



STUDY ASSISTANT

Adding a New Study & Submitting to the Review Board

Version 10.03

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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.

Select New Study Application Form Back

Cancel and Return Start selected Application

Please select a New Study Application from the list below:

Study Forms:

- Study Application
- IBC Application
- IACUC Application
- SRB Application
- RSC Application
- Initial Application

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.

The screenshot shows the 'Study Application' interface. At the top, there is a 'Back' button and two main action buttons: 'Save Section' and 'Save and Continue to Next Section'. Below these are two tabs: 'Section view of Application' and 'Entire view of the Application'. The left sidebar shows a tree view with '1.0 General Information' selected. The main content area is titled '1.0 General Information' and contains three sections:

- A yellow header: '* Please enter the full title of your study:' followed by a large text input field.
- A yellow header: '* Please enter the Study Number you would like to use to reference the study:' followed by a text input field. Below it is a note: '* This field allows you to enter an abbreviated version of the Study Title to quickly identify this study.'
- A yellow header: 'Is this Study using Subject Management?' followed by radio buttons for 'Yes' and 'No' (which is selected).

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 screenshot shows the 'Study Application' interface for Section 2.0. At the top, it displays 'Study Number: NCT01882179' and 'PI:'. There are buttons for 'Print Friendly', 'Save Section', and 'Save and Continue to Next Section', along with a 'Back' button. The tabs 'Section view of Application' and 'Entire view of the Application' are visible. The left sidebar shows a tree view with '2.0 Setup Department(s) Access' selected. The main content area is titled '2.0 Add Department(s)' and contains a section '2.1 List departments associated with this study:' with a table:

Primary Dept?	Department Name			
<input type="checkbox"/>	<input checked="" type="radio"/>	GH - Oncology	<input type="button" value="+ Add"/>	<input type="button" value="X Remove"/>

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.

Search for the Department that you would like to choose by entering Department Code , Department Name or School Code in the search box.
 If you already have Departments added they will not appear here again.

Department Name Institution Name
 Dept Code School Code

7 result(s) found... 1 - 7

Select	Department Name	Institution	School Code	Department Code
<input type="checkbox"/>	GH- Dematology	General Hospital		
<input type="checkbox"/>	GH- Gastroenterology	General Hospital		
<input type="checkbox"/>	GH- Internal Medicine	General Hospital		
<input type="checkbox"/>	GH- Pediatrics	General Hospital		
<input type="checkbox"/>	GH- Allergy and Immunology	General Hospital		
<input type="checkbox"/>	GH- Infectious Diseases	General Hospital		
<input type="checkbox"/>	GH- Neurology	General Hospital		

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.

Study Number: NCT01882179
 PI: Study Application

Section view of Application Entire view of the Application

1.0
 2.0 **2.0 Add Department(s)**

2.1 List departments associated with this study:

Primary Dept?	Department Name	<input type="button" value="+ Add"/>	<input type="button" value="X Remove"/>
<input type="checkbox"/> <input checked="" type="radio"/>	GH - Oncology		
<input type="checkbox"/> <input type="radio"/>	GH - Cardiology		

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.

Study Number: NCT01882179
 PI: **Study Application** Back

Print Friendly Save Section Save and Continue to Next Section

Section view of Application

- 1.0 General Information
- 2.0 Setup Department(s) Access
- 3.0 Grant Key Personnel access to the study

Entire view of the Application

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

3.1 * Please add a Principal Investigator for the study:

3.2 If applicable, please select the Research Staff personnel:

A) Additional Investigators	<input type="button" value="+ Add User"/>
B) Research Support Staff	<input type="button" value="+ Add User"/>

3.3 * Please add a Study Contact:

The Study Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g. The study contact(s) are typically either the Study Coordinator or the Principal Investigator themselves).

3.4 If applicable, please select the Designated Department Approval(s):

Add the name of the individual authorized to approve and sign off on this protocol from your Department (e.g. the Department Chair or Dean).

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.

Study Number: NRP104.303
 PI: **Search User Directory** Back

Save Selected User(s)

Directory
Browse/Find:

Last Name: (You may enter a partial name to search)

First Name:

by Department:

Check for Multiple	Select User	Training	User Name	Department	Email
<input type="checkbox"/>	<input checked="" type="checkbox"/>		Investigator, P	Department (primary)	
<input type="checkbox"/>	<input checked="" type="checkbox"/>		Investigator, Patrick, Ph.D	Department (primary)	pi@irisgh.edu
<input type="checkbox"/>	<input checked="" type="checkbox"/>		Investigator, Susan M., Ph.D.	Department (primary)	sinvestigator@irisgh.edu

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:

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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.

3.2 If applicable, please select the Research Staff personnel:	
A) Additional Investigators	<input type="button" value="+ Add User"/> <input type="button" value="X Remove"/>
<input type="checkbox"/> Investigator, Patrick, Ph.D. <input type="text" value="Co-Investigator"/>	

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.

B) Research Support Staff	<input type="button" value="+ Add User"/> <input type="button" value="X Remove"/>
<input type="checkbox"/> Coordinator, Mary Jane, R.N. <input type="text" value="Study Coordinator"/>	
<input type="checkbox"/> Staff, Stacy <input type="text" value="Nurse"/>	

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.

3.3 * Please add a Study Contact:	
<input type="checkbox"/> Coordinator, Mary Jane, R.N. <input type="checkbox"/> Investigator, Susan M., Ph.D.	<input type="button" value="+ Add User"/> <input type="button" value="X Remove"/>
<small>The Study Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g. The Study Contact(s) are typically either the Study Coordinator or the Principal Investigator themselves).</small>	

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.

3.4 If applicable, please select the Designated Department Approval(s):	
<input type="checkbox"/> Administrator <input type="text" value="Department Chair"/>	<input type="button" value="+ Add User"/> <input type="button" value="X Remove"/>
<small>Add the name of the individual authorized to approve and sign off on this protocol from your Department (e.g. the Department Chair or Dean).</small>	

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.

3.5 If applicable, please select the Administrative Assistant(s):		
<input type="checkbox"/> Staff, Tim	<input type="button" value="+ Add User"/>	<input type="button" value="x Remove"/>

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

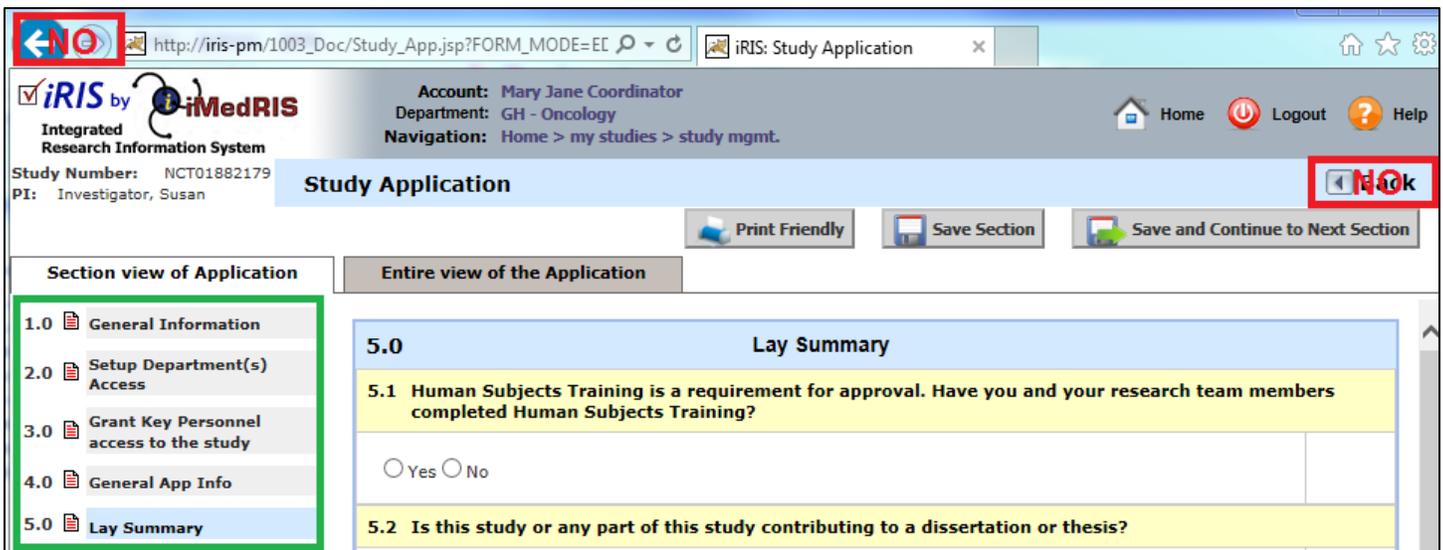
The sections in the application following the initial three sections are customized based on the configuration of your Study Application.

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.

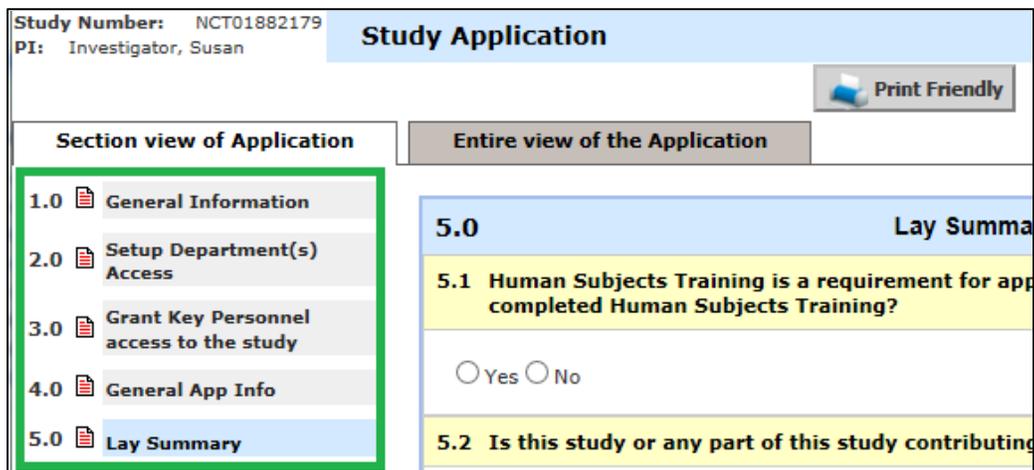
Throughout the application you may be asked to provide details for different aspects of the Study. Unique data values that capture this information are detailed below. These data values are defined in the form in the System Forms Designer by your System Administrator and may or may not be present in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

Notes regarding forms navigation

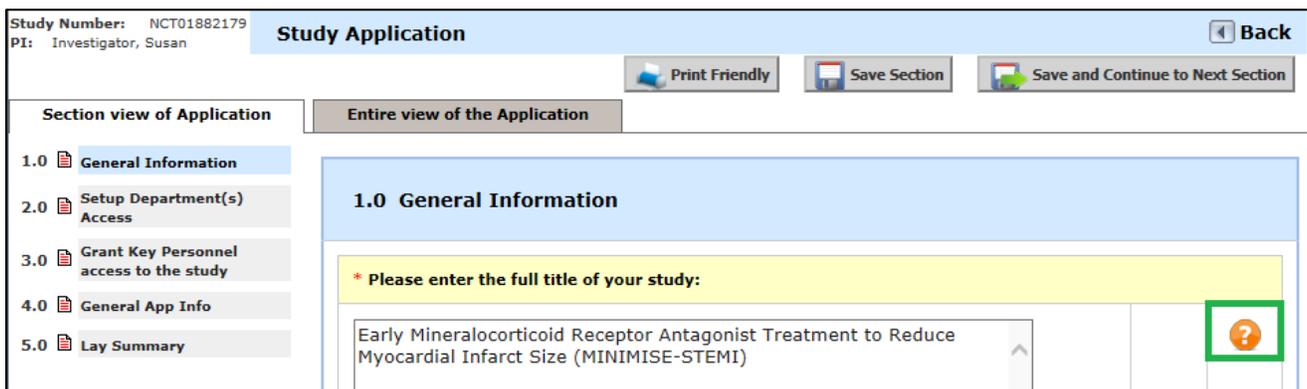
Back Button: When constructing the Study Application, it is important to remember that if you need to return to the previous section, DO NOT hit the Back button on your Internet Browser. To properly navigate to the previous section, click on the link for that section in the navigation pane.



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.



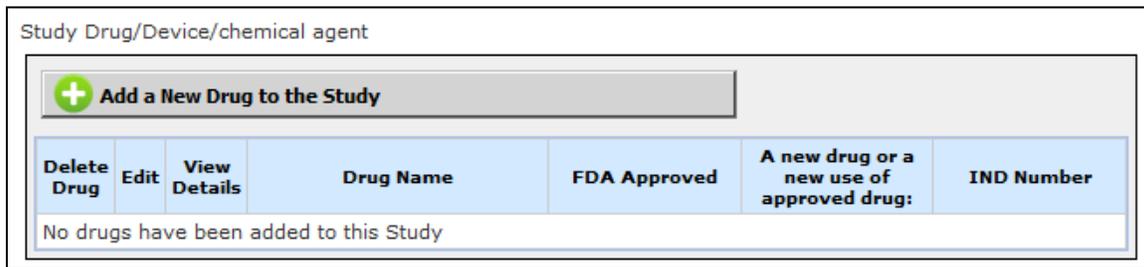
Help Icons: Some of the sections will contain help icons. Click on the icon to open a window, this will list available information about a certain question.



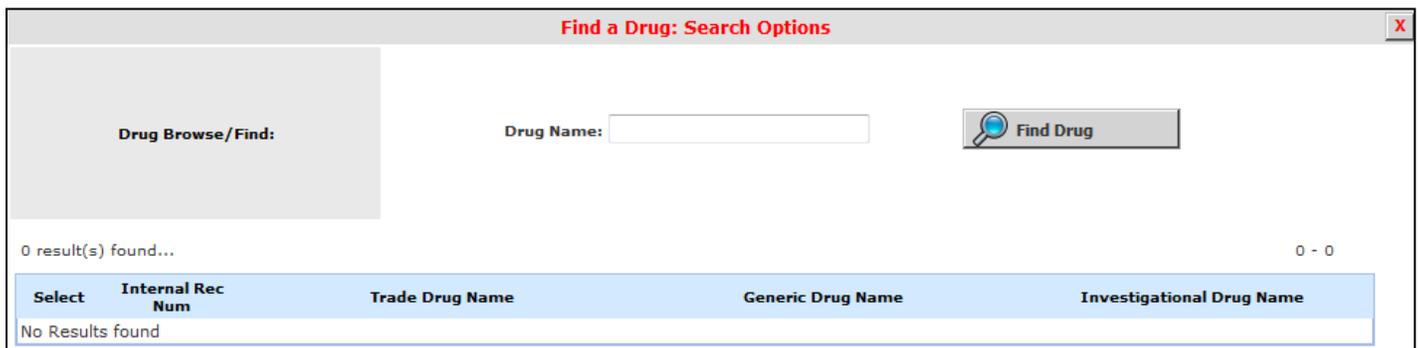
Study Drugs

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.

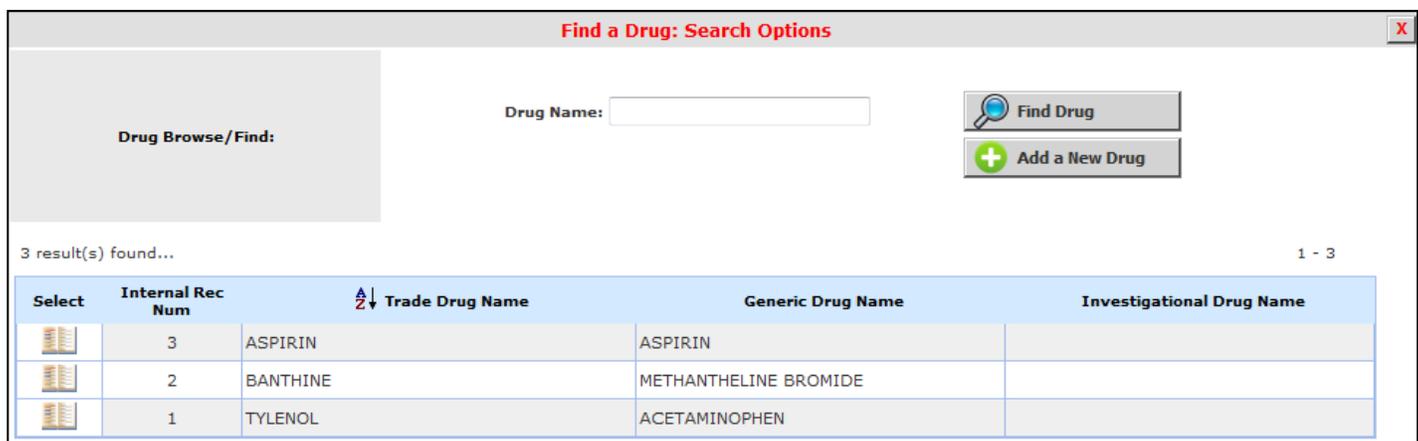


A popup window will open within your browser, as seen in the image below, allowing you to search the system for the drug you would like to add to the study. You can enter in all or part of the Drug Name or leave that field blank and click the **Find Drug** button to return all drugs in the system.



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.

Add a New Drug

Trade Drug Name: Ritalin

Generic Name: Methylphenidate

If not yet named, Investigational Drug Name:

Save Drug Info

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.

Study Drug Details:

Trade Drug Name: Ritalin

Generic Drug Name: Methylphenidate

Investigational Drug Name:

Identify the name of the manufacturer or source of investigational drug/biologic:

Is the drug supplied at no cost? Yes No

Is the Drug FDA Approved: Yes No

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

Is an IND necessary: Yes No

IND Number:

Who holds the IND: N/A Pharmaceutical company PI

Save Drug Info

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 Drug/Device/chemical agent

 **Add a New Drug to the Study**

Delete Drug	Edit	View Details	Drug Name	FDA Approved	A new drug or a new use of approved drug:	IND Number
			Trade Drug Name: Ritalin Generic Drug Name: Methylphenidate Investigational Drug Name:	Yes	No	21-284

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.

Study Device

 **Add a New Device to the Study**

Delete Device	Edit	View Details	Device Name
No devices have been added to this Study			

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.

Find A Device: Search Options

Device Browse/Find:

Device Name:

Device Mode:

Device Serial Number:



0 result(s) found... 0 - 0

Select	Device Name	Device Mode	Device Serial Number
No Results found			

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.

Find A Device: Search Options

Device Browse/Find:

Device Name:

Device Mode:

Device Serial Number:

 Find Device

 Add a New Device

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

Select	Device Name	Device Mode	Device Serial Number
	BRONCHIAL TUBE		
	GAS-MACHINE	ANESTHESIA	522246

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.

Add a New Device

***Device Name:**

Device Mode:

Device Serial Number:

 Save Device Info

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.

Study Device Details:

Device Name	Neuropsychiatric EEG-Based Assessment Aid (NEBA)
Manufacturer/Supplier of Device	<input type="text"/>
Where will the Devices Be Stored	<input type="text"/>
Will Devices be supplied at no Cost	<input checked="" type="radio"/> Yes <input type="radio"/> No
Is this a HUD (HDE)	<input type="radio"/> Yes <input checked="" type="radio"/> No
HDE Number	<input type="text"/>
Who holds the IDE	<input checked="" type="radio"/> N/A <input type="radio"/> Device Manufacturer company <input type="radio"/> PI <input type="radio"/> Outside PI
	IDE Details <input type="text"/>



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.

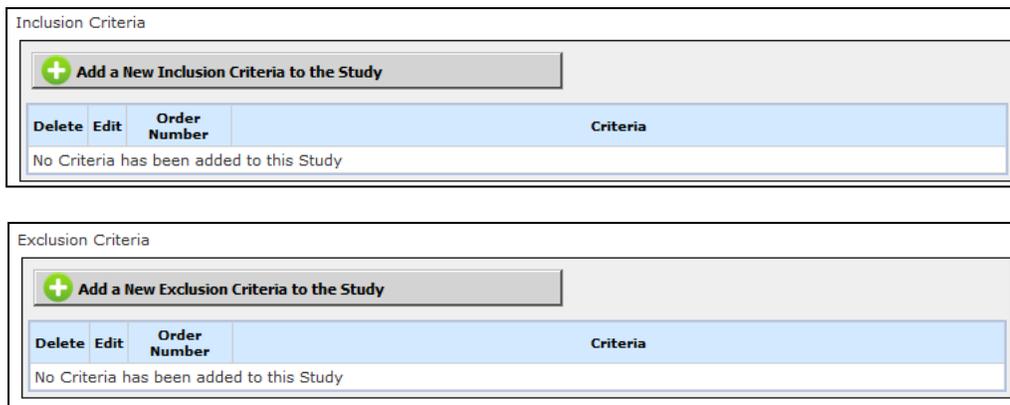
Study Device			
<div style="background-color: #ccc; padding: 5px; display: inline-block; border: 1px solid gray;"> Add a New Device to the Study </div>			
Delete Device	Edit	View Details	Device Name
			Neuropsychiatric EEG-Based Assessment Aid (NEBA)

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.

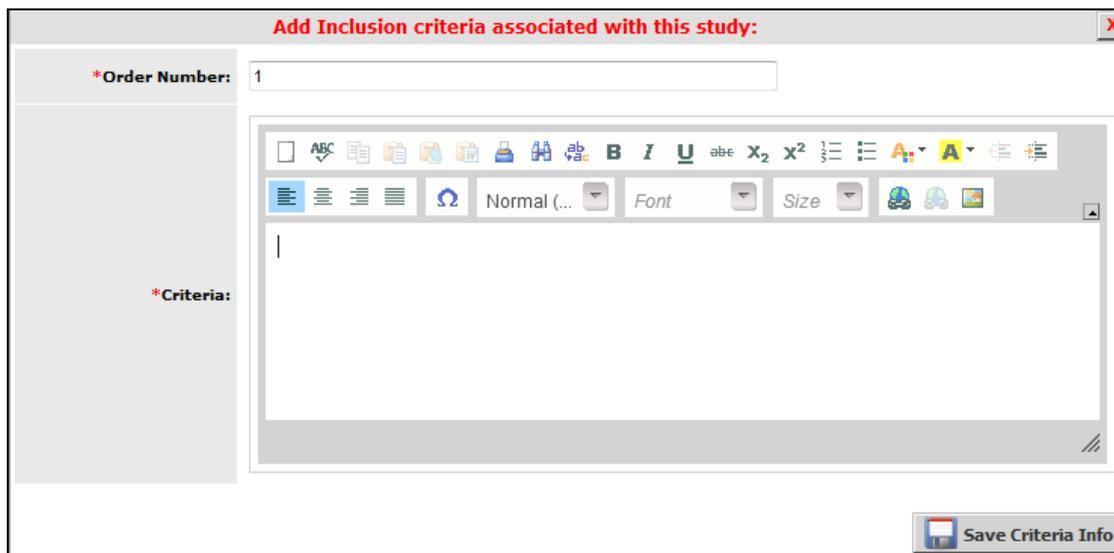
Adding criteria works the same way for both Inclusion Criteria and Exclusion Criteria and is described below using Inclusion Criteria as an example.

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

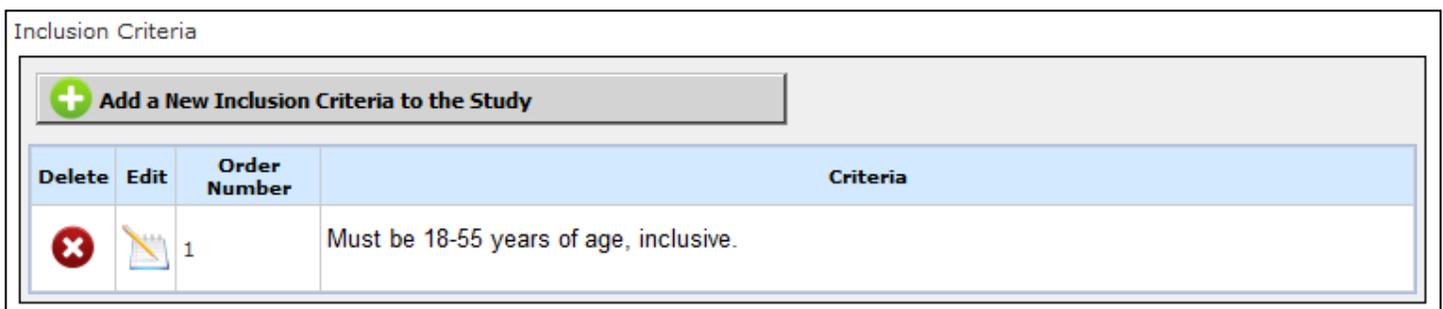


A popup window will open within your browser allowing you to specify the Inclusion Criteria Order Number and the wording for the Criteria. The Order Number will default to 1. You can change the Order Number if you have more than one Inclusion Criteria listed and would like to change the order the criteria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

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
No Sponsor has been added to this Study								

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.

Find a Sponsor: Search Options X

Sponsor Browse/Find:

Sponsor Name:

Familiar Name:

Legal Name:

0 result(s) found... 0 - 0

Select	Sponsor ID	Sponsor Name	Familiar Name	Legal Name
No Results found				

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.

Find a Sponsor: Search Options X

Sponsor Browse/Find:

Sponsor Name:

Familiar Name:

Legal Name:

202 result(s) found... ◀ 11 - 20 ▶

Select	Sponsor ID	A Z Sponsor Name	Familiar Name	Legal Name
+		American Heart Association (AHA)		
+		Arthritis Foundation		

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.

Add Sponsor to Master List Details:

Sponsor Abbr: NRPH

*Sponsor Name: New River Pharmaceuticals

*Sponsor Type: Private - Non-profit

Street 1: 1881 Grove Avenue

Street 2:

City: Radford

County:

State: VA: Virginia

Province:

Country: USA: UNITED STATES

Zip/Postal Code: 24141

Save Sponsor and add to Study

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.

Study Sponsor Details:

Sponsor Name: New River Pharmaceuticals

Sponsor Type: Private - Non-profit

Sponsor Role: (Check all that apply)

- Funding
- Protocol Control
- Data Coordination
- Monitoring
- Auditing
- Passthrough

Grant/Contract Number:

Funding Through: --none--

Is Institution the Primary Grant Holder: Yes No

Contract Type: --none--

Project Number:

Save

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.

Find a Sponsor Contact: Search Options

Sponsor Name: New River Pharmaceuticals

Find Sponsor Contact

Sponsor Contact
Browse/Find:

Last Name:

First Name:

Division:

0 result(s) found... 0 - 0

Select	Sponsor Name	Division	First Name	Last Name
No Results found				

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.

Find a Sponsor Contact: Search Options

Sponsor Name: New River Pharmaceuticals

Find Sponsor Contact

+ Add a new Contact to the Master List

Sponsor Contact
Browse/Find:

Last Name:

First Name:

Division:

1 result(s) found... 1 - 1

Select	Sponsor Name	Division	First Name	Last Name
	92374	Finance/Billing	Joan	Smith

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.

Sponsor Contact: Details

Contact Category: Legal

*Division: Grants and Contracts

*First Name: Joe

Middle Initial:

*Last Name: Contact

Prefix:

Suffix:

Title:

Primary E-mail: jcontact@newriver.com

Secondary E-mail:

Primary Phone:

Secondary Phone:

Street 1:

Street 2:

City:

County/Parish:

State: --none--

Province:

Country: --none--

Zip/Postal Code:

Save Sponsor Contact Info

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.

+ Add a New Sponsor Contact(s) to the Study								
Delete	Edit	View Details	Sponsor Name	Division	Contact Name	Title	Primary Phone	Email
			New River Pharmaceuticals	Grants and Contracts	Joe, Contact			jcontact@newriver.com

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.

+ Add a New Sponsor Contact(s) to the Study								
Delete	Edit	View Details	Sponsor Name	Division	Contact Name	Title	Primary Phone	Email
			New River Pharmaceuticals	Grants and Contracts	Joe, Contact			jcontact@newriver.com
<p>Contact Category: Legal</p> <p>*Contact Name: Joe, Contact</p> <p>Title:</p> <p>Division: Grants and Contracts</p> <p>Primary Phone:</p> <p>Secondary Phone:</p> <p>E-mail: jcontact@newriver.com</p> <p>Primary Address:</p> <p>Secondary Address:</p> <p>Street 1: 123 Main Street</p> <p>Street 2:</p> <p>City: Redlands</p> <p>County/Parish:</p> <p>State: CA: California</p> <p>Province:</p> <p>Country:</p> <p>Zip/Postal Code: 92374</p>								

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.

Study Number: NCT00334880
PI: Investigator, Susan

Initial Review Submission Packet Back

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

Section view of the Form Entire view of the Form

1.0 Submission Packet to the Review Board

1.0 Submission Packet to the Review Board

1.1 Study Title:
A Phase III, Randomized, Double-Blind, Multi-Center, Placebo-Controlled, Parallel-Group, Forced Dose Titration, Safety and Efficacy Study of NRP104 in Adults With Attention-Deficit Hyperactivity Disorder (ADHD)

1.2 Principal Investigator:
Susan Investigator

1.3 * Lay Summary:

Click here to access the text editor.

Lay Summary

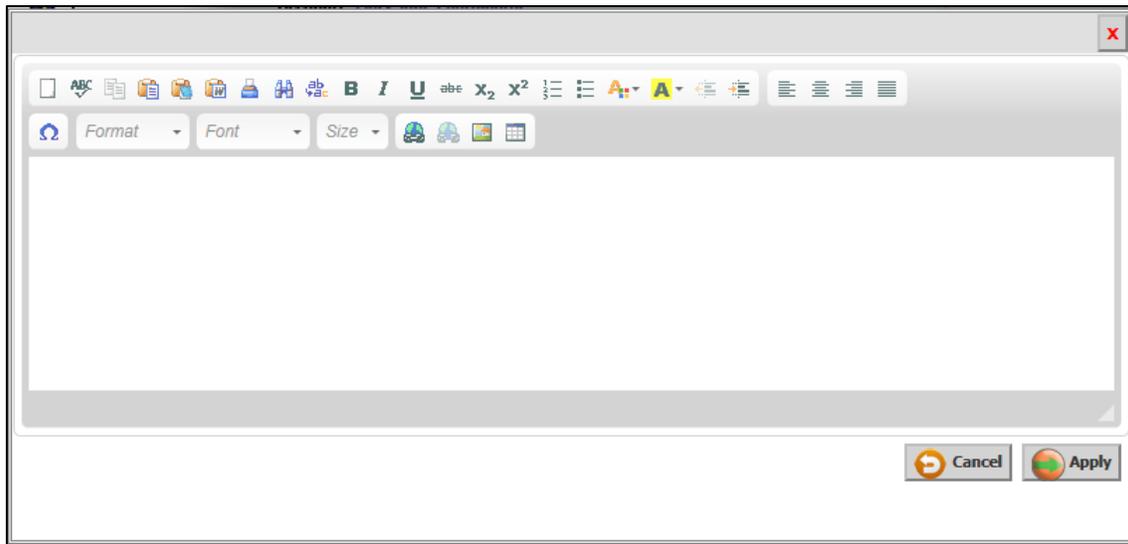
The Lay Summary data value is a required field, as highlighted in the image below, and allows you to capture the Master Lay Summary for your study. The information you enter into this field will transfer to the study's master lay summary field for the review board of record.

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

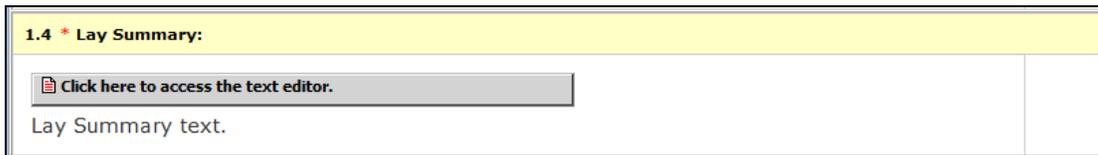
1.4 * Lay Summary:

Click here to access the text editor.

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.



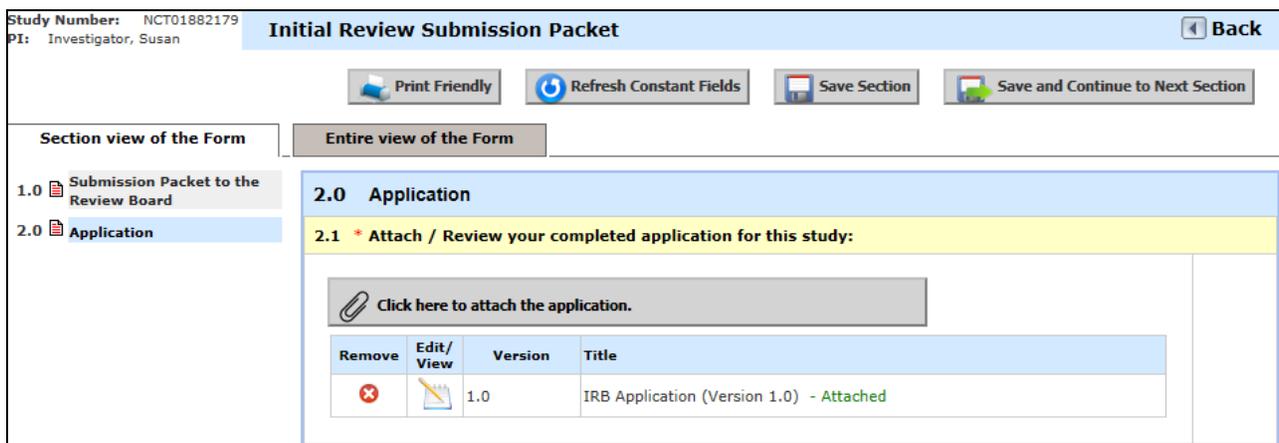
The popup will close, returning you to the Initial Review Submission packet and the Lay Summary text will populate underneath the Lay Summary section.



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.

2.0 Application

2.1 * Attach the application you completed for this protocol:

Click here to attach the application.

No Application has been associated with this submission.

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.

Attaching Study Application ✕

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

Save Attachment

Select	Show Rev.	Edit/View	Form Name	Approved	Create a Revised Application
<input checked="" type="radio"/>			Study Application (Version 1.0)	No	

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.

Study Number: NCT01882179
PI: Investigator, Susan

Initial Review Submission Packet

⏪ Back

Print Friendly

Refresh Constant Fields

Save Section

Save and Continue to Next Section

Section view of the Form

Entire view of the Form

- 1.0 Submission Packet to the Review Board
- 2.0 Application
- 3.0 Informed Consent

3.0 Informed Consent

3.1 * Attach the inform consent(s) for this study:

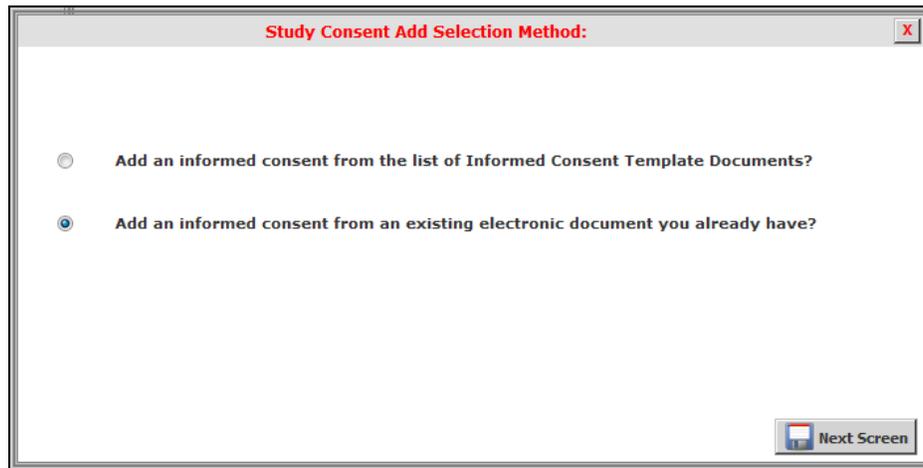
+
Add a New Consent

Detach	Version	Title	Category	Language	Expiration Date	Consent Outcome	Checked Out	View Document
No Consent(s) have been attached to this form.								

A 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.

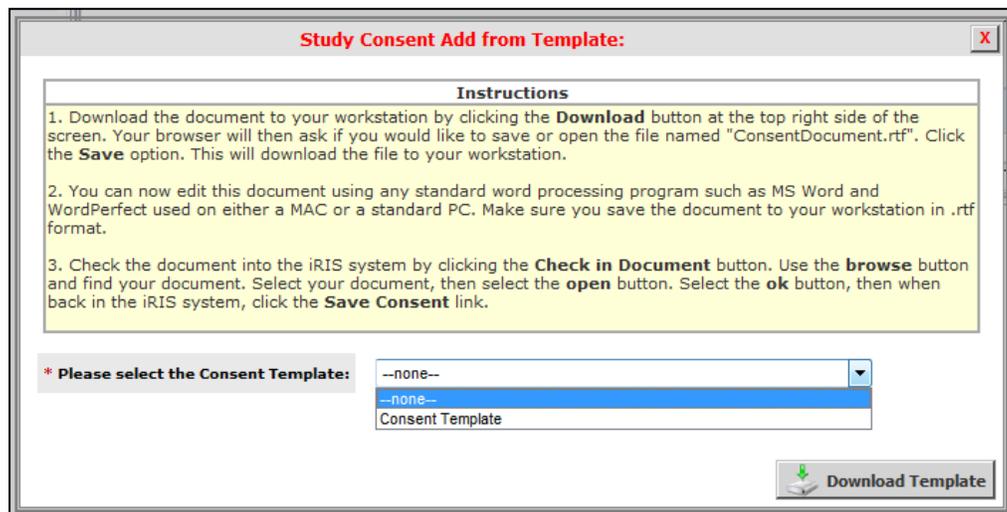
Each possible selection is described below. Choose the appropriate action then click the **Next Screen** button.



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.

 A web form titled "Study Consent Add". It contains several input fields:

- *Consent Title: A text input field.
- *Select the consent to upload: A dropdown menu with a "Browse..." button to its right.
- *Version Number: A text input field containing "1" followed by ".0".
- *Version Date: A date picker showing "02/10/2014".
- Category: A dropdown menu showing "--none--".
- *Language: A dropdown menu showing "--none--".
- Description: A large text area.
- Comments: A large text area.

 A "Save Consent" button with a floppy disk icon is located at the bottom right of the form.

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**.

 A close-up of the "*Version Number:" label and its input field. The input field contains the number "1" followed by ".0".

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 screenshot shows a web form titled "Study Consent Add". The form has the following fields and controls:

- *Consent Title:** A text input field containing "ConsentDocument".
- *Select the consent to upload:** A file selection area with a "Browse..." button.
- *Version Number:** A text input field with "1" and a ".0" suffix.
- *Version Date:** A date picker showing "02/11/2014".
- Category:** A dropdown menu showing "Consent Category 1".
- * Language:** A dropdown menu showing "English".
- Description:** A large text area for entering a description.
- Comments:** A large text area for entering comments.
- Save Consent:** A button with a floppy disk icon, located at the bottom right of the form.

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.

3.1 * Attach the inform consent(s) for this study:

📎 Select or Revise Existing
+ Add a New Consent

Detach	Version	Title	Category	Language	Expiration Date	Consent Outcome	Checked Out	View Document
✖	1.0	Informed Consent	Consent	English				14.46 KB

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.

Select Existing or Create Revised Study Consent

Select Category:

Version #: .

Version Date: between

Consent Outcome:

Title:

Search level: Top All

Expiration Date: between

1 result(s) found...

Select	Show all Versions	Edit	Delete	Version	Version Date	Title/ Category	Language	Expiration Date	Consent Outcome	Checked Out By	View Document	Create Revision
				1.0	06/30/2015	Informed Consent Consent	English				14.46 KB	

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.

Study Consent Revision:

*** Consent Title:**

Version Number: .

*** Version Date:**

Category:

*** Language:**

Description:

Check-out the Document to your workstation for editing:

Comments:

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.

Download the Consent Document Back

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



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

Download File...
 What's the Risk?
 More information

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

File Download

Do you want to open or save this file?

Name: study_documents-dummy2.doc
 Type: Microsoft Word Document, 23,908
 From: 66.220.42.146

Open Save Cancel

While files from the Internet can be useful, some files can potentially harm your computer. If you do not trust the source, do not open or save this file. What's the risk?

Complete Checkout

Cancel

To do so, click **Save**. This will open up a window similar to the one shown below that allows you to choose where in your workstation you would like to save the document. Once you've selected where you will save the document, click **Save**. After this, the Download Complete box will appear as shown below. From here you can choose to open the document to edit it, open the folder that contains the document, or Close the Download Complete box to edit the document later.

Step 3: IT IS VERY IMPORTANT that after you've saved the file to your workstation and closed the Download Complete box that you click the **Complete Checkout** button in iRIS. This allows you to check the document (or upload the document) back into iRIS once you've finished editing it.

To cancel the Document Check-out, click **Cancel**. Note: If you've already saved the file to your computer, the file will remain on your computer, however you will simply lose the option of checking the document back in.

When you select to download the file, a popup window will ask you if you'd like to open or save the document. You can do either; however, we recommend that you save the 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.

3.1 * Attach the inform consent(s) for this study:

Detach	Version	Title	Category	Language	Expiration Date	Consent Outcome	Checked Out	View Document
	1.0	Informed Consent	Consent	English			Mary Jane Coordinator 06/30/2015 02:47:38 PM	

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

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

This document is currently checked out by: Mary Jane Coordinator at 06/30/2015 02:49:45 PM	
Check-in when you are done editing upload the document back into iRIS.	<input type="button" value="Check-in Document..."/>
Revert to the document stored in iRIS.	<input type="button" value="Undo Check-out Document..."/>
Comments:	<input type="text"/>
<input type="button" value="Save Consent"/>	

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.

Document Location: <input type="text"/>	<input type="button" value="Browse..."/>
<p>Instruction: Uploading a document into iRIS™ requires locating the document on the computer. Once you have located the document click on the 'Save selected file' button. The buttons will become disabled. If the document is a large document the window will stay in place until the upload operation has completed.</p>	
<input type="button" value="Save selected file"/> <input type="button" value="Cancel"/>	

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

<p>Please Wait ...</p>  <p>iRIS is uploading the file to the server. This operation may take a moment.</p>

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.

Detach	Version	Title	Category	Expiration Date	Review Outcome	View Document
	1.0	Investigator Brochure	Investigator brochure			 189.23 KB

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.

Study Document Add Multiple:					
*Document Title	*Version	Version Date	Category	* File path	
<input type="text"/>	<input type="text" value=".0"/>	<input type="text"/>	--none--	<input type="button" value="Browse..."/>	
<input type="text"/>	<input type="text" value=".0"/>	<input type="text"/>	--none--	<input type="button" value="Browse..."/>	
<input type="text"/>	<input type="text" value=".0"/>	<input type="text"/>	--none--	<input type="button" value="Browse..."/>	
<input type="text"/>	<input type="text" value=".0"/>	<input type="text"/>	--none--	<input type="button" value="Browse..."/>	
<input type="text"/>	<input type="text" value=".0"/>	<input type="text"/>	--none--	<input type="button" value="Browse..."/>	

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.

Select or Revise Existing		+ Add a New Document		++ Add Multiple Documents			
Detach	Version	Title	Category	Expiration Date	Document Outcome	Checked Out	View Document
	1.0	flyer	Flyer				 11.54 KB
	1.0	investigator's brochure template (1)	Investigator brochure				 337.92 KB

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.

Select Existing or Create Revised Study Document

Select Category: --none--

Version #:

Version Date: between

Document Outcome: --none--

Title:

Search level: Top All

Expiration Date: between

Filter Documents

4 result(s) found...

Select	Show all Versions	Edit	Delete	Version	Version Date	Title/ Category	Expiration Date	Document Outcome	Checked Out By	View Document	Create Revision
				1.0	06/30/2015	Investigator's Brochure Template (1) Investigator brochure				 337.92 KB	
				1.0	06/30/2015	flyer Flyer				 11.54 KB	
				1.0	06/30/2015	radio script Other				 11.70 KB	
				1.0	06/16/2015	Protocol Protocol				 14.81 KB	

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.

Download the Study Document Back

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

To help protect your security, Internet Explorer blocked this site from downloading files to your computer. Click here for options...

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

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

To do so, click **Save**. This will open up a window similar to the one shown below that allows you to choose where in your workstation you would like to save the document. Once you've selected where you will save the document, click **Save**. After this, the Download Complete box will appear as shown below. From here you can choose to open the document to edit it, open the folder that contains the document, or Close the Download Complete box to edit the document later.

Step 3: IT IS VERY IMPORTANT that after you've saved the file to your workstation and closed the Download Complete box that you click the **Complete Checkout** button in iRIS. This allows you to check the document (or upload the document) back into iRIS once you've finished editing it.

To cancel the Document Check-out, click **Cancel**. Note: If you've already saved the file to your computer, the file will be saved to your computer, however you will simply lose the option of checking the document back in.

Complete Checkout
Cancel

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**.

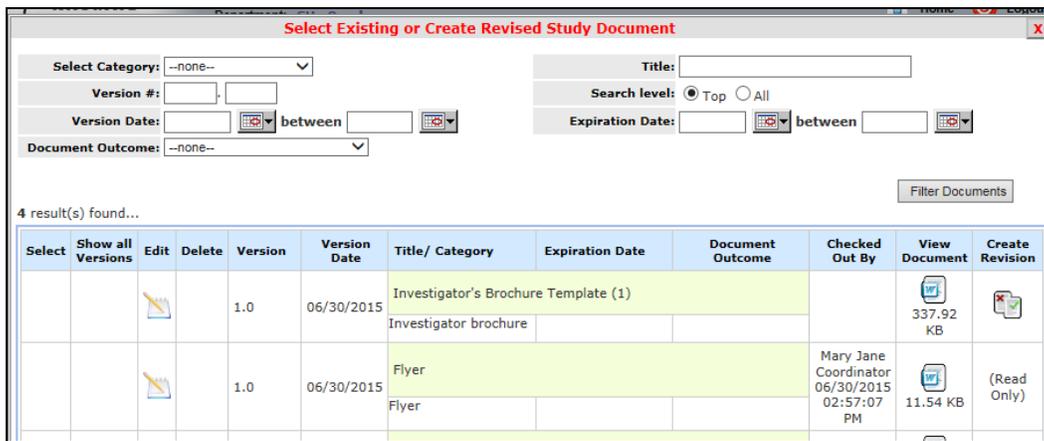
Anywhere you can view the Other Study Document, in the Other Study Documents library or within the Initial Review you will see that the document is checked out.

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**.

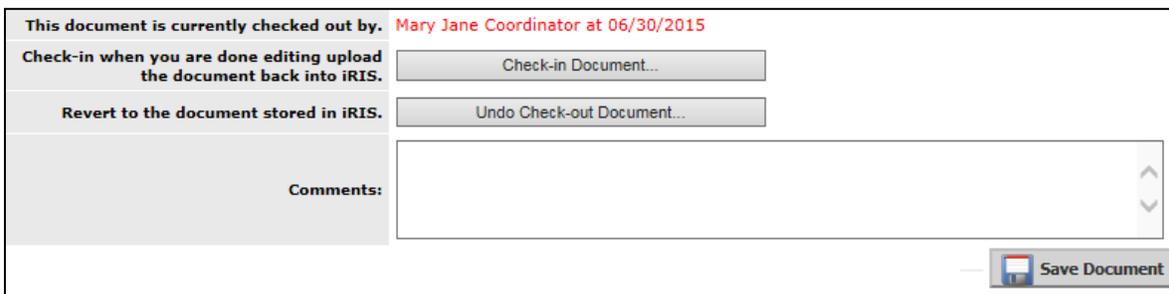
4.1 Attach any study documents to include with the initial review submission packet: Examples would include Drug Brochures, Sponsor Information, etc.

Select or Revise Existing		Add a New Document		Add Multiple Documents			
Detach	Version	Title	Category	Expiration Date	Document Outcome	Checked Out	View Document
	1.0	radio script	Other				11.70 KB
	1.0	Flyer	Flyer			Mary Jane Coordinator 06/30/2015 02:57:07 PM	

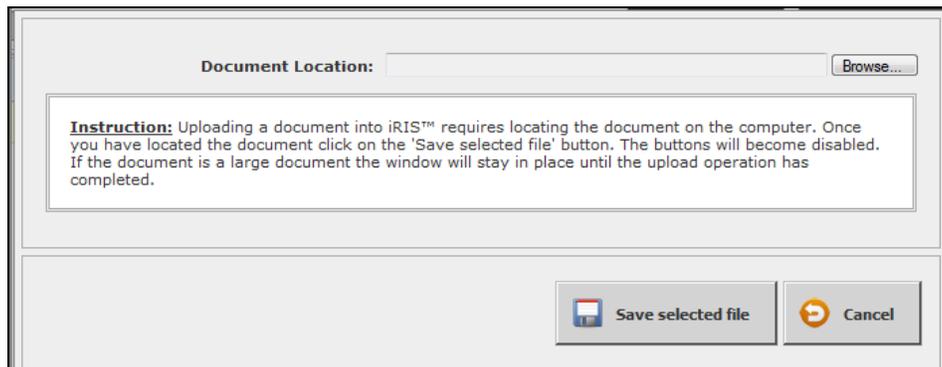
Click the icon in the **Edit** column.



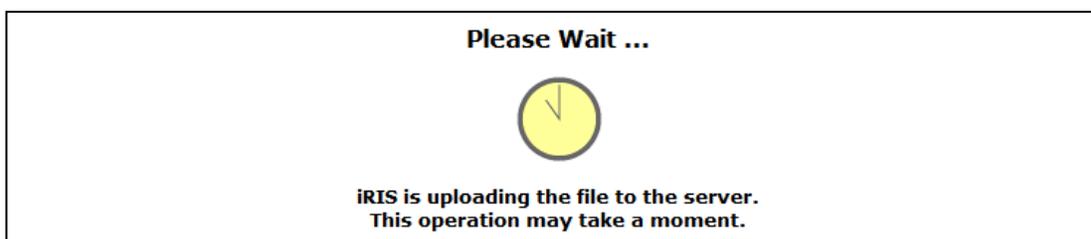
Click the **Check-in Document** button.



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.

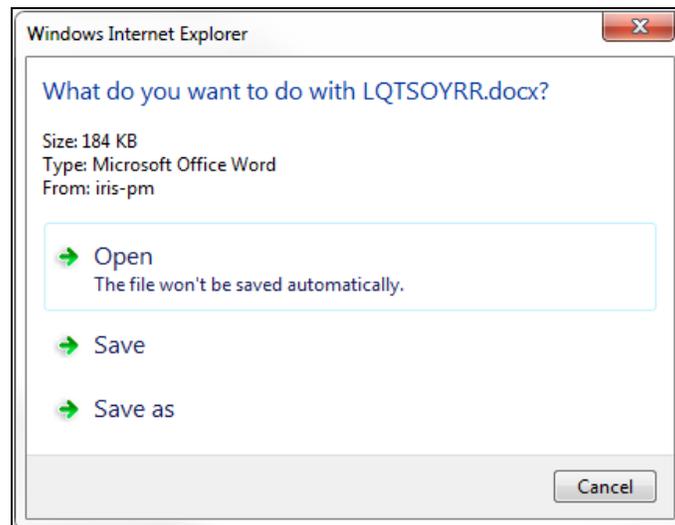
When the document is checked out, the page will read that the document is checked out and display the name of the user and the date the document was checked out.

Viewing the Document

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

Select	Show all Versions	Edit	Delete	Version	Version Date	Title / Category	Expiration Date	Document Outcome	Checked Out By	View Document	Create Revision
				1.0	06/30/2015	Investigator's Brochure Template (1) Investigator brochure				 337.92 KB	
				1.0	06/30/2015	Flyer Flyer				 11.54 KB	
				1.0	06/30/2015	radio script Other				 11.70 KB	
				1.0	06/16/2015	Protocol Protocol				 14.81 KB	

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.

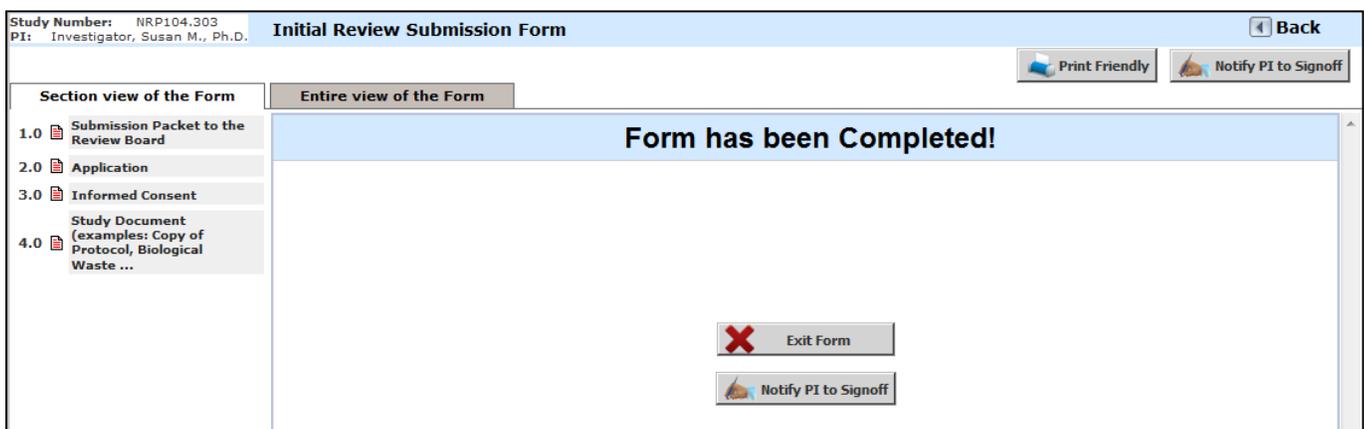
Create Revision

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.

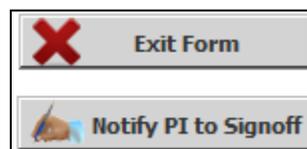
Signoff and Submit

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.

A screenshot of a web form titled "Setup Signoff Submission Routing". At the top left, it shows "Study Number: NRP104.303" and "PI: Investigator, Susan M., Ph.D.". At the top right, there is a "Back" button with a left-pointing arrow. Below the title bar, there is a "Save and Continue" button with a floppy disk icon. The main content area has a question: "Does this submission require additional routing for approval?". Below the question are two radio button options, both highlighted in yellow. The first option is "YES - Click YES to select additional personnel for routing." and the second option is "NO - Click NO to bypass selecting additional personnel for routing." The "NO" option is selected, indicated by a blue dot.

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.

Include in signoff	Approved	Name	Role
<input checked="" type="checkbox"/>		Susan Investigator	Principal Investigator
<input type="checkbox"/>		Henry Investigator	Co-Investigator
<input type="checkbox"/>		Mary Jane Coordinator	Clinical Research Coordinator

Screen Instructions:
This screen enables the selection of key study personnel required to review this form.
Check the boxes next to the names of the personnel required for routing and signoff.

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.

Include in signoff	Order	Approved	Name/Role
<input type="checkbox"/>	1		Administrator Department Chair

Screen Instructions:
This screen enables the selection of personnel required to review this form and the routing order before submission.
- Person(s) designated as Department reviewers on your application are listed on the 'Select required personnel' section to the left of these instructions.
Adding Reviewers:
1. Click on the *Add signoff* link on the iRIS control panel.
2. On the search screen enter relevant search information and click find.
3. Select the desired reviewers by checking the box to the left of the reviewer name.
4. When all reviewers are selected click the *Save and Continue* button to do signoff complete

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

3.4 If applicable, please select the Designated Department Approval(s):

<input type="checkbox"/>	Administrator	Department Chair	<input type="button" value="Add User"/>	<input type="button" value="Remove"/>
--------------------------	---------------	------------------	---	---------------------------------------

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.

Search User Directory
Back

Save Selected User(s)

Directory
Browse/Find:

Last Name: (You may enter a partial name to search)

First Name:

by Department:

Find

Check for Multiple	Select User	Training	User Name	Department	Email
<input type="checkbox"/>	<input checked="" type="checkbox"/>		Investigator, John	Oncology (primary)	investigatorco@test.com
<input type="checkbox"/>	<input checked="" type="checkbox"/>		Investigator, Principal, M.S.	Department (primary)	piuser@test.edu

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.

Study Number: NRP104.303
PI: Investigator, Susan M., Ph.D.
Setup Signoff Submission Routing
Back

Return to Previous Screen
Add signoff
Save and Continue

Select the additional personnel required for routing and signoff

Check the boxes next to the names of the personnel required for routing and signoff.

Include in signoff	Order	Approved	Name/Role
<input checked="" type="checkbox"/>	<input type="text" value="1"/>	<input type="checkbox"/>	<div style="display: flex; align-items: center;"> <div style="margin-left: 5px;"> <p>Administrator</p> <p>Department Chair</p> </div> </div>
<input checked="" type="checkbox"/>	<input type="text" value="2"/>	<input type="checkbox"/>	<div style="display: flex; align-items: center;"> <div style="margin-left: 5px;"> <p>Dr. Patrick Investigator, Ph.D</p> <p>Advisor</p> </div> </div>

Screen Instructions:

This screen enables the selection of personnel required to review this form and the routing order before submission.

- Person(s) designated as Department reviewers on your application are listed on the 'Select required personnel' section to the left of these instructions.

Adding Reviewers:

1. Click on the *Add signoff* link on the iRIS control panel.
2. On the search screen enter relevant search information and click find.
3. Select the desired reviewers by checking the box to the left of the reviewer name.

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**.

Study Number: NRP104.303
 PI: Investigator, Susan M., Ph.D.

Setup Signoff Submission Routing

Back Save and Continue

Routing Confirmation

Click here to Add/Remove Key Study Personnel from the Routing List

Approved	Name	Role
	Dr. Susan M. Investigator, Ph.D.	Principal Investigator
	Mary Jane Coordinator, R.N.	Study Coordinator

Have you completed your selection of required signatures?

Yes

No

Click here to select Additional Personnel for Signoff

Order	Approved	Name	Role
1		Administrator	Department Chair
2		Dr. Patrick Investigator, Ph.D	Advisor

Screen Instructions:

This screen enables the verification of personnel required to review and signoff.

Click on Yes to indicate selection of reviewers is complete.

Click the *Save and Continue* button to start the routing process.

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.

Study Number: NCT00334880
 PI: Investigator, Susan

Workflow - Submission Tracking

Back Print Friendly

Status	View Details	Date Received / Date Completed	Event Description
	 Waiting on Finalization of Routing Assignment List Click here to Finalize List	06/30/2015 03:00 PM PDT 06/30/2015 03:01 PM PDT	Assign Department Personnel for Signoff
		06/30/2015 02:59 PM PDT 06/30/2015 03:00 PM PDT	Initial Review Submission Packet is waiting to be submitted

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.

The screenshot shows the iRIS interface with a sidebar on the left containing navigation options: My Assistant, Project Assistant, Study Assistant, Add a New Study, My Studies, My Subjects, Find a Subject, and My Appointments. The main content area displays a welcome message for Susan Investigator and a task titled 'Submission Routing Signoff' with a count of 1. Below this is a table of tasks.

Open	Principal Investigator	IRB Number	Study Alias	Study Status	Ref Number	Submission Form Name	IRB Initial Approval	Expiration	Received
	Susan Investigator		NCT00334880	Pending - Submitted for Initial Review	14	Initial Review Submission Packet			06/30/2015

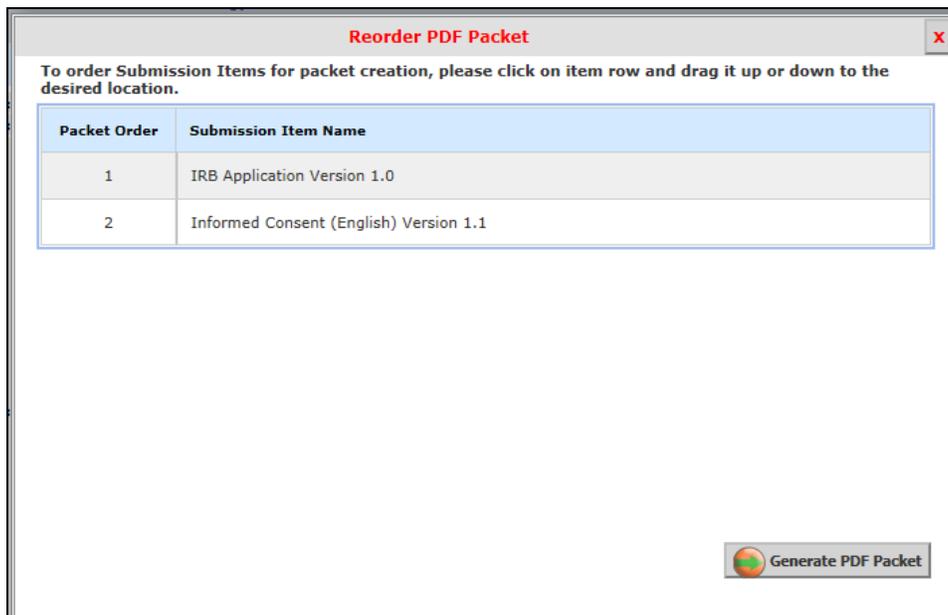
When the task is opened, the Submission Routing Signoff Sheet will display. At the top of the page, the Study Title and Submission Reference Number are listed. iRIS assigns a unique reference number to each form created in the system. The Reference Number displayed here is the number assigned to the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

The screenshot shows the 'Submission Routing Signoff Sheet' for a study titled '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)'. The submission reference number is 000014. A 'Create PDF Packet' button is visible. Below is a table of submission components.

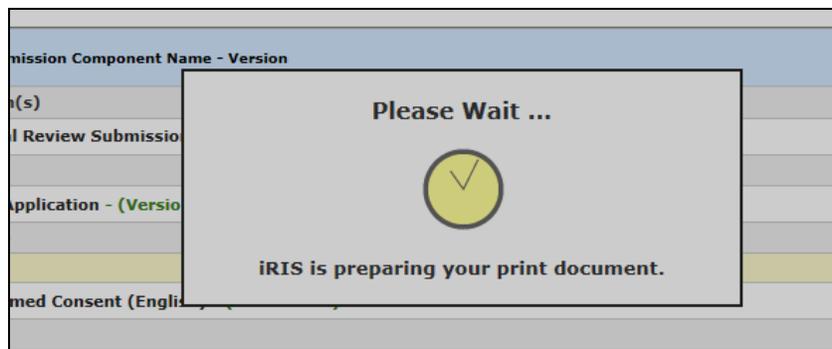
Include in PDF Packet	Submission Component Name - Version
Submission Form(s)	
<input type="checkbox"/>	Initial Review Submission Packet - (Version 1.0) (Parent of the submission package)
Application	
<input type="checkbox"/>	IRB Application - (Version 1.0)
Consent Form(s)	
Category : Consent	
<input type="checkbox"/>	Informed Consent (English) - (Version 1.0)
Document(s)	
Category : Flyer	
<input type="checkbox"/>	Flyer - (Version 1.0)
Category : Investigator brochure	
<input type="checkbox"/>	Investigator's Brochure Template (1) - (Version 1.0)
Category : Other	
<input type="checkbox"/>	radio script - (Version 1.0)

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.

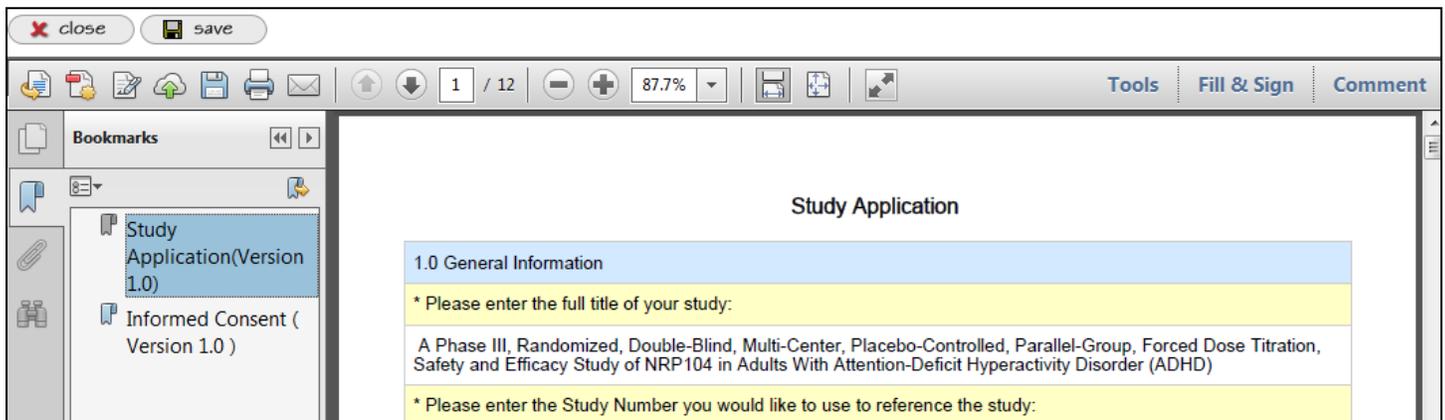
Some of the attachments are available to print. If a document can be printed, a check box will populate next to the document in the **Include in PDF Packet** column. You can select any of these items then click the **Create PDF Packet** button at the top of the table.



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.

Full Board Human Subjects Assurance

I hereby certify: (1) that the information submitted within the application is true, complete, and accurate to the best of my knowledge; (2) that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties; and (3) that I agree to accept responsibility for the scientific conduct of the research and to provide the required progress reports if the research is approved.

Susan Investigator as Principal Investigator
do you Approve or Deny this submission?

Approve **Deny**

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

User ID:

Password:

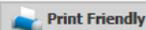


View Other Comments:

Henry Investigator	Co-Investigator	
Comments:		
Mary Jane Coordinator	Clinical Research Coordinator	Approved
Comments:		

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

Study Number: NCT00334880 **Workflow - Submission Tracking** 

PI: Investigator, Susan 

Status	View Details	Date Received / Date Completed	Event Description
		06/30/2015 03:05 PM PDT	Henry Investigator as Co-Investigator review and apply signoff
		06/30/2015 03:00 PM PDT 06/30/2015 03:03 PM PDT	Assign Department Personnel for Signoff
		06/30/2015 03:03 PM PDT 06/30/2015 03:04 PM PDT	Mary Jane Coordinator as Clinical Research Coordinator review and apply signoff
		06/30/2015 03:03 PM PDT 06/30/2015 03:10 PM PDT	Susan Investigator as Principal Investigator review and apply signoff
		06/30/2015 02:59 PM PDT 06/30/2015 03:00 PM PDT	Initial Review Submission Packet is waiting to be submitted

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

Study Number: NCT00334880		Workflow - Submission Tracking		Back
PI: Investigator, Susan		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
		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
		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

1 task(s) found... IRB Number ▾

Open	Principal Investigator	IRB Number	Study Alias	On Study Status	Ref Number	Submission Form Name	IRB Initial Approval	Expiration	Received	Denied by	Round Number
	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.

IRB Number: **GH-2015-25** **Submissions** Back
 PI: Investigator, Susan

Study Status: Pending - Submitted for Initial Review **IRB Number :** GH-2015-25 **Study Title :** A Phase III, Randomized, Double-Blind, Multi-Center, Placebo-Controlled, Parallel-Group, Forced Dose Titration, Safety and Efficacy Study of NRP104 in Adults With Attention-Deficit Hyperactivity Disorder (ADHD)

Submissions | Study Management | Subject Management

Protocol Items

- Protocol Items
- Study Application
- Informed Consent
- Other Study Documents

Initial Review

- Submissions
- Initial Review Submission Packet

IRB Items

- Submissions History
- Study Correspondence

Track Location	Ref Number	Request Type	Process Submission
	000014	Click on the hyperlink to edit/view the submission. Initial Review Submission Packet	Retract Submission

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.

IRB Number: **GH-2015-25** **Workflow - Submission Tracking** Back
 PI: Investigator, Susan Print Friend

Status	View Details	Date Received / Date Completed	Event Description
		06/30/2015 03:28 PM PDT	IRB received the submission
		06/30/2015 03:28 PM PDT 06/30/2015 03:28 PM PDT	IRB assigned with the IRB Number of GH-2015-25
		06/30/2015 03:05 PM PDT 06/30/2015 03:28 PM PDT	Henry Investigator as Co-Investigator review and apply signoff
		06/30/2015 03:03 PM PDT 06/30/2015 03:04 PM PDT	Mary Jane Coordinator as Clinical Research Coordinator review and apply signoff
		06/30/2015 03:03 PM PDT 06/30/2015 03:10 PM PDT	Susan Investigator as Principal Investigator review and apply signoff
		06/30/2015 03:00 PM PDT 06/30/2015 03:28 PM PDT	Assign Department Personnel for Signoff
		06/30/2015 02:59 PM PDT 06/30/2015 03:00 PM PDT	Initial Review Submission Packet is waiting to be submitted

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
	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**.

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

IRB Number: **GH-2015-25** Pre-Review Correction Form - IRB Back
 PI: Investigator, Susan

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

Section view of the Form Entire view of the Form

1.0 Corrections

2.0 **Stipulations and Comments**

2.1 Requested Changes

Stipulation 1 out of 3:

Description:
Please specify research locations.

Stipulation Type: (Stipulation must be addressed)

Category:

Operation	Component Name	Action	Status
Modify Existing Attachment	IRB Application (Version 1.0)	Select Already prepared Revise Existing	Pending

Links to Components
(These are the items that are linked to this stipulation)

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.

⚠ Stipulation 1 out of 1:

Description:
Please remove this Flyer and attach the current, sponsor approved flyer.

Stipulation Type: (Stipulation must be addressed)

Category: Study Document

	Operation	Component Name	Action	Status
Links to Components <small>(These are the items that are linked to this stipulation)</small>	 Remove Attachment	 Study Document flyer (Version 1.0)	 Remove Component	 Pending
	 Add New Attachment	Request Study Document be added to the IRB Application	<div style="border: 1px solid red; padding: 2px; margin-bottom: 2px;"> Add/Select Existing </div> <div style="border: 1px solid red; padding: 2px;"> Add a New Document </div>	<div style="font-size: small;"> Revise or select a document previously uploaded to this study. </div> <div style="font-size: small;"> Upload a new document and attach to this correction. </div>

Do you accept this Stipulation? N/A Yes No

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.

Operation	Component Name	Action	Status
Remove Attachment	Study Document flyer (Version 1.0)		Completed
Add New Attachment	Request Study Document be added to the IRB Application Study Document Sponsor Approved Flyer (Version 2.0)		Completed

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.

⚠ Stipulation 2 out of 3:

Description:
Consent form is not in 8th grade reading level.

Stipulation Type: (Stipulation must be addressed)

Category:

Operation	Component Name	Action	Status
Modify Existing Attachment	Study Consent Informed Consent (Version 1.0)	Revise Linked Revise or select the consent linked by the review board.	Pending
		Add/Select Existing Revise or select a consent previously uploaded to this study.	
		Add a New Consent Upload a new consent and attach to this correction.	

Do you accept this Stipulation? N/A Yes No

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.

Select	Show all Versions	Edit	Version	Title	Checked Out By	Create Revision
Already Submitted			1.0	Informed Consent		

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.

Select Existing or Create Revised Study Consent

Select Category: --none--
 Version #: .
 Version Date: between
 Consent Outcome: --none--

Title:
 Search level: Top All
 Expiration Date: between
 Submission Association: Yes No

Filter Documents

2 result(s) found...

Select	Show all Versions	Edit	Delete	Version	Version Date	Title/ Category	Language	Expiration Date	Consent Outcome	Checked Out By	View Document	Create Revision
				2.0	06/23/2015	Standard Consent Consent	English				42.59 KB	
Already Submitted				1.0	06/30/2015	Informed Consent Consent	English				14.46 KB	

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.

Study Consent Add Selection Method:

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

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

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.

Study Consent Revision:

*Consent Title: Informed Consent

Version Number: 1 .1

*Version Date: 06/30/2015

Category: Consent

* Language: English

Description: Consent description.

Check-out the Document to your workstation for editing:

Comments: Comments to review board.

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.

Stipulation Type: (Stipulation must be addressed)				
Category:				
Links to Components (These are the items that are linked to this stipulation)	Operation	Component Name	Action	Status
	 Modify Existing Attachment	 Study Consent Informed Consent (Version 1.0)	 Compare Consent Version	 Completed
	 Study Consent Informed Consent (Version 1.1)			

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.

⚠ Stipulation 1 out of 3:					
Description:					
Please specify research locations.					
Stipulation Type: (Stipulation must be addressed)					
Category:					
Links to Components (These are the items that are linked to this stipulation)	Operation	Component Name	Action	Status	
	 Modify Existing Attachment	 IRB Application (Version 1.0)	 Select Already prepared	 Revise Existing	 Pending
Do you accept this Stipulation?	<input type="radio"/> N/A <input type="radio"/> Yes <input type="radio"/> No				

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.

Operation	Component Name	Action	Status
 Modify Existing Attachment	IRB Application (Version 1.0)	 Compare Application Version	 Completed
	IRB Application (Version 1.1)		

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.

Section view of the Form | **Entire view of the Form**

1.0 Review Response Submission Form

2.0 Stipulations and Comments

Stipulation 5 out of 5:

Description:
Upload a protocol document.

Stipulation Type: (Stipulation must be addressed)

Category: Category 1

Do you accept this Stipulation? N/A Yes No

Protocol has been uploaded to submission components.

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).

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

Section view of the Form | **Entire view of the Form**

1.0 Corrections

2.0 Stipulations and Comments

1.2 Submission Components

Expand All | Compare Item(s) | **Revise Submission** | Create PDF Packet

Compare	Include in PDF Packet	Remove	Revisions	All Submission Components Previous Rounds & Currently Attached
Submission Form(s)				
<input type="checkbox"/>	<input type="checkbox"/>			Pre-Review Correction Form - IRB - (Version 2.0 (Incomplete)) (Parent of the submission package) - Submitted in round(s) Currently attached
<input type="checkbox"/>	<input type="checkbox"/>			Initial Review Submission Packet - (Version 1.1) - Submitted in round(s) Currently attached,2,1
Application				
<input type="checkbox"/>	<input type="checkbox"/>			IRB Application - (Version 1.1) - Submitted in round(s) Currently attached,2
Consent Form(s)				

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”.

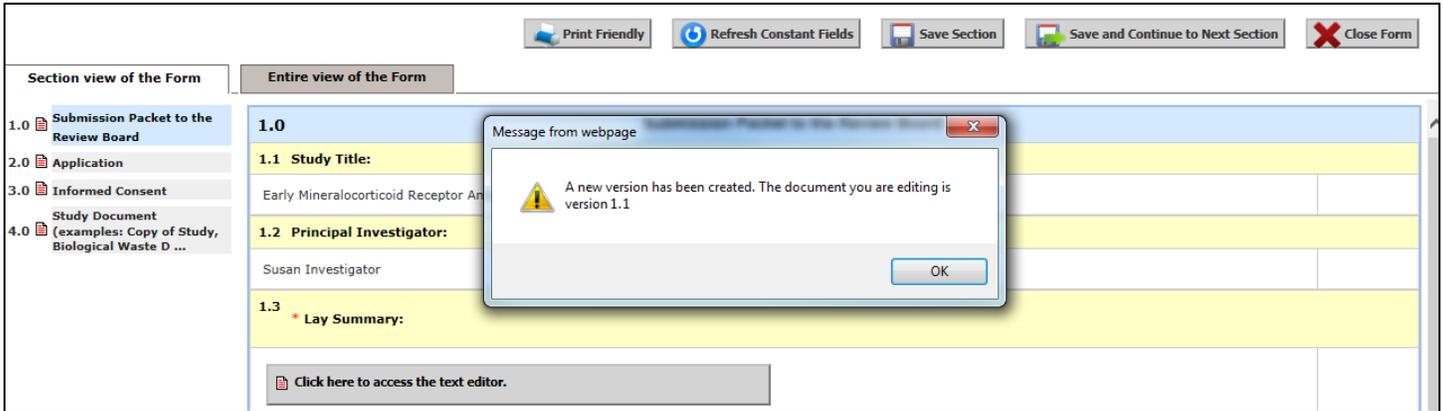
Click the **Revise Submission** button located above the submission components.

Message from webpage

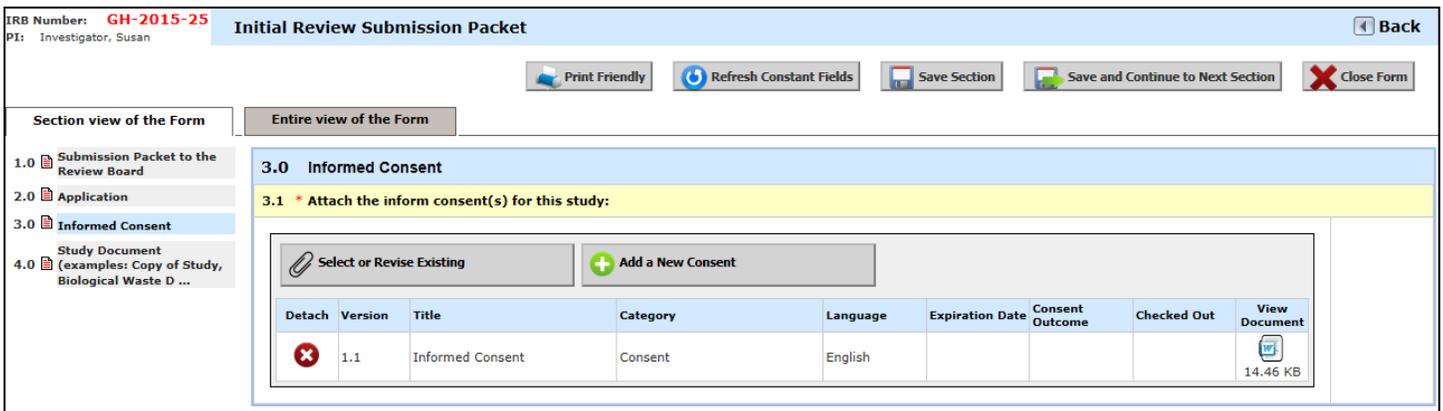
Confirm the adding a revision.
Are you sure you want to create a revision?

OK | Cancel

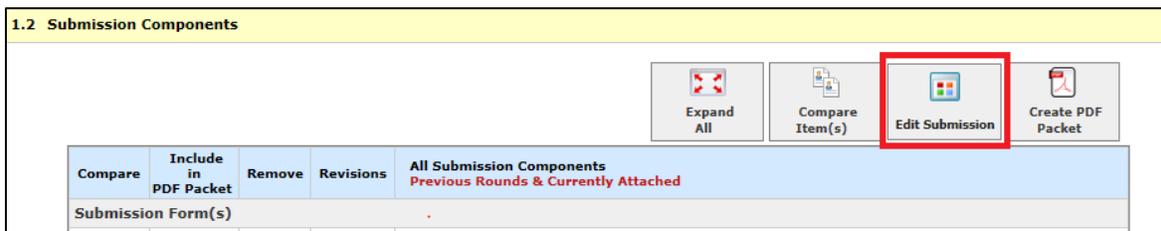
You will be asked to confirm adding a revision. Select the **OK** button.



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(s) 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.

The screenshot displays the 'Pre-Review Correction Form - IRB' interface. At the top left, it shows 'Study Number: NRP104.303' and 'PI: Investigator, Susan M., Ph.D.'. The title bar reads 'Pre-Review Correction Form - IRB' with a 'Back' button. On the right, there are 'Print Friendly' and 'Signoff and Submit' buttons. A left sidebar contains a 'Section view of the Form' with three items: '1.0 Review Response Submission Form', '2.0 Stipulations and Comments', and '3.0 Comments to the Review Board'. The main content area has a tab for 'Entire view of the Form' and a large blue banner stating 'Form has been Completed!'. Below the banner are two buttons: 'Exit Form' (with a red X icon) and 'Signoff and Submit' (with a hand icon).

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.