



STUDY ASSISTANT

Study Management Submissions

Version 10.03

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Study Management

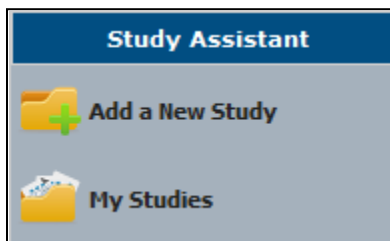
Introduction

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

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

Accessing a Study

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



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

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

My Studies Back									
Display my Studies by:		<input checked="" type="radio"/> Most Recently Used Studies:		Find by IRB Number: <input type="text"/>		<input type="button" value="Find"/>			
<input type="text" value="IRB Number"/>		<input type="radio"/> Filter my Studies by study status:		Find by Study Number: <input type="text"/>		<input type="button" value="Find"/>			
		<input checked="" type="checkbox"/> Include Studies that have not been assigned an IRB Number							
		Show Hidden Studies <input type="radio"/> Yes <input checked="" type="radio"/> No							
6 result(s) found... 1 - 6									
Click to open	View Details	Study Status	IRB Number	IRB Expiration	Study Number Study Title	Principal Investigator	Copy Study	Delete Study	Hide
		Open	GH-2015-25	06/16/2016	NCT00334880 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)	Investigator, Susan			
		Open	GH-2015-22	12/31/2015	NCT00510276 Treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) With Atomoxetine in Young Adults	Investigator, Susan			

Submissions

When you open a study, the page will open to the Submissions tab. This tab contains links to various forms that can be created, completed and submitted throughout the lifetime of the study. The top of the page lists a header with study-specific details. The left portion of the page contains links to the Study Application, Informed Consent, Other Study Documents and any form you may need to create and submit for review. The right side of the page contains a link to Submission History, which will list out all forms submitted for review on the study. Also listed is a link to Study Correspondence and an area for Outstanding Submissions.

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

Study Status: Open **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)
IRB Expiration Date: 06/16/2016

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

- Forms
 - Amendment Form

Submissions History

Study Correspondence

Outstanding Submission(s)

Track Location	Ref Number	Request Type	Process Submission
There are no outstanding submissions.			

The Header

Wherever you are within the study record, the top of the page will always display the study header. The header contains current information related to the study you are in, as displayed in the image below.

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

Study Status: Open **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)
IRB Expiration Date: 06/16/2016

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

Below this is listed the current **Study Status**, the **IRB Number**, **Study Title** and the **IRB Expiration Date**, depending on whether or not a date has been provided by the IRB.

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

Protocol Items

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

Protocol Items	
<input type="checkbox"/>	Protocol Items
<input type="radio"/>	Study Application
<input type="radio"/>	Informed Consent
<input type="radio"/>	Other Study Documents

Study Application

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

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

From here, you can view the current application and make edits, if the current version has not been submitted for review. You can also view approval information, compare versions and revise the current application.

Study Number: NRP104.303 **Study Application** [Back](#)
 PI: Investigator, Susan M., Ph.D.

Study Status: **Open** IRB Number : **GH-14-016** Study Title : A Phase III, Randomized, Double-Blind, Multi-Center, Placebo-Controlled, Parallel-Group, Forced Dose Titration, Safety and Efficacy Study of NRP104 in Adults With
 IRB Expiration Date: 02/28/2015

Compare Two Selected Versions

1 result(s) found...

<input type="checkbox"/>	Show Rev.	Edit/View	Application Type	Approved?	Approval Date	Created By	Date Created	Modified by	Date Modified	Create a Revised Application
<input type="checkbox"/>			Study Application (Version 1.1)	Yes	02/24/2014	Mary Jane Coordinator	02-13-2014 14:11	Mary Jane Coordinator	02-24-2014 15:00	

Compare Tool

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

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

Compare Two Selected Versions

1 result(s) found...

<input type="checkbox"/>	Show Rev.	Edit/View	Application Type	Approved?	Approval Date	Created By	Date Created	Modified by	Date Modified	Create a Revised Application
<input checked="" type="checkbox"/>			Study Application (Version 1.1)	Yes	02/24/2014	Mary Jane Coordinator	02-13-2014 14:11	Mary Jane Coordinator	02-24-2014 15:00	
<input checked="" type="checkbox"/>			Study Application (Version 1.0)	No		Mary Jane Coordinator	02-12-2014 16:21	Susan M. Investigator	02-12-2014 16:21	

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

This view will show you any differences in the newer version, by marking items either Green or Red. Green highlights indicate a new addition to the form and Red highlights mark items that have been removed from the form.

This view will only show you sections within the form that have changed, so if your Study Application is fifteen sections long, but there are only differences found in four sections, only those four sections will display in the comparer view.

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

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

Version: 1.0 Mary Jane Coordinator		Version: 1.1 Mary Jane Coordinator													
1	Not Defined in Version 1.0	Section 4 - Section 200 Q 4 - Sub form attach: No form has been associated.													
2	Section 6 - Section 300 Q 1 - Human Subjects Training is a requirement for approval. Have you and your research team members completed Human Subjects Trainin ... = Yes = No	Section 6 - Section 300 Q 1 - Human Subjects Training is a requirement for approval. Have you and your research team members completed Human Subjects Trainin ... = Yes = No = No													
3	Section 6 - Section 300 Q 2 - Is this study or any part of this study contributing to a dissertation or thesis? = Yes = No	Section 6 - Section 300 Q 2 - Is this study or any part of this study contributing to a dissertation or thesis? = Yes = No = No													
4	Section 12 - Study management Links Q 1 -	Section 12 - Study management Links Q 1 -													
	<table border="1"> <thead> <tr> <th>Order Number</th> <th>Criteria</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>In the opinion of the investigator, the subject is significantly underweight [e.g., Body Mass Index (BMI) < 18.5] or morbidly obese.</td> </tr> <tr> <td></td> <td>Has any comorbid psychiatric diagnosis with significant symptoms such as any severe comorbid Axis II disorders or severe Axis I disorders including Post Traumatic Stress Disorder (PTSD), psychosis, bipolar illness, severe obsessive compulsive disorder, severe depressive or severe anxiety disorder or other</td> </tr> </tbody> </table>	Order Number	Criteria	1	In the opinion of the investigator, the subject is significantly underweight [e.g., Body Mass Index (BMI) < 18.5] or morbidly obese.		Has any comorbid psychiatric diagnosis with significant symptoms such as any severe comorbid Axis II disorders or severe Axis I disorders including Post Traumatic Stress Disorder (PTSD), psychosis, bipolar illness, severe obsessive compulsive disorder, severe depressive or severe anxiety disorder or other	<table border="1"> <thead> <tr> <th>Order Number</th> <th>Criteria</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>In the opinion of the investigator, the subject is significantly underweight [e.g., Body Mass Index (BMI) < 18.5] or morbidly obese.</td> </tr> <tr> <td></td> <td>Has any comorbid psychiatric diagnosis with significant symptoms such as any severe comorbid Axis II disorders or severe Axis I disorders including Post Traumatic Stress Disorder (PTSD).</td> </tr> </tbody> </table>	Order Number	Criteria	1	In the opinion of the investigator, the subject is significantly underweight [e.g., Body Mass Index (BMI) < 18.5] or morbidly obese.		Has any comorbid psychiatric diagnosis with significant symptoms such as any severe comorbid Axis II disorders or severe Axis I disorders including Post Traumatic Stress Disorder (PTSD).	
Order Number	Criteria														
1	In the opinion of the investigator, the subject is significantly underweight [e.g., Body Mass Index (BMI) < 18.5] or morbidly obese.														
	Has any comorbid psychiatric diagnosis with significant symptoms such as any severe comorbid Axis II disorders or severe Axis I disorders including Post Traumatic Stress Disorder (PTSD), psychosis, bipolar illness, severe obsessive compulsive disorder, severe depressive or severe anxiety disorder or other														
Order Number	Criteria														
1	In the opinion of the investigator, the subject is significantly underweight [e.g., Body Mass Index (BMI) < 18.5] or morbidly obese.														
	Has any comorbid psychiatric diagnosis with significant symptoms such as any severe comorbid Axis II disorders or severe Axis I disorders including Post Traumatic Stress Disorder (PTSD).														

Revise Application

The current version of the Study Application cannot be modified if it has been submitted for review. When you click the icon in the **Edit/View** column the application will open but because it has been submitted you cannot modify it. If you do need to make changes to the application, click the icon in the **Create a Revised Application** button. Note: that this icon is only available in the most current version of the application.

When you create a revision, iRIS will increment the form to the next available number. In this case, it is 1.2. Then, the editable version of the application will open for you to make changes. If your study is not in Draft mode, you will not be able to modify the current Key Personnel in section 2.0. You will need to submit an Amendment form to the review board for approval of any change in Key Personnel.

Also, note: when you create a revision to your Study Application from this area, you can make changes as needed. However, in order for those changes to be approved you will need to associate your Study Application to a submission form and send it to the review board for approval. Without sending your application the review board has no way to see that you have made changes that need to be approved. The revised version of the Study Application will be attachable to certain submission forms, like an Amendment, which is covered later in this document.

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

		Compare Two Selected Versions		Delete Selected Version						
1 result(s) found...										
<input type="checkbox"/>	Show Rev.	Edit/View	Application Type	Approved?	Approval Date	Created By	Date Created	Modified by	Date Modified	Create a Revised Application
<input type="checkbox"/>			Study Application (Version 1.2)	No		Mary Jane Coordinator	02-24-2014 15:46	Mary Jane Coordinator	02-24-2014 15:46	
<input type="checkbox"/>			Study Application (Version 1.1)	Yes	02/24/2014	Mary Jane Coordinator	02-13-2014 14:11	Mary Jane Coordinator	02-24-2014 15:00	
<input type="checkbox"/>			Study Application (Version 1.0)	No		Mary Jane Coordinator	02-12-2014 16:21	Susan M. Investigator	02-12-2014 16:21	

Delete Application

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

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

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

Add Application

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

Study Number: NCS	Study Application					
PI: Investigator, Susan M., Ph.D.						
Study Status: Draft	Study Title : New Clinical Study					
Add a new Application						
0 result(s) found...						
<input type="checkbox"/>	Show Rev.	Edit/View	Application Type	Approved?	Approval Date	Create a Revised Application
No application versions have been added to this study						

Informed Consent

The Informed Consent link, from the main Submission screen, will direct you to the Informed Consent library which stores any consent you have attached to submission forms or added through the library. When the review board approves a 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.

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

IRB Number: **GH-2015-25**
Informed Consent Document
◀ Back

PI: Investigator, Susan

Study Status: Open

IRB Number : GH-2015-25

IRB Expiration Date: 06/16/2016

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)

Search Level: Top All

Select Category: All ▼

Version #: .

Approval Date: 📅 **between** 📅

Show Hidden: Yes No

Title:

Consent Outcome: All ▼

Expiration Date: 📅 **between** 📅

Filter Documents

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

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

2 result(s) found...

<input type="checkbox"/>	View History	Edit/View	Title	Version	Language	UnApproved Consent	Approved Consent	Consent Outcome	Approval Date	Expiration Date	Checked Out By	Create a Revised Document	Hide
Informed Consent													
<input type="checkbox"/>			Consent	1.1 06/30/2015	English			Approved	06/17/2015	06/17/2016			
Standard Consent													
<input type="checkbox"/>			Consent	2.0 06/23/2015	English								

Filters

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

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

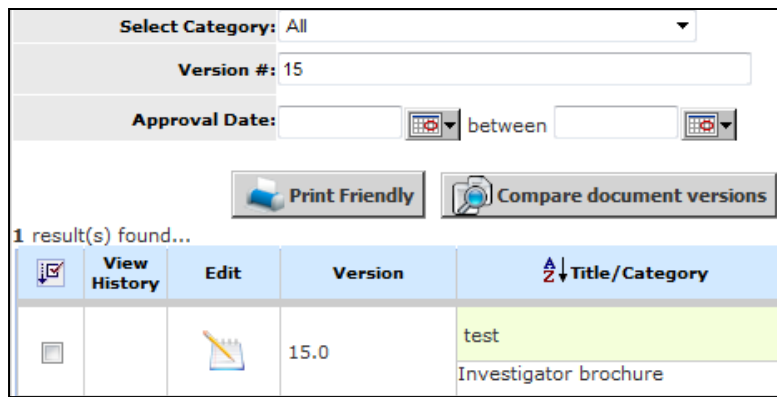
Show Hidden – The default selection for this filter is set to “No”. This means that all the documents viewed on the page are only the non-hidden documents. When you select “Yes”, the page will refresh and will display all documents for the study.

Select Category – This provides the ability to choose a Consent Category in the search. The default selection is set to “All” meaning all consents in all categories will display in the results.

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

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

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



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

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

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

Export

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

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

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

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

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.

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-dummys2.doc
 Type: Microsoft Word Document, 23.5KB
 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?](#)

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

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

Download Complete

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 spreadsheet before opening. You will want to make sure you save the document to a location on your computer that you will remember.

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



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

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

Print Friendly

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

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

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

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

close
 print

Informed Consent Document

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

1 result(s) found

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

Compare Consent Versions

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

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

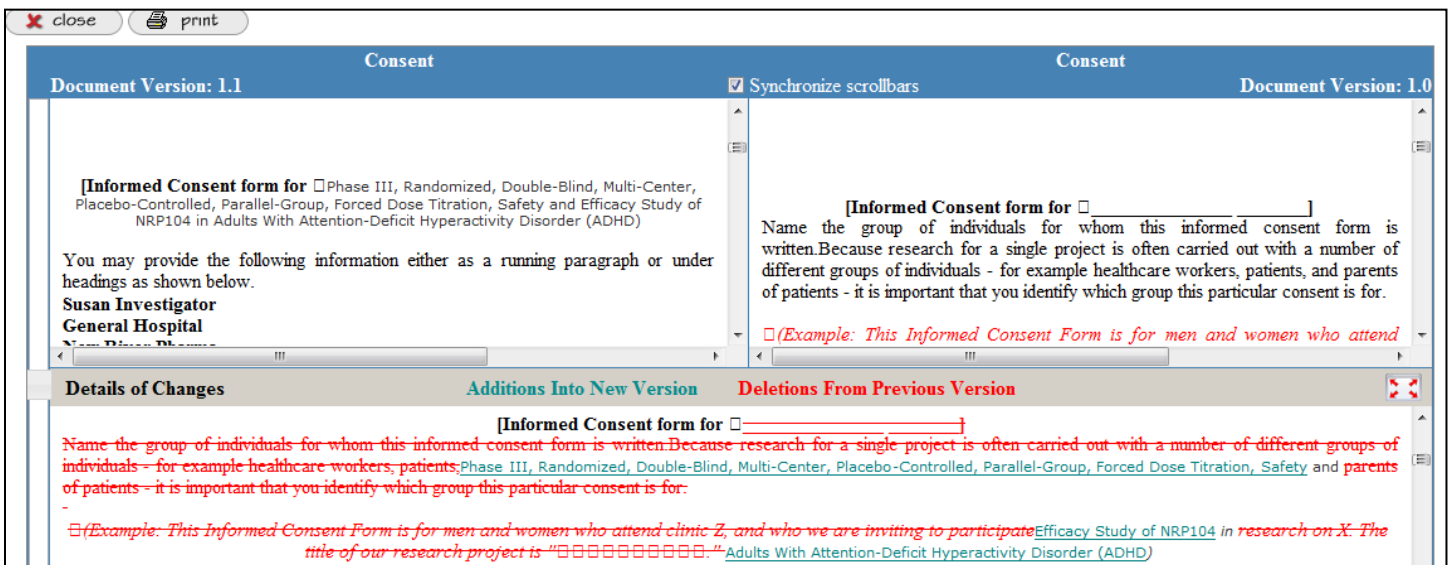
You can also compare versions of the consent, by clicking the checkbox next to two versions of the same consent and then clicking on the **Compare Consent Versions** button at the top of the page.

<input type="checkbox"/>	View History	Edit/View	Title	Version	Language	UnApproved Consent	Approved Consent	Consent Outcome	Approval Date	Expiration Date	Checked Out By	Create a Revised Document	Hide
<input checked="" type="checkbox"/>			Informed Consent	1.1 06/30/2015	English			Approved	06/17/2015	06/17/2016			
<input checked="" type="checkbox"/>			Informed Consent	1.0 06/30/2015	English								

iRIS will run the two versions of the consent through a comparer tool. This may take several moments, depending on the size of your consent documents. When the tool is complete a new window will open displaying both selected versions of the consent in a side-by-side view, with the newer version listed in the left column and the older version listed in the right column. At the bottom of the window a split view will display a combination of both versions, indicating where items have been modified.

The screenshot below shows you any differences in the newer version by marking items either Green or Red. Green highlights indicate a new addition to the consent document and Red highlights mark items that have been removed from the document.

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



Add a New Consent

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

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

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

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

IRB Number: GH-2015-25		Informed Consent Document		Back
PI: Investigator, Susan				
Study Status: Open	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)		
		IRB Expiration Date: 06/16/2016		
Next Screen				
<input checked="" type="radio"/> Add an informed consent from the list of Informed Consent Template Documents?				
<input type="radio"/> Add an informed consent from an existing electronic document you already have?				

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

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

Save Consent	
* Please select the Consent Template:	--none--
Provide the Consent Title if different from the template name:	<input type="text"/>
*Version Date:	<input type="text"/>
Category:	--none--
Description:	<input type="text"/>
*Version Number:	<input type="text"/> .0
* Language:	--none--
* Reconsent Required:	<input type="radio"/> Yes <input checked="" type="radio"/> No

Instructions

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

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

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

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

Description – A description of the document.

*Version Number:	<input type="text" value="1"/> .0
------------------	-----------------------------------

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

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

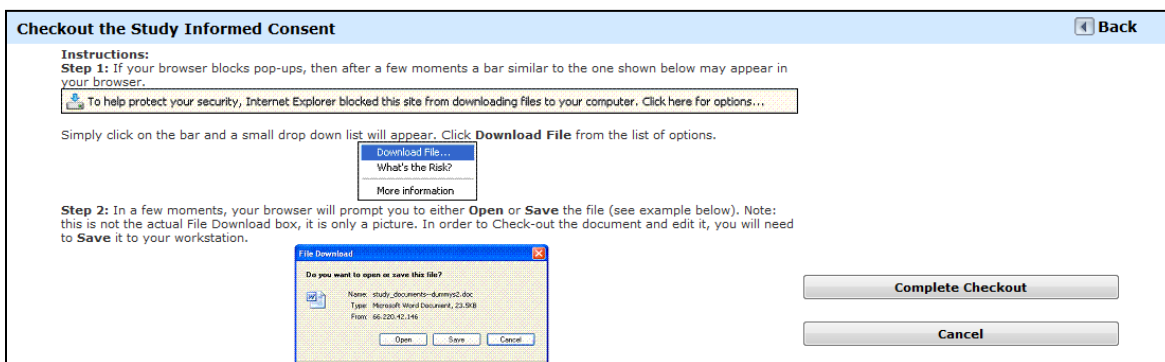
Reconsent Required – Indicate “Yes” if subject’s on the study will need to be re-consented.

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

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

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

A new page will open and your Internet browser will download the Consent document. 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. 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 document and will need to click undo the checkout in order to restore the document.



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

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



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

The system will return you to the previous page.

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

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

A small window will open allowing you to upload a document. You will need to browse for the document on your computer by clicking on the **Browse** button. This will open another window allowing you to navigate the folders on your computer so you can locate your Consent document. Once you associated a document, click the **Save selected file** button.

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

The screenshot shows the 'Informed Consent Document' form. At the top, it displays the IRB Number as 'GH-2015-25' and the PI as 'Investigator, Susan'. The Study Status is 'Open'. The Study Title is '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 IRB Expiration Date is '06/16/2016'. The Consent Title field contains 'Standard Consent'. There are buttons for 'Patient Consent List' and 'Save Consent'. A 'W RTF' icon is visible in the bottom right corner.

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

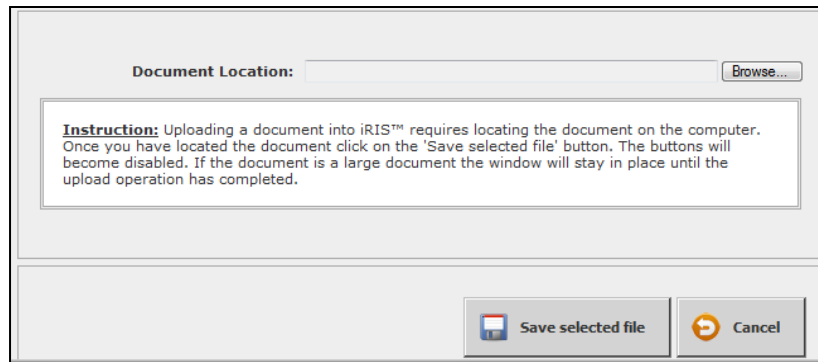
If you already have a consent document ready to upload, choose this option.

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

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

This screenshot shows the 'Informed Consent Document' form with a more detailed layout. The top section is identical to the previous screenshot. Below this, there are several input fields: '*Consent Title', '*Version Date', 'Category' (set to '--none--'), 'Description', '*Version Number' (set to '.0'), '*Language' (set to '--none--'), and 'Comments'. At the bottom, there is a button labeled 'Upload Your Consent Document...' with the note '(Microsoft Word, RTF or PDF file only)'. A 'Save Consent' button is also present. An 'Instructions' box on the right side provides guidance: 'Complete the fields to the left side of the screen, then click the Upload Your Consent Document... button. When the file browsing window comes up, click on the browse button. This will bring up your file system's file browser. Select the file you want to upload and click the Open button. NOTE: Informed consent documents must be in either Microsoft Word ".doc" format "rich text format'.

A small window will open allowing you to upload a document. You will need to browse for the document on your computer by clicking on the **Browse** button. This will open another window allowing you to navigate the folders on your computer so you can locate your Consent document. Once you associated a document, click the **Save selected file** button, as shown in the image below.



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

IRB Number: **GH-2015-25**
Informed Consent Document
Back

PI: Investigator, Susan

Study Status: Open

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)

IRB Expiration Date: 06/16/2016

Save Consent

document has been loaded.

*Consent Title:	<input style="width: 90%;" type="text"/>
*Version Date:	<input style="width: 80%;" type="text"/> <input style="width: 10%;" type="button" value="▼"/>
Category:	--none-- ▼
Description:	<div style="border: 1px solid gray; height: 30px;"></div>
*Version Number:	<input style="width: 80%;" type="text"/> .0
* Language:	--none-- ▼
Comments:	<div style="border: 1px solid gray; height: 30px;"></div>
* Upload your document	<input type="button" value="Upload Your Consent Document..."/> (Microsoft Word, RTF or PDF file only)

Instructions


Complete the fields to the left side of the screen, then click the **Upload Your Consent Document...** button. When the file browsing window comes up, click on the **browse** button. This will bring up your file system's file browser. Select the file you want to upload and click the **Open** button. **NOTE: Informed consent documents must be in either Microsoft Word ".doc" format "rich text format**

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






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

Approval Date: between Expiration Date: between

[Export](#) [Print Friendly](#) [Compare Consent versions](#) [+ Add a New Consent](#) [X Delete Selected Consent\(s\)](#)

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

3 result(s) found...

<input type="checkbox"/>	View History	Edit/View	Title	Version	Language	UnApproved Consent	Approved Consent	Consent Outcome	Approval Date	Expiration Date	Checked Out By	Create a Revised Document	Hide
<input type="checkbox"/>			Standard Consent	1.0	English								
			Standard Consent										

Delete Selected Consent(s)

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

Edit/View

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

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

IRB Number: **GH-2015-25** **Informed Consent Document** [Back](#)
 PI: Investigator, Susan

Study Status: **Open** 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)
 IRB Expiration Date: 06/16/2016 [Patient Consent List](#)

Consent Title: Informed Consent

*Version Date: 06/30/2015


Category: Consent

Description: Consent description.

*Version Number: 1 .1

* Language: English

Comments: Comments to review board.

Approved Consent


Accessing an Approved Consent

Within the Consent table are columns for the unapproved and approved versions of the Consent form. If the review board has not approved a Consent record, clicking on the icon in the UnApproved Consent column can access the copy of the consent. This will open the Consent document in a new window.

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

IRB Number: **GH-2015-25** **Informed Consent Document** Back
 PI: Investigator, Susan

Study Status: Open **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)
IRB Expiration Date: 06/16/2016

Search Level: Top All Show Hidden: Yes No

Select Category: All Title:

Version #: Consent Outcome: All Filter Document

Approval Date: between Expiration Date: between

Export Print Friendly Compare Consent versions + Add a New Consent ✖ Delete Selected Consent

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

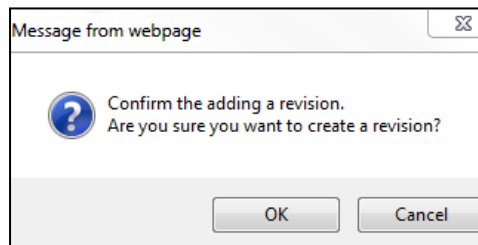
3 result(s) found...

<input type="checkbox"/>	View History	Edit/View	Title	Version	Language	UnApproved Consent	Approved Consent	Consent Outcome	Approval Date	Expiration Date	Checked Out By	Create a Revised Document	Hide
<input type="checkbox"/>			Informed Consent	1.1 06/30/2015	English			Approved	06/17/2015	06/17/2016			
<input type="checkbox"/>			Standard Consent	1.0 07/01/2015	English								

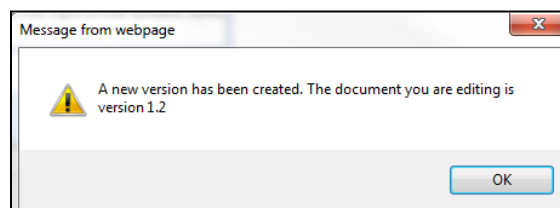
Revise a Consent

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

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



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



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

IRB Number: **GH-2015-25**
Back

Informed Consent Document

PI: Investigator, Susan

Study Status: Open **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)

IRB Expiration Date: 06/16/2016

Patient Consent List
Save Consent

Consent Title:	<input type="text" value="Informed Consent"/>
*Version Date:	<input type="text" value="06/30/2015"/>
Category:	<input type="text" value="Consent"/>
Description:	<input style="height: 30px;" type="text" value="Consent description."/>
*Version Number:	<input type="text" value="1"/> . <input type="text" value="2"/>
* Language:	<input type="text" value="English"/>

Check-out Document...

Unapproved Consent

A new page will open and your Internet browser will download the Consent document. 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, the browser may prompt you with a yellow bar at the top. 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 document and will need to click undo the checkout, in order to restore the document.

Checkout the Study Informed Consent
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.

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

Complete Checkout
Cancel

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

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

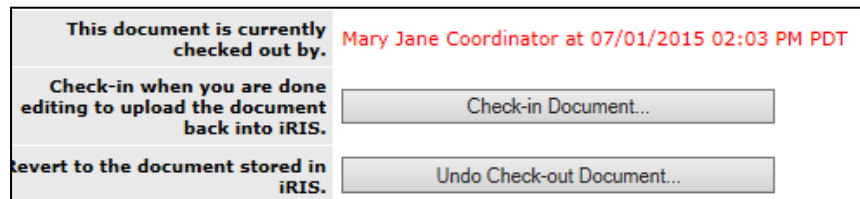
It is best to choose to **Save** the document, so you can be sure of saving the document in a known location.



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

The system will return you to the previous page.

Whenever a document is checked out, the system will indicate the document is checked out. If you are logged in as the user that has checked out the document, you will be able to **Check-in Document** or **Undo Check-out Document**.



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

IRB Number: **GH-2015-25** **Informed Consent Document** Back
 PI: Investigator, Susan

Study Status: Open **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)
IRB Expiration Date: 06/16/2016

Search Level: Top All **Show Hidden:** Yes No
 Select Category: All **Title:** _____
 Version #: _____ **Consent Outcome:** All **Filter Documents**
 Approval Date: _____ between _____ **Expiration Date:** _____ between _____

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

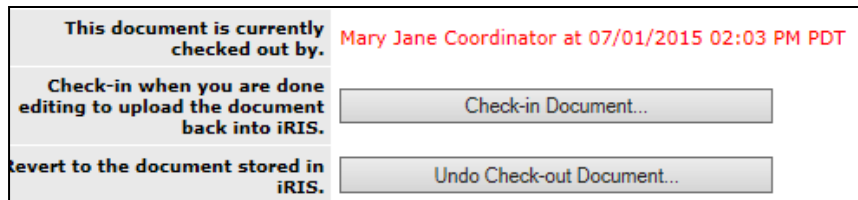
Informed consent revision history list associated with this study.
 To create a new version, click on the Add Revision icon to the right of the consent form.
 To view previous versions click on the folder icon.

3 result(s) found...

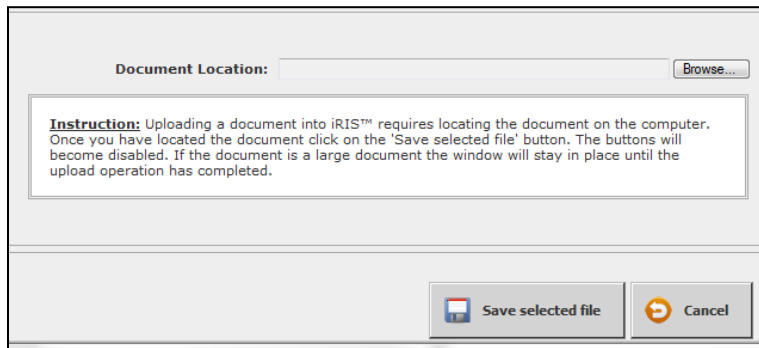
<input type="checkbox"/>			Title	Version	Language	UnApproved Consent	Approved Consent	Consent Outcome	Approval Date	Expiration Date	Checked Out By	Create a Revised Document	Hide
<input type="checkbox"/>			Informed Consent										
			Consent	1.2 06/30/2015	English						Mary Jane Coordinator at 07/01/2015 02:03:38 PM		
			Standard Consent										

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

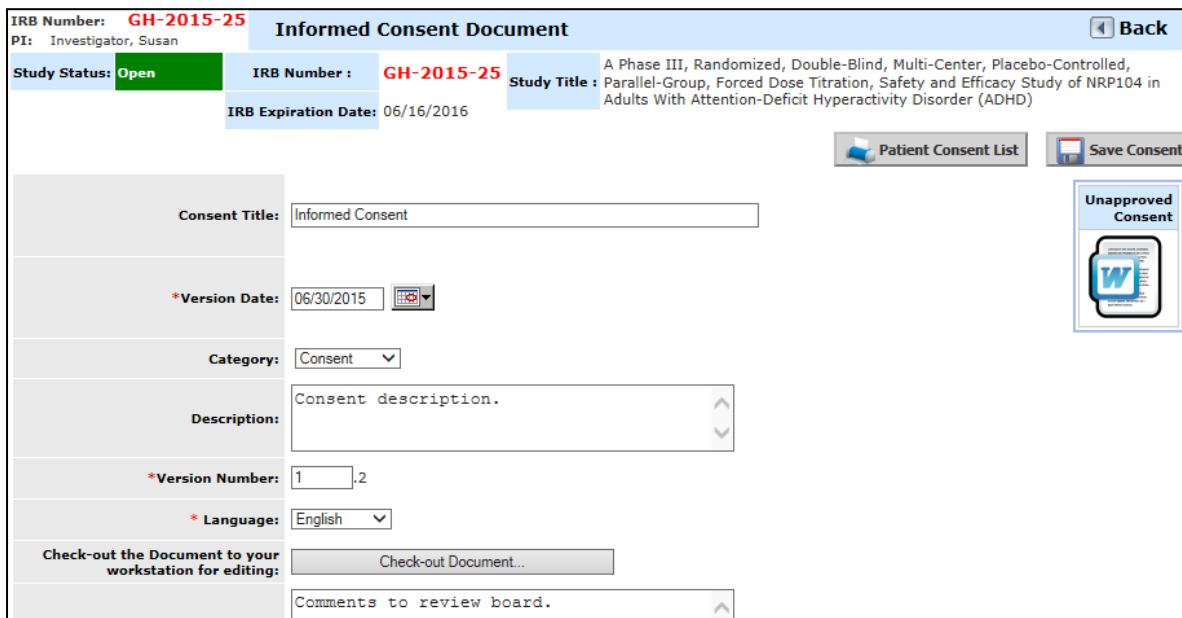
When the Informed Consent Document details page opens, you can click the **Check-in Document** button.



A window will open allowing you to upload the revised Consent. Browse for the document on your computer by clicking on the **Browse** button. This will open another window, allowing you to navigate the folders on your computer so you can locate your Consent document. Once you associated a document, click the **Save selected file** button.



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



Other Study Documents

The **Other Study Documents** link from the main Submissions page will direct you to the Other Study Document library, which stores any document you have attached to submission forms or added through the library. When the review board approves a document the approval information will update the document stored in the library which can also be accessed and printed.

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

IRB Number: **GH-2015-25**
Study Documents
Back

PI: Investigator, Susan

Study Status: Open

IRB Number : GH-2015-25

IRB Expiration Date: 06/16/2016

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)

Search Level: Top All

Select Category: All

Version #: .

Approval Date: between

Show Hidden: Yes No

Title:

Document Outcome: All

Expiration Date: between

Filter Documents

Print Friendly
Compare document versions
Add a New Document
Add Multiple Documents
Delete Selected Document(s)

4 result(s) found...

<input type="checkbox"/>	View History	Edit	Version	Title/ Category	Document Outcome	Approval Date	Expiration Date	File	Stamped File	Checked Out By	Create Revision	Hide
<input type="checkbox"/>			1.0 06/30/2015	Investigator's Brochure Template (1)								
				Investigator brochure	Approved	06/17/2015			668.51 KB		Add Revision	
<input type="checkbox"/>			1.0 06/30/2015	Flyer								
				Flyer	Approved	06/17/2015			96.59 KB		Add Revision	
<input type="checkbox"/>			1.0 06/30/2015	radio script								
				Other	Approved	06/17/2015			100.10 KB		Add Revision	
<input type="checkbox"/>			1.1 06/16/2015	Protocol								
				Protocol	Approved	06/17/2015			25.75 KB		Add Revision	

Filter Documents

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

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

Search Level: Top All

Select Category: All

Version #: .

Approval Date: between

Show Hidden: Yes No

Title:

Document Outcome: All

Expiration Date: between

Filter Documents

The available filters are as follows:

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

Select Category – You can choose a document category from the drop down menu.

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

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

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

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

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

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

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

Printer Friendly

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

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

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

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

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

Compare Document Versions

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

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

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

<input checked="" type="checkbox"/>	View History	Edit	Version	Title/ Category	Document Outcome	Approval Date	Expiration Date	File	Stamped File	Checked Out By	Create Revision	Hide
<input checked="" type="checkbox"/>			1.1 06/16/2015	Protocol	Approved	06/17/2015			 25.75 KB		 Add Revision	
<input checked="" type="checkbox"/>			1.0 06/16/2015	Protocol				 14.81 KB				

iRIS will run the two versions of the document through a comparer tool. This may take several moments, depending on the size of your documents. When the tool is complete, a new window will open displaying both selected versions of the document in a side-by-side view, with the newer version listed in the left column and the older version listed in the right column. At the bottom of the window a split view will display a combination of both versions, indicating where items have been modified.

This bottom view will show you any differences in the newer version, by marking items either Green or Red. Green highlights indicate a new addition to the document, and Red highlights mark items that have been removed from the document.

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

Add a New Document

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

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

*Version Number: .0

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

document in iRIS. You will always be able to revise your manually entered version number, but you are unable to revise the iRIS version number.

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

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

Description – A description of the document.

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

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

A small window will open allowing you to upload a document. You will need to browse for the document on your computer, by clicking on the **Browse** button. This will open another window allowing you to navigate the folders on your computer so you can locate your document. Once you associated a document, click the **Save selected file** button.

The system will return you to the previous page.

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

If you did not enter the Document Title prior to uploading the document, the system will automatically apply the name of the document to the Document Title field.

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

The screenshot shows a web form titled "Study Documents" for a study with IRB Number "GH-2015-25" and PI "Investigator, Susan". The study status is "Open". The study title is "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 IRB expiration date is "06/16/2016".

The form fields include:

- *Document Title:** Investigator's Brochure Template (1)
- *Version Number:** .0
- Version Date:** (calendar icon)
- Category:** --none--
- Description:** (empty text area)
- Load the document into iRIS:** Upload ...
- Comments:** (empty text area)

Buttons for "Save Document" and "View the document" are visible on the right side of the form.

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

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

Add Multiple Documents

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

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

Add the information for the number of documents you are uploading. If you are not uploading five documents, just populate the necessary row(s) and click the **Save Record(s)** button.

If you have more than five documents to upload, you can click the **Add New Records** button and five additional rows will populate on the page.

You can also delete records from the upload, by selecting the checkbox next to the record and clicking the **Delete Record(s)** button. You do not need to delete unused rows; the system will not upload anything that has not been entered in a row.

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

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

IRB Expiration Date: 02/28/2015

Browse for files in your local machine. Records with invalid file path will not be added. All fields other than file path will be automatically populated if not entered.

+ Add a New Records
X Delete Record(s)
Save Record(s)

	Document Title	Version	Version Date	Category	File path
<input type="checkbox"/>	<input type="text"/>	<input type="text"/> .0	<input type="text"/>	--none--	<input type="text"/> Browse...
<input type="checkbox"/>	<input type="text"/>	<input type="text"/> .0	<input type="text"/>	--none--	<input type="text"/> Browse...
<input type="checkbox"/>	<input type="text"/>	<input type="text"/> .0	<input type="text"/>	--none--	<input type="text"/> Browse...

Delete Documents

You can delete documents by selecting the checkbox next to the document record and clicking the **Delete Selected Documents(s)** button. Once a Study Document is submitted it cannot be deleted from the study.

Edit

You can view the details of any Other Study Document by clicking the icon in the **Edit** column. If the document has been submitted, you will not be able to make any edits to the record. You will need to create a revision of the document in order to do so.

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

IRB Number: **GH-2015-25** **Study Documents** Back

PI: Investigator, Susan

Study Status: **Open** 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)

IRB Expiration Date: 06/16/2016

*Document Title: Investigator's Brochure Template (1)

*Version Number: 1.0

Version Date: 06/30/2015

Category: Investigator brochure

Description: Description.

Comments: Comments to review board.

View the stamped document

Accessing Approved Documents

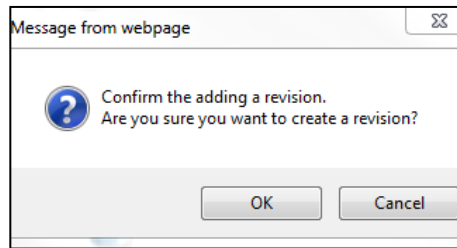
Within the Other Study Document table; there will be columns for the un-approved and approved versions of the documents. If the review board has not approved a certain document, clicking on the icon in the File column can access the copy of the document. This will open the document in a new window.

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

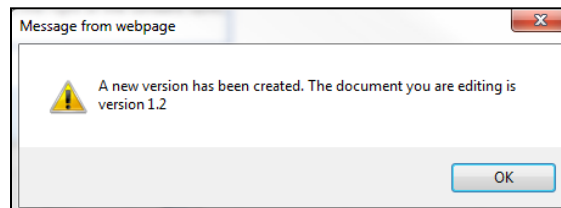
Creating Revisions

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

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



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



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

A new page will open and your Internet browser will download the document. 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. 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 document and will need to click undo the checkout in order to restore the document.

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

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

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



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

The system will return you to the previous page.

Whenever a document is checked out, the system will indicate the document is checked out. If you are logged in as the user that has checked out the document, you will be able to **Check-in Document** or **Undo Check-out Document**.

This document is currently checked out by. Mary Jane Coordinator at 07/01/2015

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

Revert to the document stored in iRIS.

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

<input type="button" value="Print Friendly"/> <input type="button" value="Compare document versions"/> <input type="button" value="Add a New Document"/> <input type="button" value="Add Multiple Documents"/> <input type="button" value="Delete Selected Document(s)"/>												
2 result(s) found...												
<input type="checkbox"/>	View History	Edit	Version	Title/ Category	Document Outcome	Approval Date	Expiration Date	File	Stamped File	Checked Out By	Create Revision	Hide
<input type="checkbox"/>			1.0	New Document Other				 337.92 KB			 Add Revision	
<input type="checkbox"/>			1.2 06/16/2015	Protocol Protocol				 14.81 KB		Mary Jane Coordinator 07/01/2015 02:18:25 PM	(Read Only)	

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

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

This document is currently checked out by. Mary Jane Coordinator at 07/01/2015

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

Revert to the document stored in iRIS.

A small window will open allowing you to upload the revised document. You will need to browse for the document on your computer by clicking on the **Browse** button. This will open another window allowing you to navigate the folders on your computer, so you can locate your document. Once you associated a document, click the **Save selected file** button.

Document Location:

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.

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

Study Status: **Open** 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)

IRB Expiration Date: 06/16/2016

***Document Title:** Protocol

***Version Number:** 1 .2

Version Date: 06/16/2015

Category: Protocol

Buttons: Save Document, View the document

Submission Forms

This area links to different submission forms that can be sent to a review board as needed. The list of forms here will change depending on the forms setup in your system. You can create and submit a form any time by clicking on the link for the form.

IRB Number: **GH-2015-25** Submissions Back

PI: Investigator, Susan

Study Status: **Open** 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)

IRB Expiration Date: 06/16/2016

Tabs: 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

Forms

- Continuing Review Submission Form
- Amendment Form
- Adverse Event
- Study Closure Form

Outstanding Submission(s)

Track Location	Ref Number	Request Type	Process Submission
There are no outstanding submissions.			

When you click on a form link from the main Submissions page you will be directed to a screen that lists any previously started or completed forms for the study. The header of the page contains buttons that allows you to **Copy Forms**, **Add a New Form**, **Compare Two Versions** or **Delete Selected Form(s)**, (provided it has not been submitted for review).

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

Study Status: **Open** **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)
IRB Expiration Date: 06/16/2016

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

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

1 result(s) found...

<input type="checkbox"/>	Show Rev	Edit/View	Ref Number	Sub. Rounds	Track Location	Process Submission	Submission Date	Created By	Date Created	Modified By	Date Modified
<input type="checkbox"/>			000018				07/01/2015	Mary Jane Coordinator	07/01/2015 02:40:00 PM	Mary Jane Coordinator	07/01/2015 02:40:58 PM

The table below the buttons lists any form already started.

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

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

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

Ref Number – For every form that is submitted in iRIS, a unique number is assigned to that form, called the Reference Number. Each form that is submitted will get assigned a Reference Number.

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

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

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

Status	View Details	Date Received / Date Completed		Event Description
		07/01/2015 02:40 PM PDT		IRB received the submission
		07/01/2015 02:40 PM PDT 07/01/2015 02:40 PM PDT		Mary Jane Coordinator as Clinical Research Coordinator review and apply signoff
	 Routing Assignment List	07/01/2015 02:40 PM PDT 07/01/2015 02:40 PM PDT		Assign Department Personnel for Signoff
		07/01/2015 02:40 PM PDT 07/01/2015 02:40 PM PDT		Amendment Form is waiting to be submitted

Any steps that are still in process will be displayed at the top of the list, with the status of **In Process** (the blue icon). The steps that are completed will be displayed with the status of **Completed** (the green checkmark). Once a step has moved

from In Process to Completed, the step will order by the date/time stamp. If any step was cancelled, the status will be cancelled and the Cancel icon will be displayed, as seen in the image below.

		12/12/2012 01:44 PM PST 12/12/2012 01:44 PM PST		Administrator as Department Chair review and apply signoff
Cancelled		12/12/2012 01:41 PM PST		John Investigator as Additional Principal Investigator review and apply signoff

The date the process was received is displayed in the **Date Received/Date Completed** column. The **Event Description** will display the description of the process. Each item in this table can be expanded to show more details in the Event Description. This can be done by clicking the expand button:

		03/03/2014 02:51 PM PST		IRB received the submission
--	--	-------------------------	--	-----------------------------

The expand icon will cause the item to appear as so, with the detailed information:

		03/03/2014 02:51 PM PST		IRB received the submission 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) Principal Investigator: Dr. Susan M. Investigator, Ph.D. Submission Type: Amendment Form Reference Number: 000108 Study Number: NRP104.303
--	--	-------------------------	--	---

To minimize this view, simply click on the small collapse button.

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

		03/03/2014 02:50 PM PST 03/03/2014 02:51 PM PST		Mary
--	--	--	--	------

Submission Routing Signoff Sheet Back

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)

Submission Reference Number: 000018

Create PDF Packet

Include in PDF Packet	Submission Component Name - Version
Submission Form(s)	
<input type="checkbox"/>	Amendment Form - (Version 1.0) (Parent of the submission package)
Document(s)	
<input type="checkbox"/>	New Document - (Version 1.0)

Mary Jane Coordinator as Clinical Research Coordinator
do you Approve or Deny this submission?

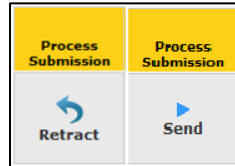
Approve Deny

This form requires your electronic signature. Please enter your User ID & Password: ELECTRONIC SIGNATURE HAS BEEN APPLIED by Mary Jane Coordinator at 07/01/2015 02:40 PM PDT

Process Submission – This column will populate with two buttons or will display empty, based on where the submission is, in relation to completion or having been submitted.

Process Submission	Submission Date	Created By	Date Created	Modified By	
Send		Principal Investigator	12/12/2012 04:43:27 PM	Principal Investigator	12/1

If the form has been filled out but not yet submitted into the workflow, a **Send** button will populate in the column, allowing you to send the form without opening it. If the form has been submitted into the workflow but has not been processed by the review board, a **Retract** button will populate in the column, allowing you to pull the form back to make any corrections. Otherwise this column will be blank.



Submission Date – Will display the date the form was submitted into the workflow.

Created By – Will display the name of the user who created the form record.

Date Created – Will display the date and time the form record was created.

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

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

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

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

The form will open in a new window. You can fill out the form, using the **Save and Continue** button, at the top right of the page, to navigate through the sections.

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

Submissions History

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

This section can be viewed three ways:

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

Submissions												
IRB Number: GH-2015-25		PI: Investigator, Susan										
Study Status: Open		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)								
IRB Expiration Date: 06/16/2016												
Submissions in Process			Completed Submissions			Submissions Returned with Changes			Print Friendly			
Reference Number	Track Location	Status	Request Type	Details	Review Board	View Outcome Letters	Review Process	Meeting Date	Review Outcome	Date Received		
000018			Amendment Form									
			Amendment Form		IRB							07/01/2015 02:40:58 PM PDT

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

Submissions Returned with Changes - Lists the submissions that have been returned for corrections from the review board.

Within all three tabs an icon appears under the Track Location, Request Type and Details columns.

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

Request Type- Click on this icon to view the submission form.

Details – Click this icon to view the forms and attachments within the submission. From this screen, you can open any of the components of the submission by clicking on the item.

Show History		Open	Type	Document Name	Version	Date Submitted into Workflow
Submission Form:						
			Submission Form	Amendment Form	Version 1.0	07/01/2015 02:40 PM PDT
Submission Attachments below:						
			Document - Other	New Document	Version 1.0	07/01/2015 02:40 PM PDT
			Outcome:	Approval Date:		Expiration Date:

Study Correspondence

This section is used for any correspondence, between study personnel and any review board, related to the study and is located on the main Submission screen. This area will contain a list of any study related correspondence that has been sent out at any point of the life of the study. The system will send out automatic notifications at certain points – Principal Investigator signoff notifications, Review Response requested by the review board notifications, Submission signoff denied notifications, Continuing Review Due notifications, etc. Whenever a notification is generated and sent related to the study a record of that notification will post to the Study Correspondence.

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

The review board and the study share the Study Correspondence, meaning any correspondence generated is visible by both sides. There is one restriction: if the study generates and sends a correspondence that does not include a recipient listed on the review board, the correspondence record will not be visible to the review board. Any correspondence that does not pertain to the review board will not be accessible to the review board.

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

The screenshot shows the 'Study Correspondence' page for study GH-2015-25. At the top, it displays the IRB Number (GH-2015-25), PI (Investigator, Susan), and Study Status (Open). The Study Title is '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 IRB Expiration Date is 06/16/2016. There are buttons for 'Print Friendly', 'Add A New Correspondence', and 'Delete Selected Correspondence'. Below this, it says '5 result(s) found...' and shows a table of messages.

<input type="checkbox"/>	View Message	Author	Subject
<input type="checkbox"/>		Administrator	Posted: 07/01/2015 12:22 PM PDT NCT00334880 GH-2015-25 Outcome Letter (attachment)
<input type="checkbox"/>		Administrator	Posted: 06/30/2015 03:41 PM PDT NCT00334880 GH-2015-25 Submission Correction

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

- Select the checkbox if you want an **Email** notification sent to the recipient(s). This checkbox is selected by default. If you do not want the correspondence to send as an email, make sure the checkbox is not selected. You would choose not to send an email if you simply want to generate a correspondence that posts to the study without actually emailing to users.
- Enter a **Subject** for the correspondence.
- Assign **Recipients** to the correspondence.
- Add any **Additional Recipients** to which you would like a copy of the correspondence sent.
- Add **Reply To(s)** if necessary. This means that any user added here will receive a reply, if the original recipient replies to the email from their email inbox.
- Add **Additional Reply To(s)** if necessary. This works the same as the **Reply To(s)** and allows you to add any additional users, who should receive a reply.
- Add any **Attachments** you would like to include with the correspondence.
- Enter the **Content** in the text editor.

Once you have completed the correspondence, click the **Save and Send Correspondence** button. If the Send Email checkbox is selected, an email will send to the recipients and will also be posted in their Un-opened Correspondence on their homepage. If the Send Email is not selected, the recipients will only have the correspondence in their Un-opened Correspondence and a record of the correspondence will post in Study Correspondence.

	View Message	Author	Subject
		Post a Reply to this Topic / Forward this Topic	
		Susan Investigator	Posted: Delivery in Progress NCT00334880 New Correspondence
		Mary Jane Coordinator	Posted: Delivery in Progress NCT00334880 New Correspondence

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

Outstanding Submissions

Any submission form created for the study will populate in the Outstanding Submission(s) table at some point. Submissions are listed here if the form has been completed, but not yet sent. The submission will also populate if the form has been sent, but is still being routed to the review board, (example, not all required signoffs have been collected). When the review board receives the submission and begins processing the form, the link in Outstanding Submissions will be removed. At this point, if you need to find information related to your form, you would go to Submissions History to find it. Any submission that is returned by the review board for corrections will also post here, allowing the user to access the correction form, to make necessary changes and re-submit the form to the board.

Initial Review

Submissions





- Initial Review Submission Packet

IRB Items

Forms

- Continuing Review Submission Form
- Amendment Form
- Adverse Event

Study Correspondence

Outstanding Submission(s)			
Track Location	Ref Number	Request Type	Process Submission
	000019	Click on the hyperlink to edit/view the submission.  Adverse Event	<input type="button" value="Send Submission"/>
	000018	Click on the hyperlink to edit/view the submission.  Amendment Form	<input type="button" value="Retract Submission"/>

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

IRB Number: GH-2015-25		Workflow - Submission Tracking		Back
PI: Investigator, Susan				
Print Friendly				
Status	View Details	Date Received / Date Completed		Event Description
		07/01/2015 02:40 PM PDT		IRB received the submission
		07/01/2015 02:40 PM PDT 07/01/2015 02:40 PM PDT		Mary Jane Coordinator as Clinical Research Coordinator review and apply signoff
	 Routing Assignment List	07/01/2015 02:40 PM PDT 07/01/2015 02:40 PM PDT		Assign Department Personnel for Signoff
		07/01/2015 02:40 PM PDT 07/01/2015 02:40 PM PDT		Amendment Form is waiting to be submitted

This will open the same Workflow – Submission Tracking screen you may have seen earlier after completing a signoff task. The workflow will update as the submission moves forward in its processing. The screenshot above shows that the submission successfully passed required signoffs and is currently sitting in the IRB queue.

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

Outstanding Submission(s)			
Track Location	Ref Number	Request Type	Process Submission
	000019	Click on the hyperlink to edit/view the submission. Adverse Event	
	000018	Click on the hyperlink to edit/view the submission. Amendment Form	

In the **Request Type** column, you can click on the link to open the form. If the form has not been submitted yet, you can make changes to the form; otherwise the form will be read only.

The **Process Submission** column will contain buttons depending on the status of the submission. If the form has not been submitted, there will be a **Send Submission** button. If the form has been submitted, but has not been processed by the review board, you will be able to **Retract Submission**, if a situation arises where you need to pull the form back to make revisions. If you retract the submission, you will be able to modify the form and its components, but you must also send it back through for required signoffs again.

Submitting a Continuing Review

When a study is up for Continuing Review, the system will begin to send notifications to the Principal Investigator and Study Contact. The amount of time before the Continuing Review Due Date, that these notifications send out depends on your systems configuration. Typically, notifications are sent 90, 60, and 30 days before the IRB Expiration Date.

Continuing Review Due Task

Once the study begins to receive notification that the Continuing Review is due, the Principal Investigator and any user’s noted as the Study Contact, will receive a Continuing Review Due Task on their homepage. This task will remain on the homepage, until a Continuing Review form is submitted to the review board.

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

Welcome Dr. Susan M. Investigator, Ph.D.

Below are your incomplete IRB tasks:

Continuing Review Due 1

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

Open	Principal Investigator	IRB Number	On Study Status	Study Alias	IRB Initial Approval	Expiration	Approved	Review Due	Review Cycle	Received
	Susan Investigator	GH-14-016	Open	NRP104.303	03/01/2014	03/31/2014		03/31/2014	1 Year	03/03/2014

Filling out the form

The form will open in a new window. You can fill out the form using the **Save and Continue** button at the top right of the page to navigate through the sections.

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

Continuing Review Submission Form Back

Print Friendly Refresh Constant Fields Save and Continue

Section view of the Form | Entire view of the Form

- 1.0 General Hospital Continuing Review Form
- 2.0 Re-approval Requested

GH-14-016

1.3 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)

1.4 Principal Investigator:
Susan M. Investigator, Ph.D.

1.5 Expiration Date:
03/31/2014

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

Submitting the Form

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

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

Continuing Review Submission Form Back

Print Friendly Signoff and Submit

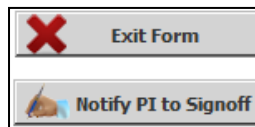
Section view of the Form | **Entire view of the Form**

Form has been Completed!

1.0 General Hospital Continuing Review Form
 2.0 Re-approval Requested
 3.0 Subject and Demographic Information
 4.0 Narrative Summary
 5.0 Adverse Events
 6.0 Informed Consent Evaluation
 7.0 Current Risk/Benefit Assessment
 8.0 Study Personnel
 9.0 Conflict of Interest

Exit Form
Signoff and Submit

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



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



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



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

You may be prompted to route for additional signatures.

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

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

Save and Continue

Does this submission require additional routing for approval?

YES - Click YES to select additional personnel for routing.

NO - Click NO to bypass selecting additional personnel for routing.

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

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

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

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

Return to Previous Screen Save and Continue

Select the Key Personnel required for routing and signoff

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

Include in signoff	Approved	Name	Role
<input checked="" type="checkbox"/>		Dr. Susan M. Investigator, Ph.D.	Principal Investigator
<input type="checkbox"/>		Patrick Investigator, Ph.D.	Co-Investigator
<input type="checkbox"/>		Mary Jane Coordinator, R.N.	Study Coordinator
<input type="checkbox"/>		Stacy Staff	Nurse

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.

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 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.

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

Section view of Application | Entire view of the Application

1.0 General Information

2.0 Setup Department(s) Access

3.0 Grant Key Personnel access to the study

4.0 General App Info

5.0 Lay Summary

6.0 Subject Info

7.0 Study Drugs

8.0 Medical Devices

Investigator, Susan

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):

Administrator

Department Chair

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).

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

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

Search User Directory

Back

Save Selected User(s)

Directory Browse/Find:

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

First Name:

by Department: All Departments

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 by changing the order, if one reviewer should receive the task before another. Click the **Save and Continue** button 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"/>	1	<input type="checkbox"/>	Administrator Department Chair
<input checked="" type="checkbox"/>	2	<input type="checkbox"/>	Dr. Patrick Investigator, Ph.D. Advisor

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:

- Click on the *Add signoff* link on the iRIS control panel.

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

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

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

Click here to select Additional Personnel for Signoff

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

Have you completed your selection of required signatures?

Yes

No

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.

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

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

Workflow - Submission Tracking Back

Status	View Details	Date Received / Date Completed	Event Description
	<p>Waiting on Finalization of Routing Assignment List</p> <p>Click here to Finalize List</p>	03/04/2014 04:23 PM PST 03/04/2014 04:23 PM PST	Assign Department Personnel for Signoff
		03/04/2014 04:23 PM PST 03/04/2014 04:23 PM PST	Continuing Review Submission Form is waiting to be submitted

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

If you choose “Yes” and **Save and Continue** and you are NOT assigned to sign off on the form, you will be brought to the Workflow – Submission Tracking page and the users assigned to sign off will receive notifications from iRIS regarding their new assignments.

A user who is assigned to sign off on a submission form will receive a notification, sent to the email address stored in their user account information. They will also receive a Submission Routing Signoff task on their homepage. This task will remain on their homepage until the user opens the task and completes the sign off.

My Assistant

Study Assistant

Department

My Effort

Correspondence

Completed Tasks

Welcome Dr. Susan M. Investigator, Ph.D.

Below are your incomplete Study tasks:

Submission Routing Signoff
1

IRB Number ▾

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

Open	Principal Investigator	IRB Number	Study Alias	Study Status	Ref Number	Submission Form Name	IRB Initial Approval	Expiration	Received
	Dr. Susan M. Investigator, Ph.D.	GH-14-016	NRP104.303	Open	141	Continuing Review Submission Form	03/01/2014	03/31/2014	03/04/2014

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

Submission Routing Signoff Sheet ◀ Back

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)

Submission Reference Number: 000027

Create PDF Packet

Include in PDF Packet	Submission Component Name - Version
Submission Form(s)	
<input type="checkbox"/>	Continuing Review Submission Form - (Version 1.0) <small>(Parent of the submission package)</small>
Document(s)	
Category : Flyer	
<input type="checkbox"/>	Flyer - (Version 1.1)
Category : Investigator brochure	
<input type="checkbox"/>	Investigator's Brochure Template (1) - (Version 1.1)

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:

Save Signoff

Also listed on this page is a link to the Submission Components. This table contains a link to the Submission Form and if attached, the Study Application and any Consent and Other Study Document that has been associated to the form. This is the package that is being submitted to the review board for review.








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

Submission Form(s):	<input type="checkbox"/>	Continuing Review Submission Form - (Version 1.0) (Parent of the submission package)
	Document(s)	
	Category : Flyer	
	<input type="checkbox"/>	Flyer - (Version 1.1)
	Category : Investigator brochure	
<input type="checkbox"/>	Investigator's Brochure Template (1) - (Version 1.1)	

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

<p>Dr. Susan M. Investigator, Ph.D. as Principal Investigator do you Approve or Deny this submission?</p> <p>This form requires your electronic signature. Please enter your User ID & Password:</p>	<p style="text-align: center;"> <input type="radio"/> Approve <input type="radio"/> Deny </p> <p>User ID: <input type="text"/></p> <p>Password: <input type="password"/></p> <p style="text-align: center;"></p>
View Other Comments:	
Mary Jane Coordinator, R.N.	Study Coordinator
Comments:	

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

Study Number: NRP104.303		Workflow - Submission Tracking		Back
PI: Investigator, Susan M., Ph.D.				
Status	View Details	Date Received / Date Completed		Event Description
		02/12/2014 03:51 PM PST	⊕	Mary Jane Coordinator, R.N. as Study Coordinator review and apply signoff
	 Routing Assignment List	02/12/2014 03:04 PM PST 02/12/2014 03:51 PM PST	⊕	Assign Department Personnel for Signoff
		02/12/2014 03:51 PM PST 02/12/2014 04:15 PM PST	⊕	Dr. Susan M. Investigator, Ph.D. as Principal Investigator review and apply signoff
		02/12/2014 02:55 PM PST 02/12/2014 03:04 PM PST	⊕	Initial Review Submission Form is waiting to be submitted

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

Study Number: NRP104.303 PI: Investigator, Susan M., Ph.D.		Workflow - Submission Tracking		Back
Status	View Details	Date Received / Date Completed		Event Description
		02/12/2014 04:17 PM PST		Submission rejected
		02/12/2014 04:17 PM PST 02/12/2014 04:17 PM PST		Mary Jane Coordinator, R.N. as Study Coordinator review and apply signoff
		02/12/2014 04:17 PM PST 02/12/2014 04:17 PM PST		Patrick Investigator, Ph.D as Co-Investigator review and apply signoff
		02/12/2014 04:17 PM PST 02/12/2014 04:17 PM PST		Dr. Susan M. Investigator, Ph.D. as Principal Investigator review and apply signoff
		02/12/2014 04:16 PM PST 02/12/2014 04:17 PM PST		Assign Department Personnel for Signoff
		02/12/2014 04:16 PM PST 02/12/2014 04:16 PM PST		Initial Review Submission Form is waiting to be submitted

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

Below are your incomplete Study tasks:

Submission Signoff Denied 1

IRB Number ▾

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

Open	Principal Investigator	IRB Number	Study Alias	On Study Status	Ref Number	Submission Form Name	IRB Initial Approval	Expiration	Received	Denied by	Round Number
	Dr. Susan M. Investigator, Ph.D.		NRP104.303	Draft	94	Initial Review Submission Form			02/12/2014	Dr. Susan M. Investigator, Ph.D.	1

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

Responding to Corrections

The review board may return items to you for correction. When a submission is returned for corrections, the Principal Investigator and any Study Contacts listed on the study will receive a notification from iRIS alerting of the request. They will also receive a task on the homepage called Submission Correction, or if a review board has met on your submission and returned it for corrections based on the review, the task will be called Review Response.

The screenshot below shows a task for Pre-Review Changes, called a Submission Correction. This task will remain on your homepage until you respond to the corrections and re-submit the form to the review board. Click the icon in the **Open** column to open the Pre-Review Corrections form.

Below are your incomplete IRB tasks:

Submission Correction **2**

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

Open	Principal Investigator	IRB Number	Study Alias	Study Status	Submission Form Name	Submission Date	Review Process	IRB Initial Approval	Expiration	Received
	Dr. Susan M. Investigator, Ph.D.	GH-14-016	NRP104.303	Pending - Submitted for Initial Review	Initial Review Submission Form	02/12/2014	Returned			02/12/2014

When you open the task a Pre-Review Correction or a Review Response Form will open. This form works similar to other forms in the system, where you navigate through the form using the **Save and Continue** button.

Receiving Approval

When the review board approves your form an Outcome Letter will be generated and sent to the study. If you have been listed as a recipient of this letter a PDF copy will be emailed to you. A copy will also be accessible in the Correspondence button on your homepage.

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

IRB Number: **GH-2015-25** **Study Correspondence**

PI: Investigator, Susan

Study Status: Open 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)

IRB Expiration Date: 06/16/2016

Print Friendly
 Add A New Correspondence
 Delete Selected Correspondence

6 result(s) found...

<input checked="" type="checkbox"/>	View Message	Author	Subject
<input type="checkbox"/>		Post a Reply to this Topic / Forward this Topic	
<input type="checkbox"/>		Administrator	Posted: 07/01/2015 12:22 PM PDT NCT00334880 GH-2015-25 Outcome Letter (attachment)

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

Submitting an Amendment Form

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

Accessing the Form

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

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

Submissions

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

IRB Expiration Date: 03/03/2015

Submissions Study Management Subject Management

Protocol Items

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

Submission Items

Initial Submission

- Initial Review Submission Form

IRB Forms

- Continuing Review Submission Form
- Amendment Form
- Adverse Event Initial Form

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

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

Amendment Form Back

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

IRB Expiration Date: 03/03/2015

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

1 result(s) found...

<input type="checkbox"/>	Show Rev	Edit/View	Ref Number	Sub. Rounds	Track Location	Process Submission	Submission Date	Created By	Date Created	Modified By	Date Modified
<input type="checkbox"/>			000108				03/03/2014	Mary Jane Coordinator	02/25/2014 03:21:50 PM	Mary Jane Coordinator	03/03/2014 02:51:45 PM

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

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

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

Amendment Form Back

1.0 **Amendment Form**

1.0 Amendment Form


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)

Modifying the Study Application

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



2.3 * Click the link below to create a new version of the study application and modify it for any changes requested with this amendment. You will need to open and modify any sections of the application that are applicable to change. Documents should be uploaded in the new version of the application.




 [Click here to attach the application.](#)

No Application has been associated with this submission.

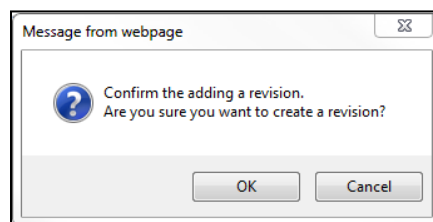
Once you click the link a window will open within your browser and the current version of the Study Application will be displayed. The current version of the Study Application cannot be modified if it has been submitted for review. When you click the icon in the **Edit/View** column the application will open but because it has been submitted you cannot modify it or add it to the Amendment form. You will need to create a revision and click the icon in the **Create a Revised Application** button. Note: this icon is only available in the most current version of the application.

Attaching Study Application ✖

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

Select	Show Rev.	Edit/View	Form Name	Approved	Create a Revised Application
Already Submitted			IRB Application (Version 1.1)	Yes	 Add Revision

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



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

Note: If you need to modify the current Key Personnel in section 2.0 you will need to access Personnel Change Request data value. You will not be able to change KSP in the revised version of the Study Application.

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

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

Print Friendly Save Section Save and Continue to Next Section

Section view of Application Entire view of the Application

- 1.0 General Information
- 2.0 Setup Department(s) Access
- 3.0 Grant Key Personnel access to the study
- 4.0 General App Info
- 5.0 Lay Summary
- 6.0 Subject Info
- 7.0 Study Drugs
- 8.0 Medical Devices

1.0 General Information

* Please enter the full title of your study:

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)

Once your changes are made, you will return to the Amendment form.

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

2.3 * Click the link below to create a new version of the study application and modify it for any changes requested with this amendment. You will need to open and modify any sections of the application that are applicable to change. Documents should be uploaded in the new version of the application.

[Click here to attach the application.](#)

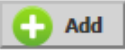
Remove	Show Rev.	Edit/View	Version	Title
			1.2	IRB Application (Version 1.2) - Attached

Requesting a Change in Key Personnel

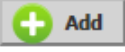

If you need to request additional or removal study personnel, you will be directed to the Personnel Change Request data value. This value looks similar to section 2.0 of the Study Application where you add personnel to the study. This value will allow you to specify users you would like to add to the study, by adding them to the appropriate group and selecting their role. Any user added to the study will have the ability to access the study in iRIS but not until the review board approves the change in personnel.

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

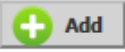
***Please add a Principal Investigator for the study:**



If applicable, please select the Protocol Staff personnel:


A) Additional Investigators	
B) Research Staff	

***Please add a Study Contact:**




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

Please select any existing Personnel you wish to remove:



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

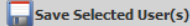
Search User Directory 


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"/>			Investigator, P	Department (primary)	
<input type="checkbox"/>			Investigator, Patrick, Ph.D	Department (primary)	pi@irisgh.edu
<input type="checkbox"/>			Investigator, Susan M., Ph.D.	Oncology (primary)	sinvest@ightest.edu

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

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

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

A) Additional Investigators
+ Add User
✖ Remove

Investigator, Patrick, Ph.D

Co-Investigator

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

B) Research Support Staff
+ Add User
✖ Remove

Coordinator, Mary Jane, R.N.

Study Coordinator

Staff, Stacy

Nurse

Study Contact – You may add additional Study Contacts as needed. A Study Contact is a user on the study who will receive study related notifications from the system like Continuing Review notifications, Submission Correction notifications, Review Response notifications, etc. The Study Contact is usually also another role on the study, like a Research Coordinator, PI, etc.

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

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

Please select any existing Personnel you wish to remove:

+ Select

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

<input type="checkbox"/>	Name	Role on the Study
<input type="checkbox"/>	Dr. Susan M. Investigator, Ph.D.	Principal Investigator
<input type="checkbox"/>	Mary Jane Coordinator, R.N.	Study Contact
<input type="checkbox"/>	Dr. Susan M. Investigator, Ph.D.	Study Contact
<input type="checkbox"/>	Dr. Patrick Investigator, Ph.D	Co-Investigator
<input type="checkbox"/>	Mary Jane Coordinator, R.N.	Study Coordinator
<input type="checkbox"/>	Stacy Staff	Nurse

Save Selections

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

Please select any existing Personnel you wish to remove:

Investigator, Henry Co-Investigator

Any change in personnel will not take effect on the study until the review board approves the request. This means that any user requested on the study will not have access to the study until the review board approves their role.

Modifying a Consent or Other Study Document

Any modifications to Consent Forms or Other Study Documents will need to be submitted to the review board for approval. Within the Amendment form you will be presented with data values that will allow you to attach Consent forms and Other Study Documents. Using these data values you can choose to add or revise any existing document on your study or you can add a brand new document. The process is the same for both Consent forms and Other Study Documents but they are two separate data values in the system forms designer. The process for revising and adding new documents is described below using the Consent form as an example. However, the process is the same for adding Other Study Documents.

3.1 Click here to modify the Consent

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

Select or Revise Existing Consent or Other Study Document

If you would like to select an already revised Consent, Other Study Document or revise an existing document, click the **Select or Revise Existing** button.

A window will open within the browser that lists existing documents. This table lists details about the documents on the study. You can choose a document to attach by clicking the icon in the **Select** column.

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

Select Existing or Create Revised Study Consent

Select Category: --none-- Title: _____

Version #: _____ Search level: Top All

Version Date: _____ between _____ Expiration Date: _____ between _____

Consent Outcome: --none--

Filter Documents

3 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
<input type="button" value="+"/>			<input type="button" value="X"/>	1.2	06/30/2015	Informed Consent Consent	English				 14.46 KB	
<input type="button" value="+"/>			<input type="button" value="X"/>	1.0	07/01/2015	Standard Consent Consent	English				 42.59 KB	
<input type="button" value="+"/>			<input type="button" value="X"/>	2.0	06/23/2015	Standard Consent Consent	English				 42.59 KB	

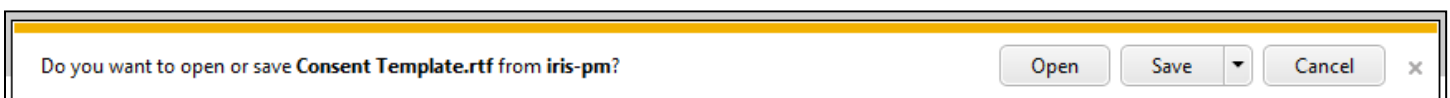
The window will refresh and populate with details of the document you are revising, allowing you to change details and checkout the revised document. Click the **Check-out Document** button.

A new page will open and your Internet browser will download the document. 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. 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 document and will need to click undo the checkout in order to restore the document.

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

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

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



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

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

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**.

Click the icon in the **Edit** column in the document record that you have checked out.

Select	Show all Versions	Edit	Delete	Version	Version Date	Title/ Category	Language	Expiration Date	Consent Outcome	Checked Out By	View Document	Create Revision
				1.3	06/30/2015	Informed Consent Consent	English			Mary Jane Coordinator 07/01/2015 03:39:46 PM	 14.46 KB	(Read Only)
				1.0	07/01/2015	Standard Consent Consent	English				 42.59 KB	
				2.0	06/23/2015	Standard Consent Consent	English				 42.59 KB	

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

Description:	<input type="text"/>
This document is currently checked out by:	Mary Jane Coordinator at 07/01/2015 03:39:46 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:	Comments to review board.


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

Document Location:

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

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

Please Wait ...



**iRIS is uploading the file to the server.
This operation may take a moment.**



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



Study Consent Revision:

* Consent Title:	<input type="text" value="Informed Consent"/>
Version Number:	<input type="text" value="1"/> _3
* Version Date:	<input type="text" value="06/30/2015"/> <input type="button" value="Calendar"/>
Category:	<input type="text" value="Consent"/>
* Language:	<input type="text" value="English"/>
Description:	<input type="text" value="Consent description."/>
Check-out the Document to your workstation for editing:	<input type="button" value="Check-out Document..."/>
Comments:	<input type="text" value="Comments to review board."/>

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

3.1 Click here to modify the Consent

 Select or Revise Existing
 Add a New Consent

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

Add a New Consent or Other Study Document

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


Modifying a Study Drug or Device




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

Within the Amendment form you will be presented with a Drug or Device data value. This value will contain a list of current Study Drugs or Devices on the study.

If you need to request a new drug or device on the study, click the **Add a New Drug to the Study** or **Add a New Device to the Study** button. This will take you through the steps of adding a drug or device to a study. If you need to request that a drug or device be removed from the study, locate the item in the list and select the icon in the **Delete** column. If you need to request changes to a current study drug or device, locate that item in the list and select the icon in the **Edit** column.

Drug

 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

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

Study Drug Details:	
Trade Drug Name:	Ritalin
Generic Drug Name:	Methylphenidate
Investigational Drug Name:	
Identify the name of the manufacturer or source of investigational drug/biologic:	<input type="text"/>
Is the drug supplied at no cost?	<input checked="" type="radio"/> Yes <input type="radio"/> No
Is the Drug FDA Approved:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Is this a new drug or a new use of an already approved drug:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Is an IND necessary:	<input checked="" type="radio"/> Yes <input type="radio"/> No
IND Number:	21-284
Who holds the IND:	<input type="radio"/> N/A <input type="radio"/> CTEP <input type="radio"/> Pharmaceutical company

Save Drug Info

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

Signoff

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

Submitting an Adverse Event Form

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

Accessing the Form

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

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

Study Status: **Open** 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)

IRB Expiration Date: 06/16/2016

Submissions Study Management Subject Management

Protocol Items

- Study Application
- Informed Consent
- Other Study Documents

Initial Review

Submissions

- Initial Review Submission Packet

IRB Items

Forms

- Continuing Review Submission Form
- Amendment Form
- **Adverse Event**
- Study Closure Form

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

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

Study Status: **Open** 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)

IRB Expiration Date: 06/16/2016

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

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

1 result(s) found...

	Show Rev	Show Follow-Up	Edit/View	Apply to Multiple	Form Number	Ref Number	Sub. Rounds	Track Location	Process Submission	Submission Date	Created By	Date Created	Modified By	Date Modified
<input type="checkbox"/>					AE-1.0	000019					Mary Jane Coordinator	07/01/2015 02:54:00 PM	Mary Jane Coordinator	07/01/2015 02:54:39 PM

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

IRB Number: **GH-2015-25** Subject Selection List Back
 PI: Investigator, Susan

Please select the subject this Form is associated with:

Select	On Study Status	(MRN) Last, First MI	Participant Number	Sex	Register Date	Date of Birth	Survival Status	Off Study Details
<input type="radio"/>	Active	Subject, Micky()	01-01	M	07/01/2015	09/30/1985	Alive	
<input type="radio"/>	Active	Subject, Rose(123456)	01-02	F	06/30/2015	06/06/1982	Alive	
<input type="radio"/>	Other (Subject is not tracked in iRIS)							

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

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

IRB Number: **GH-2015-25** **Adverse Event** 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 General Hospital Adverse Event Report Form

1.0 General Hospital Adverse Event Report Form

1.1 Principal Investigator:
Susan Investigator

1.2 RB #:
GH-2015-25

1.3 Title of project:

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

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

1.5 * Report type:

New report
 Follow-up report

If **Follow-up**, select the report that this is a follow-up to:

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

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

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

Return back to the Form Save Selected Event

List of records associated with form: Adverse Event.

1 result(s) found...


Version	Ref Number	Created By	Date Created	Modified By	Date Modified
<input checked="" type="radio"/> GH-2015-25-AE-1.0	000019	Mary Jane Coordinator	07/01/2015 02:54:00 PM	Mary Jane Coordinator	07/01/2015 02:54:39 PM

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

1.5 * Report type:










New report
 Follow-up report

If Follow-up, select the report that this is a follow-up to:

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

Reference Number:	000019
Created By:	Mary Jane Coordinator
Date Created:	07/01/2015 02:54:00 PM
Modified By:	Mary Jane Coordinator
Date Modified:	07/01/2015 02:54:39 PM

Any Adverse Event that you create as a Follow-up Report will become associated to the Initial Report in the list of Adverse Event forms. You can expand the folder in the **Show Follow-up** column, to view and Follow-up reports.

IRB Number: <b style="color: red;">GH-2015-25 Adverse Event										Back							
PI: Investigator, Susan																	
Study Status: Open		IRB Number: <b style="color: red;">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)													
		IRB Expiration Date: 06/16/2016															
										Copy Form		Add a New Form		Compare Two Versions		Delete Selected Form(s)	
<p> List of records associated with form: Adverse Event. To view previous versions click on the folder icon .</p> <p>1 result(s) found...</p>																	
☐	Show Rev	Show Follow-Up	Edit/View	Apply to Multiple	Form Number	Ref Number	Sub. Rounds	Track Location	Process Submission	Submission Date	Created By	Date Created	Modified By	Date Modified			
<input type="checkbox"/>					AE-1.0	000019					Mary Jane Coordinator	07/01/2015 02:54:00 PM	Mary Jane Coordinator	07/01/2015 02:54:39 PM			
<input type="checkbox"/>					AE-1.0 F1.0	000021					Mary Jane Coordinator	07/01/2015 03:57:22 PM	Mary Jane Coordinator	07/01/2015 03:57:27 PM			

Signoff

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

Submitting a Study Closure Form

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

Accessing the Form

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

IRB Number: **GH-2015-25**

PI: Investigator, Susan

Study Status: Open

Submissions

IRB Number : **GH-2015-25** Study Title :

IRB Expiration Date: 06/16/2016

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

Forms

- Continuing Review Submission Form
- Amendment Form
- Adverse Event
- Study Closure Form

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

IRB Number: **GH-2015-25**

PI: Investigator, Susan

Study Status: Open

Study Closure Form ⏪ Back

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)

IRB Expiration Date: 06/16/2016

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

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

0 result(s) found...

	Show Rev	Edit/View	Ref Number	Sub. Rounds	Track Location	Process Submission	Submission Date	Created By	Date Created	Modified By	Date Modified
No records have been created.											

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

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

IRB Number: GH-2015-25

PI: Investigator, Susan

Study Closure Form

Back

Print Friendly

Refresh Constant Fields

Save Section

Save and Continue to Next Section

Section view of the Form

1.0 Closure

Entire view of the Form

1.0 IRB Study Closure

1.1 Study Information

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)

Principal Investigator:
Susan Investigator

Other Personnel:
Henry Investigator, Stacy Staff, Jean Biostatistician

Initial Approval Date:

Signoff

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