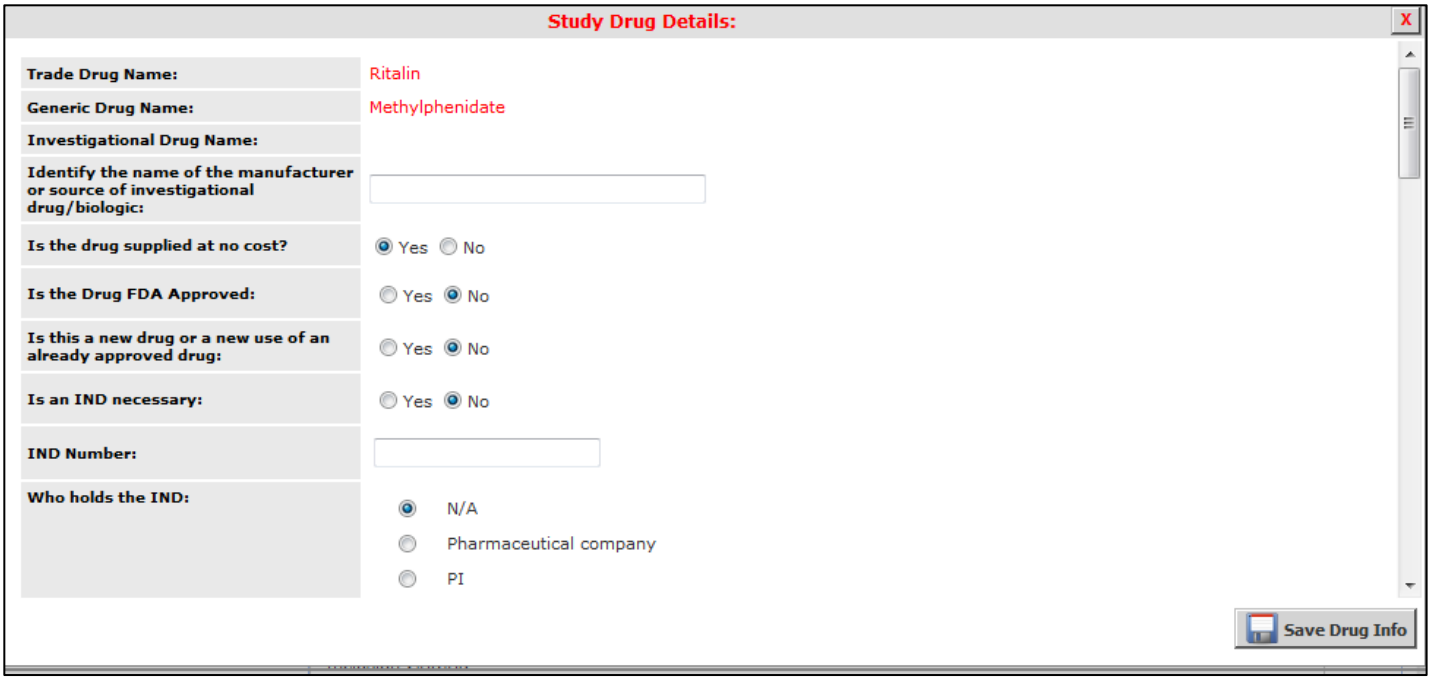


When you click **Save Drug Info**, the drug is added to the master list.

Whether you chose an existing drug by clicking on the icon in the **Select** column, or by adding a new drug to the master list, the next screen will be the Study Drug Details.

This screen allows you to enter the study-specific information for the drug. You may or may not see the same information listed on this page, depending on your system configuration.

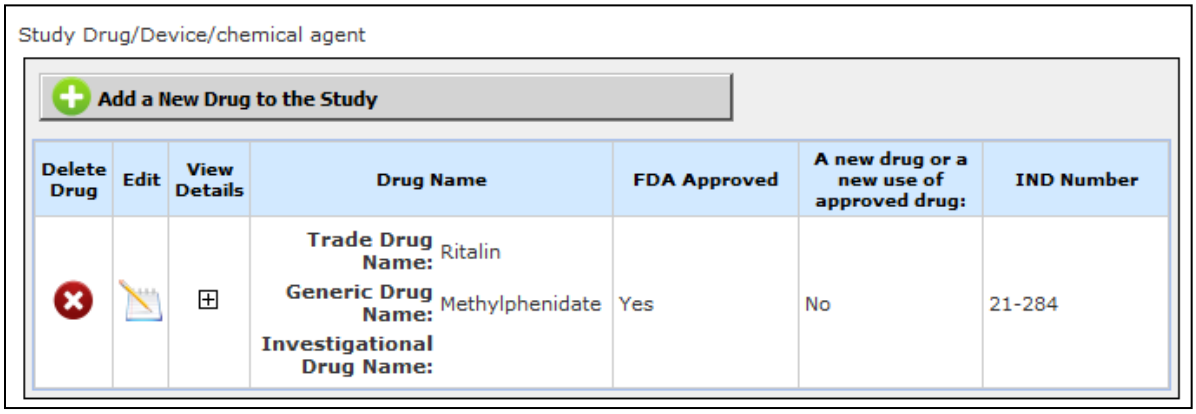
Enter in the appropriate information and click on the **Save Drug Info** button.



You will be returned to the Study Application and the drug you added will appear in the table below the **Add a New Drug to the Study** button.

You can delete the drug by clicking the icon in the **Delete Drug** column. To edit the study-specific drug information, click the icon in the **Edit** column. You can also view the study-specific details by clicking the icon in the **View Details** column, as seen in the image below.

You can add additional drugs by clicking the **Add a New Drug to the Study** button and follow the steps listed above.

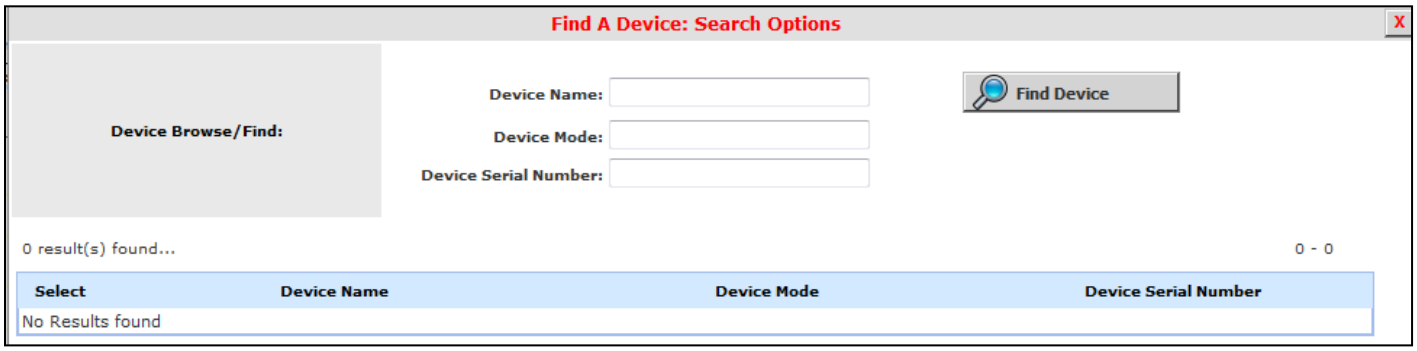


Study Devices

The Study Device data value will allow you to search iRIS' database for a study device to add to your study. You can have any number of devices on the study. Follow the process described below to add each record.

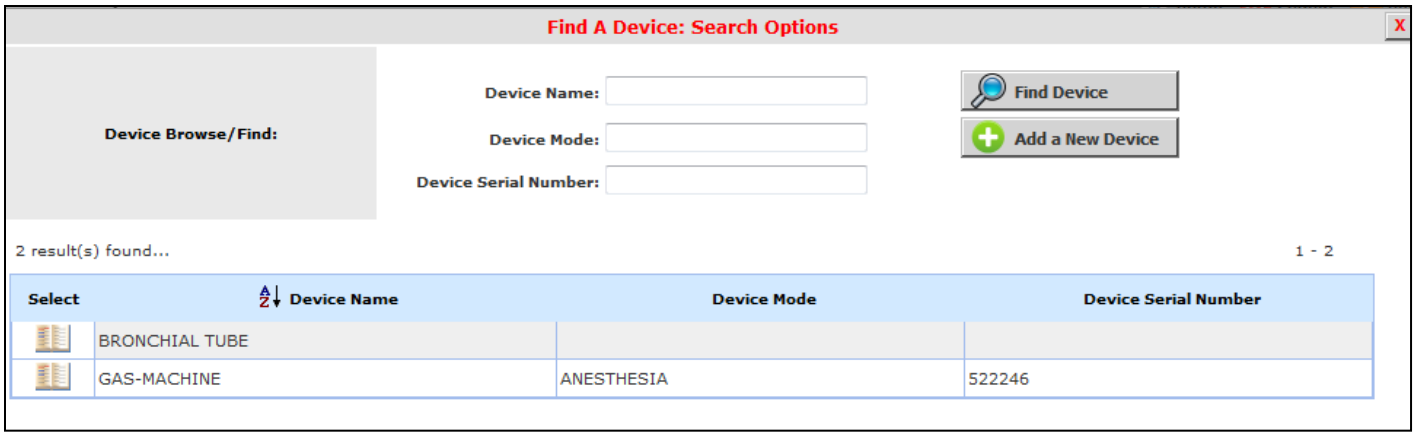
Begin by clicking on the **Add a New Device to the Study** button.

A popup window will open within your browser allowing you to search the system for the device you would like to add to the study. You can enter in all or part of the Device Name, Device Mode and/or Device Serial Number or leave these fields blank and click the **Find Device** button to return all devices in the system.

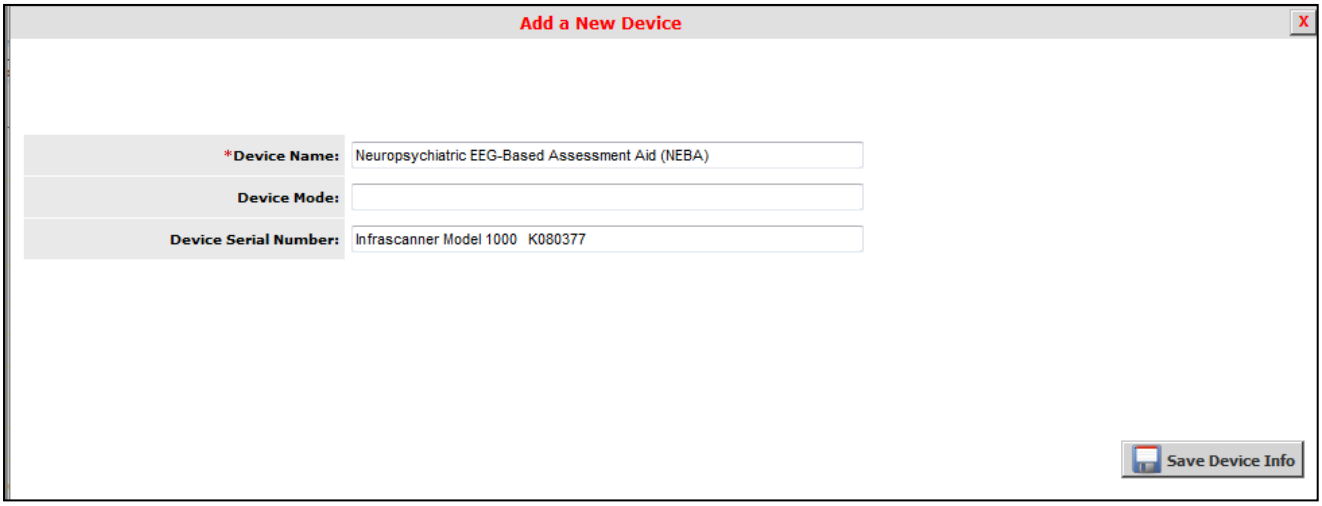


Once your search returns results, you can choose the device you need to add by clicking on the icon in the **Select** column.

If the device you need to add to the study is not in the list, you can add a device to the master list by clicking on the **Add a New Device** button.



After you choose to add a new device, the window will update, allowing you to specify the **Device Name** (required field), **Device Mode** and **Device Serial Number**. When you are finished, click the **Save Device Info** button.

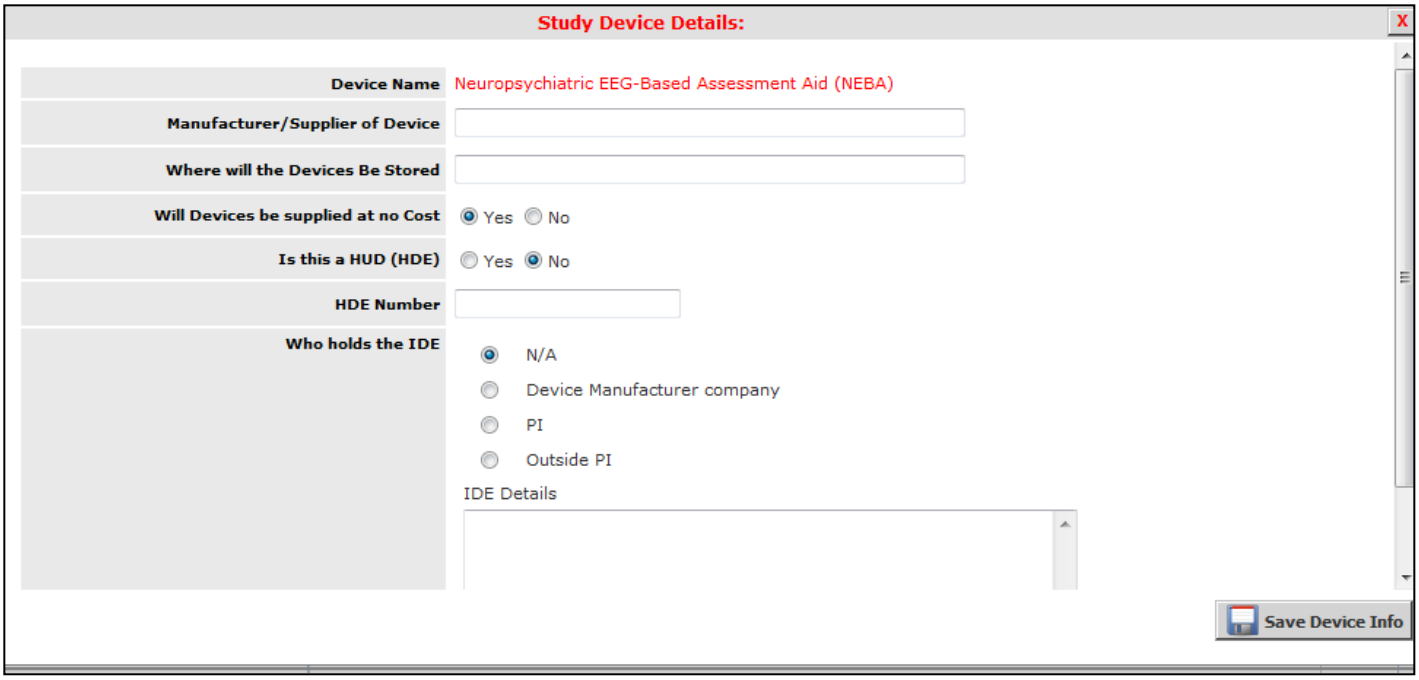


When you click **Save Device Info**, the device is added to the master list.

Whether you chose an existing device by clicking on the icon in the **Select** column, or by adding a new device to the master list, the next screen will be the Study Device Details.

This screen allows you to enter the study-specific information for the device. You may or may not see the same information listed on this page, depending on your system configuration.

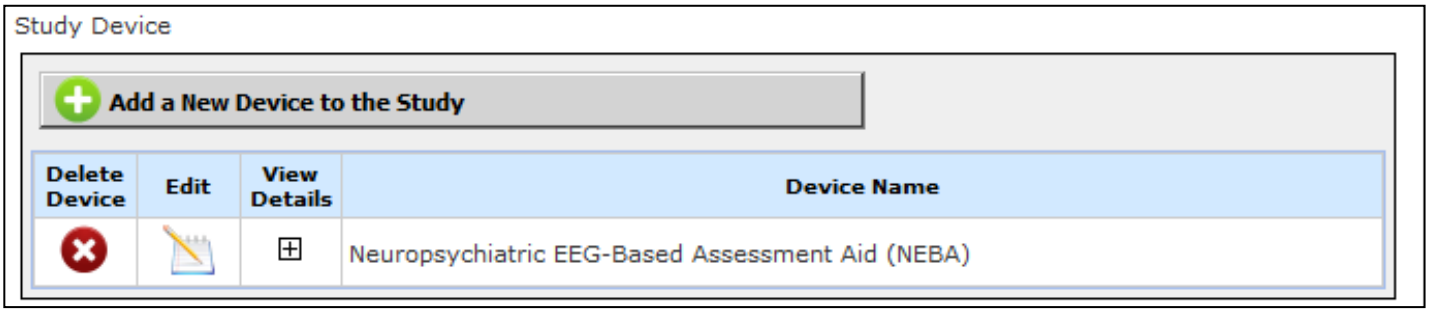
Enter in the appropriate information and click on the **Save Device Info** button.



You will be returned to the Study Application and the device you added will appear in the table below the **Add a New Device to the Study** button.

You can delete the device by clicking the icon in the **Delete Device** column. To edit the study-specific device information, click the icon in the **Edit** column. You can also view the study-specific details by clicking the icon in the **View Details** column.

You can add additional devices by clicking the **Add a New Device to the Study** button and follow the steps listed above.

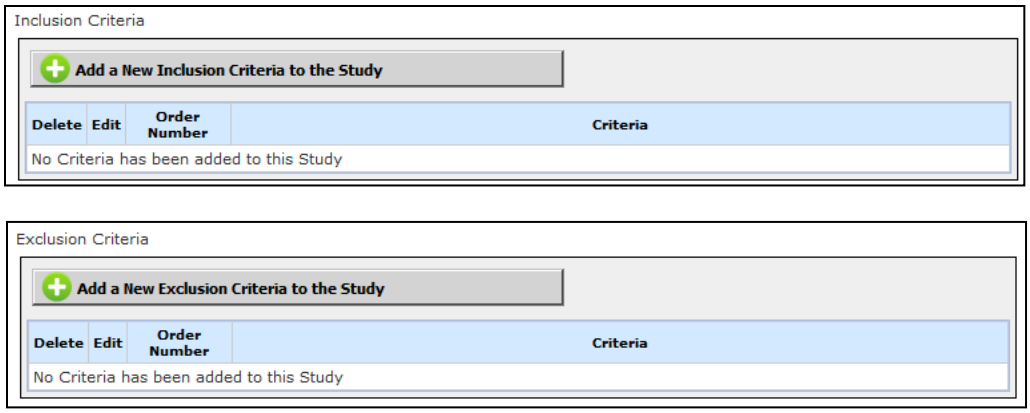


Inclusion/Exclusion Criteria

The Inclusion Criteria and Exclusion Criteria data values allow you to enter your inclusion/exclusion criteria for potential subjects on the study. You can add the criteria to your Study Application for IRB review, and later, when you begin to enroll subjects on the study you will be able to flag which criteria the subject meets or does not meet.

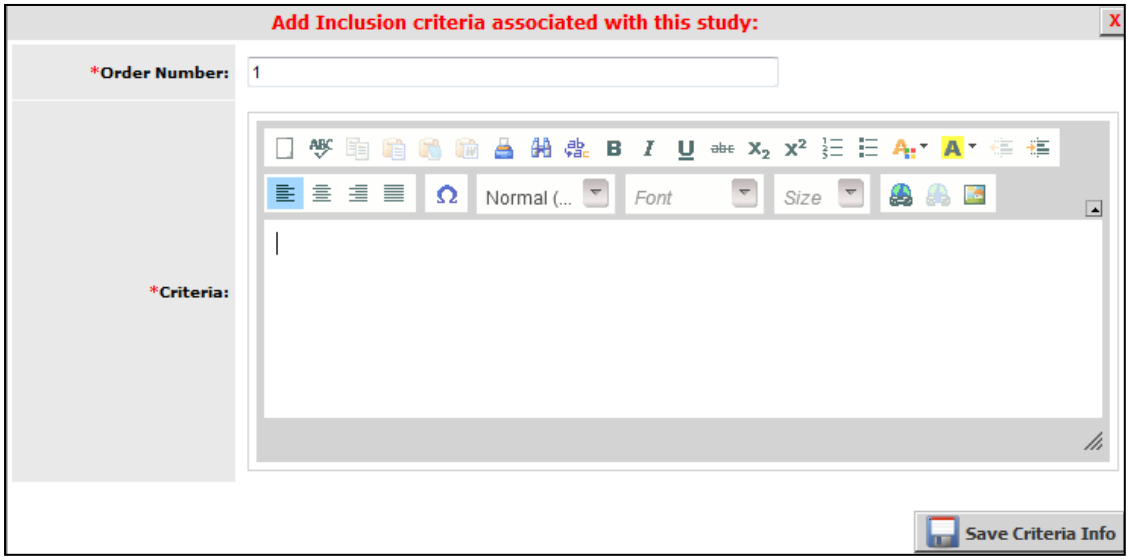
Adding criteria works the same way for both Inclusion Criteria and Exclusion Criteria and is described below using Inclusion Criteria as an example.

Begin by clicking on the **Add a New Inclusion Criteria to the Study** button.

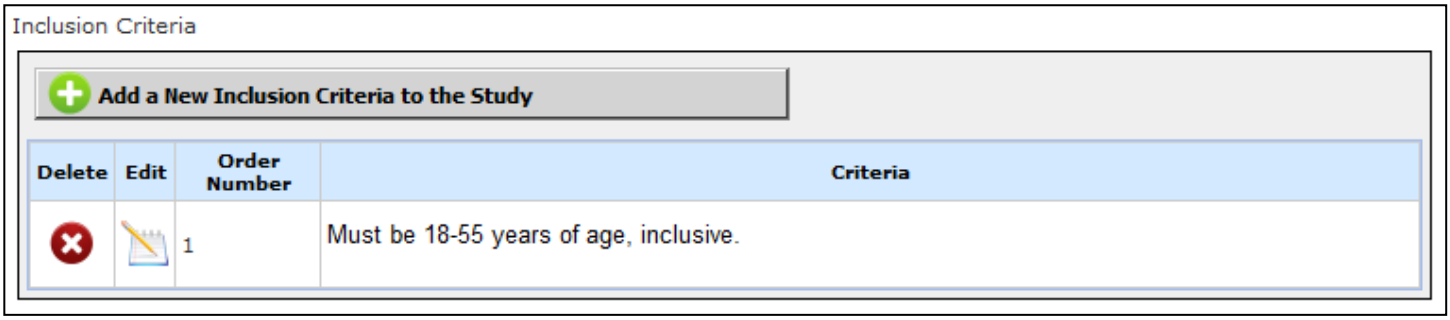


A popup window will open within your browser allowing you to specify the Inclusion Criteria Order Number and the wording for the Criteria. The Order Number will default to 1. You can change the Order Number if you have more than one Inclusion Criteria listed and would like to change the order the criteria is presented in the data value.

The required Criteria field allows you to copy and paste or type in the text for your criteria.



When you are finished, click the **Save Criteria Info** button. You will return to the Study Application and the Inclusion Criteria will be listed in the table.

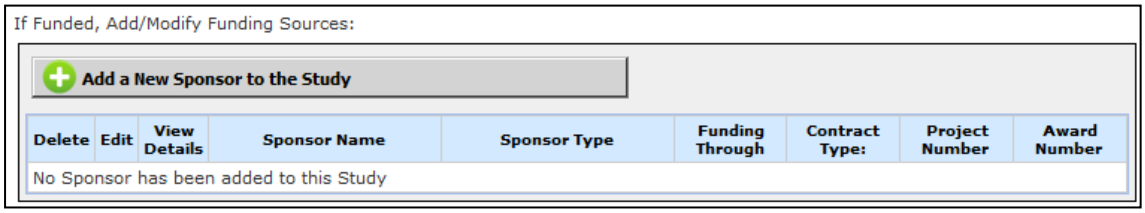


You can have additional Inclusion Criteria, as needed. Click the **Add a New Inclusion Criteria to the Study** button and repeat the steps above. You can delete an Inclusion Criteria record by clicking the icon in the **Delete** column. You can modify existing records by clicking the icon in the **Edit** column.

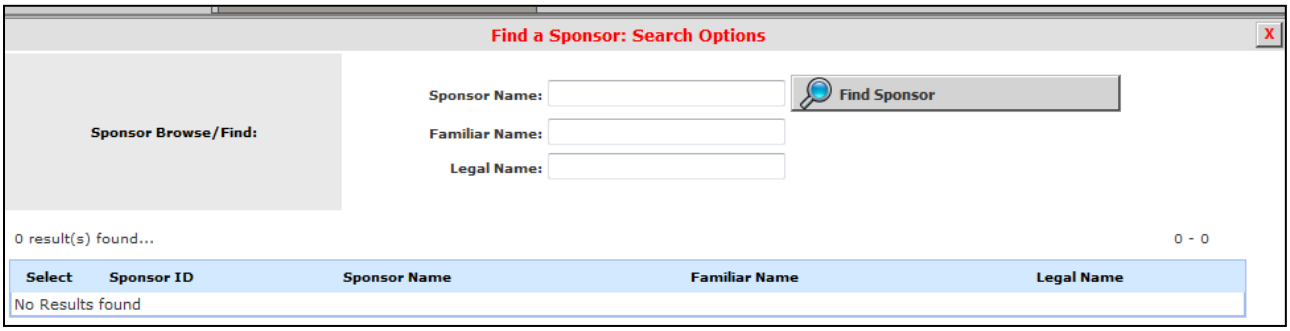
Sponsor

The Sponsor data value will allow you to search iRIS' database for a sponsor to add to your study. Depending on your system settings, you may be able to list more than one sponsor or only one sponsor. Follow the process described below to add a sponsor record.

Begin by clicking on the **Add a New Sponsor to the Study** button.

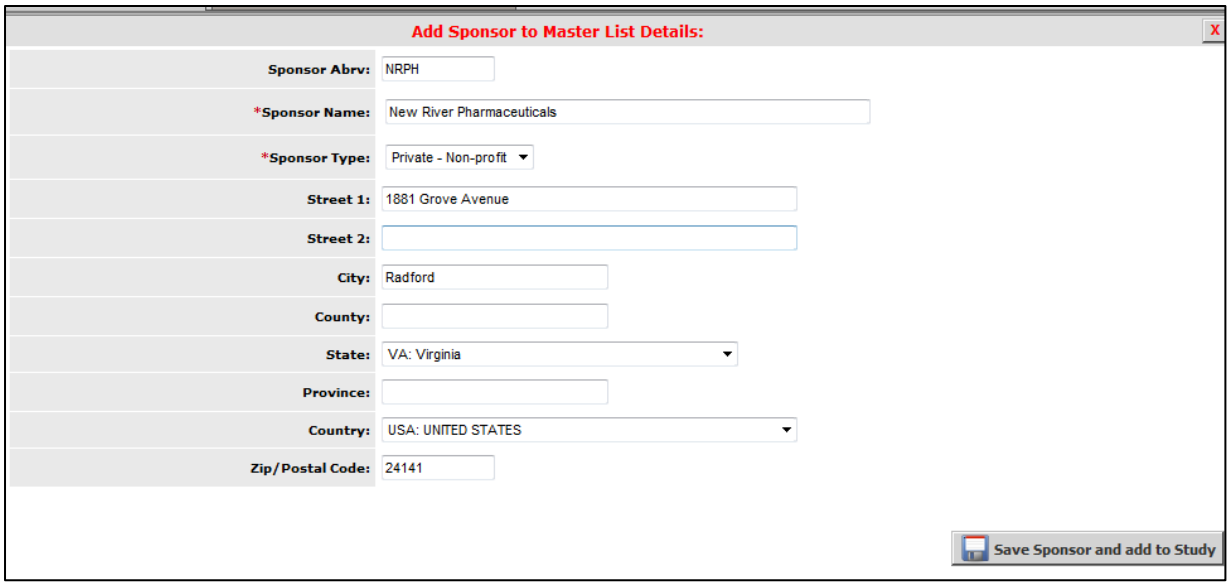


A popup window will open within your browser allowing you to search the system for the sponsor you would like to add to the study. You can enter in all or part of the Sponsor Name, Familiar Name and/or Legal Name, or leave these fields blank and click the **Find Sponsor** button to return all sponsors in the system.



If you cannot find the sponsor in the master list, you can add a new sponsor by clicking on the **Add a New Sponsor to the Master List** button.

After you choose to add a new sponsor, the window will update, allowing you to specify the Sponsor Abbreviation, Sponsor Name (required field), Sponsor Type (required field) and information for the sponsor's location. When you are finished, click the **Save Sponsor and Add to Study** button.

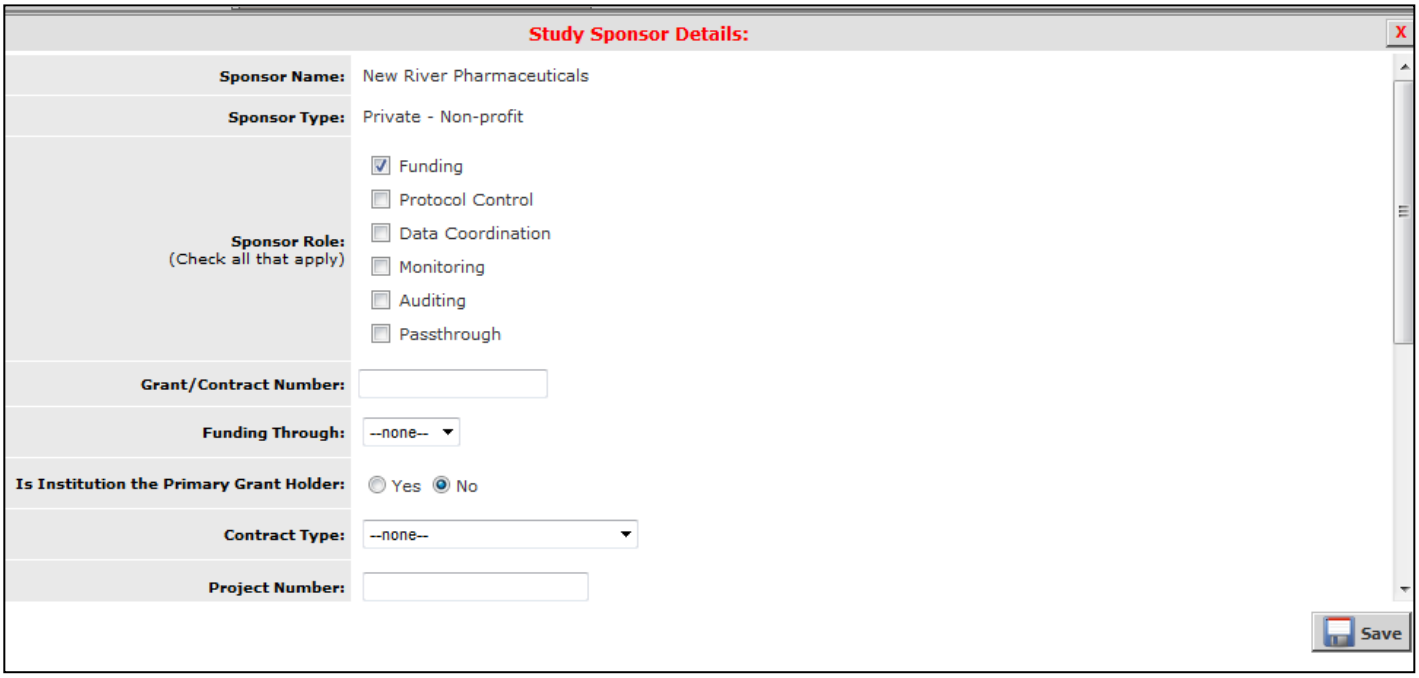


Whether you chose an existing sponsor by clicking on the icon in the **Select** column, or by adding a new sponsor to the master list, the next screen will be the Study Sponsor Details screen.

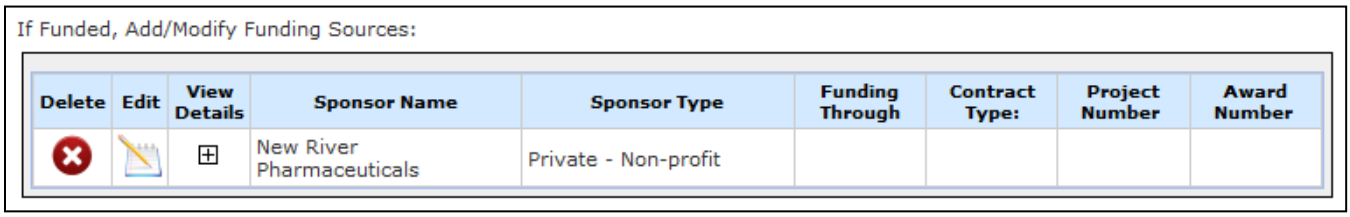
This screen allows you to enter the study-specific information for the sponsor. You may or may not see the same information listed on this page, depending on your system configuration.

The **Sponsor Role** field allows you to indicate what this sponsor's role is for this study. If you indicate this is the Funding sponsor and you are using the Finance portion of iRIS with Subject Management, later in the project you will be able to generate invoices to the sponsor when study events and milestones are triggered.

Enter in the appropriate information and click on the **Save** button.



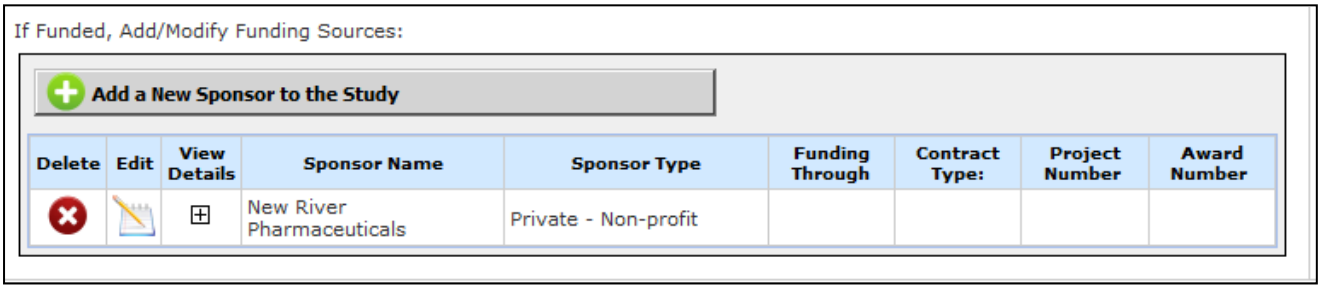
When you select a sponsor to add them to a study, the table for Sponsor Information will populate with that sponsor and any additional details available for the sponsor. You can delete the sponsor from the study by clicking on the icon in the **Delete** column. If your system is setup to allow only one sponsor per study, the button to add sponsors to the study will not appear, as seen in the image below. If you delete the sponsor, the button will reappear, allowing you to add a different sponsor.


If Funded, Add/Modify Funding Sources:

Delete	Edit	View Details	Sponsor Name	Sponsor Type	Funding Through	Contract Type:	Project Number	Award Number
			New River Pharmaceuticals	Private - Non-profit				

If your system does not restrict the number of sponsors allowed per study, you can add additional sponsors to the study by clicking on the **Add a New Sponsor to the Study** button and following the same steps above.

You can view additional details related to the sponsor by clicking on the expand icon in the **View Details** column.


If Funded, Add/Modify Funding Sources:

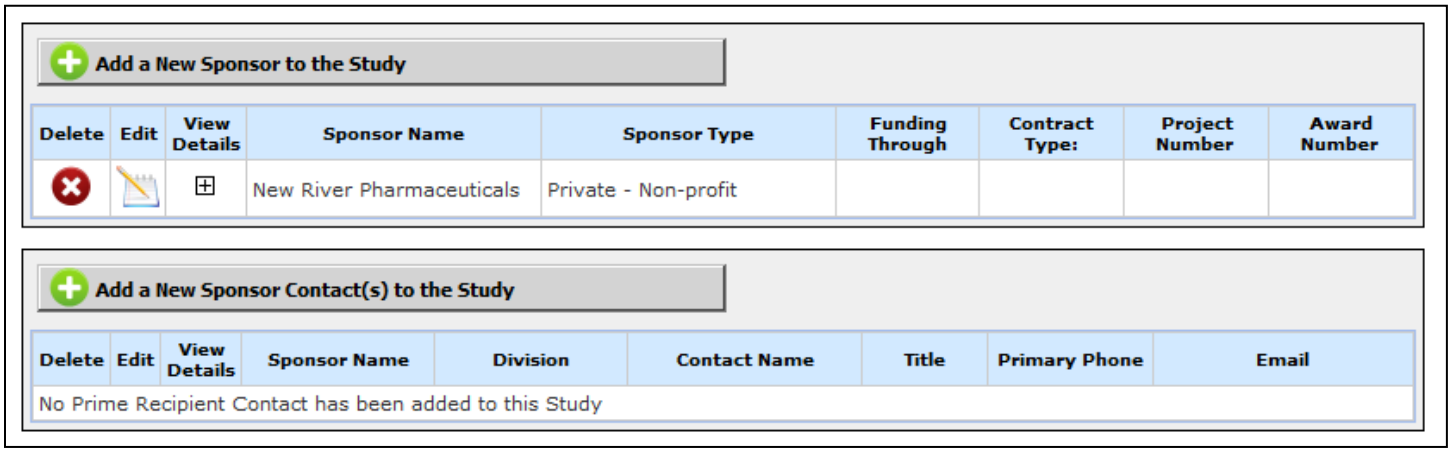
Add a New Sponsor to the Study

Delete	Edit	View Details	Sponsor Name	Sponsor Type	Funding Through	Contract Type:	Project Number	Award Number
			New River Pharmaceuticals	Private - Non-profit				

Sponsor Contact

After adding a Sponsor to a study, you will also be able to specify contacts associated to the sponsor.

The data value for Sponsor Contacts will allow you to add as many contacts to the study for the sponsor as necessary. Click on the **Add a New Sponsor Contact(s) to the Study** button.

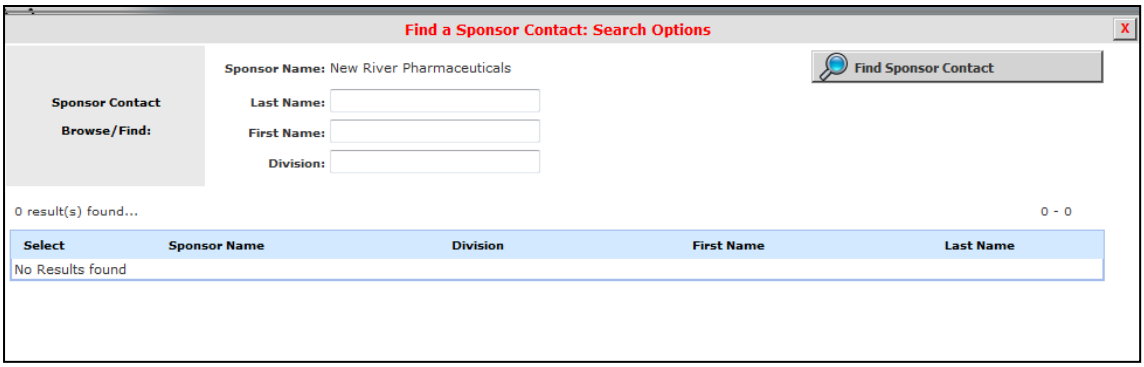

Add a New Sponsor to the Study

Delete	Edit	View Details	Sponsor Name	Sponsor Type	Funding Through	Contract Type:	Project Number	Award Number
			New River Pharmaceuticals	Private - Non-profit				

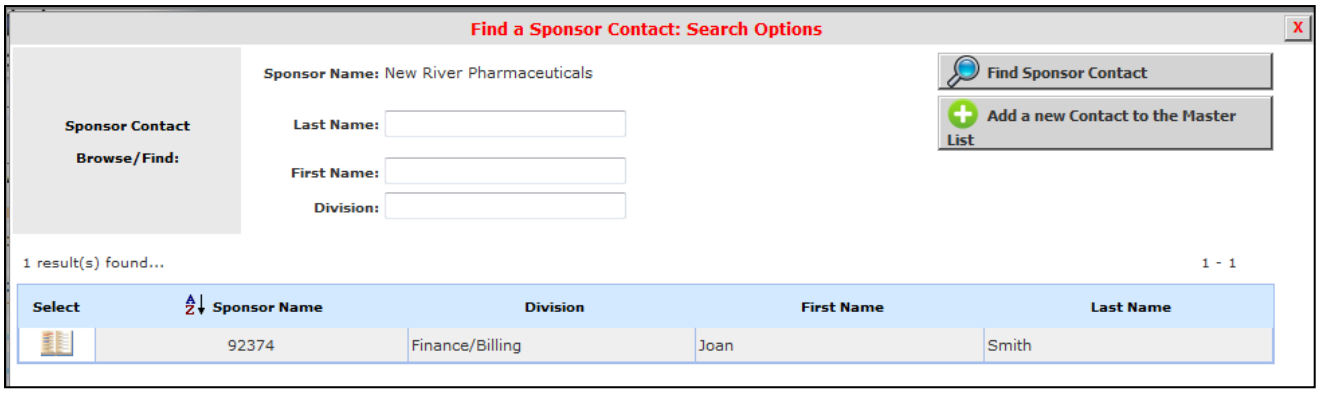
Add a New Sponsor Contact(s) to the Study

Delete	Edit	View Details	Sponsor Name	Division	Contact Name	Title	Primary Phone	Email
No Prime Recipient Contact has been added to this Study								

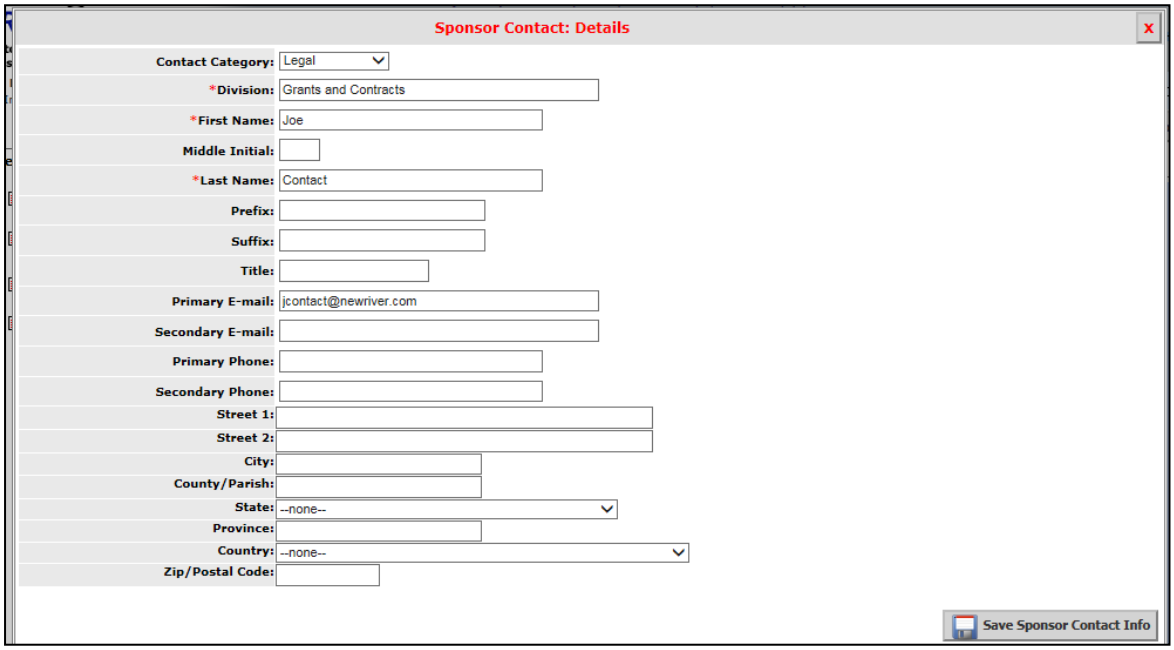
A new popup will display within the browser allowing you to search for existing sponsor contacts. Any contact already associated to the Sponsor can be searched using the Last Name, First Name and/or Division search fields. You can enter all or partial information in any of these fields or leave these fields blank and click the **Find Sponsor Contact** button to return all sponsor contacts associated to the sponsor you added to the study.



If you cannot find the sponsor contact in the list, you can add a new sponsor by clicking on the **Add a new Contact to the Master List** button.



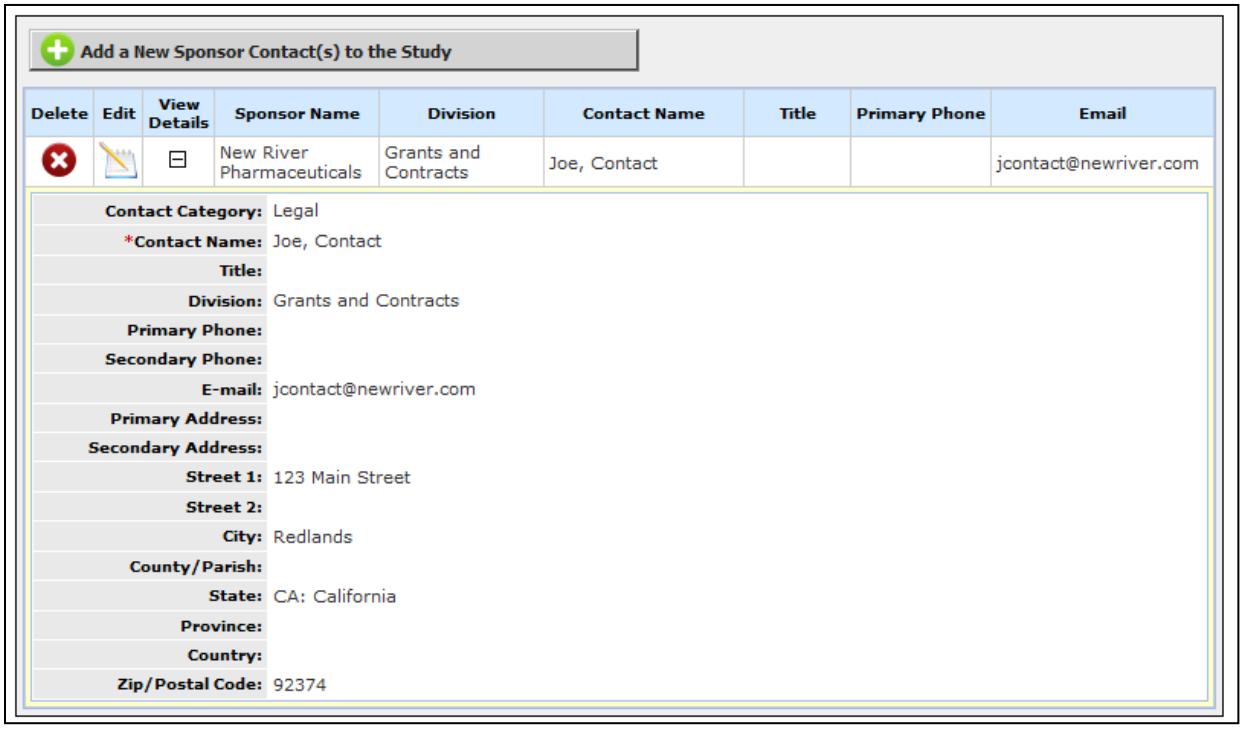
After you choose to add a new contact, the window will update, allowing you to specify the Contact Category, **Division** (required field), **First Name** (required field), Middle Initial, **Last Name** (required field) and information for the sponsor contact. When you are finished, click the **Save Sponsor and Contact Info** button.



Whether you chose an existing sponsor contact by clicking on the icon in the **Select** column, or by adding a new sponsor contact to the master list, the contact will be added to the study and you will return to the Study Application. Any sponsor contact you added will display in the table for Sponsor Contacts section.

You can add any number of contacts, so to add another, click on the **Add a New Sponsor Contact(s) to the Study** button again. You can delete a contact from the study by clicking on the icon in the **Delete** column.

You can view additional details related to the sponsor contact by clicking on the expand icon in the **View Details** column. Your system may or may not have the fields shown in the screenshot below, depending on system settings.



Initial Review Transition

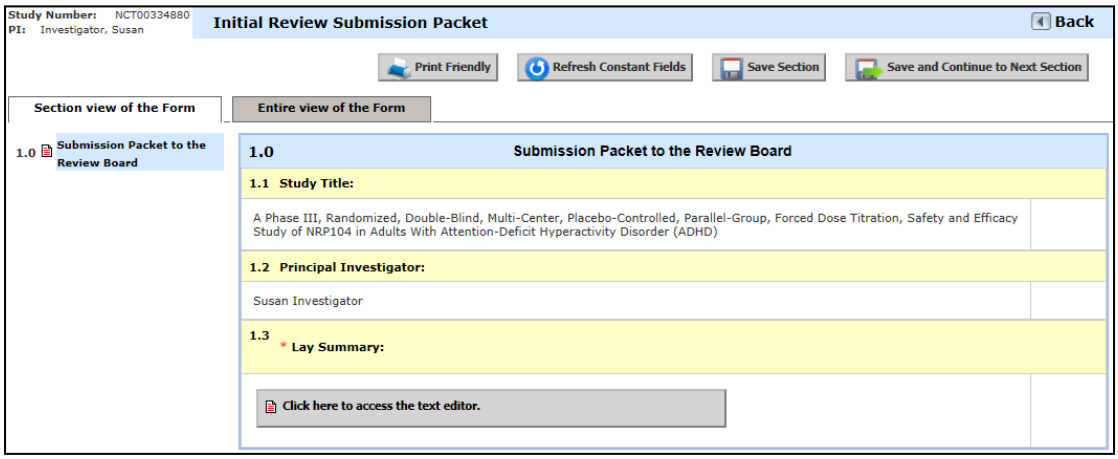
When you are finished filling out the Study Application, the system will transition into the Initial Review Submission Form.

You will have transitioned to the next section when the screen appears that is shown in the image below. The Navigation Pane will reset, displaying Section 1.0 as the current section. This does not mean the Study Application has reset, rather, you have been placed into a new form.

The Initial Review serves as the actual submission form that will go to the review board when submitted. The Study Application will be attached to this form, along with any other Informed consents and supporting study documents.

The Initial Review functions the same way as the Study Application, in regards to navigating and completing sections by adding information into the fields within each section. Complete this form by completing each section, attaching the necessary documentation and clicking the **Save and Continue** button to proceed.

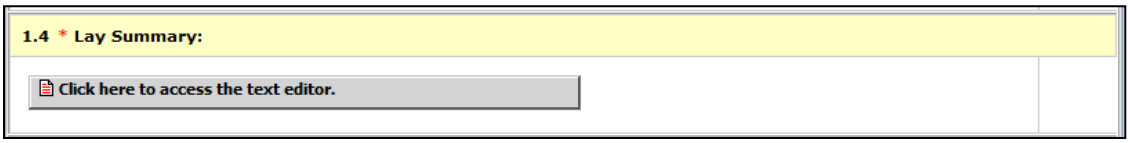
The first section will contain information related to the study, based on your input from the Study Shell screens. Unique data values that capture this information are detailed below. These data values are defined in the form in the System Forms Designer by your System Administrator and may or may not be present in your form.



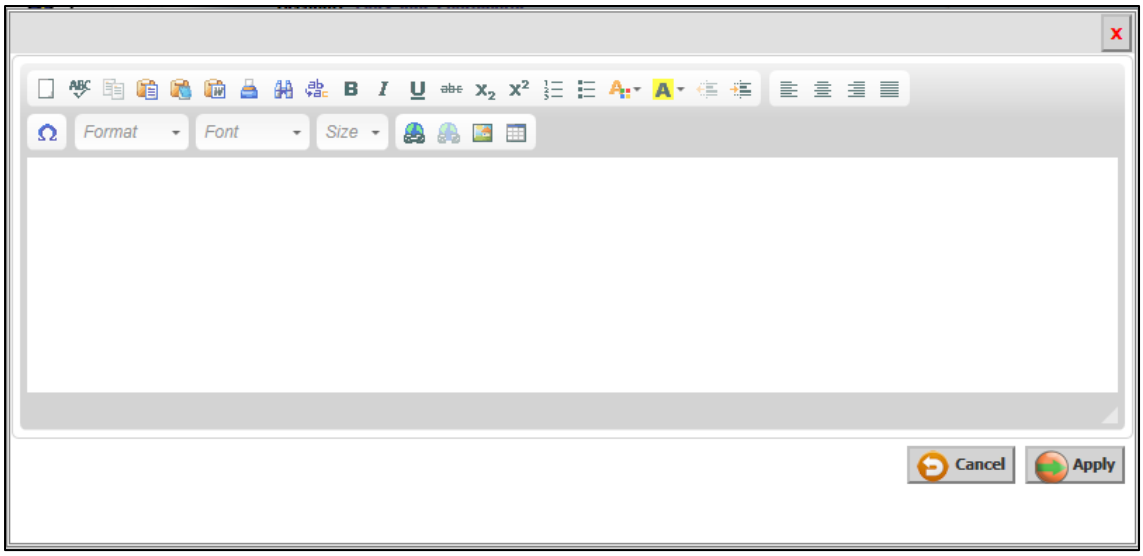
Lay Summary

The Lay Summary data value is a required field, as highlighted in the image below, and allows you to capture the Master Lay Summary for your study. The information you enter into this field will transfer to the study's master lay summary field for the review board of record.

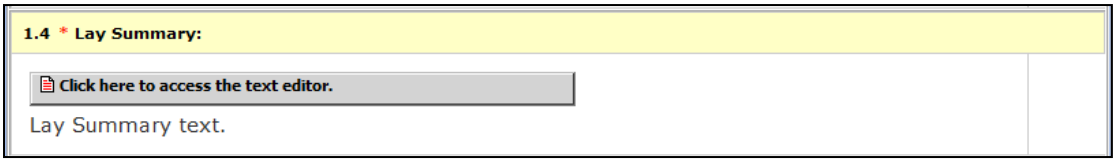
You can enter the study Lay Summary by clicking the **Click here to access the text editor** button.



A small popup will display, allowing you to copy and paste or type in the text of your Lay Summary. When you are finished, click the **Apply** button.



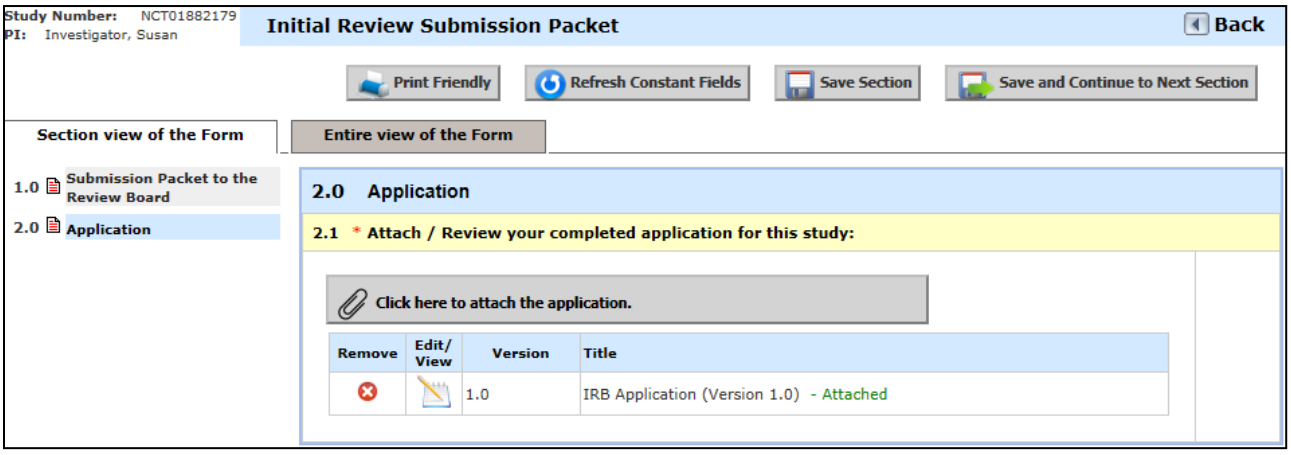
The popup will close, returning you to the Initial Review Submission packet and the Lay Summary text will populate underneath the Lay Summary section.



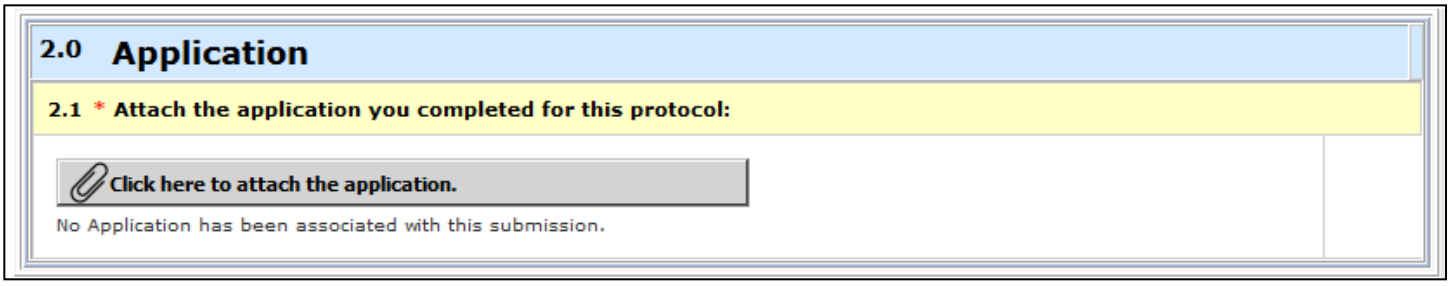
Application Attachment

The purpose of the Initial Review Submission Form is to bring the Study Application to a board for review. One of the sections of the Initial Review will present the ability to attach the application. Because the Study Application has already been completed and you transitioned in to the Initial Review Submission Form, the Study Application will auto-attach.

The Application Attachment value will display the Study Application, as shown in the screenshot below. If the application is attached, you will not need to do anything at this point. Later, if the review board returns the submission for correction, you may need to navigate to this section to make changes, depending on the nature of the change.



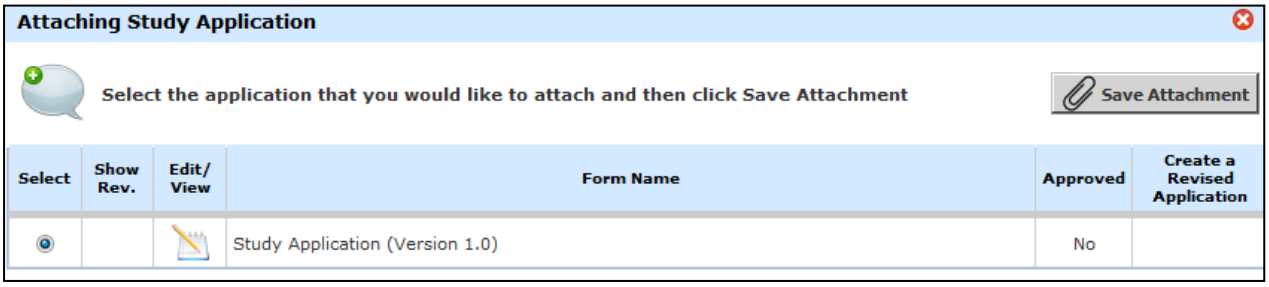
If the Study Application is not attached, the data value will indicate that "No Application has been associated with this submission." You can attach the application by clicking on the **Click here to attach the application** button.



A window will open within the browser, listing the available Study Application you can attach.

Later, when revisions of the application are created, more information will populate in this window. Currently, as a new study, there will only be one version of the application available, and because it has not been submitted, there is no need to create a revision.

Make sure the application is selected and click the **Save Attachment** button.

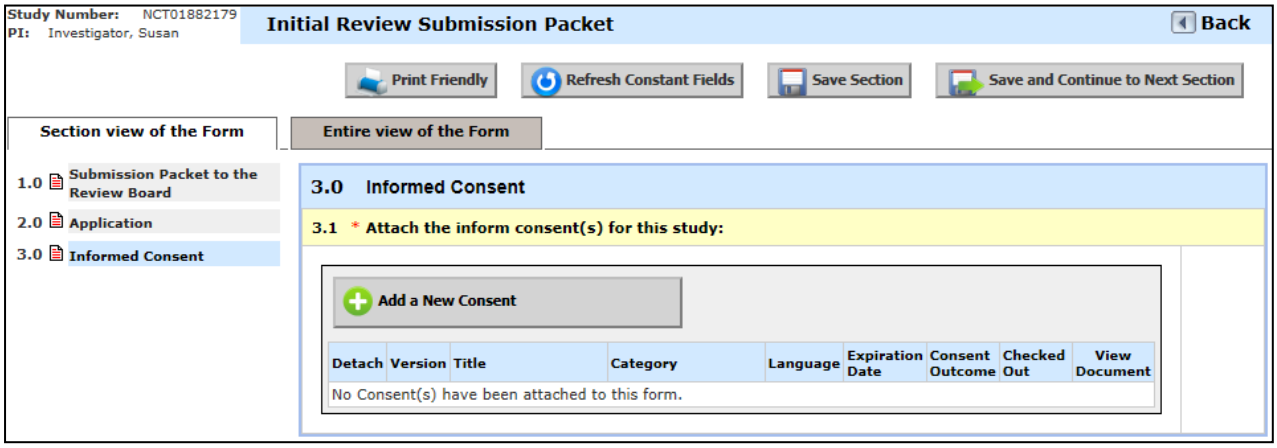


You will return to the Initial Review, with the attached application listed in the Application section. Click the **Save and Continue** button.

Informed Consent Attachments

You may be directed to attach any necessary Informed Consent documents. Any consent document you upload to the Initial Review will be attached to the form and will be submitted for review. The document(s) you upload will also be stored in the Informed Consent document library in the study record. When the review board approves the document, the approval information will update the document stored in the library, which can also be accessed and printed. If your system is using Subject Management, you will also be able to update consent information for subjects on the study.

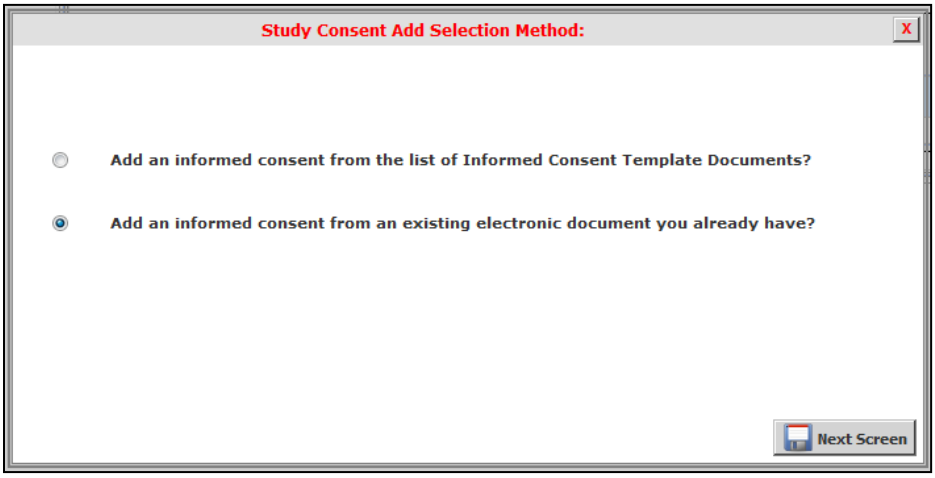
Click the **Add a New Consent** button.



A small window will open within the window, asking for input on how you will upload the Consent document, as seen in the image below.

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

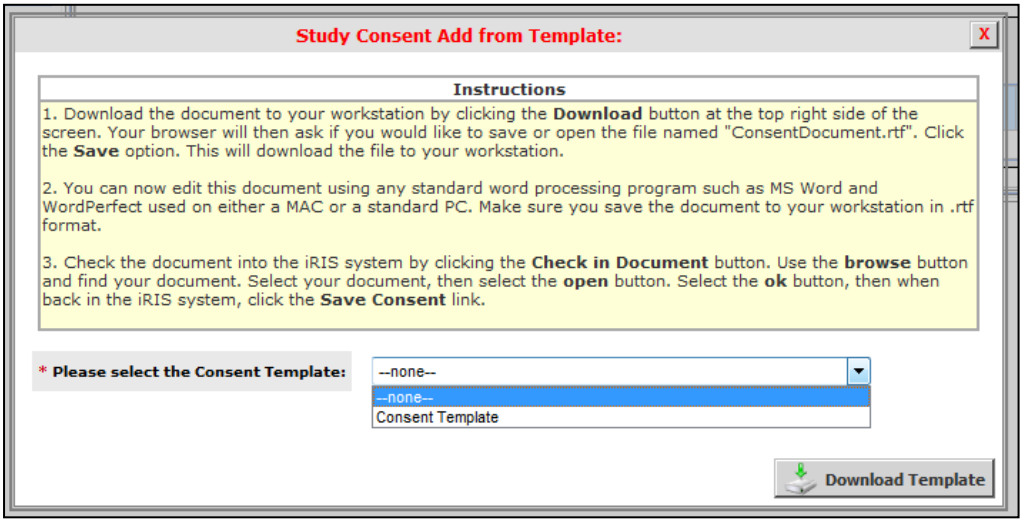
Each possible selection is described below. Choose the appropriate action then click the **Next Screen** button.



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

Review boards may make consent templates available for you to download, modify, and then upload to the study. If you would like to download a copy and use the review board's consent template, choose this option.

Selecting this option will present you with the ability to select the desired template from a dropdown list. Select the template and then click the **Download Template** button.

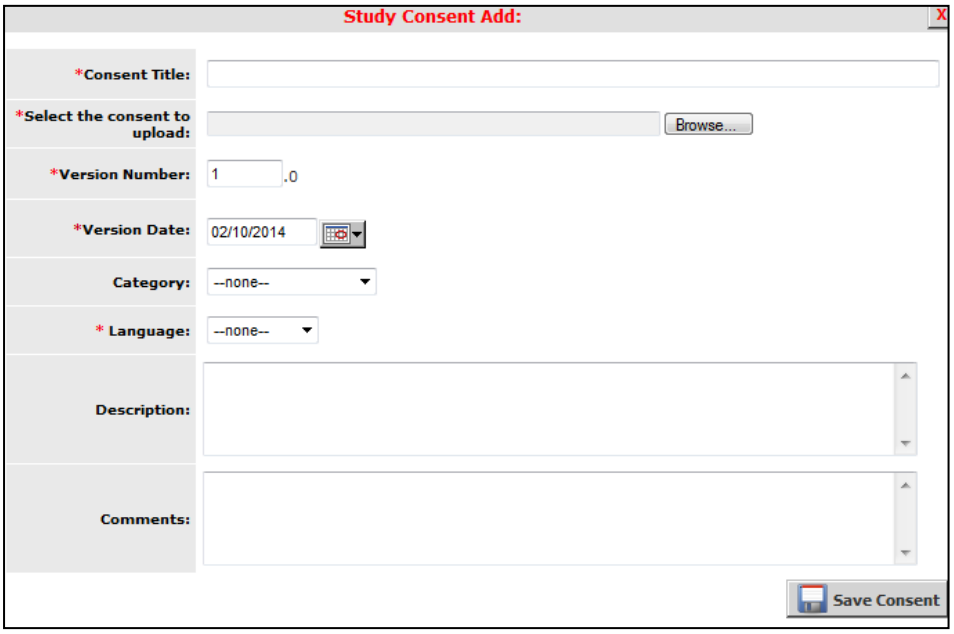


Depending on your Internet Browser, version and settings, you may or may not be prompted with the file download information.

In this example, IE9 is used. 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 of saving the document in a known location.

The Initial Review 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. The asterisked fields are required.



Once you are finished making your edits to the consent form, return to this screen to upload the consent.

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 popup will open within the browser. Here you will specify the name of the document in the **Consent Title** field. Then 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.

You must also specify the **Version Number**.

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

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

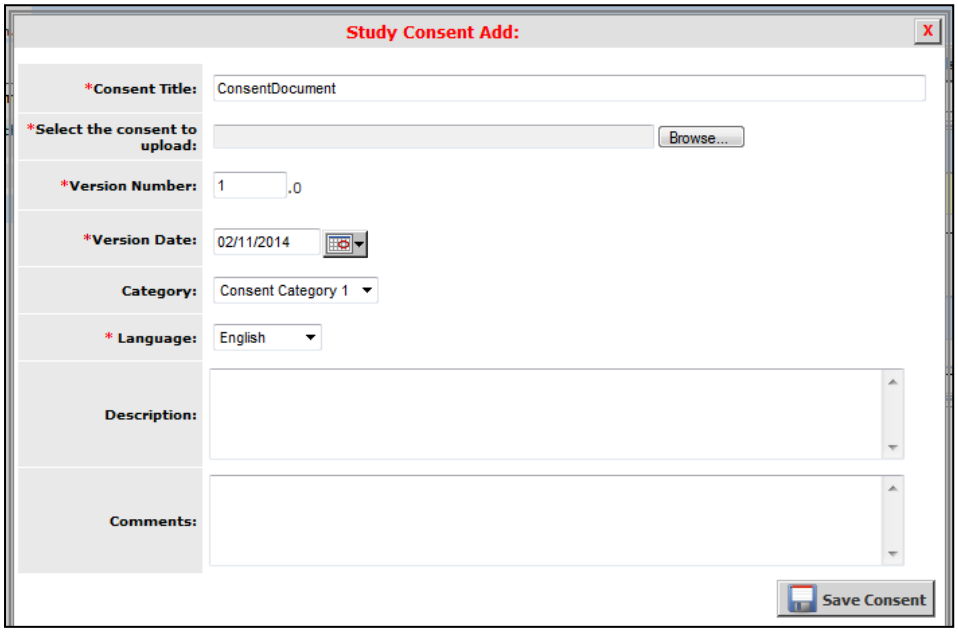
Category – This configurable drop down list allows you to group documents into certain categories.

Language – This configurable drop down list allows you to select which language the consent is written in.

Description – A description of the document.

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

Enter the required information including the document itself then click the **Save Consent** button.

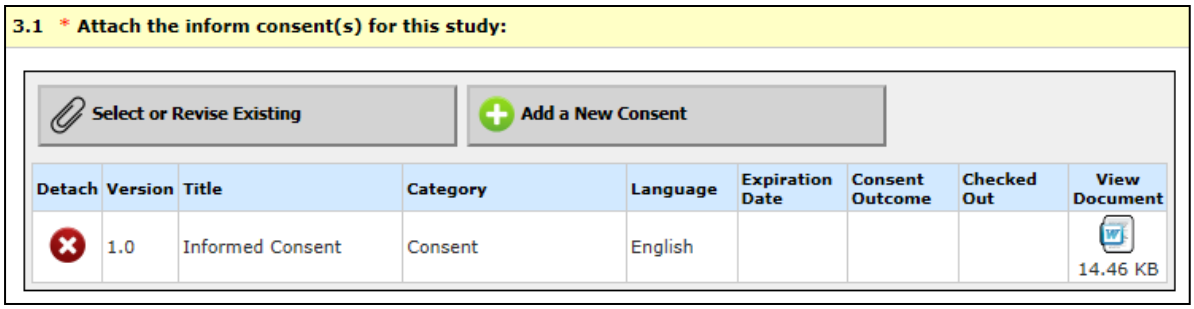


The Consent document will be uploaded to the study, and it will appear as attached to the Initial Review Submission Packet in the Consent Attachment section.

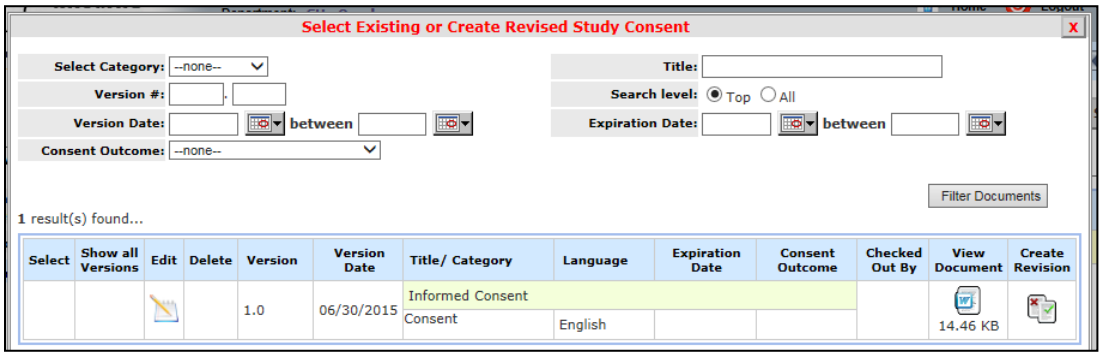
Information you added to the Consent record will display in the table, including fields reserved for the review board, Expiration Date and Review Outcome. This information will populate when the review board gives the Consent form an outcome. There is a column called **Checked Out**. This column only populates if the Consent is checked out for edits.

You can remove the attached consent by clicking the icon in the **Detach** column. When you detach the Consent you are removing it from the submission. If the record needs to be deleted, you will need to navigate to the study Submissions page and open the Informed Consent library. Once a document is submitted it cannot be deleted from the study.

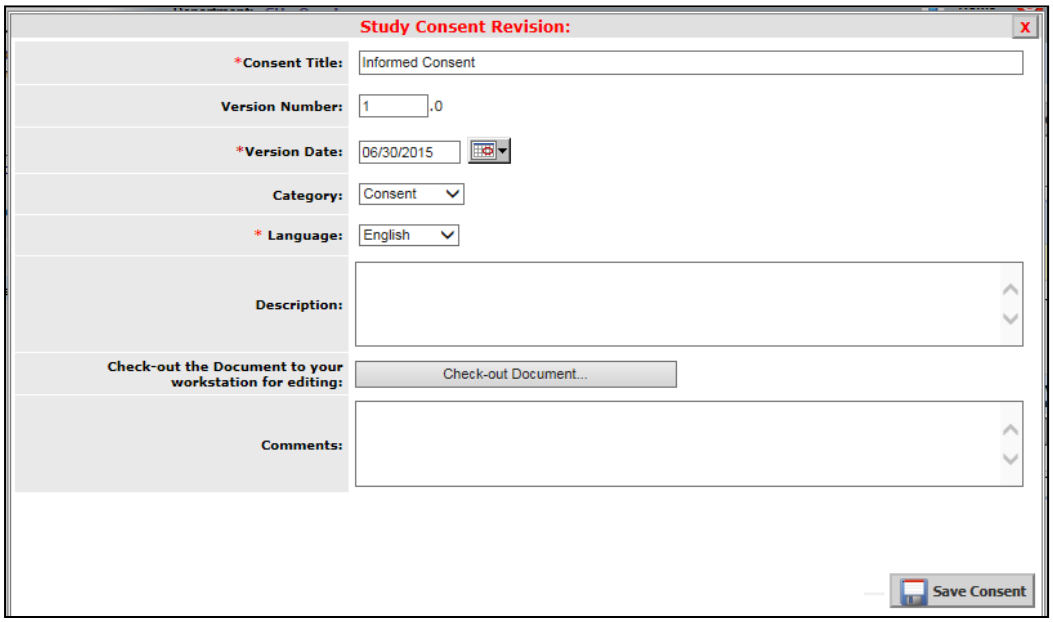
Once a Consent document is uploaded, an additional button will populate within the Informed Consent data value, called **Select or Revise Existing**. This button is available whenever you have documents in the Informed Consent library and allows you to select from the existing Consent documents on the study. You can also make any edits to the attached Consent, if needed, by clicking this button.



A new window will open, listing any existing Consent documents. Because only one record has been created for the study, only one record will display. It is already attached to the Initial Review Submission Packet, so you will not be able to re-attach it. To make changes to the document, click the icon in the **Edit** column, as highlighted in the image below.

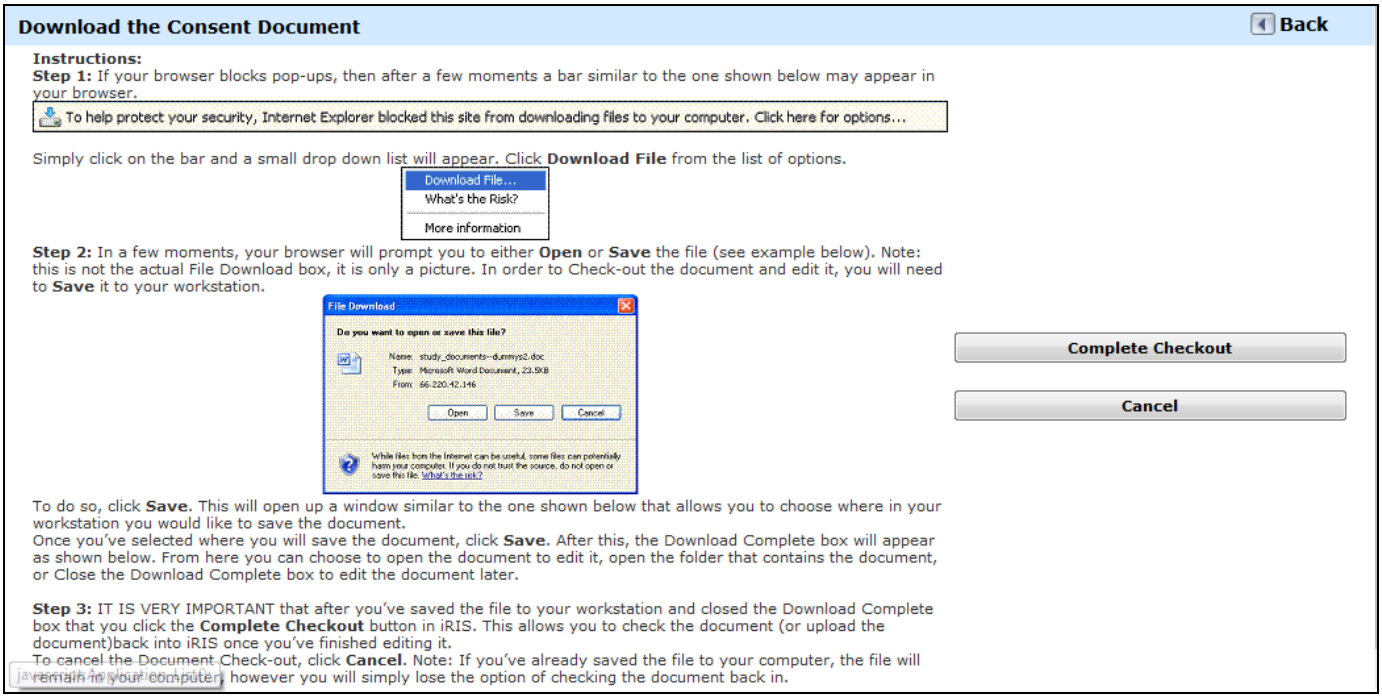


This triggers the Study Consent Revision window to open. From here you can make any changes to the Consent details **(Consent Title, Version Number, Version Date, Category, Language, Description** and **Comments**), or if you need to modify the content of the consent itself, you can **check-out** the consent.



A new page will open and your Internet browser will download the template. Internet Explorer 9 is used in this example. Depending on your Internet settings, you may have a blocker installed that prevents you from downloading files without approval. Wait a few moments and the browser may prompt you with a yellow bar at the top of the page. Click the

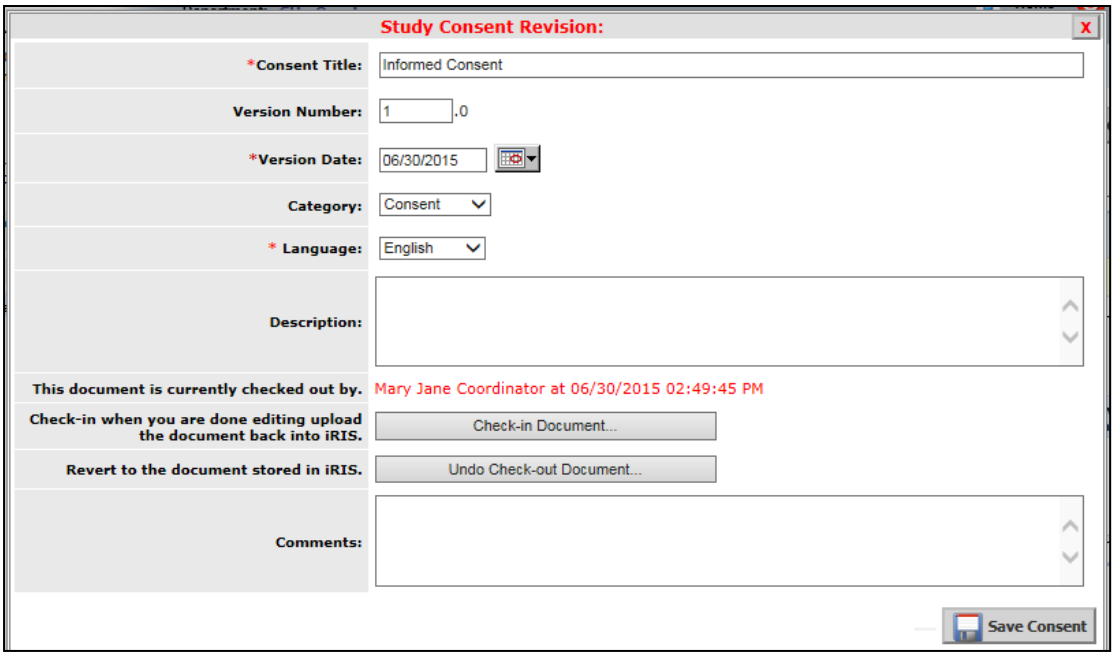
yellow bar then select Download File from the menu. Do this before clicking the **Complete Checkout** button. If you click Complete Checkout before saving the file, you will lose the template and will need to undo the check out.



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

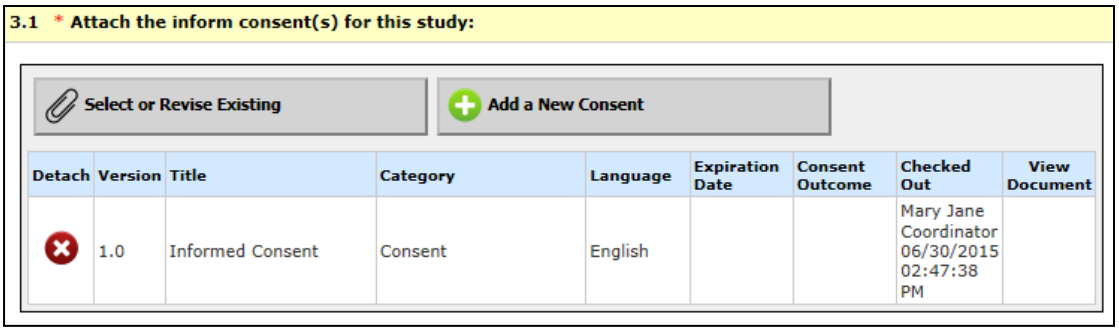
Once you save the document, you need to click on the **Complete Checkout** button within the browser. If you did not want to check out the document, click the **Cancel** button. This will return you to the previous page without checking out the Consent document.

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

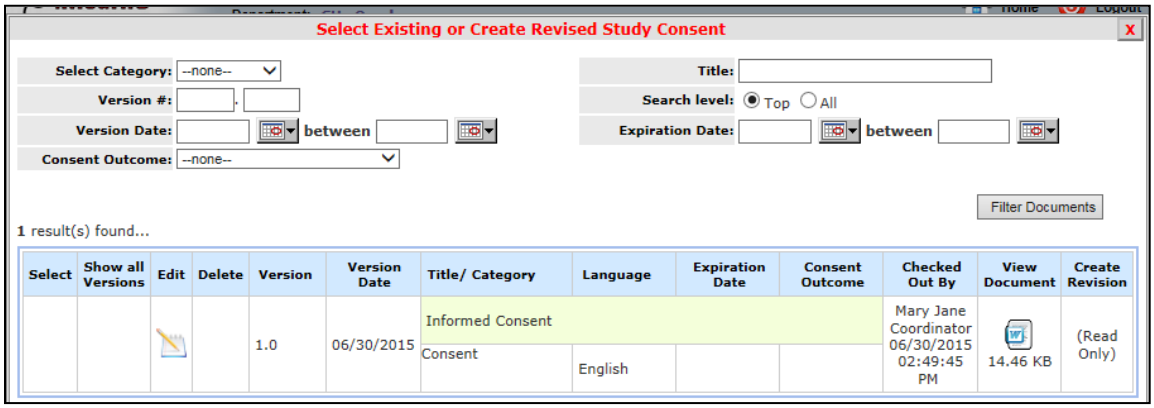


Anywhere you can view the Consent form, in the Informed Consent library or within the Initial Review Submission Form you will see that the document is checked out.

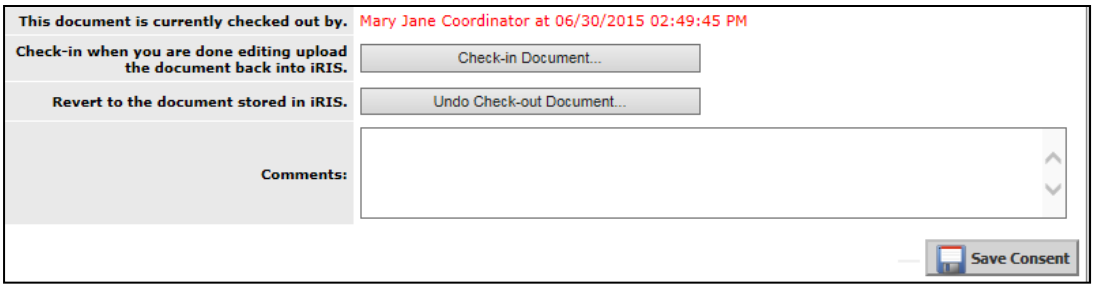
When you have made changes to the document in Microsoft Word, you can check it back in by navigating to the consent section in the Initial Review. Click **Select or Revise Existing**, as shown in the image below.



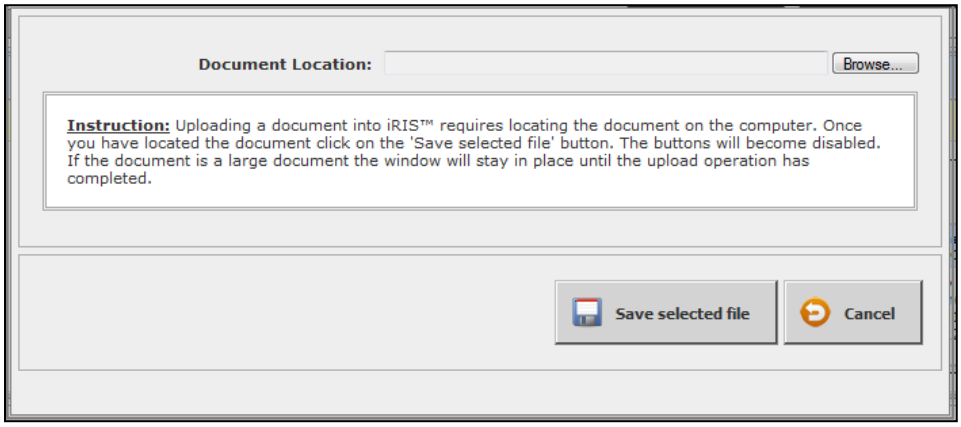
Click the icon in the **Edit** column.



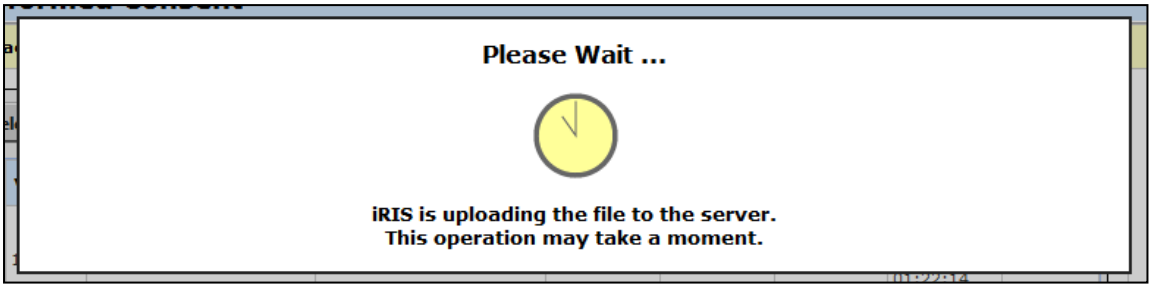
Click the **Check-in Document** button.



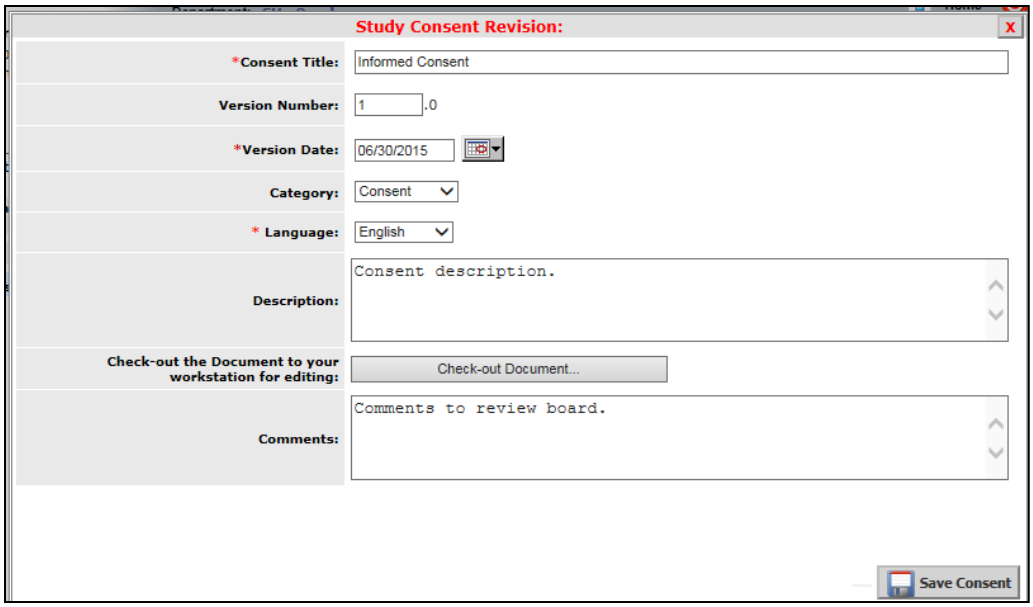
A popup window will open allowing you to browse your computer for the Consent document you would like to upload. Click the **Save selected file** button once you specify the document location. If you do not want to upload the document, click on the **Cancel** button.



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



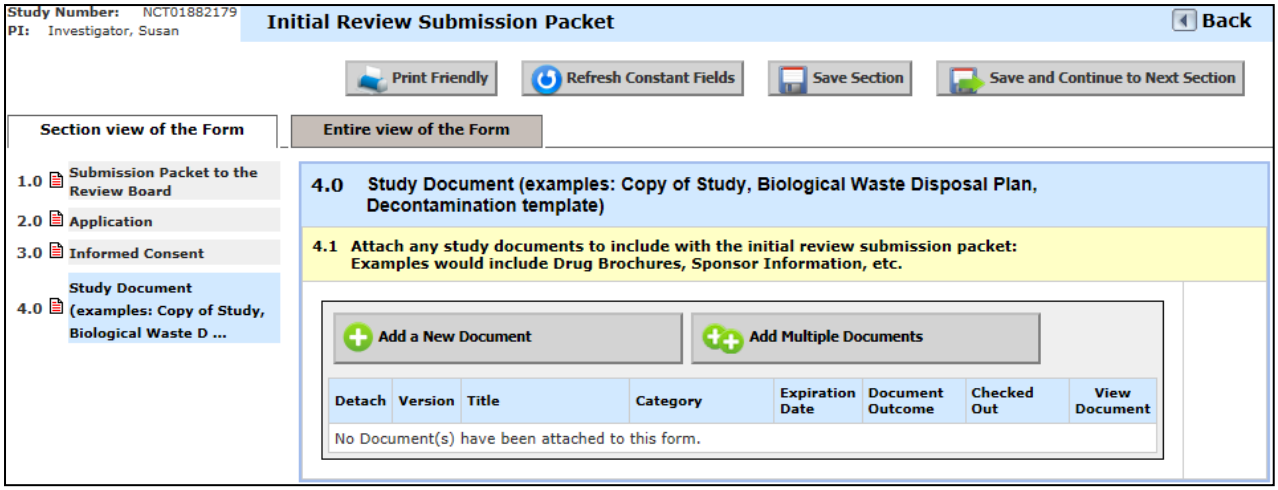
You will then be returned to the Study Consent Revision window, with the document successfully checked in and associated to the study. Click the **Save Consent** to apply the changes to the Initial Review.



Study Document Attachments

You may be directed to attach other supporting Study Documents. Any document you upload to the Initial Review Submission Packet will be attached to the form and will be submitted for review. The document(s) you upload will also be stored in the Other Study Document library in the study record. When the review board approves the document, the approval information will update the document stored in the library, which can also be accessed and printed.

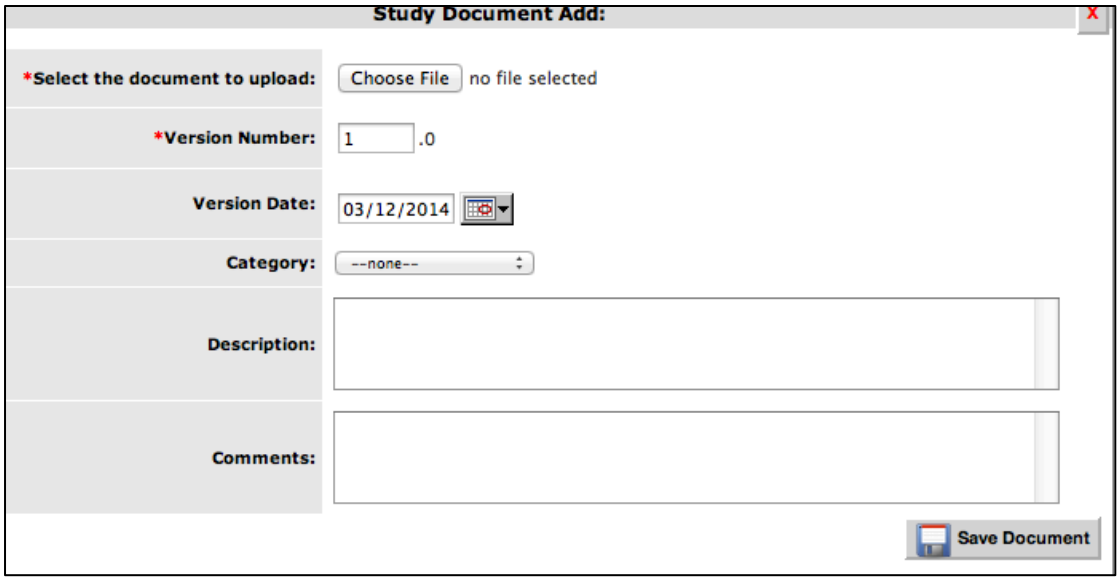
You can add as many documents as needed to the Document attachment data value. You can choose to add one document at a time, or if you have multiple documents, you can add them all at once, by clicking the appropriate button, as highlighted in the image below.



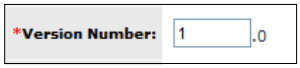
Add a New Document

To add one document to the Document attachment data value, click **Add a New Document**.

A new popup will open within the browser. Here you will specify the name of the document in the **Document Title** field. Then 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 compute so you can locate your document.



You must also specify the **Version Number**.



Version Number allows you to specify the version number. This can be any character or number. After the editable version number is a hard coded '.0'. This is 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.

Select the Document to Upload and **Version Number** are required fields and you cannot upload a document without providing these details. Depending on your system configuration, you may also be required to enter the **Document Title** here.

The remaining fields are optional and can be filled out as needed.

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

Category – Select from a configurable drop down list to group documents into certain categories.

Description – Enter a description of the document.

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

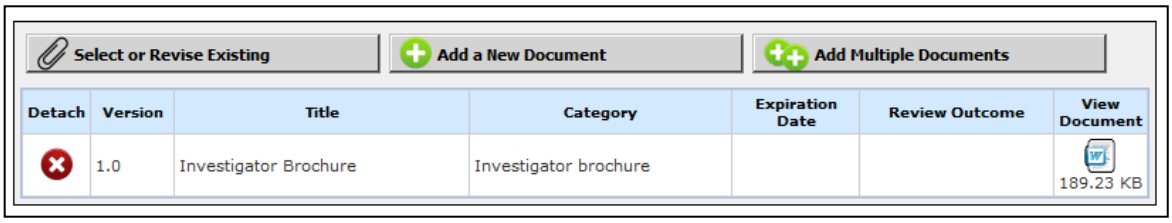
Click the **Save Document** button after adding the necessary details.

The study document will be uploaded to the study, and it will appear as attached to the Initial Review in the Other Study Documents Attachment section.

Information you added to the study document will display in the table, including fields reserved for the review board, Expiration Date and Review Outcome. This information will populate when the review board gives the study document an outcome.

You can remove the attached document by clicking the icon in the **Detach** column. When you detach a study document you are removing it from the submission. If the record needs to be deleted entirely, you will need to navigate to the study Submissions page and open the Other Study Document library. Also, once a document is submitted it cannot be deleted from the study.

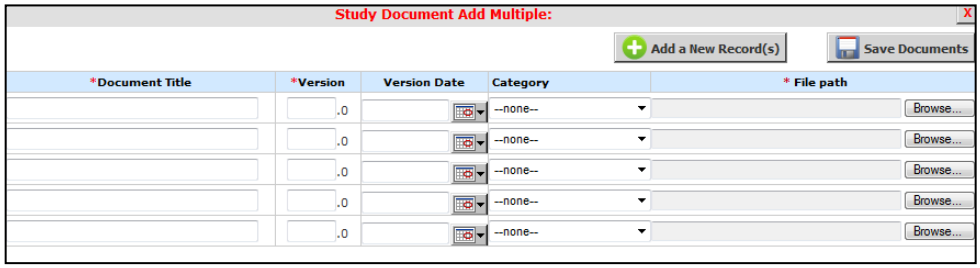
Once a document is uploaded, an additional button will populate in the Other Study Document data value: **Select or Revise Existing**. This button is available when you have documents in the Other Study Documents library and allows you to select from existing documents on the study. You can also make any edits to the attached document by clicking this button.



Add Multiple Documents

You can add multiple documents to the Document attachment field at once. Click on the **Add Multiple Documents** button.

This will open a popup within the browser. Here you will be able to specify details for multiple documents at a time.



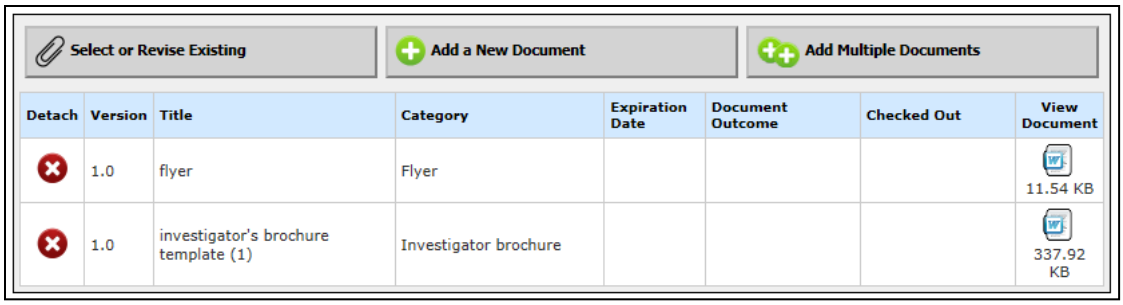
Document Title, Version and **File Path** are all required fields. See the area above for information on each item.

If necessary you can also add the **Version Date** and **Category**.

If you need to add more than five documents at a time, click on the **Add New Record(s)** button and an additional five rows will populate in the window.

Once you enter the needed number of documents and the needed details, click on the **Save Documents** button.

Any document you uploaded will now display in the table.



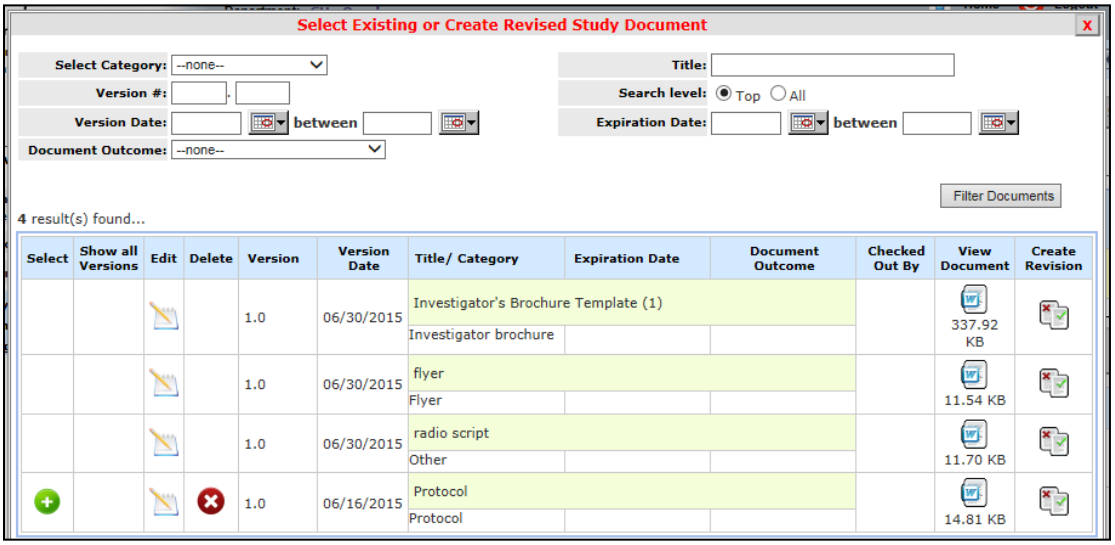
The document details will display in the Other Study Documents attachment data value.

After you upload one document, one more button at the top of the table is available: **Select or Revise Existing**. This will be addressed below.

Select or Revise Existing

Anytime you see this button available in the Other Study Documents attachment data value, it means that your study already has documents uploaded and you can select an existing document to add to the Initial Review Submission Form.

Clicking the **Select or Revise Existing** button will open a popup within the browser. Listed in the window will be any Other Study Document associated to the study.



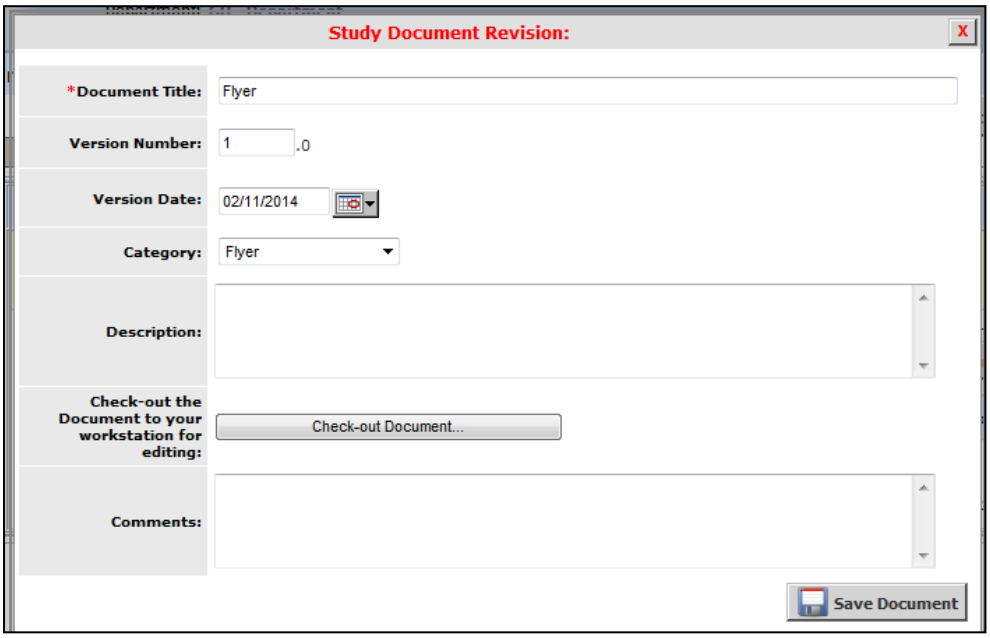
Attaching the Document:

You can attach any document to the form by clicking on the icon in the **Select** column. This will associate the document to the form. Note: If a document is already associated to the form, no icon will display in this column. Also, you cannot delete a document that is associated to the form. If no icon displays in the **Delete** column, the document needs to first be removed from the submission, then it can be deleted (provided the document has not been submitted for review).

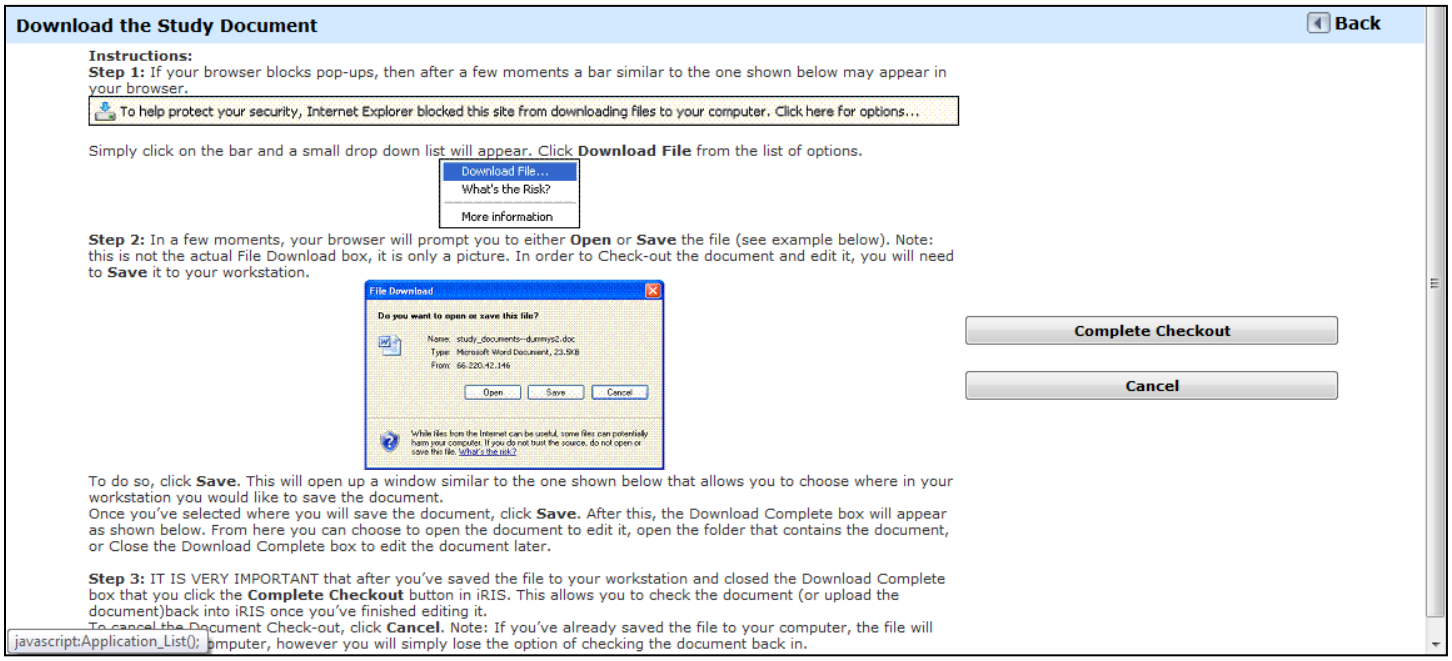
Checkout the Document for Editing:

You can also edit the details of the document prior to attaching to the form by clicking on the icon in the **Edit Details** column.

This will cause the Study Document Revision window to open. From here you can make any changes to the document details (**Document Title, Version Number, Version Date, Category, Description and Comments),** or if you need to modify the content of the document itself, you can **check out** the document.



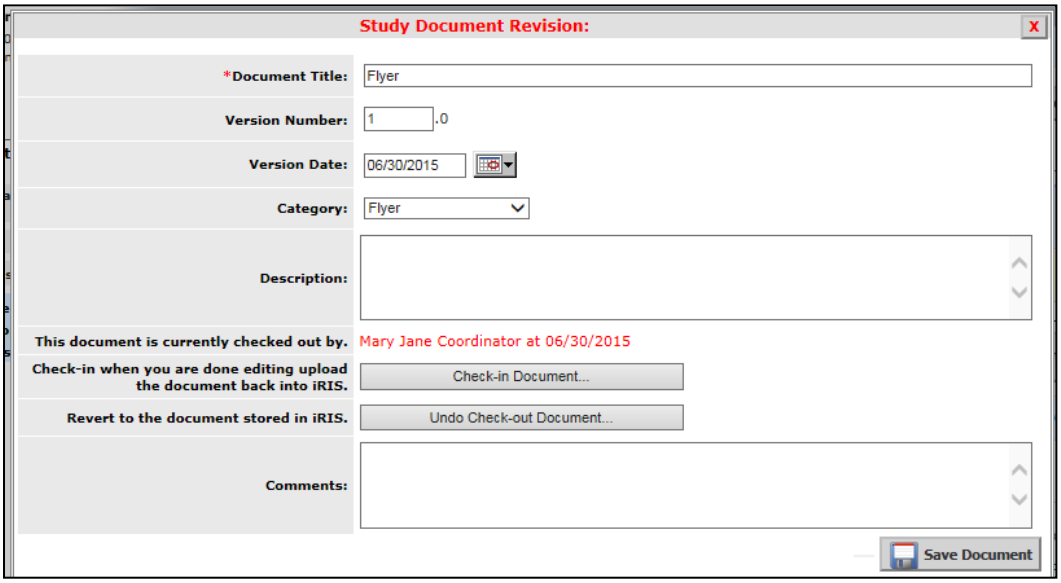
A new page will open and your Internet browser will download the template. Internet Explorer Version 9 is used in this example. Depending on your Internet settings, you may have a blocker installed that prevents you from downloading files without approval. Wait a few moments and the browser may prompt you with a yellow bar at the top of the page, as shown in the image below. Click the yellow bar 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 template and will need to undo the check out.



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

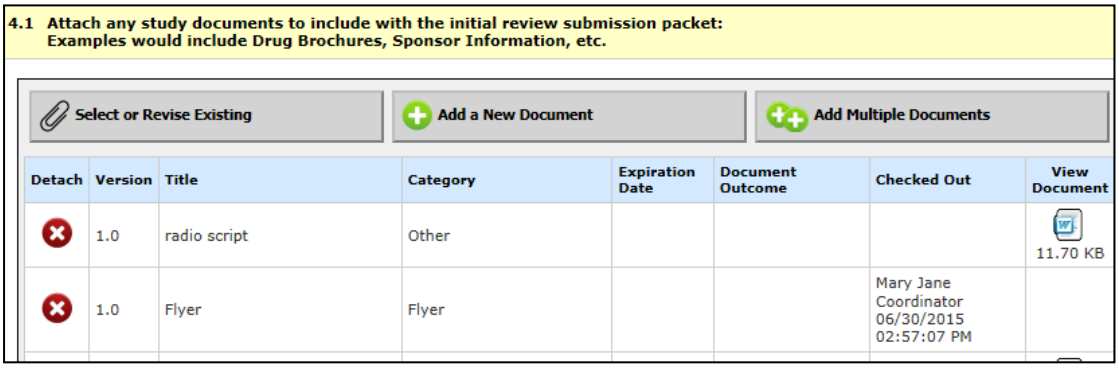
Once you save the document to a location on your computer, you need to click on the **Complete Checkout** button within the browser. If you did not want to check out the document, click the **Cancel** button. This will return you to the previous page without checking out the document.

You will return to the Study Document 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**.

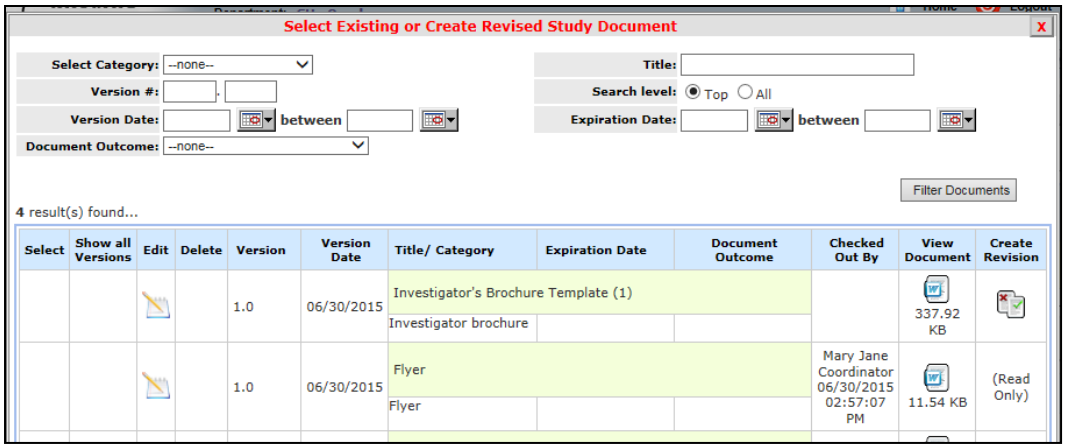


Anywhere you can view the Other Study Document, in the Other Study Documents library or within the Initial Review you will see that the document is checked out.

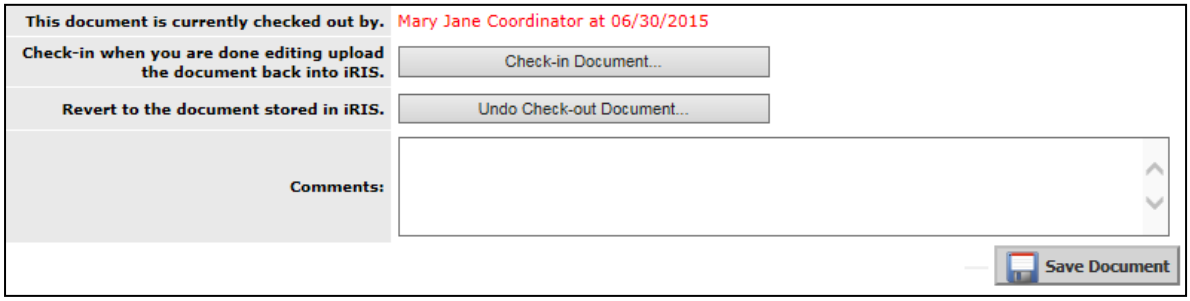
When you have made changes to the document in Microsoft Word, you can check it back in by navigating to the Other Study Document section in the Initial Review. Click **Select or Revise Existing**.



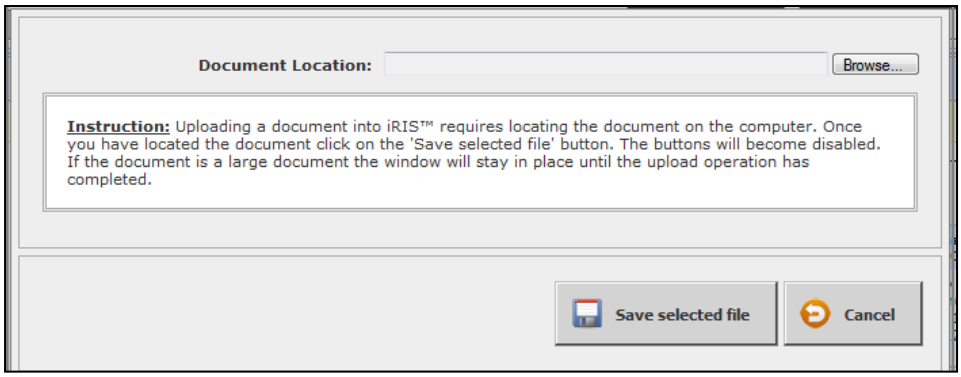
Click the icon in the **Edit** column.



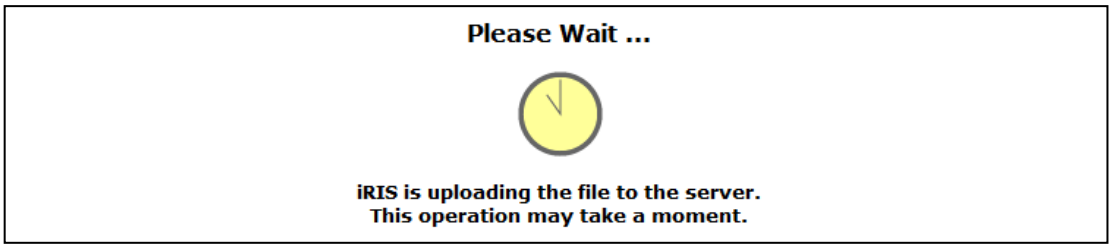
Click the **Check-in Document** button.



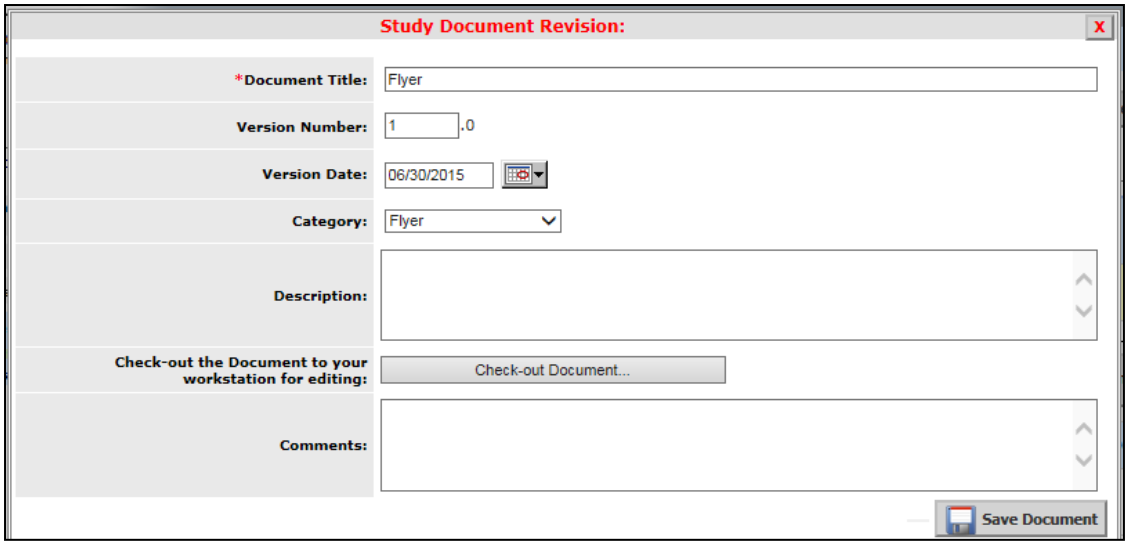
A popup window will open allowing you to browse your computer for the document you would like to upload. Click the **Save selected file** button once you specify the document location. If you do not want to upload the document, click on the **Cancel** button.



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



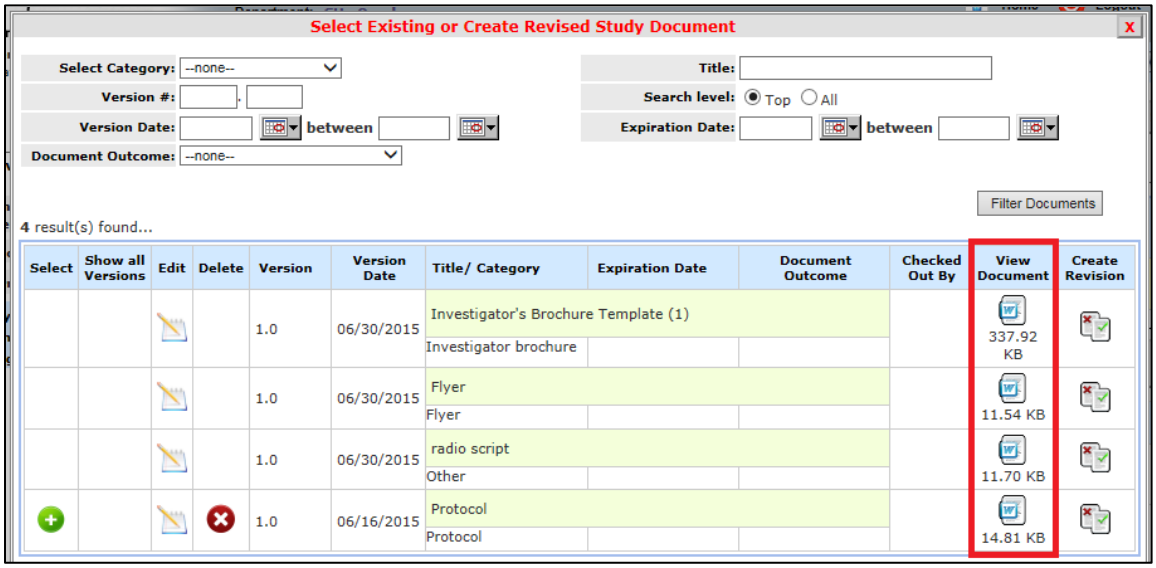
You will then be returned to the Study Document Revision window, with the document successfully checked in and associated to the study. Click the **Save Document** to apply the changes to the Initial Review Submission Packet.



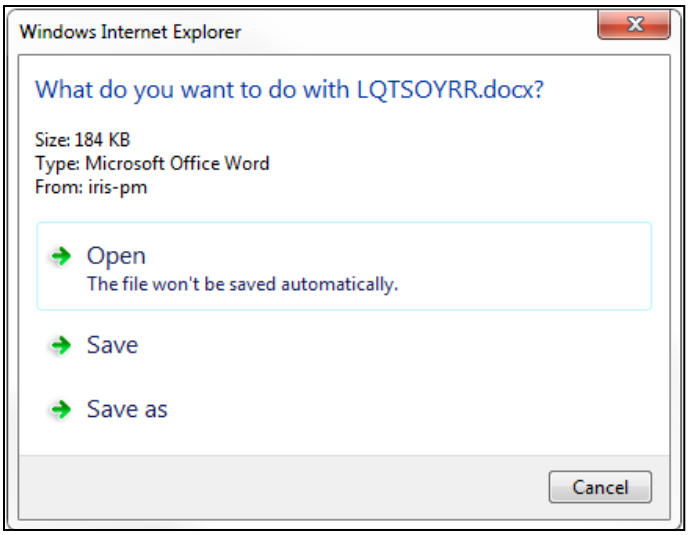
When the document is checked out, the page will read that the document is checked out and display the name of the user and the date the document was checked out.

Viewing the Document

To view any document prior to attaching it to a form, click on the icon in the **View the Document** column.



This will open the document in a new window.



Depending on your Internet Browser settings you may need to allow the download and you may also receive a popup window asking if you want to Open or Save the file.

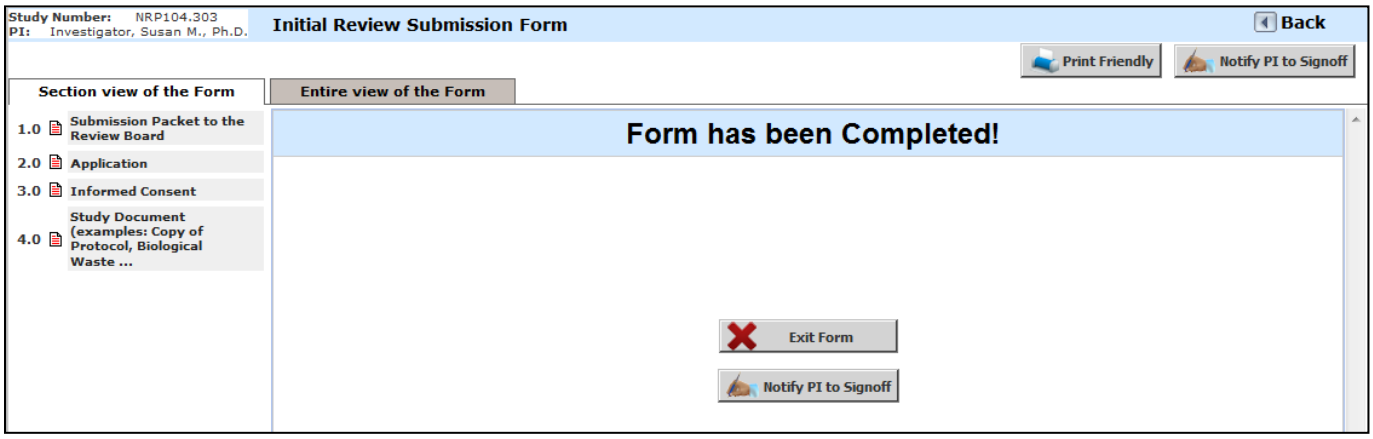
Create Revision

You also have the ability to choose to revise a document. The system will version the document to the next version number, changing the version number from *x*.0 to *x*.1 when you choose to create a revision.

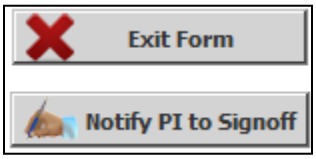
Signoff and Submit

Once the Study Application is complete and the required documents are attached the form is ready to send to the Review Board.

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



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



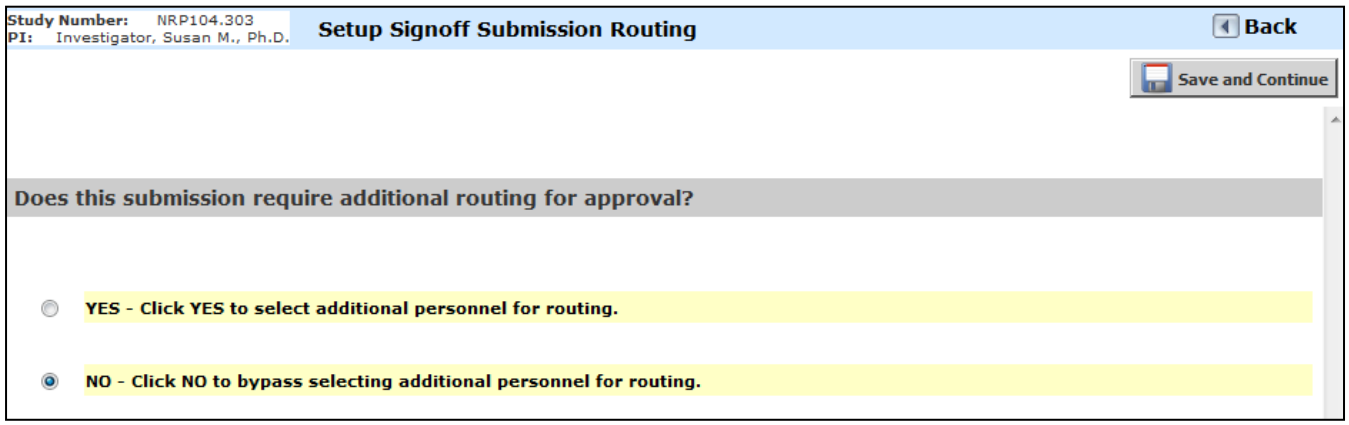
If you are the Principal Investigator, or the form does not require a PI signoff, the **Notify PI to signoff** button will be replaced with **Signoff and Submit**.

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

To initiate the signoff process, click the **Signoff and Submit** or **Notify PI to signoff** button, depending on which is available to you.

You may be prompted to route for additional signatures.

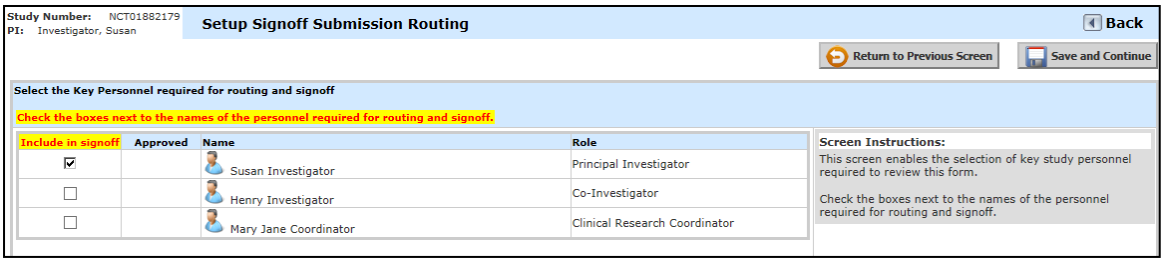
You may choose to route for additional signatures if you need to have other personnel on the study review the form before it reaches the review board and if you need department approval. Make your selection and click the **Save and Continue** button.



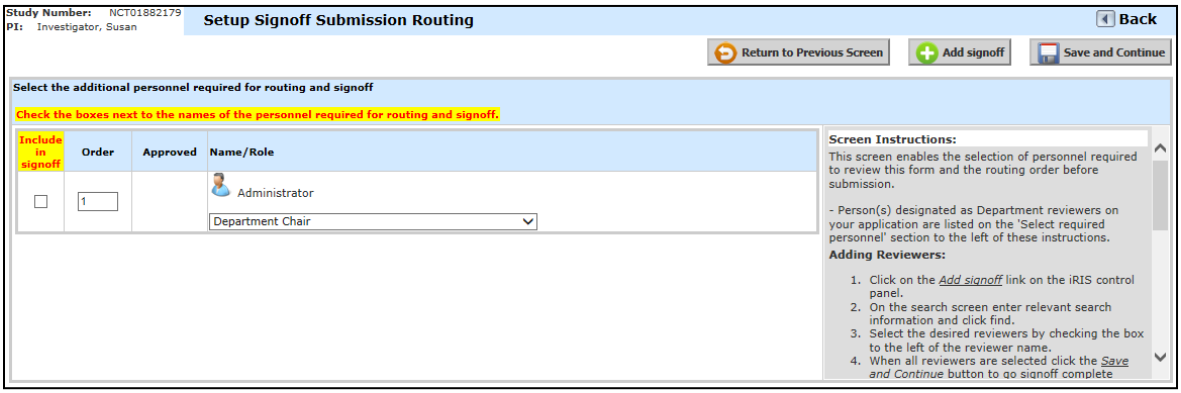
If you opted to route for additional signatures, you will be brought to a page that will list Key Personnel that you can include to signoff. If you chose not to route, you would immediately transition to a signoff page.

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

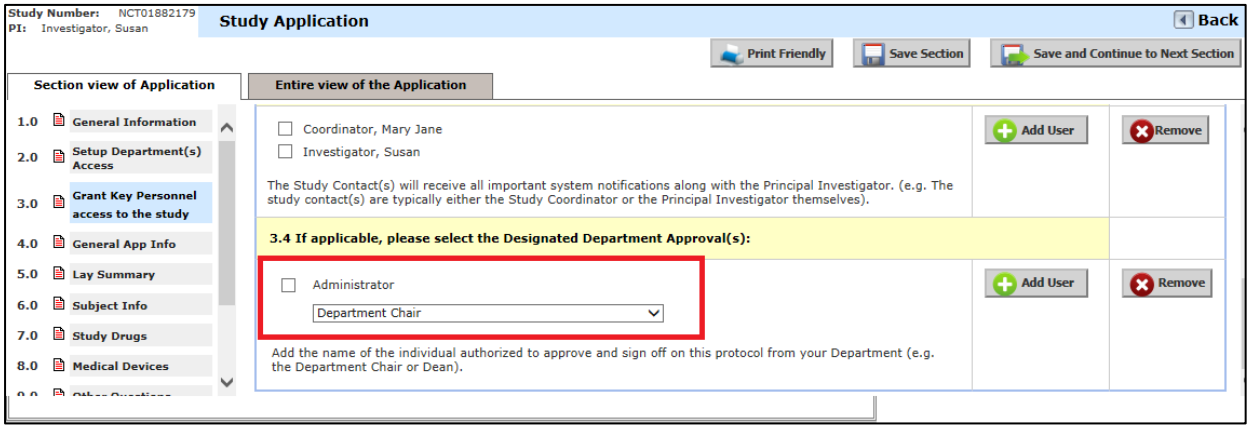
Select check box next to the name(s) of the any additional personnel you would like to include in the signoff process. Click the **Save and Continue** button when you are ready to proceed.



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

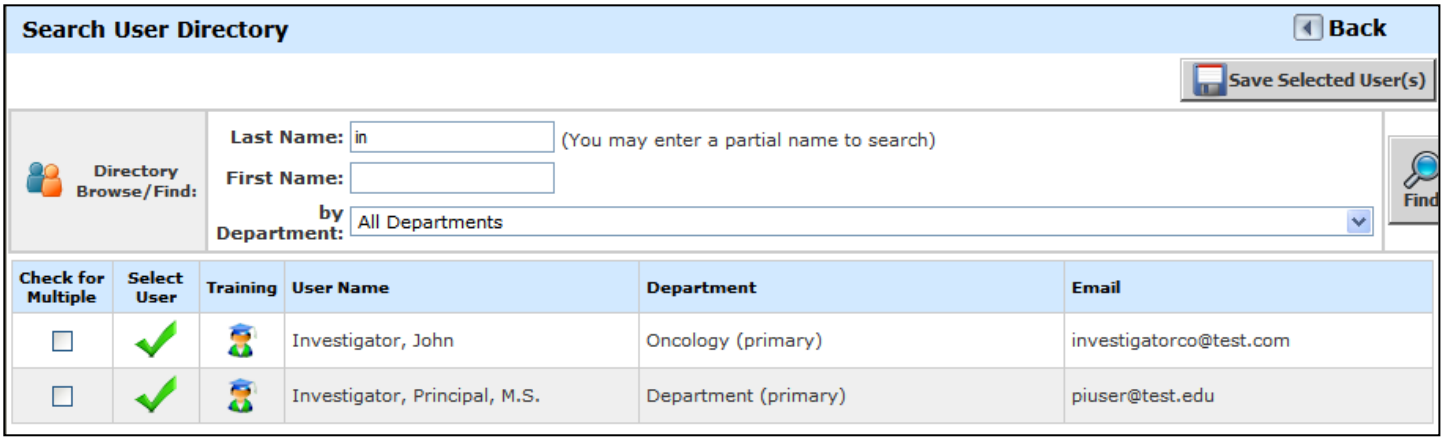


The user in the screenshot above was added in Designated Department Approvals in the Grant Key Personnel section of the Study Application.

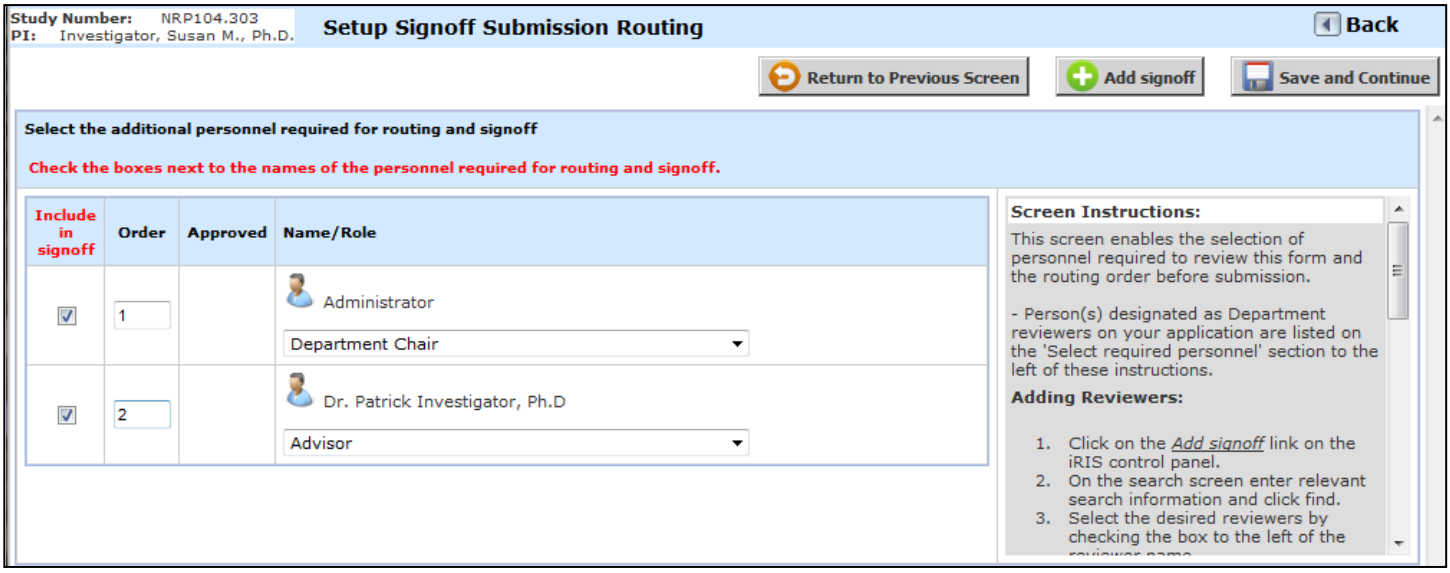


You can also add reviewers from iRIS by clicking the **Add Signoff** button, as shown in the previous screen.

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

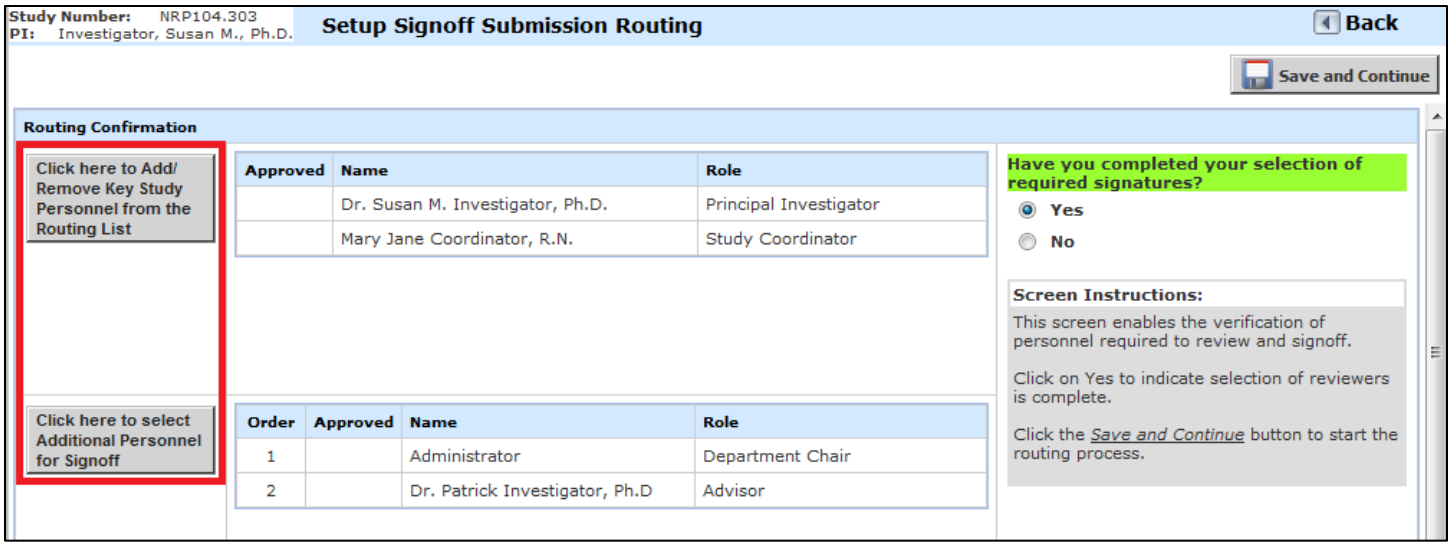


The user you selected will add to the list. Make sure you check the checkbox next to users you want to include in the signoff process. You can also set the **Order** in which the users will receive their signoff task. iRIS will default each user to the order of 1, which means they will all receive their task at the same time. You can change this if one reviewer should receive the task before another. Click the **Save and Continue** button when you are ready to proceed.

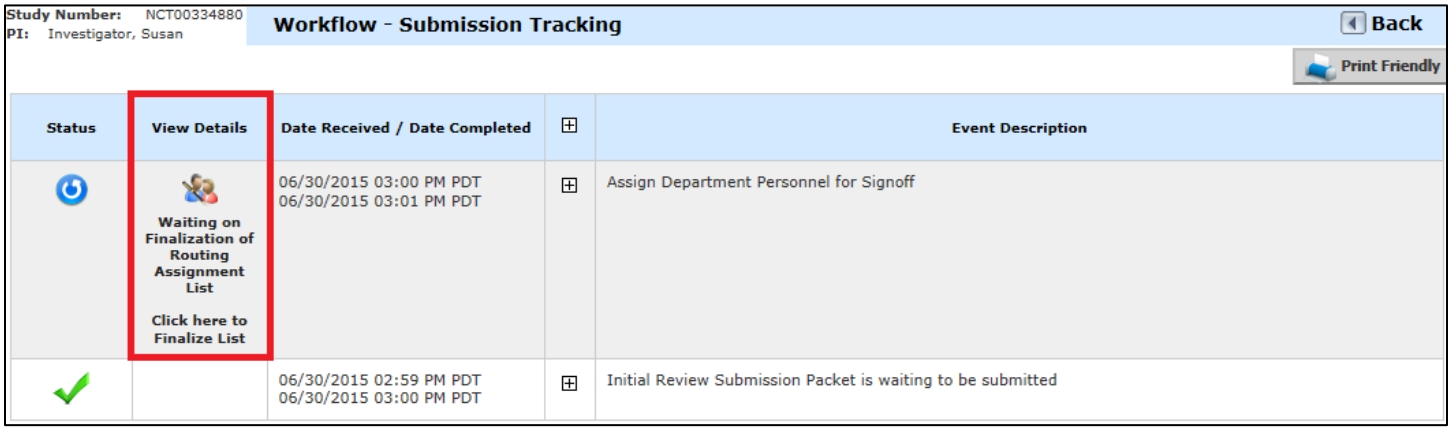


The next page is a summary page, displaying all the users you selected for the signoff process. If you need to add any more signoffs, click the grey button to the left of the Key Study Personnel and Additional Personnel groups. This will open the screen in the second image below, .and allows you to remove 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, click No before clicking **Save and Continue.**



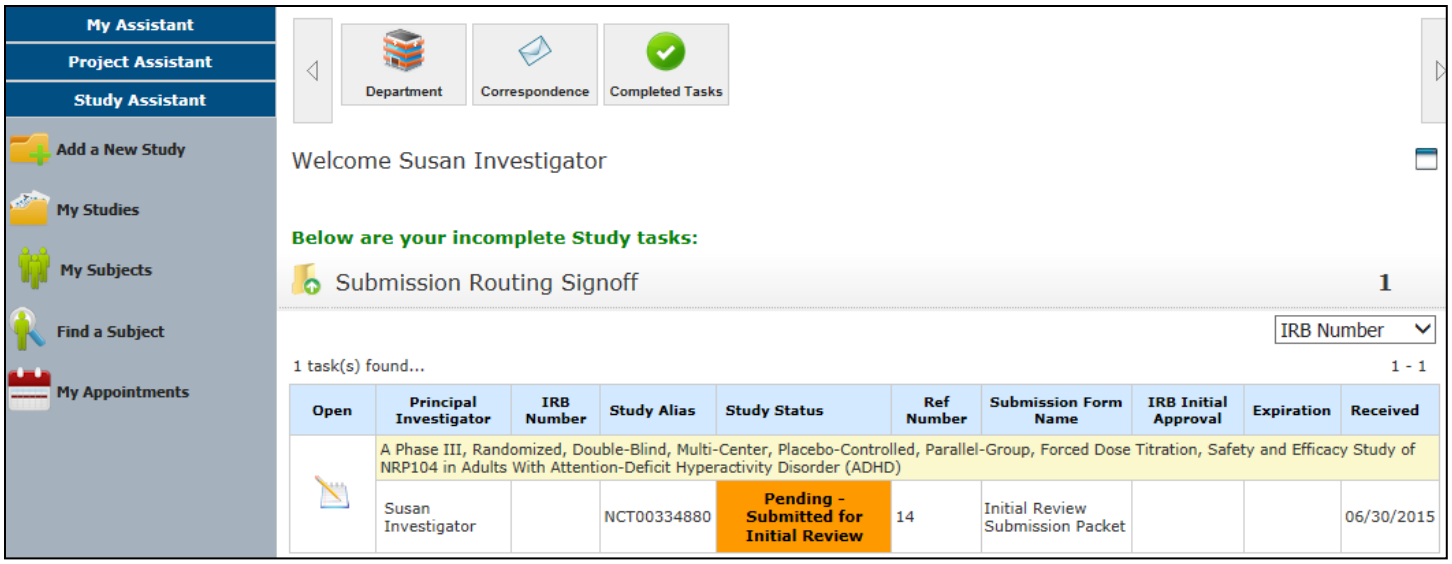
If you choose "No" and click the **Save and Continue** button, you will be brought to the Workflow Submission Tracking page. This page displays the steps your Study Application has taken to date. There is a record on this page 'Assign Department Personnel for Signoff' listed at the top of the page. You can click on the icon in the **View Details** column to return to the Signoff Submission Routing pages.



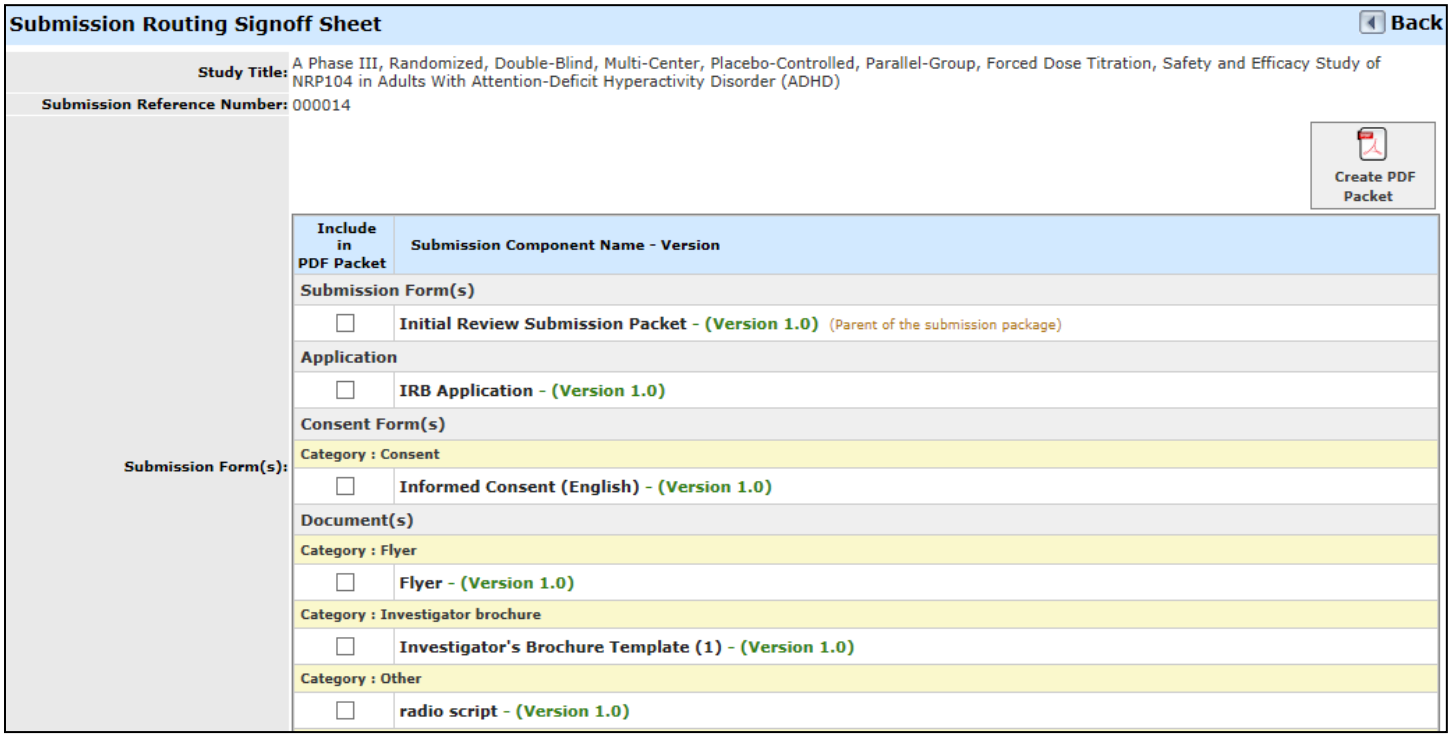
If you choose "Yes" and click the **Save and Continue** button, and you are assigned to sign off on the application, you will be brought to the Signoff Page.

If you choose "Yes" and click the **Save and Continue** button, and you are NOT assigned to sign off on the application, 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 the Initial Review Submission Form/Study Application will receive a notification sent to the email address stored in their user account information. They will also receive a Submission Routing Signoff task on their homepage. This task will remain on their homepage until the user opens the task and completes the sign off.

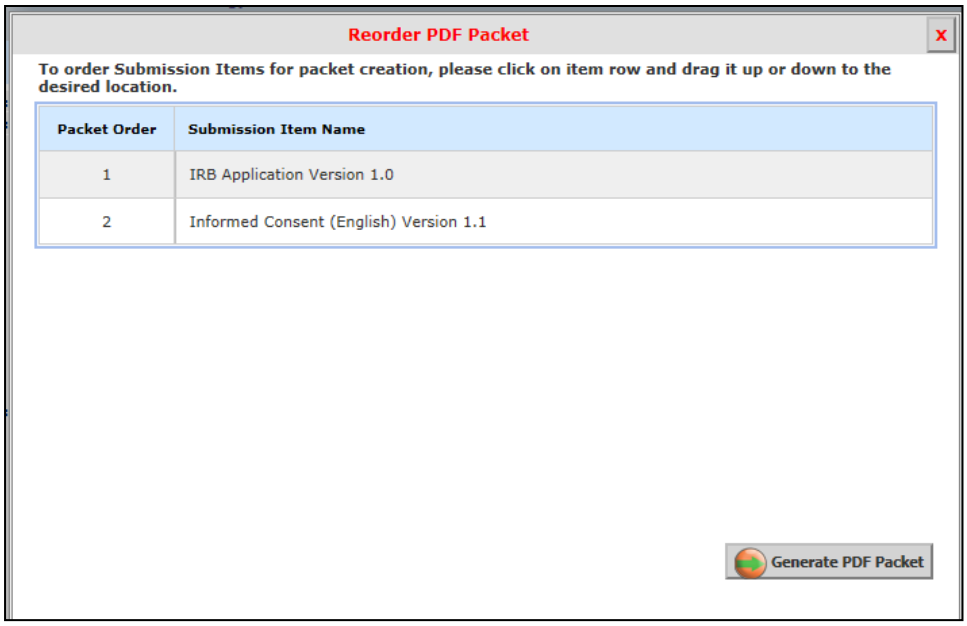


When the task is opened, the Submission Routing Signoff Sheet will display. At the top of the page, the Study Title and Submission Reference Number are listed. iRIS assigns a unique reference number to each form created in the system. The Reference Number displayed here is the number assigned to the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

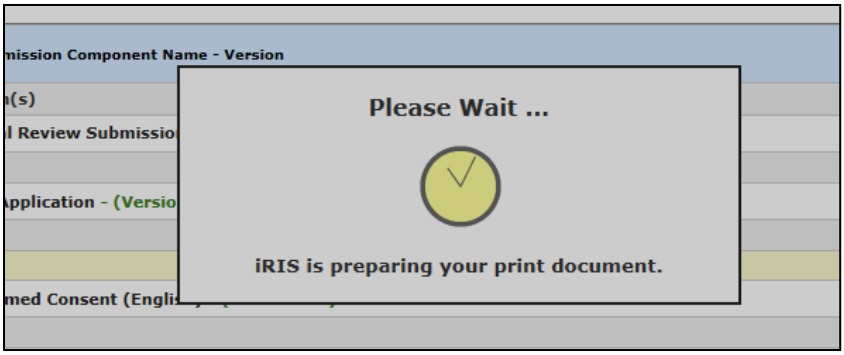


Also listed on this page is a link to the Submission Components. This table contains a link to the Initial Review Submission Form and the Study Application and any Consent and Other Study Document that has been associated to the form. This is the package that is being submitted to the review board for review. Before applying your signature you can review any of the attachments and make any necessary changes.

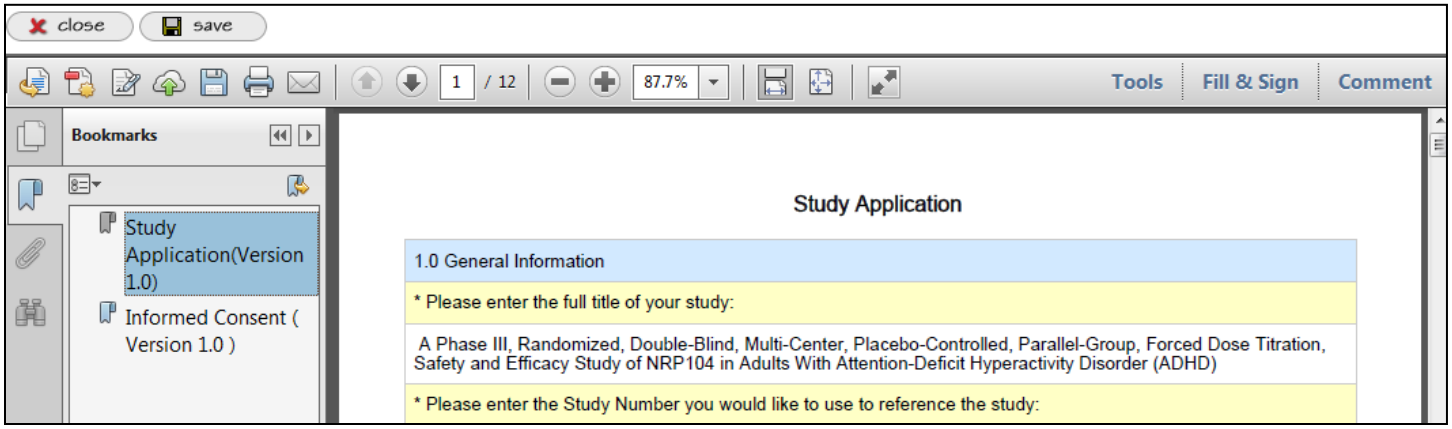
Some of the attachments are available to print. If a document can be printed, a check box will populate next to the document in the **Include in PDF Packet** column. You can select any of these items then click the **Create PDF Packet** button at the top of the table.



A popup window will display the items selected. You can drag the items to reorder them, then click the **Generate PDF Packet** button.

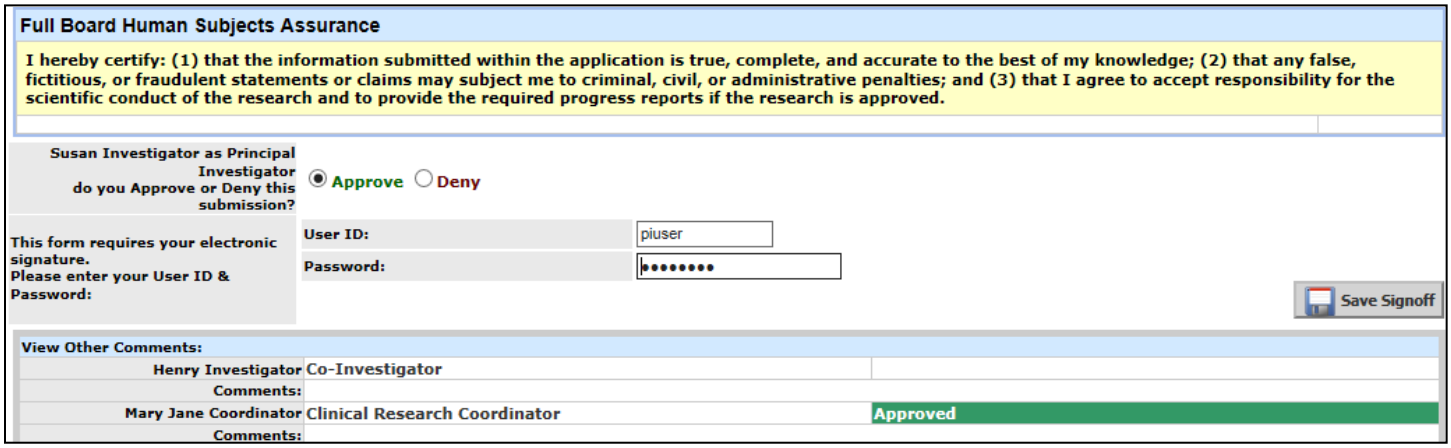


While the system prepares your documents, the screen will be grayed out.

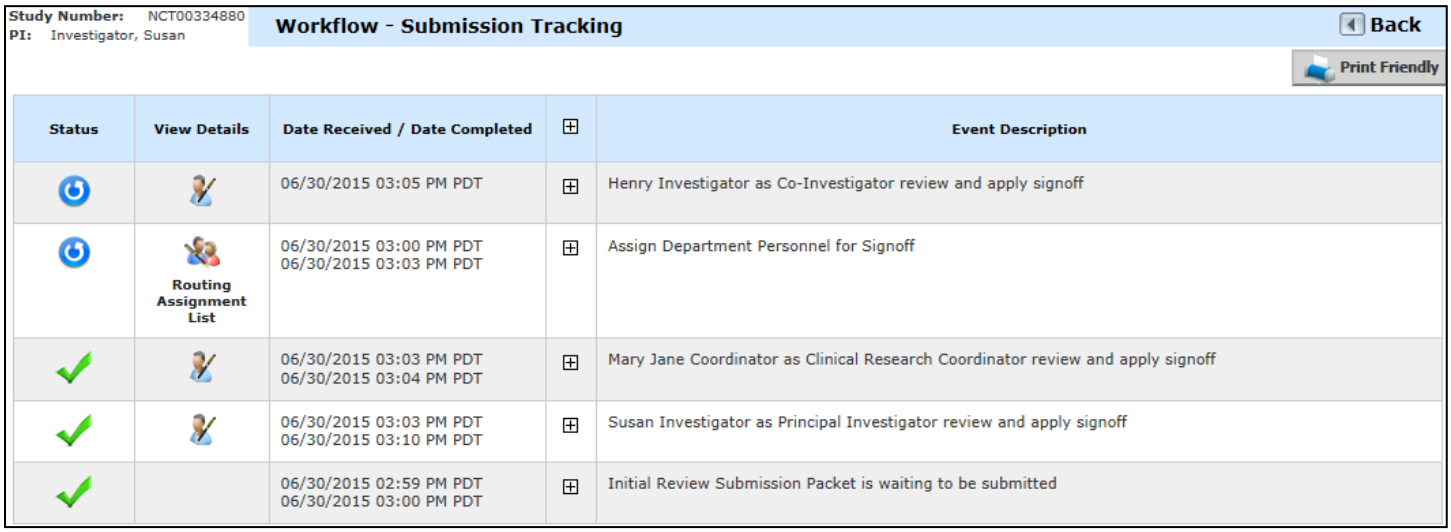


After the PDF is created, it will open in a new window. You can save this PDF or print it. When you are finished, click the **Close** button.

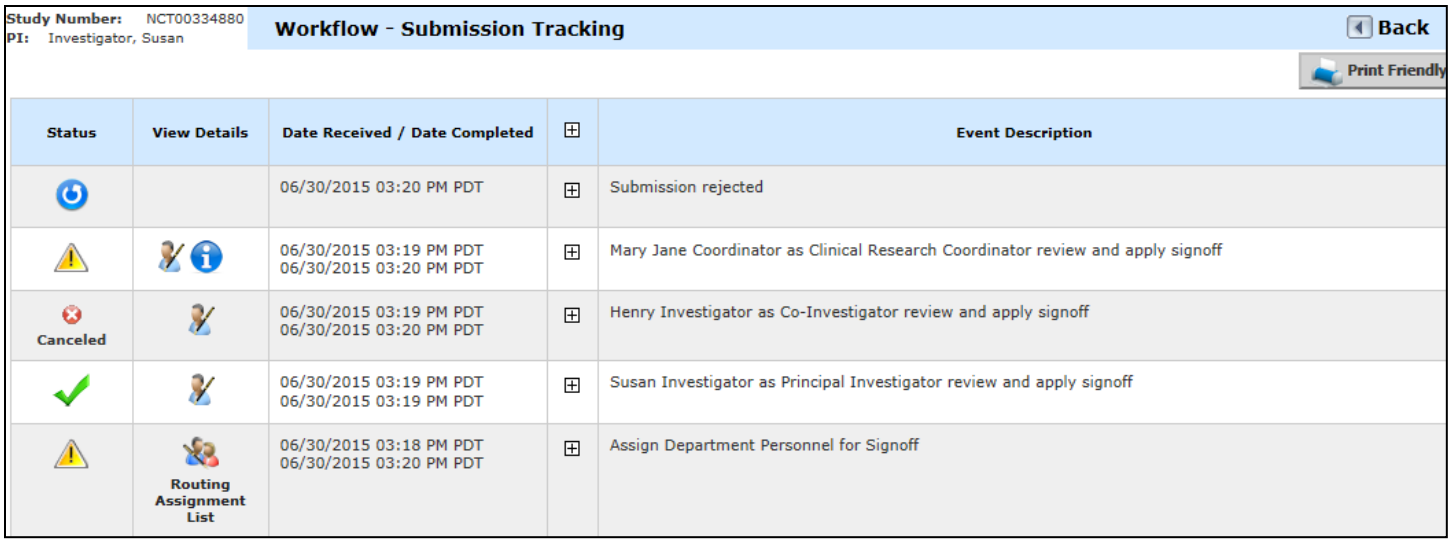
Below Submission Components table you will be able to enter your electronic signature. You must indicate whether you **Approve** or **Deny** the submission then enter your User ID and Password then click on the **Save Signoff** button. Below the electronic signature portion of the page you will be able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



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



If you select **Deny** any other sign off task will cancel.

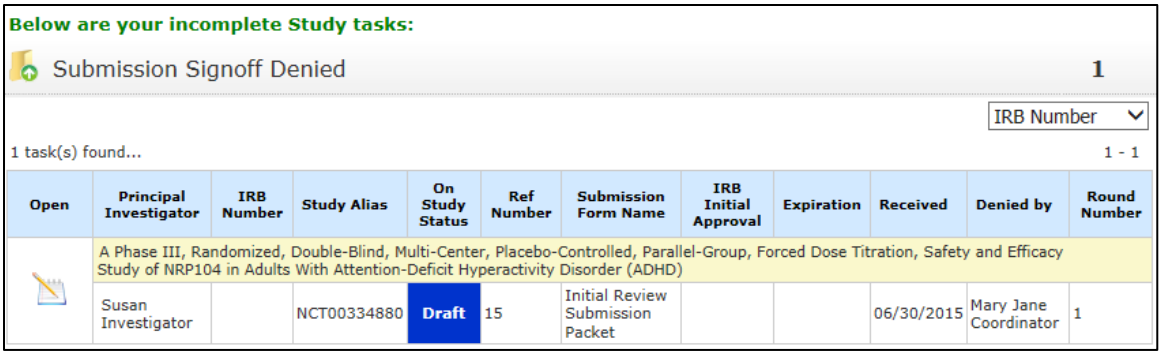


Study Number: NCT00334880
PI: Investigator, Susan

Workflow - Submission Tracking Back Print Friendly

Status	View Details	Date Received / Date Completed	⊞	Event Description
		06/30/2015 03:20 PM PDT	⊞	Submission rejected
		06/30/2015 03:19 PM PDT 06/30/2015 03:20 PM PDT	⊞	Mary Jane Coordinator as Clinical Research Coordinator review and apply signoff
Canceled		06/30/2015 03:19 PM PDT 06/30/2015 03:20 PM PDT	⊞	Henry Investigator as Co-Investigator review and apply signoff
		06/30/2015 03:19 PM PDT 06/30/2015 03:19 PM PDT	⊞	Susan Investigator as Principal Investigator review and apply signoff
	Routing Assignment List	06/30/2015 03:18 PM PDT 06/30/2015 03:20 PM PDT	⊞	Assign Department Personnel for Signoff

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



Below are your incomplete Study tasks:

Submission Signoff Denied 1

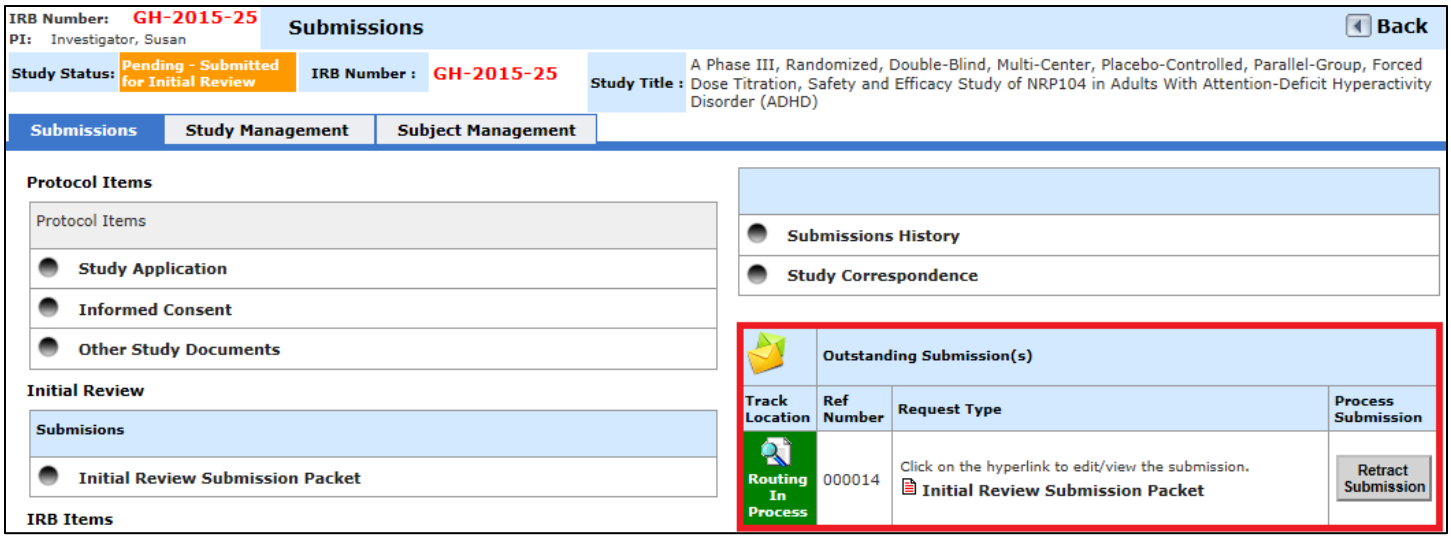
IRB Number

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

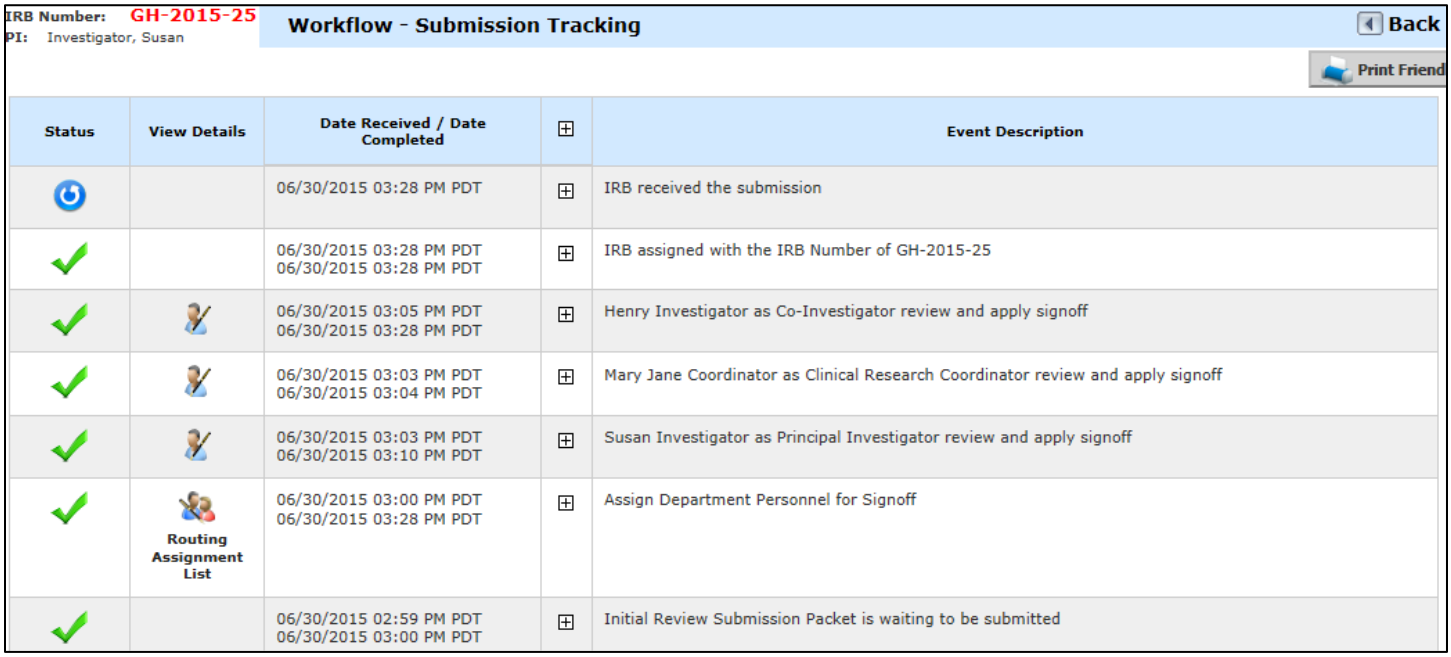
Open	Principal Investigator	IRB Number	Study Alias	On Study Status	Ref Number	Submission Form Name	IRB Initial Approval	Expiration	Received	Denied by	Round Number
	A Phase III, Randomized, Double-Blind, Multi-Center, Placebo-Controlled, Parallel-Group, Forced Dose Titration, Safety and Efficacy Study of NRP104 in Adults With Attention-Deficit Hyperactivity Disorder (ADHD)										
	Susan Investigator		NCT00334880	Draft	15	Initial Review Submission Packet			06/30/2015	Mary Jane Coordinator	1

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

At any time during the sign off process, or while the review board is processing your submission, you can check the status of the form and where it is currently located. Open your study record in My Studies and navigate to the Submissions page. Your submission will display in the Outstanding Submission(s) queue. You can click on the icon in the **Track Location** column.



This will open the same Workflow Submission Tracking screen 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 submission queue.

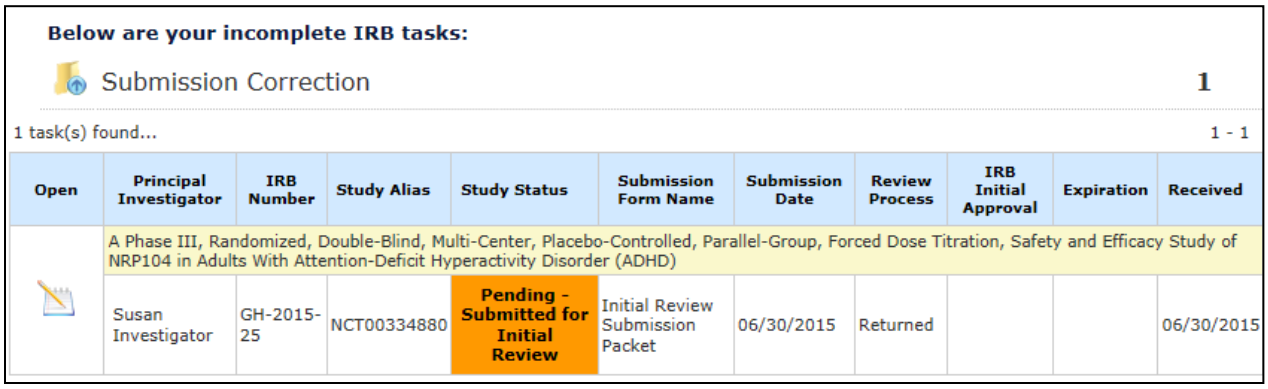


If users you have assigned have not completed their signatures, the Workflow would show that they are still in process. The Principal Investigator and the Study Contact would also receive notifications from the system to alert them that a certain user has not completed signoff yet.

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 resubmit 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 1

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

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)									
	Susan Investigator	GH-2015-25	NCT00334880	**Pending - Submitted for Initial Review**	Initial Review Submission Packet	06/30/2015	Returned			06/30/2015

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 on the top right and the navigation pane on the left side of the page.

Responding to Stipulations

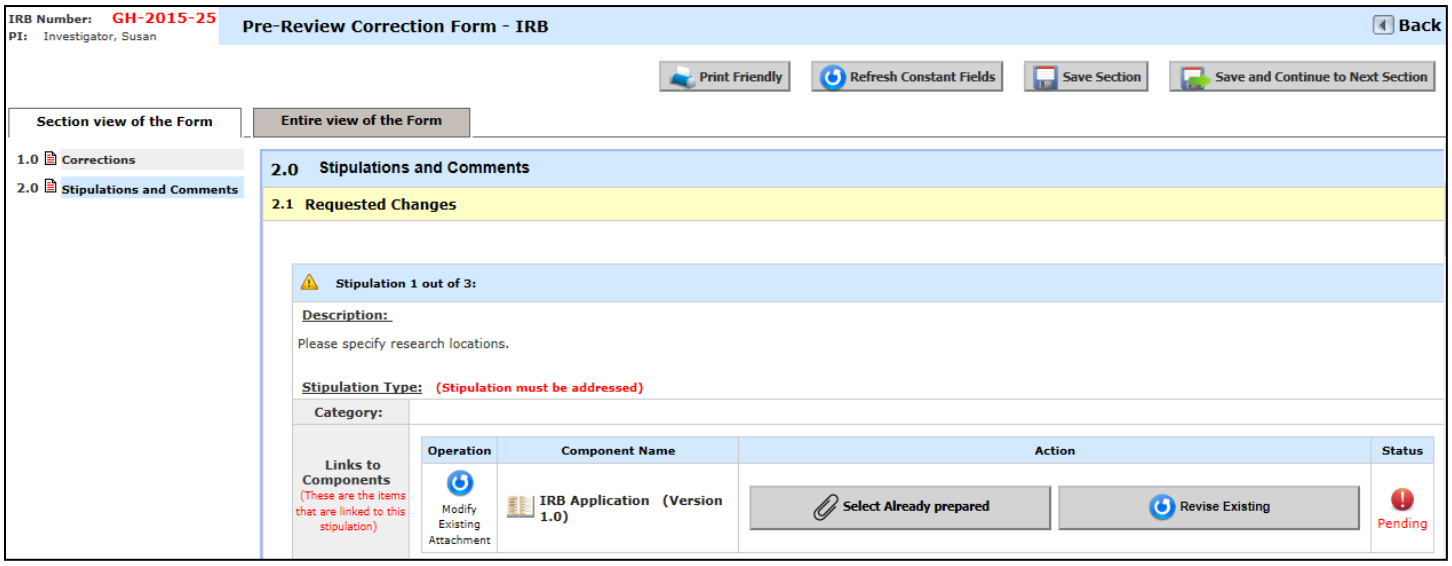
Stipulations Linked to Forms or Documents

The Review Board will post Stipulations to the form. These Stipulations will detail out what they are requesting to be changed, and some stipulations may direct you to a document or form that needs to be changed.

Any stipulations added by the review board will populate within the Pre-Review Corrections form. The **Description** at the top of the stipulation will detail what the review board is requesting for the change.

The **Stipulation Type** will display either **Stipulation must be addressed, Comment must be addressed**, or **Comments**.

Links to Components section of the stipulation will list the details about the linked component(s).



For each linked component, as seen above, you will be given the following:

Operations – A Read-only icon used to distinguish the modification request type.

Component Name – The component the link is associated to.

Action –This is the available corrective action that can be taken on the component.

Status – This is the current state of the requested change as it pertains to the linked component.

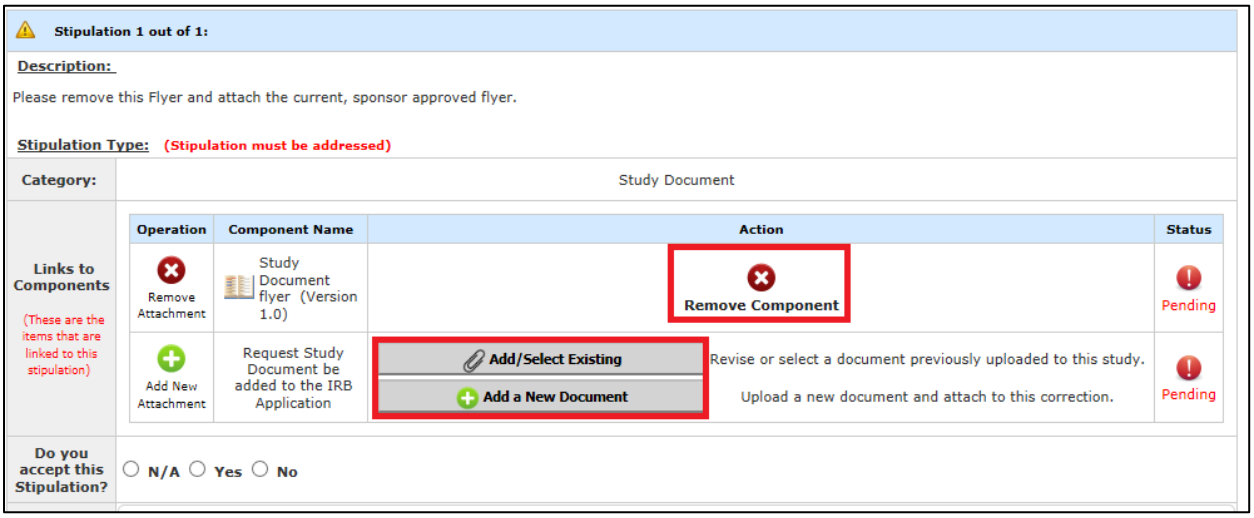
Add and Remove Components

If the stipulation is requesting a document to be added and / or removed from the submission, the stipulation will appear similar to this example.

The first operation is to remove the attachment (Study Documents, Consent Forms, Sub/Attachment forms). In order to remove the study document from the submission, click on the **Remove Component** button located in the Action column. You will be promoted to confirm the removal of document. Click "Yes" to remove.

Note: Removing a document from a submission will not delete the document. The document will still be located in the document library for the study.

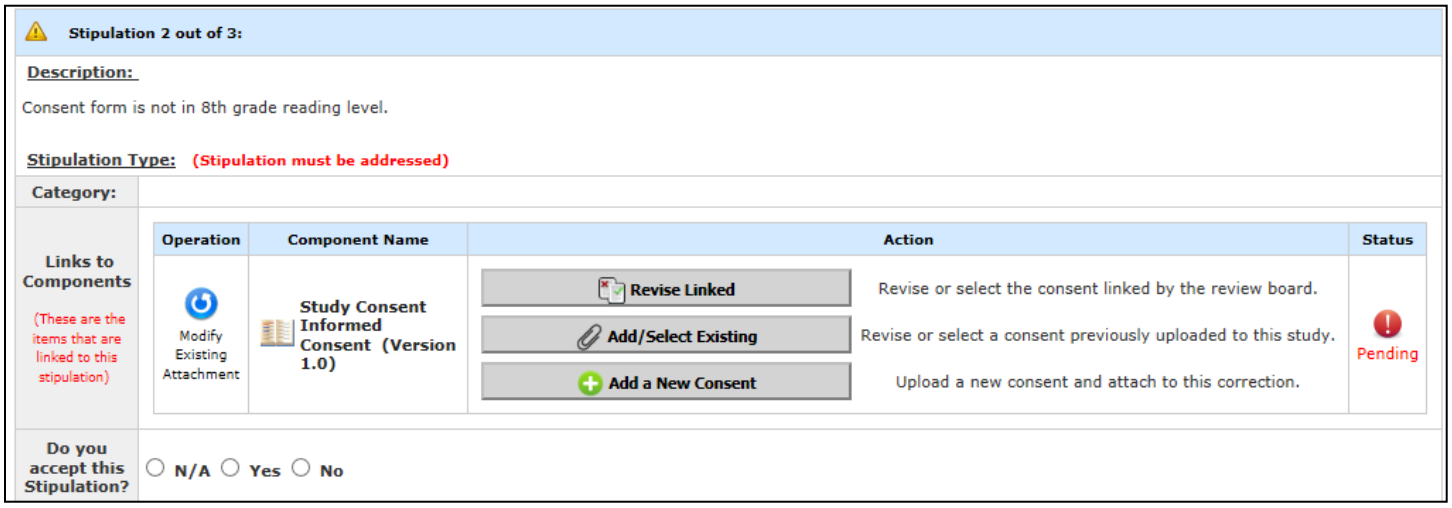
The second operation is to add a new attachment (Study Documents, Consent Forms, Sub/Attachment forms) to the Initial Review form. For this operation you are given multiple options to respond to the request. You can choose to **Select/Revise Existing** or **Add a New Document**. The **Select/Revise Existing** action button will retrieve the study document library where you can select to attach or create a revision of an existing document. The **Add a New Document** action button will allow you to search your local machine for a document that can be uploaded.



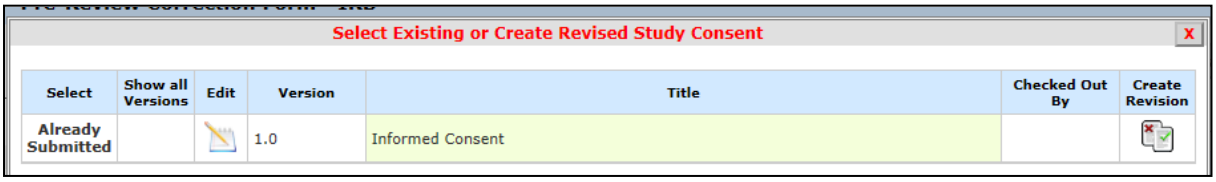
After you have completed the actions associated to each operation the status of those items will move to complete. The Action column of the component will also update as the action is completed. If you need to view or make any other changes to the document you may open the document from the edit/view icon in the Component Name column.

Revise Components – Consents and Other Study Documents

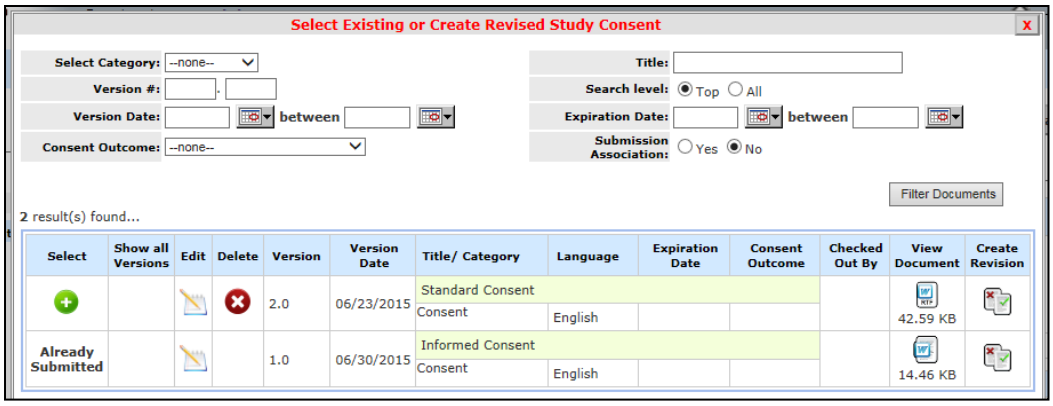
If the submission component is requesting a change to a Consent or Other Study Document already attached, you will be given the ability to modify the details about the document and you can replace the document with your revised document you have saved to your computer or you can associate a completely new document.



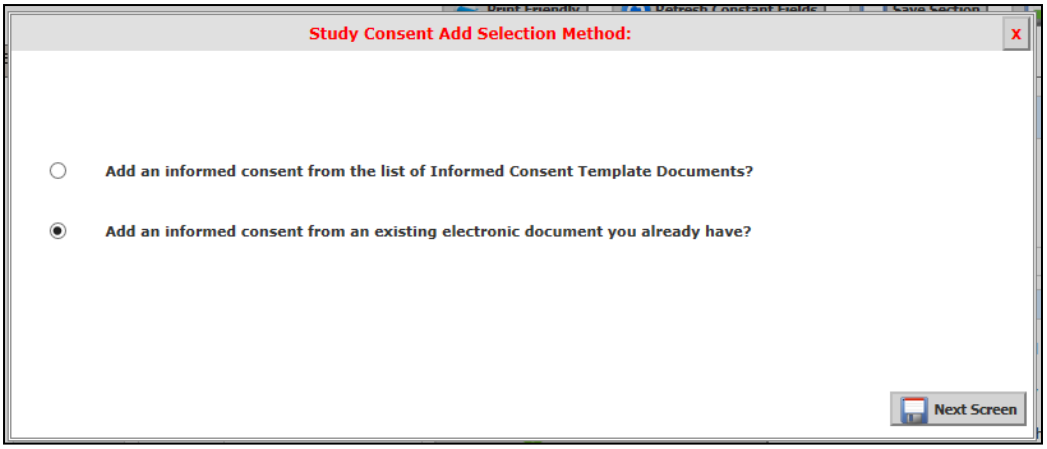
Revise Linked – Select this option to revise the already attached document. You will be given the ability to **Create Revision** and check out the document for modifications.



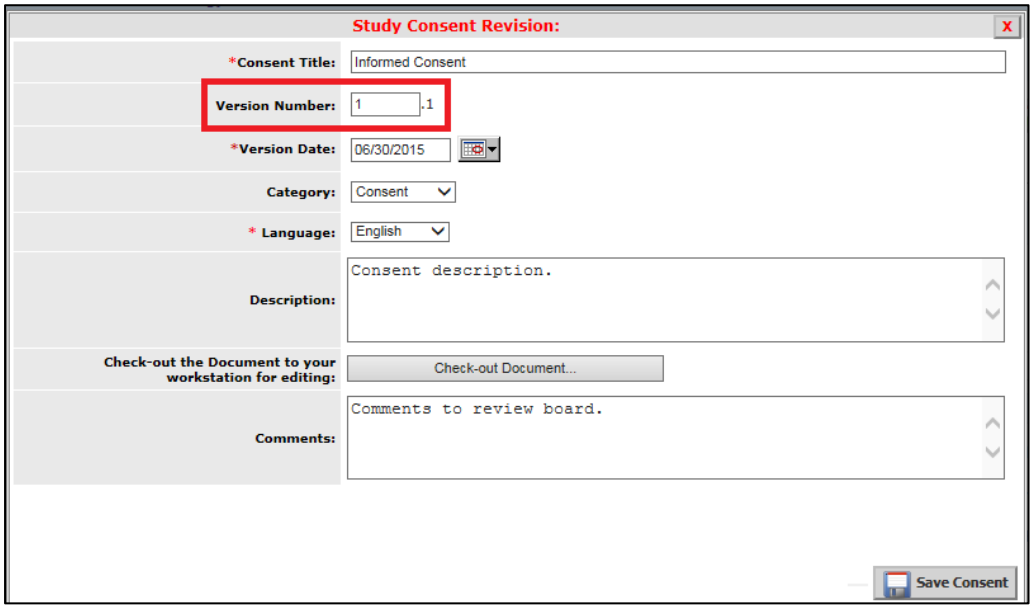
Add/Select Existing – This option will bring up the Consent or Other Study Document library and present you with a list of all documents available to the study. You can revise an already attached document or select a document that has not been attached to the submission.



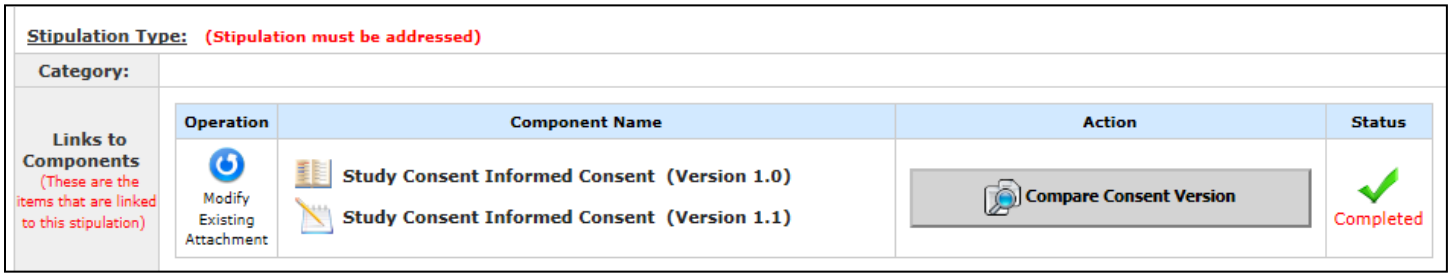
Add a New Consent – This option will provide the steps of adding a brand new consent to the study. If this stipulation is linked to an Other Study Document, you will have the ability to add a new document here as well.



If you select to revise, the system will create the next version of the revised document. An example of a revised Consent form is shown below. You are able to edit any of the fields. The version number updates from 1.0 to 1.1 and you are able to check out the document for edits. Click **Save Changes** to return to the Pre-Review Corrections form.



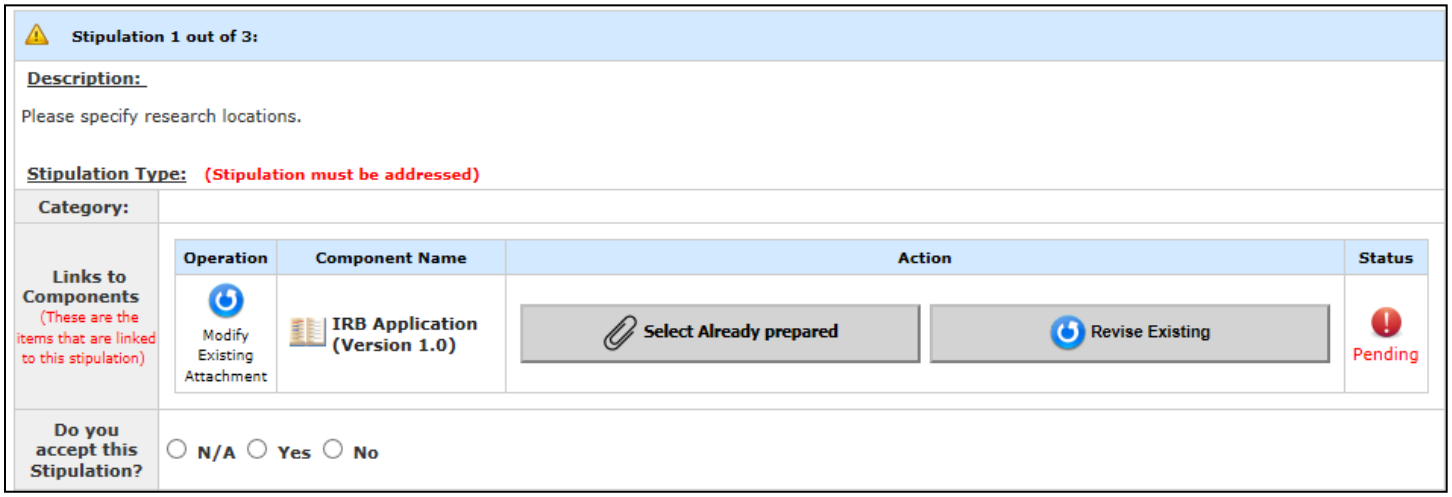
After revising the document or adding a new one, the previous document and the current document will display in the **Component Name** column. You can view the previous document by clicking the link to the document. You can modify the current document by clicking the link to the current document. The **Status** column will update to reflect the action is complete.



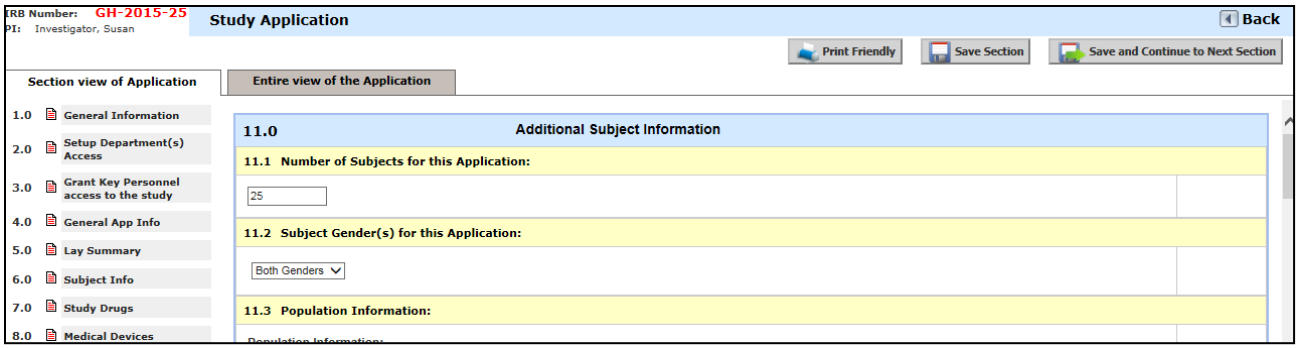
Revise Components – Study Application or Submission Forms

If the submission component is requesting a revision to a Submission Form or a Study Application, the system will create a revision of that form and open the new version for you to make your changes.

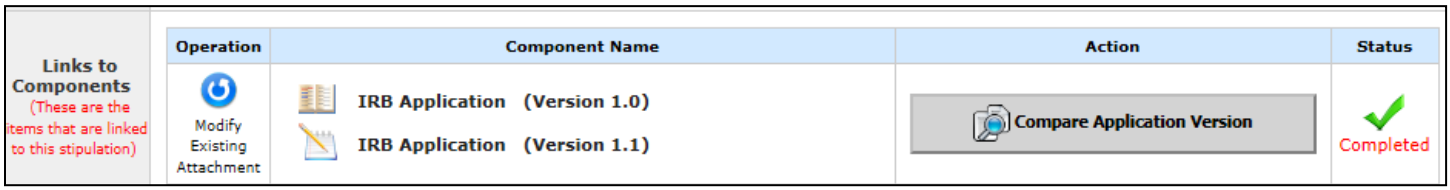
For this operation you are given multiple options to respond to the request. You can choose to **Select Already prepared** or **Revise Existing**. The **Select Already prepared** action button will retrieve the study application library where you can select to attach a newer version of the application. The **Revise Existing** action button will allow you to create a new, editable, version of the application where the changes can be made.



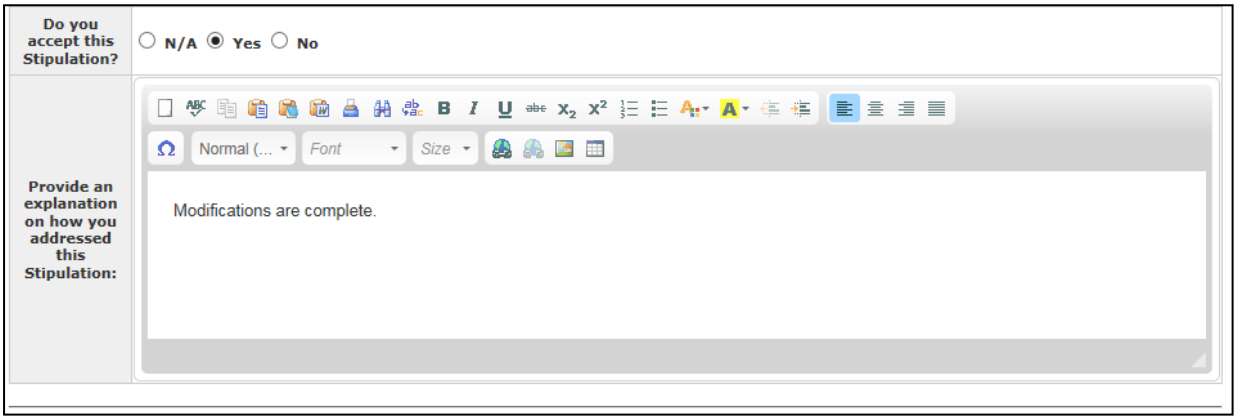
An example of revising the Study Application is shown below. The form being viewed is version 1.1 of the Study Application. You would make any necessary changes then click on the **Back** button to return to the Pre-Review Corrections Form.



After revising the form or selecting an already prepared form, both versions will display in the **Component Name** column. You can view either item by clicking on their names. The **Status** column will update to reflect the action is complete.



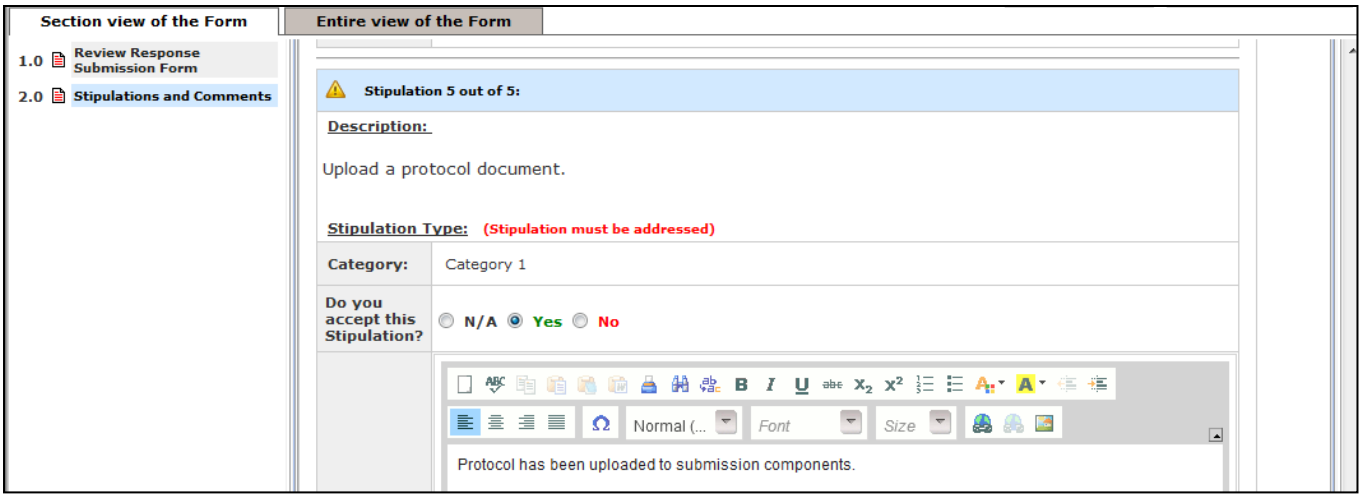
After you make the requested changes based on the stipulation, you then indicate how you accept the stipulation by answering N/A, Yes or No to **Do you accept this Stipulation?** You can also add an explanation to how the stipulation was addressed in the text editor.



Stipulations Not Linked to Forms or Documents

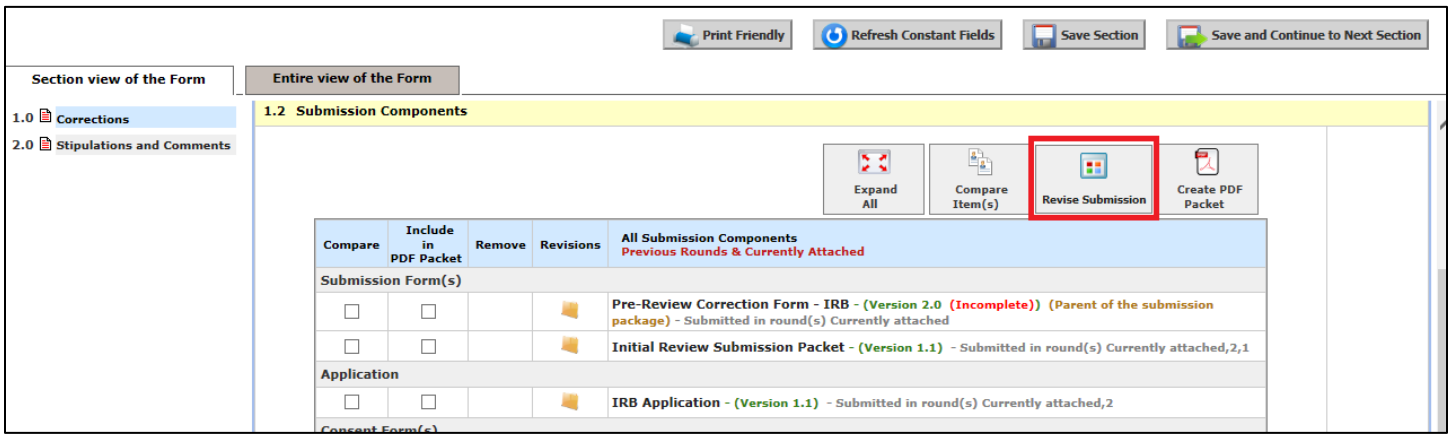
Some stipulations from the review board may ask you to upload a document that was not originally submitted. If this is the case, the stipulation will be listed with other stipulations within the form, but there will be no associated item to revise.

You can respond to the stipulation by indicating “N/A”, “Yes”, or “No” and adding your explanation, then you can locate the Submission Components data value within the form to upload the item requested by the review board.



Submission Components

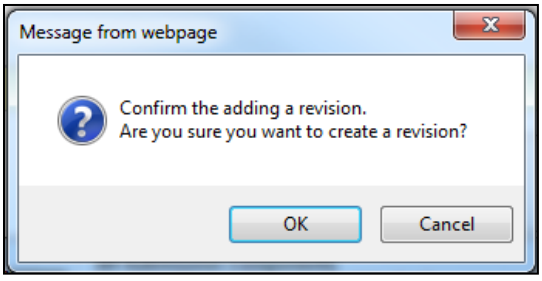
Listed in this form will be a list of your current submission components. You can modify or remove items from this screen as needed. This table will update with any revisions made to components through the stipulations. The screenshot below shows an update to the IRB Application (version 1.1 instead of 1.0).



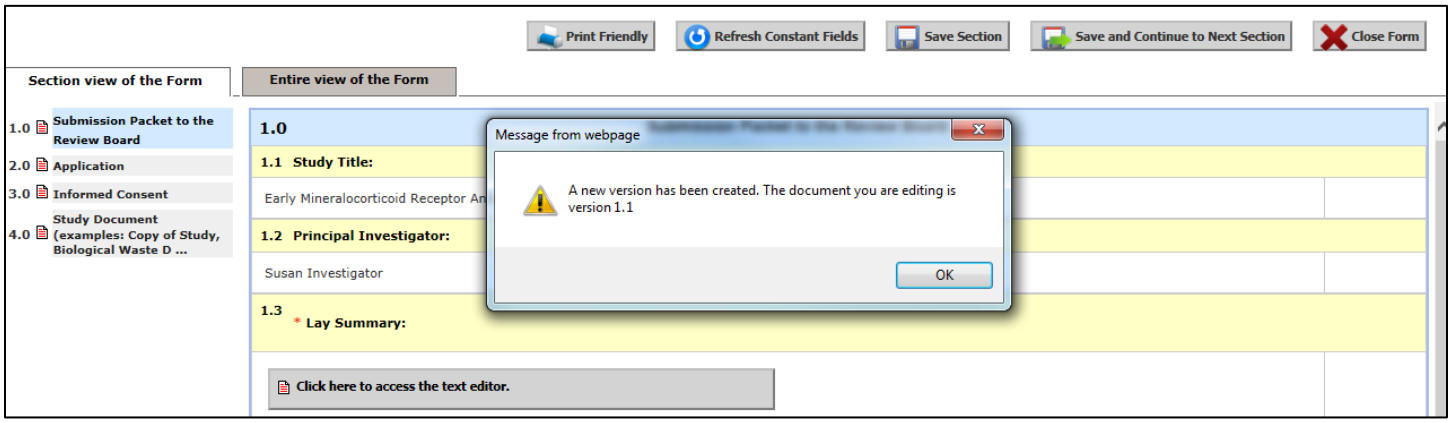
If you need to make corrections or add items to the submission that were not included in the Stipulations, you could revise the Initial Review form and make any necessary changes. To initiate this process, you must first revise the Initial Review so that you can add attachments or modify existing items.

Note: This functionality is only available if the property “system.use_response_wizard_window” within System Administration -> System Configuration -> System Signoff and Submission Settings is set to “Yes”.

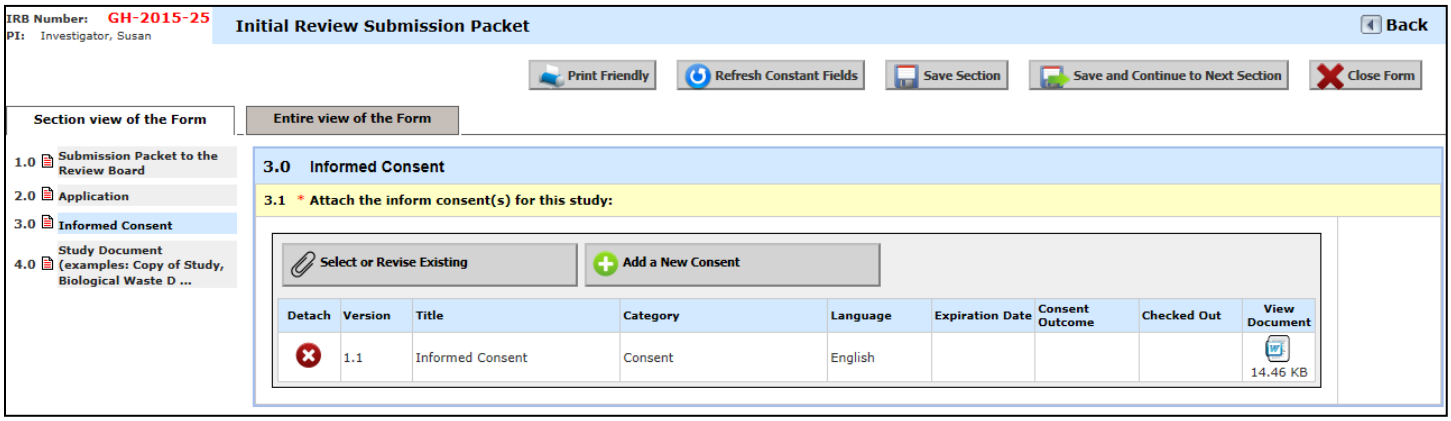
Click the **Revise Submission** button located above the submission components.



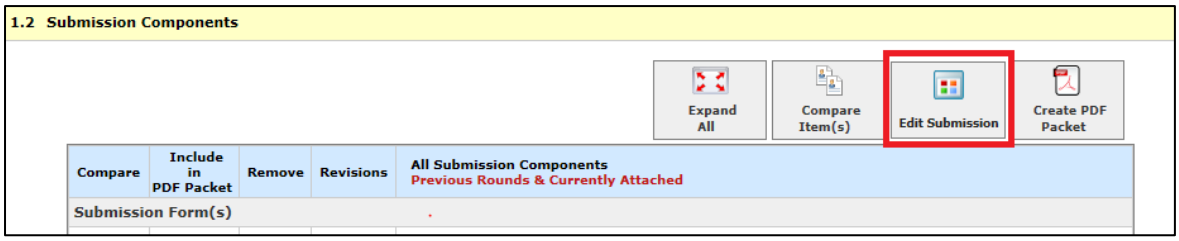
You will be asked to confirm adding a revision. Select the **OK** button.



Selecting the **OK** button will open the Initial Review, and a message informing you that you are editing the next version of the form.



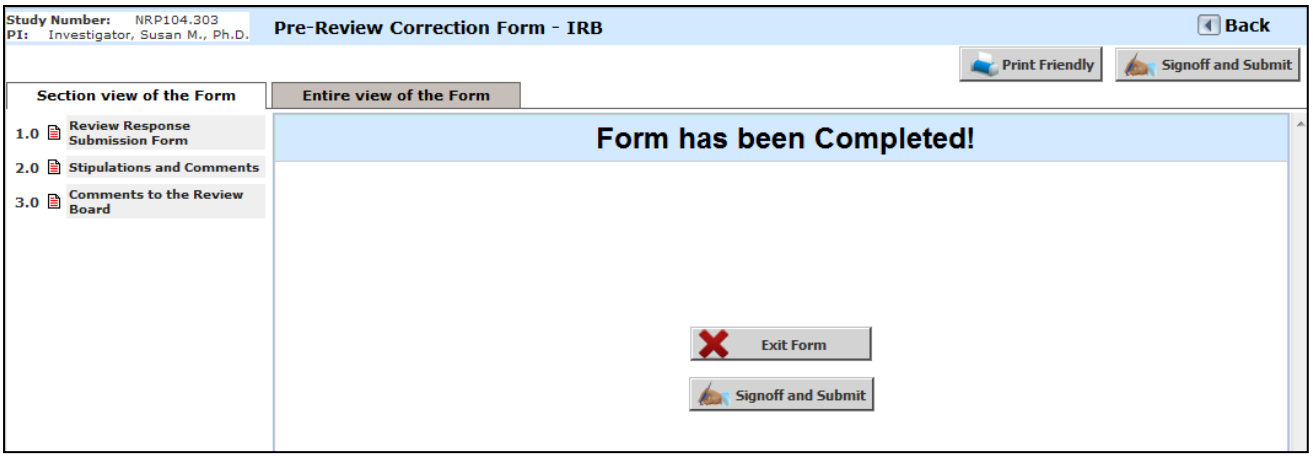
You will be able to navigate to any section within the submission, to access the Application, Consents, and Other Study Document attachments. From each section you can add or revise associated items, just as you did when you initially completed the Initial Review form.



Note: Once the Initial Review has been revised, the button within Submission Components will now read **Edit Submission**.

Return the Form to the Review Board

When you are finished modifying items and responding to stipulations, and you save and continue through the rest of the form, the system will alert you that the form has been completed.



At this point you can choose to **Exit Form** and return later to finish any additional corrections (if you do this, the Submission Correction task will stay on your homepage) or you can click the **Signoff and Submit** button to initiate the signoff. Once you complete the signoff, the Submission Correction task will remove from your incomplete tasks on your homepage. The review board will receive your corrections and will further process your submission. If any additional changes are requested, the review board will return the submission for another round of changes. At that point, you would receive a new Submission Correction task and notification from the system.