STUDY ASSISTANT

Study Assistant

Software Version: 12.01

Manual Version: P-1

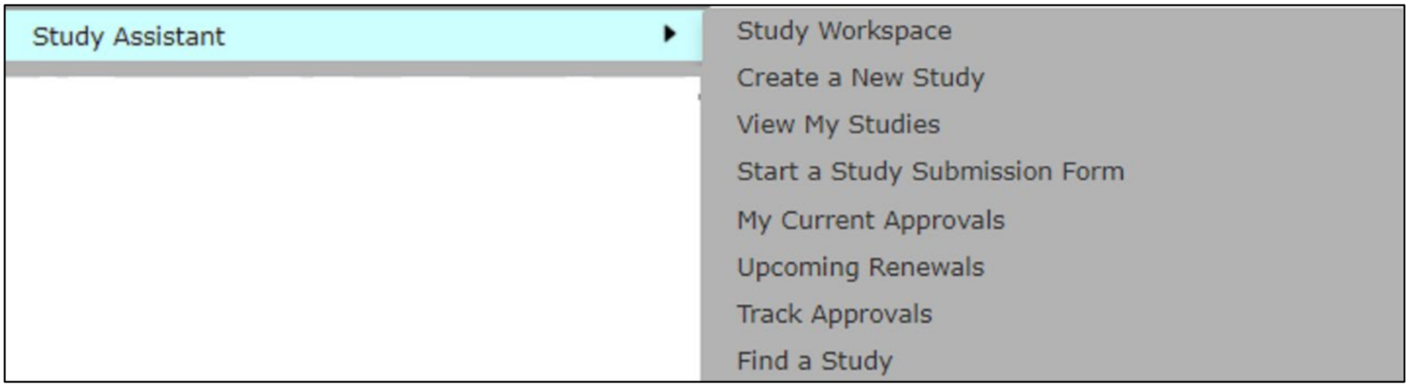
Manual Published: 12/20/2020

CHAPTER 1 Contents

Study Assistant

CHAPTER 2 Introduction

This manual will guide you through the process of using the available 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.



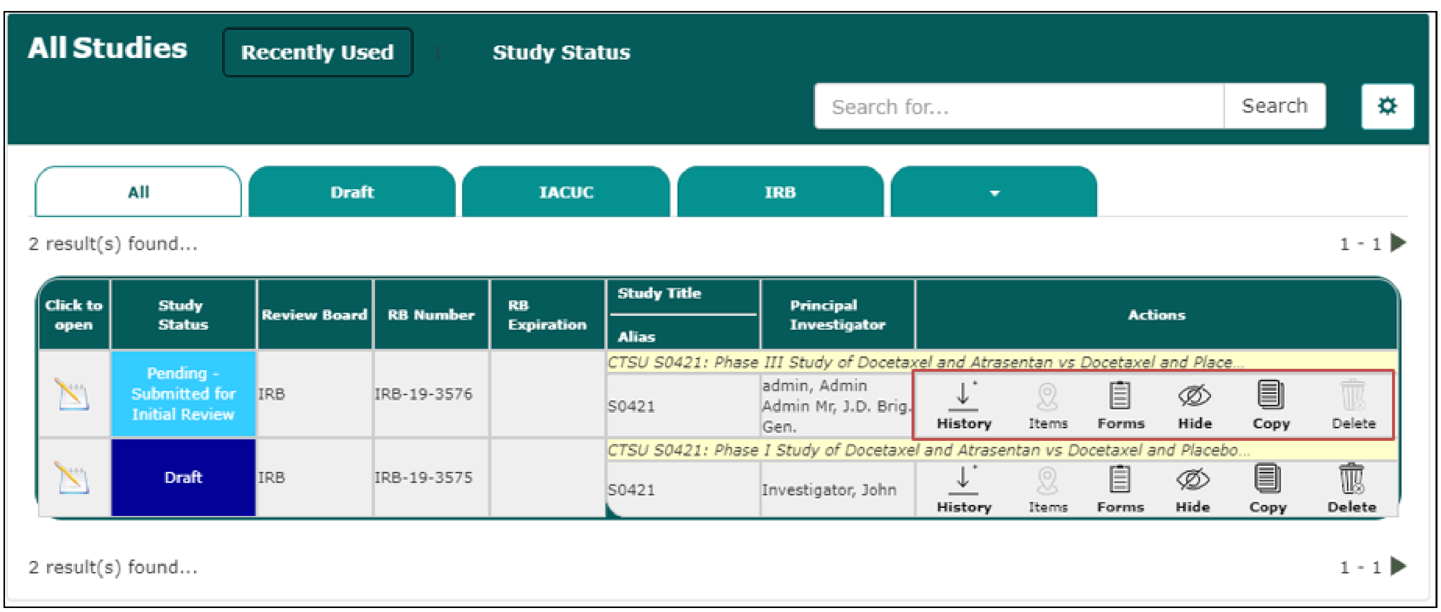
CHAPTER 3 Create a New Study

The Create 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.

CHAPTER 4 View My Studies

The View 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.



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:

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

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

Review Board – This display which review board the study is associated with (e.g. IRB, IACUC, SRS). This column will be blank if the study is in Draft mode and hasn't been submitted to a board.

RB Number – If an RB 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.

RB 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.

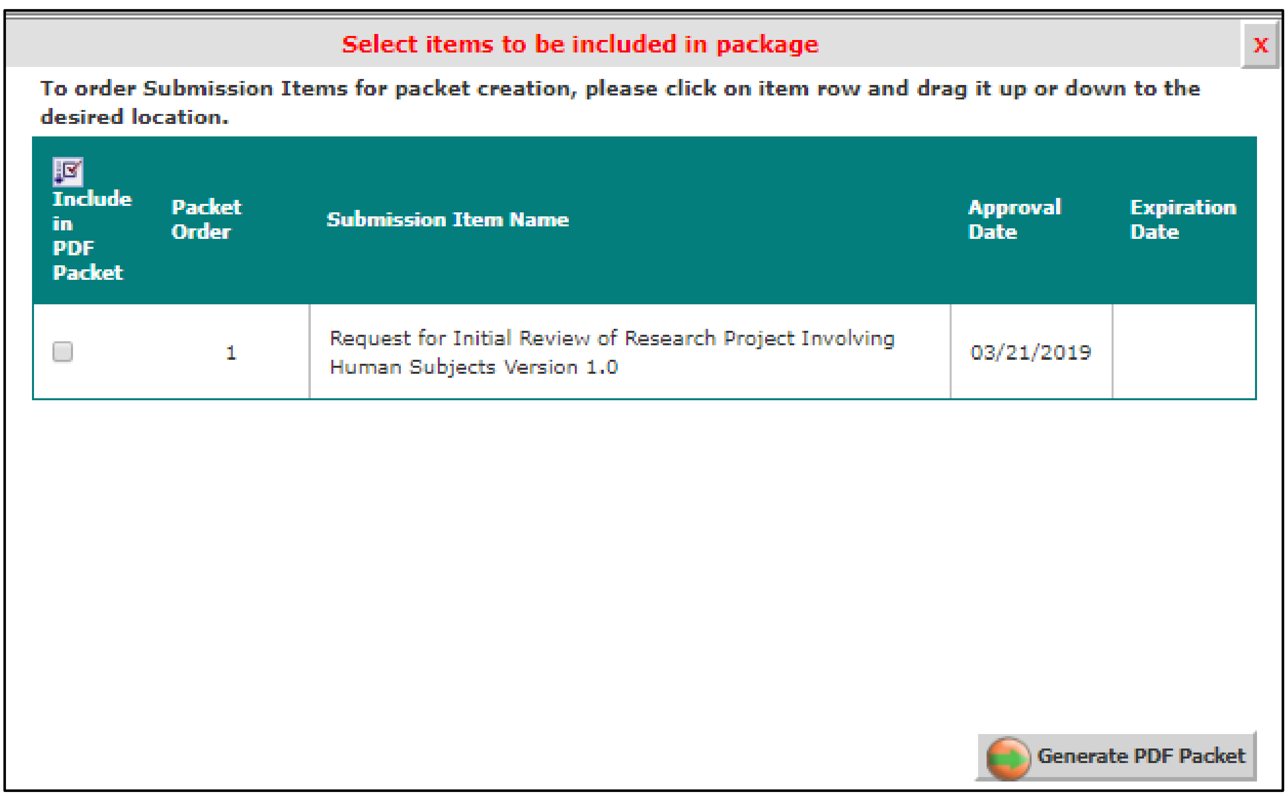
Study Title / Alias- This displays the Study Title given to the study in the initial section of the Study Application. Also listed in this same column is the Study Number/Study Nickname.

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

Actions- Each study has actions that you can apply to that studies such as:

History- Allows the user to view the submission based on where the submission is in the review process. The user can also view the workflow of the submission under **Track Location** to view specific details of the submission path.

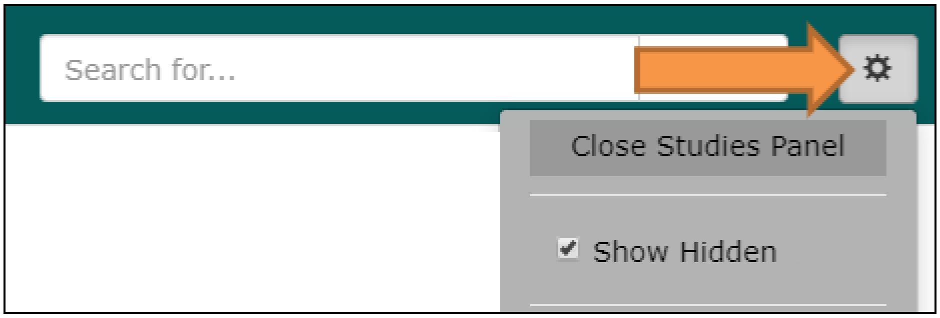
Items- This action will become available once the submission has been given an approval outcome. Once available the user can view all approved components of the submission and generate PDF packets of each.



Forms- This icon will list all your submission forms that are available in the system. The user will be able to view and submit all the submission forms currently in the system. This would include Modification forms, Attachment forms, etc.

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

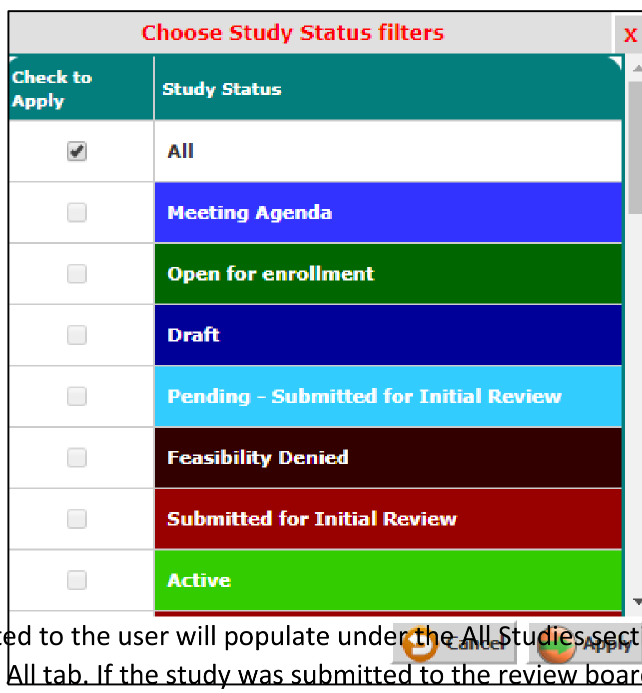
To find hidden studies, the user must change the search setting filter at the top right of the banner to include hide studies in your search criteria of studies (See image below).



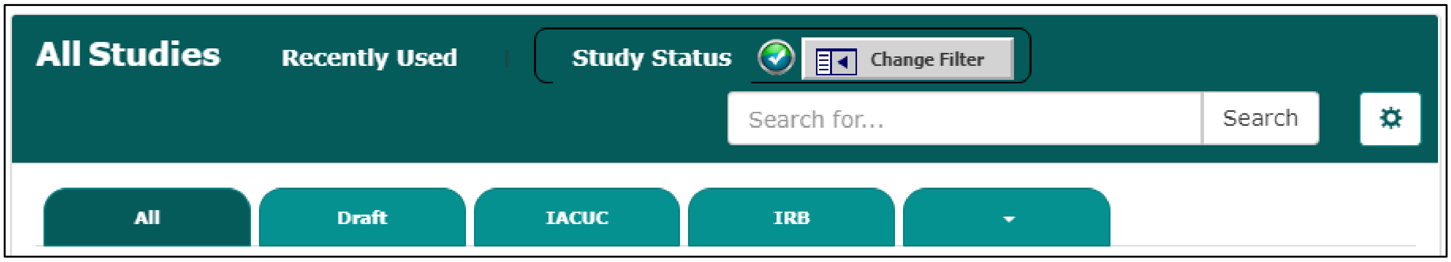
Copy Study – You can copy a study by clicking the icon in this column. This will copy the contents of the Study Shell, Study Application, Study Plans, Timelines, Budgets, Milestones, Devices, Drugs, Sponsors, and Inclusion and Exclusion Criteria. Now when users copy a study and the application has a submission form associated to it, the system will copy the sub form along with the study.

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.

At the top of the banner the user can choose different ways to view studies. The two modes of viewing studies are the mostly recently used studies and view studies based on the status of the study. When you change the filter, the page will refresh, and you will have the ability to associate one or more study status to your filter by clicking the **Change Filter** button.



All the studies that are associated to the user will populate under the All Studies section. Users will have the ability to view all their studies under the All tab. If the study was submitted to the review board then it will fall under the appropriate review board tab.

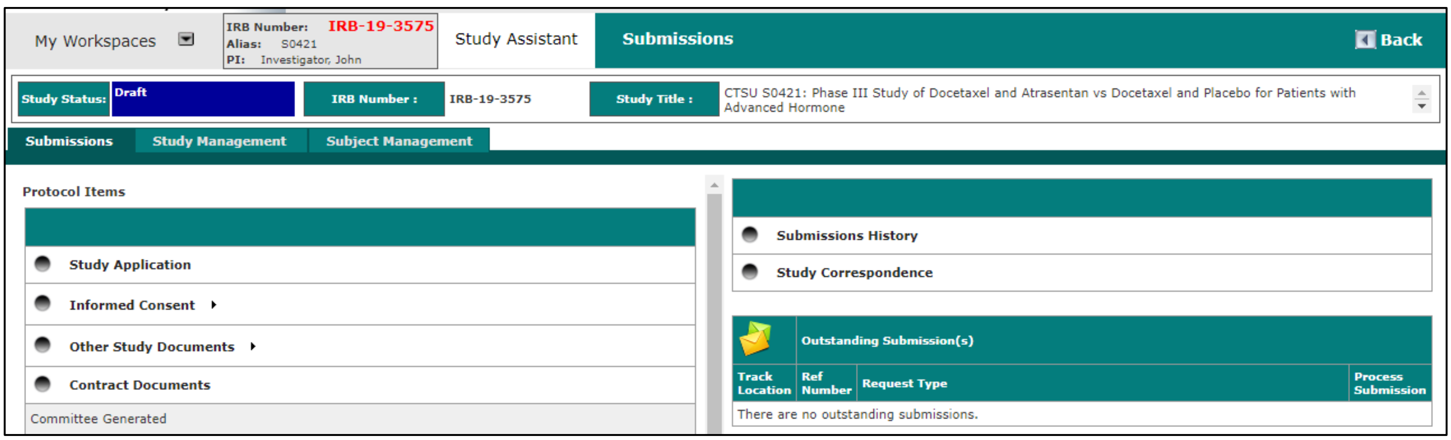


You can also look up a particular study by the IRB Number (or, if you have selected another number from the dropdown list, the search would update to allow you to search by that number: IACUC, IBC, etc.) or Study Number. You can type in all or part of the number, and then click the **Search** button.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

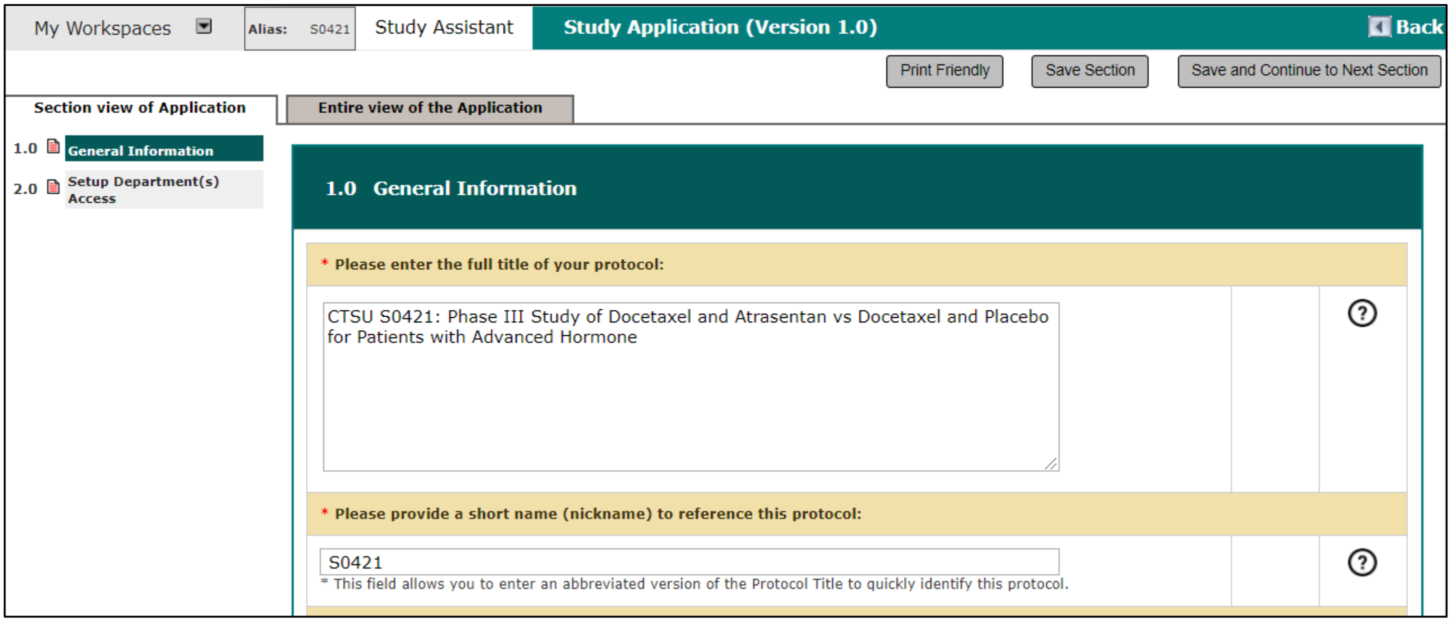
When you locate the study you need to access, click the icon in the Click to Open column. Depending on the status of the study and what has been completed for the study, you will be directed to different screens.

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.

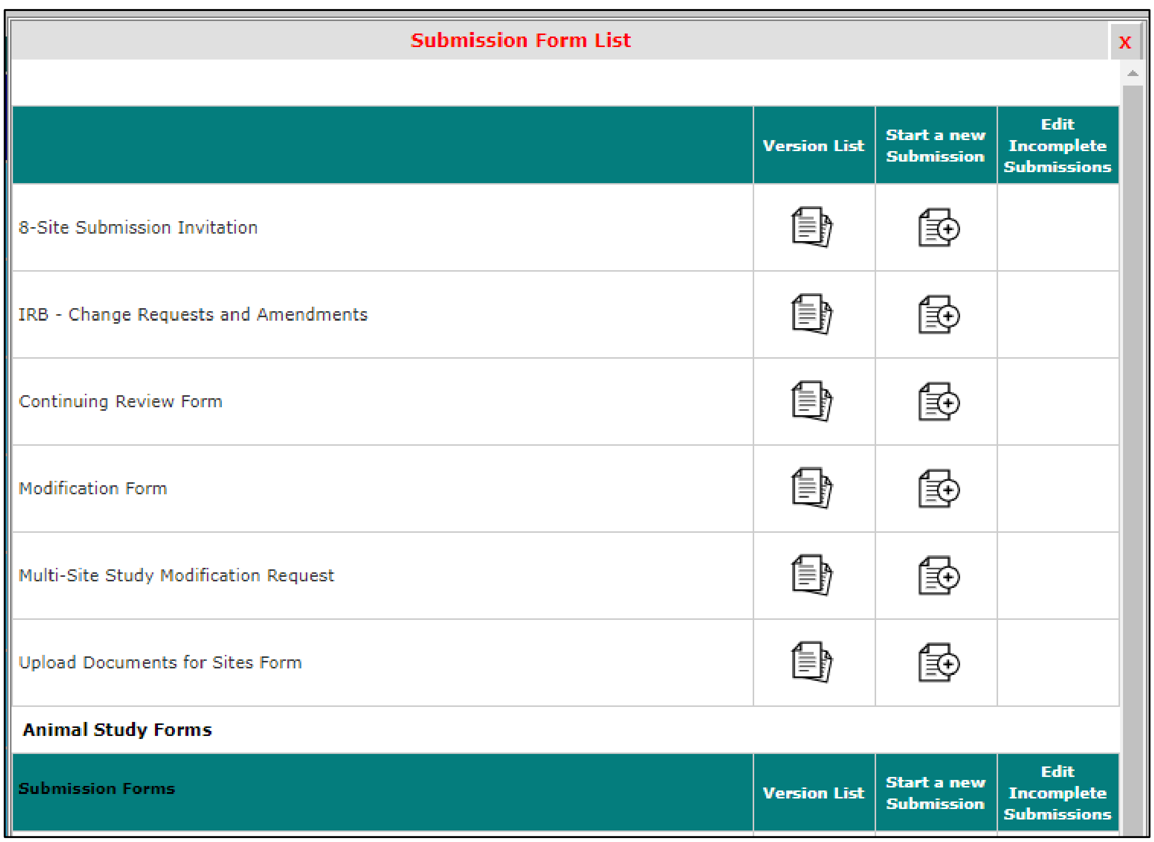


If the study is in Draft status and you open the record, you will be directed to either the Study Application or the Initial Review Submission Form, depending on whether the Study Application or Initial Review is complete. Once either of these forms is complete and the Initial Review has been submitted,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



CHAPTER 5 Start a Submission Form

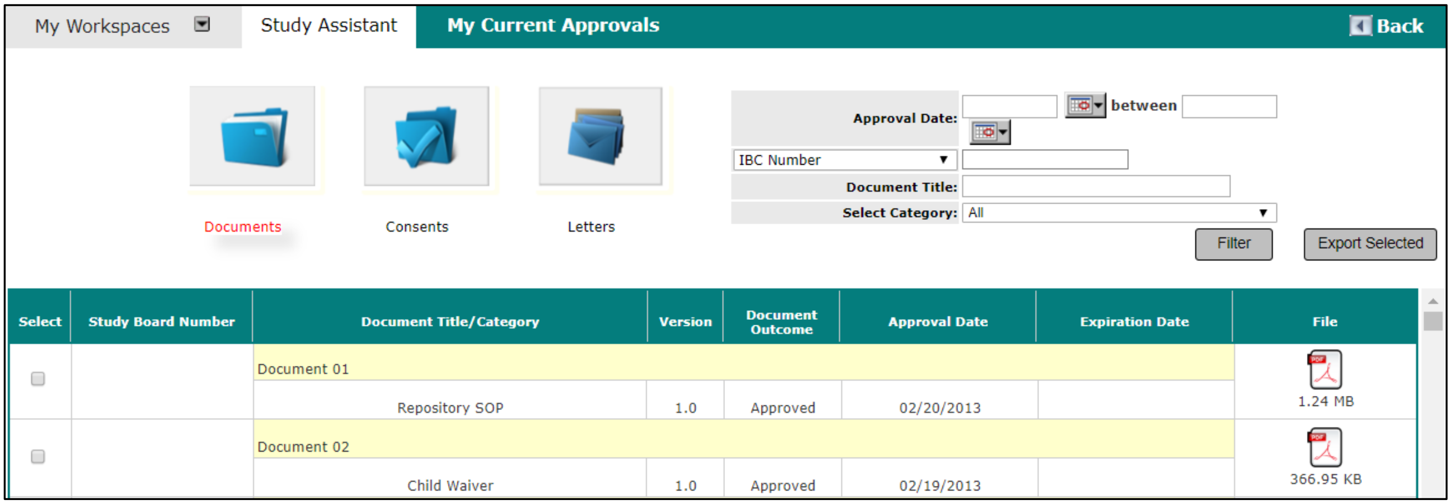
When you select the Start a Submission Form from the main menu, you will be navigated to the All Studies section were all the studies associated to you will display. You will have the ability to start a new submission form from the Action section. When you click on Forms icon, a list of all active submission forms will show in pop-up window.



The pop-up window shown below, allows you to view the submission forms list that can be applied to the study. From this menu, you can view a list of all the vision made from the form, start a new submission or continue to work on an incomplete submission.

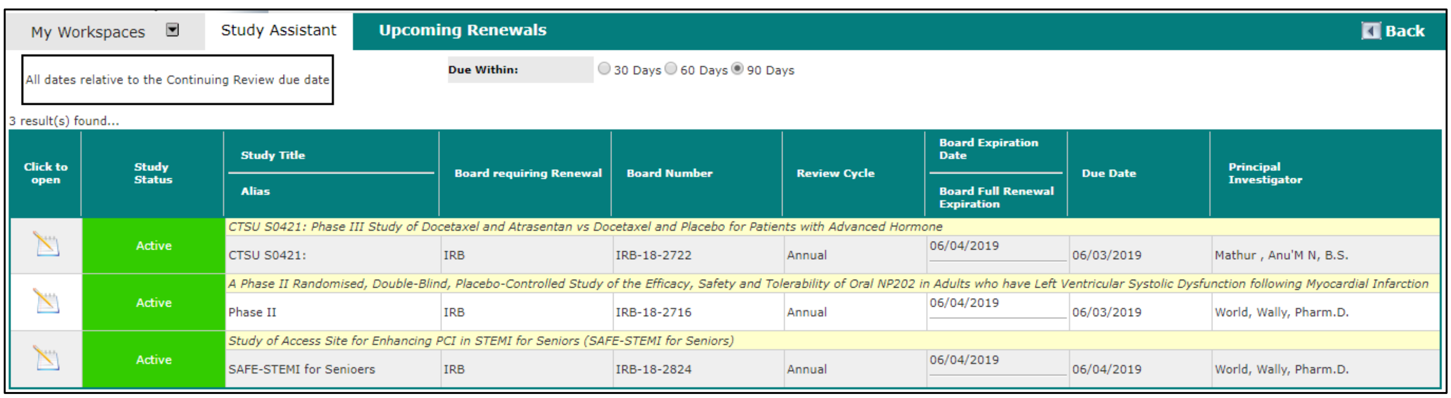
5.1 My Current Approval

My Current Approvals allows access to all Documents, Consents forms, and Letters that have been approved. The search functionality allows to search based on Document Title, Approval Date, or Category of Document, etc. After locating a specific document, the user can download it clicking Export Selected.



5.2 Upcoming Renewals

Upcoming Renewals show upcoming continuing review dates within 30, 60 and 90 days



5.3 Track Approvals

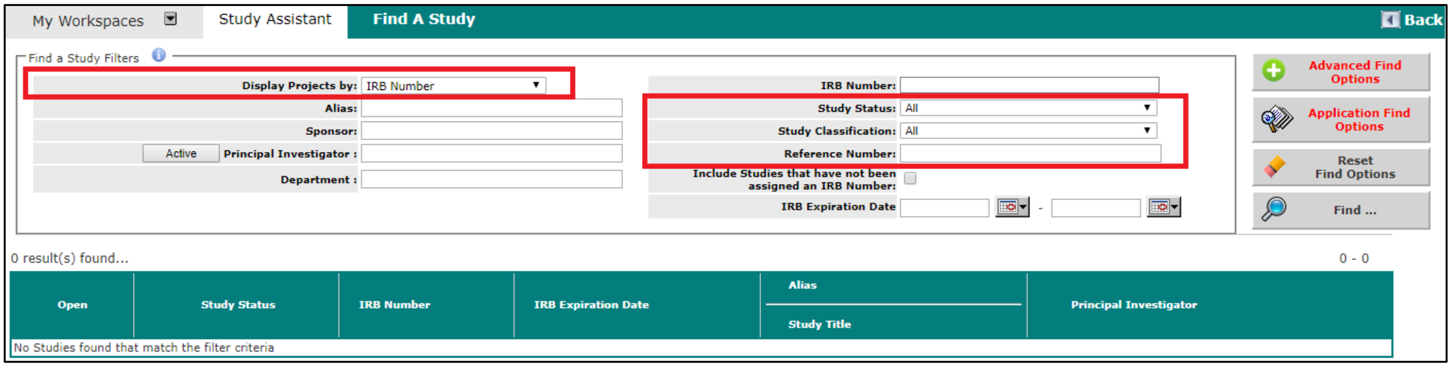
Once you click Track Approval the system will guide you to all the studies associated to you found on the Study Assistant home screen. Under all studies a you can search for approved studies.

5.4 Find A Study

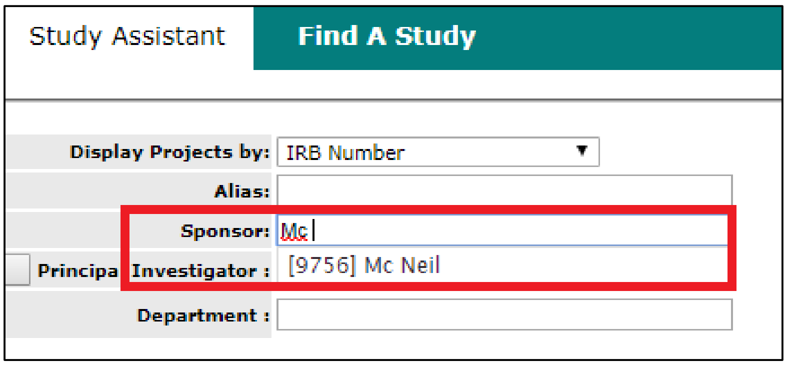
The Find a Study item allows users to search the entire system for studies, regardless of having a role on the study. Find a Study is a tool typically used by System Administrators and Department Administrators.

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.

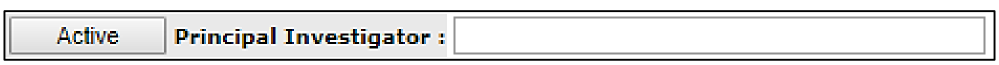
You can also change the display of the study numbering by selecting from the “Display Projects By” dropdown list. The numbers available here depend on what modules are configured in your system. The example below shows the page when IRB Number is selected from the dropdown list. The page reflects IRB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



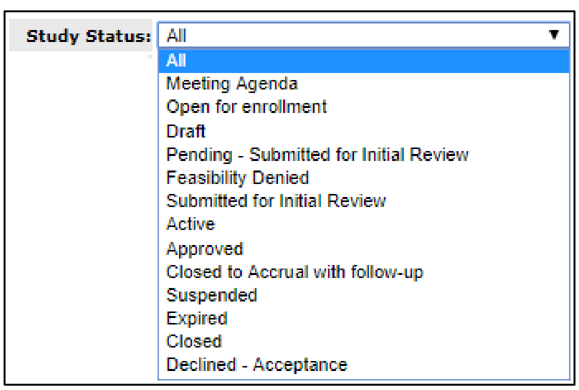
Some of the search fields on this screen are auto-populating fields. You begin by typing the name, and the system will return any resulting matches for you to select. Sponsor, Principal Investigator, Department, and IRB Number are all auto-populating fields.



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.



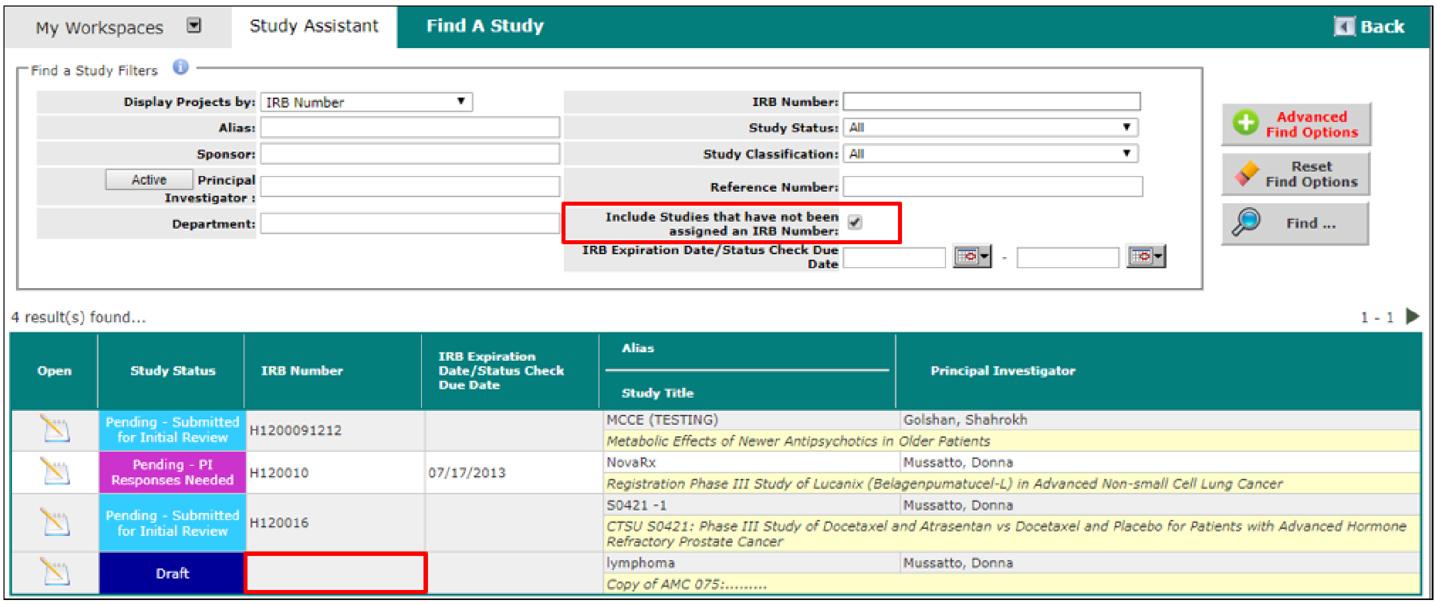
Dropdown lists of available Study Statuses and Study Classifications are also available.



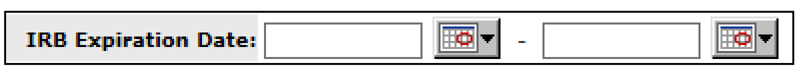
The Reference Number field allows you to search for studies by Submission Reference Number. Enter a reference number for a specific submission form. When you filter the results, the study matching the reference number will populate in the results.

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 whichever 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.

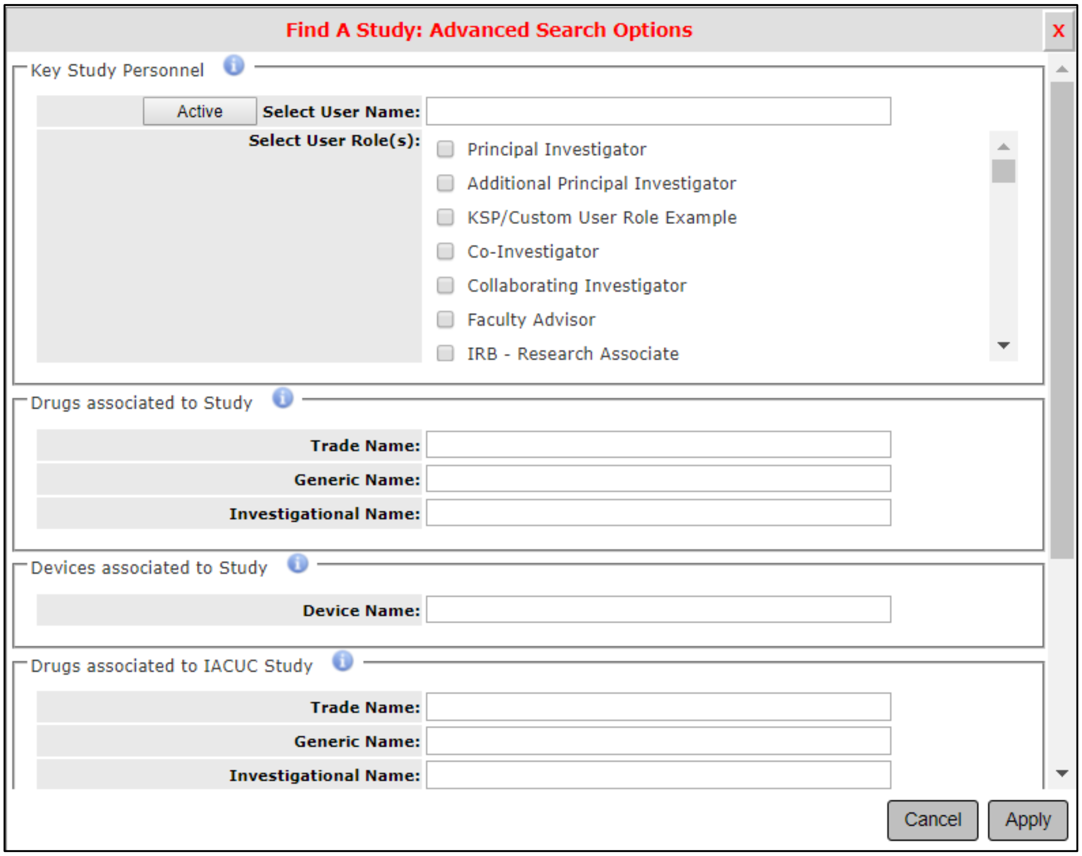


You can search for an expiration date range by entering in a beginning and an end date in the Expiration Date fields. To search for a single day, enter the same date in both fields.

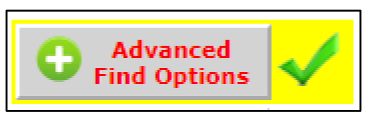


For more advanced search options, click on the **Advanced Find Options** button.

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.

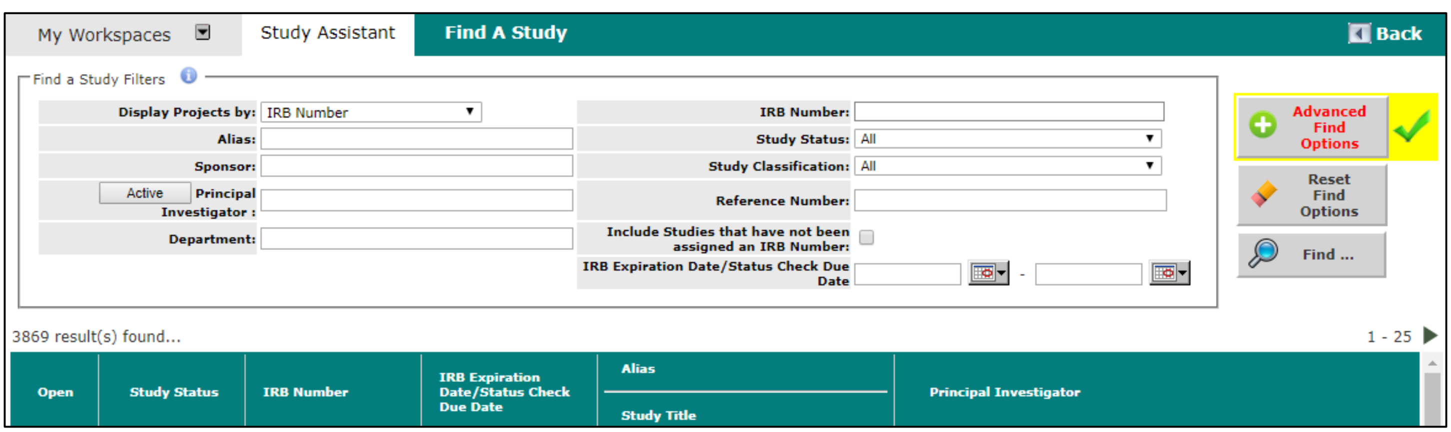


When you click the **Find** button, the system will return any matching studies, depending on the filters you selected. If you added Advanced Search Options, the button will update with a yellow border to indicate extra filters are in use.



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.



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.

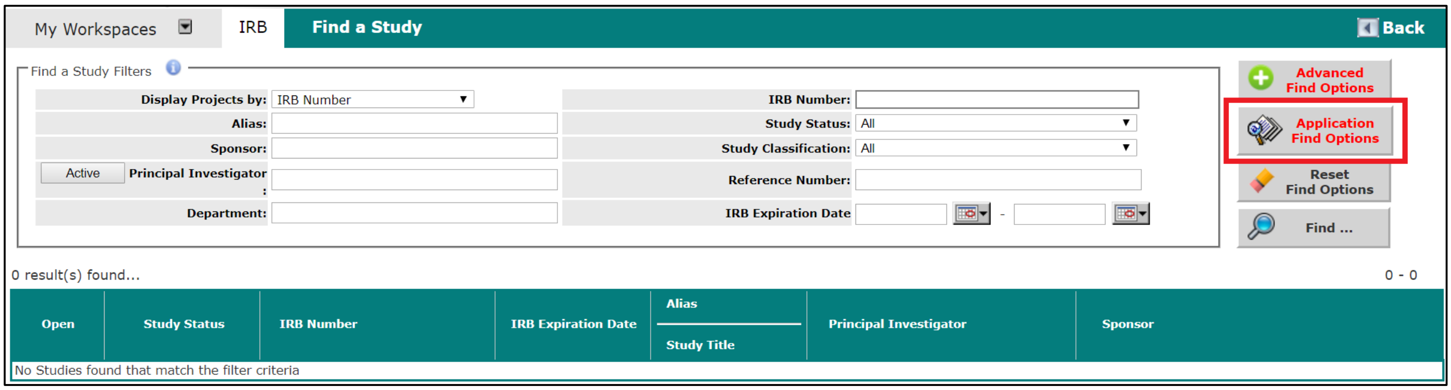
IRB Expiration Date- If an expiration date has been associated with a study, it will display here. The review board in this column will also change according to your display choice.

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

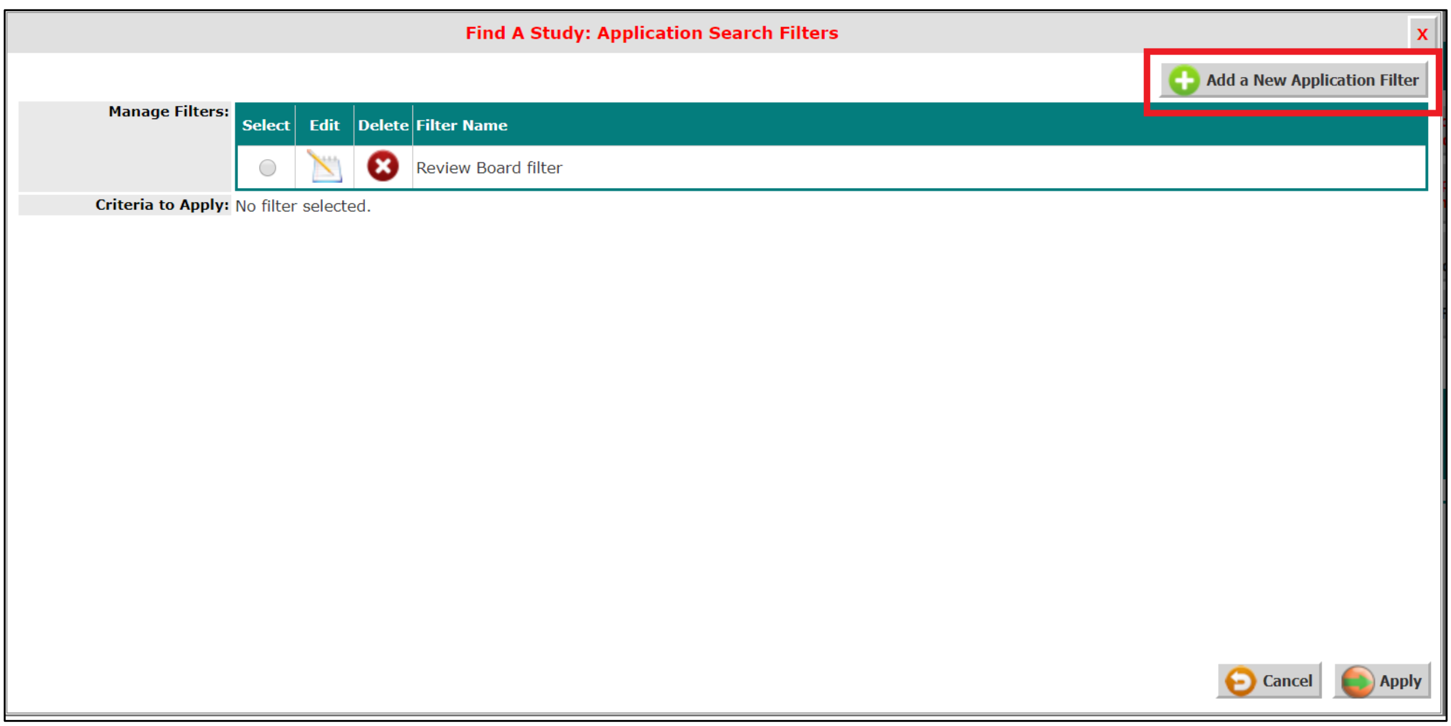
Study Title- This displays the Study Title given to the study in the initial section of the Study Application.

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

Users can also their own filter and apply different search parameters.



After clicking on **Application Find Options,** another window will appear where the user can define new filters. Any existing filters will appear at the top under “Manage filters”. Click **Add a New Application Filter** to define a new filter.



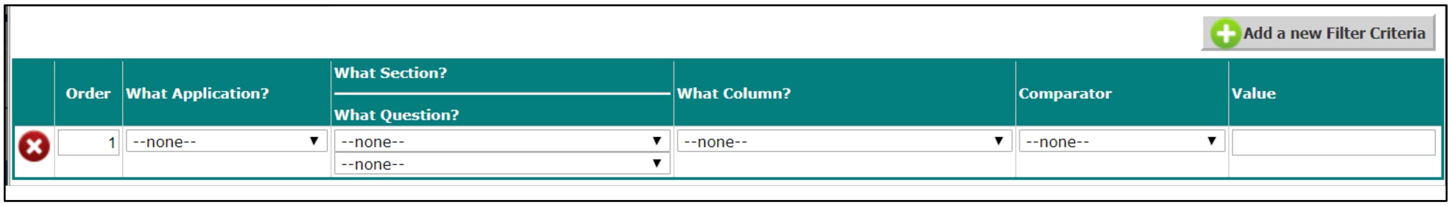
The following screen will allow the user to define the different parameters.

Filter Name: The name of the filter.

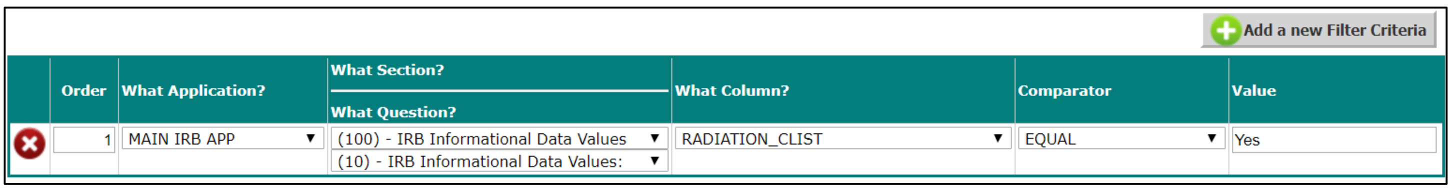
Share this Filter: This will determine if the filter will be sharable with other users. When "Yes" is selected, it will be available for other users. When "No" is selected, the filter will only be available for the user who is defining the filter.

Comments: This section is for the user to input any comments or description if they choose to do so.

At the bottom, users will input the different parameters and logic that they wish to use to search for specific studies. Click **Add a new Filter Criteria** to add a validation.

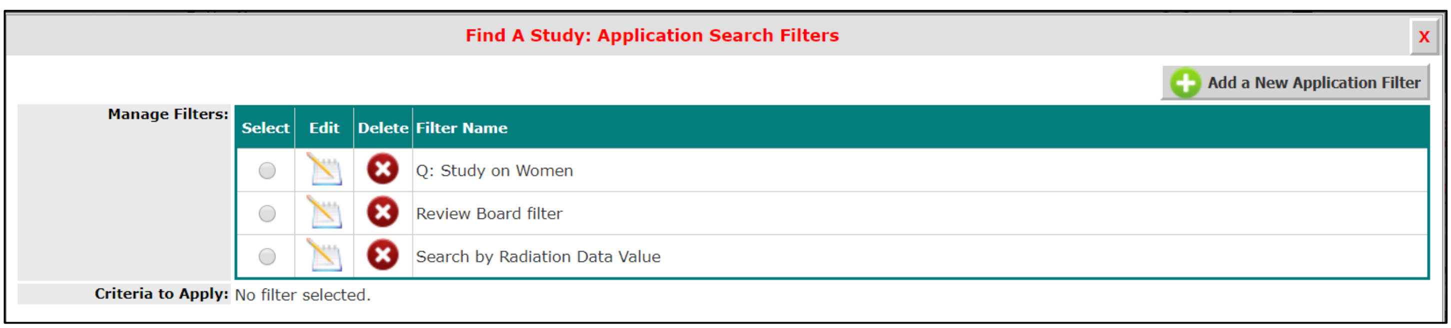


Add the desired validation for your search. Below is an example of a completed validation.

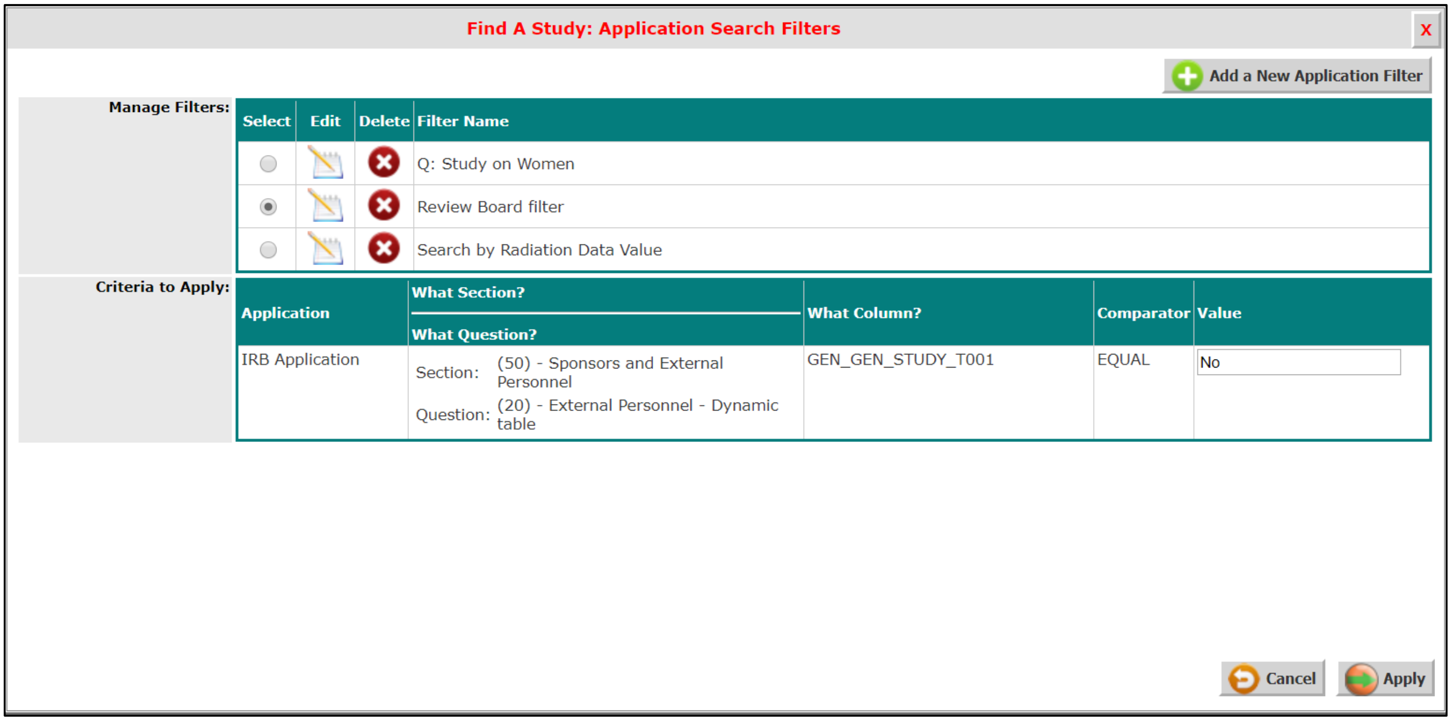


Users are able to add more than one validation per filter as well. When the user is done, click **Save** to save and return back to the original screen where you can apply the filter.

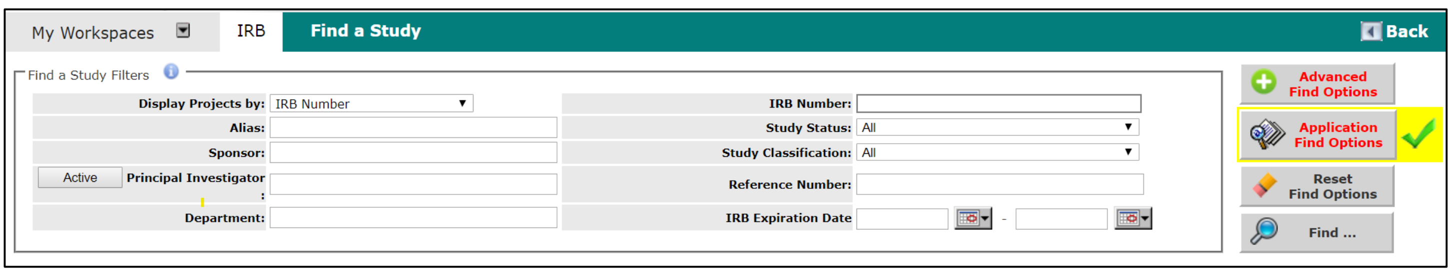
Here at the "Find a Study: Application Search Filters", users are able to Select, Edit, or Delete the filters.



To select a filter to apply to the search, select the radio button next to the desired Filter. The filter will then show the details in the section, Criteria to Apply. Click **Apply** to click the filter to the search.



The highlighted yellow checkmark will indicate that the filter has been applied.



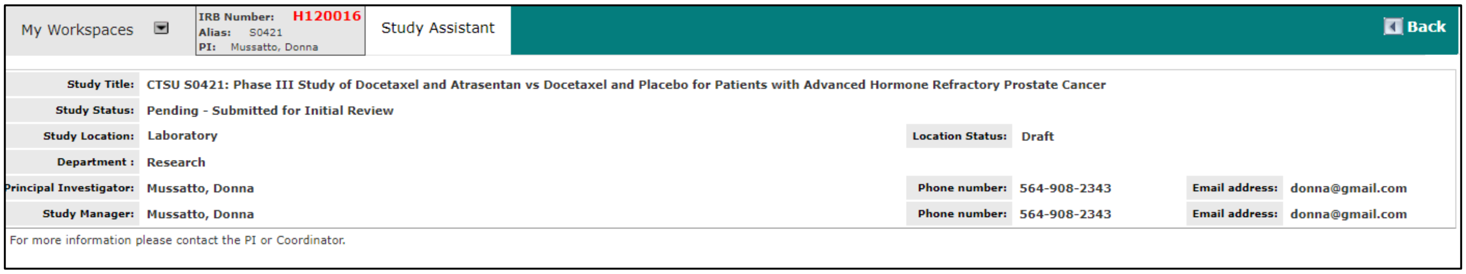
Find a Study for All Users

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.

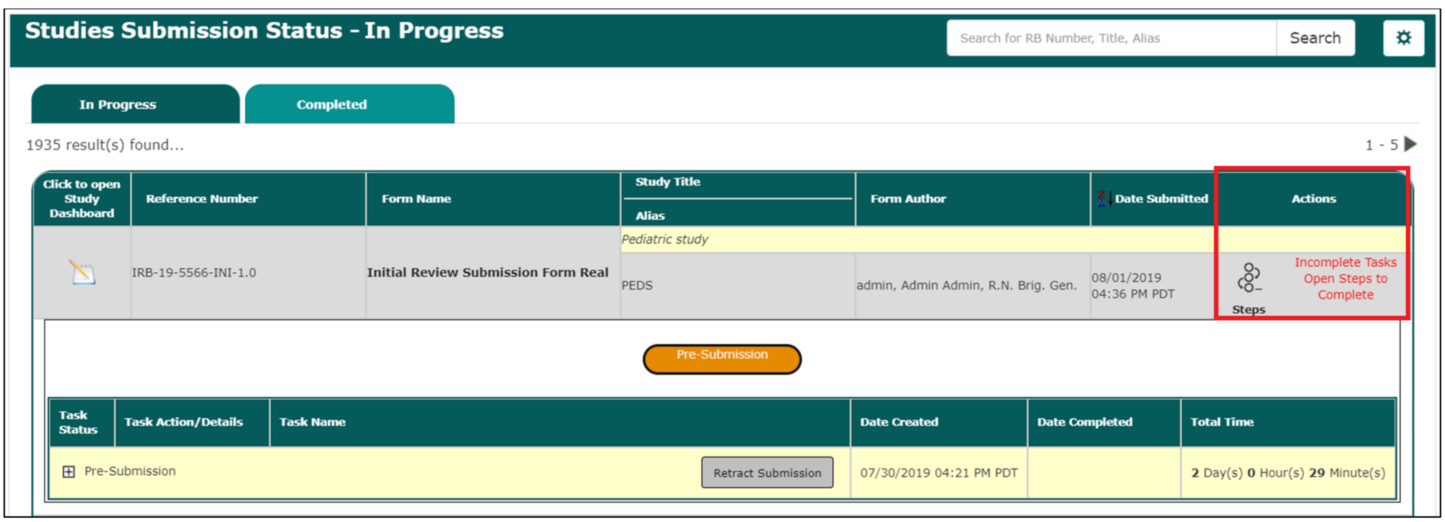


5.5 Studies Submission Status

This section allows uses to respond, address, and view different tasks, issues, and the status of their submissions.

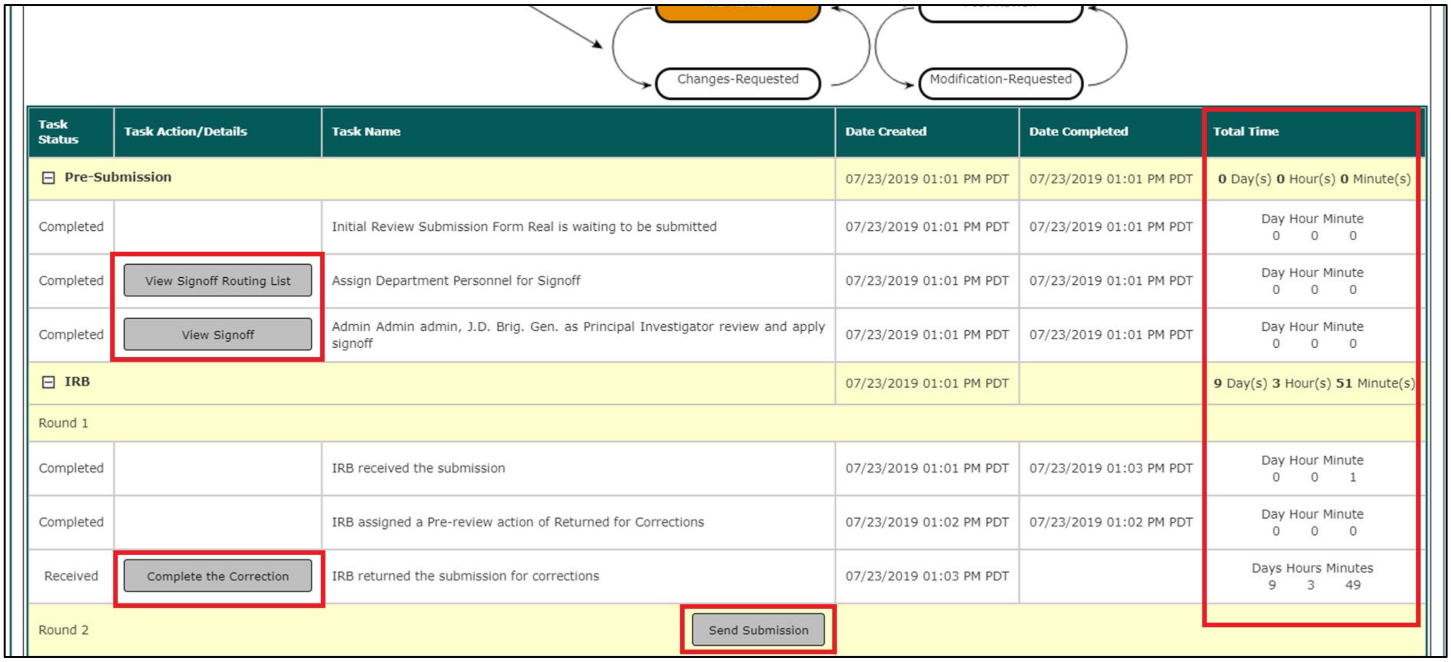
There are two tabs – "In Progress" and "Completed". Users are able to click into their Study, see the reference number, form name, study title, alias, form author, date submitted, and actions needed to be taken / track where the submission is.

Under the "Actions" tab, users are able to click on the **Steps** button to see the details.



Here, users are able to see the task status, task action / details, task name, date created, date completed, and total time.

Past the workflow diagram, users can now see that the column "Total Time" has been added, showing the time that each step has taken. Users can also respond to different tasks or address issues from this screen, by clicking on the different buttons like **Retract Submission, View Signoff Routing List, View Signoff, Compete the Correction, Send Submission** etc.



Task Status	Task Action/Details	Task Name	Date Created	Date Completed	Total Time
⊟ Pre-Submission			07/23/2019 01:01 PM PDT	07/23/2019 01:01 PM PDT	**0** Day(s) **0** Hour(s) **0** Minute(s)
Completed		Initial Review Submission Form Real is waiting to be submitted	07/23/2019 01:01 PM PDT	07/23/2019 01:01 PM PDT	Day Hour Minute 0 0 0
Completed	View Signoff Routing List	Assign Department Personnel for Signoff	07/23/2019 01:01 PM PDT	07/23/2019 01:01 PM PDT	Day Hour Minute 0 0 0
Completed	View Signoff	Admin Admin admin, J.D. Brig. Gen. as Principal Investigator review and apply signoff	07/23/2019 01:01 PM PDT	07/23/2019 01:01 PM PDT	Day Hour Minute 0 0 0
⊟ IRB			07/23/2019 01:01 PM PDT		**9** Day(s) **3** Hour(s) **51** Minute(s)
Round 1					
Completed		IRB received the submission	07/23/2019 01:01 PM PDT	07/23/2019 01:03 PM PDT	Day Hour Minute 0 0 1
Completed		IRB assigned a Pre-review action of Returned for Corrections	07/23/2019 01:02 PM PDT	07/23/2019 01:02 PM PDT	Day Hour Minute 0 0 0
Received	Complete the Correction	IRB returned the submission for corrections	07/23/2019 01:03 PM PDT		Days Hours Minutes 9 3 49
Round 2		Send Submission			

By clicking into individual steps in the workflow, users are able to see further details and the rounds the submission is in (if applicable).