



STUDY ASSISTANT

Study Assistant

Version 10.03

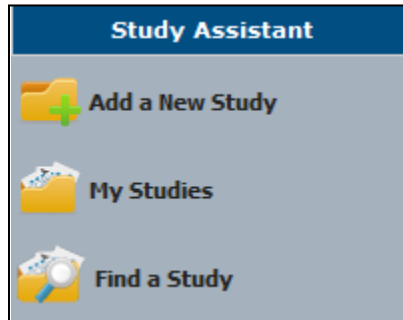
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Study Assistant

Introduction

This manual will guide you through the process of using the three menu items within Study Assistant, **Add a New Study**, **My Studies**, and **Find a Study**. Depending on your system settings, these options may be available to your end users.



Add a New Study

The Add a New Study item is available to any user with access to Study Assistant. Creating a study in the system allows a user to choose a study application, complete the study shell, associate any supporting documents, assign appropriate key personnel, and submit that study application for review.

For more information on adding a study to the system, see the Add a Study manual.

My Studies

The My Studies item is available to any user with access to Study Assistant; however, the list of studies that populates this list is restricted to studies that the user has a role on. Users will not be able to access any other study in the system unless they have been granted a role in Key Study Personnel.

My Studies Back

Display my Studies by: Most Recently Used Studies: Find by IRB Number:

Filter my Studies by study status: Find by Study Number:

Include Studies that have not been assigned an IRB Number

Show Hidden Studies Yes No

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

View History	Click to open	View Details	Study Status	IRB Number	IRB Expiration	Study Number Study Title	Principal Investigator	Copy Study	Delete Study	Hide
			Pending - Submitted for Initial Review	GH-2015-25		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			
			Pending - Submitted for Initial Review	GH-2015-23		NCT01882179 Early Mineralocorticoid Receptor Antagonist Treatment to Reduce Myocardial Infarct Size (MINIMISE-STEMI)	Investigator, Susan			
			Draft			Mouse Study I Mouse Study I	Investigator, Susan			
			Open	GH-2015-22	12/31/2015	NCT00510276 Treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) With Atomoxetine in Young Adults and Its Effects on Functional Outcomes	Investigator, Susan			

The list of studies that populate in this list default to the most recently accessed study at the top of the list.

The columns listed on this page are as follows:

View History

Click to open – When you click this icon, the study record will open.]

View Details - Selecting to expand the details will display the Submission History area (Submissions in Process, Completed Submissions, and Submissions Returned with Changes tabs).

View History	Click to open	View Details	Study Status	IRB Number	IRB Expiration	Study Number Study Title	Principal Investigator	Copy Study	Delete Study	Hide																																																																		
			Open	GH-2015-22	12/31/2015	NCT00510276 Treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) With Atomoxetine in Young Adults and Its Effects on Functional Outcomes	Investigator, Susan																																																																					
<table border="1"> <thead> <tr> <th colspan="3">Submissions in Process</th> <th colspan="3">Completed Submissions</th> <th colspan="5">Submissions Returned with Changes</th> </tr> <tr> <th>Reference Number</th> <th>Track Location</th> <th>Status</th> <th>Request Type</th> <th>Details</th> <th>Review Board</th> <th>View Outcome Letters</th> <th>Review Process</th> <th>Meeting Date</th> <th>Review Outcome</th> <th>Date Received</th> </tr> </thead> <tbody> <tr> <td>000011</td> <td></td> <td></td> <td>Adverse Event</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> <td>Adverse Event</td> <td></td> <td>IRB Committee 1</td> <td></td> <td>On Agenda</td> <td>07/15/2015</td> <td></td> <td>06/19/2015 01:27:41 PM PDT</td> </tr> <tr> <td>000010</td> <td></td> <td></td> <td>Amendment Form</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> <td>Amendment Form</td> <td></td> <td>IRB Committee 1</td> <td></td> <td>On Agenda</td> <td>07/15/2015</td> <td></td> <td>06/19/2015 01:25:57 PM</td> </tr> </tbody> </table>											Submissions in Process			Completed Submissions			Submissions Returned with Changes					Reference Number	Track Location	Status	Request Type	Details	Review Board	View Outcome Letters	Review Process	Meeting Date	Review Outcome	Date Received	000011			Adverse Event											Adverse Event		IRB Committee 1		On Agenda	07/15/2015		06/19/2015 01:27:41 PM PDT	000010			Amendment Form											Amendment Form		IRB Committee 1		On Agenda	07/15/2015		06/19/2015 01:25:57 PM
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Note: This functionality is only available if the property “system.use_my_study_view_details within System Administration -> System Configuration -> Study Default Settings is set to “Yes”.

Study Status – This displays the current status of the study (i.e. Open, Pending, Draft, Completed).

IRB Number – If an IRB Number has been associated with a study it will display here. This column will change to whatever you choose to display the studies by, when using the “Display my Studies by:” filter.

IRB Expiration Date- If an expiration date has been associated with a study, it will display here. This column will also change with whatever you choose to display the studies by, when using the filters.

Principal Investigator- This displays the name of the Principal Investigator on the study.

Study Title- This displays the Study Title given to the study in the initial section of the Study Application. Also listed in this same column is the Study Number.

Copy Study – You can copy a study by clicking the icon in this column. This will copy the contents of the Study Shell, Study Application, Study Plans, Timelines, Budgets, Milestones, Devices, Drugs, Sponsors, Inclusion and Exclusion Criteria. Any uploaded Study Consents or Other Study Documents will not copy.

Delete Study – Some study records may contain an icon in the Delete Study column. A study can only be deleted if you are the Study Author (the user that clicked the “Add a New Study” button and created the shell) and the study has not been submitted. If you are looking at a study that you did not author, you will not be able to delete the study. If the Study Application has been submitted, you will not be able to delete the study.

Hide – The icon in this column will allow you to hide certain studies from the main view.

You can use the search filters at the top of the screen to narrow down the list of studies.

Depending on your system configuration, you may be able to switch screen views between different types of study numbers. IRB Number is the default, but other options may be available to you.

The screenshot shows the 'My Studies' filter panel. The 'Display my Studies by:' dropdown menu is set to 'IRB Number'. Other options include 'Most Recently Used Studies' (selected with a radio button), 'Filter my Studies by study status:', and 'Include Studies that have not been assigned an IRB Number' (checked with a checkbox). There are also search fields for 'Find by IRB Number' and 'Find by Study Number', each with a 'Find' button. At the bottom, there are radio buttons for 'Show Hidden Studies' set to 'No'.

When you change the display type of the study number, the page will refresh with the appropriate number. As an example, the IACUC Number was chosen below and the page refreshed accordingly.

This screenshot shows the 'My Studies' filter panel with 'IACUC Number' selected in the 'Display my Studies by:' dropdown. The 'Include Studies that have not been assigned an IACUC Number' checkbox is also checked. Below the filter panel, a table view is shown with 7 results found. The table has columns for 'View History', 'Click to open', 'View Details', 'Study Status', 'IACUC Number', 'IACUC Expiration', 'Study Number', 'Study Title', 'Principal Investigator', 'Copy Study', 'Delete Study', and 'Hide'. The 'IACUC Number' and 'IACUC Expiration' columns are highlighted with a red box.

You can also choose to change the filter by study status. You can do this by choosing a status from the **Filter my Studies by study status** drop-down list. When you change the filter, the page will refresh, and you will then have the ability to associate one or more study status to your filter by clicking the **Change Filter** button.

My Studies

Display my Studies by: Most Recently Used Studies: Find by IRB

Filter my Studies by study status: Change Filter Find by Stu

Include Studies that have not been assigned an IRB Number

Show Hidden Studies Yes No

Select the desired study status filters from the list then click the **Apply** button.

Choose Study Status filters X

Check to Apply	Study Status
<input type="checkbox"/>	All
<input type="checkbox"/>	Open
<input type="checkbox"/>	Returned for Corrections
<input type="checkbox"/>	Pending Acceptance to Participate
<input checked="" type="checkbox"/>	Draft
<input type="checkbox"/>	Pending
<input type="checkbox"/>	Pending - Submitted for Initial Review
<input type="checkbox"/>	Closed to Accrual with follow-up
<input type="checkbox"/>	Closed

Cancel
Apply

The page will refresh again, this time displaying only the studies that are in the selected study status.

My Studies Back

Display my Studies by: Most Recently Used Studies: Find by IRB Number: Find

Filter my Studies by study status: Change Filter Find by Study Number: Find

Include Studies that have not been assigned an IRB Number

Show Hidden Studies Yes No

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

View History	Click to open	View Details	Study Status	IRB Number	IRB Expiration	Study Number Study Title	Principal Investigator	Copy Study	Delete Study	Hide
			Draft			Mouse Study I	Investigator, Susan			
						Mouse Study I				
			Draft			NCT01882179	Investigator, Susan			
Copy of Early Mineralocorticoid Receptor Antagonist Treatment to Reduce Myocardial Infarct Size (MINIMISE-STEMI)										

By default, the selection for **Include Studies that have not been assigned an IRB Number** is used in the My Studies results. This number display will change based on what is selected in the **Display my Studies by** drop down list.

When the filter is set, all studies associated to the user will display in My Studies, regardless of the assigned Review Board number.

Click to open	View Details	Study Status	IRB Number	IRB Expiration	Principal Investigator	Study Title Study Number	Copy Study	Delete Study	Hide
		Open	GH-14-031	09/29/2015	Investigator, Susan M., Ph.D.	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) Adults with ADHD			
		Pending - Submitted for Initial Review	GH-14-025		Investigator, Susan M., Ph.D.	Copy of A Phase III, Randomized, Double-Blind, Multi-Center, Placebo-Controlled, Parallel-Group, Forced Dose Titration, Safety and Efficacy Study of NRP104 in Adults With Attention-Deficit Hyperactivity Disorder (ADHD) Title of Study			

When the checkbox is deselected, only studies with an associated number will display in the results. In the example above, the page is listed by IRB Number, so only studies with an IRB Number display.

You can also look up a particular study by the IRB Number (or if you have selected another number from the drop-down list, the search would update to allow you to search by that number, IACUC, IBC, etc.) or Study Number. You can type in all or part of the number then click the **Find** button. iRIS will return any associated results.

View History	Click to open	View Details	Study Status	IRB Number	IRB Expiration	Study Number Study Title	Principal Investigator	Copy Study	Delete Study	Hide
			Open	GH-2015-22	12/31/2015	NCT00510276 Treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) With Atomoxetine in Young Adults and Its Effects on Functional Outcomes	Investigator, Susan			

Hidden studies can be included in the view by indicating “Yes” to the **Show Hidden Studies** filter. Any study that has been flagged as hidden will display with the icon in the **Hide** column.

My Studies Back

Display my Studies by: Most Recently Used Studies: Find by IRB Number: Find

Filter my Studies by study status: Find by Study Number: Find

Include Studies that have not been assigned an IRB Number

Show Hidden Studies Yes No

5 result(s) found... 1 - 5

View History	Click to open	View Details	Study Status	IRB Number	IRB Expiration	Study Number Study Title	Principal Investigator	Copy Study	Delete Study	Hide
			Open	GH-2015-22	12/31/2015	NCT00510276 Treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) With Atomoxetine in Young Adults and Its Effects on Functional Outcomes	Investigator, Susan			
			Pending	GH-2015-21	01/01/2016	NCT01594333 Cardiovascular Inflammation Reduction Trial	Investigator, Susan			
			Pending - Submitted for Initial Review	GH-2015-25		NCT00334880 A Phase III, Randomized, Double-Blind, Multi-Center, Placebo-Controlled, Parallel-Group, Fixed-Dose Titration, Safety and Efficacy Study of MDR104 in Adults With Attention-Deficit	Investigator, Susan			

When you locate the study you need to access, click the icon in the **Click to open** column. Depending on the status of the study, and where it is at within that status, you will be directed to different screens.

A study that is not in Draft status will direct you to the **Submissions** tab of the study, as shown in the screenshot below.

For more information on items within the Submissions tab, see the Study Submissions manual.

Study Number: XYZ
PI: Investigator, Susan M., Ph.D. **Submissions** Back

Study Status: **Open** IRB Number: **GH-14-003** Study Title: Research Study on xyz
IRB Expiration Date: 01/12/2015

Submissions | Study Management | Subject Management

Protocol Items

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

Regulatory Forms

- IRB Forms
- Amendment Form

- Submissions History
- Study Correspondence

Outstanding Submission(s)

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

If the study is in Draft status and you open the record, you will be directed to either the Study Application or the Initial Review Submission Form, depending on whether the Study Application or Initial Review is complete. Once either of these forms is complete and the Initial Review has been submitted, you will be directed to the same Submissions tab as any other study status.

Find a Study

The Find a Study item allows users to search the entire system for studies, regardless of having a role on the study. Find a Study is a tool used by System Administrators and Department Administrators, allowing them to search the system for certain studies.

You are able to use the available filters to search for a study or you can click the **Find** button to return all studies in the system.

You can also change the display of the study numbering by selecting from the **Display Projects By** drop-down list. The numbers available here depend on what modules are configured to in your system. The example below shows the page when IBC Number is selected from the drop-down list. The page reflects IBC information, as opposed to the default, IRB Number information.

Some of the search fields are auto-populating fields. You begin by typing the name, and the system will return any resulting matches for you to select. **Sponsor**, **Principal Investigator**, **Department**, and **IRB Number** are all auto-populating fields.

The screenshot shows the 'Find A Study' interface. At the top, there is a header 'Find A Study' and a sub-header 'Find a Study Filters'. Below this, there are several filter fields: 'Display Projects by:' (set to 'IRB Number'), 'Study Number:', 'Sponsor:', 'Principal Investigator:', and 'Department:'. The 'Sponsor:' field is highlighted with a red box, and a dropdown menu is open, showing three options: 'Bausch & Lomb', 'Baxter', and 'Bayer'. The 'Principal Investigator:' field has an 'Active' checkbox next to it. To the right of the filters, there are labels for 'Study', 'Refer', and 'Include Stu'.

The **Principal Investigator** field allows you to flip between Active and Inactive PI’s. Inactive PI’s are any user accounts in the system that have been flagged as Inactive that also are listed as Principal Investigators on studies. Active PI’s are any user accounts that are flagged as Active and also are listed as Principal Investigators on studies.

This is a close-up of the 'Principal Investigator' field. It features a checkbox labeled 'Active' and a text input field. The label 'Principal Investigator:' is positioned below the input field.

A drop down list of available Study Status and Study Classification that you can choose from is also available.

The screenshot shows a dropdown menu for 'Study Status' and 'Study Classification'. The 'Study Status' dropdown is open, showing a list of options: 'All', 'Open', 'Returned for Corrections', 'Pending Acceptance to Participate', 'Draft', 'Pending', 'Pending - Submitted for Initial Review', 'Closed to Accrual with follow-up', 'Closed', 'Suspended', and 'Inactive - Administratively Closed'. The 'Study Classification' dropdown is also visible, showing options: 'Returned for Corrections', 'Pending Acceptance to Participate', 'Draft', 'Pending', 'Pending - Submitted for Initial Review', 'Closed to Accrual with follow-up', 'Closed', 'Suspended', and 'Inactive - Administratively Closed'. The 'Reference Number:', 'IRB Number:', and 'IRB Expiration Date:' fields are also visible on the left side of the dropdown menu.

The **Reference Number** field allows you to search for studies by Submission Reference Number. Enter a reference number for a specific submission form. When you filter the results, the study matching the reference number will populate in the results.

Note: You must enter the entire Reference Number in this field, except for the leading zeros. Example, a submission is Reference Number “000288” you would need to enter “000288” or “288” to filter the results correctly.

If you want to include study records that do not have an **IRB Number** assigned (or whatever number you indicated in **Display Project by**), select the checkbox for “Include Studies that have not been assigned an IRN Number”. When you filter the results, the system will include studies that do not have an IRB Number assigned. If you only want studies that have been assigned an IRB Number, make sure this option is not selected.

Find A Study Back

Find a Study Filters

Display Projects by: IRB Number

Study Status: All

Study Classification: All

Study Number:

Sponsor:

Reference Number:

IRB Number:

IRB Expiration Date: -

Department:

Active Principal Investigator: Investigator, Susan

Include Studies that have not been assigned an IRB Number

Advanced Find Options

Reset Find Options

Find ...

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

Open	Study Status	IRB Number	IRB Expiration Date	Study Number	Study Title	Principal Investigator
	Draft			Mouse Study I	Mouse Study I	Investigator, Susan
	Draft			NCT01882179	Copy of Early Mineralocorticoid Receptor Antagonist Treatment to Reduce Myocardial Infarct Size (MINIMISE-STEMI)	Investigator, Susan
	Pending	GH-2015-21	01/01/2016	NCT01594333	Cardiovascular Inflammation Reduction Trial	Investigator, Susan
	Open	GH-2015-22	12/31/2015	NCT00510276	Treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) With Atomoxetine in Young Adults and Its Effects	Investigator, Susan

You can search by an expiration date range by entering in the appropriate information in the **Expiration Date** fields.

IRB Expiration Date: -

For more advanced search options, click on the **Click here for Advanced Find Options** button.

This will allow you to filter by study personnel, study drugs, devices, and key words in the Study Title or Sponsor name. You can choose to use one or all options in the Advanced Search Options by selecting an item from a drop-down list and/or typing in the keywords. When you are finished, click the **Apply** button at the bottom right corner. Click the red x in the top right to close the window without applying the filters.

Find A Study: Advanced Search Options X

Key Study Personnel

Active Select User Name:

Select User Role(s):

- Principal Investigator
- Study Author
- Study Contact
- Department Administrator
- Administrative Assistant
- Co-Investigator
- Research Nurse

Drugs associated to Study

Trade Name:

Generic Name:

Investigational Name:

Devices associated to Study

Device Name:

Cancel Apply

When you click the **Find** button, the system will return any matching studies, depending on the filters you selected. If you added Advanced Search Options, the button will update with a yellow border to indicate extra filters are in use.



Once you find the study you are looking for, you can click the icon in the **Open** column to open the study record.

Find A Study
Back

Find a Study Filters ⓘ

<p>Display Projects by: IRB Number</p> <p>Study Number: <input style="width: 90%;" type="text"/></p> <p>Sponsor: <input style="width: 90%;" type="text"/></p> <p>Active <input type="checkbox"/> Principal <input type="checkbox"/></p> <p>Investigator: <input style="width: 90%;" type="text"/></p> <p>Department: <input style="width: 90%;" type="text"/></p>	<p>Study Status: All</p> <p>Study Classification: All</p> <p>Reference Number: <input style="width: 90%;" type="text"/></p> <p>IRB Number: <input style="width: 90%;" type="text"/></p> <p>Include Studies that have not been assigned an IRB Number: <input type="checkbox"/></p> <p>IRB Expiration Date: <input style="width: 40%;" type="text"/> - <input style="width: 40%;" type="text"/></p>
--	--

+ Advanced Find Options ✓

Reset Find Options

Find ...

5 result(s) found... 1 - 5

Open	Study Status	IRB Number	IRB Expiration Date	Study Number <small>Study Title</small>	Principal Investigator
	Pending	GH-2015-21	01/01/2016	NCT01594333 <i>Cardiovascular Inflammation Reduction Trial</i>	Investigator, Susan
	Open	GH-2015-22	12/31/2015	NCT00510276 <i>Treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) With Atomoxetine in Young Adults and Its Effects on Functional Outcomes</i>	Investigator, Susan

The other columns on this page are as follows:

Study Status- This displays the current status of the study (i.e. Open, Pending, Draft, Completed).

IRB Number- If an IRB Number has been associated with a study it will display here. This column will change to whatever you choose to display the projects by, when using the “Display my Studies by:” filter.

IRB Expiration Date- If an expiration date has been associated with a study, it will display here. This column will also change with whatever you choose to display the projects by, when using the filters.

Study Number- This displays the Study Number given to the study in the initial section of the Study Application.

Study Title- This displays the Study Title given to the study in the initial section of the Study Application.

Principal Investigator- This displays the name of the Principal Investigator on the study.

Find a Study for All Users

Find a Study can be made available for all users within Study Assistant using the system property located in System Admin > System Configuration > Study Default Settings > system.find_study_for_all_users.

When this property is set to Yes, any user with access to Study Assistant will have the ability to use Find a Study, not just System Administrators and Department Administrators.

This will allow users to look up studies that they are not associated to, in order to look up contact information on the study.

When the user opens the study record, they will be presented with a page that displays the Study Title, Study Status, Departments, Principal Investigator, PI Phone and Email, and Study Coordinators, and their Phone and Email.

Below is an example of the only information the user will have access to.

[◀ Back](#)

Study Title:	Combination Chemotherapy, Bone Marrow Transplantation, and Peripheral Stem Cell Transplantation in Treating Patients With Ovarian Epithelial Cancer		
Study Status:	Pending - Changes Requested		
Department:	Department		
Principal Investigator:	Investigator, Susan M., Ph.D.	Phone number: (909) 555-2323	Email address: sinvest@ightest.edu
Study Manager:	Investigator, Susan M., Ph.D.	Phone number: (909) 555-2323	Email address: sinvest@ightest.edu

For more information please contact the PI or Coordinator.