



STUDY ASSISTANT

Study Assistant

Version 10.03.02

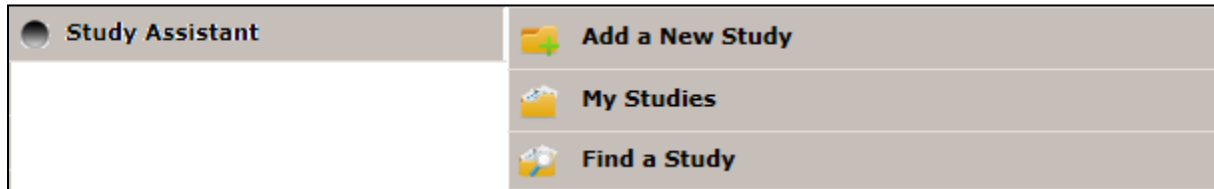
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Study Assistant

Introduction

This manual will guide you through the process of using 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:		<input checked="" type="radio"/> Most Recently Used Studies: <input type="radio"/> Filter my Studies by study status: <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		Find by IRB Number: <input type="text"/>		Find		Find by Study Number: <input type="text"/>		Find	
7 result(s) found... 1 - 7											
View History	Click to open	View Details	Study Status	IRB Number	IRB Expiration	Study Number	Principal Investigator	Copy Study	Delete Study	Hide	
			Pending - Submitted for Initial Review	GH-2015-25		NCT00334880	Investigator, Susan				
						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)					
			Pending - Submitted for Initial Review	GH-2015-23		NCT01882179	Investigator, Susan				
						Early Mineralocorticoid Receptor Antagonist Treatment to Reduce Myocardial Infarct Size (MINIMISE-STEMI)					
			Draft			Mouse Study I	Investigator, Susan				
						Mouse Study I					
			Open	GH-2015-22	12/31/2015	NCT00510276	Investigator, Susan				
						Treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) With Atomoxetine in Young Adults and Its Effects on Functional Outcomes					





























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

The columns listed on this page are as follows:

View History – If an IACUC or IBC study has any linked studies created to satisfy a three year renewal, a folder will appear in this column.

Click to open – When you click the  icon in this column, 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 <i>Treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) With Atomoxetine in Young Adults and Its Effects on Functional Outcomes</i>	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> IRB Committee 1</td> <td></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> IRB Committee 1</td> <td></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 system.use_my_study_view_details property within System Administration > System Configuration > Study Default Settings is set to Yes.

Study Status – This displays the current status of the study (e.g. 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 whichever reference number 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 to reflect the chosen filter.

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/Study Nickname.

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, and 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 a study 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' search interface. On the left, there is a dropdown menu labeled 'Display my Studies by:' with 'IRB Number' selected. To the right, there are two radio buttons: 'Most Recently Used Studies:' (selected) and 'Filter my Studies by study status:'. Below these is a checked checkbox for 'Include Studies that have not been assigned an IRB Number'. At the bottom, there are radio buttons for 'Show Hidden Studies' with 'Yes' and 'No' options. On the right side, there are two search input fields: 'Find by IRB Number:' and 'Find by Study Number:', each with a 'Find' button.

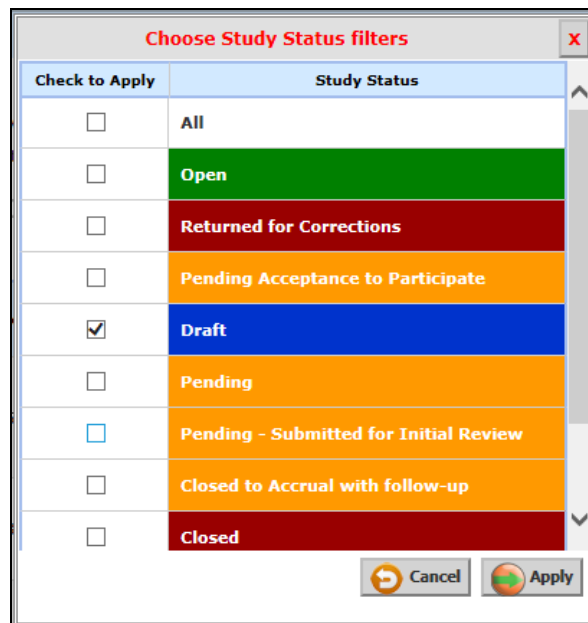
When you change the display type of the study number, the page will refresh with the appropriate number. As an example, the IACUC Number was chosen below and the page refreshed accordingly.

This screenshot shows the 'My Studies' search interface after a refresh. The 'Display my Studies by:' dropdown is now set to 'IACUC Number'. The 'Filter my Studies by study status:' radio button is selected, and the 'Include Studies that have not been assigned an IACUC Number' checkbox is checked. The search results section shows '7 result(s) found...' and a table with columns: '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.

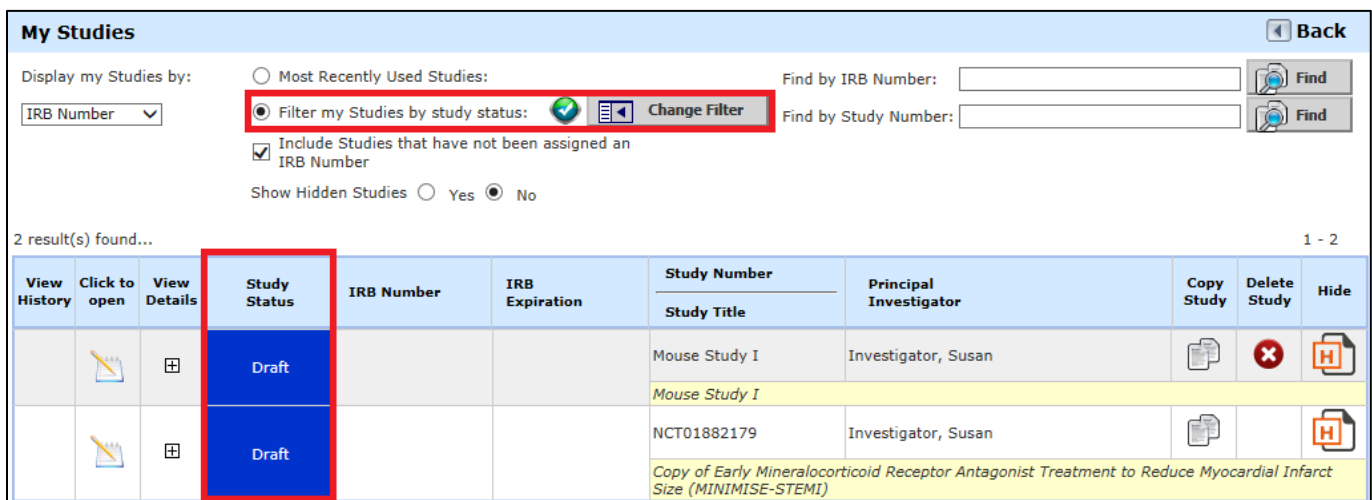
You can also choose to change the filter by study status. You can do this by choosing a status from the “Filter my Studies by study status” dropdown list. When you change the filter, the page will refresh, and you will then have the ability to associate one or more study status to your filter by clicking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

The screenshot shows the 'My Studies' search interface with the 'Filter my Studies by study status:' radio button selected. A green checkmark icon is next to it, and a 'Change Filter' button is visible. The 'Include Studies that have not been assigned an IRB Number' checkbox is checked. The 'Show Hidden Studies' radio buttons are set to 'No'.

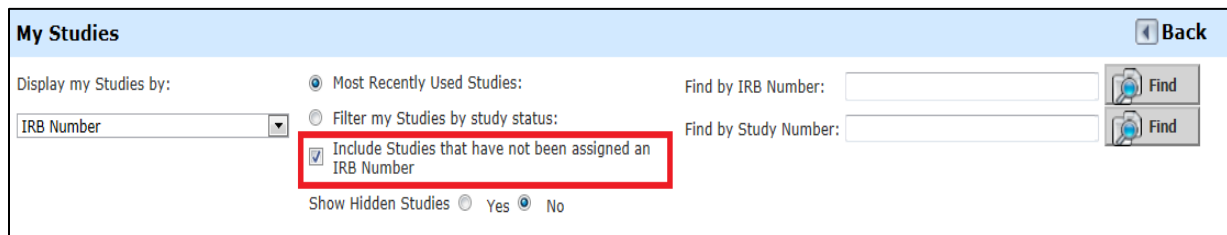
Select the desired study status filters from the list, and then click the **Apply** button.



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



By default, “Include Studies that have not been assigned an IRB Number” is selected. This number display will change based on what is selected in the “Display my Studies by” dropdown list.



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

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

12 result(s) found... 1 - 12

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 dropdown 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, and then click the **Find** button. iRIS will return any associated results.

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

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

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	Investigator, Susan			

Treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) With Atomoxetine in Young Adults and Its Effects on Functional Outcomes

Hidden studies can be included in the view by indicating “Yes” for 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, Forced-Dose Titration, Safety and Efficacy Study of MPR104 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 what has been completed for the study, 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 typically used by System Administrators and Department Administrators.

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” dropdown list. The numbers available here depend on what modules are configured in your system. The example below shows the page when IBC Number is selected from the dropdown list. The page reflects IBC information, as opposed to the default, IRB Number information.

Some of the search fields on this screen 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 Principal Investigator field allows you to flip between Active and Inactive PIs. Inactive PIs are any inactive user accounts in the system that are also listed as Principal Investigators on studies. Active PIs are any active user accounts that are listed as Principal Investigators on studies.

Dropdown lists of available Study Statuses and Study Classifications are also available.

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. For example, for a submission with 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 Projects by”), select the checkbox for “Include Studies that have not been assigned an IRB 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.

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 for an expiration date range by entering in a beginning and an end date in the Expiration Date fields. To search for a single day, enter the same date in both fields.


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

This will allow you to filter by study personnel, study drugs, devices, and key words in the Study Title. 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 **Cancel** to close the window without applying the filters.

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.



To reset all the filters and begin your search again, click **Reset Find Options**.

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
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Find a Study Filters i



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

+
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 (e.g. 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 Projects by:” filter.

IRB Expiration Date- If an expiration date has been associated with a study, it will display here. The review board in this column will also change according to your display choice.

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 and view contact information for 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, the PI’s Phone and Email, Study Coordinators, and the Study Coordinators’ Phone and Email.

Below is an example of the 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.