ALL APPLICABLE MODULES

Find a Study

Software Version: 12.01

Manual Version: P1

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Contents

Introduction

The iRIS™ system includes a robust, flexible search tool for locating studies by study number, study alias, study key words, reference number, Principal Investigator (whether active or inactive), Key Study Personnel, drugs or devices associated to the study, and more. The tool also allows for creation of custom, saved search filters.

Note that while the screenshots shown in this manual are from specific iRIS™ modules (e.g., IACUC, Animal Resource Center, etc.), Find a Study features and functionality are the same across all modules where the Find a Study link and page are employed.

System labels are configurable by the institution. The terms “study” and “protocol” are used interchangeably in this manual and the included screenshots.

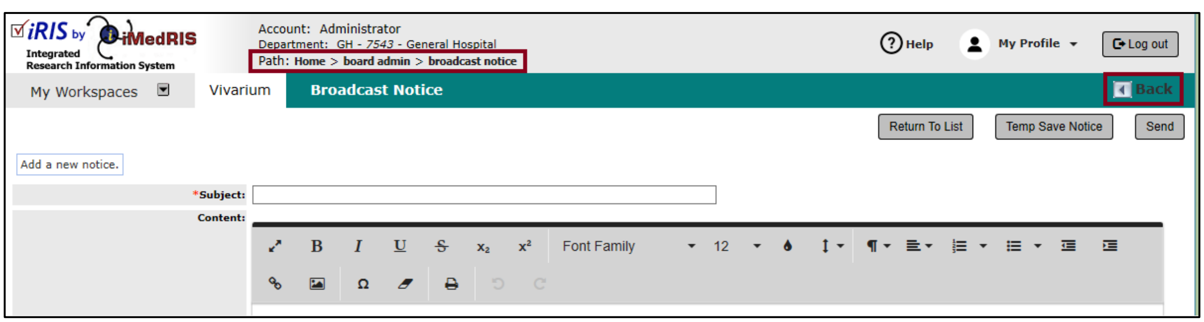
Navigation in iRIS™

iRIS™ includes two standard navigation tools on all pages nested one or more levels beneath the primary Workspace page of the module currently in use (e.g., Study Assistant, Conflict of Interest Assistant, Animal Resource Center, etc.): a Path directory tree, and Back buttons.

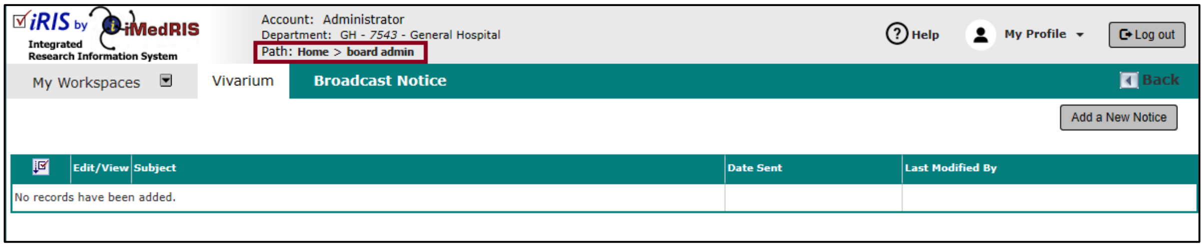
Path Directory Tree

The **Path** item at the upper left of iRIS™ pages provides a hyperlinked menu directory tree, allowing the user to quickly navigate back through the path they followed to get to their current location. **Path** appears on all pages nested at least one level beneath the main workspace

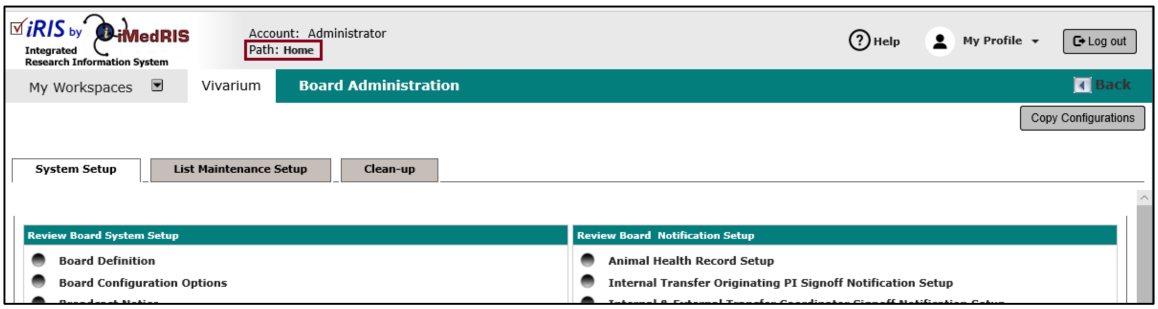
In the example shown the user is viewing the **Broadcast Notice Add a new notice** page. This page is nested three levels beneath the main workspace page, as indicated by the three links available in the **Path** directory tree: **Home**, **board admin** and **broadcast notice**.



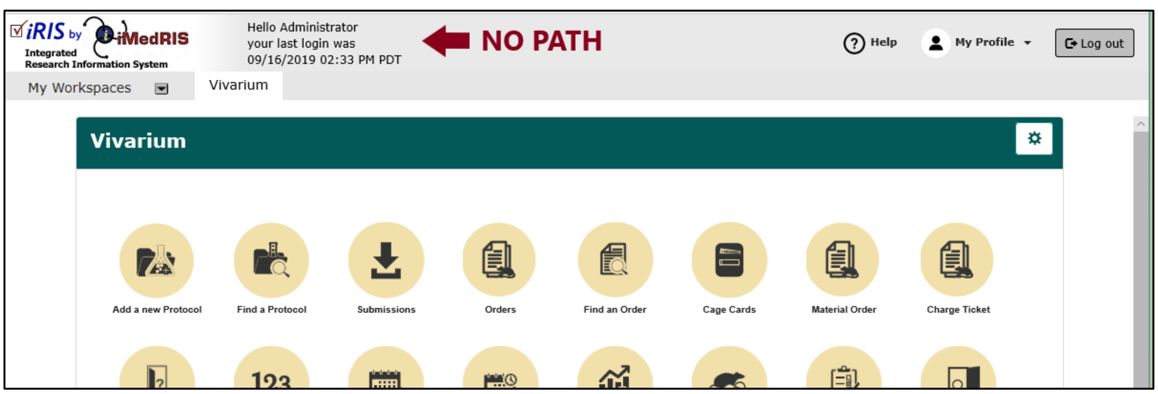
Click on **broadcast notice** in the **Path** to navigate up one level in the directory tree, to the main **Broadcast Notice** page. There are now two levels in the **Path** directory tree: **board admin** and **Home**.



Click on **board admin** in the **Path** to navigate up one level in the directory tree, to the **Board Administration** page. There is now one level in the **Path**: **Home**.

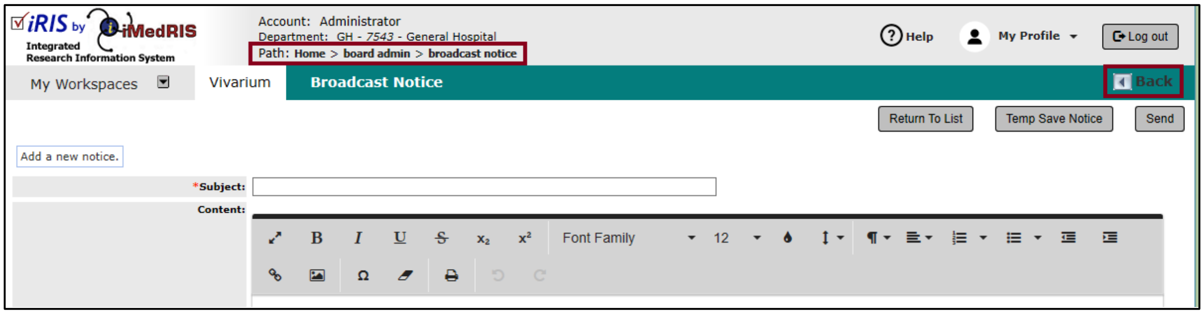


Click on **Home** in the **Path** to navigate up one level in the directory tree, to the main Workspace page. No Path item is displayed here because the user is now at the top-most level of the directory tree.

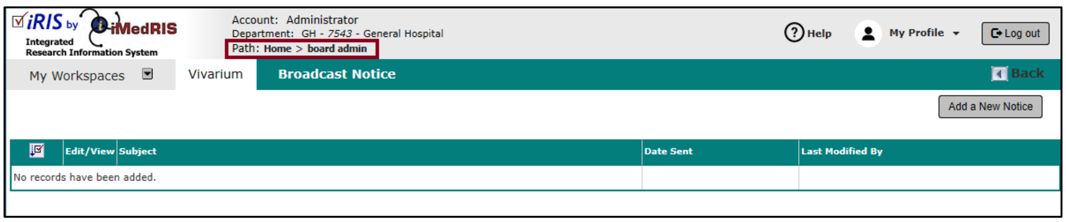


Back Button

The second navigation tool is the **Back** button, which appears on all pages nested at least one level beneath the main workspace. The **Back** button takes the user to the same location as the last link shown in the **Path**.



In the example shown above, both the **Back** button and the **broadcast notice** link in the **Path** return the user to the **Broadcast Notice** page:

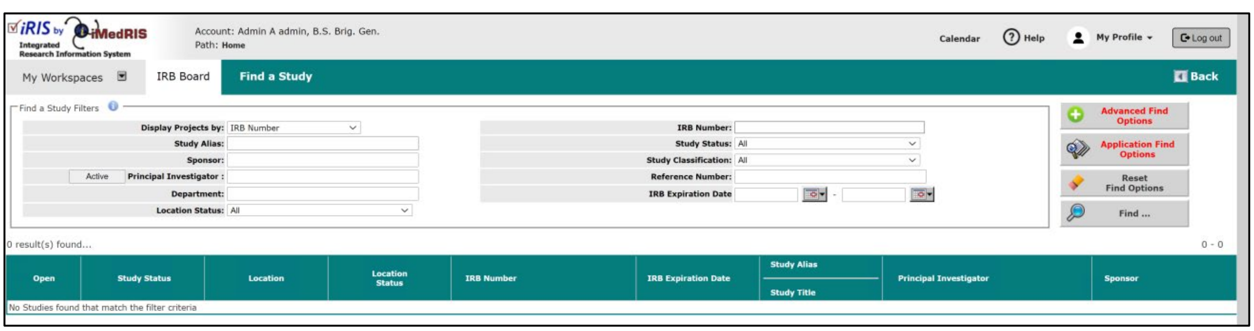


Clicking the **Back** button on the **Broadcast Notice** page returns the user to the Board Administration page, as indicated by the last link in the **Path** directory tree shown in the screenshot above.

*Note that where the **Back** button appears on a page with editable fields or document upload controls, clicking the button before saving changes returns the user to the same location as the last link shown in the **Path** without saving changes.*

Find a Study Page

Click the applicable **Find a Study** link (Home > [module] > Find a Study) to open the **Find a Study** page (shown below).



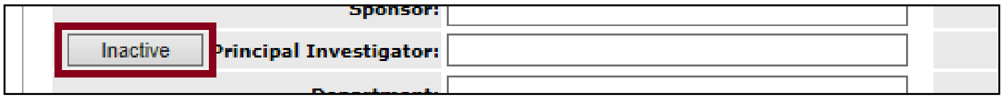
Enter / select desired search criteria in the **Find a Study Filters** section (described below), and click the **Find** button to execute the search. Click the **Reset Find Options** button to reset all filter fields.

The **Display Projects by** dropdown allows for selection by number type (e.g., study/protocol number, IRB number).

Text entry fields are provided to search by full or partial **Study Number/Alias**, **Sponsor** name, **Department**, **IRB Number** or **Reference** number.

The **Principal Investigator** (PI) field can be used to search by full or partial PI name and includes a button to toggle the search between **Active** or **Inactive** PIs. As shown below, the button is toggled to **Active** by default.

Click the **Active** button to toggle it to **Inactive**, as shown below.



*Note that it is not possible to search by both **Active** and **Inactive** PIs simultaneously.*

The **Location Status** dropdown allows for selection by **Location Status**. *Note that Location Status is configured by the institution under System Administration > Setup Locations Status.*

The **Study Status** dropdown provides a pick list to filter the search by study status. Click an item in the list to select it.

The **Study Classification** dropdown provides a pick list to filter the search by study classification. Click an item in the list to select it.

Calendar widgets are provided for searching by **IRB Expiration Date** range. Available date range options are as follows:

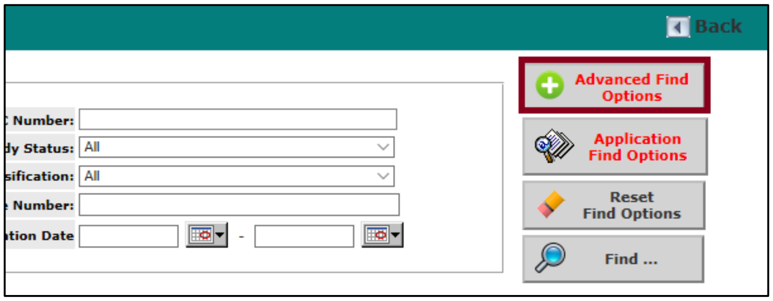
— to limit the search to studies whose **IRB Expiration Date** occurs on or *after* a specific date, click the left-hand calendar widget and select the desired start date; leave the right-hand date field blank

— to limit the search to studies whose **IRB Expiration Date** occurs on or *before* a specific date, click the right-hand calendar widget and select the desired end date; leave the left-hand date field blank

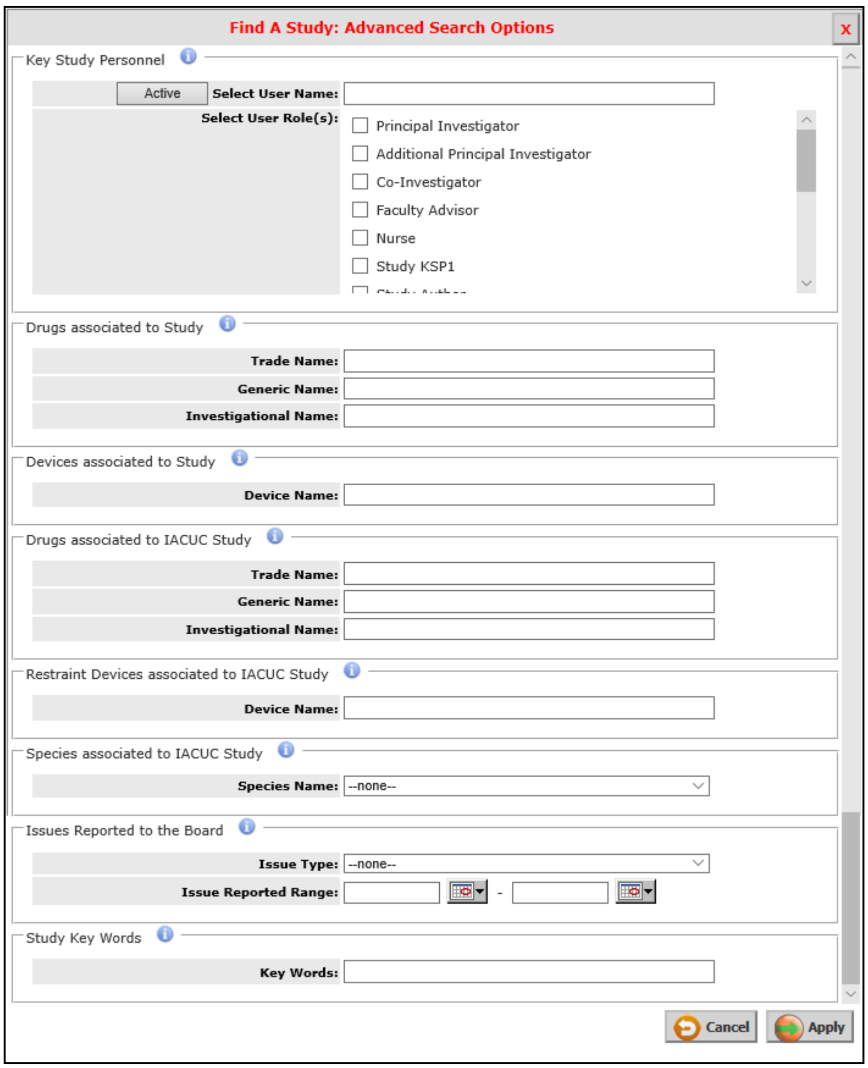
— to limit the search to studies whose **IRB Expiration Date** occurs *between* two specific dates, select the desired start date using the left-hand calendar widget and the end date using the right-hand calendar widget

Find a Study Advanced Find Options

Additional search options and filters are available via the **Advanced Find Options** button, as shown below.



Click the button to open the **Find A Study: Advanced Search Options** popup, shown below.



The popup includes panels for eight (8) different advanced search criteria:

— Key Study Personnel

— Drugs associated to Study

— Devices associated to Study

— Drugs associated to IACUC Study

— Restraint Devices associated to IACUC Study

— Species associated to IACUC Study

— Issues Reported to the Board

— Study Key Words

Enter desired search criteria in one or more panels (see following subsections) and click the **Apply** button to apply the desired criteria to the main **Find A Study** search page. As shown below, when advanced search criteria are selected the **Advanced Find Options** button on the **Find A Study** page updates with a yellow background and green checkmark to indicate these options are in use.

Click the **Cancel** button on the **Find A Study: Advanced Search Options** popup to close it without applying any of its search criteria to the main **Find A Study** page.

To clear individual **Advanced Find Options**, click the **Advanced Find Options** button to reopen the **Find A Study: Advanced Search Options** popup. Clear any search criteria previously entered there and click the **Apply** button at the bottom of the popup.

Click the **Reset Find Options** button on the **Find A Study** page to clear all selected filters and/or search criteria.

For the remainder of this subsection, individual panels of the **Find A Study: Advanced Search Options** popup are shown in isolation.

Key Study Personnel

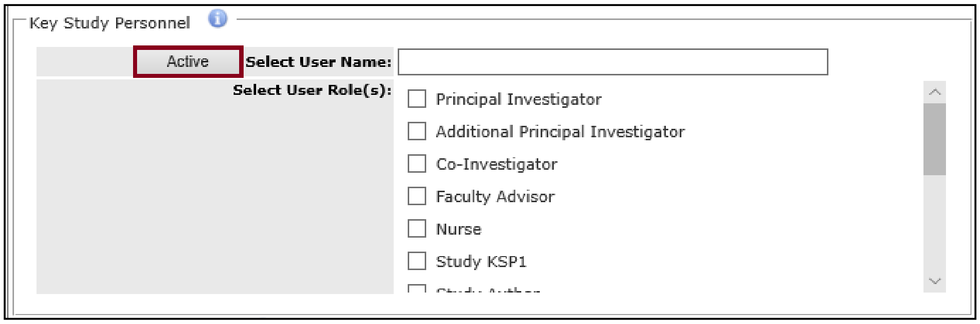
The **Key Study Personnel** panel provides three (3) search options:

— Search for studies by the full or partial **User Name** of assigned **Active** study personnel

— Search for studies by the full or partial **User Name** of assigned **Inactive** study personnel

— Search for studies by **User Role** of assigned study personnel

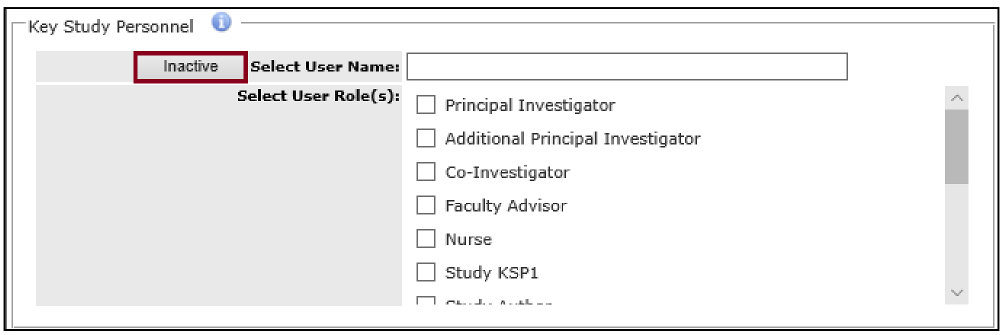
As shown below, when the **Find a Study: Advanced Search Options** popup initially loads the **Active** button is enabled for the **Select User Name** field.



To search **Active** study personnel by **User Name**, enter the full or partial name in the **Select User Name** field.

To search **Inactive** study personnel by **User Name**, click the **Active** button to toggle it to **Inactive**, then enter the full or partial name in the **Select User Name** field.

*Note that it is not possible to search by both **Active** and **Inactive** study personnel at the same time.*



To search by **User Role(s)**, select the desired checkbox(es) in the **Select User Role(s)** section. The full list includes the following roles:

— Principal Investigator

— Additional Principal Investigator

— Co-Investigator

— Faculty Advisor

— Nurse

— Study KSP1

— Study Author

— Contact

— Department Administrator

— Administrative Assistant

— Site Contact

— Additional Project Manager

— Project Staff

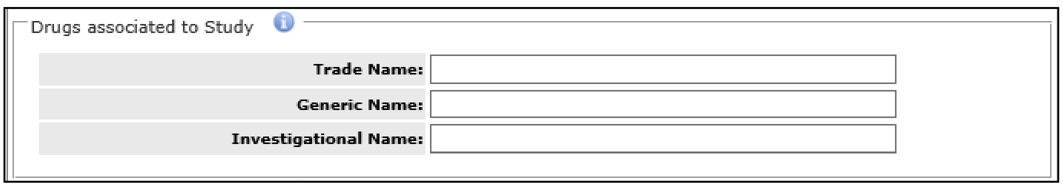
— Project Manager

— Post Doctoral (Grants.gov - Post Doctoral)

The **Active/Inactive Select User Name** and **Select User Role(s)** fields can be used separately or in combination.

Drugs associated to Study

This panel is used to search for studies based on **Drugs associated to Study** by **Trade Name**, **Generic Name** and/or **Investigational Name**.

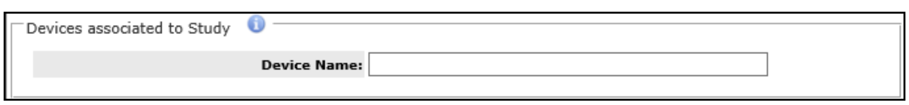


Enter the full or partial drug name in the desired field(s).

Note that a separate panel, Drugs associated to IACUC Study, is provided further down in the popup for searching by IACUC study drugs.

Devices Associated to Study

This panel is used to search for studies by **Devices associated to Study**.

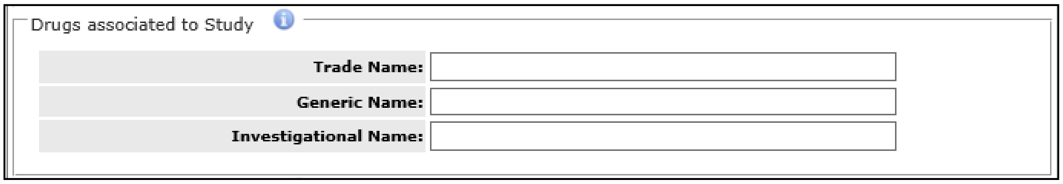


Enter the full or partial **Device Name** to use this search option.

Note that a separate panel, Restraint Devices associated to IACUC Study, is provided further down in the popup for searching by IACUC study restraint devices.

Drugs associated to IACUC Study

This panel is used to search for IACUC studies based on **Drugs associated to IACUC Study** by **Trade Name**, **Generic Name** and/or **Investigational Name**.

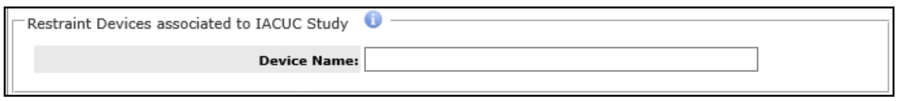


Enter the full or partial drug name in the desired field(s).

Note that a separate panel, Drugs associated to Study, is provided higher up in the popup for searching by non-IACUC study drugs.

Restraint Devices associated to IACUC Study

This panel is used to search for IACUC studies by **Restraint Devices associated to IACUC Study**.

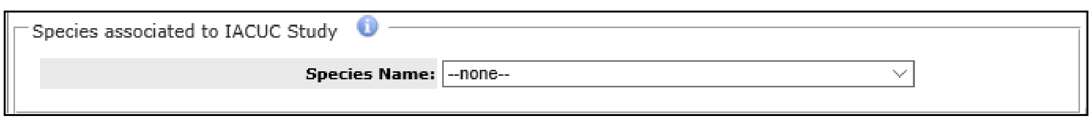


Enter the full or partial **Device Name** to use this search option.

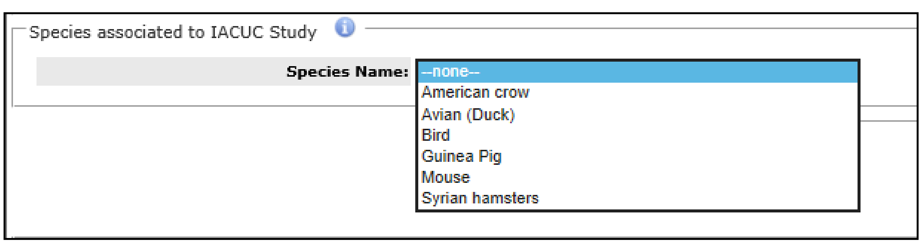
Note that a separate panel, Devices associated to Study, is provided higher up in the popup for searching by non-IACUC study devices.

Species associated to IACUC Study

This panel is used to search for IACUC studies by **Species associated to IACUC Study**.



Click in the field to open the **Species Name** dropdown list.

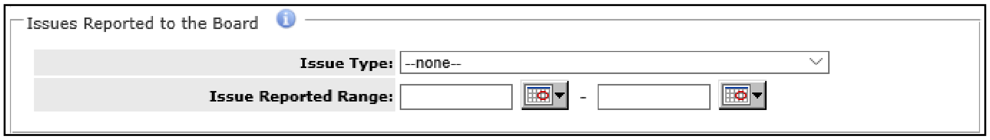


Click to select the desired **Species Name** from the dropdown list.

Note that only one item can be selected in the dropdown list.

Issues Reported to the Board

This panel is used to search for studies by **Issues Reported to the Board**.



The panel provides four (4) search options:

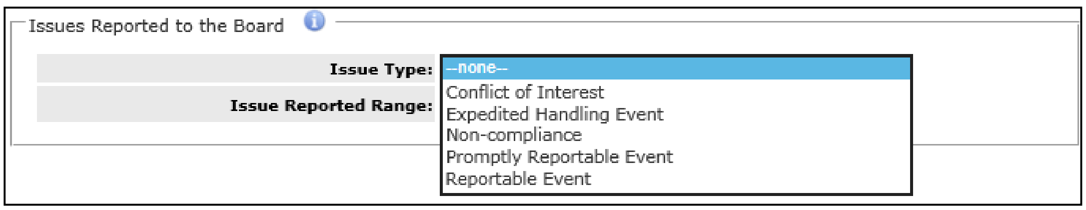
— Issue Type

— Issue reported on or *after* a specified date

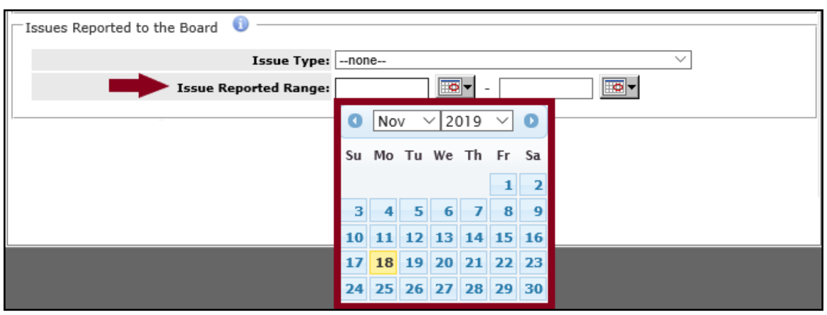
— Issue reported on or *before* a specified date

— Issue reported *between* two specified dates

Click in the **Issue Type** dropdown list and click an item in the list to select it.



Calendar widgets are provided for searching by issue reporting date.



Available date range options are as follows:

— to limit the search to studies whose issue reporting date occurs on or *after* a specific date, click the left-hand calendar widget and select the desired start date; leave the right-hand date field blank

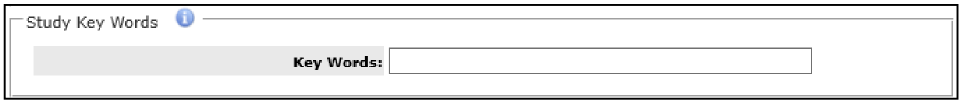
— to limit the search to studies whose issue reporting date occurs on or *before* a specific date, click the right-hand calendar widget and select the desired end date; leave the left-hand date field blank

— to limit the search to studies whose issue reporting date occurs *between* two specific dates, select the desired start date using the left-hand calendar widget and the end date using the right-hand calendar widget

Note that the **Issue Type** and **Issue Reporting Range** fields can be used individually or in combination to search by reported issues.

Study Key Words

Use the **Study Key Words** field to search for studies by keyword.

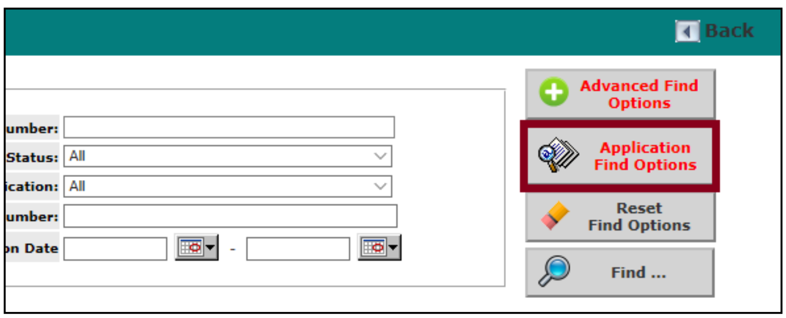


Enter desired **Key Words** to use this search option.

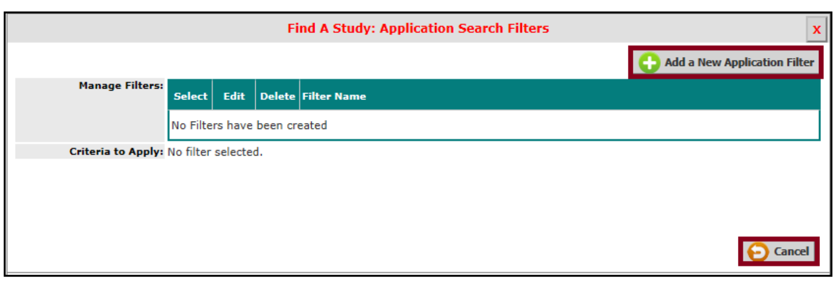
Find a Study Application Find Options

Click the **Application Find Options** button to create and save application (module) -specific filters for re-use as needed.

*Note that **Application Find Options** filters can be used in conjunction with any other search criteria and filters on the **Find a Study** page, including **Advanced Find Options**.*

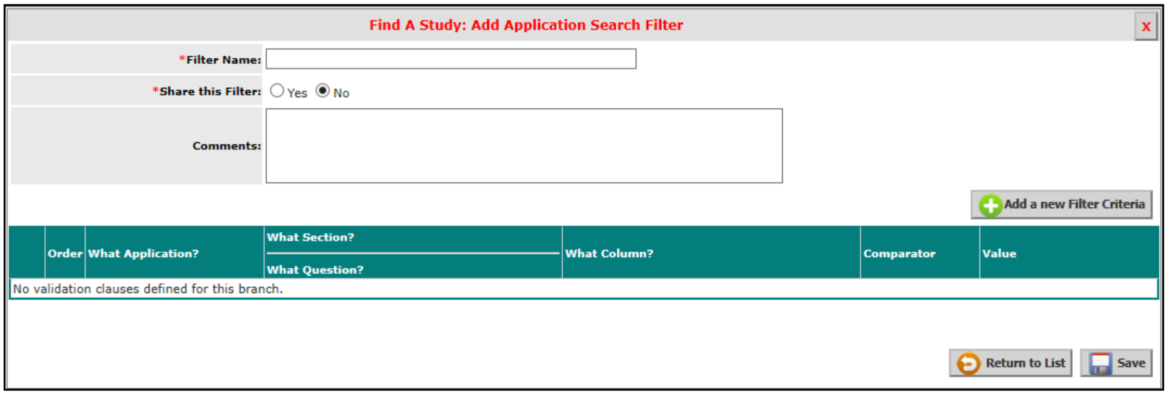


The **Find A Study: Application Search Filters** page opens.



Click the **Cancel** button to close the page without making changes and/or applying filters to the current search.

Click the **Add a New Application Filter** button to open an add panel. *In the following example a search filter is created for IACUC applications, but the same general process applies to creating IRB application filters.*

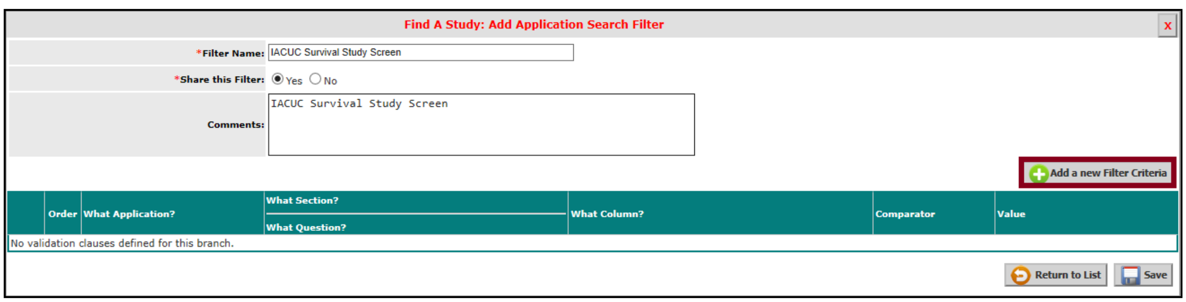


Enter the desired **Filter Name**.

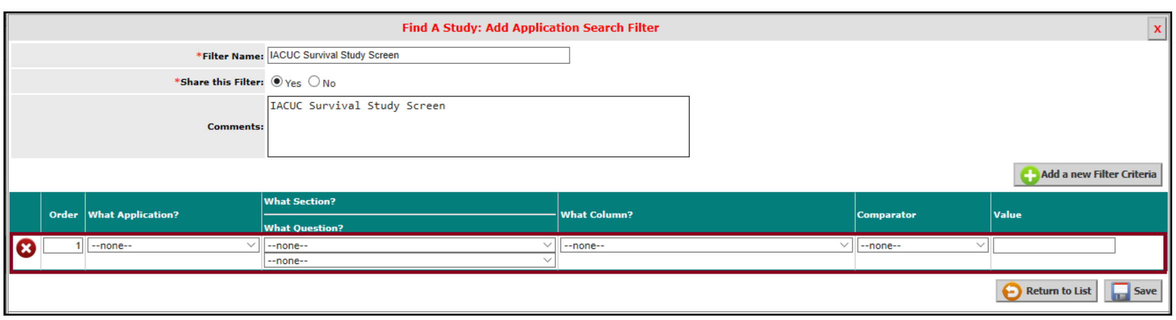
Select “Yes” or “No” for **Share this Filter**. A selection of “Yes” makes the filter available to other users, a selection of “No” keeps the filter private to the person who created it.

Enter any desired **Comments** (e.g., a description of the filter’s purpose).

Click the **Add a new Filter Criteria** button to construct the filter.



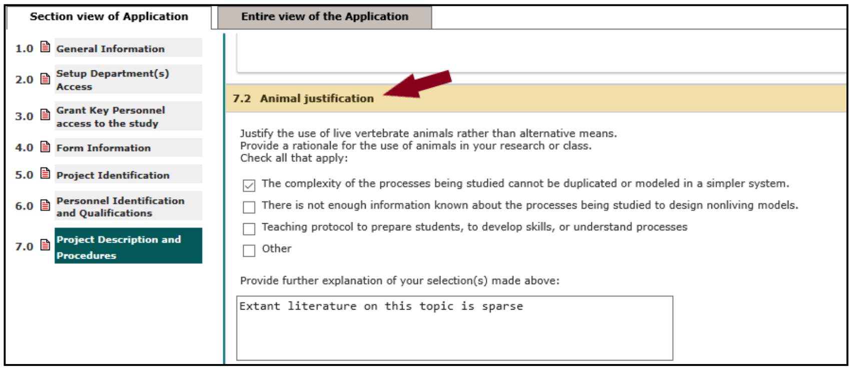
As shown below, available text entry fields and dropdown lists are activated.



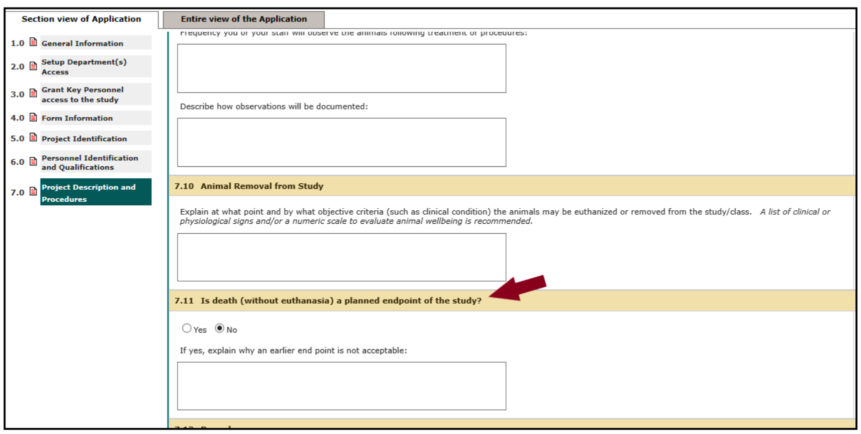
The activated fields are used to filter search results based on the answer(s) to specific question(s) in the study/project application form.

In this example, the filter will limit search results to those studies where the justification for using animal subjects is based on complexity of the study model, *and* all study animals are expected to survive. Two different study application criteria must be added to the filter:

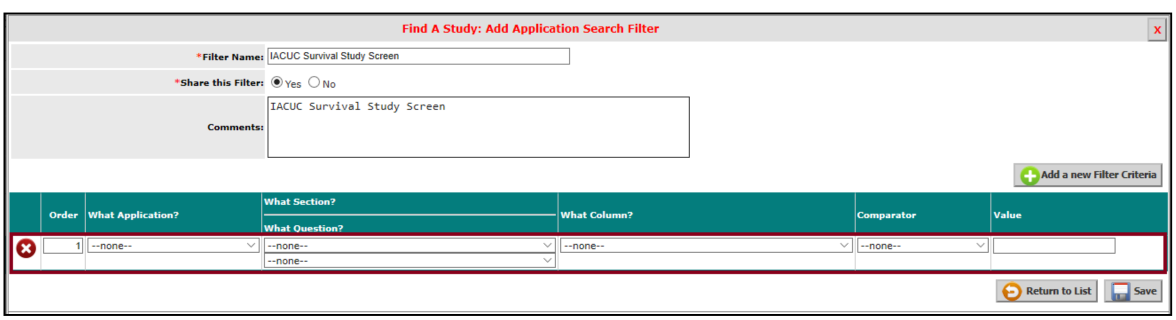
— a rationale of "The complexity of the processes being studied cannot be duplicated or modeled in a simpler system," must be selected in response to the Animal Justification field of the application



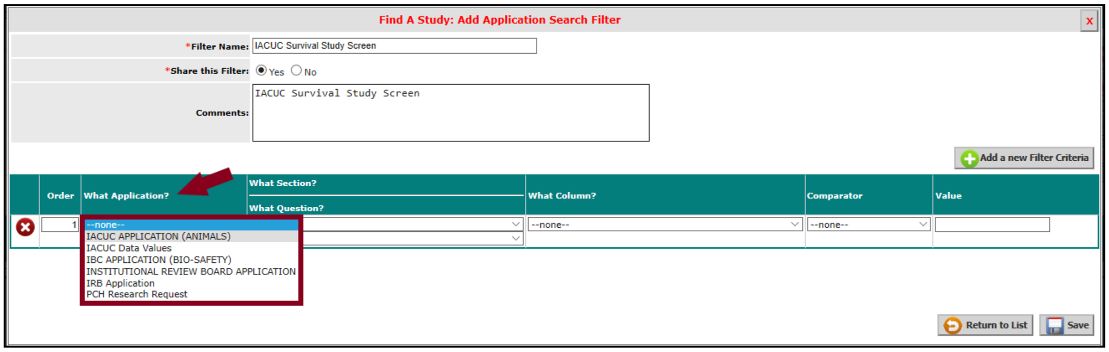
— the answer to the question, "Is death (without euthanasia) a planned endpoint of the study?" must be "No", as shown below



The **Order** field dictates the priority level of the criteria item in the overall filter. When the filter consists of a single criterion, the **Order** for that criterion is "1". When multiple criteria are added to the filter their **Order** values can vary.

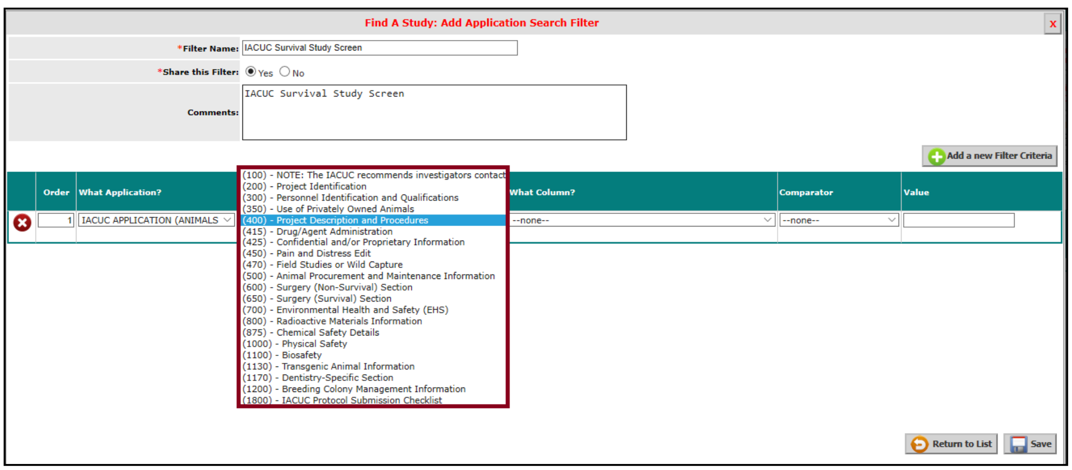


Click in the **What Application?** field and select the applicable application/module from the dropdown list. In this example the "IACUC APPLICATION (ANIMALS)" option is selected, as shown below.

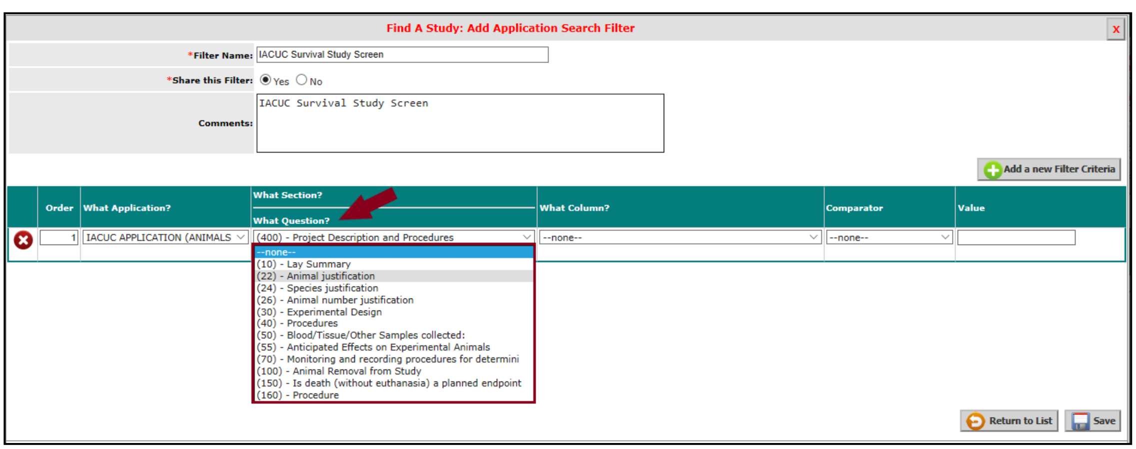


The **What Section?** and **What Question?** dropdown lists are automatically populated with items applicable to the application/module selected in the **What Application?** field.

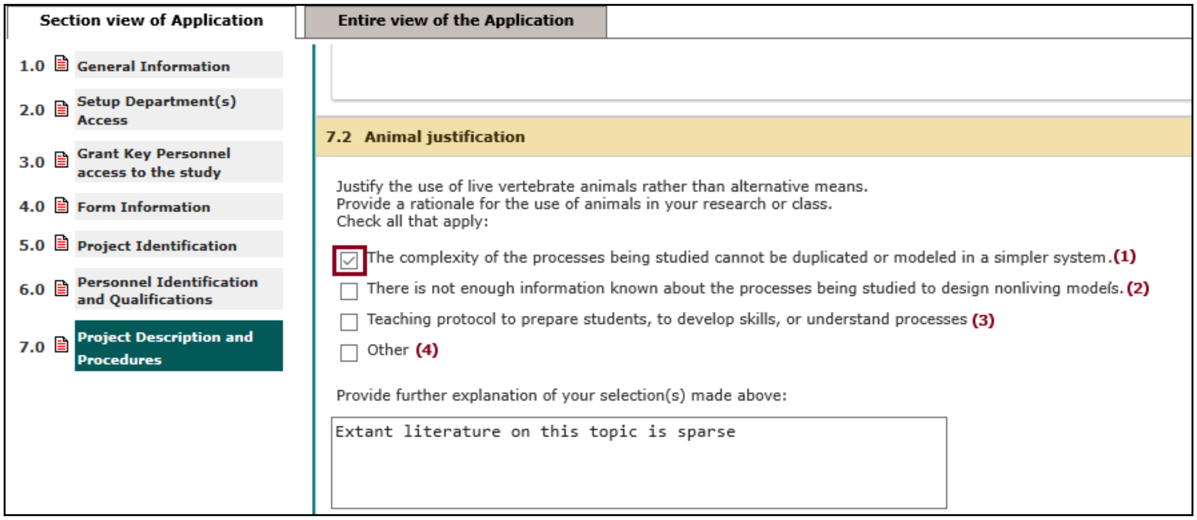
Click in the **What Section?** field and select the study application section in which the first question applicable to the filter is found from the dropdown list. In this example the “(400) - Project Description and Procedures” section is selected, as shown below.



Click in the **What Question?** field and select the question applicable to the filter from the dropdown list. In this example the “(22) – Animal justification” question is selected, as shown below.



Recall that in the IACUC study application four possible answers to this question and an explanation field are provided, as shown below.



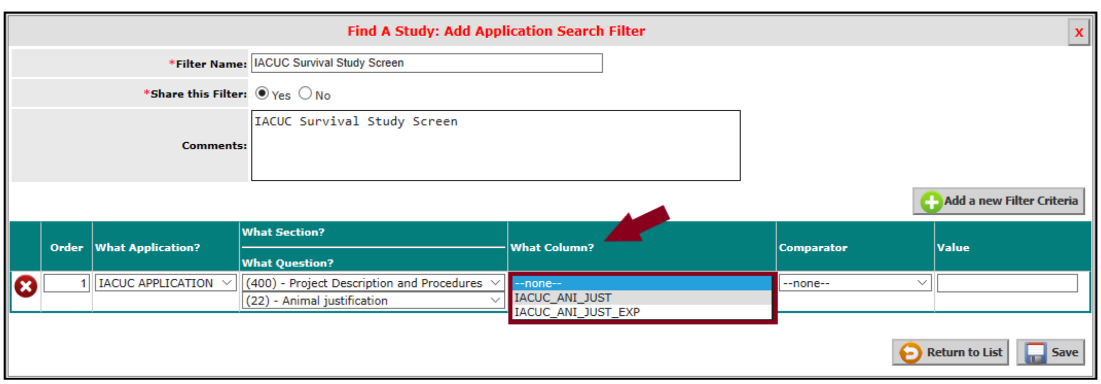
Two components, or columns, are stored as the answer to this question.

The first column contains one or more entries of the number(s) one (1) to four (4), indicating which checkbox(es) is(are) selected. Multiple entries can be stored in the response because the user can select more than one checkbox. In the database this column is named “IACUC_ANI_JUST”.

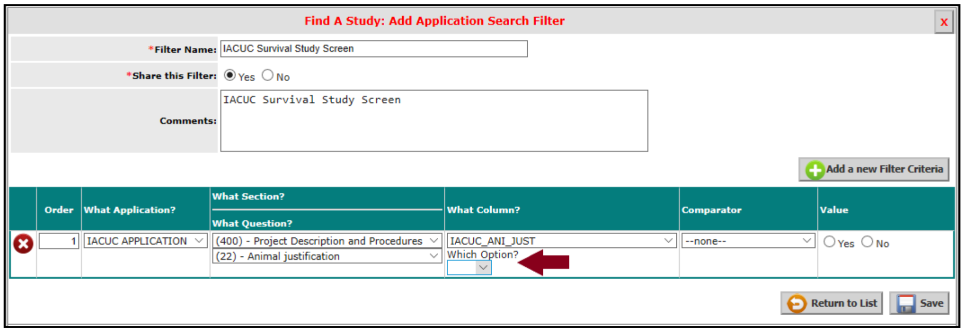
The second column contains any text entered in the “Provide further explanation of your selection(s) made above:” text box. In the database this column is named “IACUC_ANI_JUST_EXP”.

Note: Because column titles are not always named in descriptive, plain English, strong knowledge of the fields and tables involved in constructing the filter is required to avoid errors.

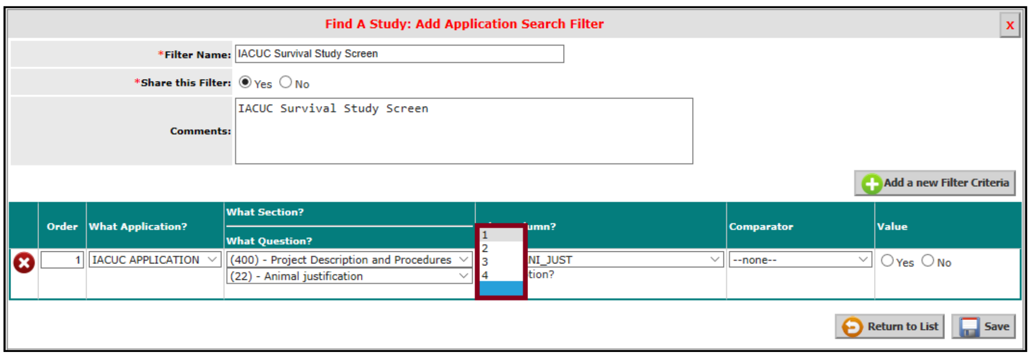
Click in the **What Column?** field and select the column that contains the data value applicable to the filter from the dropdown list. In this example “IACUC_ANI_JUST” is selected.



As shown below, because the answer to this question offers four possible options in response, a “Which Option?” field is added.



As explained above, the dropdown select list contains four options. In this example the first option (“The complexity of the processes being studied cannot be duplicated or modeled in a simpler system.”) is selected, as shown below.



Click in the **Comparator** field and select the desired item from the dropdown list. Comparators are used as follows:

— EQUAL is used for comparisons against either text or numeric field values and is equivalent to the “=“mathematical operator; the **Value** entered for comparison must *exactly* match the value entered in the application form, including all letters, spaces and characters when used for text field comparisons

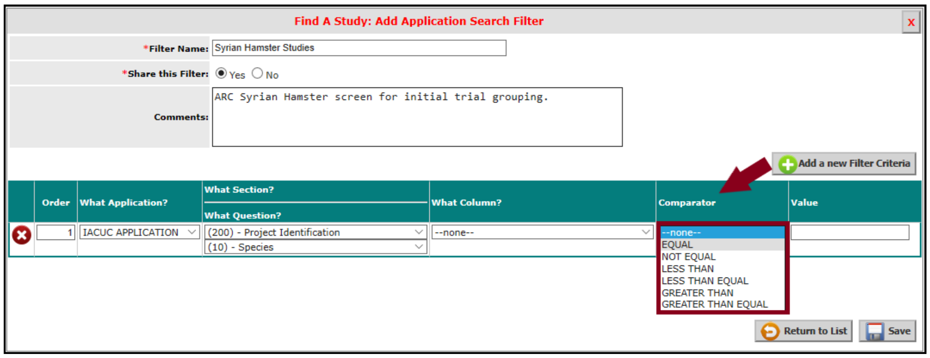
— NOT EQUAL is used for comparisons against either text or numeric field values and is equivalent to the “≠“mathematical operator; the **Value** entered for comparison must *exactly* match the value being compared in the application form, including all letters, spaces and characters when used for text field comparisons (e.g., NOT EQUAL to “Syrian hamsters” is not the same comparison as NOT EQUAL to “hamster”; the former comparison would exclude all records containing the specified species “Syrian Hamsters”, the latter would exclude all records with the word “hamster” anywhere in the species field)

— LESS THAN is used for numeric field value comparisons only, and is equivalent to the “<“ mathematical operator

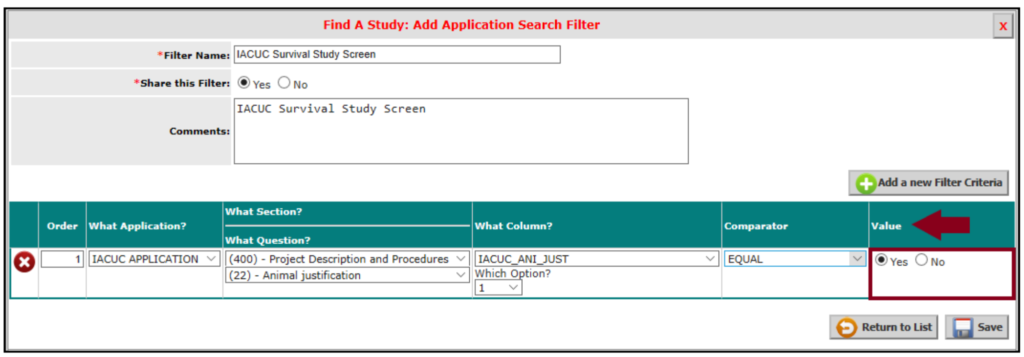
— LESS THAN EQUAL is used for numeric field value comparisons only, and is equivalent to the “≤“ mathematical operator

— GREATER THAN is used for numeric field value comparisons only, and is equivalent to the “>“ mathematical operator

— GREATER THAN EQUAL is used for numeric field value comparisons only, and is equivalent to the “≥“ mathematical operator



Select the **Value** against which the **Comparator** will be used.



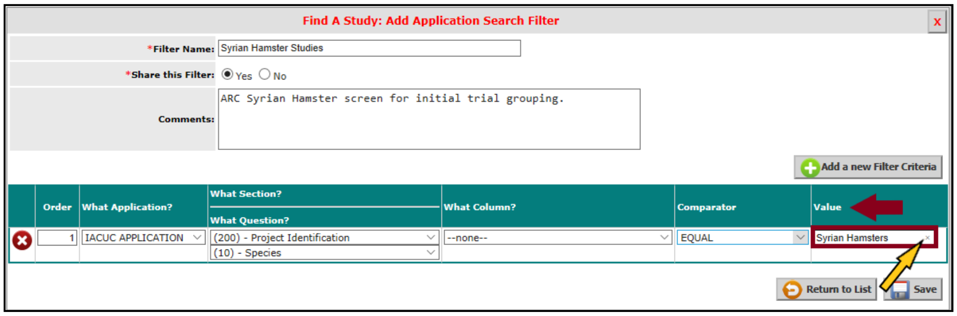
In the case of Yes/No select checkboxes or radio buttons three possible options may be shown in the **Value** column:

— “Yes”, which is the value stored in the database when the checkbox/radio button for the item is selected

— “No”, which is the value stored in the database when the checkbox/radio button for the item is *not* selected

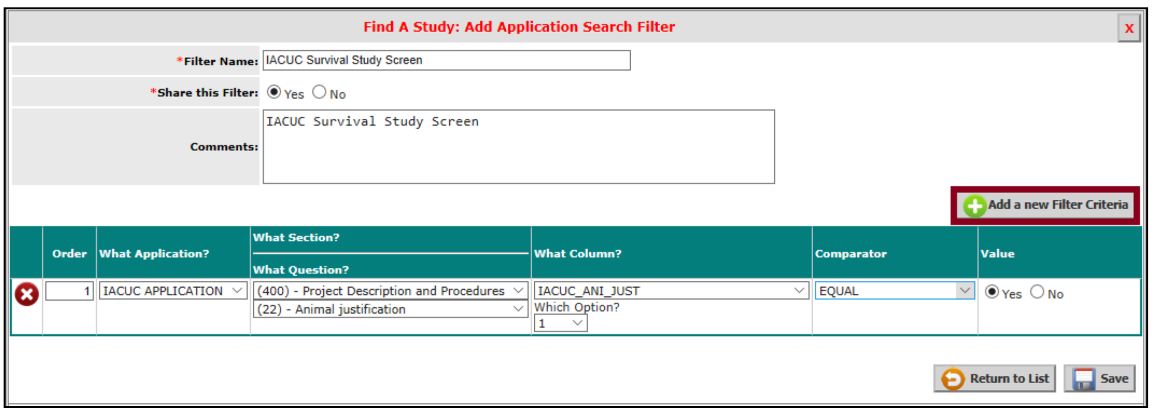
— “Not Set”, which is the value stored in the database when no checkbox(es)/radio button(s) for the item is(are) selected, indicating that the question was not answered; this option is only available for fields where a response is not required in the study application, or for draft applications where the question has not yet been answered

The example shown below demonstrates behavior of the **Value** field when the filter comparison is against a text entry.

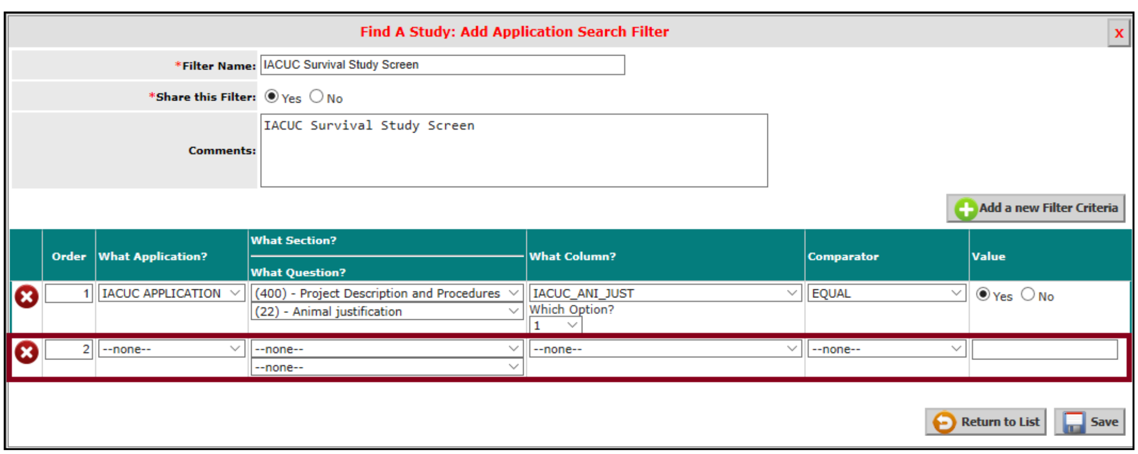


In this type of comparison, the **Value** column contains a text entry field. If anything is entered in the field in error, click the small “x” at the far right of the field (yellow arrow in screenshot above) to clear it, then enter the desired **Value**.

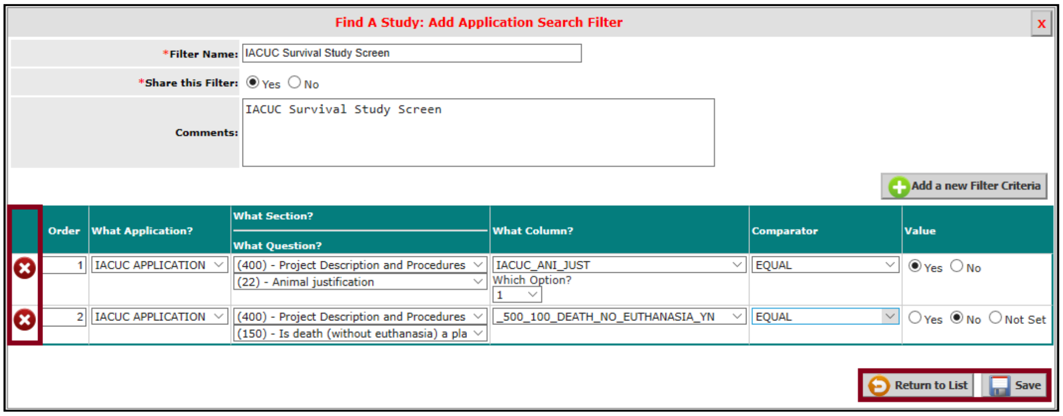
Returning to the original filter example, a second filter criterion is required to fulfill the filter parameters. Click the **Add a new Filter Criteria** button to add another filter criterion.



An additional row of fields is activated in the lower section of the popup, as shown below.

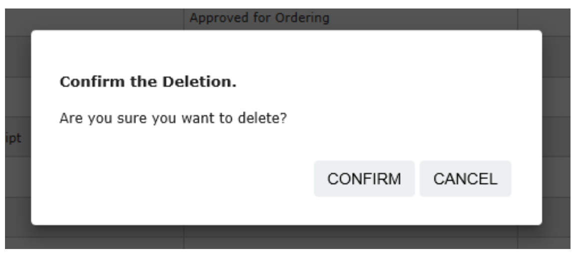


Follow the same steps as for the first criterion row to populate the new row. In this example, the second comparison is against the answer to the question, “Is death (without euthanasia) a planned endpoint?”



The filter in this example is now complete. If additional criteria rows are needed, click the **Add a new Filter Criteria** button and follow the steps outlined above to add and populate them.

If any criteria are added in error, click the delete icon in the far-left column to remove the unwanted criteria. A confirmation popup window displays.



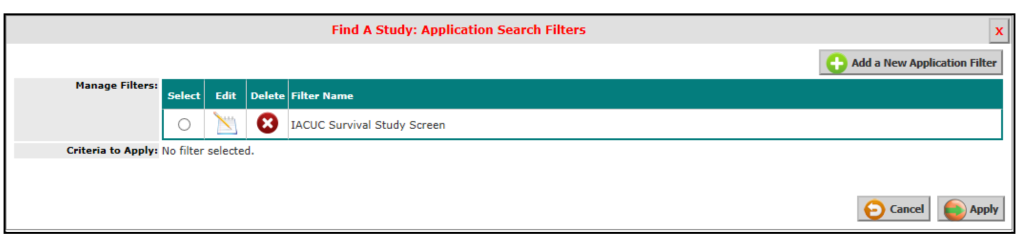
Click **CANCEL** to close the popup without deleting the criterion.

Click **CONFIRM** to delete the record and close the popup.

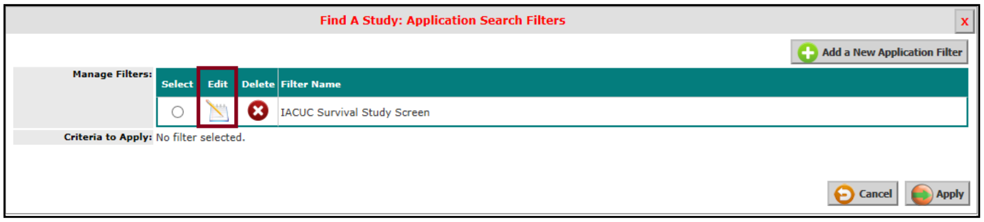
Back on the **Find A Study: Add Application Search Filter** add panel popup, click the **Return to List** button to close the popup without saving the filter.

Click the **Save** button to save the filter and close the popup.

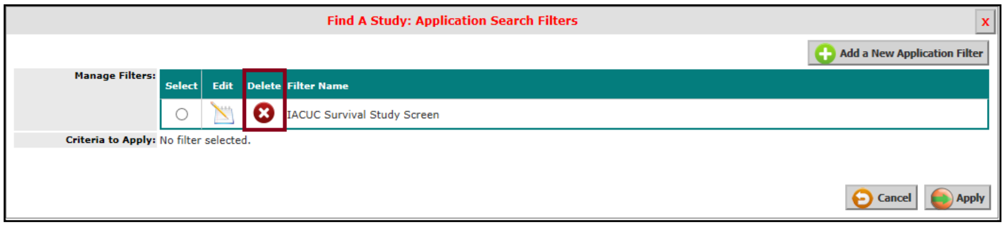
The filter is added on the **Find A Study: Application Search Filters** page.



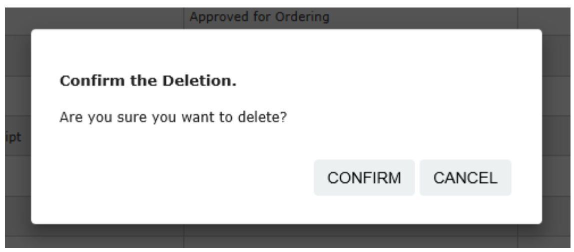
Click the icon in the **Edit** column (shown below) for any filter on the page to reopen the add panel for that filter and make revisions.



Click the icon in the **Delete** column (shown below) for any filter on the page to delete the associated filter.



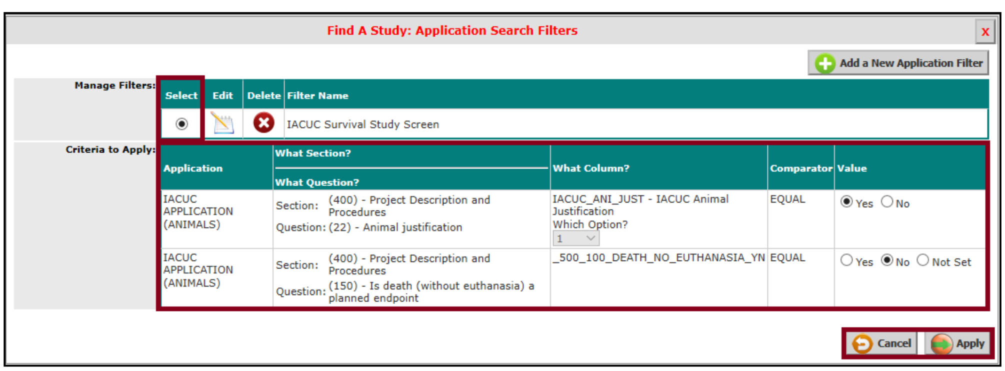
A confirmation popup window displays.



Click **CANCEL** to close the popup without deleting the filter.

Click **CONFIRM** to delete the filter and close the popup.

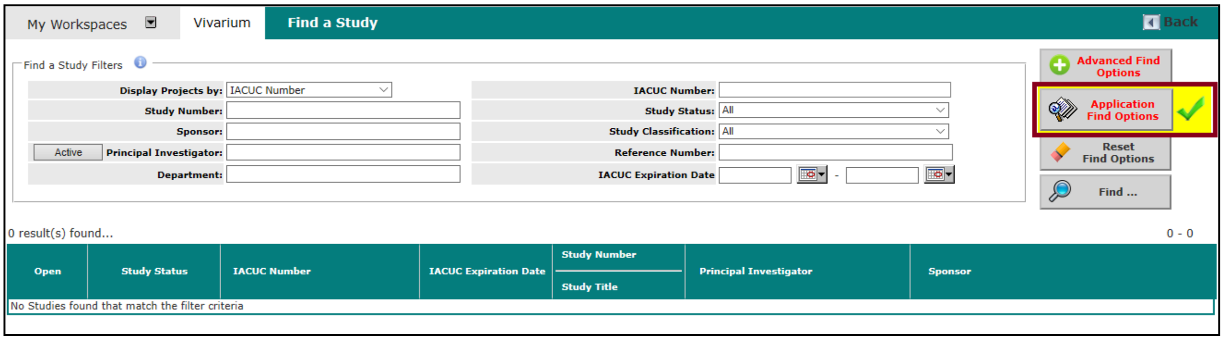
Select the radio button in the **Select** column to display a preview of **Criteria to Apply** for the applicable filter, as shown below.



Note that temporary changes can be made to active fields in the ***Criteria to Apply*** *preview before applying the filter, but these changes will not be saved to the filter. To make and save changes to the filter, click the icon in the* ***Edit*** *column.*

Click the **Cancel** button to close the **Find A Study: Application Search Filters** page *without* applying the selected filter.

Click the **Apply** button to close the page *and* apply the selected filter. As shown below, the **Application Find Options** button on the **Find A Study** page updates with a yellow background and green checkmark to indicate saved application filters are in use.



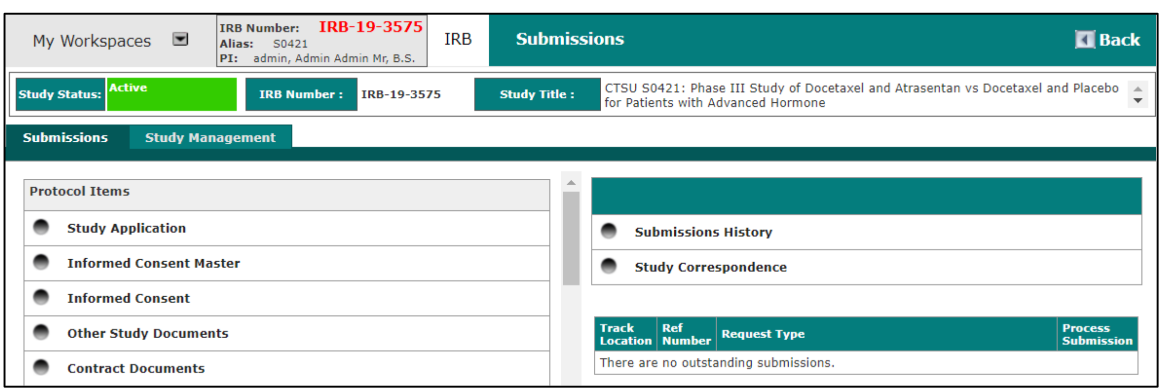
Application Find Options remain active on the **Find a Study** page until the filter selection is cleared.

Where more than one **Application Find Options** filter is in use, to clear an active filter click the **Application Find Options** button to reopen the **Find A Study: Application Search Filters** page. Clear the **Select** column radio button for any filter(s) to be removed from the search and click the **Apply** button at the bottom of the page.

Click the **Reset Find Options** button on the **Find a Study** page to clear *all* selected filters and/or search criteria.

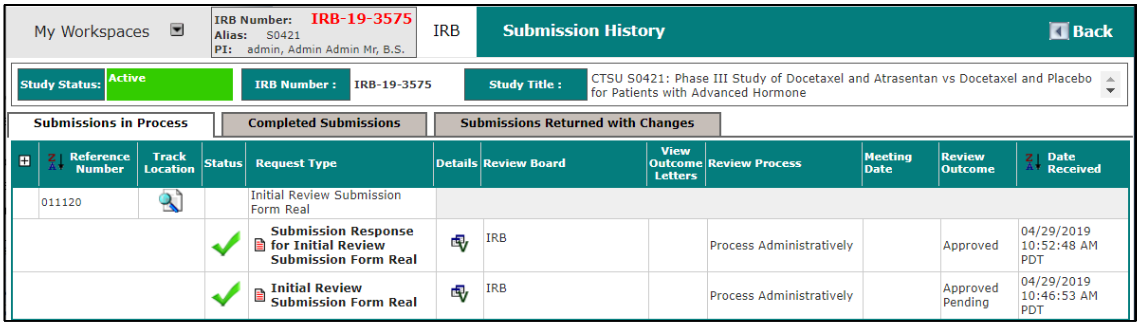
Application Find Options filters can be used in conjunction with any other search criteria and filters on the **Find a Study** page, including **Advanced Find Options**.

To view a study in the result set, click the icon in the **Open** column. The selected study is opened in the study **Submissions** page. By default, this page opens to the **Submissions** tab, as shown in the screenshot below.

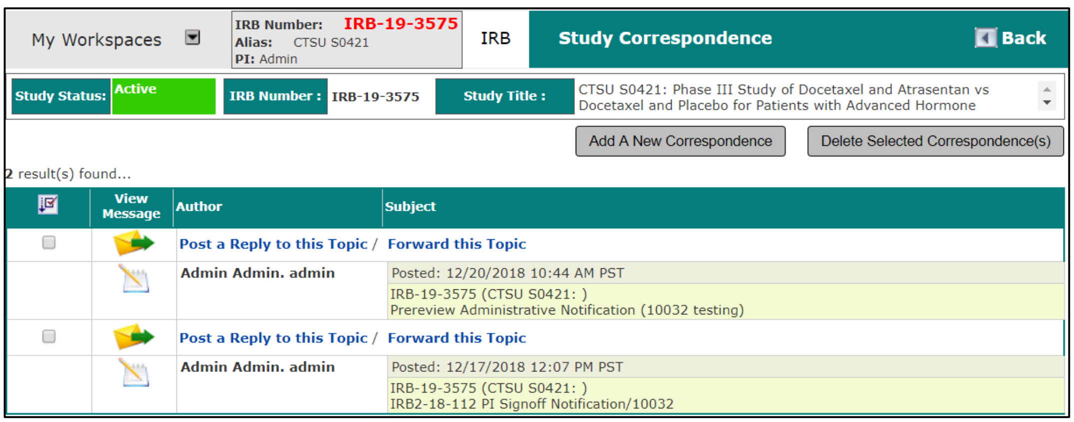


The **Submissions** tab displays any forms available for viewing by the IRB. The study's Informed Consents, Other Study Documents, Submission History and Study Correspondence are also accessible from this tab.

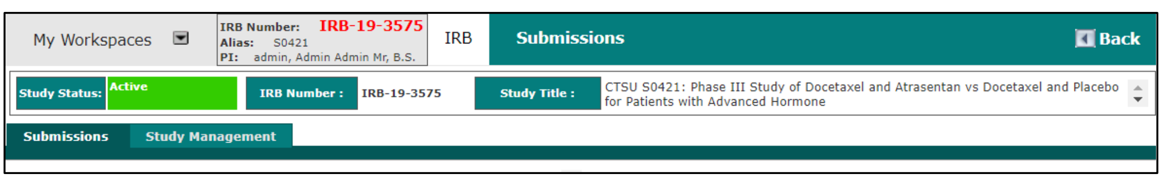
The **Submissions History Link** provides access to track the workflow of the initial submission and any other submission forms processed by the review board (shown in screenshot below). Clicking on a link under **Request Type** opens submission processing screens for that submission.



Click the **Study Correspondence** link to access a list of all notifications, signature requests and notices that pertain to the study (shown in screenshot below).

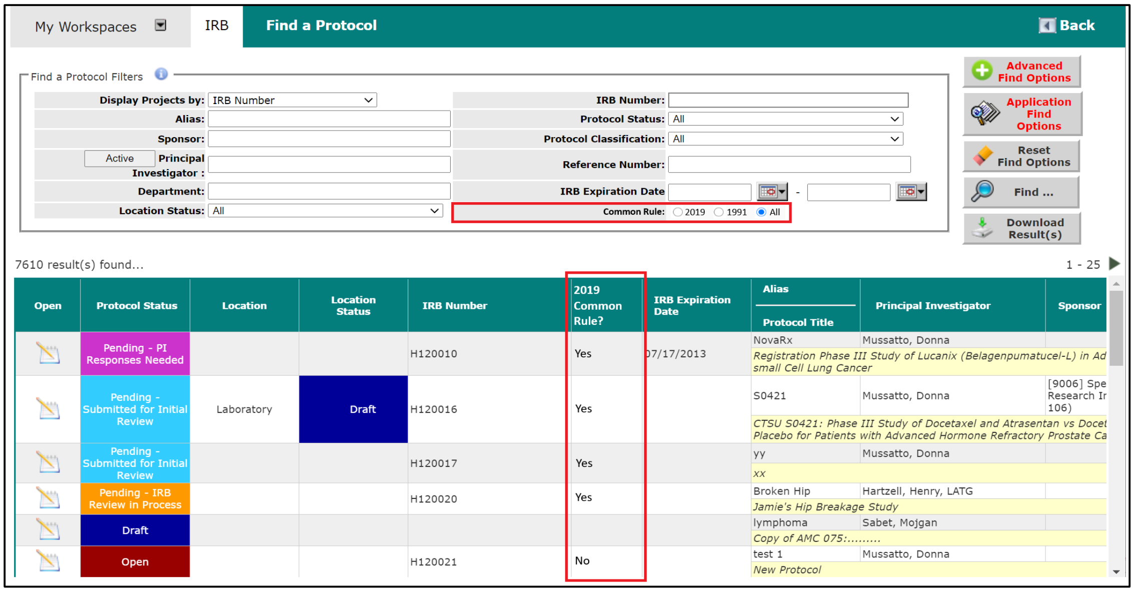


Back on the **Submissions** page, click the **Study Management** tab (shown in screenshot below) to access additional study information and tracking tools.



Common Rule Display Option

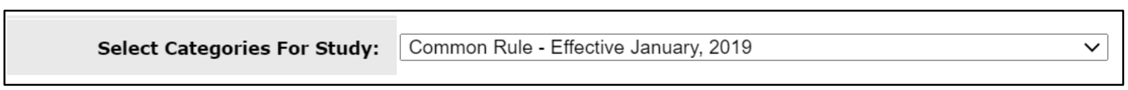
When the *rb.use_common_rule_display* property (under [module] > System Configuration) is set to “Yes” a **Common Rule** filter is added to the search form on the **Find A Protocol** page and a **2019 Common Rule?** column is added to the result set (see red boxes in screenshot below).



Note that when the property is set to "Yes" these same changes are applied to the Find a Protocol/Study page under Submissions. See the Submissions > Common Rule Display Option section of this manual for more information.

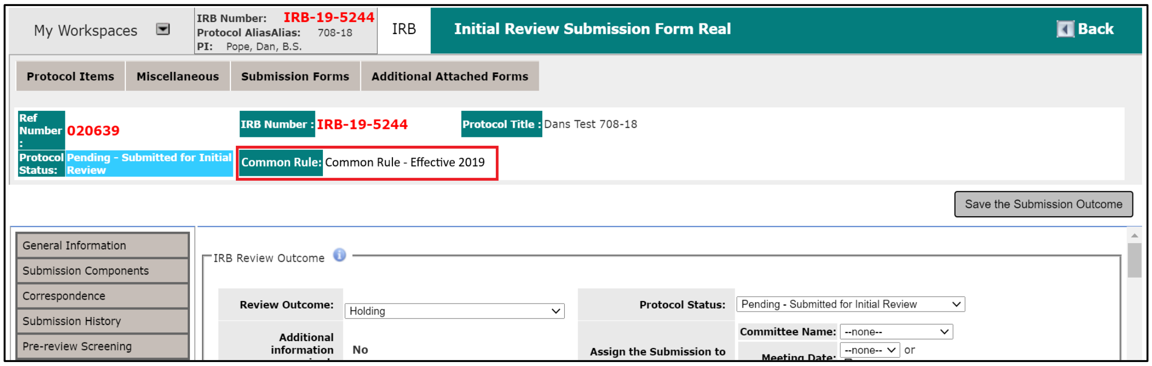
The **Common Rule** filter field includes radio buttons to select "2019" Common Rule studies, "1991" Common Rule studies, or "All" studies. The default selection is "All".

This value is based on the selection made in the **Select Categories For Study** dropdown on the Outcome tab (see screenshot below).



Where the *rb.use_common_rule_display* property is set to "Yes" an associated Merge Code ("Common Rule") is made available for use in Meeting Minutes, Meeting Agendas and Outcome Letters. The Merge Code field populates with the applicable rule.

Also, where the property is set to "Yes" the applicable rule displays in the Study / Submission header (shown below).


My Workspaces
IRB Number: IRB-19-5244
Protocol AliasAlias: 708-18
PI: Pope, Dan, B.S.
IRB
Initial Review Submission Form Real
Back
Protocol Items
Miscellaneous
Submission Forms
Additional Attached Forms
Ref Number: 020639
IRB Number : IRB-19-5244
Protocol Title : Dans Test 708-18
Protocol Status: Pending - Submitted for Initial Review
Common Rule: Common Rule - Effective 2019
Save the Submission Outcome
General Information
Submission Components
Correspondence
Submission History
Pre-review Screening
IRB Review Outcome
Review Outcome:
Holding
Protocol Status:
Pending - Submitted for Initial Review
Committee Name:
--none--
Additional information
No
Assign the Submission to
--none--
or