



IRB ASSISTANT

IRB Assistant Overview

Software Version: 13.01

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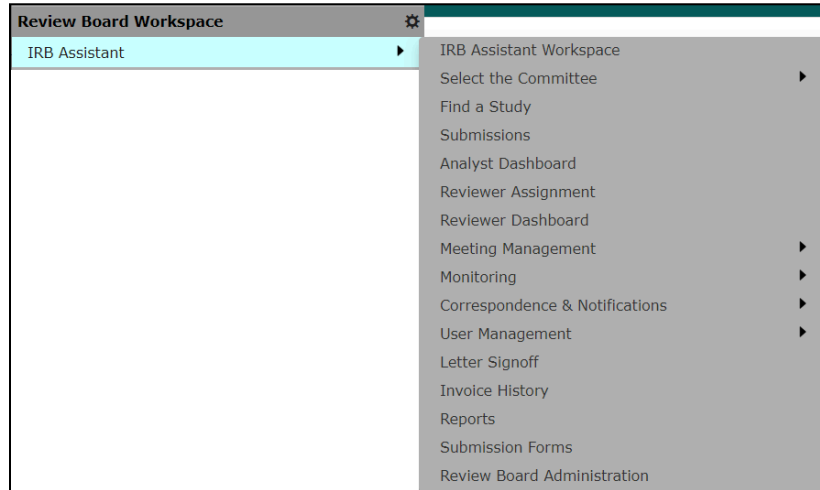
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Introduction

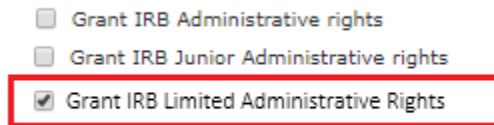
The **IRB Assistant** menu provides links to tools for processing and tracking of submission reviews, signoffs, member reviews, meetings, and more.



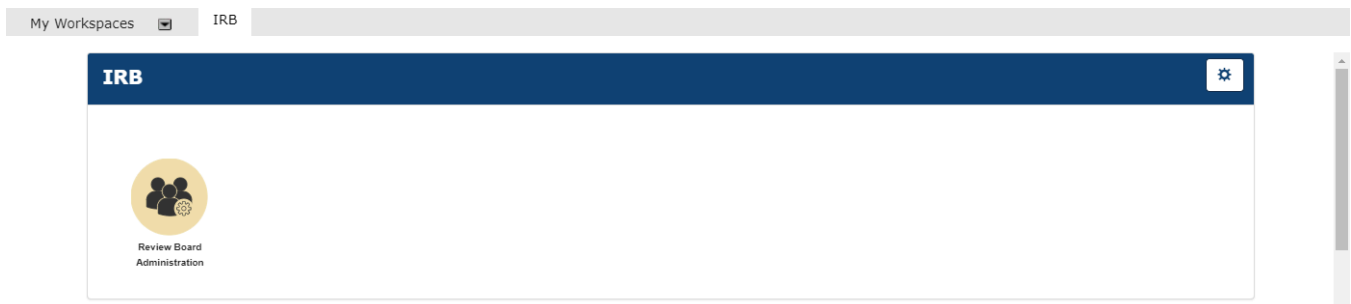
Note that menu items are dictated by the institution’s specific system configuration and may differ from those shown in the screenshot above.

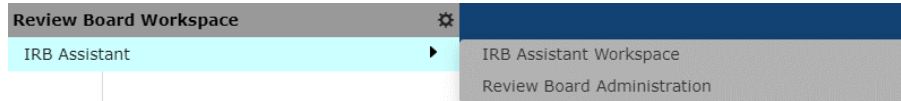
Review Board Limited Administrator Role

When the `rb.use_limited_admin_rights` property (under Board Configuration > Board Setup) is set to “Yes” an option for limited administrator rights is made available when giving users administrative board level access.

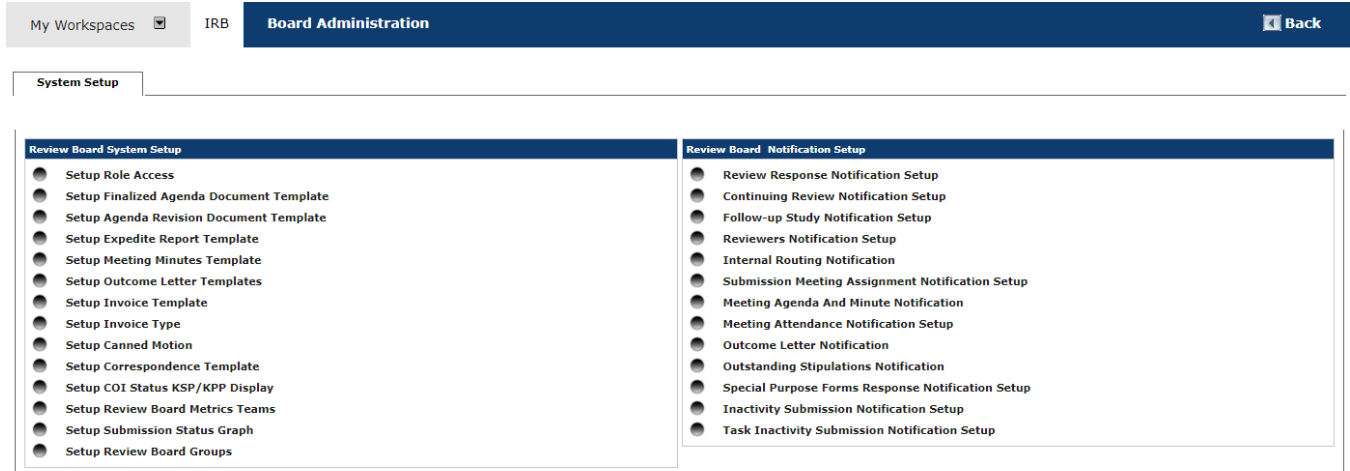


As shown below, users granted this rights level are given access to the **Review Board Administration** icon in their main workspace, as well as the corresponding menu link.





Clicking the icon or link loads the limited version of the **Board Administration** menu, shown below.



An example of a standard, full **Board Administration** menu is included below for comparison. *Note that the full **Board Administration** menu is configurable by the institution and may differ from that shown below.*

My Workspaces ▾ IRB **Board Administration** Back

Download Board Configurations Upload Board Configurations ... Copy Selected Configurations

System Setup List Maintenance Setup Clean-up

Review Board System Setup	Review Board Notification Setup
<ul style="list-style-type: none"> <input type="radio"/> Board Definition <input type="radio"/> Board Configuration Options <input type="radio"/> Broadcast Notice <input type="radio"/> Setup Committee List <input type="radio"/> Setup Review Board Roles <input type="radio"/> Setup Role Access <input type="radio"/> Setup Consent Template <input type="radio"/> Setup Consent Builder Template <input type="radio"/> Setup Consent Checklist <input type="radio"/> Setup Electronic Document Stamp <input type="radio"/> Setup Study Numbering <input type="radio"/> Setup Agenda Categories <input type="radio"/> Setup Finalized Agenda Document Template <input type="radio"/> Setup Agenda Revision Document Template <input type="radio"/> Setup Expedite Report Template <input type="radio"/> Setup Meeting Minutes Template <input type="radio"/> Setup Management Plan <input type="radio"/> Setup Outcome Letter Groups <input type="radio"/> Setup Outcome Letter Templates <input type="radio"/> Setup Invoice Template <input type="radio"/> Setup Invoice Type <input type="radio"/> Setup Canned Motion <input type="radio"/> Setup Correspondence Template <input type="radio"/> Setup Review Cycle <input type="radio"/> Setup Submission Codes <input type="radio"/> Setup Submission Outcome Validation <input type="radio"/> Setup COI Status KSP/KPP Display <input type="radio"/> Setup Review Board Metrics Teams <input type="radio"/> Setup Submission Status Graph <input type="radio"/> Setup Review Board Groups 	<ul style="list-style-type: none"> <input type="radio"/> Review Response Notification Setup <input type="radio"/> Continuing Review Notification Setup <input type="radio"/> Follow-up Study Notification Setup <input type="radio"/> Reviewers Notification Setup <input type="radio"/> Internal Documents Notification <input type="radio"/> Internal Routing Notification <input type="radio"/> Pre Review Assignment Notification <input type="radio"/> Submission Meeting Assignment Notification Setup <input type="radio"/> Meeting Agenda And Minute Notification <input type="radio"/> Meeting Attendance Notification Setup <input type="radio"/> Designated Review to be placed on the Agenda Notification <input type="radio"/> Outcome Letter Notification <input type="radio"/> Outstanding Stipulations Notification <input type="radio"/> Special Purpose Forms Response Notification Setup <input type="radio"/> Inactivity Submission Notification Setup <input type="radio"/> Task Inactivity Submission Notification Setup

Find a Study

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

My Workspaces ▾ Study Assistant **Find A Study** Back

Find a Study Filters ⓘ

Display Projects by: IRB Number ▾	IRB Number: <input type="text"/>	<div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 5px;"> <input type="button" value="Advanced Find Options"/> </div> <div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 5px;"> <input type="button" value="Application Find Options"/> </div> <div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 5px;"> <input type="button" value="Reset Find Options"/> </div> <div style="border: 1px solid #ccc; padding: 5px;"> <input type="button" value="Find ..."/> </div>
Study Alias: <input type="text"/>	Study Status: All ▾	
Sponsor: <input type="text"/>	Study Classifications: All ▾	
Active <input type="checkbox"/> Principal Investigator: <input type="text"/>	Reference Number: <input type="text"/>	
Department: <input type="text"/>	<input type="checkbox"/> Include Studies that have not been assigned an IRB Number:	
IRB Expiration Date: <input type="text"/> - <input type="text"/>		
Common Rule: All ▾		

0 result(s) found... 0 - 0

Open	Study Status	IRB Number	2019 Common Rule?	IRB Expiration Date	Study Alias Study Title	Principal Investigator
No Studies found that match the filter criteria						

Enter or 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.

Find a Study Filters

The screenshot shows the 'Find a Study Filters' interface. It includes a dropdown for 'Display Projects by' set to 'IRB Number'. Text input fields are provided for 'Study Alias', 'Sponsor', 'Department', and 'Principal Investigator'. A date range selector is used for 'IRB Expiration Date'. On the right side, there are dropdowns for 'IRB Numbers', 'Study Status' (set to 'All'), and 'Study Classification' (set to 'All'). A 'Reference Number' field and a checkbox for 'Include Studies that have not been assigned an IRB Number' are also present. A 'Common Rule' dropdown is set to 'All'. A button labeled 'Inactive' is positioned to the left of the 'Principal Investigator' field.

The **Display Projects by** dropdown allows for study filtering 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, 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.

This is a close-up view of the 'Find a Study Filters' form. A red rectangular box highlights the 'Active' button located to the left of the 'Principal Investigator' text input field. Other visible fields include 'Display Projects by' (set to 'IRB Number'), 'Study Alias', 'Sponsor', 'Department', 'IRB Expiration Date' (with date pickers), and 'Common Rule' (set to 'All').

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

This is a close-up view of the 'Find a Study Filters' form, showing the 'Principal Investigator' field. A red rectangular box highlights the 'Inactive' button, which has replaced the 'Active' button from the previous screenshot.

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

The **Location Status** dropdown enables filtering 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.

Note that the number of panels that appear in this popup window is dependent on which module “Find a Study” is being access from. In this particular example, the IACUC assistant “Find a Study” is used, and the popup includes panels for 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 of the panels (see following subsections) and click the **Apply** button to apply the filter 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 that 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.

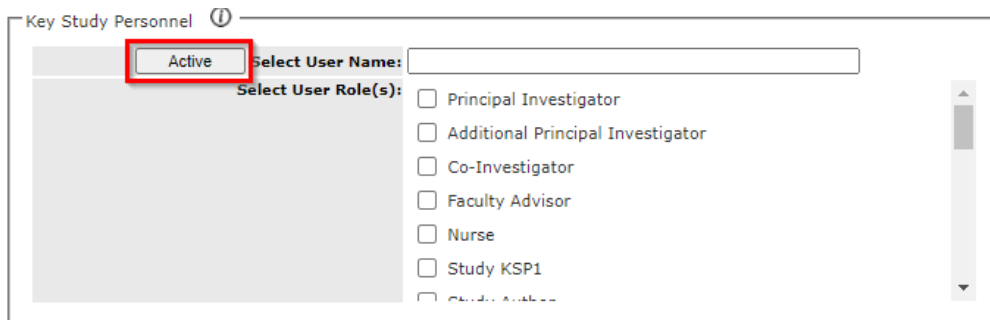
For the remainder of this subsection, individual panels of the **Find A Study: Advanced Search Options** popup are discussed in isolation.

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

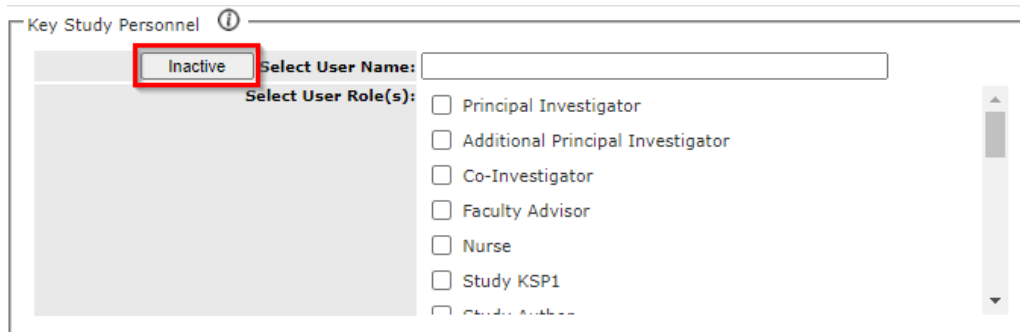
As shown below, when the **Find a Study: Advanced Search Options** is initially opened, the **Active** button is enabled for the **Select User Name** field.



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.*



The screenshot shows a window titled "Key Study Personnel" with an information icon. Inside, there is a search interface. A button labeled "Inactive" is highlighted with a red box. To its right is a text input field labeled "Select User Name:". Below this is a section labeled "Select User Role(s):" containing a list of roles, each with an unchecked checkbox: Principal Investigator, Additional Principal Investigator, Co-Investigator, Faculty Advisor, Nurse, Study KSP1, and Study Author. A vertical scrollbar is visible on the right side of the role list.

To search by **User Role(s)**, select the desired checkbox(es) in the **Select User Role(s)** section. Note that the roles available here will depend on your specific system configurations. Some common roles that may appear are:

- 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

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

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**.

Drugs associated to Study ⓘ

Trade Name:	<input style="width: 60%;" type="text"/>
Generic Name:	<input style="width: 60%;" type="text"/>
Investigational Name:	<input style="width: 60%;" type="text"/>

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 window for searching by IACUC-specific study drugs.

Devices Associated to Study

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

Devices associated to Study ⓘ

Device Name:	<input style="width: 60%;" type="text"/>
---------------------	--

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 window for searching by IACUC-specific 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**.

Drugs associated to IACUC Study ⓘ

Trade Name:	<input style="width: 60%;" type="text"/>
Generic Name:	<input style="width: 60%;" type="text"/>
Investigational Name:	<input style="width: 60%;" type="text"/>

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**.

Restraint Devices associated to IACUC Study ⓘ

Device Name:

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**.

Species associated to IACUC Study ⓘ

Species Name: --none--

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

Species associated to IACUC Study ⓘ

Species Name: --none--

Issues Reported to the Board ⓘ

Axis deer

Mouse

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**.

Issues Reported to the Board ⓘ

Issue Type: --none--

Issue Reported Range: -

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.

Issues Reported to the Board ⓘ

Issue Type: --none--

Issue Reported Range:

Study Key Words ⓘ

Key Words:

Calendar widgets are provided for searching by issue reporting date.

Issues Reported to the Board ⓘ

Issue Type: --none--

Issue Reported Range:

Study Key Words ⓘ

Key Words:

Jul 2021

Su	Mo	Tu	We	Th	Fr	Sa
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31

Cancel Appl

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.

Study Key Words ⓘ

Key Words:

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 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.*

Find A Study: Add Application Search Filter X

***Filter Name:**

***Share this Filter:** Yes No

Comments:

+ Add a new Filter Criteria

Order	What Application?	What Section? What Question?	What Column?	Comparator	Value
No validation clauses defined for this branch.					

Return to List
Save

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.

Find A Study: Add Application Search Filter X

***Filter Name:**

***Share this Filter:** Yes No

Comments:

+ Add a new Filter Criteria

Order	What Application?	What Section? <small>What Question?</small>	What Column?	Comparator	Value
No validation clauses defined for this branch.					

Return to List Save

As shown below, a new record populates in the filter criteria table.

Find A Study: Add Application Search Filter

*Filter Name:

*Share this Filter: Yes No

Comments:

+ Add a new Filter Criteria

Order	What Application?	What Section? What Question?	What Column?	Comparator	Value
1	--none--	--none--	--none--	--none--	

Return to List
Save

The fields in this criterion record are used to filter search results based on the answer(s) to specific question(s) in a 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

Section view of Application	Entire view of the Application
<ul style="list-style-type: none"> 1.0 General Information 2.0 Setup Department(s) Access 3.0 Grant Key Personnel access to the study 4.0 Form Information 5.0 Project Identification 6.0 Personnel Identification and Qualifications <li style="background-color: #003366; color: white; padding: 2px;">7.0 Project Description and Procedures 	<div style="border: 1px solid gray; padding: 5px; margin-bottom: 5px;"> <p>7.2 Animal justification</p> <p>Justify the use of live vertebrate animals rather than alternative means. Provide a rationale for the use of animals in your research or class. Check all that apply:</p> <p><input checked="" type="checkbox"/> The complexity of the processes being studied cannot be duplicated or modeled in a simpler system.</p> <p><input type="checkbox"/> There is not enough information known about the processes being studied to design nonliving models.</p> <p><input type="checkbox"/> Teaching protocol to prepare students, to develop skills, or understand processes</p> <p><input type="checkbox"/> Other</p> <p>Provide further explanation of your selection(s) made above:</p> <p>Extant literature on this topic is sparse</p> </div>

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

The screenshot shows the 'Project Description and Procedures' section of the application. The question '7.11 Is death (without euthanasia) a planned endpoint of the study?' is highlighted in yellow. Below the question, there are two radio buttons: 'Yes' and 'No'. The 'No' radio button is selected. A red arrow points to the 'No' radio button.

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.

Order	What Application?	What Section? What Question?	What Column?	Comparator	Value
1	--none--	--none--	--none--	--none--	

Add a new Filter Criteria

Click on 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. Note that all comboboxes in this window are searchable via the text box displayed directly above the dropdown list.

Find A Study: Add Application Search Filter
X

***Filter Name:**

***Share this Filter:** Yes No

Comments:

Order	What Application?	What Section?	What Column?	Comparator	Value
⊗ 1	<input type="text" value="--none--"/> <div style="border: 1px solid gray; padding: 2px; margin-top: 2px;"> <ul style="list-style-type: none"> --none-- Apliacion de IACUC <li style="border: 2px solid red; padding: 2px;">IACUC APPLICATION (ANIMALS) IACUC Data Values IBC APPLICATION (BIO-SAFETY) INSTITUTIONAL REVIEW BOARD APPLICATION </div>	<input type="text" value="--none--"/> <input type="text" value="--none--"/>	<input type="text" value="--none--"/>	<input type="text" value="--none--"/>	<input type="text"/>

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. In this example, the “(400) - Project Description and Procedures” section is selected, as shown below.

Find A Study: Add Application Search Filter

*Filter Name: IACUC Survival Study Screen

*Share this Filter: Yes No

Comments: IACUC Survival Study Screen

Add a new Filter Criteria

Order	What Application?	What Section?	What Column?	Comparator	Value
1	IACUC APPLICATION (ANIMALS)	--none--	--none--	--none--	

--none--

- (100) - NOTE: The IACUC recommends investigators contact
- (200) - Project Identification
- (300) - Personnel Identification and Qualifications
- (350) - Use of Privately Owned Animals
- (400) - Project Description and Procedures**

Return to List Save

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

Find A Study: Add Application Search Filter
X

*Filter Name:

*Share this Filter: Yes No

Comments:

Order	What Application?	What Section? What Question?	What Column?	Comparator	Value
(X) 1	IACUC APPLICATION (ANIMALS)	(400) - Project Description and Procedures	--none--	--none--	

--none--
(10) - Lay Summary
(22) - Animal justification
(24) - Species justification
(26) - Animal number justification
(30) - Experimental Design
(40) - Procedures
(50) - Blood/Tissue/Other Samples

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

Section view of Application	Entire view of the Application
<ul style="list-style-type: none"> 1.0 General Information 2.0 Setup Department(s) Access 3.0 Grant Key Personnel access to the study 4.0 Form Information 5.0 Project Identification 6.0 Personnel Identification and Qualifications <li style="background-color: #003366; color: white; padding: 2px;">7.0 Project Description and Procedures 	<div style="border: 1px solid gray; height: 30px; margin-bottom: 10px;"></div> <div style="background-color: #fff9c4; padding: 5px; border: 1px solid gray;"> <p>7.2 Animal justification</p> <p>Justify the use of live vertebrate animals rather than alternative means. Provide a rationale for the use of animals in your research or class. Check all that apply:</p> <p><input checked="" type="checkbox"/> The complexity of the processes being studied cannot be duplicated or modeled in a simpler system. (1)</p> <p><input type="checkbox"/> There is not enough information known about the processes being studied to design nonliving models. (2)</p> <p><input type="checkbox"/> Teaching protocol to prepare students, to develop skills, or understand processes (3)</p> <p><input type="checkbox"/> Other (4)</p> <p>Provide further explanation of your selection(s) made above:</p> <div style="border: 1px solid gray; padding: 5px; min-height: 30px;"> Extant literature on this topic is sparse </div> </div>

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

The first column contains one or more entries of the number 1 to 4), indicating which checkbox is 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 on the **What Column?** field and select the column that contains the data value applicable to the filter. In this example “IACUC_ANI_JUST” is selected.

Order	What Application?	What Section?	What Question?	What Column?	Comparator	Value
1	IACUC APPLICATION (ANIMALS)	(400) - Project Description and Procedures	(22) - Animal justification	--none--	--none--	

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

Find A Study: Add Application Search Filter

*Filter Name: IACUC Survival Study Screen

*Share this Filter: Yes No

Comments: IACUC Survival Study Screen

Add a new Filter Criteria

Order	What Application?	What Section?	What Column?	Comparator	Value
1	IACUC APPLICATION (ANIMALS)	(400) - Project Description and Procedures	IACUC_ANI_JUST	--none--	<input type="radio"/> Yes <input type="radio"/> No
		(22) - Animal justification	Which Option?		
			--none--		

Return to List Save

As explained above, the dropdown list contains four options. In this particular 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.

Find A Study: Add Application Search Filter
X

*Filter Name:

*Share this Filter: Yes No

Comments:

Order	What Application?	What Section? What Question?	What Column?	Comparator	Value
⊗ 1	IACUC APPLICATION (ANIMALS) ▾	(400) - Project Description and Procedures ▾ (22) - Animal justification ▾	IACUC_ANI_JUST ▾ Which Option? 1 ▾	--none-- ▾	Yes <input type="radio"/> No <input type="radio"/>

1

--none--

2

3

4

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 *not* 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

Find A Study: Add Application Search Filter

*Filter Name:

*Share this Filter: Yes No

Comments:

Order	What Application?	What Section?	What Column?	Comparator	Value
(X) 1	IACUC APPLICATION (ANIMALS)	(400) - Project Description and Procedures (22) - Animal justification	IACUC_ANI_JUST Which Option? 1	--none-- --none-- EQUAL NOT EQUAL LESS THAN LESS THAN EQUAL GREATER THAN GREATER THAN EQUAL	<input type="radio"/> Yes <input type="radio"/> No

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

Find A Study: Add Application Search Filter
X

*Filter Name:

*Share this Filter: Yes No

Comments:

Order	What Application?	What Section? <small>What Question?</small>	What Column?	Comparator	Value
⊗ 1	IACUC APPLICATION (ANIMALS) ▾	(400) - Project Description and Procedures ▾ (22) - Animal justification ▾	IACUC_ANI_JUST ▾ <small>Which Option?</small> 1 ▾	EQUAL ▾	<input checked="" type="radio"/> Yes <input type="radio"/> No

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.

Find A Study: Add Application Search Filter

*Filter Name: IACUC Survival Study Screen

*Share this Filter: Yes No

Comments: IACUC Survival Study Screen

Add a new Filter Criteria

Order	What Application?	What Section? What Question?	What Column?	Comparator	Value
1	IACUC APPLICATION (ANIMALS)	(300) - Personnel Identification and Qualifications (10) - Project Participants Prior to approval of the AU	PI_EM_PHONE	--none--	(555) 555-5555

Return to List Save

In this type of comparison, the **Value** column contains a text entry field.

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.

Find A Study: Add Application Search Filter

***Filter Name:**

***Share this Filter:** Yes No

Comments:

Add a new Filter Criteria

Order	What Application?	What Section?	What Column?	Comparator	Value
(X) 1	IACUC APPLICATION (ANIMALS) ▾	(400) - Project Description and Procedures ▾ (22) - Animal justification ▾	IACUC_ANI_JUST ▾ Which Option? 1 ▾	EQUAL ▾	<input checked="" type="radio"/> Yes <input type="radio"/> No

A second criterion record appears below the first.

Find A Study: Add Application Search Filter
X

*Filter Name:

*Share this Filter: Yes No

Comments:

Order	What Application?	What Section? What Question?	What Column?	Comparator	Value
⊗ 1	IACUC APPLICATION (ANIMALS)	(400) - Project Description and Procedures (22) - Animal justification	IACUC_ANI_JUST Which Option? 1	EQUAL	<input checked="" type="radio"/> Yes <input type="radio"/> No
⊗ 2	--none--	--none-- --none--	--none--	--none--	

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?”

Find A Study: Add Application Search Filter
X

*Filter Name:

*Share this Filter: Yes No

Comments:

Order	What Application?	What Section? What Question?	What Column?	Comparator	Value
⊗ 1	IACUC APPLICATION (ANIMALS)	(400) - Project Description and Procedures (22) - Animal justification	IACUC_ANI_JUST Which Option? 1	EQUAL	<input checked="" type="radio"/> Yes <input type="radio"/> No
⊗ 2	IACUC APPLICATION (ANIMALS)	(400) - Project Description and Procedures (150) - Is death (without euthanasia) a planned endpoint	_500_100_DEATH_NO_EUTHANASIA_YN	EQUAL	<input type="radio"/> Yes <input checked="" type="radio"/> No <input type="radio"/> Not Set

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.

Order	What Application?	What Section?	What Question?	What Column?	Comparator	Value
1	IACUC APPLICATION (ANIMALS)	(400) - Project Description and Procedures	(22) - Animal justification	IACUC_ANI_JUST	EQUAL	<input checked="" type="radio"/> Yes <input type="radio"/> No
2	IACUC APPLICATION (ANIMALS)	(400) - Project Description and Procedures	(150) - Is death (without euthanasia) a planned endpoint	_500_100_DEATH_NO_EUTHANASIA_YN	EQUAL	<input type="radio"/> Yes <input checked="" type="radio"/> No <input type="radio"/> Not Set

Approved for Ordering

Confirm the Deletion.

Are you sure you want to delete?

CONFIRM CANCEL

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** 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.

Find A Study: Add Application Search Filter
X

***Filter Name:**

***Share this Filter:** Yes No

Comments:

Add a new Filter Criteria

	Order	What Application?	What Section? What Question?	What Column?	Comparator	Value
⊗	1	IACUC APPLICATION (ANIMALS)	(400) - Project Description and Procedures (22) - Animal justification	IACUC_ANI_JUST Which Option? 1	EQUAL	<input checked="" type="radio"/> Yes <input type="radio"/> No
⊗	2	IACUC APPLICATION (ANIMALS)	(400) - Project Description and Procedures (150) - Is death (without euthanasia) a planned endpoint	_500_100_DEATH_NO_EUTHANASIA_YN	EQUAL	<input type="radio"/> Yes <input checked="" type="radio"/> No <input type="radio"/> Not Set

Return to List
Save

If **Save** was clicked, the filter is added to the **Find A Study: Application Search Filters** page.

Find A Study: Application Search Filters
X

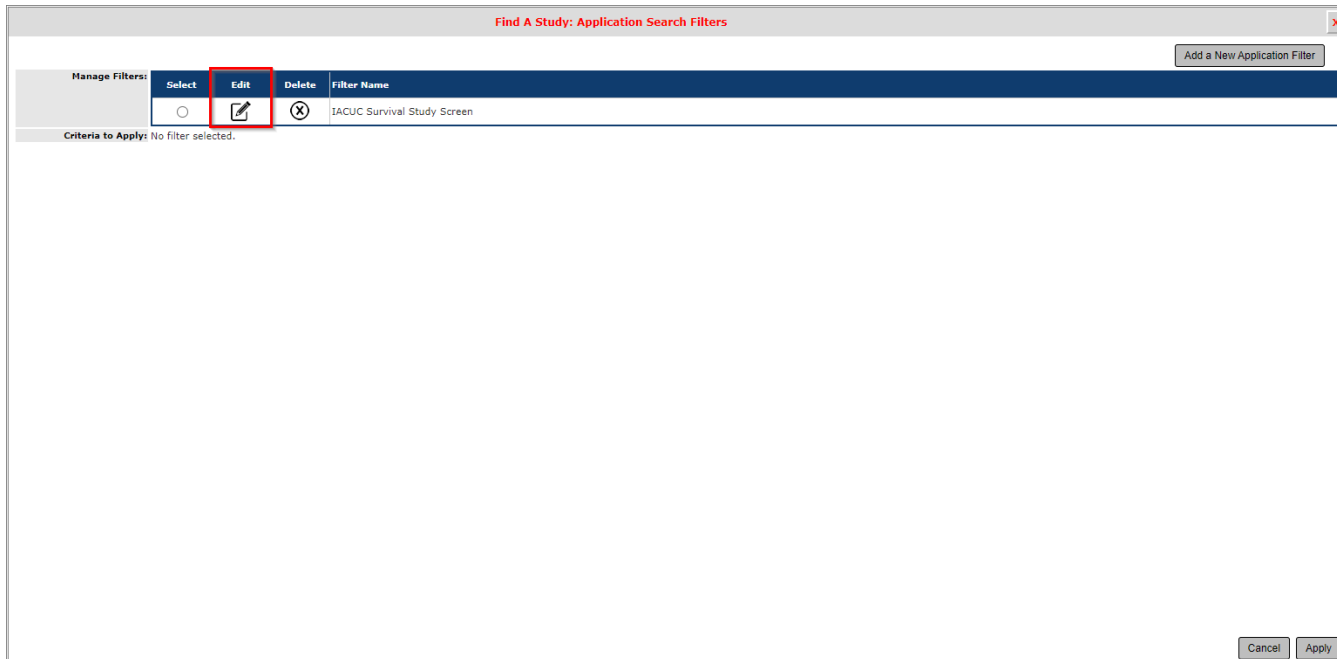
Add a New Application Filter

	Select	Edit	Delete	Filter Name
<input type="radio"/>	<input checked="" type="checkbox"/>			IACUC Survival Study Screen

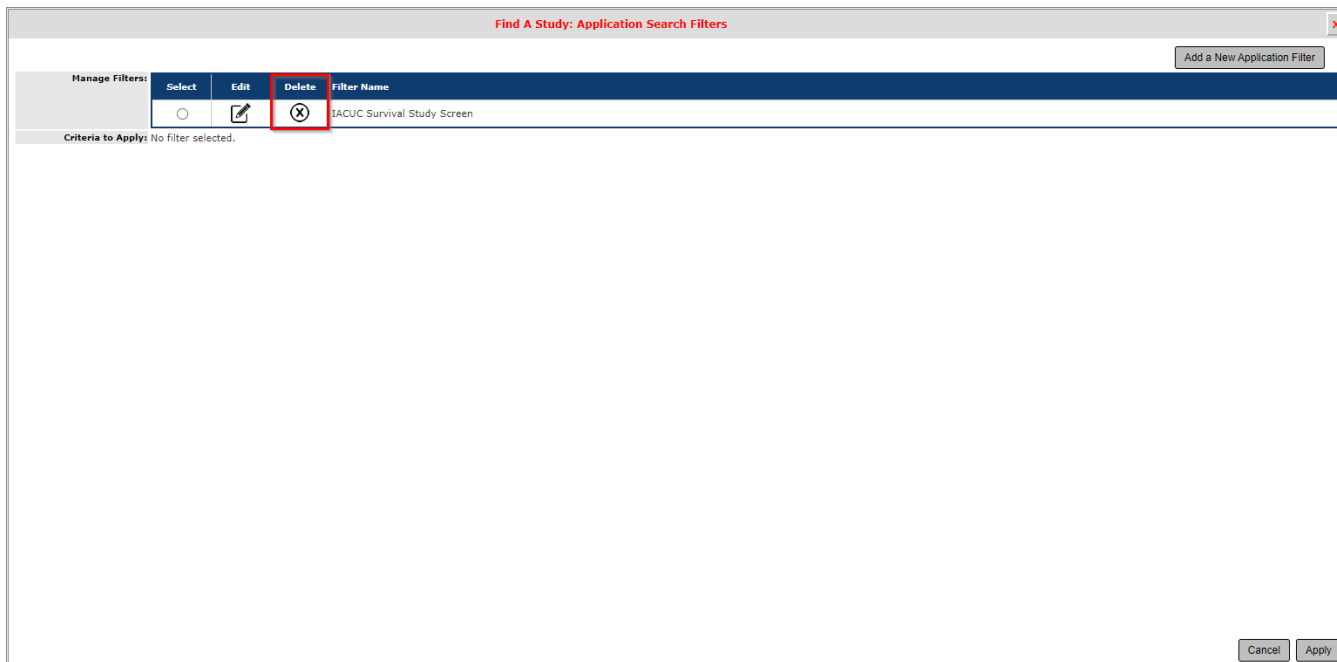
Criteria to Apply: No filter selected.

Cancel
Apply

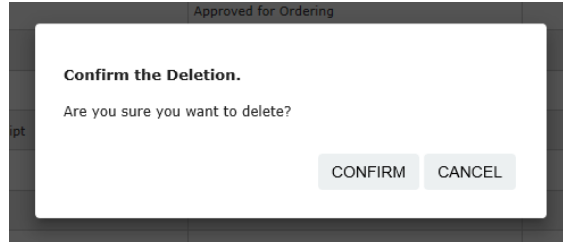
Click the icon in the **Edit** column (shown below) for any filter on the page to reopen the add panel for that filter and make revisions.



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.

Find A Study: Application Search Filters

Add a New Application Filter

Select	Edit	Delete	Filter Name
<input checked="" type="radio"/>			IACUC Survival Study Screen
<input type="radio"/>			UGM Filter

Application	What Section?	What Column?	Comparator	Value
IACUC APPLICATION (ANIMALS)	Section: (400) - Project Description and Procedures Question: (22) - Animal justification	IACUC_ANI_JUST - IACUC Animal Justification Which Option? 1	EQUAL	<input checked="" type="radio"/> Yes <input type="radio"/> No
IACUC APPLICATION (ANIMALS)	Section: (400) - Project Description and Procedures Question: (150) - Is death (without euthanasia) a planned endpoint	_500_100_DEATH_NO_EUTHANASIA_YN	EQUAL	<input type="radio"/> Yes <input checked="" type="radio"/> No <input type="radio"/> Not Set

Cancel
Apply

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 checkmark to indicate saved application filters are in use.

My Workspaces ▾ Study Assistant **Find A Study** Back

Find a Study Filters ⓘ

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

+ Advanced Find Options
Application Find Options
Reset Find Options
Find ...

68 result(s) found... 1 - 25 ▶

			2019		Study Alias				

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

When 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 study's icon in the **Open** column.

Find a Study Filters ⓘ

Display Projects by: IRB Number ▾ Study Alias: malaria Sponsor: <input type="text"/> <input type="checkbox"/> Active <input type="checkbox"/> Principal Investigator: <input type="text"/> Department: <input type="text"/> IRB Expiration Date: <input type="text"/> - <input type="text"/> Common Rule: All ▾	IRB Number: 21-476 Study Status: All ▾ Study Classification: All ▾ Reference Number: <input type="text"/> Include Studies that have not been assigned an IRB Number: <input type="checkbox"/>
---	---

+ Advanced Find Options
Application Find Options
Reset Find Options
Find ...
Download Result(s)

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

Open	Study Status	IRB Number	2019 Common Rule?	IRB Expiration Date	Study Alias	Principal Investigator
	Active	IRB-21-476	Yes	06/24/2022	Malaria in Juveniles <i>Malaria in Juveniles</i>	Investigator, John

The selected study is opened and the user is taken into the study record. By default, this page opens to the **Submissions** tab, as shown in the screenshot below.

Study Status: Active	IRB Number : IRB-21-476	Study Title : Malaria in Juveniles
IRB Expiration Date: 06/24/2022		

Submissions	Study Management	Subject Management
--------------------	-------------------------	---------------------------

Current Approval Packet

Protocol Items

- Study Application
- Informed Consents ▶
- Other Study Documents ▶
- Contract Documents

Protocol Items

- Reportable Event Form

- Initial Review Submission Form

Regulatory Forms

Regulatory Submission Forms

- Continuing Review Submission Form
- Study Amendment Form
- Study Closure Form
- Unanticipated Events Form
- Yearly Check-in Form

Outstanding Submission(s)			
Track Location	Ref Number	Request Type	Process Submission
Waiting for Finalization of Routing List	001316	Click on the hyperlink to edit/view the submission. <input type="radio"/> Study Amendment Form	<input type="button" value="Retract Submission"/>

The **Submissions** tab displays any forms available for viewing by the review board. If the study is being accessed from the study side of the system, this page will display all forms available to the research team for submitting to a review board. 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.

Study Status: Active	IRB Number : IRB-21-476	Study Title : Malaria in Juveniles
IRB Expiration Date: 06/24/2022		

Submissions in Process	Completed Submissions	Submissions Returned with Changes	<input type="button" value="Print Friendly"/>
-------------------------------	------------------------------	--	---

Reference Number	Track Location	Status	Request Type	Details	Review Board	View Outcome Letters	Review Process	Meeting Date	Review Outcome	Date Received
001316			Study Amendment Form							
			<input type="radio"/> Study Amendment Form ⓘ							

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).

Study Status: Active	IRB Number : IRB-21-476	Study Title : Malaria in Juveniles
	IRB Expiration Date: 06/24/2022	

11 result(s) found... 1 - 10

<input type="checkbox"/>	View Message	Author	Subject
<input type="checkbox"/>		Post a Reply to this Topic / Forward this Topic	
<input type="checkbox"/>		John Smith	Posted: 06/25/2021 02:07 PM PDT Malaria in Juveniles NOTICE OF PREREVIEW ADMINISTRATIVE ASSIGNMENT
<input type="checkbox"/>		Post a Reply to this Topic / Forward this Topic	
<input type="checkbox"/>		John Smith	Posted: 06/25/2021 12:12 PM PDT Malaria in Juveniles Outcome Letter Notification
<input type="checkbox"/>		Post a Reply to this Topic / Forward this Topic	
<input type="checkbox"/>		John Smith	Posted: 06/25/2021 12:12 PM PDT Malaria in Juveniles NOTICE OF PREREVIEW ADMINISTRATIVE ASSIGNMENT

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

Study Status: Active	IRB Number : IRB-21-476	Study Title : Malaria in Juveniles
	IRB Expiration Date: 06/24/2022	

Study Details <ul style="list-style-type: none"> ● Study Summary/Profile ● Screen Access ● Key Personnel ● External Personnel ● COI Status ● Review Board Selection ● Department Access ● Associated Projects 	Finance Set-up <ul style="list-style-type: none"> ● Construct Study Plan ● Study Plan Timeline ● Study Accounts ● Budget Management ● Milestone Management Finance Tracking <ul style="list-style-type: none"> ● Subject on Study Financial Tracking ● Invoice Management
--	--

Common Rule Display Option

When the `rb.use_common_rule_display` property (under *[review board module] > Review Board Administration > Board Configuration Options*) 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).

My Workspaces ▾ IRB Find a Study Back

Find a Study Filters ⓘ

Display Projects by: IRB Number ▾

Study Alias:

Sponsor:

Active Principal Investigator:

Department:

IRB Number:

Study Status: All ▾

Study Classification: All ▾

Reference Number:

IRB Expiration Date: -

Common Rule: All ▾

Advanced Find Options

Application Find Options

Reset Find Options

Find ...

0 result(s) found... 0 - 0

Open	Study Status	IRB Number	2019 Common Rule?	IRB Expiration Date	Study Alias	Study Title	Principal Investigator	Sponsor
No Studies found that match the filter criteria								

The **Common Rule** filter field is comprised of a dropdown menu with the following options: “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).

Select Categories For Study: Common Rule - Effective January, 2019 ▾

When 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, when the property is set to “Yes”, the applicable rule displays in the Study/Submission header (shown below).

My Workspaces IRB Number: **IRB-21-456** IRB Initial Review Submission Form Back

Protocol Items Miscellaneous **Submission Forms**

Ref Number : **001275** IRB Number : **IRB-21-456** **Common Rule:** Common Rule - Effective January, 2019 Study Title : NIH - TD - 54345 - COVID-19 vaccine BNT162b1 elicits human antibody and TH1 T cell responses

Study Status: **Pending - Submitted for Initial Review**

Submission Details **Submission Component(s)** **Pre-review Screening** **Submission Review** **Submission Outcome**

Submission Review Status

Submission Received	Analyst Assigned	Review Process Assigned	Reviewer(s) Assigned	All Reviewer(s) Complete	Submission Items Reviewed/Approved	Submission Outcome Assigned	Response Letter Generated	Submission Completed
<div style="width: 100%; height: 10px; background-color: #008080;"></div>	<div style="width: 100%; height: 10px; background-color: #008080;"></div>	<div style="width: 100%; height: 10px; background-color: #008080;"></div>	<div style="width: 100%; height: 10px; background-color: #008080;"></div>	<div style="width: 100%; height: 10px; background-color: #008080;"></div>	<div style="width: 50%; height: 10px; background-color: #cccccc;"></div>	<div style="width: 50%; height: 10px; background-color: #cccccc;"></div>	<div style="width: 100%; height: 10px; background-color: #008080;"></div>	<div style="width: 100%; height: 10px; background-color: #cccccc;"></div>

General Information

Study Alias: NIH - TD - 54345

Codes: **BIO** **DRG** **Cov19**

[Edit the Master Lay Summary](#)

Submissions

The **Submissions** link provides access to view and process submissions sent to the IRB.

- IRB Assistant Workspace
- Select the Committee
- Add a new Study
- Find a Study
- Submissions**
- Analyst Dashboard
- Reviewer Assignment
- Reviewer Dashboard

See the Submission Processing manual for more information about this feature.

Common Rule Display Option

When the `rb.use_common_rule_display` property (under IRB > System Configuration) is set to “Yes” a **Common Rule** filter is added to the search form on the **Board Submissions** page and a **2019 Common Rule?** column is added to the result set (see red boxes in screenshot below).

The screenshot shows the 'Board Submissions' page in the IRB Assistant software. At the top, there are navigation tabs for 'Not Assigned', 'Pre-Review', 'Review in Progress', 'Review Complete', 'Returned from Researchers', 'Pending Response', 'Completed Submissions', and 'Agendas'. Below these are search filters for 'Submission Type', 'Principal Investigator', 'Date Board Received', 'IRB Number', 'Ref Number', and 'Common Rule'. The 'Common Rule' dropdown is highlighted with a red box and set to 'All'. Below the filters, a table of submissions is displayed. The table has columns for 'Open', 'Codes', 'IRB Number', 'Ref Number', 'Type', '2019 Common Rule?', 'Date Board Received', 'IRB Expiration Date', 'Principal Investigator', and 'Assigned Analyst'. The '2019 Common Rule?' column is highlighted with a red box, and the value 'No' is visible in the first row. The table also shows a submission with IRB Number 'IRB-19-180' and Ref Number '001318'.

Note that when the property is set to “Yes” these same changes are applied to the main Find a Study page. See the Find a Study > 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).

The screenshot shows a dropdown menu labeled 'Select Categories For Study:'. The selected option is 'Common Rule - Effective January, 2019'.

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).

Analyst Dashboard

The **Analyst Dashboard** link provides access to study tracking and management tools used by Analysts.

See the Analyst Dashboard manual for more information about this feature.

Reviewer Assignment

The **Reviewer Assignment** link provides access to the logged in user’s current Incomplete, Complete and Canceled Reviewer assignments.

Incomplete Tab

By default, the **Assigned Submissions for Review** page opens to the **Incomplete** tab.

My Workspaces ▾		IRB		Assigned Submissions for Review						Back	
Incomplete		Complete		Canceled		Print Friendly		Display Submissions by: IRB Number ▾			
Click to open	IRB Number	Ref Number	Type	Review Process	Date Board Received	Expiration Date	Principal Investigator	Assigned Reviewers	Assigned Analyst		
Serum Ferritin as a Predictor for Development of Anemia in Pregnancy											
	IRB-21-375	001271	Study Amendment Form	Expedite	06/18/2021 1:27:43 PM PDT		Investigator, John	Primary John Smith	Coordinator, Jane		

Click the icon in the **Click to open** column to open the corresponding assignment. Use the **Display Submissions by** dropdown menu to display submissions by “IRB Number” or other study numbering.

Complete Tab

Completed review assignments are listed on the **Complete** tab.

My Workspaces ▾		IRB		Assigned Submissions for Review						Back	
Incomplete		Complete		Canceled		Print Friendly		Display Submissions by: IRB Number ▾			
Reviews Completed within the last : <input type="text" value="30"/> days Refresh											
Click to open	Letters	IRB Number	Ref Number	Type	Principal Investigator	Department Study Alias	Reviewers	Date Board Received			
		IRB-21-404	001196	Submission Correction for Initial Review Submission Form	Investigator, John	*GHW - 7543 - General Hospital Demo Test	Primary John Smith	03/02/2021 10:17:51 AM PST			
		IRB-21-433	001238	Initial Review Submission Form	Investigator, John	GUR - Pediatric MSUD12	Primary John Smith	06/16/2021 1:25:05 PM PDT			
		IRB-21-478	001309	Initial Review Submission Form	Investigator, John	GHW - 7543 - General Hospital Malaria in Juveniles	Primary John Smith	06/28/2021 8:18:10 AM PDT			

Enter a number in the **Reviews Completed within the last** text box on the **Complete** tab to specify the date range for assignments to be displayed. Click the icon in the **Click to open** column to open the corresponding assignment and access the completed form.

Canceled Tab

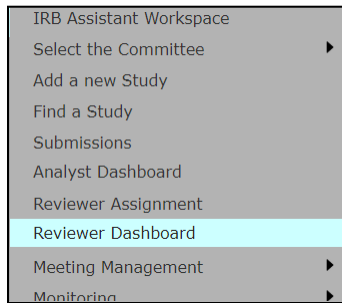
Canceled review assignments are listed on the **Canceled** tab.

My Workspaces ▾		IRB		Assigned Submissions for Review						Back	
Incomplete		Complete		Canceled		Print Friendly		Display Submissions by: IRB Number ▾			
3 result(s) found... 1 - 3											
Letters	IRB Number	Ref Number	Type	Principal Investigator	Department Study Alias	Reviewers	Date Board Received				
	IRB-19-176	000675	Initial Review Submission Form	Investigator, John	GHW - 7543 - General Hospital LTPUA 11523	Primary Administrator	07/09/2019 10:43:30 PM PDT				
	IRB-20-328	001035	Initial Review Submission Form	Investigator, John	GHW - 7543 - General Hospital USCSD -13323	Primary John Smith	08/25/2020 12:28:44 PM PDT				
	IRB-21-387	001162	Submission Correction for Initial Review Submission Form	Investigator, John	*GHW - 7543 - General Hospital PFF	Primary John Smith	01/26/2021 10:14:52 AM PST				

Notice that there is no **Click to open** column as these assignments are inactive and retained for audit log purposes only.

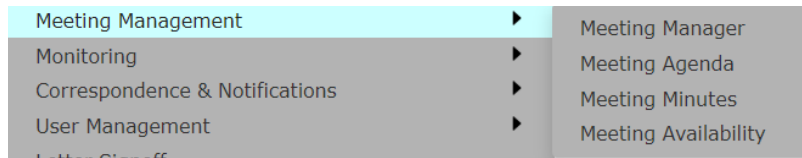
Reviewer Dashboard

The **Reviewer Dashboard** link provides access to submissions for which the logged in user is assigned as Reviewer.



See the Reviewer Dashboard manual for more information about this feature.

Meeting Management

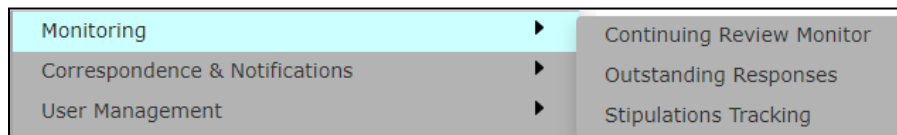


The **Meeting Management** menu contains links for **Meeting Manager**, **Meeting Agenda**, **Meeting Minutes**, and **Meeting Availability**.

See the Meetings manual for more information about these features.

Monitoring

The **Monitoring** menu contains links for **Continuing Review Monitor**, **Outstanding Responses**, and **Stipulations Tracking**.



Continuing Review Monitor

The **Continuing Review Monitor** link provides access to study management tools for submissions under continuing review. Submissions within 120 days of their continuing review date populate in this list.

The list can be sorted by the number type selected in the **Display by** dropdown list (upper right corner in screenshot below).

My Workspaces IRB **Continuing Review Monitor** Back

Print Friendly Display by: IRB Number

5 result(s) found...

Open	Study Title/Study Alias	IRB Number	IRB Initial Approval	IRB Expiration	Principal Investigator	Submission Posted
<input checked="" type="checkbox"/>	Sleep disorder after COVID recovery					
	Sleep disorder after COVID recovery	IRB-21-405	03/02/2020	03/31/2021	Investigator, John	No
<input checked="" type="checkbox"/>	The Barrow 5-ALA Intraoperative Confocal Evaluation (BALANCE)trial					
	BALANCE Trial	IRB-19-135	04/25/2019	07/09/2021	Investigator, John	No
<input checked="" type="checkbox"/>	Serum Metal Ion Concentration after Insertion of Pediatric Flexible Nail					
	Serum Metal Ion Concentration after Insertion of Pediatric Flexible Nail	IRB-20-336		07/14/2021	Smith, Betty	No
<input checked="" type="checkbox"/>	Use of stem cells on subjects currently being treated for Diabetes Type 2					
	USCSD -13323	IRB-19-180		07/29/2021	Investigator, John	No
<input checked="" type="checkbox"/>	Factors Associated with Inflammatory Markers in Endometrial Cancer Survivors					
	Factors Associated with Inflammatory Markers in Endometrial Cancer Survivors	IRB-20-366		09/14/2021	Investigator, John	No

The results list includes fields for selected **Display by** number, **IRB Initial Approval**, **IRB Expiration**, **Principal Investigator**, and whether the submission is **Posted** (meaning that an in-process submission exists to satisfy Continuing Review requirements).

This list allows the review board to monitor studies coming up for Continuing Review and take action on any study that missed its Continuing Review deadline. Applicable studies remain in this list until the study record is updated by either closing it for lack of Continuing Review submission or extending the **IRB Expiration** date. Click the icon in the **Open** column to open the corresponding submission in the Study Management page.

My Workspaces IRB **Continuing Review Monitor** Back

Print Friendly Display by: IRB Number

5 result(s) found...

Open	Study Title/Study Alias	IRB Number	IRB Initial Approval	IRB Expiration	Principal Investigator	Submission Posted
<input checked="" type="checkbox"/>	Sleep disorder after COVID recovery					
	Sleep disorder after COVID recovery	IRB-21-405	03/02/2020	03/31/2021	Investigator, John	No
<input checked="" type="checkbox"/>	The Barrow 5-ALA Intraoperative Confocal Evaluation (BALANCE)trial					
	BALANCE Trial	IRB-19-135	04/25/2019	07/09/2021	Investigator, John	No
<input checked="" type="checkbox"/>	Serum Metal Ion Concentration after Insertion of Pediatric Flexible Nail					
	Serum Metal Ion Concentration after Insertion of Pediatric Flexible Nail	IRB-20-336		07/14/2021	Smith, Betty	No
<input checked="" type="checkbox"/>	Use of stem cells on subjects currently being treated for Diabetes Type 2					
	USCSD -13323	IRB-19-180		07/29/2021	Investigator, John	No
<input checked="" type="checkbox"/>	Factors Associated with Inflammatory Markers in Endometrial Cancer Survivors					
	Factors Associated with Inflammatory Markers in Endometrial Cancer Survivors	IRB-20-366		09/14/2021	Investigator, John	No

The full Study Profile is accessible via the **Study Management** tab of the **Submissions** page.

My Workspaces IRB Number: **IRB-21-405** IRB Submissions Back

PI: Investigator, John

Study Status: **Active** IRB Number: IRB-21-405 Study Title: Sleep disorder after COVID recovery

IRB Expiration Date: 03/31/2021

Submissions Study Management

Protocol Items

- Study Application
- Informed Consents
- Other Study Documents
- Contract Documents
- Initial Review Submission Form

- Submissions History
- Study Correspondence

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

Outstanding Responses

The **Outstanding Responses** link provides access to the **Response Due** page.

Monitoring	Continuing Review Monitor
Correspondence & Notifications	Outstanding Responses
User Management	Stipulations Tracking

The **Response Due** page is used for management of submissions sent back to the PI / KSP for corrections or changes.

My Workspaces IRB Response Due Back

Outstanding Response Filters

Display Response by: IRB Number

Principal Investigator:

IRB Number:

Form: All

Analyst:

Outcome: All

Follow-up Due Begin:

Follow-up Due End:

Reviewer:

Date Sent Begin:

Date Sent End:

Print Friendly

Reset Find Options


Find ...

13 result(s) found... 1 - 10

Letters	Outcome	IRB Number	Ref Num	Type	Date Sent	Follow-Up Due	Principal Investigator	Department Study Alias	Analyst Assigned	Reviewer(s)	Meeting Date
		IRB-20-314	1015	Submission Correction for Initial Review Submission Form			Investigator, John	GHW - 7543 - General Hospital GUH - Study Team GUR - Oncology JPI - Veterinary IRB-BA-9090	Coordinator, Jane	Primary Luke Reviewer, Ph.D	08/05/2020
		IRB-20-319	1021	Initial Review Submission Form	08/06/2020		Investigator, John	GHW - 7543 - General Hospital GUH - Study Team GUR - Oncology JPI - Veterinary IRB- Z&Z - 2021	Coordinator, Jane		
		IRB-21-482	1313	Initial Review Submission Form	06/30/2021		Investigator, John	GHW - 7543 - General Hospital Malaria in Juveniles	Coordinator, Jane		




Filters are provided at the top of the page to search by **Principal Investigator, IRB Number, Form, Analyst, Outcome, Follow-up** date range, **Reviewer** or **Date Sent** range. Click in the **Display Response by** field to select the desired number type (e.g., IRB Number, IACUC Number, etc.).

Set filters as desired and click the **Find** button. Click the **Reset Find Options** button to clear all filters.

Click the  icon in the far-left column of the result set to view a table of results for the corresponding original submission, and to access the Outcome tab for the submission. Submission location tracking and KSP correspondence options can be accessed from the submission processing screens.

13 result(s) found...

1 - 10

Letters	Outcome	IRB Number	Ref Num	Type	Date Sent	Follow-Up Due	Principal Investigator	Department Study Alias	Analyst Assigned	Reviewer(s)	Meeting Date
		IRB-19-130	566	Initial Review Submission Form	04/27/2019		Investigator, John	GH - General Hospital Use of stem cells on subjects currently being treated for Diabetes Type 2	Coordinator, Jane		
	Pending Approval - Requesting Corrections	IRB-19-140	595	Initial Review Submission Form	04/29/2019		Investigator, John	GH - General Hospital ECOG 3611; A Randomized Phase II Study of Ipilimumab at 3 mg/kg or 10 mg/kg Alone or in Combination	Coordinator, Jane	Primary IRB Reviewer	
	Pending Approval - Requesting Corrections	IRB-19-143	601	Initial Review Submission Form	04/29/2019		Investigator, John	GH - General Hospital Effects of Controlled Whole-body Vibration Training on Reducing Falls among Healthy Population	Coordinator, Jane		

The following columns are shown in the result set:

Letters –an icon will only appear in this column if an outcome letter was created and sent; hover the mouse over the icon to view letter type(s) (see below)



Outcome - submission review outcome

IRB Number - review board number used to reference the study

Ref Number - system-generated reference number for the submission

Type - type of submission

Date Sent – date that the submission was sent back to the PI/KSP for corrections or changes

Follow-up Due - follow-up date (see the Submission Processing manual for more information)

Principal Investigator - Principal Investigator assigned to the study

Department /Study Number - Primary Department on the study and Study Number/Nickname

Analyst Assigned – Analyst, if any, assigned to the submission

Reviewer(s) - Reviewer(s), if any, assigned to the submission

Meeting Date - if the submission was put on an agenda, the agenda date is displayed here

Note that **Review Outcome** for a submission is assigned on the Outcome tab (see screenshot below). Submissions with a **Review Outcome** selected where the **Additional Information required** field is set to “Yes” remain in the Outstanding Responses queue until a new version of the submission is received.

Review Outcome:	--none--
Additional information required:	No

Stipulations Tracking

The **Stipulations Tracking** page is used for tracking and editing submission stipulations.

My Workspaces
IRB
Stipulations Tracking
 Back

Display by: IRB Number

Reference Number:

Stipulation Type: --none--

IRB Number:

Follow-up Date: -

Open Stipulations
Closed Stipulations

57 result(s) found... 1 - 10

Open	Edit	IRB Number	Ref Num	Type	Principal Investigator	Stipulation Type	Follow-up Due	Response Acknowledge	Assigned Reviewers	Assigned Analyst	Review Board Committee
		IRB-19-130	000566	Initial Review Submission Form	Investigator, John	Stipulation must be addressed				Coordinator, Jane	IRB
<p>Stipulation:</p> <p>Please change value under Description aof Study and Responsibilities for question 6.1 under Section Qualifications of KSP</p> <p>Response:</p>											
		IRB-19-130	000566	Initial Review Submission Form	Investigator, John	Stipulation must be addressed				Coordinator, Jane	IRB
<p>Stipulation:</p> <p>Application Stipulation (not associated)</p> <p>Response:</p>											

Stipulations are displayed on **Open Stipulations** and **Closed Stipulations** tabs. Search filters for review board **Number** (based on the **Display by** selection of “IRB Number”, “IACUC Number”, etc.), **Reference Number**, **Follow-up Date** range and **Stipulation Type** are provided at the top of each tab.

Columns in the **Open Stipulations** tab display as follows:

IACUC/IRB/IBC Number –review board number assigned to the study

Ref Num –submission reference number

Type – type of submission form in which this stipulation was entered

Principal Investigator –Principal Investigator associated with the study

Stipulation Type – type of stipulation

Follow-up Due –follow-up due date, where the stipulation type is “Comments that must be addressed”

Response Acknowledge – whether the PI accepted the stipulation

The actual **Stipulation** entered by the review board and the **Response** from the study side display in the green highlighted area. *Note: study management cannot create a **Response** to the stipulation until the review board returns the submission to the study.*

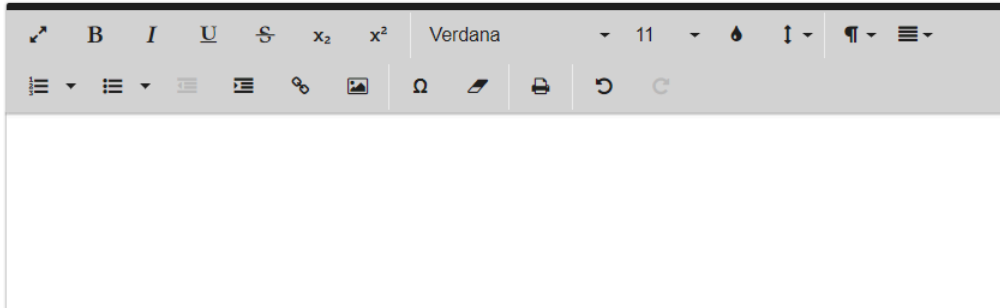
Click the icon in the **Open** column for the applicable stipulation to open the submissions screen (shown below).

Click the **Edit** icon to open the **Process Stipulation** screen (shown below). A **Review Board Action** can be assigned, and the date that the stipulation was closed can be entered in the **Review Board Date Closed** field.

Click the **Add Memo** button to add a memo to the stipulation. A text editor page opens for creation of the memo. Click the **OK** button to save the memo and close the text editor.

Save

Stipulation Memo



Any memos added display in a table.

Add Memo Delete Memo Save Stipulation

Review Board Action:	--none--
Review Board Date Closed:	<input type="text"/>
Stipulation Type:	Stipulation must be addressed
Follow-up Due:	
Stipulation:	Please change value under Description of Study and Responsibilities for question 6.1 under Section <u>Qualifications of KSP</u>
Response Acknowledge:	
Response Statement:	

	Edit	Name	Last Date Modified	Memo Details
<input type="checkbox"/>		John Smith	07/14/2021	This stipulation has been addressed.

To delete a memo in the table, select its corresponding checkbox in the far-left column and click the **Delete Memo** button.

To edit a memo in the table, click its corresponding icon in the **Edit** column.

Click the **Save Stipulation** button to return to the **Stipulations Tracking** page. If a **Review Board Action** and a **Review Board Date Closed** were entered, the stipulation moves from the **Open Stipulations** tab to the **Closed Stipulations** tab.

Select the **Closed Stipulations** tab. A screen similar to the **Open Stipulations** tab opens, listing all closed stipulations (see below).

My Workspaces ▾ IRB **Stipulations Tracking** Back

Display by: IRB Number IRB Number:

Reference Number: Follow-up Date: - Find ...

Stipulation Type: --none-- Date Closed: -

Open Stipulations **Closed Stipulations** Print Friendly

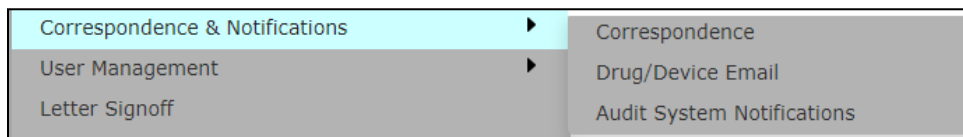
42 result(s) found... 1 - 10

Open	Edit	IRB Number	Ref Num	Type	Principal Investigator	Stipulation Type	Follow-up Due	Response Acknowledge	Action	Date Closed	Assigned Reviewers	Assigned Analyst	Review Board Committee
<input type="checkbox"/>	<input type="checkbox"/>	IRB-21-446	001252	Submission Correction for Initial Review Submission Form	Ramirez, Yvette	Comments that must be addressed	06/17/2021		Accepted	06/17/2021	Primary Bob Carmichael	Ramirez, Yvette	IRB
Stipulation: This comment requires a response. Response:													
<input type="checkbox"/>	<input type="checkbox"/>	IRB-21-446	001252	Submission Correction for Initial Review Submission Form	Ramirez, Yvette	Comments			Accepted	06/17/2021	Primary Bob Carmichael	Ramirez, Yvette	IRB
Stipulation: This comment does not require a response. Response:													

Two additional columns appear on the **Closed Stipulations** tab – **Action** and **Date Closed**. These are populated with selections made in the **Process Stipulation** screen as described previously. Submissions corresponding to the stipulation can be opened or edited here as well, as described previously.

Correspondence & Notifications

The **Correspondence & Notifications** menu includes links for **Correspondence**, **Drug/Device Email** and **Audit System Notifications**.



Correspondence

The **Correspondence** tool allows provides access for processing and tracking all IRB correspondence sent through the system.

The **Correspondence** menu group is typically available only to Review Board Coordinators and Administrators. However, read/write access can be granted to any role on the board through Review Board Administration – Setup Role Access.

The **Correspondence** link opens the **Board Correspondence** page. Any correspondence generated through the IRB Assistant module or sent to the IRB Assistant module creates an audit log entry on this screen.

My Workspaces		IRB	Board Correspondence	Back
		Add a New Correspondence		Delete Selected Correspondence
4218 result(s) found... 1 - 10				
View Message	Author	Subject		
	Post a Reply to this Topic / Forward this Topic			
	John Smith	Posted: 07/13/2021 09:22 AM PDT IRB-21-481 (MJ0630) Notice of Expedited Review Assignment		
	Post a Reply to this Topic / Forward this Topic			
	John Smith	Posted: 07/13/2021 09:22 AM PDT IRB-21-481 (MJ0630) NOTICE OF PREREVIEW ADMINISTRATIVE ASSIGNMENT		
	Post a Reply to this Topic / Forward this Topic			
	John Smith	Posted: 07/13/2021 09:17 AM PDT IRB-21-481 (MJ0630) Review Response		

Columns on the page populate as follows:

Author –author of the correspondence

Subject –date and time the correspondence was sent, its subject title, and IRB number (if applicable)

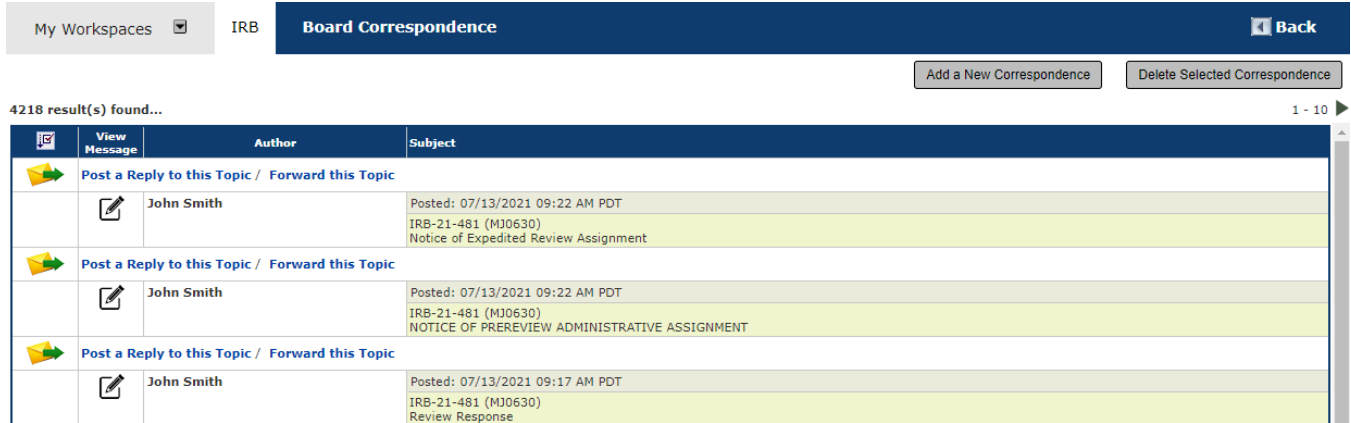
Posted – “Delivery in Progress” displays when a newly-sent correspondence is in process, the date and time stamp display when the item is delivered

Click the icon in the **View Message** column to open the corresponding message. The correspondence is displayed in read-only format, as shown below. The **Subject**, **IRB Number**, **Recipient(s)**, any **Additional Recipient(s)**, and any attachments to the correspondence are also displayed. **Delivery in Progress** is displayed if the correspondence is newly-sent and in process.

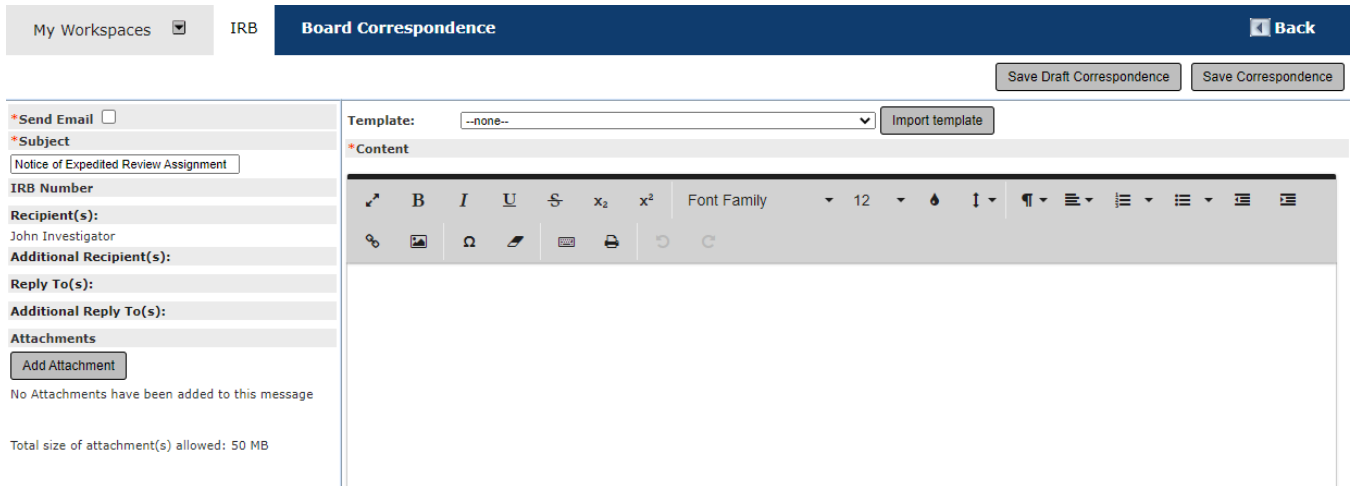
My Workspaces		IRB	Board Correspondence	Back
		Add a New Correspondence		Delete Selected Correspondence
4218 result(s) found... 1 - 10				
View Message	Author	Subject		
	Post a Reply to this Topic / Forward this Topic			
	John Smith	Posted: 07/13/2021 09:22 AM PDT IRB-21-481 (MJ0630) Notice of Expedited Review Assignment		
	Post a Reply to this Topic / Forward this Topic			
	John Smith	Posted: 07/13/2021 09:22 AM PDT IRB-21-481 (MJ0630) NOTICE OF PREREVIEW ADMINISTRATIVE ASSIGNMENT		
	Post a Reply to this Topic / Forward this Topic			
	John Smith	Posted: 07/13/2021 09:17 AM PDT IRB-21-481 (MJ0630) Review Response		

<p>Posted: 07/13/2021 09:22 AM PDT</p> <p>*Send Email <input checked="" type="checkbox"/></p> <p>*Subject</p> <p>Notice of Expedited Review Assignment</p> <p>IRB Number</p> <p>IRB-21-481</p> <p>* Recipient(s):</p> <p>John Investigator</p> <p>Additional Recipient(s):</p> <p>Reply To(s):</p> <p>Additional Reply To(s):</p> <p>Attachments</p> <p>No Attachments have been added to this message</p> <p>Total size of attachment(s) allowed: 50 MB</p>	<h3>NOTICE OF EXPEDITED REVIEW ASSIGNMENT</h3> <p>DATE: July 13, 2021 STUDY TITLE: "Malaria in Juveniles" RB #: IRB-21-481</p> <p>REFERENCE #: 001315 P.I.: Investigator, John</p> <p>It would be appreciated if you would review the above mentioned proposal.</p> <p>The information regarding this protocol has been entered into the electronic system. You should review the protocol within iRIS and enter your comments, recommendations and stipulations directly into the reviewers panels associated with the protocol.</p> <p>Thank You.</p> <p>Please do not respond to this email via the reply button. It was auto generated by the iRIS database system.</p>
--	---

Back on the **Board Correspondence** page, to reply to a correspondence, click the **Post a Reply to this Topic** link above the correspondence.



The **Board Correspondence** page opens for creation of the reply (see below).



Fields and controls on this page are as follows:


Send Email – select this checkbox to send the correspondence to specified recipients via email

Subject – defaults to the original correspondence subject, but is editable

IRB Number – if the correspondence is associated to a study, the IRB Number of that study displays here

Recipient(s) – recipient(s) of the correspondence, pre-populated with prior recipient(s) and/or author(s) of the original correspondence unless the recipient/author is the current user; select the heading link to configure this field in the **Correspondence contact** page (see below)

My Workspaces ▾		IRB	Correspondence contact		Back
Save Changes					
Contacts	Role	<input type="checkbox"/>			
Study Personnel					
<input checked="" type="checkbox"/>	Principal Investigator	<input checked="" type="checkbox"/>		Investigator, John	
<input type="checkbox"/>	Nurse	<input type="checkbox"/>		Jefferson, George	
<input type="checkbox"/>		<input type="checkbox"/>		Sykes, Jeff	
<input checked="" type="checkbox"/>	Study Author	<input checked="" type="checkbox"/>		Investigator, John	
<input checked="" type="checkbox"/>	Contact	<input checked="" type="checkbox"/>		Investigator, John	

If the correspondence is associated to a study, Key Study Personnel are listed by name and role. To add personnel to the recipient list, select the checkbox next to the appropriate user. Use the  icon in the select column header to select or deselect all. When selections are complete, click the **Save Changes** button.

Additional Recipient(s) – Select this link to send this correspondence to person(s) not already listed in the system; the **Correspondence Additional Contacts** page opens for creation of the new contact (see below.)

My Workspaces ▾		IRB	Correspondence Additional Contacts		Back
Add A New Contact Save And Return					
<input checked="" type="checkbox"/>	Name	E-mail Address			
No Additional Recipients have been added.					

Click the **Add A New Contact** button. A new row populates for entry of contact information (see screenshot below).

My Workspaces ▾		IRB	Correspondence Additional Contacts		Back
Add A New Contact Remove Selected Contacts Save And Return					
<input checked="" type="checkbox"/>	Name	E-mail Address			
<input type="checkbox"/>	<input type="text"/>	<input type="text"/>			

Name and **E-mail Address** fields are required. **E-mail Address** must be entered in name@domain.com format or an error message will be displayed.

Repeat this process for additional new contacts.

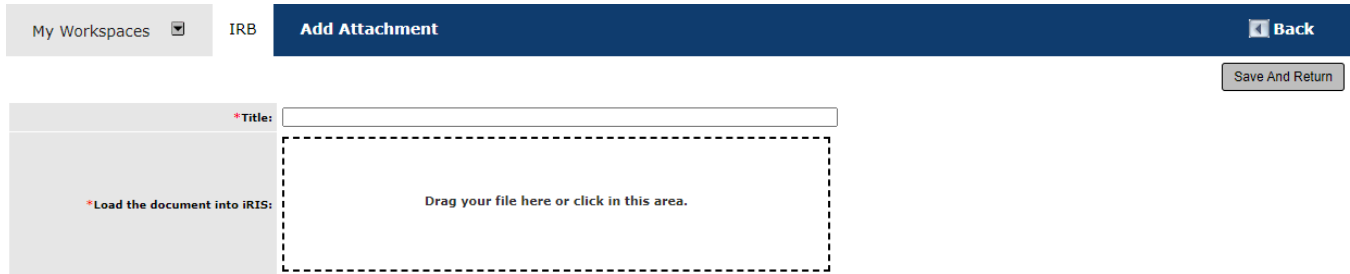
To delete a contact added to the list in error, select its corresponding checkbox in the far-left column and click the **Remove Selected Contacts** button.

After all contacts are entered click the **Save and Return** button to save changes and close the **Correspondence Additional Contacts** page.

The **Reply To(s):** field lists users in the **Recipient(s)** list when a reply is posted to this correspondence, either from the system or from an inbox; users can be added to this list in the same manner as adding Recipient(s).

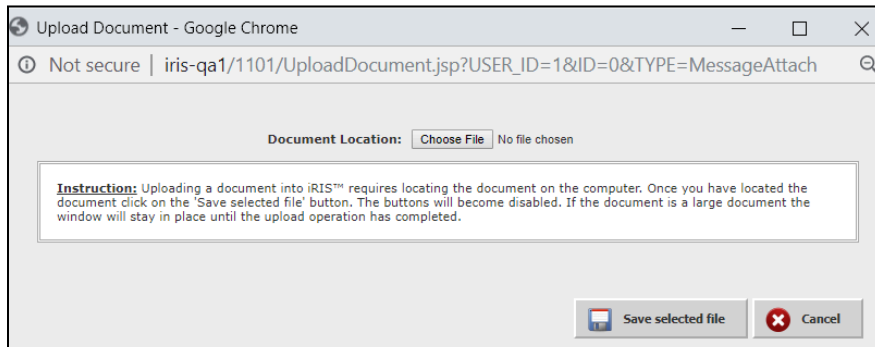
The **Additional Reply To(s)**: field lists users in the **Additional Recipient(s)** list when a reply is posted to the correspondence either from within the system or from an inbox; contacts can be added to the list in the same manner as adding Additional Recipient(s).

Click the **Add Attachments** button to add a document to the correspondence as an attachment; the **Add Attachment** page opens for upload of the attachment (see screenshot below).



A **Title** must be entered for the attachment.

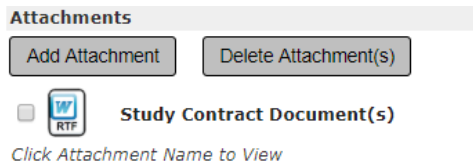
You can either drag and drop your file into the box or click inside the box to open the upload dialog box (see below).



Click the **Browse** button to navigate to the document.

Click **Cancel** to close the upload dialog without adding an attachment.

Click **Open** to proceed with the upload. When the upload is complete click the **Save And Return** button; the section refreshes as shown in the screenshot below.



Click an attachment name or icon to view the attachment.

To delete an attachment, select the checkbox next to the corresponding attachment(s) and click the **Delete Attachment** button.

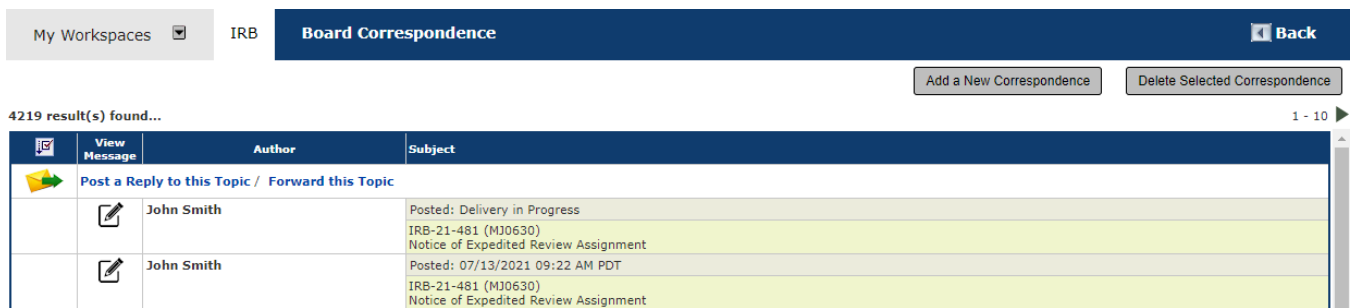
More attachments can be added via the **Add Attachment** button. *Note that while there is no limit on the size of the documents uploaded, certain email systems will have a limit on the size of incoming mail; therefore, it is advisable that the uploaded documents do not exceed a total of 1 MB when sending correspondence as email.*


Enter the body of the correspondence text in the **Content** field of the text editor.

Click the **Save and Send Correspondence** button to save the correspondence and send it to the specified recipients.

Click the **Save Correspondence as a Draft** button to save the correspondence as a draft and not send it.

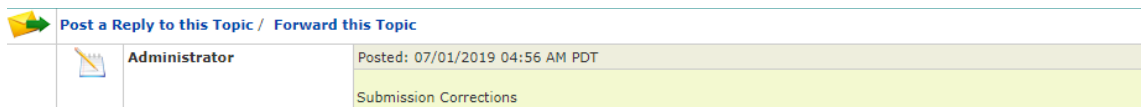
Click the **Forward this Topic** link, located next to the **Post a Reply to this Topic** link, to forward a copy of a correspondence.



Correspondence(s) saved as draft(s) are editable via the applicable  icon(s) on the **Review Board Correspondence** page.

To add a new correspondence, click the **Add a New Correspondence** button. This opens a page similar to the **Post a Reply** page, but without any pre-populated data.

Only correspondence(s) saved as draft and never sent may be deleted (see screenshot below).



A checkbox appears next to correspondences that may be deleted. To delete a correspondence, select the applicable checkbox and click the **Delete Selected Correspondence** button.

Drug/Device Email

The **Drug/Device Email** link opens the **Drug/Device Email** page (shown below).

My Workspaces ▾ IRB
Drug/Device Email
Back

Select one item(drug or device) from any one of the four lists.

Select a Drug by Trade Name: --none-- ▾

Select a Drug by Generic Name: --none-- ▾

Select a Drug by Investigation Name: --none-- ▾

Select a Device: --none-- ▾

Include In Email	Study Title	PI Name	Study Contact
<input type="checkbox"/>	No Studies and Investigations related to this Drug/Device.		

*Subject:

Content:

B I U S x₂ x² Font Family 12

Send Email

This page is used to send a study-related drug or device email to that study’s contacts. Emails of this type are typically used for pharmaceutical recalls or notes that must be sent to all study contacts using a specific drug or device.

Four filters are provided to search for the drug/device: **Select a Drug by Trade Name**, **Select a Drug by Generic Name**, **Select a Drug by Investigation Name**, or **Select a Device**. A result list containing all studies matching filter conditions populates in the table beneath the filters.

To send a drug/device email, select the checkbox next to the applicable study. Enter a **Subject** line for the email and desired body text. Click the **Send Email** button in the upper right-hand corner to send the email.

The email is sent to all applicable study contacts.

Audit System Notifications

The **Audit System Notification** link opens the **Setup Audit Notifications** page (shown below).

My Workspaces ▾ IRB
Setup Audit Notifications
Back

Filter By:	Notification Type: --none-- ▾ Date Range: From <input style="width: 40px;" type="text"/> To <input style="width: 40px;" type="text"/> Display Projects by: IRB Number ▾ IRB Number: <input style="width: 100px;" type="text"/>	Recipient(s): Select User Clear User <input style="width: 100%; height: 20px;" type="text"/> Subject: <input style="width: 100%; height: 20px;" type="text"/> Content: <input style="width: 100%; height: 20px;" type="text"/>	Search
-------------------	---	---	---

0 result(s) found... 0 - 0

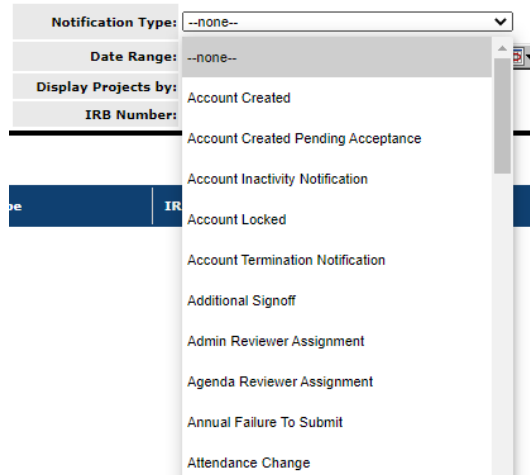
View	Notification Type	IRB Number	Date Posted	Subject	Recipient(s)	Additional Recipient(s)
------	-------------------	------------	-------------	---------	--------------	-------------------------

Every notification sent by the system is logged and can be tracked. All system notifications can be audited here to verify they are sent.

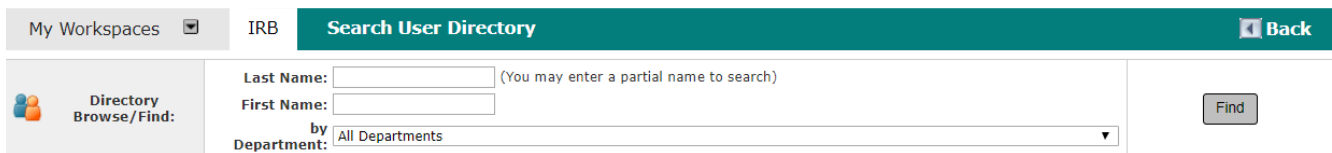
The **Audit Notifications** page includes several filters at the top to assist in searching for notifications.

Available filters include **Notification Type**, **Recipient(s)**, **Date Range**, **IRB Number**, or keyword search of the **Subject** or **Content** of the notification.

Select a **Notification Type** from the dropdown list (shown below) to filter by **Notification Type**.



Use the **Recipient(s)** option to perform an audit for a specific user in the system who was in the distribution list for the applicable notification. Click the **Select User** button to open the **Search User Directory** page (shown below).



Enter desired search criteria and click the **Find** button. Use the “%” symbol to perform a wildcard search, displaying a list of all users in the system.

My Workspaces ▾ IRB **Search User Directory** Back

Save Selected User(s)

Directory Browse/Find: Last Name: (You may enter a partial name to search)
 First Name:
 by Department:

Find

Check for Multiple	Select User	Training	User Name	Department	Email
<input type="checkbox"/>	<input checked="" type="checkbox"/>		Investigator, Andrew	Study Team (primary)	
<input type="checkbox"/>	<input checked="" type="checkbox"/>		Investigator, ARC, Ph.D.	Study Team (primary)	
<input type="checkbox"/>	<input checked="" type="checkbox"/>		Investigator, Co	Study Team (primary)	
<input type="checkbox"/>	<input checked="" type="checkbox"/>		Investigator, COI, Ph.D.		
<input type="checkbox"/>	<input checked="" type="checkbox"/>		Investigator, IACUC, Ph.D.	Study Team (primary)	
<input type="checkbox"/>	<input checked="" type="checkbox"/>		Investigator, IBC, Ph.D.	Study Team (primary) [+]	
<input type="checkbox"/>	<input checked="" type="checkbox"/>		Investigator, John	General Hospital (primary) [+]	
<input type="checkbox"/>	<input checked="" type="checkbox"/>		Investigator, OSF	Office of Human Protection (primary)	

Click the icon next to the applicable name to select the user, close the search page and return to the **Setup Audit Notifications** page with that user added.

My Workspaces ▾ IRB **Setup Audit Notifications** Back

Filter By: Notification Type:
 Recipient(s):
 Date Range: From To
 Display Projects by:
 IRB Number:
 Subject:
 Content:

Search

1261 result(s) found... 1 - 50 ▶

View	Notification Type	IRB Number	Date Posted	Subject	Recipient(s)	Additional Recipient(s)
	Submission Reviewer by Study Role Reminder Notification	IRB-21-471	07/14/2021 03:32 AM PDT	Submission Reviewer by Study Role Reminder Notification	John Investigator	
	Reminder Notification for Review and Signoff	IRB-21-483	07/14/2021 03:32 AM PDT	Study Notification Reminder for Review and Signoff	John Investigator	
	Pre-review Expedited Assignment	IRB-21-481	07/13/2021 09:22 AM PDT	Notice of Expedited Review Assignment	John Investigator	
	Pre-review Administrative Assignment	IRB-21-481	07/13/2021 09:22 AM PDT	NOTICE OF PREREVIEW ADMINISTRATIVE ASSIGNMENT	John Investigator	

Click the **Clear User** button to clear the selected user name. Note that it is only possible to search by user with one name at a time; click **Select User** after clearing the name to search by user again.

Use the **Date Range** filter to search by the approximate date of the notification.

The type of number to enter for **Review Board Number** depends on the selection made from the “Display Studies by” dropdown list.

Enter a key word or phrase that appears in the **Subject** to filter by **Subject** key word. Use the “%” symbol to perform a wildcard search.

Enter a key word or phrase that appears in the **Content** of the notification to filter by **Content** key word. Use the “%” symbol to perform a wildcard search.

Provide information for one or all of the search fields to locate the necessary notification, or click **Search** with no filters entered to return all results in the system.

Results are displayed in a table under the filter options, with the most recent notification at the top of the page, in sets of fifty (50) results per page. The following columns populate in the search results: **View**, **Notification Type**, review board **Number**, **Date Posted**, **Subject**, **Recipient(s)**, and **Additional Recipient(s)**.

My Workspaces ▾ IRB Setup Audit Notifications Back

Filter By:	Notification Type: --none--	Recipient(s): <input type="button" value="Select User"/> <input type="button" value="Clear User"/>
	Date Range: From <input type="text"/> To <input type="text"/>	<input type="text" value="John Investigator"/>
	Display Projects by: IRB Number	Subject: <input type="text"/>
	IRB Number: <input type="text"/>	Content: <input type="text"/>

1261 result(s) found...

1 - 50 ▶

View	Notification Type	IRB Number	Date Posted	Subject	Recipient(s)	Additional Recipient(s)
	Principal Investigator Notification	IRB-19-180	07/10/2019 06:56 AM PDT	PI Signoff	John Investigator	
	Reminder Notification for Review and Signoff	IRB-19-180	07/10/2019 07:01 AM PDT	Study Notification Reminder for Review and Signoff	John Investigator	
	Principal Investigator Notification		07/10/2019 08:52 AM PDT	PI Signoff	John Investigator	
	Pre-review Agenda Assignment	IRB-19-180	07/10/2019 09:02 AM PDT	NOTICE OF AGENDA REVIEW ASSIGNMENT	John Investigator	

Notifications can be sorted to display in ascending or descending order by clicking the applicable column heading (shown above). Sorting is not available for the **View** and **Recipient(s)** columns.

Click the icon in the **View** column to view the sent notification. The notification opens as read-only in a page similar to the screenshot below.

My Workspaces ▾ IRB Setup Audit Notifications Back

<input checked="" type="checkbox"/> Send Email	Content
Subject	Please do not respond to this message. These messages are automatically generated from the iRIS system.
PI Signoff	TO: John Investigator
Author	Other Study Personnel: Jorge Alvarenga
Mike Research Coord	Reference Number: IRB-19-180-NEW-1.0
Recipient(s):	Protocol Number (if available): IRB-19-180
John Investigator	A(an) Initial Review Submission Form for the protocol titled, Use of stem cells on subjects currently being treated for Diabetes Type 2 is being submitted to the IRB IRB for review. As the Principal Investigator of this study, you need to review and sign-off on this protocol.
Additional Recipients(s):	Please log into the iRIS system to access the protocol and apply your electronic signature. After completing your signoff, you will be brought to a panel that allows you to select the additional persons required to also sign off on your submission. You or your study coordinator must complete this panel and mark the page "complete" before the protocol will continue to be routed through the appropriate areas.
Attachments	Thank you.
No Attachments have been added to this message	Click Here

User Management

The **User Management** menu provides access to links for **Grant User Access & Define Roles**, **Member History**, and **User Training**.

User Management ▶	Grant User Access & Define Roles
Letter Signoff	Member History
Invoice History	User Training

Grant User Access & Define Roles

The **Grant User Access & Define Roles** page lists any users in the system who currently have a role on the review board.

My Workspaces IRB **Grant User Access & Define Roles** **Back**

Group: -- All -- Add a New Member Delete Selected Member(s)

22 result(s) found... 1 - 10

	Edit	Member Name	Committee Name	Role	Voting	Experienced Member	Specialty	Affiliation
<input type="checkbox"/>		accpunt1, account						
<input type="checkbox"/>		Admin, ORA						
<input type="checkbox"/>		Administrator	Adverse Event Committee 1	Board Member Board Member	Yes Yes	No No		
<input type="checkbox"/>		Analyst, John	Committee 1	Coordinator	No	No		
<input type="checkbox"/>		Carmichael, Bob	Committee 1	Coordinator	Yes	No	Pediatric Oncology	
<input type="checkbox"/>		Coordinator, Jane	Committee 1	Coordinator	No	No		
<input type="checkbox"/>		Coordinator, Jillian	Committee 1	Coordinator	No	No		
<input type="checkbox"/>		Coordinator, OSF	Adverse Event Committee 1	Coordinator Coordinator	No No	No No		
<input type="checkbox"/>		Member, RB Coordinator	Committee 1	Board Member	Yes	No		
<input type="checkbox"/>		michelle, meecho	Committee 1	Board Member	Yes	No		

The list includes board member names, committees, roles, voting member status and board experience status. Where available in the system, board member specialty and affiliation are displayed as well.

To delete a board member, select the box in the far-left column for the applicable name and click the **Delete Selected Member(s)** button.

To change a board member’s access rights, click the icon in the **Edit** column for the applicable name. The user record is opened in an edit panel (shown below).

My Workspaces ▾ IRB
Grant User Access & Define Roles
Back

Save Member Info

Name: Analyst, John

Highest Degree Earned:

Specialty: Add Remove

Relationship to the Institution: Affiliated Non-Affiliated

Affiliations: Add Remove

Representational Capacity: Scientist Non-Scientist

Representative of Specific Entity: Add Remove

Group: Add Remove
 Oncology

Address:

Primary Number:
Cell Number:
Pager Number:
Fax Number:
Primary Email:

Grant IRB Administrative Rights
 Grant IRB Junior Administrative Rights

Committee Access	Committee Name	Voting Member	Experienced Member
<input checked="" type="checkbox"/>	Committee 1	<input type="checkbox"/>	<input type="checkbox"/>

Roles

Board Member

Coordinator

Chairperson

Data Entry Member

Non-Voting Member

Vice-Chairperson

Expediting Board Member

Administrative Assistant

Ex-Officio Member

Consultant/Ad Hoc Reviewer

Alternate Member

For: Administrator
 Member, RB
 Coordinator
 michelle, meecho
 Pithavath, Suchitra
 Rands, Jeffery, PhD
 Reviewer, IRB
 Reviewer, Luke, Ph.D
 Reviewer, Leia
 Reviewer, OSF
 Smith, Betty
 Stewart, Andrew

Change the user’s board member role by selecting a different role within the applicable committee on the right-hand side of the edit panel. Where applicable, select the checkbox(es) for:

Committee Access – select to grant this board member access to this committee

Voting Member – select to indicate this member has voting rights on the committee

Experienced Member – select to indicate this member has prior experience on this board/committee

Click the **Save Member Info** button to save changes, then click **Back** to return to the list.

Click the **Add a New Member** button to assign any other user in the system who is not already on the board to a board member role. The **Add new Review Board Members** page opens, as shown below.

My Workspaces ▾ IRB **Add new Review Board Members** Back

Save Selected Members

Last Name: Find User

First Name:

User ID:

Status: All ▾

55 result(s) found... 1 - 10 ▶

<input type="checkbox"/>	User Name	User ID	Primary Department	Login Enabled	Status
<input type="checkbox"/>	I, Coordinator	excoordinator	None Selected	Yes	Active
<input type="checkbox"/>	Aarons, Emily	eaarons	GUR - Oncology	Yes	Active
<input type="checkbox"/>	Aballay, Alejandro	aaballay	GUR - Oncology	Yes	Active
<input type="checkbox"/>	abar, Bijan	abijan	GUR - Pediatric	Yes	Active
<input type="checkbox"/>	Bartz, Raquel	rbartz	None Selected	Yes	Active

Click the **Save Selected Members** button to save changes and close the page.

After assigning a system user to a board member role, it is necessary to navigate to their user account to configure their specific board role. This process is the same as that described previously for editing access details of a current board member.

Review Board Member History

The **Member History** link provides access to audit logs of review board member role history.

*Note that access to this feature is controlled under Review Board Administration > User Roles and Access, and the **Member History** menu item only populates for users in roles that are granted access.*

By default the **Member History** page opens to the **Active** tab, for lookup of current board member role assignments.

My Workspaces ▾ IRB **Member History** Back

Last Name: Role: --none-- ▾ Find ...

First Name: Specialty: --none-- ▾

Username: Group: --none-- ▾

Active **History** Print Display by Committee: Adverse Event ▾

10 results found... 100 records per page Displaying 1 to 7 >

Name	Role	Specialty	Group
Reviewer, OSF	Board Member		
Smith, Betty	Board Member		Neurology NHLBI
Smith, John	Coordinator	Anesthesiology	Neurology NHLBI
Stewart, Andrew	Coordinator		
Ramirez, Yvette	Coordinator		Neurology Oncology
Administrator	Board Member		
Coordinator, OSF	Coordinator		

Enter desired search criteria (**Last Name, First Name, Username, Role, Status**, date range) and click the **Find** button to run the search. Use the **Display by Committee** dropdown list at the upper right of the page to filter search results further.

Notice that each user can have multiple history entries, one for each role assignment on each board. A user may also have multiple entries for a role if they held that role for two periods of time.

Click the **Print** button to print the results displayed on the screen. To print all of the records in the result set, change the **records per page** dropdown to “All”. It is also possible to print to PDF using that browser function.

Click the **History** tab (shown below) for lookup of role assignment history for *past* board member role assignments.

My Workspaces ▾
IRB
Member History
Back

Last Name:

First Name:

Username:

Role: --none-- ▾

Specialty: --none-- ▾

Group: --none-- ▾

Status: All ▾

Active Between: -

Find ...

Active
History

Print
Display by Committee: Adverse Event ▾

10 results found... 100 ▾ records per page Displaying 1 to 7 >

Name	Role	Specialty	Group	Status	Start Date	End Date
Reviewer, OSF	Board Member			Active	04/21/2021	
Smith, Betty	Board Member		Neurology NHLBI	Active	02/15/2021	
Smith, John	Coordinator	Anesthesiology	Neurology NHLBI	Active	01/28/2020	
Stewart, Andrew	Coordinator			Active	06/24/2021	
Ramirez, Yvette	Coordinator		Neurology Oncology	Active	06/16/2021	
Administrator	Board Member			Active	10/29/2019	
Coordinator, OSF	Coordinator			Active	04/21/2021	

Notice that the filter form at the top of this tab includes the same fields as on the **Active** tab but adds fields for **Status** and date range. The search form on the page defaults to a range from the current date going back one year, but the dates can be changed.

There are two areas in the system where board role assignments and changes can be entered. The first is the **Grant User Access & Define Roles** page within a review board module, as shown below.

My Workspaces ▾ IRB **Grant User Access & Define Roles** Back

[Save Member Info](#)

Name: Analyst, John

Highest Degree Earned:

Specialty: [Add](#) [Remove](#)

Relationship to the Institution: Affiliated Non-Affiliated

Affiliations: [Add](#) [Remove](#)

Representational Capacity: Scientist Non-Scientist

Representative of Specific Entity: [Add](#) [Remove](#)

Group: [Add](#) [Remove](#)
 Oncology

Address:

Primary Number:
Cell Number:
Pager Number:
Fax Number:
Primary Email:

Grant IRB Administrative Rights
 Grant IRB Junior Administrative Rights

Committee Access	Committee Name	Voting Member	Experienced Member
<input checked="" type="checkbox"/>	Committee 1	<input type="checkbox"/>	<input type="checkbox"/>

Roles

- Board Member
- Coordinator
- Chairperson
- Data Entry Member
- Non-Voting Member
- Vice-Chairperson
- Expediting Board Member
- Administrative Assistant
- Ex-Officio Member
- Consultant/Ad Hoc Reviewer
- Alternate Member
 - For: Administrator
 - Member, RB Coordinator
 - michelle, meecho
 - Pithavath, Suchitra
 - Rands, Jeffery, PhD
 - Reviewer, IRB
 - Reviewer, Luke, Ph.D
 - Reviewer, Leia
 - Reviewer, OSF
 - Smith, Betty
 - Stewart, Andrew

See the Grant User Access & Define Roles section of this manual for more information.

The second is at the System Administration level, and is accessed via System Administration > System Administration Workspace > User Accounts > **Assign Access** link for applicable user.

My Workspaces ▾ System Administration **User Accounts** Back

Last Name: [Find User](#) [Download User Profile Template](#) [Upload User Profile](#)

First Name:

User ID:

Status:

Email Address:

Institution:

[Add a New User](#)

77 result(s) found... 1 - 10

Delete	Switch to User	User Name	Assign Access	User Training	User ID	Primary Department	Login Enabled	Status	Date Created	Notes
<input checked="" type="checkbox"/>		1, Coordinator			excoordinator	None Selected	Yes	Active	09/05/2018	
<input checked="" type="checkbox"/>		Aarons, Emily			eaarons	GUR - Oncology	Yes	Active	10/15/2020	
<input checked="" type="checkbox"/>		Aballay, Alejandro			aaballay	GUR - Oncology	Yes	Active	10/15/2020	
<input checked="" type="checkbox"/>		abar, Bijan			abijan	GUR - Pediatric	Yes	Active	10/15/2020	
<input checked="" type="checkbox"/>		accpunt1, account			useraccount1	None Selected	Yes	Active	12/18/2018	
<input checked="" type="checkbox"/>		Admin, ORA			ORAadmin	GHOSP - Grants Office	Yes	Active	02/22/2018	
<input checked="" type="checkbox"/>		Administrator			grant_admin	GHOSP - Grants Office	Yes	Active	10/29/2019	
<input checked="" type="checkbox"/>		Analyst, John			john_reviewer	HCRH - Pediatric	Yes	Active	09/06/2018	
<input checked="" type="checkbox"/>		Bartz, Raquel			rbartz	None Selected	Yes	Active	10/15/2020	
<input checked="" type="checkbox"/>		Boardmember			Mboardmember	GCH - Office of Human Protection	Yes	Active	02/21/2018	

See the System Administration manual for more information about this feature.

Member History Audit Log

When a user is added to a review board the system creates an audit log entry that includes the user name, the start and end dates for the role assignment, the role title, and the name of the user who made the role assignment.

When a current board member is assigned to a different role on the same board, the system automatically enters the date of the new assignment as the end date for the user’s previous review board role, and as the start date for the new review board role. These dates are then saved to the audit log, along with the name of the user being reassigned, the new role title, and the name of the user who made the change.

Deactivating, terminating or retiring a user account populates the end date(s) for any role(s) the user holds at that time.

User Training

The **User Training** menu link provides access for viewing and configuration of each user’s training record. See the Sys Admin - User Training - Full manual for full details of training management features in the system.


Validation of user training can be part of the submission workflow, allowing for verification that Key Study Personnel are up to date with the review board’s required training or education. Entry of user training data is only necessary if this verification step is part of the institution’s workflow. Contact your site’s system administrator for questions concerning your site’s workflow.

The **User Training List** page displays a list of all users associated with the active review board.


The table includes columns for **Edit/View**, **User Name**, **User ID**, **Primary Department**, **Training Group**, training **Status** (Active, Never Active, or Expired) and **Override**.

Edit/View	User Name	User ID	Primary Department	Training Group	Status	Override
	1, Coordinator	excoordinator		General Training Course	Never Active	No
				CITI Training	Never Active	No
				Continuing Review	Never Active	No
				Modification Form	Never Active	No
	Aarons, Emily	eaarons	GUR - Oncology		Never Active	No
	Aballay, Alejandro	aaballay	GUR - Oncology		Never Active	No
	abar, Bijan	abijan	GUR - Pediatric		Never Active	No
	accpunt1, account	useraccount1			Never Active	No
	Admin, ORA	ORAadmin	GHOSP - Grants Office		Never Active	No

The icon (note checkmark in circle) in the column between **Primary Department** and **Training Group** signifies the user has at least one active training record on file. The (note prohibited crossbar in circle) icon

means there is no valid training record on file. The  (note exclamation point in circle) icon signifies the user has a training record on file but that record is expired.





A search form is provided at the top of the page to search for users by **Last Name, First Name, User ID** or **Status**. Enter desired search criteria and click the **Find User** button.

To set up a user training record, click the  icon in the **Edit/View** column for the applicable user or click on the applicable user name. The user’s **Training record list** is opened in read-only format or editable format depending on user access.

My Workspaces ▾ IRB **Training record list for Ramirez, Yvette** ⏪ Back

*User_ID: yramirez Job Title: Degree: Employee ID: Specialty: Relationship to the Institution: <input type="radio"/> Affiliated <input type="radio"/> Non-Affiliated	Name: Yvette Ramirez Status: Active Email Address: Primary Number: Cell Number: Pager Number: Fax Number:	Login Enabled: Yes Mailing Address:
---	---	--

User Training Group Status | User Training Courses | Reevaluate Training Status | Add a New Training Group | Delete Training Group(s)

☑	Edit/View	Training Group	Courses (Course Date - Expiration) <small>All Courses must be green within one rule for the group to be valid</small>	Status	Override
<input type="checkbox"/>		General Training Course	Rule 1  Human Research Subjects Training (06/16/2021 - 06/16/2025)	Active	No
<input type="checkbox"/>		CITI Training		Never Active	No
<input type="checkbox"/>		Test IRB Group		Never Active	No

Tabs for user **Training Group Status** and **User Training Courses** are provided at the bottom of the page.

The **Training Group Status** tab lists **Training Groups** to which the user is assigned. A **Training Group** is a set of courses that form a required curriculum.

Next to each group is a list of courses the user has taken that are applicable to that group. The page provides access to **Edit/View User Training Courses**, **Reevaluate Training Status**, **add a New Training Group**, or **Delete Training Group(s)**.

Click the **Edit/View** icon for a **Training Group** to open its configuration details, as shown below.

My Workspaces ▾ IRB **User Training** ⏪ Back

Save Training Group

Group Name:	CITI Training
Override Flag:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Status:	Active ▾

Group Name is read-only. The **Override Flag** and (training) **Status** fields are editable.

Set the **Override Flag** to “Yes” to override any necessary training rules set up for the group for this user only.

The (training) **Status** dropdown list includes the following options:

Never Active — training was never set; default setting

Active — training is currently active

Expired — training is expired

Click the **Save Training Group** button to save changes and close training group configuration details.

Click the **Reevaluate Training Status** button to revalidate the active user’s training.

To add a new training group, click the **Add New Training Group** button. The same configuration form used for revising an existing training group is opened for creation of the new group.

Group Name – select the desired training group name from the dropdown list

Set the **Override Flag** to “Yes” to override any necessary training rules set up for the group for this user only.


Select the desired option from the (training) **Status** dropdown list:

Never Active — training was never set; default setting

Active — training is currently active

Expired — training is expired

Click the **Save Training Group** button to save the new group and close training group configuration details.

Back on the **User Training Group Status** tab (shown below), to delete a training group, select the box to the left of the applicable training group and click the **Delete Training Group(s)** button. Click the  button at the top of the column in the table to select or deselect all groups.

My Workspaces ▾ IRB **Training record list for Ramirez, Yvette** Back

*User_ID: yramirez
 Job Title:
 Degree:
 Employee ID:
 Specialty:
 Relationship to the Institution Affiliated Non-Affiliated

Name: Yvette Ramirez
 Status: Active
 Email Address:
 Primary Number:
 Cell Number:
 Pager Number:
 Fax Number:

Login Enabled: Yes
 Mailing Address:

User Training Group Status **User Training Courses** Reevaluate Training Status Add a New Training Group Delete Training Group(s)

<input type="checkbox"/>	Edit/View	Training Group	Courses (Course Date - Expiration) All Courses must be green within one rule for the group to be valid	Status	Override
<input checked="" type="checkbox"/>		General Training Course	Rule 1 Human Research Subjects Training (06/16/2021 - 06/16/2025)	Active	No
<input type="checkbox"/>		CITI Training		Never Active	No
<input type="checkbox"/>		Test IRB Group		Never Active	No

Click the **User Training Courses** tab to view the user’s training record list, as shown below.

My Workspaces ▾ IRB **Training record list for Ramirez, Yvette** Back

*User_ID: yramirez
 Job Title:
 Degree:
 Employee ID:
 Specialty:
 Relationship to the Institution Affiliated Non-Affiliated

Name: Yvette Ramirez
 Status: Active
 Email Address:
 Primary Number:
 Cell Number:
 Pager Number:
 Fax Number:

Login Enabled: Yes
 Mailing Address:

User Training Group Status **User Training Courses** Add a New Training Course Delete Training Course(s)

<input type="checkbox"/>	Edit/View	Course Name	Course Date	Expiration Date	Score	Description
<input type="checkbox"/>		GCP course (US FDA focus)	06/16/2021	06/16/2025		
<input type="checkbox"/>		Human Research Subjects Training	06/16/2021	06/16/2025		
<input type="checkbox"/>		Social Behavioral Research investigators and Key Personnel Group.	06/16/2021	06/16/2025		
<input type="checkbox"/>		Sponsored Projects Training 101	06/16/2021	06/16/2025		

The list table includes columns for **Course Name**, **Course Date**, **Expiration Date**, **Score** and course **Description**.

Click the icon in the **Edit/View** column for a course to open its configuration details (shown below).

My Workspaces ▾ IRB **User Training Course** Back

Save Training Course

*Course Name: GCP course (US FDA focus)

Course Date: 06/16/2021

Expiration Date: 06/16/2025

Score:

Description:

Comments:

Add a New Document Delete Selected Document(s)

0 result(s) found...

<input type="checkbox"/>	Edit	Title	File
No documents have been added.			

The **Course Name** field is read-only.

The fields for **Course Date**, **Expiration Date**, **Score** and **Description** are editable. A field is also provided to add **Comments** about the course. Click the **Add a New Document** button to attach a document to the course (e.g., a certificate of completion). Complete fields as desired and click the **Save Training Course** button to save changes. Click the **Back** link to close the configuration form.

Back on the **User Training Course** tab (shown previously in this manual section), to add a new training course for the selected user, click the **Add New Training Course** button. The same configuration form used for revising an existing training course is opened for creation of the new course.

Course Name – select the desired training course name from the dropdown list

Course Date – date the course was taken

Expiration Date – training course expiration date; if no **Expiration Date** is entered the user remains in good standing with the associated course indefinitely

Score – training course score

Description — course description

A field is also provided to enter **Comments** about the course.

Click the **Save Training Course** button to save changes and the ability to add documents to the record will appear as shown below.

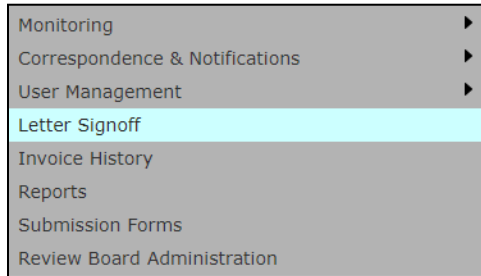
Once saved the course record is added to the list of courses within the applicable group for the selected user.

To delete a training course, select the checkbox for the applicable course in the far-left column, then click the **Delete Training Course(s)** button.

The system automatically checks the expiration dates for training courses and automatically updates course status as per the rules defined for a particular training group.

Letter Signoff

The **Letter Signoff** feature allows for application of an electronic signature to outcome letters routed to the logged in user for approval. Click the **Letter Signoff** link in the **IRB Assistant** menu.



The **Assigned Letter Signoff List** page opens, as shown below.

My Workspaces IRB - Assigned Letter Signoff List Back

Print Friendly Display Submissions by: IRB Number

Incomplete Complete

Filter Letters By: All Sign all selected Letters

<input type="checkbox"/>	Edit/View Letter	Click to open	IRB Number	Ref Number	Type	Review Process	Date Letter Created	Continuing Review Due	Expiration Date	Principal Investigator	Assigned Analyst
<i>Changes Requested</i>											
<i>Use of stem cells on subjects currently being treated for Diabetes Type 2</i>											
<input type="checkbox"/>			IRB-19-130	000566	Initial Review Submission Form	Returned for Corrections	04/22/2019			Investigator, John	Coordinator, Jane

Signoff for individual letters can also be accessed through the task list displayed on the home screen.

The page includes an **Incomplete** tab and a **Complete** tab. The **Incomplete** tab lists submission letters awaiting application of electronic signature. Submission letters to which the electronic signature has been applied are listed on the **Complete** tab.

The page opens to the **Incomplete** tab by default. Submissions shown here are listed by the selection made in the **Display Submissions by** field (IACUC Number, IRB Number, etc.).

Data columns shown for each record include **IACUC Number** (or other number selected in the **Display Submissions by** field), **Ref Number**, **Type**, **Review Process**, **Date Letter Created**, **Continuing Review Due** date, **Expiration Date**, **Principal Investigator** and **Assigned Analyst**.

Click in the **Filter Letters By** field and select **Batched only** or **Non-Batched only** to filter by batched status. *Note that batched or non-batched status is set when the letter is created.*

Incomplete	Complete
Filter Letters By : <input type="text" value="Batched only"/>	

Click the icon in the **Click to open** column to review the submission before signing its letter(s). Submission processing screens open for the study. Use one of the following two methods to apply the electronic signature:

1. Batch Review and Sign Off (fastest method)

Select the checkboxes in the first column for all items to be signed off and click the **Sign all selected Letters** button. A warning message appears, as shown below.

Confirm applying your Signature to all the selected letters.
Are you sure you want to sign all the selected letters?

Click **OK** to confirm the batch signoff. A form opens for entry of user credentials, as shown below.

This form requires your electronic signature.

Admin Admin admin Mr, B.S. please enter your User ID and Password below:

User ID:

Password:

Enter the logged in user’s **User ID** and **Password** (electronic signature) and click the **Save** button. The countdown alert popup shown below displays briefly.

Please Wait ...

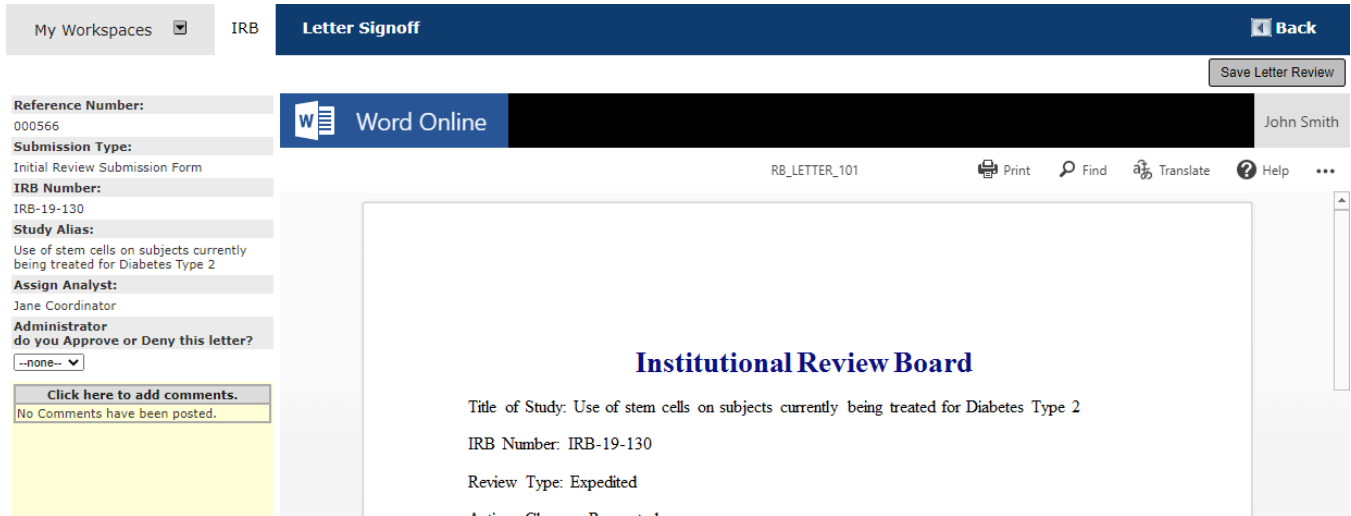


The Letters are being generated into a PDF files, Signed and Sent to the Key Study personnel.
This operation may take several minutes.

Note that this popup displays regardless of whether the letter is already in PDF format, or if the letter must still be routed for signature.

2. Non-Batch (Individual) Review and Signoff (more time consuming)

Click the **Edit/View Letter** icon for the applicable signoff item. The item is opened in a page like that shown below.



If letter content is editable, it is presented in Word format. Otherwise, it is presented in PDF format.

Submission information (**Reference Number**, **Submission Type**, and **Approve/Deny**) appears on the left side of the page.

Click the **Click here to add comments** button to open the **Signoff Comments Editor** popup, shown below. Enter desired comments and click the **OK** button.



Approve or deny the letter by selecting the appropriate choice from the dropdown menu. A new field for application of electronic signoff appears after this selection is made (see below).

Reference Number:
007105

Submission Type:
Initial Review Submission Form

IRB Number:
IRB-18-2323

Alias:
4808

admin, Admin Admin, B.S. Brig. Gen.
do you Approve or Deny this letter?
Approve ▾

This letter requires your electronic signature.
ELECTRONIC SIGNATURE HAS BEEN APPLIED
by Admin Admin admin, B.S. Brig. Gen.

Comments.
No Comments have been posted.

Enter the logged in user’s **User ID** and **Password** (electronic signature) when prompted and click the **Save Letter Review** button.

After this process is complete the main **Assigned Letter Signoff** list is updated to read, “No Letters to Review and signoff.”

The **Complete** tab displays all letters to which the logged in user’s electronic signature has been applied. This list can be filtered to a specific date range using the **Start Date** and **End Date** fields. After setting a date range, click the **Refresh page** button to apply the date range filter.

My Workspaces ▾ IRB - Assigned Letter Signoff List Back

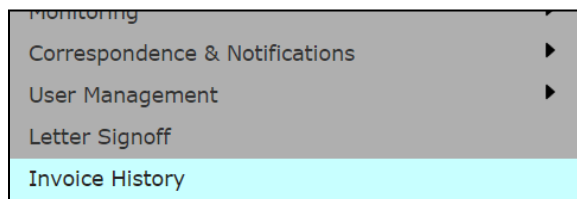
Start Date: 06/14/2021 End Date: 07/14/2021 Refresh page Print Friendly Display Submissions by: IRB Number ▾

Incomplete **Complete**

Click to View the Letter	Click to open	IRB Number	Ref Number	Type	Review Process	Date Letter Created	Continuing Review Due	Expiration Date	Principal Investigator	Assigned Analyst
		<i>Changes Requested</i>								
		<i>Use of stem cells on subjects currently being treated for Diabetes Type 2</i>								
		IRB-19-130	000566	Initial Review Submission Form	Returned for Corrections	04/22/2019			Investigator, John	Coordinator, Jane
		<i>Initial Review Approval</i>								
		IRB-21-454	001267	Initial Review Submission Form	Process Administratively	07/12/2021	05/01/2022	06/16/2022	Mossman, Nathan	Coordinator, Jane

Invoice History

The **Invoice History** link opens the **Board Invoice History** page.



This page is used for tracking and managing invoices associated with “fee applied” submissions.

Open	IRB Number	Ref Number	Type	Date Board Received	IRB Expiration Date	Principal Investigator	Assigned Analyst
	Copy of COI Study IRB-20-305	001006	Initial Review Submission Form	07/29/2020 8:47:44 AM PDT		Alvarenga, Jorge	Coordinator, Jane

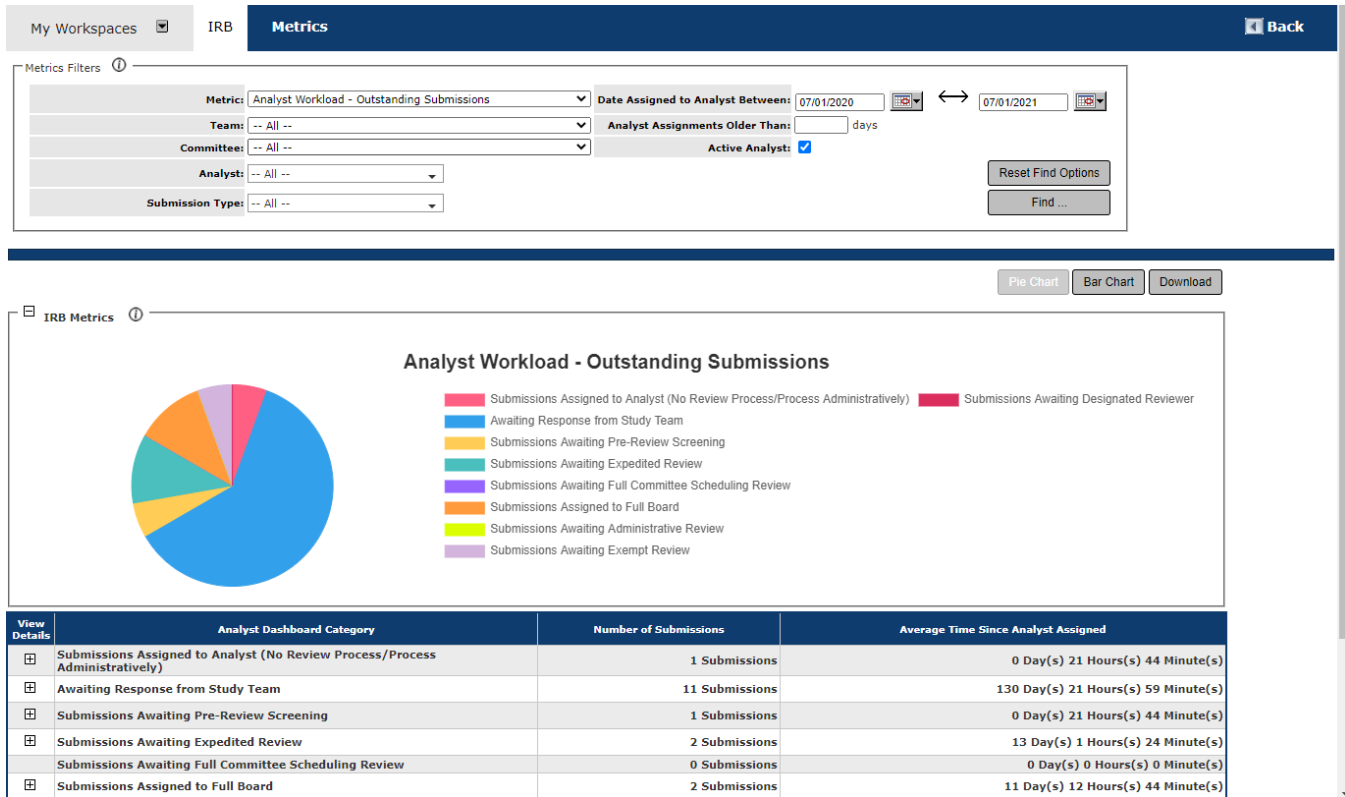
See the Invoices manual for more information about this functionality

Metrics

Metrics is new functionality that will allow users to manage both current and historical data around Analyst and Reviewer workload and performance. Access to the Metrics link shown below is controlled by the role matrix and team setup (under Review Board Administration).

Institutions can create teams of Managers and Analysts for use in this feature, to help managers track performance and time spent processing submissions. Managers will only have access to view their team if they are assigned as a team leader. Anyone not on a team but given role access will have access to all analysts. Teams can be selected from the dropdown shown below (teams are created at the board level in Review Board Administration).

The screenshot shown below is of the Analyst Workload – Outstanding Submissions. This view organizes the workload for Analysts by the same queues that are on the Analyst Dashboard, but at a higher level, allowing higher level administrators and managers a birds-eye view of activity within their institution.



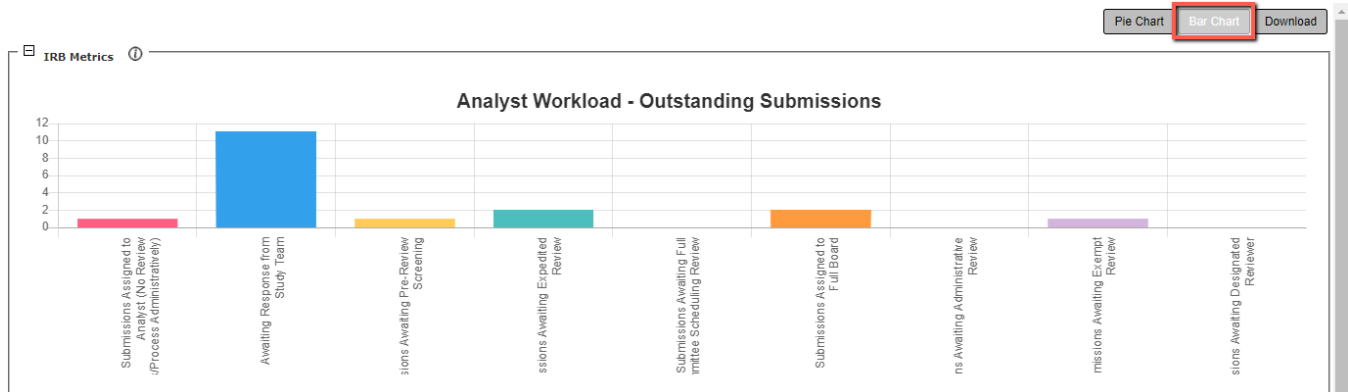
A number of filters are provided above that allow the user to filter and drill down into the view. Clicking on the plus sign next to an Analyst Dashboard category will display Analysts with submissions currently in that category, as shown below.

View Details	Analyst Dashboard Category	Number of Submissions	Average Time Since Analyst Assigned
+	Submissions Assigned to Analyst (No Review Process/Process Administratively)	1 Submissions	0 Day(s) 21 Hours(s) 44 Minute(s)
+	Awaiting Response from Study Team	11 Submissions	130 Day(s) 21 Hours(s) 59 Minute(s)
+	Coordinator, Jane	9 Submission(s)	156 Day(s) 21 Hours(s) 54 Minute(s)
+	Ramirez, Yvette	2 Submission(s)	13 Day(s) 22 Hours(s) 19 Minute(s)
+	Submissions Awaiting Pre-Review Screening	1 Submissions	0 Day(s) 21 Hours(s) 44 Minute(s)
+	Submissions Awaiting Expedited Review	2 Submissions	13 Day(s) 1 Hours(s) 24 Minute(s)
+	Submissions Awaiting Full Committee Scheduling Review	0 Submissions	0 Day(s) 0 Hours(s) 0 Minute(s)

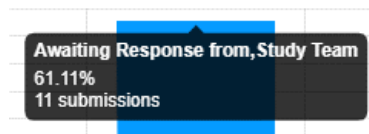
Clicking on the Analyst name or number of submissions will open the following window, providing the user with drilldown capabilities and detail on all submissions that are in that category.

Awaiting Response from Study Team				
Analyst - Coordinator, Jane				
Date Assigned to Analyst	Protocol Number	Submission Type	Principal Investigator	Time Since Analyst Assigned
07-15-2020	IRB-20-299	Initial Review Submission Form	Investigator, John	350 Day(s) 23 Hours(s) 6 Minute(s)
08-04-2020	IRB-20-309	Study Amendment Form	Smith, Betty	330 Day(s) 21 Hours(s) 50 Minute(s)
10-09-2020	IRB-20-344	Initial Review Submission Form	Investigator, John	264 Day(s) 23 Hours(s) 37 Minute(s)
02-15-2021	IRB-21-389	Initial Review Submission Form	Investigator, John	135 Day(s) 19 Hours(s) 7 Minute(s)
03-09-2021	IRB-21-417	Initial Review Submission Form	Investigator, John	114 Day(s) 5 Hours(s) 38 Minute(s)
03-09-2021	IRB-21-418	Initial Review Submission Form	Investigator, John	114 Day(s) 5 Hours(s) 0 Minute(s)
04-07-2021	IRB-21-427	Initial Review Submission Form	Reviewer, Luke, Ph.D	85 Day(s) 1 Hours(s) 26 Minute(s)
06-16-2021	IRB-21-438	Initial Review Submission Form	Investigator, John	14 Day(s) 23 Hours(s) 49 Minute(s)
06-30-2021	IRB-21-482	Initial Review Submission Form	Investigator, John	0 Day(s) 23 Hours(s) 10 Minute(s)
Average Time: 156 Day(s) 21 Hours(s) 38 Minute(s)				

In addition, data can be viewed graphically in a Bar Chart format by clicking on the **Bar Chart** button.



Hovering over each bar will give the user a short description of the data presented, as shown below.



Additional views are shown below, with completed views looking at historical data.

Analyst Workload - Outstanding Submissions

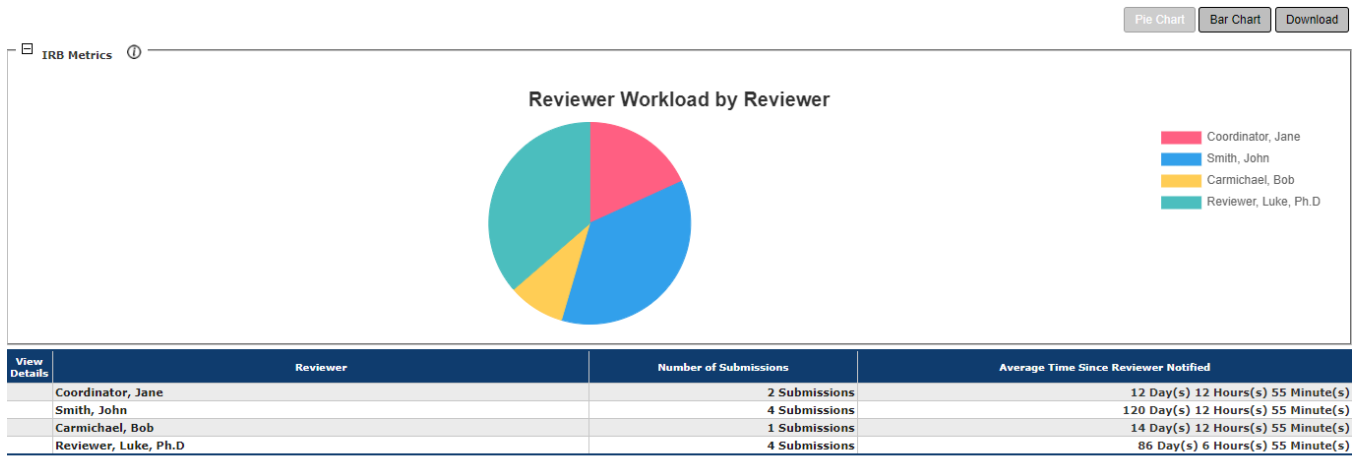
Analyst Workload - Completed Submissions by Submission Type

Analyst Workload - Completed Submissions by Outcome

Reviewer Workload by Submission Review Process

Reviewer Workload by Reviewer

Reviewer Workload by Reviewer is shown below.



Clicking on a reviewer or the number of submissions will open the drilldown window similar to other views.

Coordinator, Jane

X

Reviewer - Coordinator, Jane

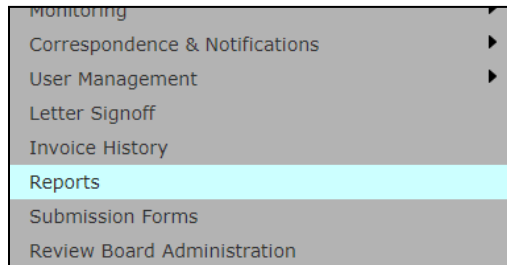
Date Reviewer Notified	Protocol Number	Principal Investigator	Time Since Reviewer Notified
06-17-2021	IRB-21-404	Investigator, John	14 Day(s) 12 Hours(s) 56 Minute(s)
06-21-2021	IRB-21-463	Investigator, John	10 Day(s) 12 Hours(s) 56 Minute(s)
Average Time: 12 Day(s) 12 Hours(s) 56 Minute(s)			

This data can also be download into a excel file that will provide the user with a detailed view of all of the submissions making up each data point in each category.

Protocol Number	Reference Number	Committee	Review Process	Submission Outcome	Submission Type	PI Name	Analyst Assigned	Reviewer Name	Date Reviewer Notified	Time to Completion
IRB-20-364	IRB-20-364-NEW-1.0		Full Committee		Initial Review Submission Packet	Investigator, John		Carmichael, Bob	2/24/2021	1 day
IRB-20-364	IRB-20-364-NEW-1.0		Full Committee		Initial Review Submission Packet	Investigator, John		Pithavath, Suchitra	2/24/2021	1 day
IRB-20-364	IRB-20-364-NEW-1.0		Full Committee		Initial Review Submission Packet	Investigator, John		Reviewer, Leia	2/24/2021	1 day
IRB-19-241	IRB-19-241-NEW-1.0		Full Committee		Initial Review Submission Packet	Investigator, John		Reviewer, Luke	11/20/2019	462 days
IRB-21-372	IRB-21-372-NEW-1.0		Full Committee		Initial Review Submission Packet	Investigator, John		Reviewer, Luke	1/12/2021	43 days
IRB-19-226	IRB-19-226-AMD-1.0		Expedite		Study Amendment Form	Investigator, John		Alvarenga, Jorge	10/24/2019	489 days
IRB-19-144	IRB-19-144-NEW-1.0		Expedite		Initial Review Submission Packet	Investigator, John		Reviewer, IRB	4/30/2019	666 days
IRB-19-224	IRB-19-224-NEW-1.0		Expedite		Initial Review Submission Packet	Investigator, John		Smith, John	11/19/2019	463 days
IRB-20-328	IRB-20-328-NEW-1.0		Process Administratively		Initial Review Submission Packet	Investigator, John		Smith, Betty	9/14/2020	163 days
IRB-19-176	IRB-19-176-AE-1.0		Process Administratively		Adverse Event Reporting Form	Investigator, John		Smith, John	8/21/2019	553 days
IRB-20-328	IRB-20-328-NEW-1.0		Process Administratively		Initial Review Submission Packet	Investigator, John		Smith, John	9/14/2020	163 days

Reports

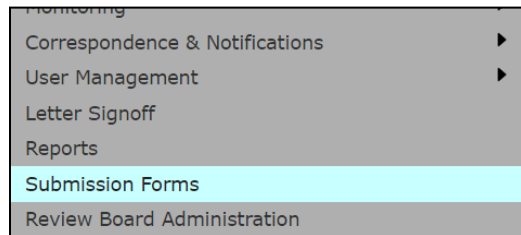
The **Reports** link provides access to boilerplate reports for the IRB Assistant module.



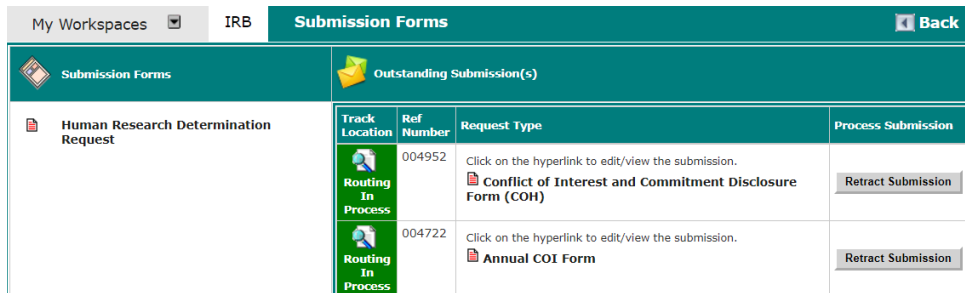
See the Reports manual for more information about this feature.

Submission Forms

The **Submission Forms** link opens the **Submission Forms** page.

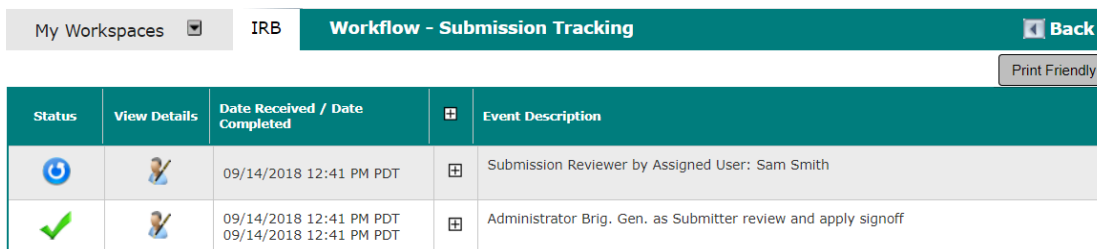


The **Submission Forms** page provides access to all non-study **Submission Forms** available to the IRB, as well as a list of **Outstanding Submission(s)** for these forms.



The left side of the screen provides a **Submission Forms** section. Click the name of a form in this list to open it in the form library, where all versions of the form available in the system are accessible. Options are available to **Copy Form**, **Add a New Form**, **Compare Two Versions** if more than one version of a form is available, and **Delete Selected Form(s)** that have not yet been submitted.

The **Outstanding Submission(s)** section of the page lists outstanding submissions of non-study submission forms in the system. Click the **Routing in Progress** icon in the **Track Location** column to open the **Workflow - Submission Tracking** page for the form, as shown below.



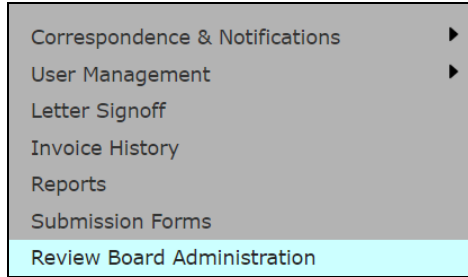
Click **Back** to close the **Workflow - Submission Tracking** page and return to the **Submission Forms** screen.

To view a read-only copy of the form, click the name of the form in the **Request Type** column.

To edit the form, click the **Retract Submission** button. The button changes to read **Send Submission**. Open the form again to revise it. After making and saving desired changes to the form, exit the form and click the **Send Submission** button to re-submit the form.

Review Board Administration

The **Review Board Administration** menu is used to set up configuration lists, define outcome letters and invoices, define meeting agenda and minutes templates, and set up automatic review board related notifications.



See the IRB Assistant – Review Board Administration manual for more information about these features.

Tasks

The Tasks panel on the IRB Assistant Workspace allows the user to view and manage all action tasks that are generated by the system. If configured, the panel will have three tabs: “All Tasks”, “Study Tasks”, and “Project Tasks”.

“All Tasks” displays all action items in one queue.

Click to open	Task Type	Date Received	Description	Priority	Complete By
<input type="checkbox"/>	Reviewer Assignment	07/21/2021 12:40 PM PDT	John Smith has been assigned as the Primary for a Designated Review on the Study Amendment Form, assigned by John Smith	No Priority	<input type="text"/>
<input type="checkbox"/>	Project Waiting Submission	07/21/2021 09:19 AM PDT	Sponsor Approval Request Form is waiting to be submitted	No Priority	<input type="text" value="07/30/2021"/>
<input type="checkbox"/>	Analyst Assignment	07/20/2021 03:48 PM PDT	John Smith has been assigned as the analyst, assigned by John Smith	Low	<input type="text"/>
<input type="checkbox"/>	Analyst Assignment	07/20/2021 10:05 AM PDT	John Smith has been assigned as the analyst, assigned by John Smith	Medium	<input type="text"/>
<input type="checkbox"/>	Reviewer Assignment	07/20/2021 09:50 AM PDT	John Smith has been assigned as the Primary for a Designated Review on the Initial Review Submission Form, assigned by John Smith	High	<input type="text" value="09/15/2021"/>

If a user clicks on the check box for an item a **Clear All Task(s)** button will appear.

Click to open	Details	Task Type	Date Received	Study Status	Study Title	Study Alias	Principal Investigator	Review Board
<input checked="" type="checkbox"/>		Reviewer Assignment	06/18/2021 01:30 PM PDT	Active	Serum Ferritin as a Predictor for Development of Anemia in Pregnancy		Investigator, John	IRB
<input type="checkbox"/>		Submission Cutoff	06/10/2021	Draft	SKK Lumbar Disc Herniation Study			

Clicking this button will dismiss the task but will not complete the action item. When clicked the user is presented with the following warning message.

Confirm

Warning: Clearing the selected task(s) will remove them from your list.

This does not mean they are COMPLETED! The work behind these task(s) remains open.

Are you sure you want to clear these task(s)?

Within each task queue, the user can also filter by Outstanding and Completed tasks, RB number, Title, and Alias using the functionality at the top of the task queue.

All Tasks Outstanding Completed

All Tasks Study Tasks Project Tasks

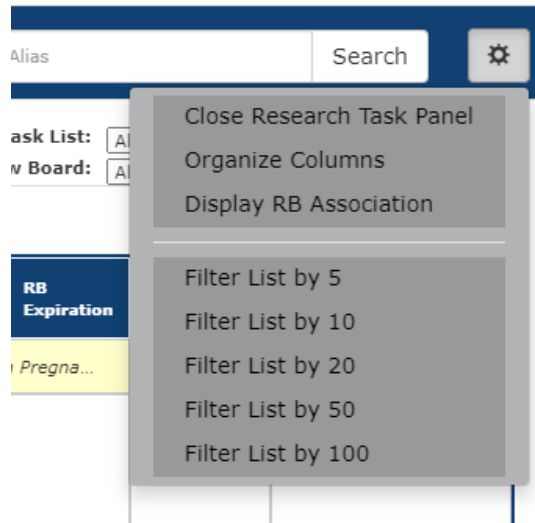
Task List : All
Filter By : --none--

Clicking on the icon will open the task and take the user to the area of the system or form to complete the task. Users can also click on the icon to view more detail about a task.

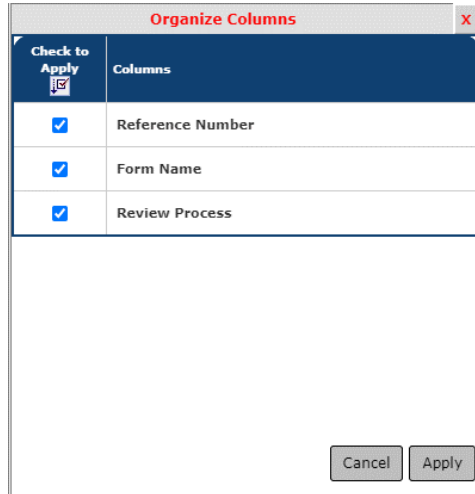
The screenshot shows the 'Study Tasks' interface. At the top, there are tabs for 'Outstanding' and 'Completed', a search bar, and a gear icon. Below the tabs are buttons for 'All Tasks', 'Study Tasks', and 'Project Tasks'. On the right, there are dropdown menus for 'Task List', 'Review Board', and 'Filter By'. The main area displays a table of tasks. The first task is highlighted with a red box, showing a detailed view with columns for 'Reference Number', 'Form Name', and 'Review Process'. The second task is also highlighted with a red box, showing a detailed view with columns for 'Reviewer status', 'Date Received', 'Study Status', 'Study Title', 'Principal Investigator', 'Review Board', 'RB Number', 'RB Expiration', 'Priority', and 'Complete By'.

Click to open	Details	Task Type	Date Received	Study Status	Study Title	Principal Investigator	Review Board	RB Number	RB Expiration	Priority	Complete By
<input type="checkbox"/>		Reviewer Assignment	07/21/2021 12:40 PM PDT	Active	COVID 19 Complications in adults 55 and older	Investigator, John	IRB	IRB-21-483	06/30/2022	No Priority	<input type="text"/>
Reference Number			Form Name			Review Process					
001330			Study Amendment Form			Process Administratively					
<input type="checkbox"/>		Analyst Assignment	07/20/2021 10:05 AM PDT	Active	COVID 19 Complications in adults 55 and older	Investigator, John	IRB	IRB-21-483	06/30/2022	Medium	<input type="text"/>

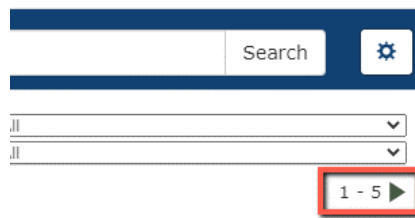
Clicking on the gear icon in the right-hand corner will open the following menu options.



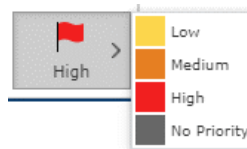
From here the user can close the panel, organize the additional detail columns that were displayed when the icon was clicked, filter by RB association and choose how many results to view at one time. Clicking on the Organize Columns link will open the following popup window, allowing the user to turn on or off columns they do not want to display.



The user may toggle through the tasks displayed by clicking on the right facing arrow in the right corner as shown below.






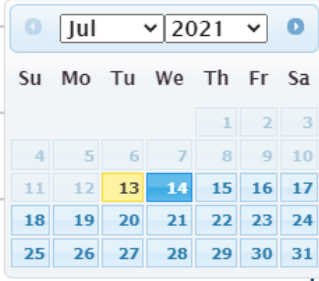


Users can also set the priority of their tasks as Low, Medium and High Priority. Users can click on the button to open the priority menu as shown below.



Users can then select the desired priority and the task will update immediately with page refresh.

<input type="checkbox"/>			Reviewer Assignment	06/18/2021 01:30 PM PDT	Active	Serum Ferritin as a Predictor for Development of Anemia in Pregna...	Investigator, John	IRB	IRB-21-375			<input type="text"/>	
--------------------------	--	--	---------------------	-------------------------	--------	--	--------------------	-----	------------	--	--	----------------------	--

Users can also set the **Complete By** date for a task.

Priority	Complete By
 > Medium	⊗ 07/14/2021 
 > Medium	⊗ 
 > High	⊗
 > High	⊗

This will place an event on the system calendar that will link the user to the task as shown below.

Calendar

prev next today July 2021 month week day

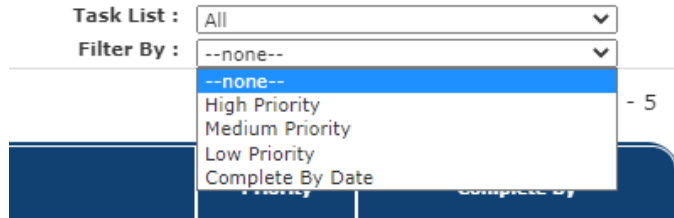
Sun	Mon	Tue	Wed	Thu	Fri	Sat
27	28	29	30	1	2	3
4	5	6	7	8	9	10
11	12	13	14 Reviewer Assignment	15	16	17
18	19	20	21	22	23	24

Clicking on the task on the calendar will take the user to the task to be completed.

If configured, users will also receive a calendar invite to their notification email on file for the event. Accepting the event will place an All-Day appointment on their email calendar. Any changes in iRIS™ to the **Complete By** date will send an updated calendar invite for the user to accept.

A notification can also be configured in System Administration to send out reminder messages regarding tasks with **Complete By** dates. Please see your System Administration manual for more details.

Users can also filter tasks by priority and by **Complete By** date from the “All Tasks” view as shown below.



Users can then click on the “Study Tasks” or “Project Tasks” tab to view specific information regarding studies and projects that the task is linked to. Below is the view from “Study Tasks”.

Study Tasks												
Outstanding											Completed	
All Tasks											Study Tasks	Project Tasks
Click to open	Details	Task Type	Date Received	Study Status	Study Title	Principal Investigator	Review Board	RB Number	RB Expiration	Priority	Complete By	
<input type="checkbox"/>		Reviewer Assignment	06/18/2021 01:30 PM PDT	Active	Serum Ferritin as a Predictor for Development of Anemia in Pregna...	Investigator, John	IRB	IRB-21-375		Low	<input type="text"/>	
<input type="checkbox"/>		Submission Signoff Denied	06/10/2021 01:15 PM PDT	Draft	SKK Lumbar Disc Herniation Study	Smith, John	IRB	IRB-21-422		High	<input type="text"/>	

Any changes to the priority and **Complete By** date will display on other tabs as applicable.