IRB Assistant

IRB Assistant Overview

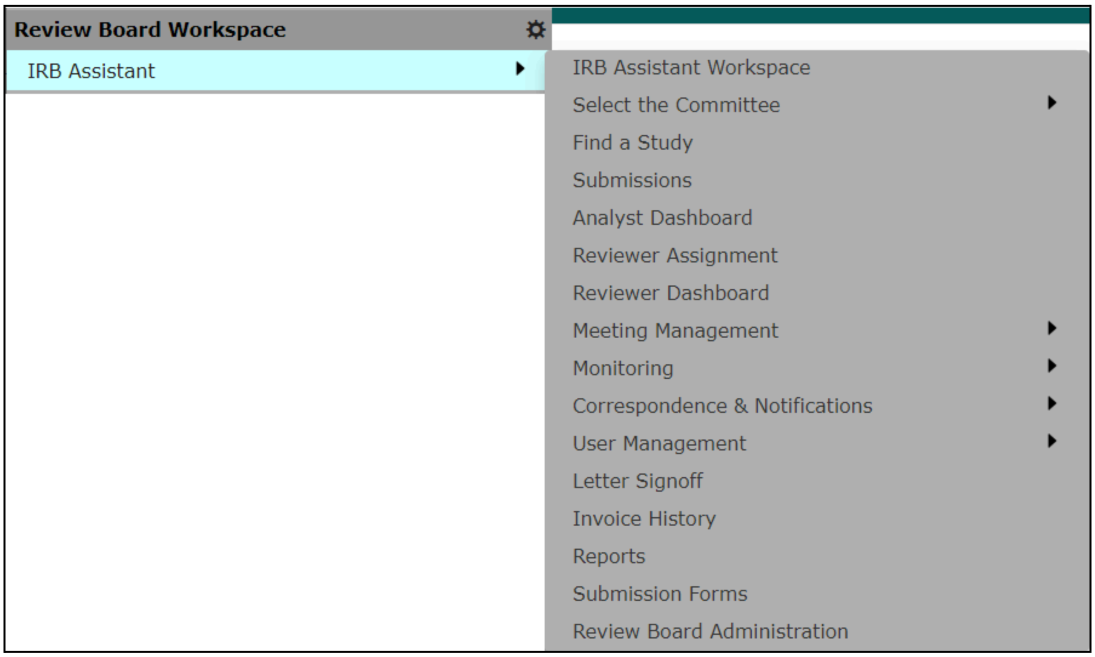
Version 11.02

Contents

IRB Assistant Manual

IRB Assistant Overview

The IRB Assistant is available to streamline your institution's entire Review Board management process. The IRB Assistant works similarly to other review boards. The IRB Assistant is used throughout the entire process of submission reviews, signoffs, member reviews, meetings, and more.



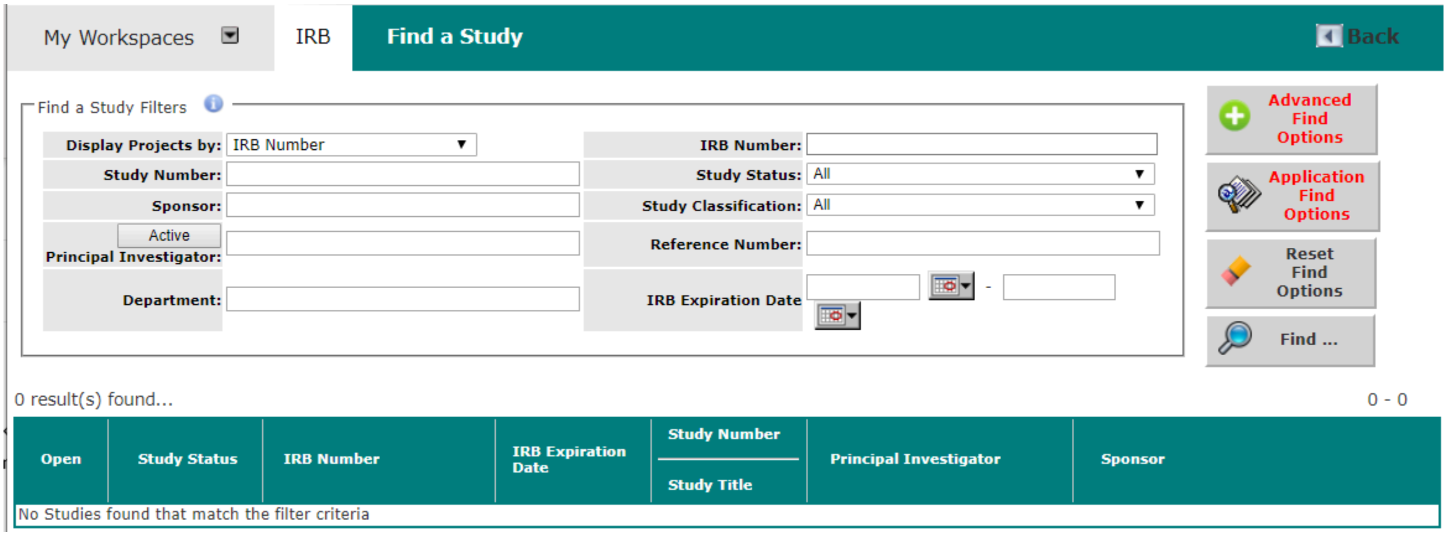
Note: Depending on a user's access, they may not have all the items shown above available to them. See the Review Board Administration manual for additional details regarding adding or removing access for roles on review boards. Depending on the setup of your system label, the terminology throughout this manual might differ.

Find a Study

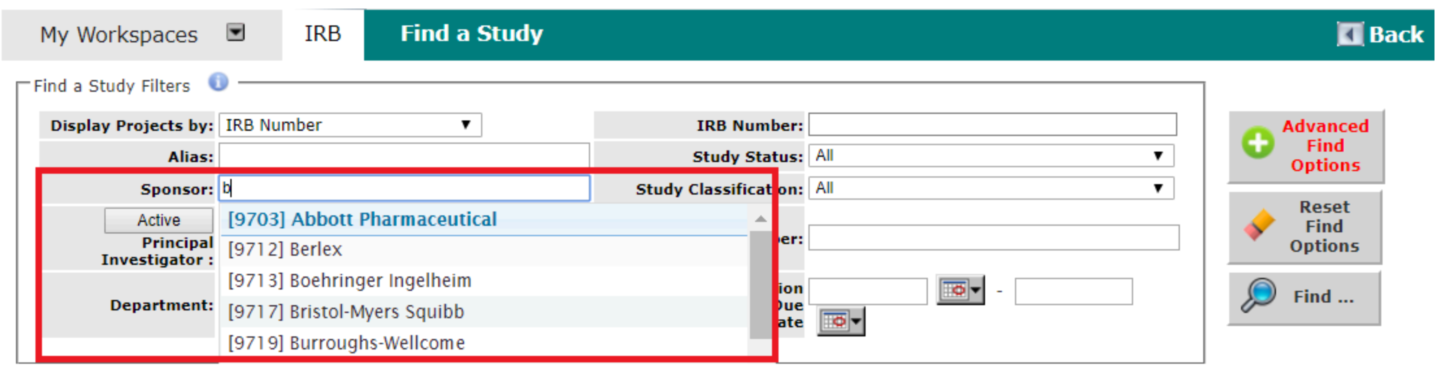
The **Find a Study** item allows users to search the entire system for studies. Find a Study is a tool generally used by System Administrators and IRB Coordinators. Depending on system settings, Find a Study within IRB Assistant may or may not allow the search to expand across the entire system, or just for studies within the IRB.

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

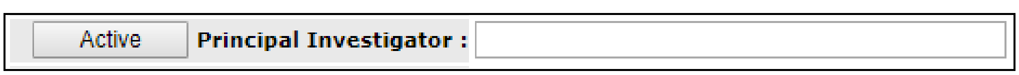
You can also change the display of the study numbering by selecting from the **Display Projects By** drop-down list. The numbers available here depend on what modules are configured into your system. The example below shows the page when IBC Number is selected from the drop-down list. The page reflects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



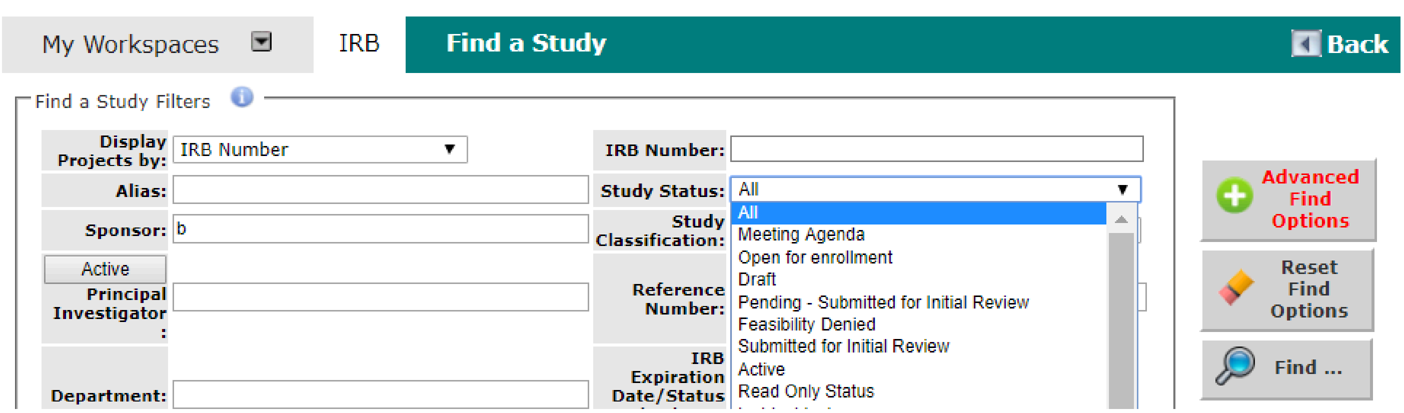
Some of the search fields are auto-populating fields. You begin by typing the name, and the system will return any resulting matches for you to select. **Sponsor**, **Principal Investigator**, **Department**, and **IRB Number** are all auto-populating fields.



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



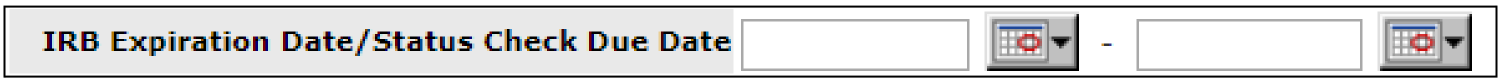
Also available are drop-down menus of available Study Statuses and Study Classifications that you can choose from.



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

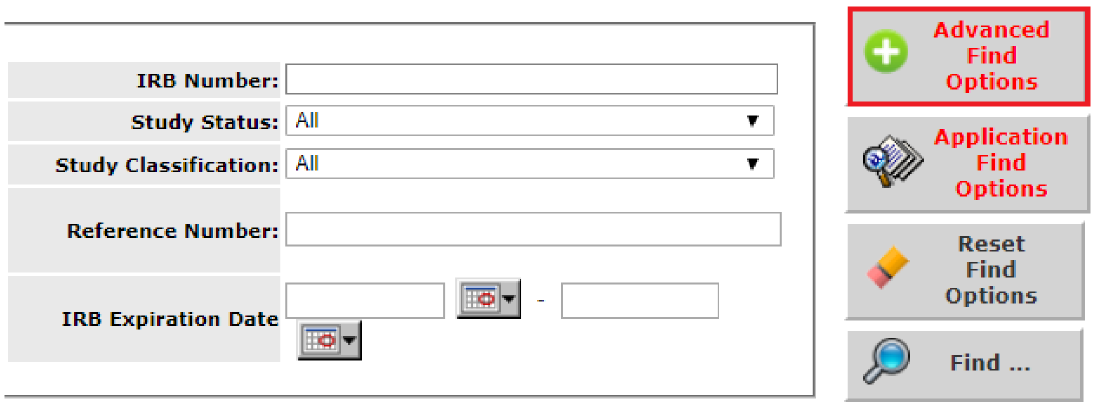
Note: You must enter the entire Reference Number in this field, except for the leading zeros. For example, if a submission is Reference Number “000288” you would need to enter “000288” or “288” to filter the results correctly.

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

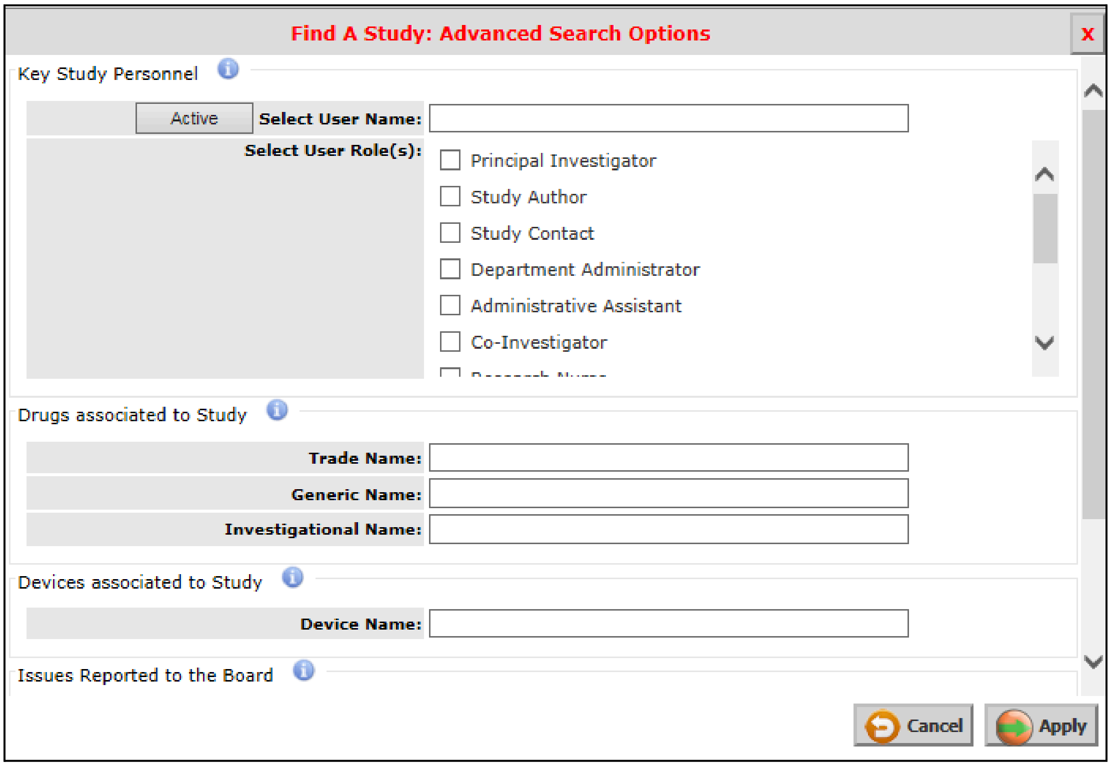


Reset Find Options – This button will allow you to reset the study filters and begin a new search.

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

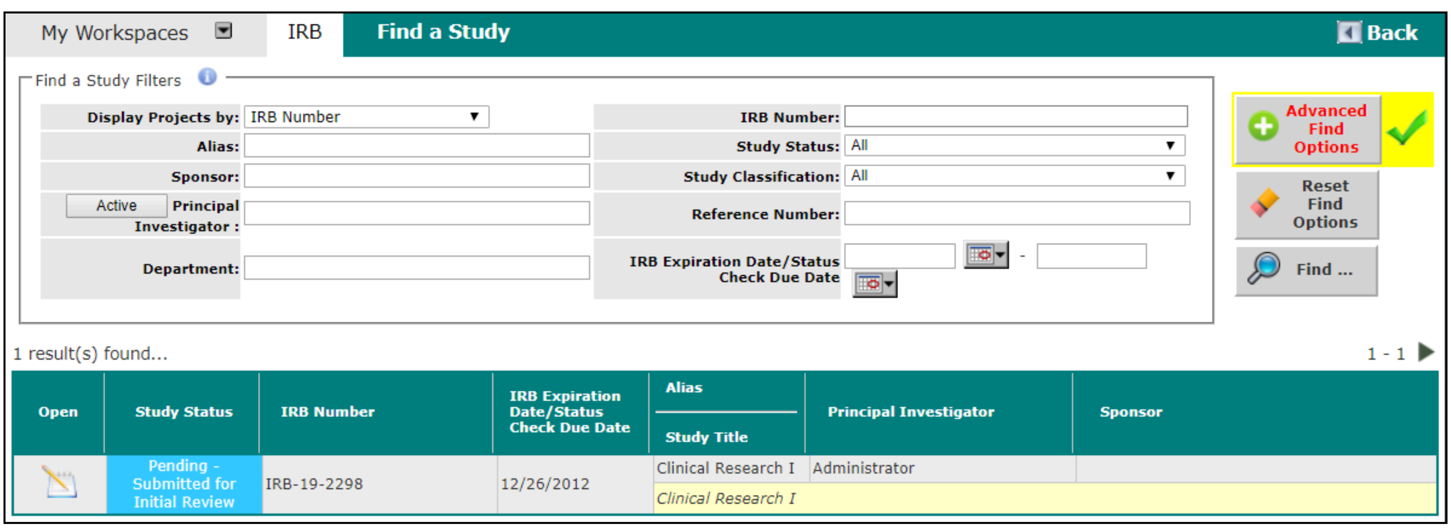


This will allow you to filter by study personnel, study drugs, devices, issue reports, and key words in the Study Title. You can choose to use one or all options in the Advanced Search Options by selecting an item from a drop-down list and/or typing in the keywords. When you are finished, click the **Apply**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

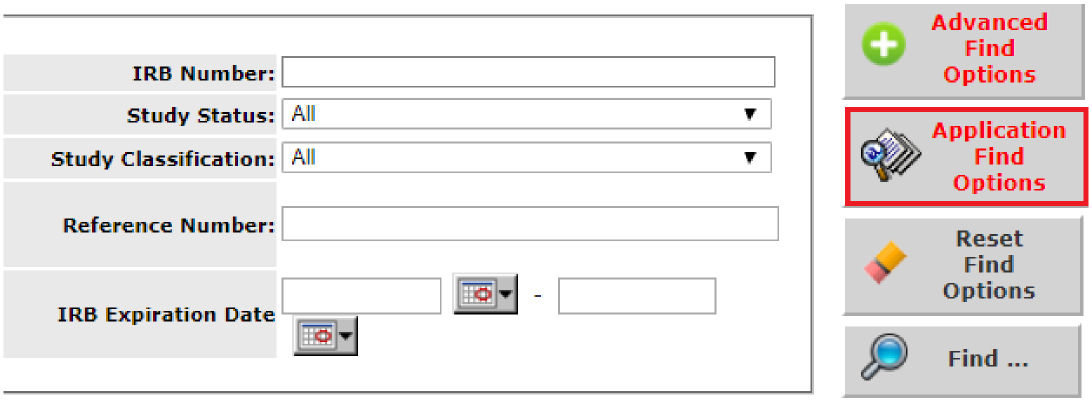


When you click the **Find** button, the system will return any matching studies, depending on the filters you selected. If you added Advanced Search Options, the button will update with a yellow border to indicate extra filters are in use.

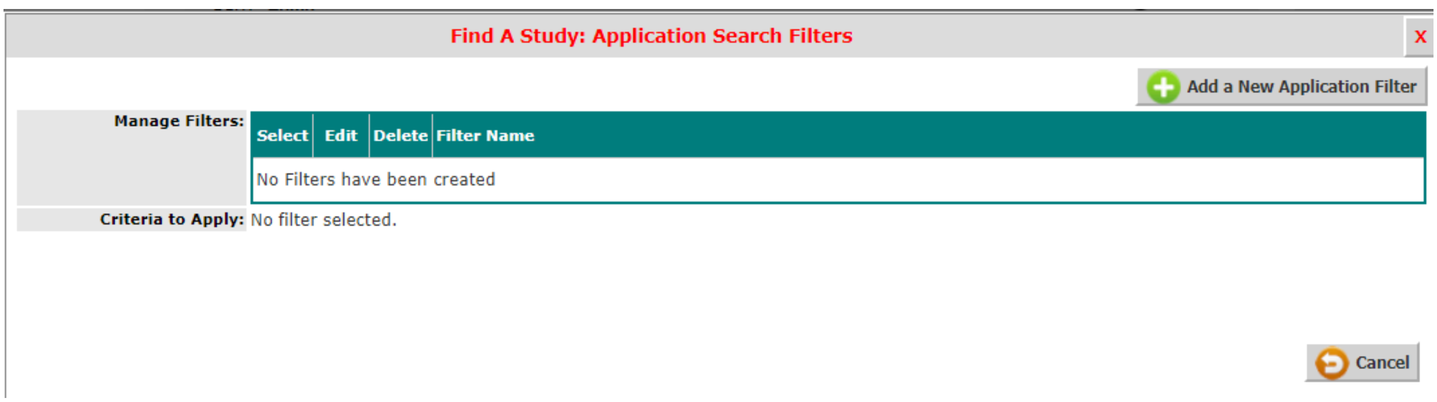
Once you find the study you are looking for, you can click the  icon in the Open column to open the study record.



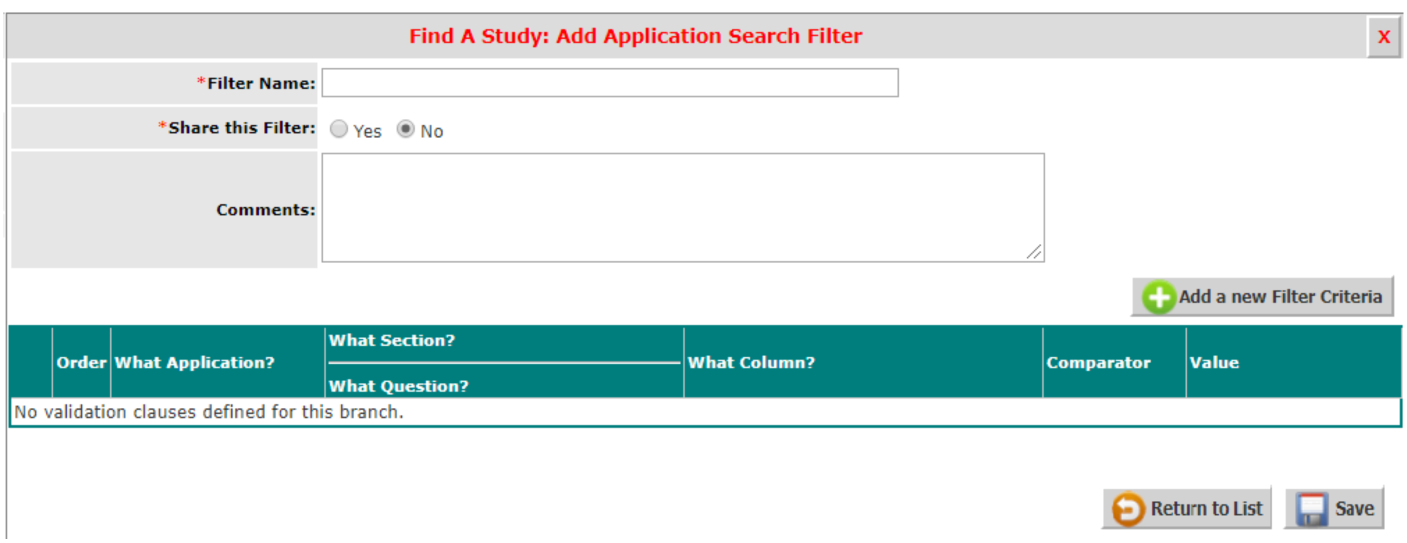
For application specific search options, click on the **Application Find Options** button.



The Application Find Options will allow you to define new filters in the pop-up window. Any existing filters will appear in the **Manage Filters** tab.



Click the Add a **New Application** Filter.



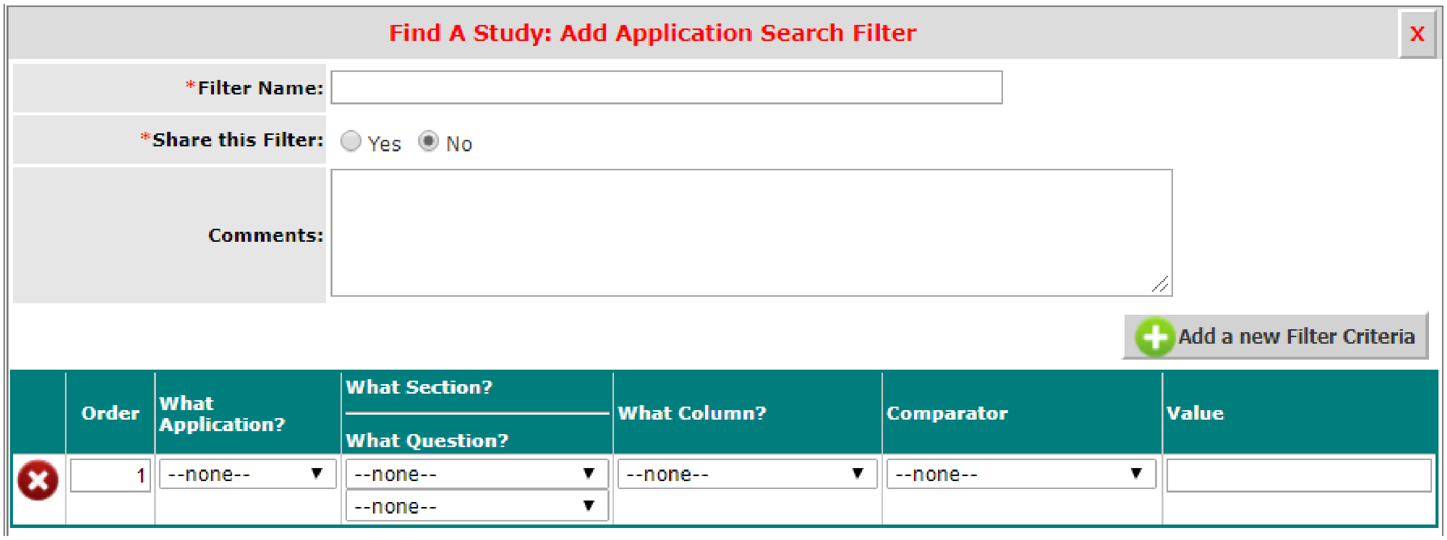
The following screen will allow the user to define the different parameters.

Filter Name -The name of the filter being defined.

Share this Filter-This will determine if the filter will be shared with other users. If set to yes, then all iris users who have global study access will have the ability to view and use the filter created.

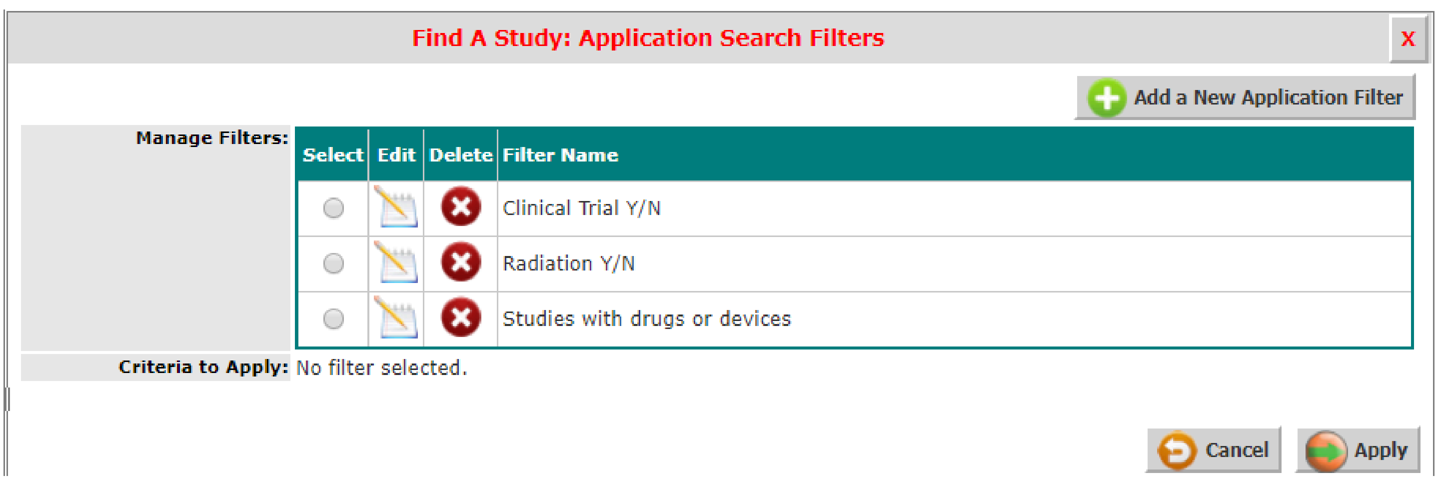
Comments – a description added for the filter.

Select the **Add a New Filter Criteria** to create the parameters define for the filter.

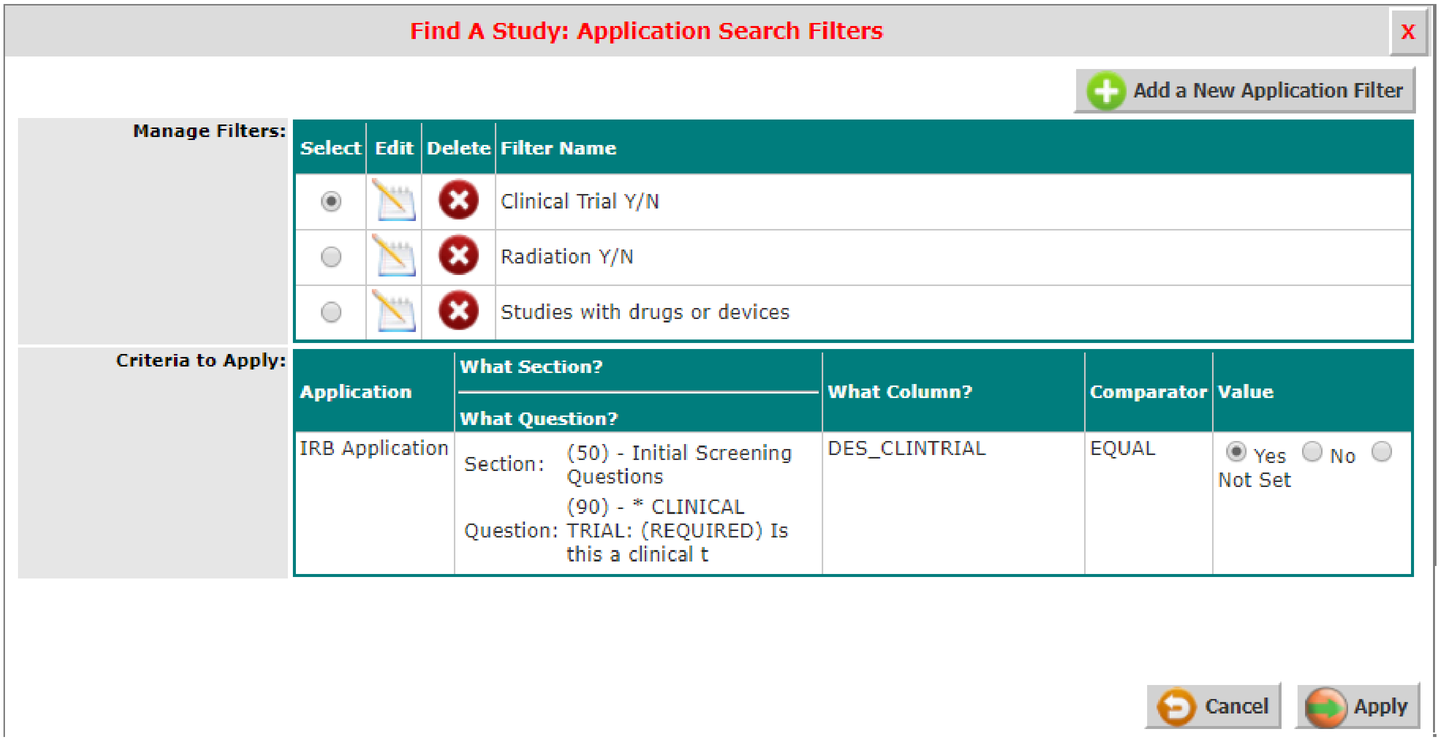


At the bottom of the window you can setup a filter based on the values in the form. The filter criteria are setup to look at the single selection value for a question within the application sections. Select the desired validation from the drop-down list in each column.

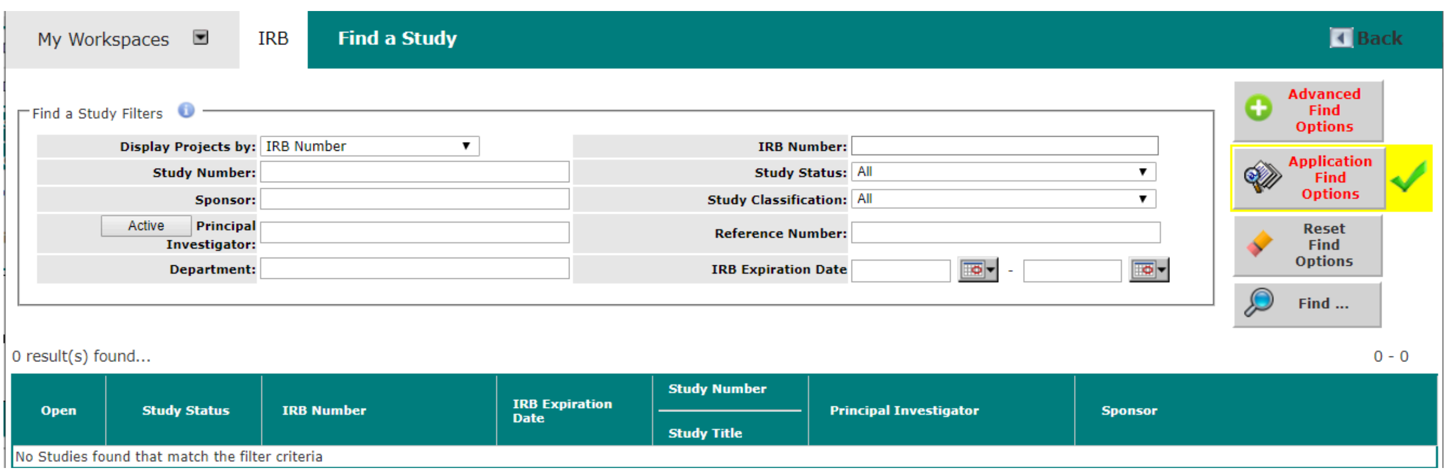
Once you are done creating a filter criterion, select the **Apply** button. The system will then display the criteria that was added to the Manage Filters section. You may add multiple filter criteria in the section.



In the Manage Filters section, you will be able to Select, Edit, or Delete the filter. To select a filter to apply to the search, select the radio button next to the desired filter. When a Filter is selected, it will display in the **Criteria to Apply** section.



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



The other columns on this page are as follows:

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

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

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

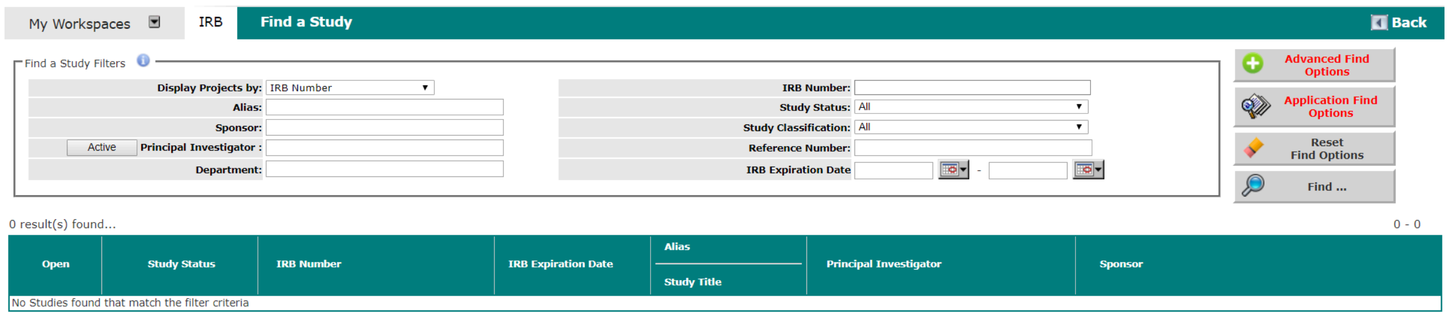
Study Number - This displays the Study Number/Nickname given to the study in the initial section of the Study Application.

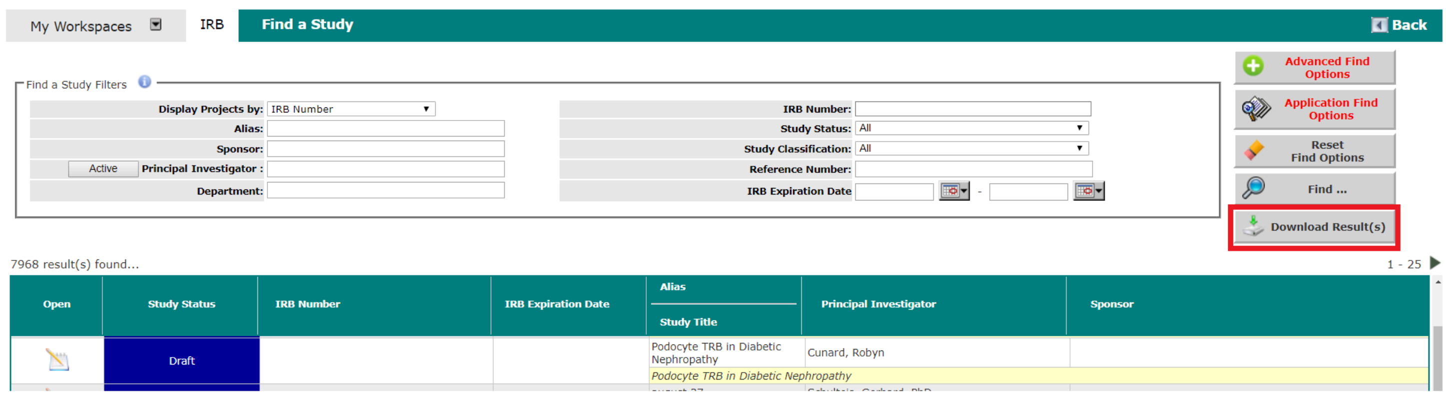
Study Title - This displays the Study Title given to the study in the initial section of the Study Application.

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

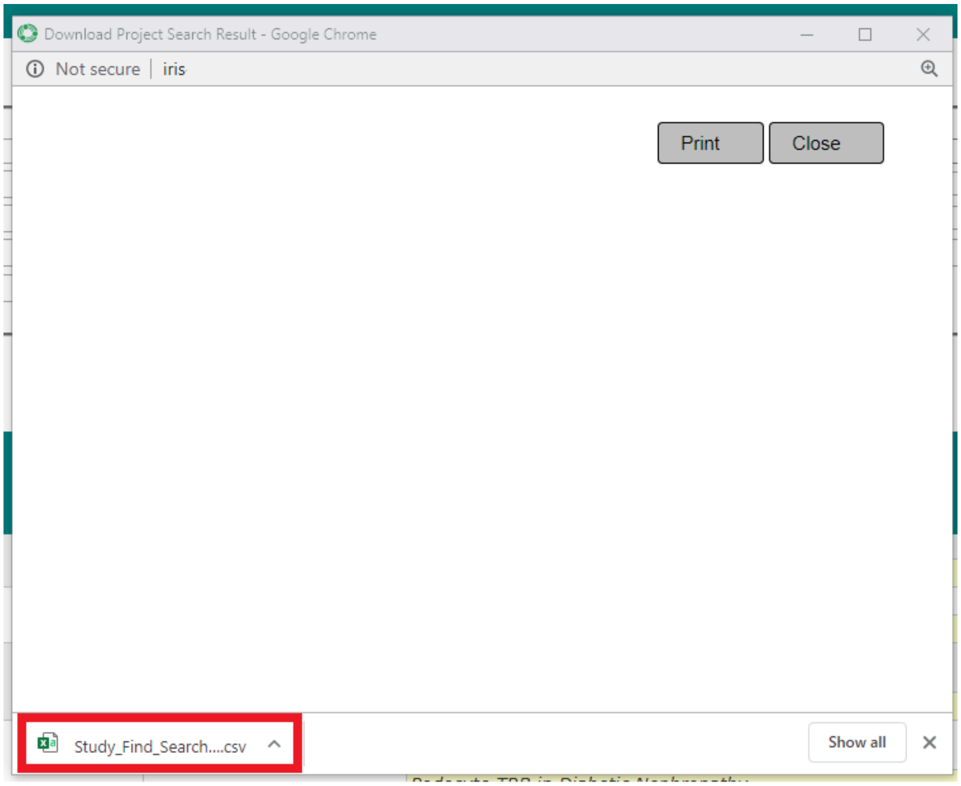
Sponsor – This displays the name of the Sponsor on the study.

After users set their study filters and clicked the Find button, users will now have the option to download the results by clicking on the Download Result(s) button under the Find button.

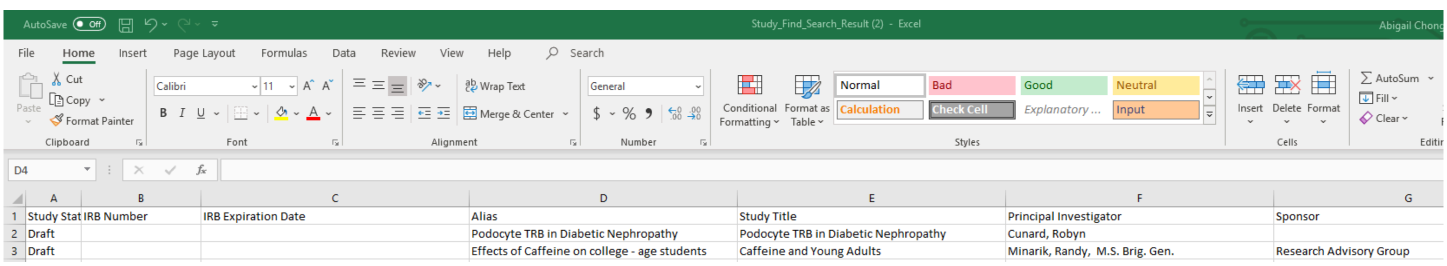




A new window will appear, and the Excel file will download onto the user's computer.

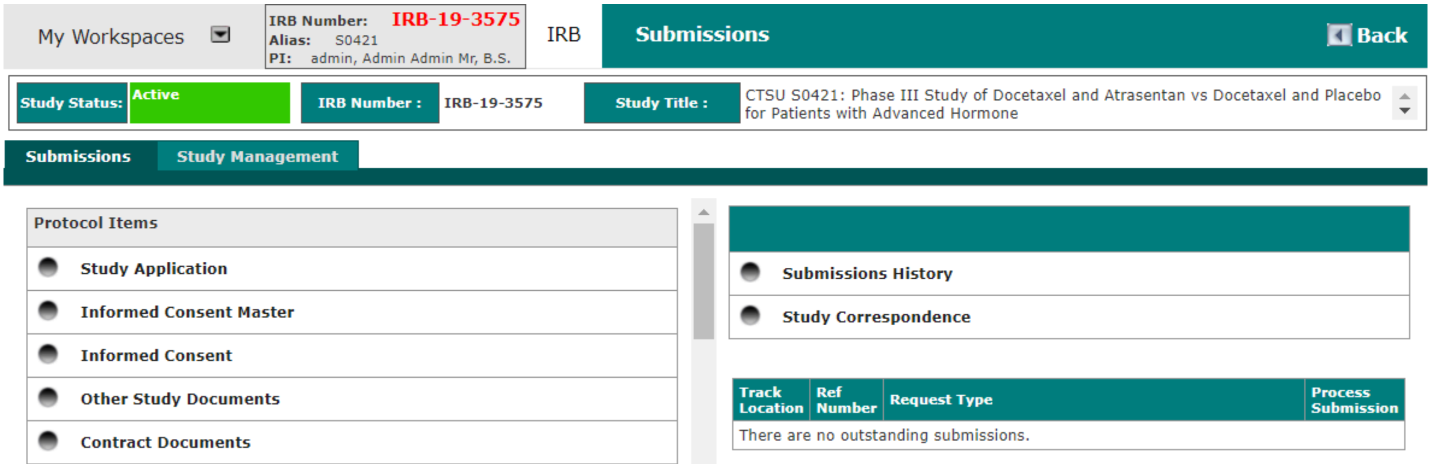


The screen is taken using Google Chrome – other browsers have different download functions.



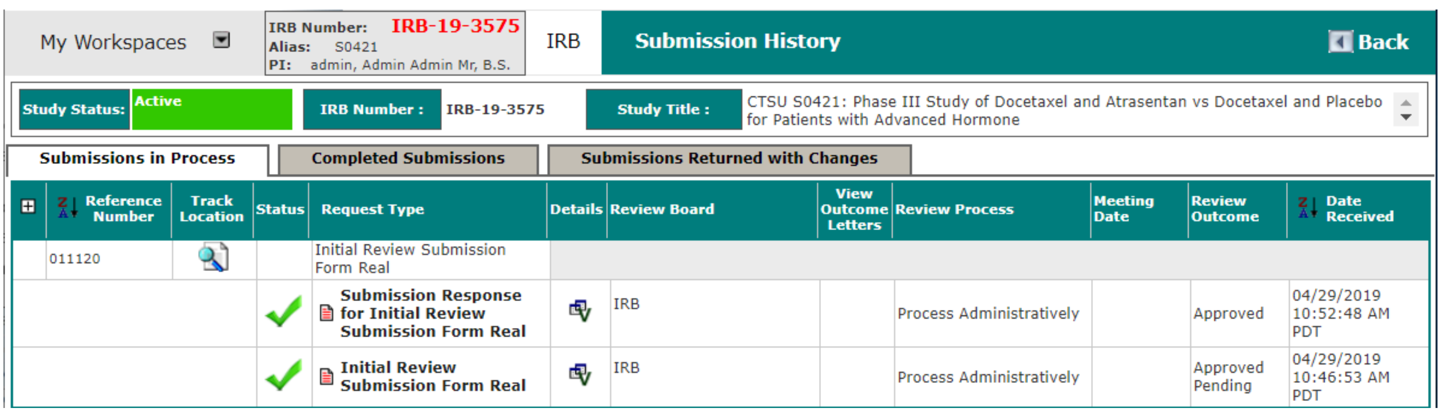
View a Study

To view a study, click the icon in the Open column and you will be brought to the Study Management screens. By default, this page opens to the Submissions tab, which will look similar to the screenshot below.

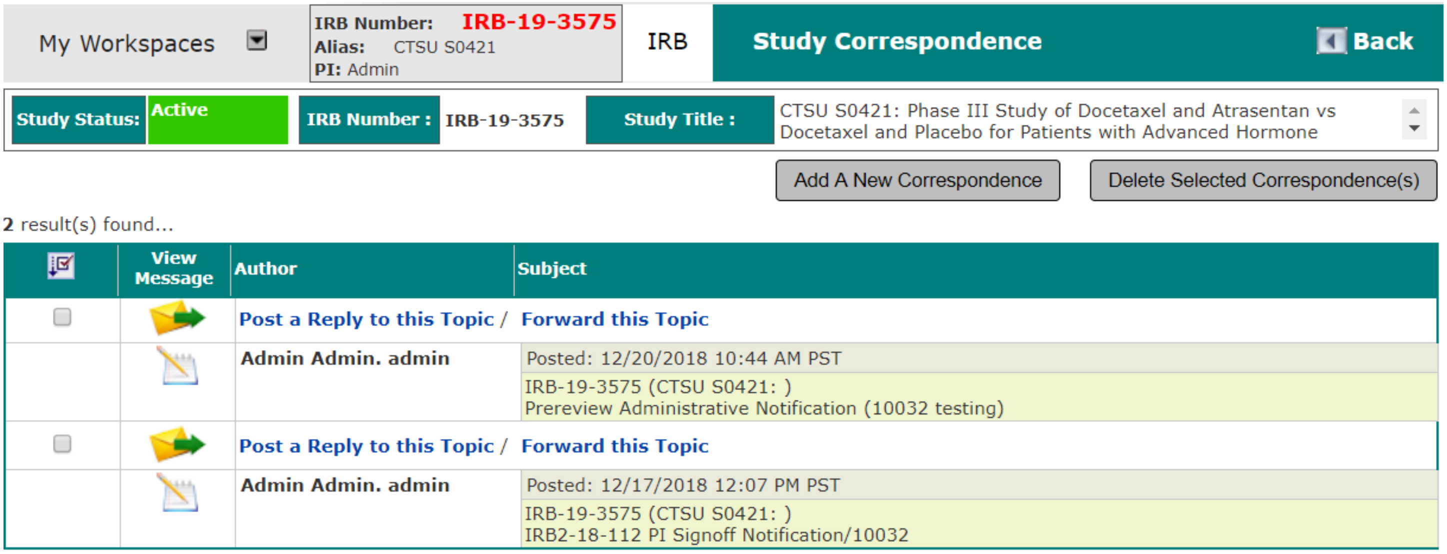


The Submissions tab will display any forms available for viewing by the IRB. You can also access the study's Informed Consents and Other Study Documents, view the Submission History, and view Study Correspondence from this tab.

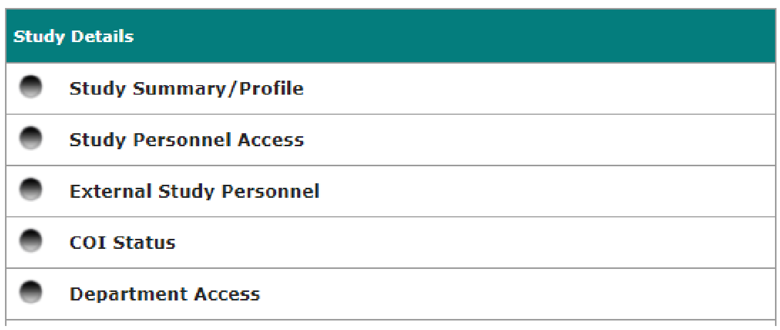
From the **Submissions History Link**, you can track the workflow of the initial submission and any other submission forms processed by the review board (as seen in screen shot below). Clicking on a link under Request Type will open the submission processing screens for that submission.



Clicking on the **Study Correspondence** link provides you with a list of all notifications, signature requests, and notices that pertain to the study (see screenshot below).

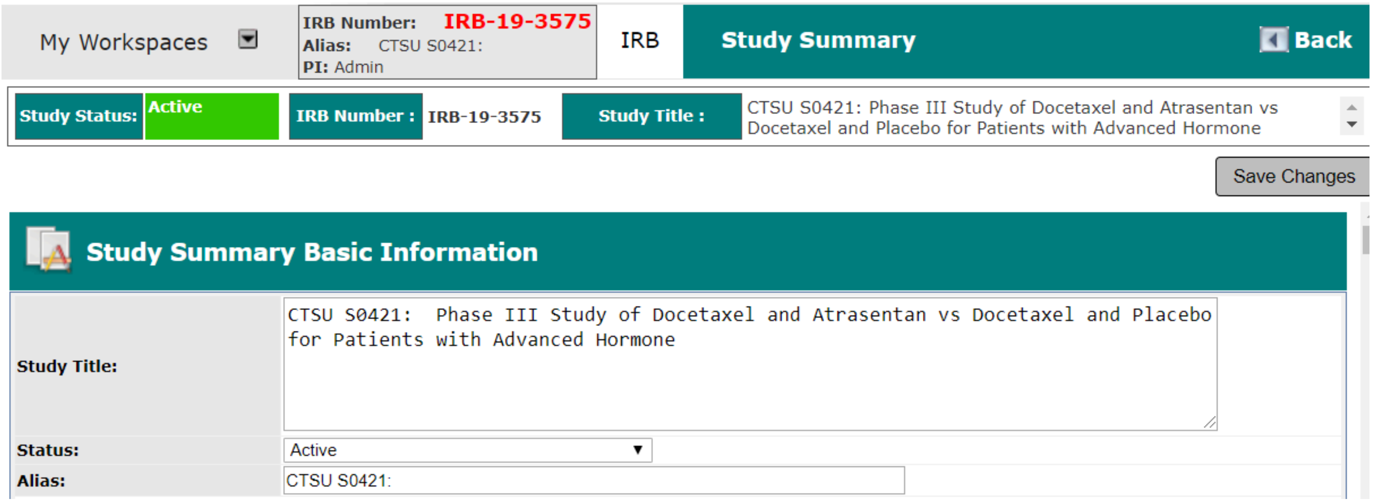


Clicking on the **Study Management** tab brings you to a screen where you can access information regarding the Study (with the exception of patient information).



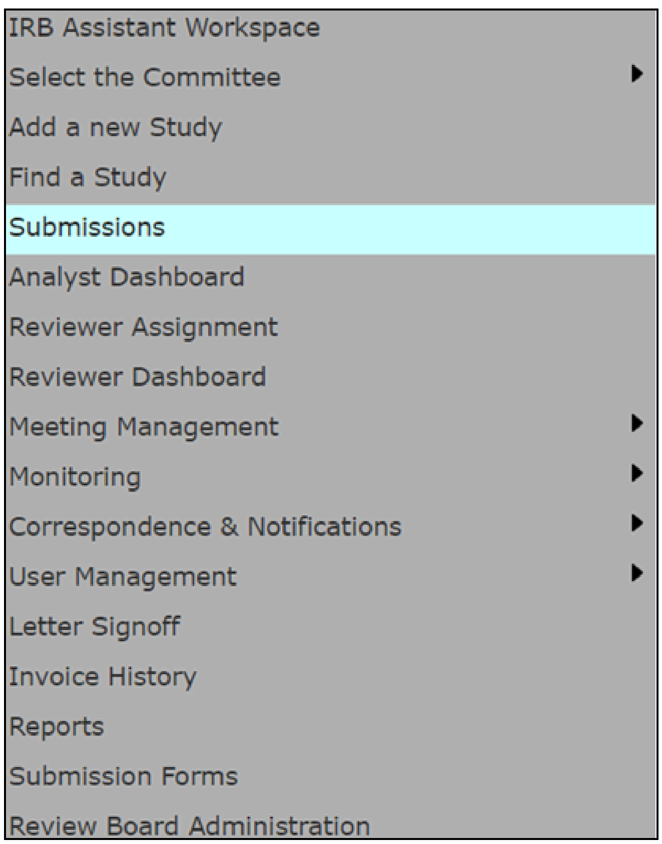
By selecting the icons under one of the main headings (e.g. **Study Details**, **Sponsors & Subrecipients**, you will be linked to various information that has been completed for this particular study.

The Study Summary/Profile contains basic information about the study like personnel, review board information, study details, and so on. The screenshot below should look similar to your Study Summary screen but might contain extra fields about the study. Certain fields may or may not be in use and can be turned on and off under Review Board Administration.

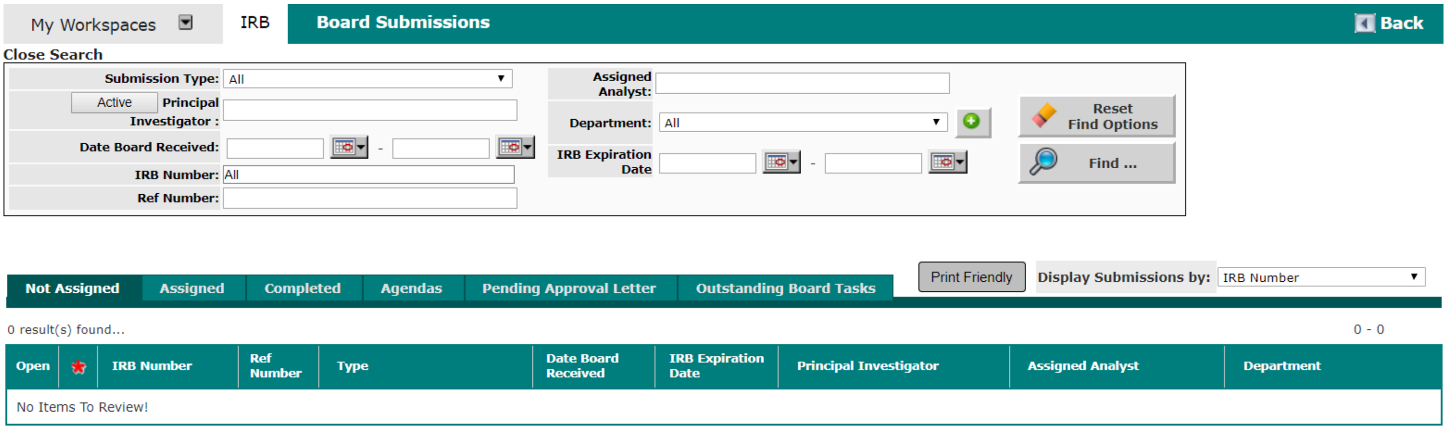


Submissions

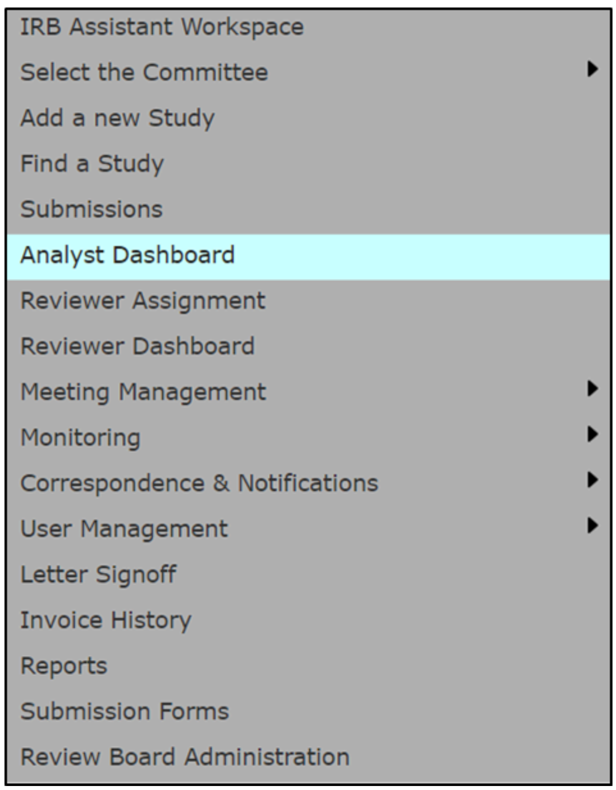
The **Submissions** link allows you to view all submissions sent to the IRB, as well as process those submissions. Your instance of iRIS may display either **Submissions** or **Committee Submissions** in the IRB Assistant list, depending on how your system is setup according to the review board property. See the IRB Assistant - RB Administration Manual for more information.



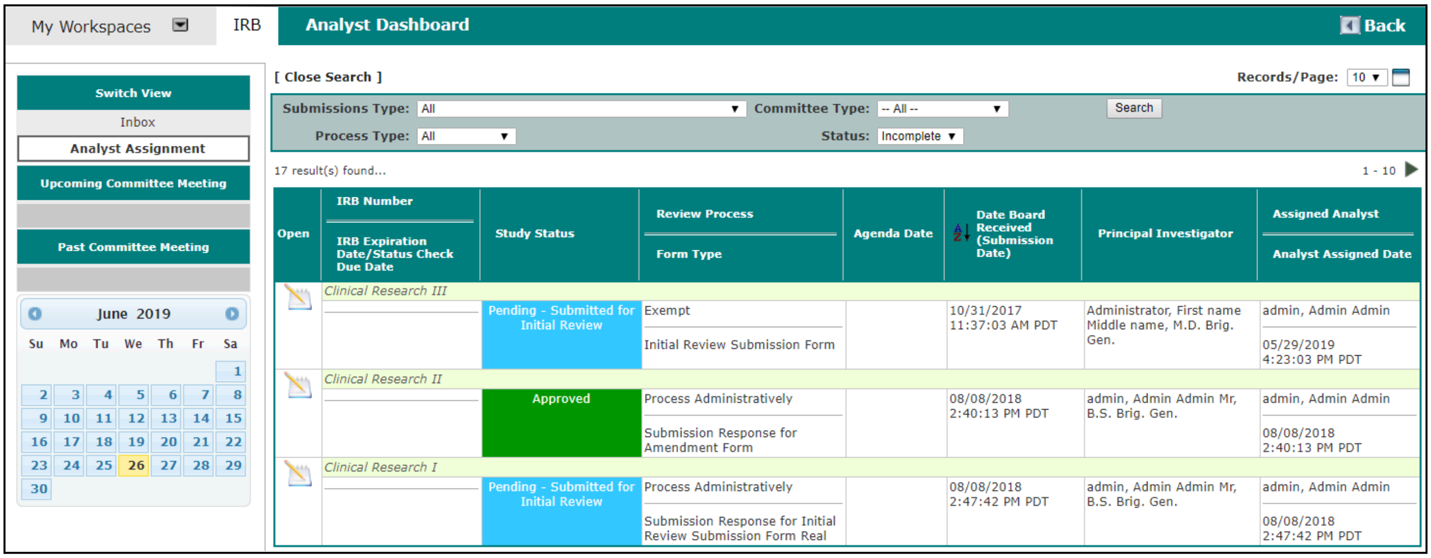
When you click on the Submissions or Committee Submissions link, a page will open displaying all submissions, divided into four tabs: **Not Assigned**, **Assigned**, **Completed**, **Agendas, Pending Approval** and **Outstanding Board Tasks**. Upon opening the Submissions link, the system will automatically default to the Not Assigned tab. Information regarding each submission populates in sortable columns to make it easier to locate a particular submission. See the IRB Assistant - Submission Processing manual for more information.



Analyst Dashboard

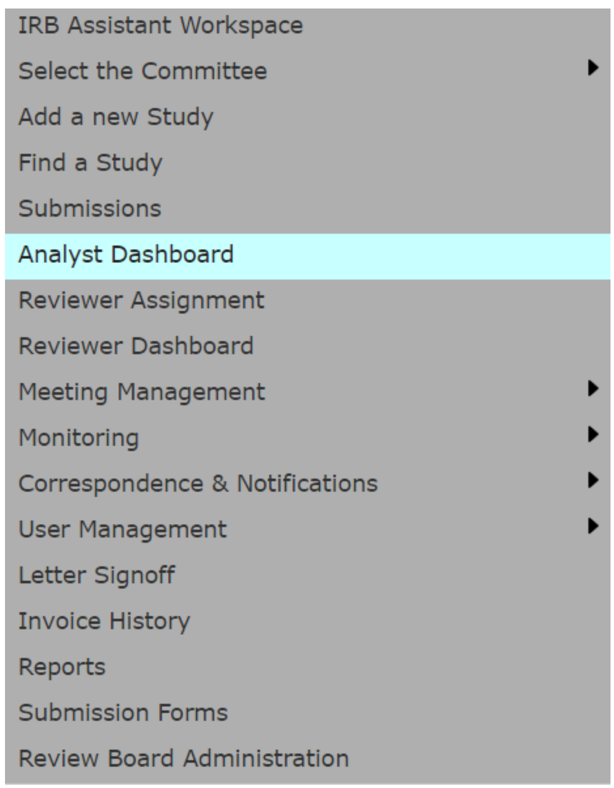


The **Analyst Dashboard** allows you to search for and access studies in the system. Within the Analyst Dashboard you can view your specific analyst assignments and open the associated submissions, which will allow you to access study-related information, determine a review process, assign reviewers, add stipulations, designate a submission outcome and approval dates, generate outcome letters, access upcoming meeting dates, and more. You can also view the agendas for upcoming and past meeting dates.

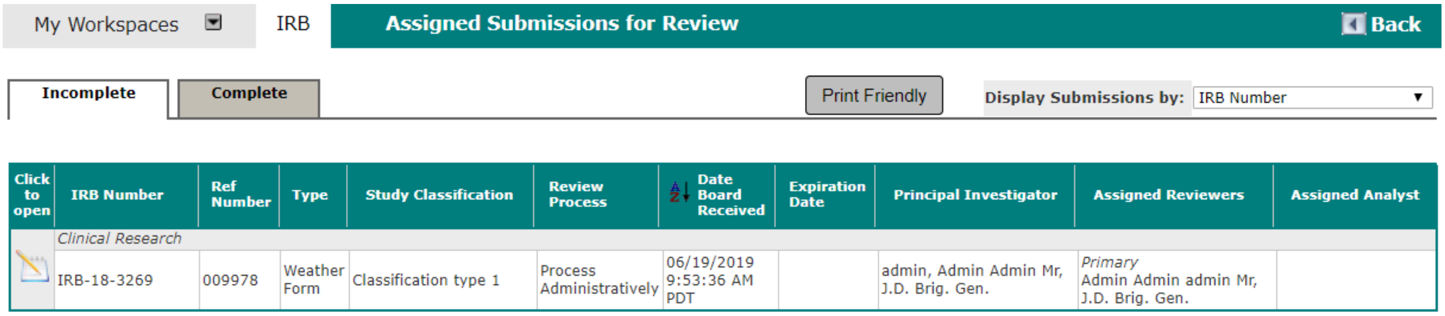


See the IRB Assistant - Analyst Dashboard manual for more information.

Reviewer Assignment



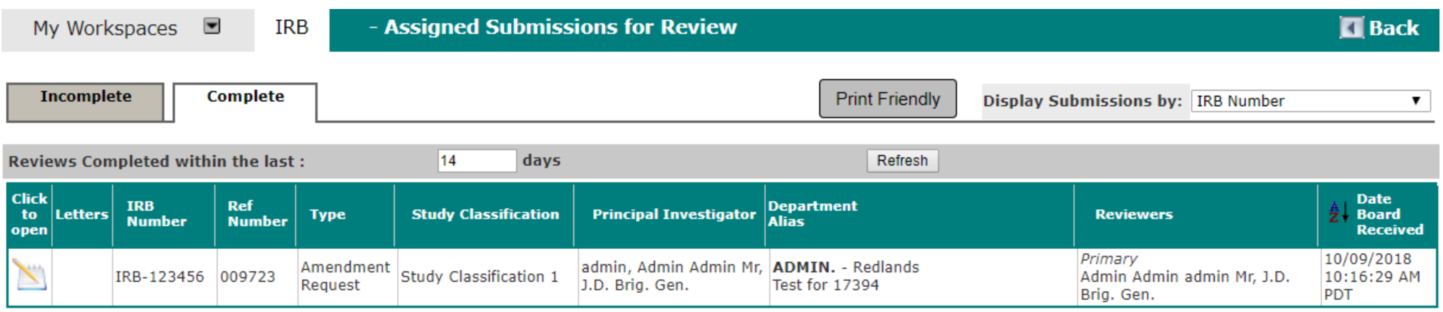
The **Reviewer Assignment** area of IRB Assistant allows you to view and open your current Incomplete and Complete reviewer assignments. By default, the Reviewer Assignment screen opens to the Incomplete tab.



Click to open	IRB Number	Ref Number	Type	Study Classification	Review Process	Date Board Received	Expiration Date	Principal Investigator	Assigned Reviewers	Assigned Analyst
	Clinical Research									
	IRB-18-3269	009978	Weather Form	Classification type 1	Process Administratively	06/19/2019 9:53:36 AM PDT		admin, Admin Admin Mr, J.D. Brig. Gen.	*Primary* Admin Admin admin Mr, J.D. Brig. Gen.	

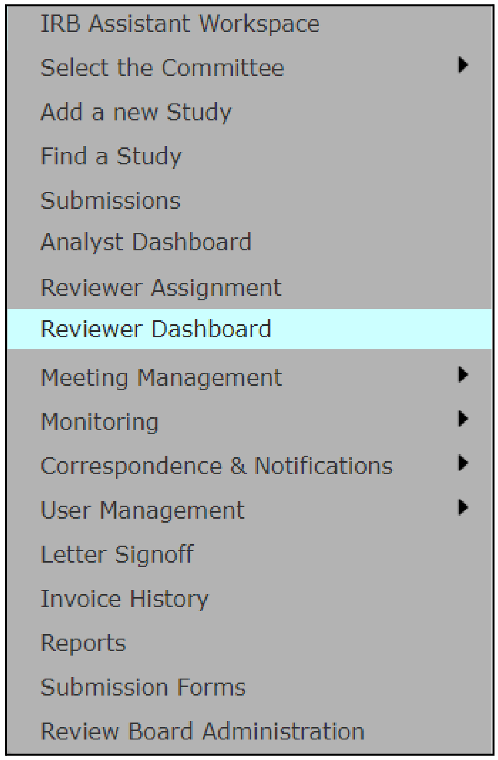
By clicking the icon in the “Click to open” column, you will be directed to your reviewer assignment. You can choose to display submissions by IRB Number or by another type of study numbering using the “Display Submissions by:” dropdown menu.

On the Complete tab, you can enter a number in the “Reviews Completed within the last:” text box. This will determine how far back your completed review assignments will be displayed. Opening an assignment will take you to your completed form.



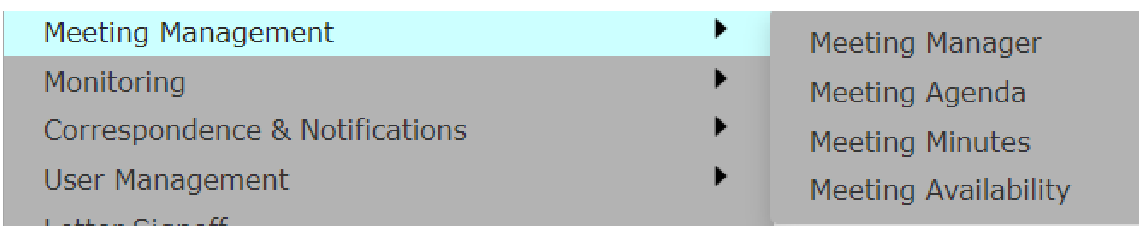
Click to open	Letters	IRB Number	Ref Number	Type	Study Classification	Principal Investigator	Department Alias	Reviewers	Date Board Received
		IRB-123456	009723	Amendment Request	Study Classification 1	admin, Admin Admin Mr, J.D. Brig. Gen.	**ADMIN.** - Redlands Test for 17394	*Primary* Admin Admin admin Mr, J.D. Brig. Gen.	10/09/2018 10:16:29 AM PDT

Reviewer Dashboard



The **Reviewer Dashboard** allows you to access any submission you have been assigned to review, access internal submission routing assignments, and review submissions for both upcoming and past committee meetings. See the IRB Assistant - Reviewer Dashboard manual for more information.

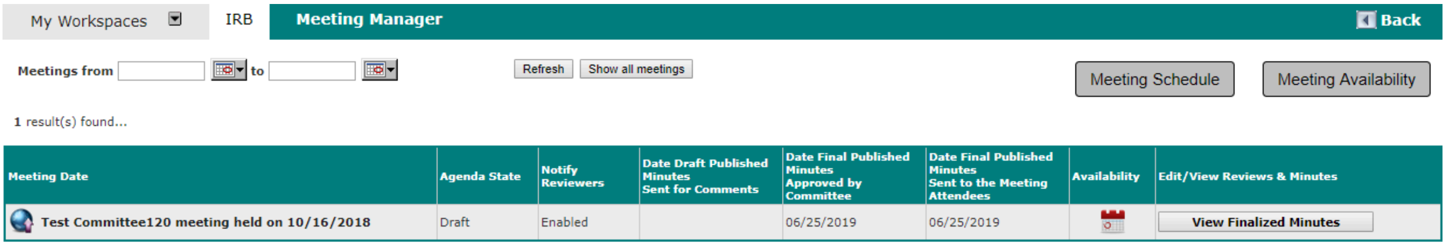
Meeting Management



The **Meeting Management** section of IRB Assistant contains four subsections, **Meeting Manager**, **Meeting Agenda**, **Meeting Minutes**, and **Meeting Availability**. This functionality will allow you to manage all aspects of meetings within iRIS.

Meeting Manager

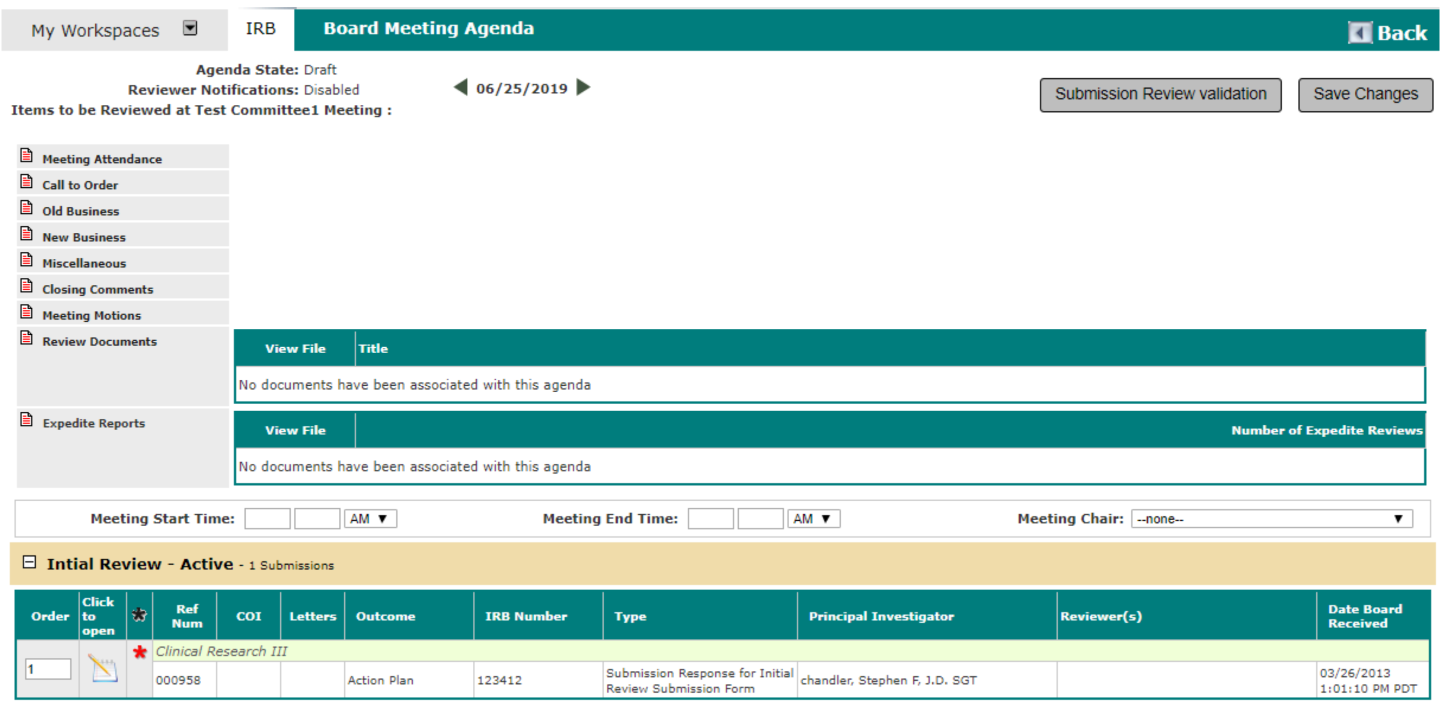
Meeting Manager allows you to view meeting agendas and set meeting availability. Access to this menu item can be controlled through the Role Access Matrix in Review Board Administration. The Meeting Manager is typically reserved for a review board administrator. You can view current agendas and publish/create Word document versions of Agendas and Meeting Minutes to send to IRB members. The Agenda and Meeting Minutes templates are created under Review Board System Setup.



Please see the IRB Assistant - Meetings manual for more information.

Meeting Agenda

The **Meeting Agenda** area of the system allows you to view information related to specific meeting dates. You can access past and future meetings from this area. If you have a review board administrator role, you can come to this area to prepare for an upcoming meeting. If your role does not have this administrative privilege, you can come to this area to look at submissions placed on a particular meeting date. Read/write access for the meeting agenda is configured under Setup Role Access in Review Board Administration.

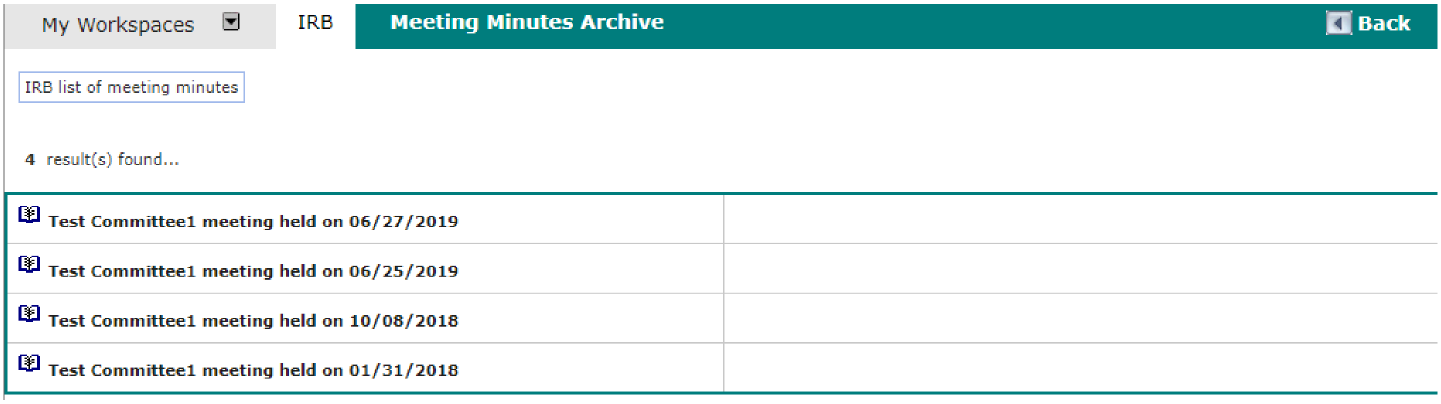


The meeting agenda page will open by default to the next upcoming meeting. You can flip to a different meeting date by clicking on the arrows by the meeting date at the top of the page. See the IRB Assistant - Meetings manual for more information

Meeting Minutes

Meeting Minutes allows you to access published meeting minutes for any past meeting. This is an area where board members can go to pull minutes from a past meeting.

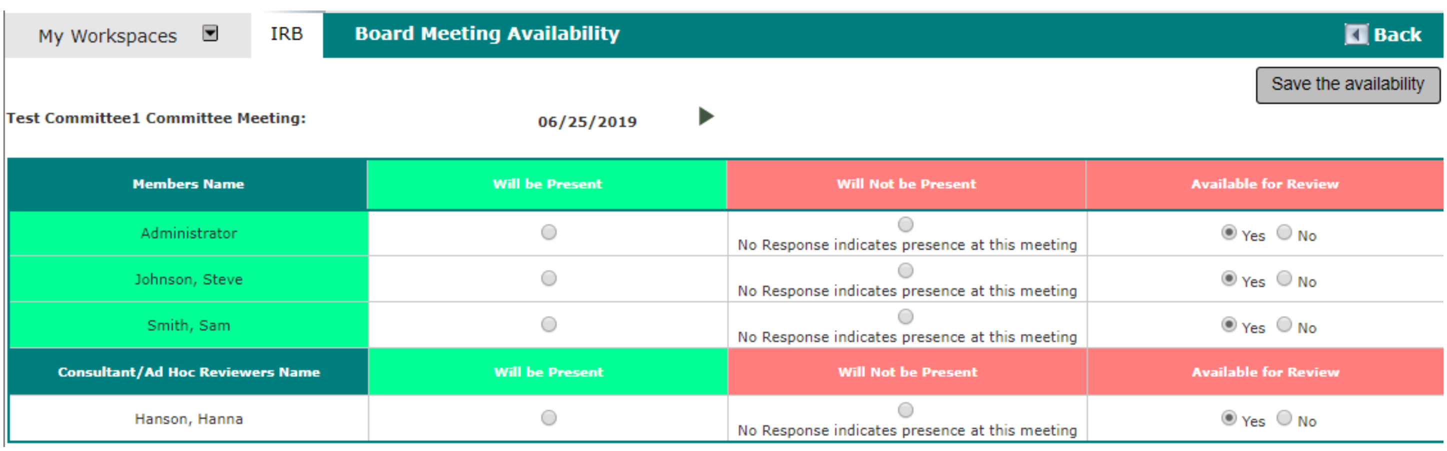
This page will display a link for each board meeting that has been held from newest to oldest. If minutes have been generated and a Finalized version has been published, a **View Finalized Minutes** button will populate next to the meeting link. If a Draft version of the minutes has been published, the button will read **View Draft Minutes**. If the meeting minutes have not been published yet, no button will display. You can click on the **View Finalized Minutes** or **View Draft Minutes** button to view the PDF document for that meeting. You can also open to the meeting agenda by clicking the link for the meeting date.



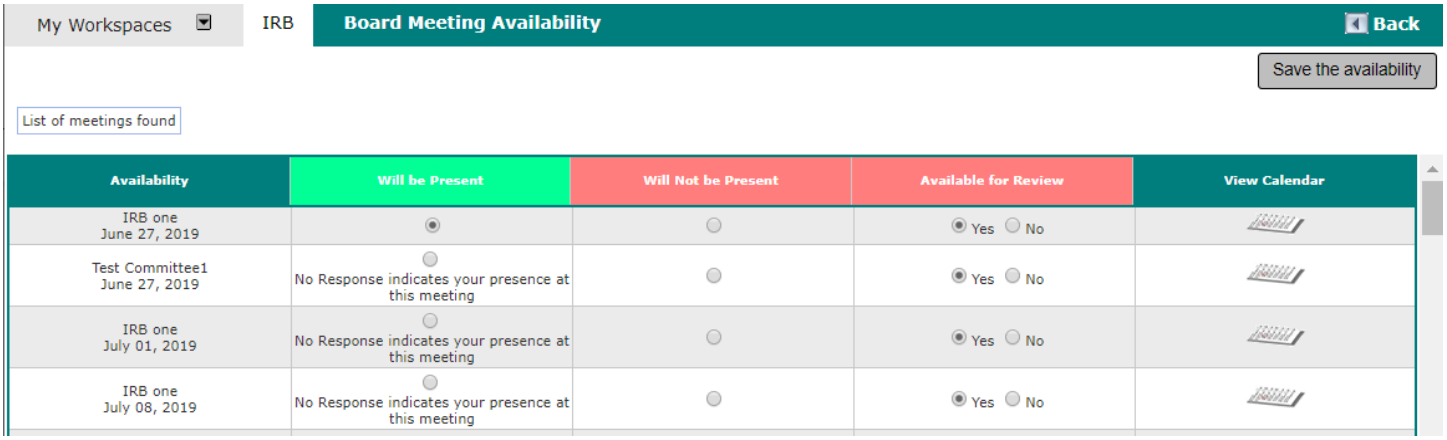
When you click to view the draft or finalized minutes, they will open in a new screen displaying the information entered from the meeting. The fields in the minutes document will reflect what was defined in the Meeting Minutes Template. If it is a draft version of the minutes, a watermark will appear with the word **DRAFT** across the minutes. See the IRB Assistant -Meetings manual for more information.

Meeting Availability

The **Meeting Availability** menu option brings you to a screen where, if you are an IRB administrator, you can scroll through meeting dates and set the availability for different board members for those dates.

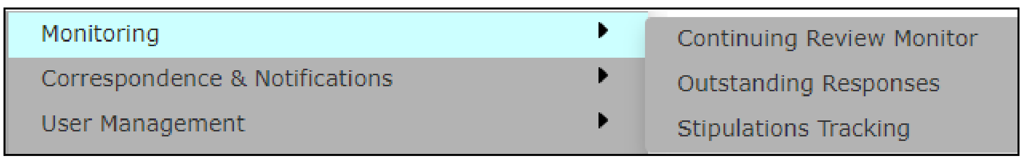


If you open the screen with a non-administrative IRB role, you will be able to set your own availability for upcoming meetings.



For more information about Meeting Availability, see the IRB Assistant – Meetings manual.

Monitoring



The **Monitoring** menu under IRB Assistant contains three sub-items, the **Continuing Review Monitor**, **Outstanding Responses**, and **Stipulations Tracking**.

Continuing Review Monitor

The **Continuing Review Monitor** allows you to access the study management screens of the submissions that are up for continuing review. Submissions that are within 120 days of their continuing review date will populate in this list.

The list can be displayed by the IRB Number, IACUC Number, IBC Number, and others (depending on which modules are setup in your instance of iRIS) by selecting the desired option from the" Display by:" dropdown list. The Study Title/Study Number, IRB Number (or other selected number), IRB Initial Approval, IRB Expiration, Principal Investigator, and whether the Submission is Posted (meaning that a submission is currently in process that can satisfy the Continuing Review) will display for each study in the list.

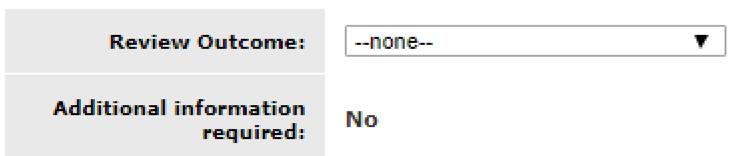
This list will allow your IRB team to monitor any studies coming up for Continuing Review, as well as take action on any study that missed the Continuing Review deadline. A study record will display in this list until the study record is updated by either closing it for lack of Continuing Review submission or updating the IRB Expiration date to a later date. Clicking the Open icon next to any submission will bring you to the Study Management Page.

From Study Management, you can access the Study Profile, which will allow you to make any necessary changes to the study record.

Outstanding Responses

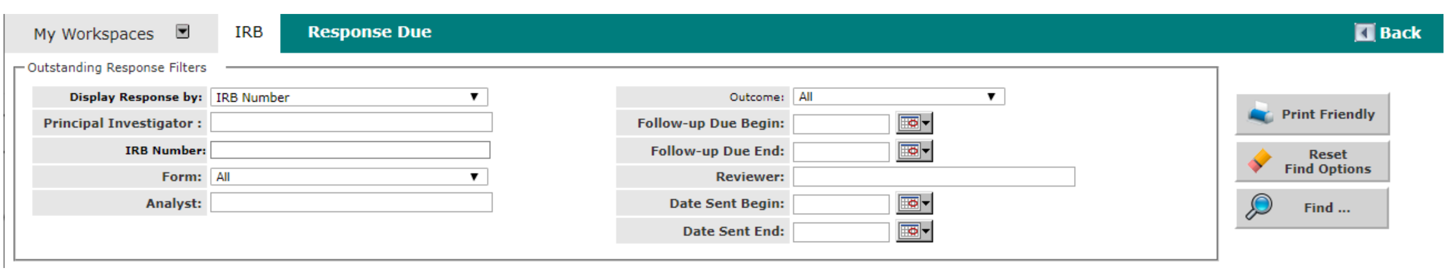
Outstanding Responses allows you to manage submissions that have been sent back to the PI for corrections.

The Outstanding Responses functionality provides a way to manage submissions that were sent back to the KSP for changes. The determination of a submission's status is set in the Outcome tab (see box below). Here the Review Outcome, along with a Yes/ No for Additional Information Required is set. If a submission has an outcome with additional information required, then this submission will remain in Outstanding Responses until a new version of the submission is received.

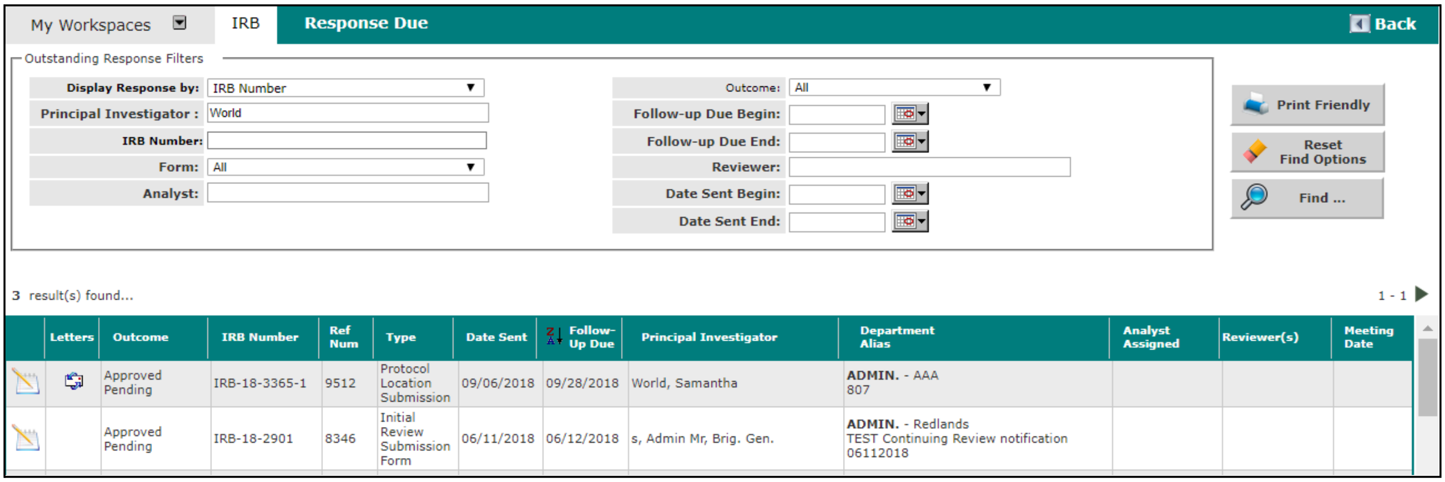


The submissions in the list can be displayed by their IRB Number or other type of study number (depending on which modules are setup in your instance of iRIS). Other Outstanding Response Filters can be used at the top of the screen to narrow down your results. You can search by Form, which will list all of the submission, submission correction, and submission response forms in your iRIS system. You can also search by the Analyst or Reviewer assigned to the submission, as well as submission outcomes.

There are also date range fields that you can use to search for submissions based on the Follow-Up Due date and the Date Sent. Enter a beginning and end date to search for submissions that fall within a particular date range. After you have set your desired filters, click the **Find** button. To start your search over, click **Reset Find Options**.

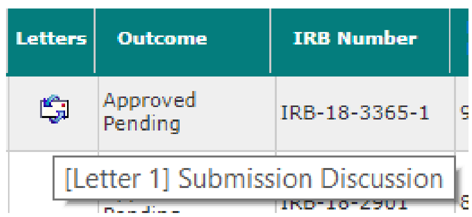


Click on an  icon in the table of results to access the original submission; this icon will take you directly to the Outcome tab of the submission. From the submission processing screens, you can track the location of the submission or send correspondence to the KSP.



The following columns will populate for the submissions:

Letters -If an outcome letter was created and sent, an icon will appear in this column. Hover the mouse over the icon and the type of letters will appear (see below).



Outcome - The review outcome of the submission.

IRB Number - The review board number used to reference the study.

Ref Number - The iRIS-generated reference number for the submission.

Type - The type of submission.

Date Sent – The date that the submission was sent back to the PI for corrections.

Follow-up Due - The follow-up date (See the IRB Assistant - Submission Processing Manual for more details).

Principal Investigator - The Principal Investigator assigned to the study.

Department /Study Number - This information will pull the Primary Department on the study and the Study Number/Nickname.

Analyst Assigned – The analyst, if any, assigned to the submission.

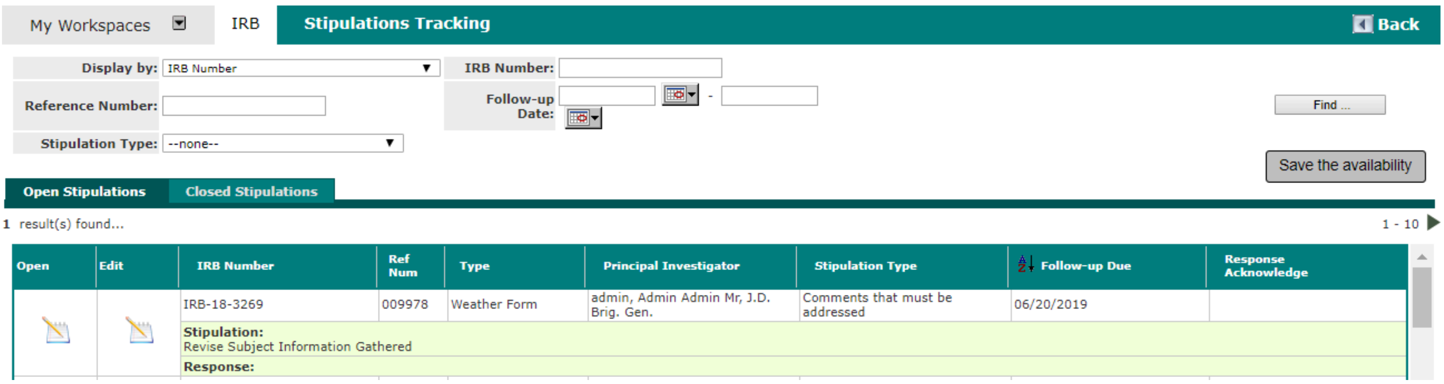
Reviewer(s) - The reviewer(s), if any, that were assigned to the submission.

Meeting Date - If the submission was put on an agenda, the agenda date will be displayed here.

Stipulations Tracking

Stipulations Tracking allows you to track and edit stipulations for each submission in your system.

When clicking on the Stipulations Tracking link in the menu, you will be brought to a screen similar to the one below.



The stipulations will be displayed by **Open Stipulations** and **Closed Stipulations** tabs. You can filter the stipulations using the options at the top of the screen in either tab. You have the ability to filter by the Review Board Number (which depends on the selection made from the "Display by:" dropdown), Reference Number, Follow-up Date Range, and Stipulation Type. The stipulations can be displayed by IRB Number, Project Number, or IBC Number (or other types of review board numbers depending on your system's configuration.

The columns in the Open Stipulations tab are as follows:

IRB Number – The review board number assigned to this study will be displayed in this column.

Ref Num – The submission's reference number will be displayed in this column.

Type – This column will display the form that the stipulation is associated to.

Principal Investigator – The Principal Investigator associated with the study will be displayed here.

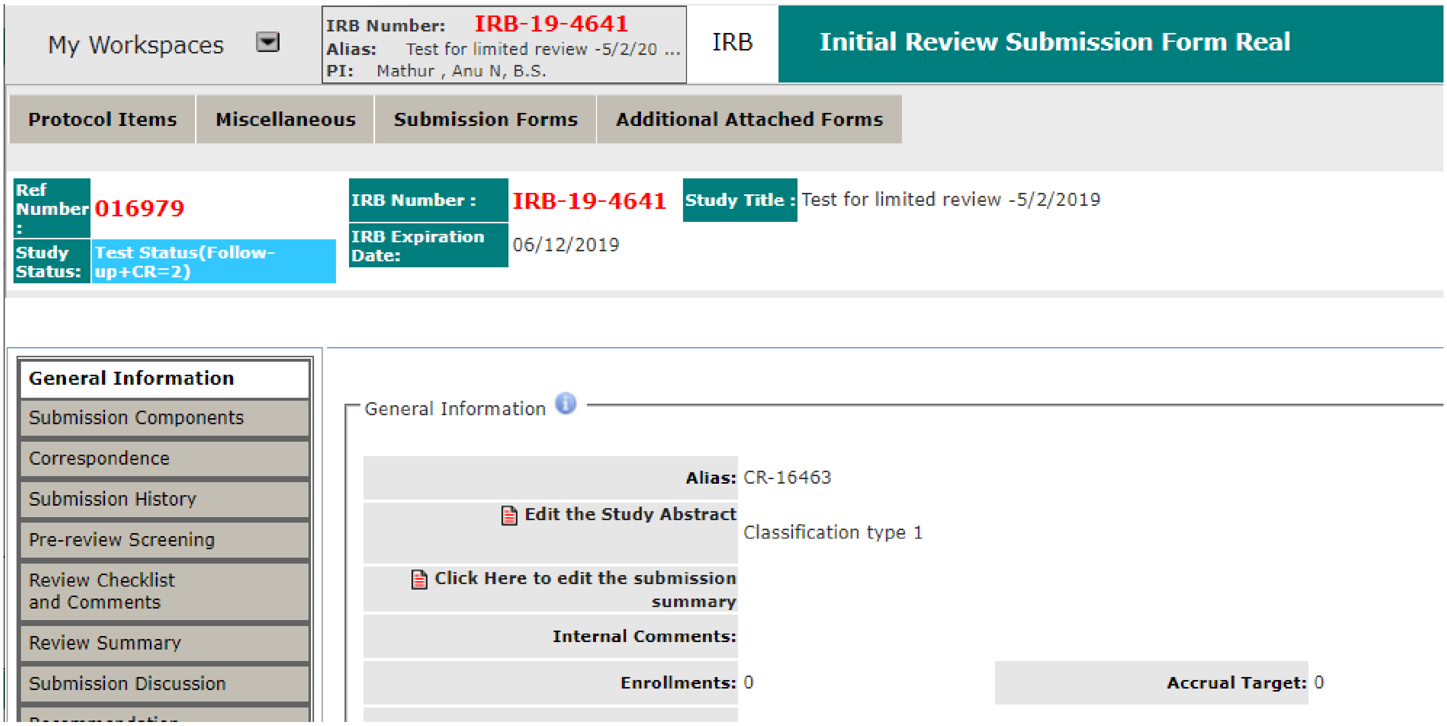
Stipulation Type – The type of stipulation will be displayed here.

Follow-up Due – If the stipulation type is "Comments that must be addressed," then this area will populate with the Follow-up Due date.

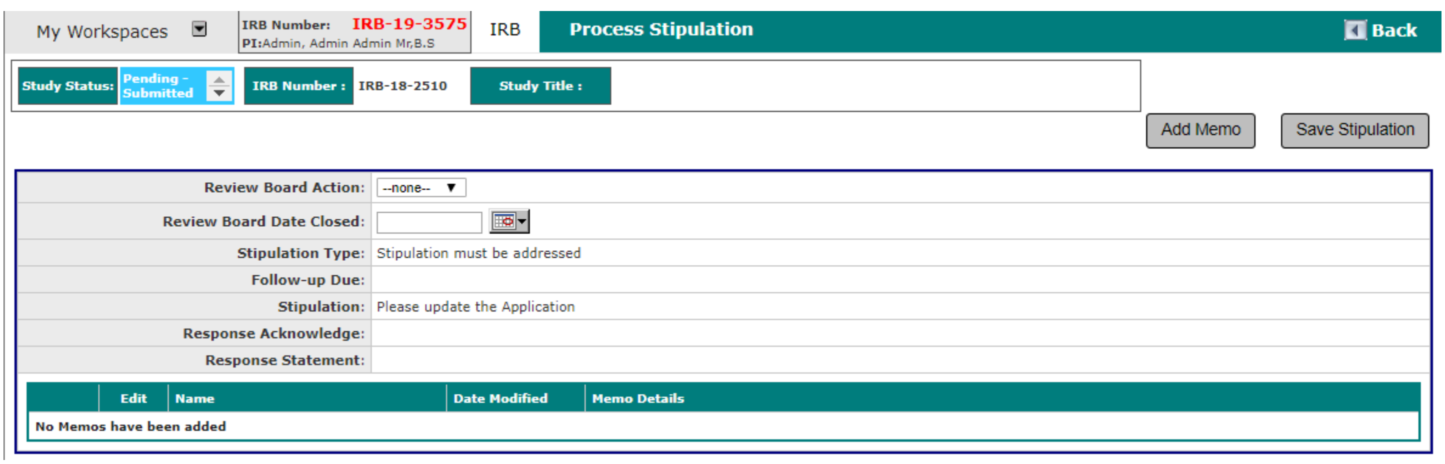
Response Acknowledge – This area will display whether or not the PI accepted the stipulation.

The actual Stipulation entered by the Review Board and the Response from the study side will be displayed in the green highlighted area. Note: Study Management will not be able to create a Response to the stipulations if the submission has not been returned to the study by the review board.

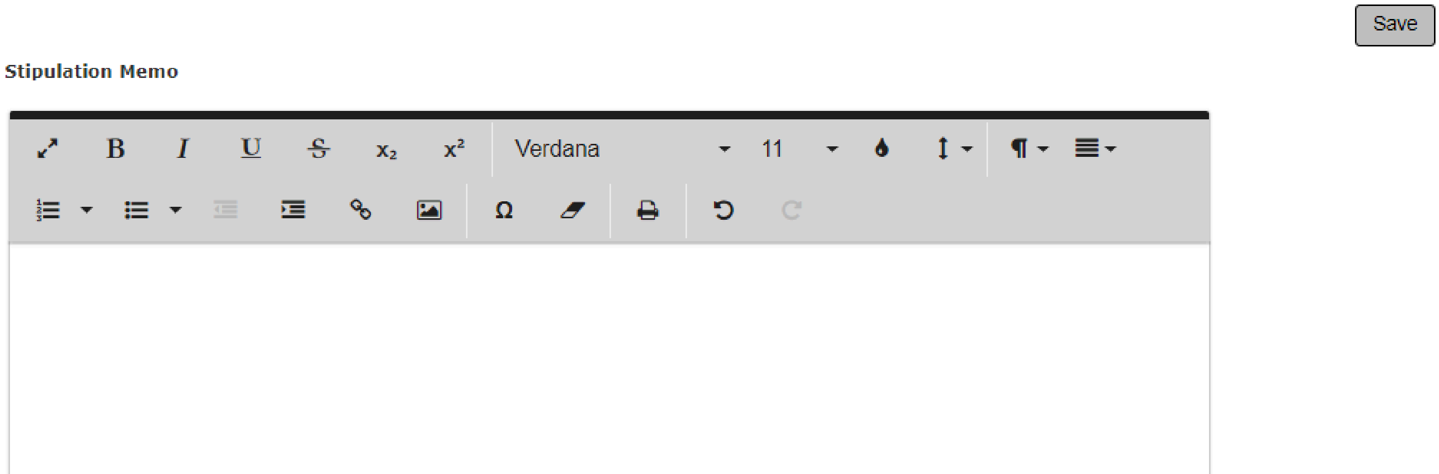
Select the  icon in the Open column next to the appropriate stipulation to open the submissions screen (shown below).



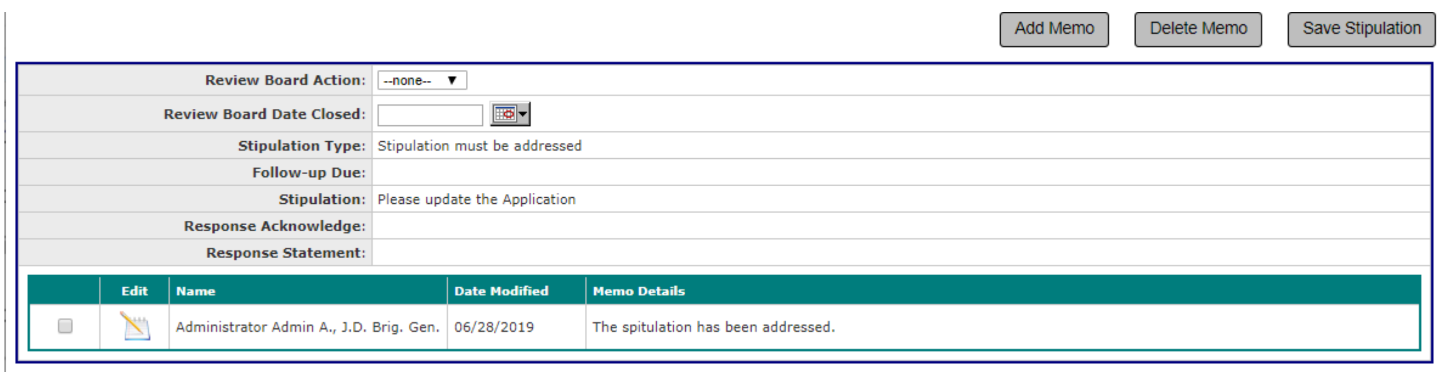
Selecting the  icon in the Edit column will open the Process Stipulation screen (shown below):



On this page, the Review Board Action (configured under Review Board Administration) can be selected from a dropdown menu. After this has been set, the Review Board Date Closed must be entered. Click the **Add Memo** button to add a memo to the stipulation. This will bring up a text editor screen:



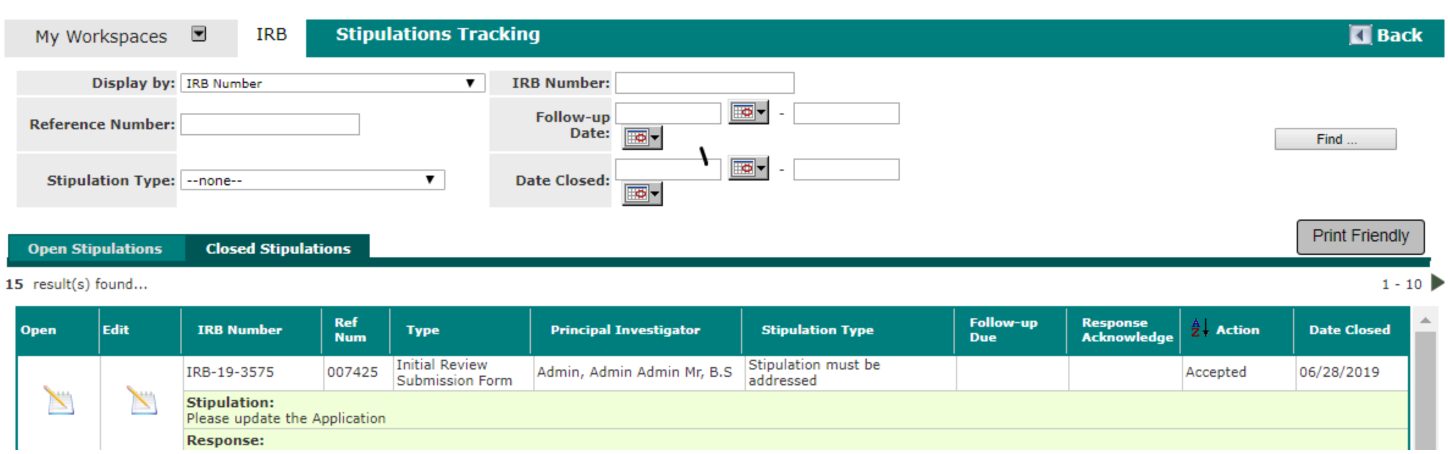
Any memos added will display in the table.



Memos added can also be deleted by checking the box next to the corresponding memo and clicking the **Delete Memo** button. Existing memos can also be edited by clicking the  icon in the table.

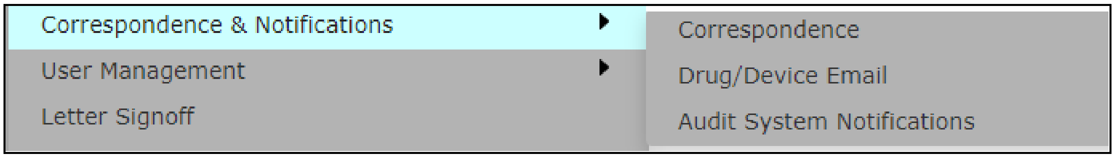
Select the **Save Stipulation** button after the appropriate fields have been filled out and you will return to the stipulations list page. The stipulation will automatically be moved to the Closed Stipulations tab.

Select the Closed Stipulations tab. A screen similar to the Open Stipulations tab will be displayed, listing all of the stipulations that have been closed (see below):



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

Correspondence & Notifications



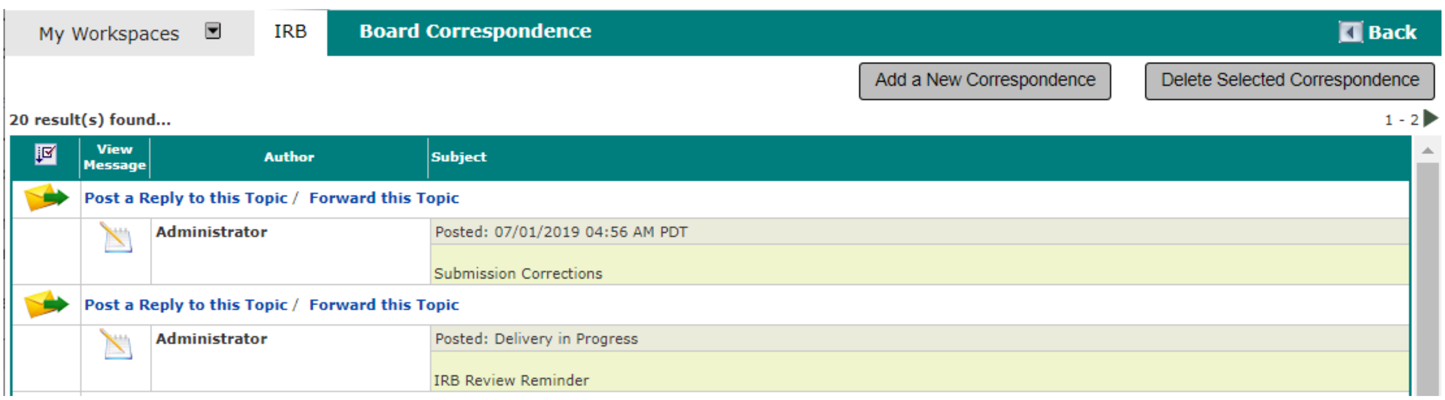
The **Correspondence & Notifications** menu contains three sub-items, **Correspondence**, **Drug/Device Email**, and **Audit System Notifications**.

Correspondence

The **Correspondence** tool allows you to view all IRB correspondence that has been sent out through the system as well as add and reply to correspondence.

The Correspondence menu item is typically used by Review Board Coordinators and Administrators and read-only access is frequently given to other board members.

Clicking the **Correspondence** link brings you to the following screen:

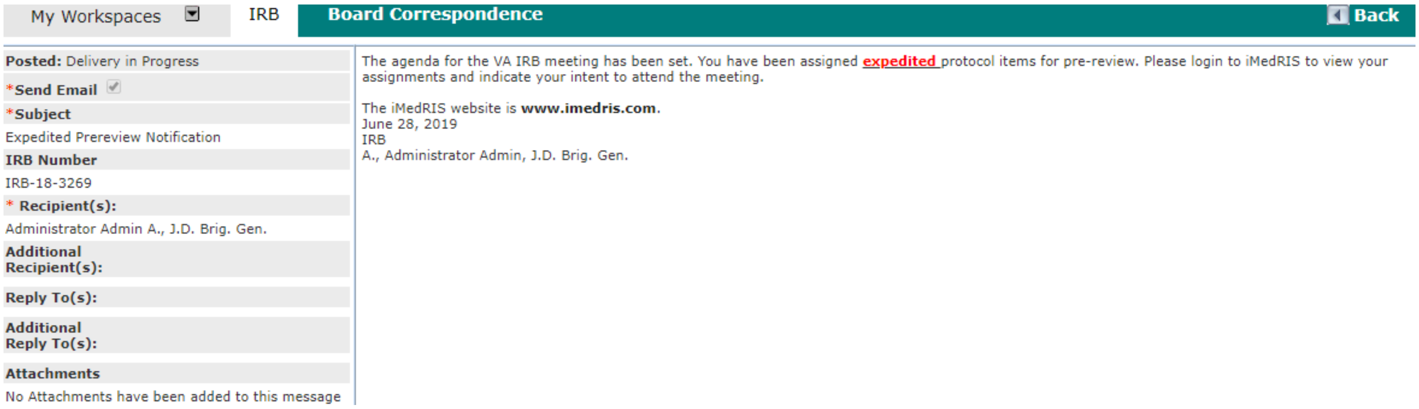


Author – The author of the correspondence will be displayed here.

Subject – This column will contain the date and time the correspondence was sent, the subject title, and IRB number (if applicable).

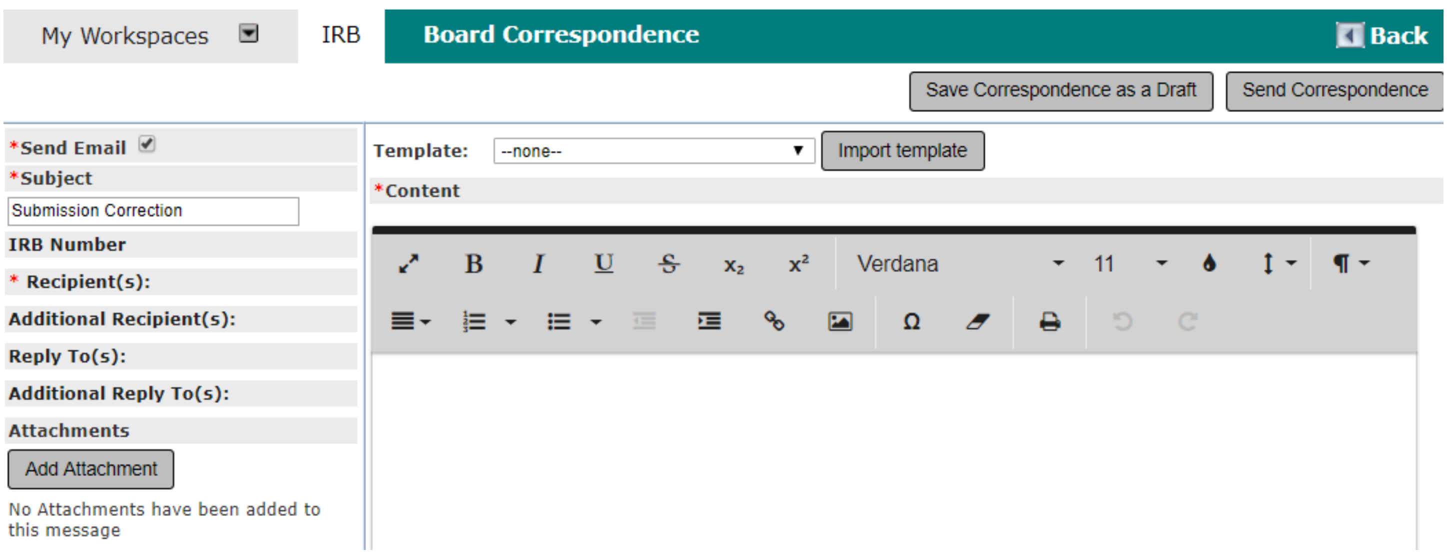
Delivery in Progress – This will be displayed if the correspondence is newly sent.

View Message – Click on the  icon next to the correspondence you want to view. The correspondence will be displayed in read-only format, as shown below. The Subject (*required field), IRB number, the Recipient(s) of the correspondence (*required field), any Additional Recipient(s), and any attachments that might be included with the correspondence will also be displayed. Delivery in Progress will be displayed if the correspondence is newly sent.



Click **Back** to return to the main Review Board Correspondence screen.

To reply to a correspondence, select the **Post a Reply to this Topic** link above the correspondence. A new page will be displayed (see below).

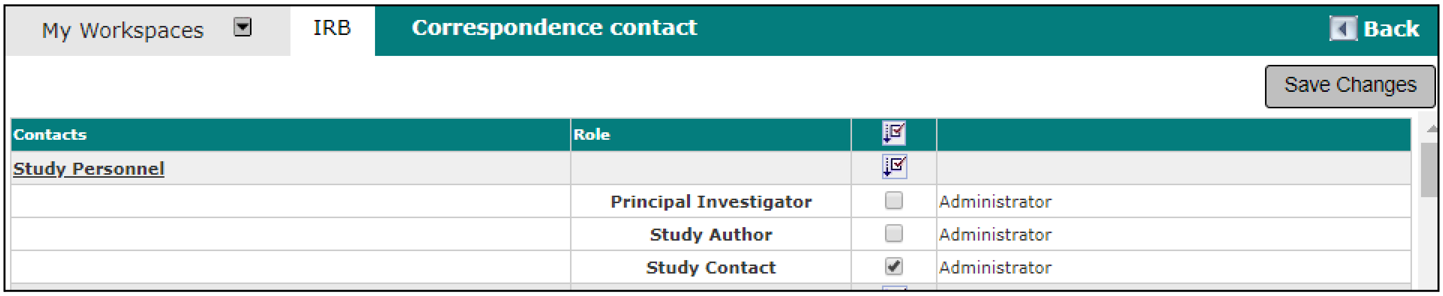


Send Email – When checked, this correspondence will be sent to the recipients via email. To turn this, feature off, uncheck the checkbox.

Subject – This will display in the subject field of the correspondence. This is modifiable. However, since this is a reply, it will default to the original correspondence's subject.

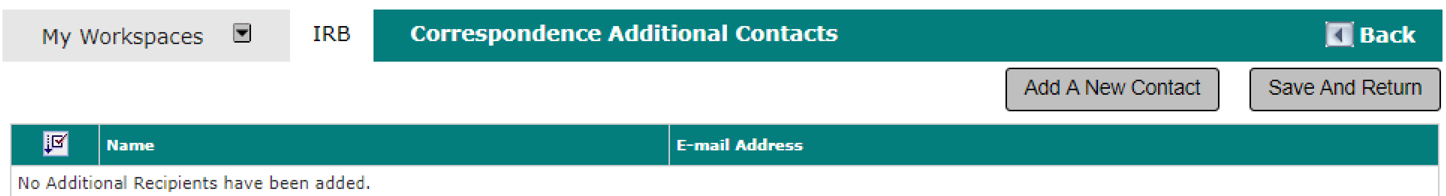
IRB Number – If this correspondence is associated to a study, the IRB Number of that study will be displayed here.

Recipient(s) – The recipient(s) of the correspondence will be displayed here. This will be pre-populated with prior recipient(s) and/or author of the original correspondence unless the recipient/author is the current user. This field is required and can be configured by selecting the heading link. A new page will be displayed (see below).

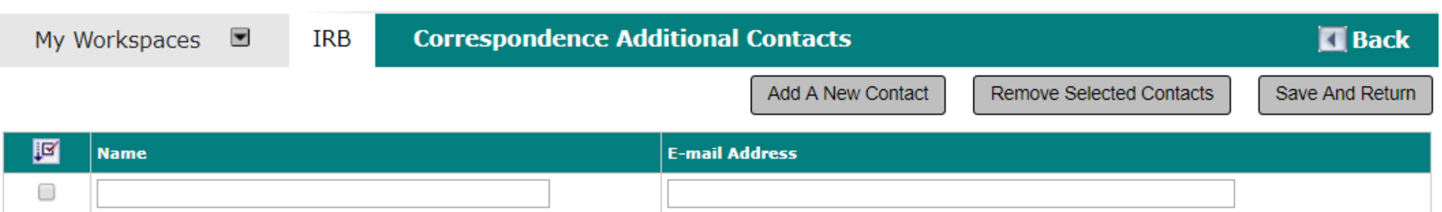


If the correspondence was associated to a study, the Key Study Personnel will be listed. Their name and their role will be listed with a checkbox next to each. To add personnel to the recipient list, select the checkbox next to the appropriate user. You may select or unselect all by clicking on the icon above the checkboxes. After the appropriate user(s) have been selected, click on the **Save Changes** button.

Additional Recipient(s) – Select this link to send this correspondence to person(s) outside of iRIS. A new page will be displayed when this link is selected. (See below.)



Select the **Add A New Contact** button. A new row will appear, allowing you to add the contact information. (See screenshot below.)



The Name and E-mail Address fields will both be required. Note: The E-mail address must be entered in the name@domain.com format or an error message will be displayed.

You may add more contacts by repeating the steps above. Delete a contact by selecting the checkbox next to the appropriate contact(s) and clicking the **Remove Selected Contacts** button.

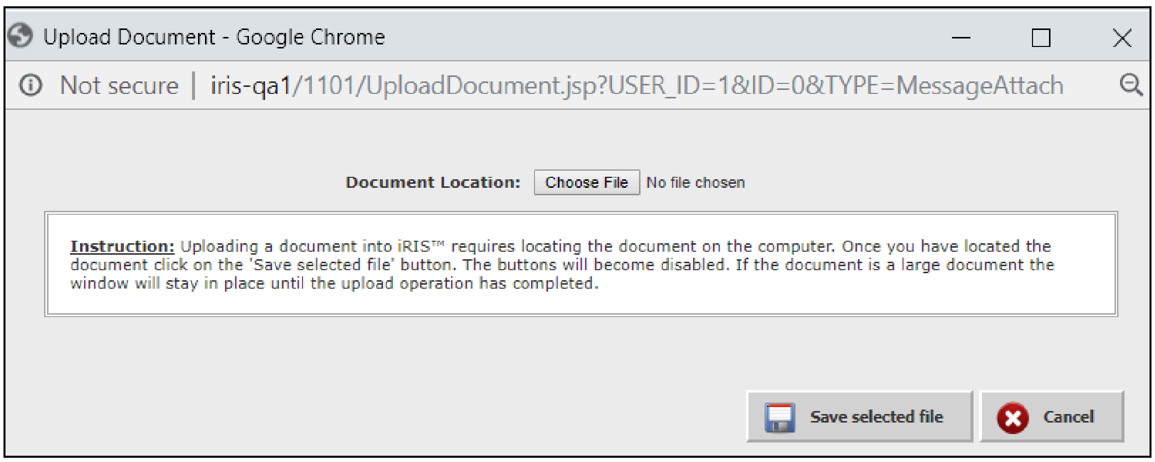
After the appropriate contacts have been entered, select the **Save and Return** button. Note: If this button is not selected, any changes made will not be saved.

Reply To(s): This list is the group of users that will be placed in the recipients list when a reply is posted to this correspondence either from iRIS or from an inbox. You can add users to this list in the same way as adding Recipient(s).

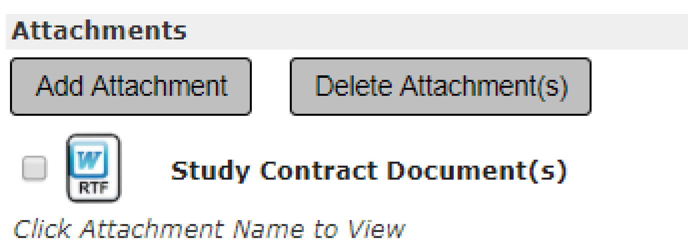
Additional Reply To(s): This is the group of users that will be placed in the Additional Recipient (s) list when a reply is posted to this correspondence either from iRIS or from an inbox. You can add contacts to this list in the same way as adding Additional Recipient(s).

Attachments – Select the **Add Attachments** button to add any documents to the correspondence. A new page will be displayed, allowing you to upload the document.

A **Title** must be entered for the attachment. Select the **Upload** button to upload the document. The upload dialog box will be displayed.



Select the **Browse** button to look for the document to be uploaded on your computer. Select the **Open** button after the document has been located or select the **Cancel** button to cancel the upload. After the appropriate document is uploaded, select the **Save And Return** button. This section will appear as displayed in the screenshot below.



Select the attachment name or icon to view the attachment. To delete an attachment, select the checkbox next to the appropriate attachment(s) then select the **Delete Attachment(s)** button. You may add more attachments by selecting the **Add Attachment** button again. Note: Though there is no limit on the size of the documents uploaded, please note that 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 the correspondence out as an email.

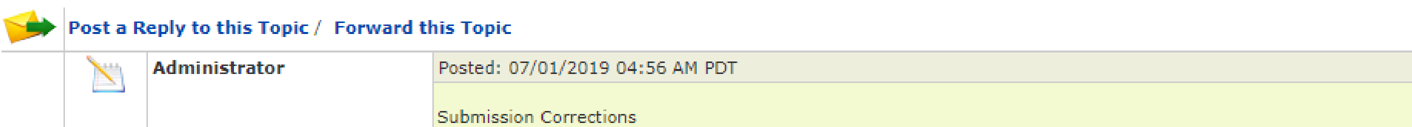
Content – Enter the content of the correspondence here. If you would like to use a template, configured under Review Board Administration > Setup Correspondence Template, select a template from the Template dropdown menu and click **Import template**.

When you are finished entering the necessary information, you can click **Save Correspondence as a Draft** to save a draft of the message you have created or **Send Correspondence** to send the message.

When you return to the main Review Board Correspondence screen, correspondence that has been saved as a draft will still be editable when you click the icon to view it.

To add a new correspondence, select the **Add a New Correspondence** button. This will display a page similar to the **Post a Reply** page, except there will be no pre-populated data.

Correspondence may be deleted only when they are first created and saved as a draft. You will not be able to delete correspondence that has already been sent out as an email. The screenshot below shows an example of a draft message that can still be deleted.



A checkbox will appear next to correspondence that may be deleted. Select the checkbox and click on the **Delete Selected Correspondence** button.

Drug/Device Email

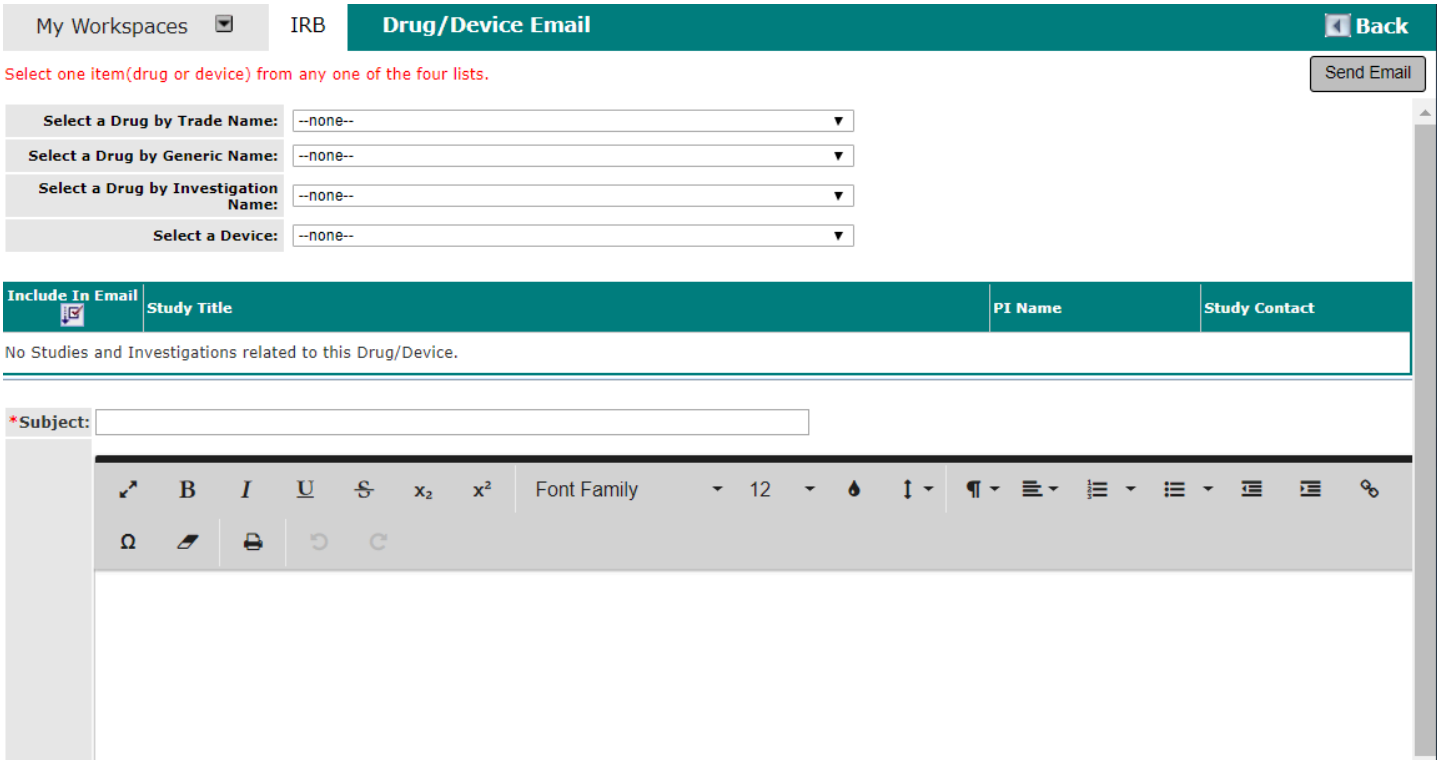
The **Drug/Device Email** tool allows you to send a study-related drug or device email to the contacts of that study. To begin, click on the **Drug/Device Email** link in your IRB Assistant.

Note: This tool is typically used for pharmaceutical recalls or notes that need to go out to all study contacts who are utilizing a specific drug or device.

A user can search for the drug/device from one of the four drop down menus: **Select a Drug by Trade Name**, **select a Drug by Generic Name**, **select a Drug by Investigation Name,** or **Select a Device.**

Once you have made your selection from the dropdown menu, all studies associated with your selection will populate with a checkbox next to each one. Click the checkbox next to the study you wish to send an email regarding.

Enter a Subject (* required field) and any necessary content. When you have finished, click the **Send Email** button in the upper right-hand corner.



This will trigger the email, and all study contacts on the selected studies will receive the drug/device related email.

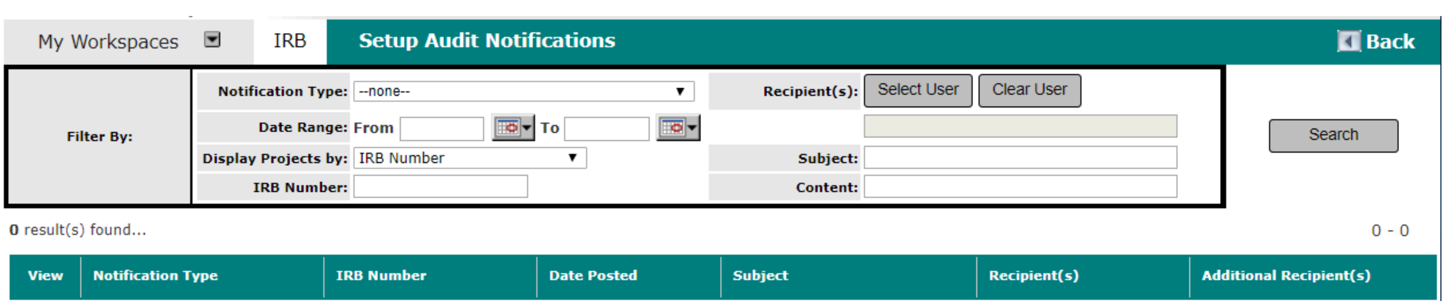
Audit System Notifications

The **Audit System Notification** tool allows you to search through and view system notifications.

The Audit System Notifications menu item will usually be accessible to Review Board Coordinators and Administrators. However, its accessibility can be controlled for all roles through the Setup Role Access matrix found in Review Board Administration.

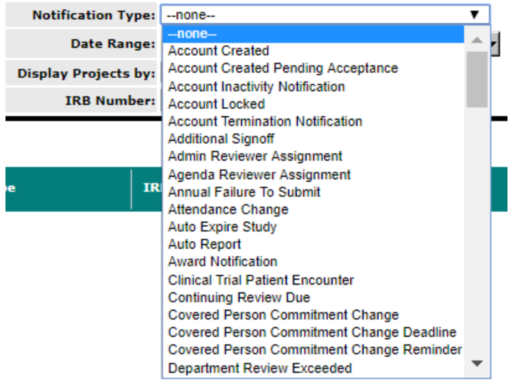
Every notification that is sent out by the iRIS system is logged and can be tracked. Since the system automatically generates the notifications, this notification audit tool can be very useful for Coordinators who need to check up on other members of their review board or on study personnel. All system notifications can be audited here to ensure that they are sent.

Clicking on this icon opens the following Audit Notifications screen with several filters to pull up notifications:



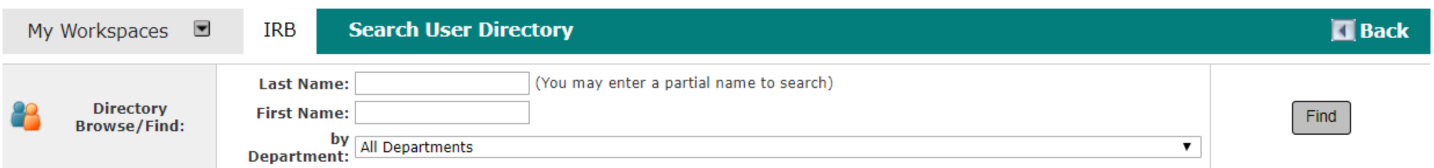
Notifications will be displayed with fifty items per page. Selections can be made using the following filter tools:

Notification Type – Select a notification type from the dropdown list to filter by Notification Type.

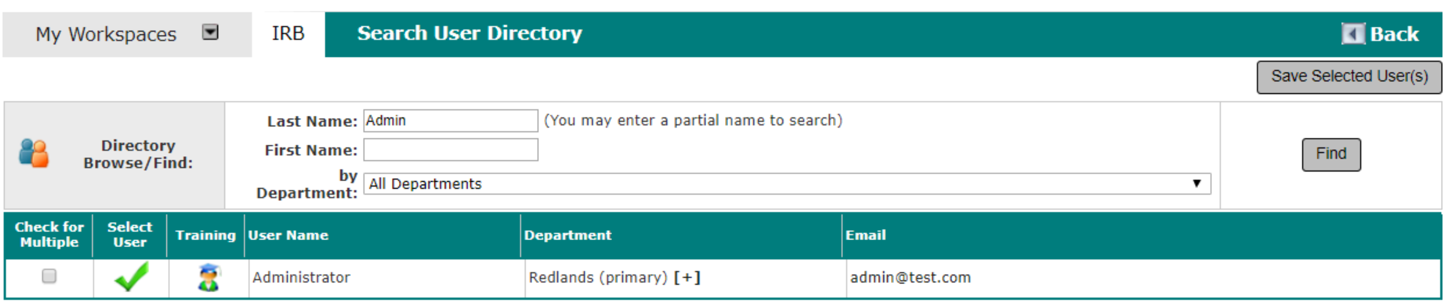


Recipient(s) – Use this field if you wish to perform an audit for a specific user in the system who would have received the notification you are searching for. Only user(s) that match your search criteria that have received notifications will be displayed.

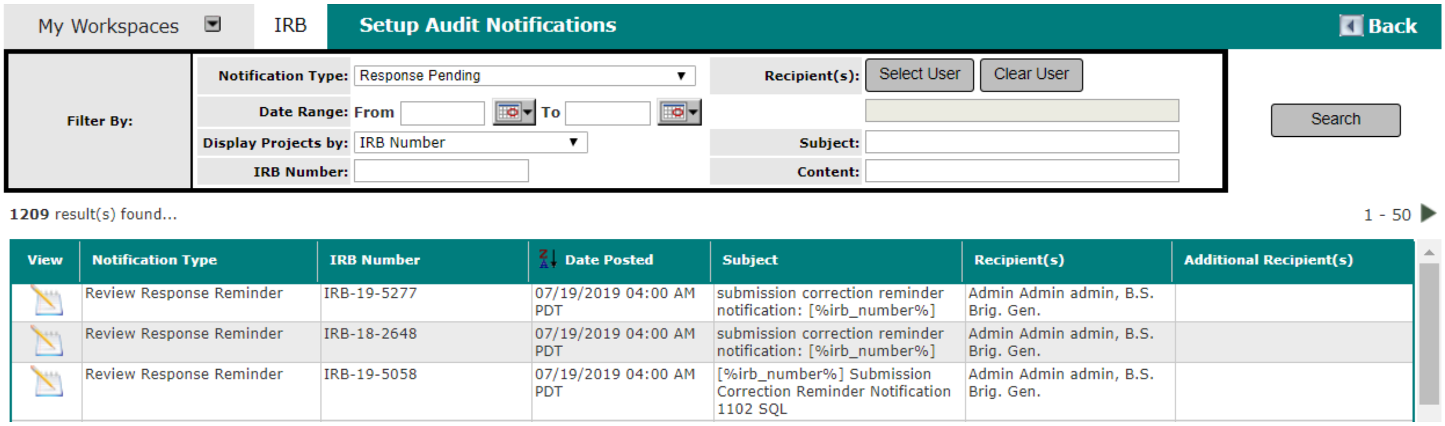
When the **Select User** button is clicked, a new screen will be displayed.



Enter the search criteria and click the **Find** button. Use the "%" to do a wildcard search and pull up all users in the system.



When you have found the user you are looking for, click the  Icon next to their name and you will return to the previous screen with that user added. Once added to the search filter, you can clear a name by selecting the **Clear User** button. This tool can only be used for one user at a time, so if you need to change the user, click **Select User** again.



Additional filtering can be selected from the other fields on the page.

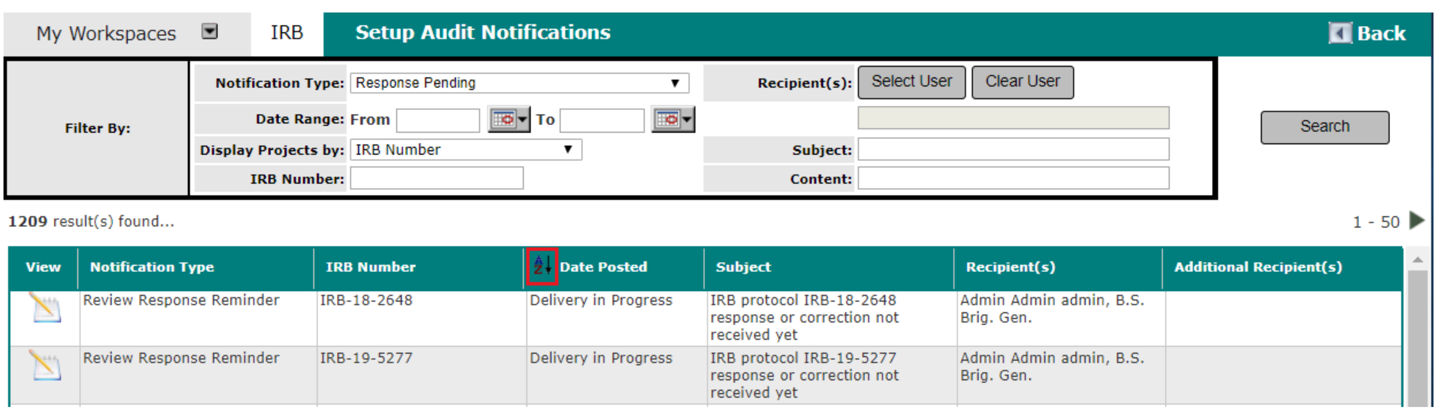
Date Range – This filter is useful if the approximate date of a notification is known.

Review Board Number – The type of number to enter here depends on the selection made from the "Display Studies by" dropdown list.

Subject – Enter a key word or phrase that appears in the subject. Use the "%" to do a wildcard search.

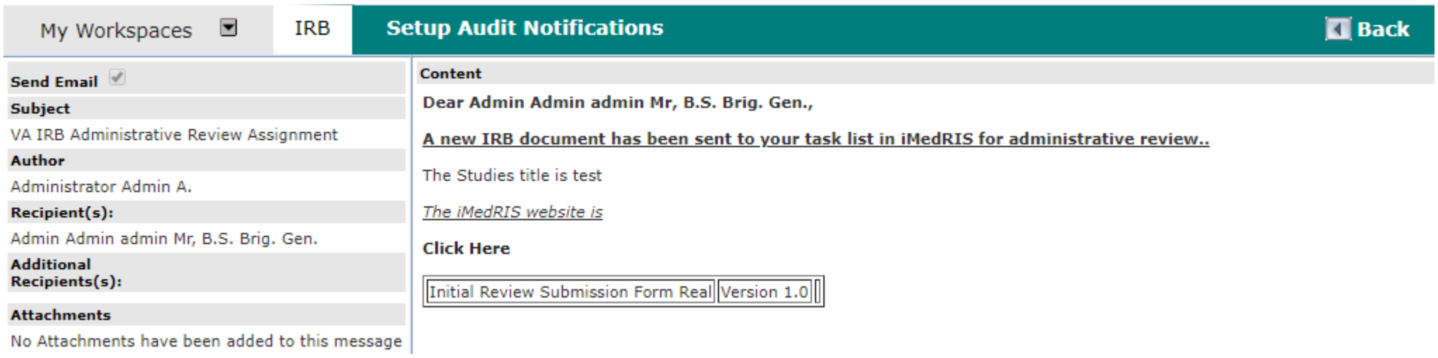
Content – Enter a key word or phrase that would appear within the content of the notification. Use the "%" to do a wildcard search.

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. The results will be displayed in the table under the filter options, with the most recent notification at the top of the page. You can further sort the notifications to display in ascending or descending order by clicking the column headings (as shown below). This feature is not included for the View and Recipient(s) columns.



The following columns populate for your search results: View, Notification Type, Review Board Number, Date Posted, Subject, Recipient(s), and Additional Recipient(s).

Click the  icon in the View column to view the actual notification that was sent. You will see a screen similar to the screenshot below (information is read-only):

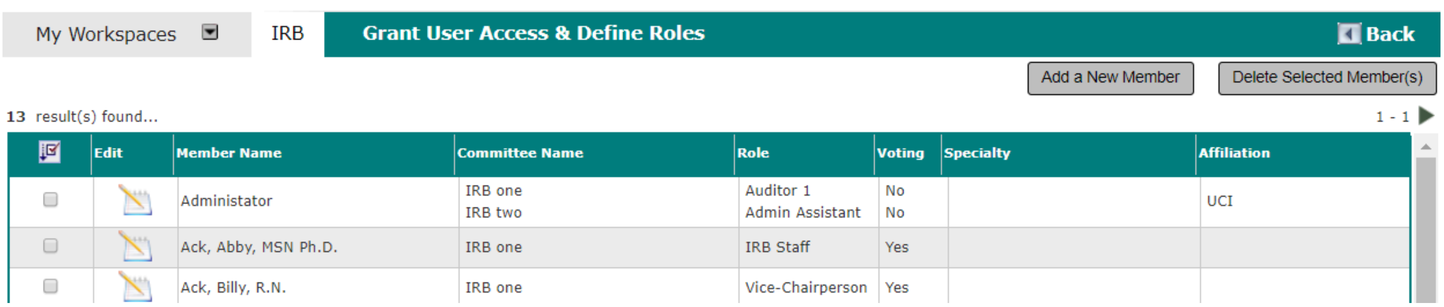


User Management

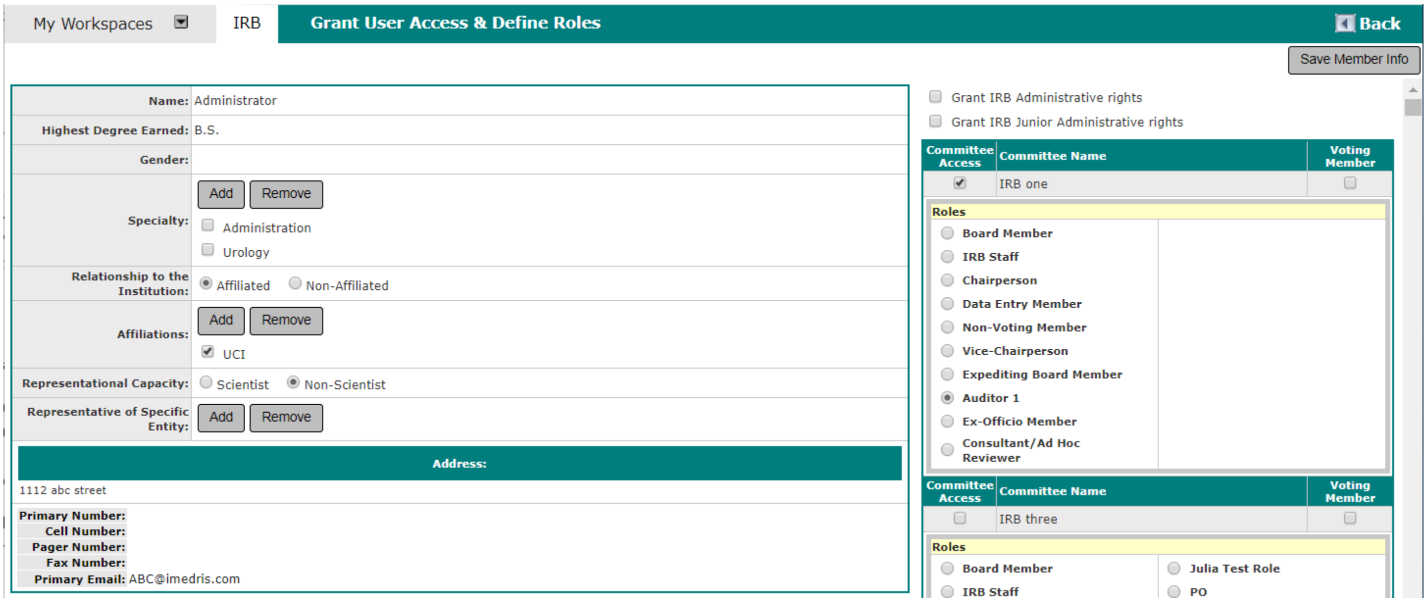
The **User Management** menu contains two sub-items, **Grant User Access & Define Roles** and **User Training**.

Grant User Access & Define Roles

This page will list any users who currently have a role on the review board.



In this list, you can view the board members' names, committees, roles, and whether or not they are voting members of the board. If their account has the information set up, their Specialty and Affiliation will display as well. To delete a board member, check the box next to their name and click **Deleted Selected Member(s)**. You can change a user's access by clicking on the icon in the Edit column next to their name.



A page listing their contact information as well as their role information will open. You can change their role by selecting another role within a committee. Click on the **Save Member Info** button if you make any changes before clicking **Back** to return to the list.

You can also add a new member to the board if their account has already been created in iRIS. Click on the **Add a New Member** button. This will take you to a list of all other users in the database who do not have a role on the board. You can check the box next to a user and click on the **Save Selected Members** button to add them to the board.

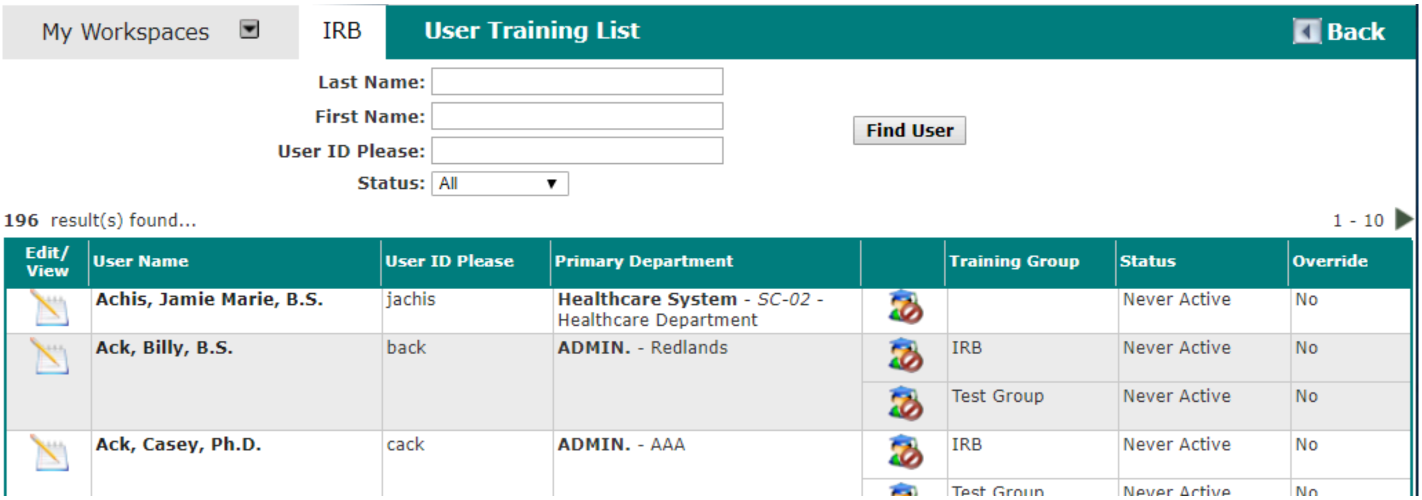
You can also use the **Add** and **Remove** buttons to change the board member's Specialty, Affiliations, and Representative of Specific Entity fields and the radio buttons to edit the board member's Relationship to the Institution and Representational Capacity.

User Training

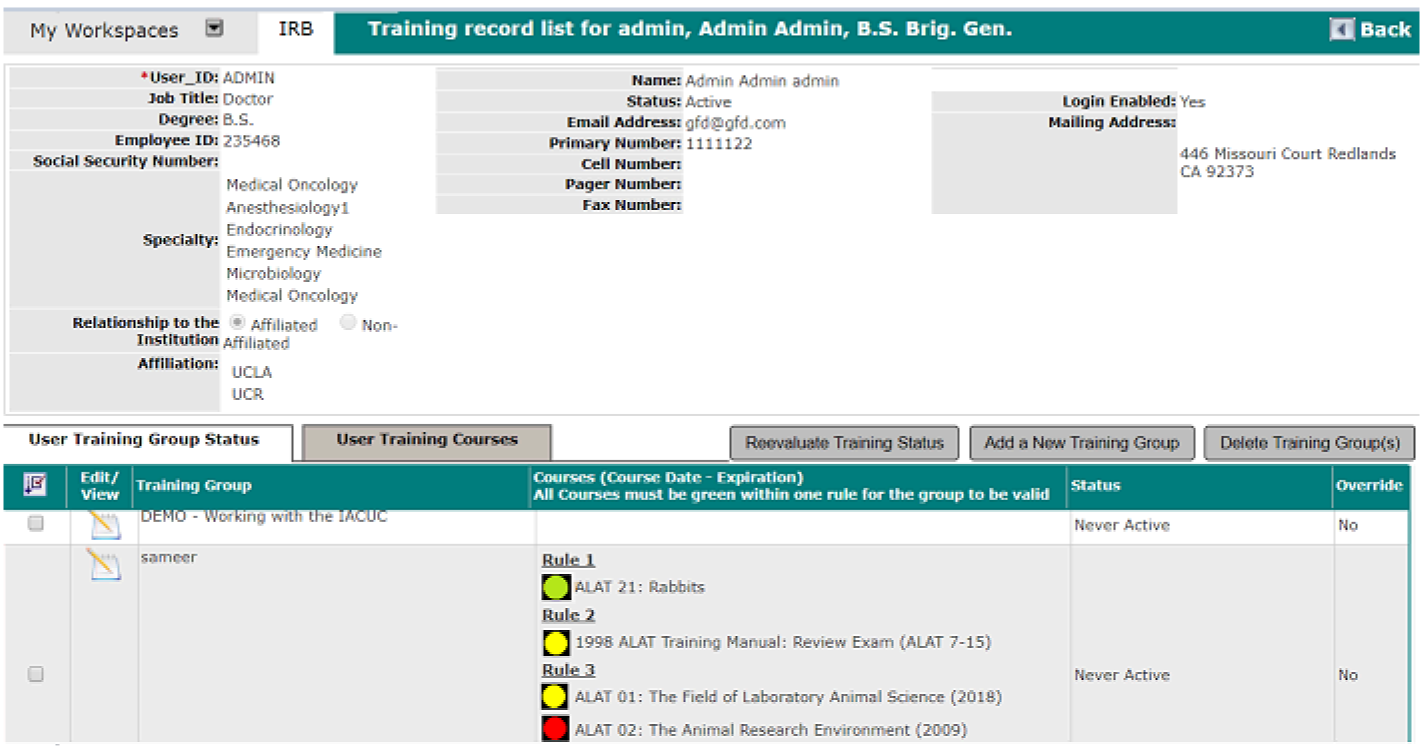
The **User Training** tool allows you to view and set each user's training record. For additional information aside from what is listed here, please see the Sys Admin - User Training - Full manual.

User training can be part of your submissions' workflow to check if Key Study Personnel are up to date with the review board's required training or education. If your site does not involve your training verification in the workflow, it is not required that you enter this information into the system. Contact your site's system administrator for questions concerning your site's workflow.

The opening screen will initially display a list of the users associated with your review board. The table displays the user's Name, UIN, Primary Department, Training Group, and Status of the training (Active, Never Active, or Expired). The  icon signifies that the user has at least one active training record on file which is not expired. The  icon means that there is no valid training record on file. The  icon signifies that this user's training record has expired. Specific users can be found by adding any known information into the search options at the top of the screen and clicking the **Find User** button.



To set up the training record for a user, select the icon next to the appropriate user or click on their name. A new page will be displayed (see below). The user's information will be displayed in read-only format.



The above screen shows the user's Training Group Status. Listed on this page are Training Groups associated to the user. A Training Group is a group of courses set up with rules that certain courses must be completed to fulfill your training requirements.

Next to each group is a list of courses the user has taken that are applicable to that group. From this screen you can **Edit/View User Training Courses**, **Reevaluate Training Status**, **add a New Training Group**, or **Delete Training Group(s)**.

If you click the icon next to a Training Group, you are brought to the following screen:

Within this screen, the Group Name is read-only, but you are able to edit the Override Flag or the (training) Status.

Override Flag – Set this to Yes to override any necessary training rules setup for the group for this user only (this feature is applicable for administrator accounts in the system).

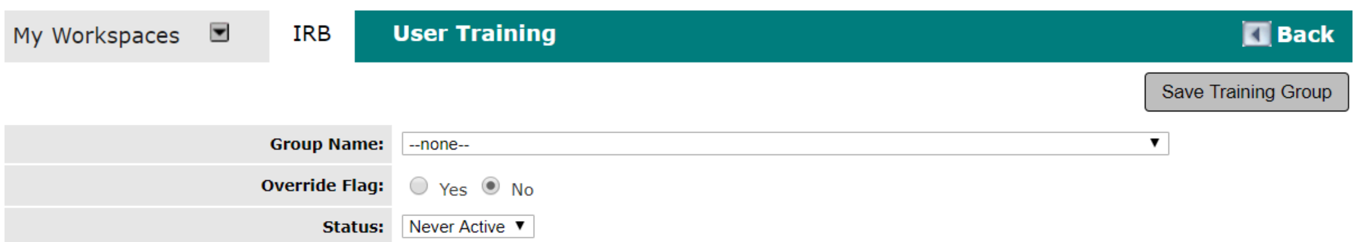
(Training) Status – This dropdown list contains:

1. **Never Active**: This means that the training was never set. When a user is created, this is the default setting.
2. **Active:** This means your training is currently active.
3. **Expired**: This means your training has passed its expiration date.

If any changes are made, click **Save Training Group** and you will return to the previous page.

Clicking the **Reevaluate Training Status** button will revalidate the current user's training.

To add a new training group, click the **Add New Training Group** button which brings you to the following page (this is the same page you would see if you were to edit a Training Group):

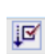


Group Name – Select your desired training group from the dropdown list. This is a configurable list that can be updated from System Administration > List Configuration and Maintenance, under Define Training Groups.

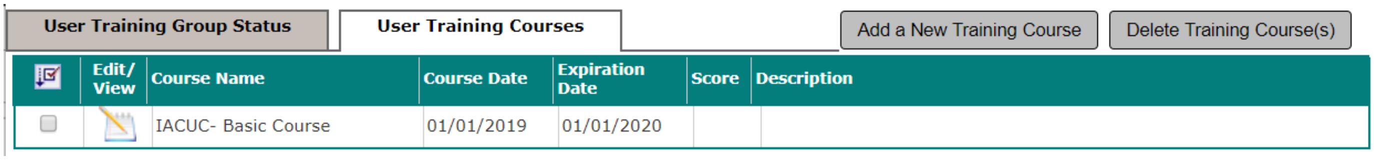
Override Flag – Set this to Yes to override any training rules set up for the group, for this user only.

(Training) Status – Select from the dropdown list as defined above.

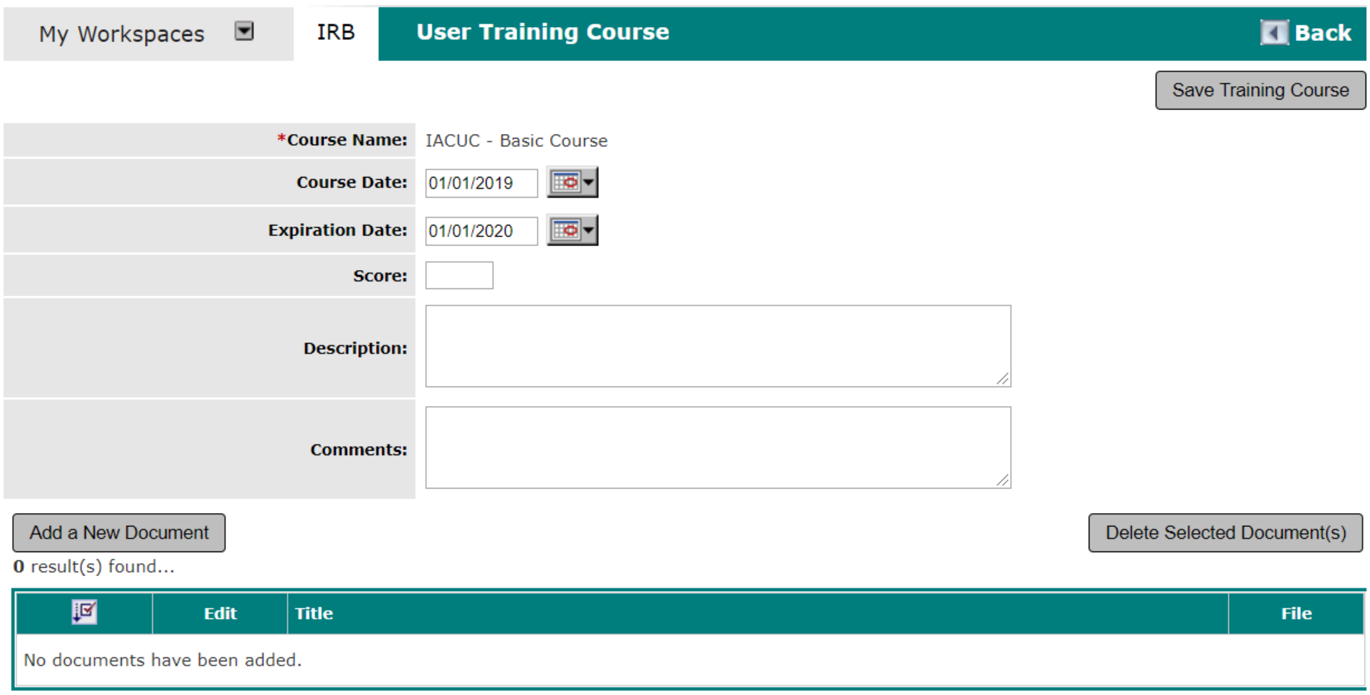
Upon making your selections, click **Save Training Group** and you will be brought back to the user's Training Record List.

To delete a training group, check the box to the left of the training group you wish to remove from the list and click the **Delete Training Group(s)** button. By clicking the  button at the top of the column in the table, you have the option to select/deselect all groups if needed.

Within the training record list for the user you have selected, there is a tab for **User Training Courses**. Click this tab and you will be brought to the following screen displaying a Training Record List with specific courses taken by the user:

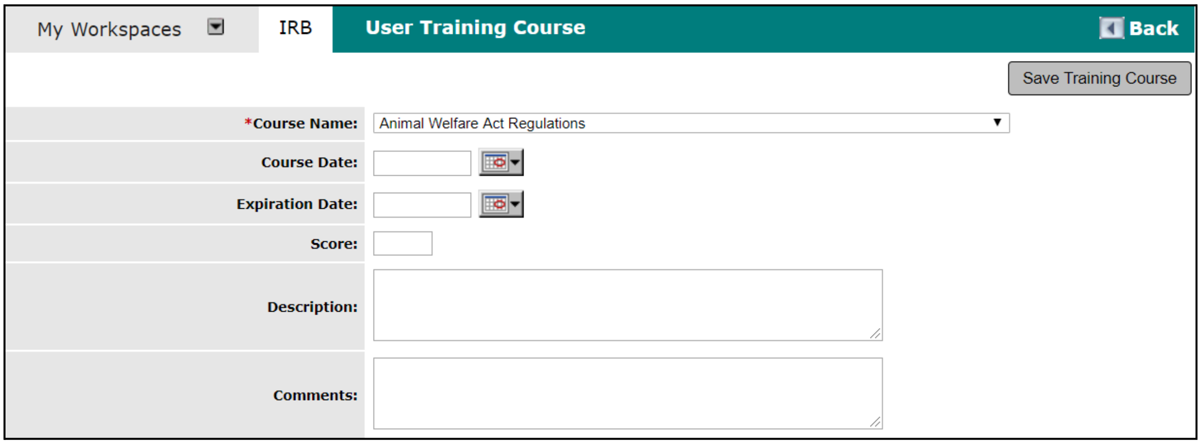


This screen displays a table that includes the Course Name, Course Date, Expiration Date, Score, and a Description of the course. By clicking the icon to the left of a course, you are brought to the screen below:



This screen displays with the Course Name as read-only. However, you are able to update the Course Date and Expiration Date, change/add the Description, add Comments, and Add or Delete New Document(s) (e.g., a training certificate). After making any necessary changes, click **Save Training Course** and **Back**.

To add a new training course for the selected user, click the **Add New Training Course** button and you will be brought to the following screen:



Course name – This field contains a dropdown list of all the courses that are defined under System Administration > List Configuration and Maintenance > Define Training Courses. This is a required field.

Course Date – The date the course was taken.

Expiration Date – The date that the training course expires.

Score – If you received a score in the training course, record it here.

A **Description** of the course and **Comments** can be added as well, if needed.

When finished adding the necessary information, click the **Save Training Course** button. This will cause the document section of the screen to display (as shown below). Here, you can add document(s) associated with the particular training course.

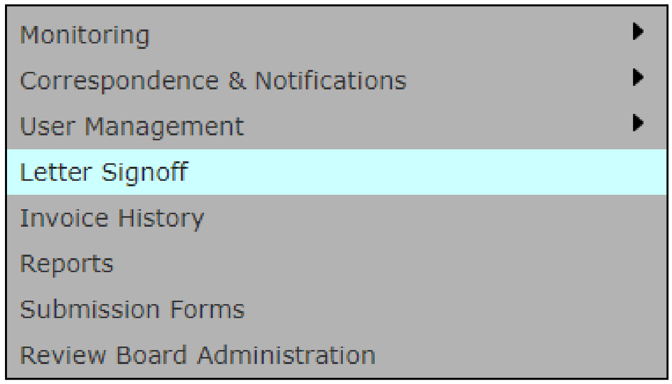
Click **Save Training Course** and **Back** to return to the previous screen. When the course is saved, it will be added to the list of courses within that group for that user.

To delete a training course, check the box next to the course record, and then click the **Delete Training Course(s)** button.

The system automatically checks the expiration dates for training courses and will automatically update the status of the course (based on the rules defined for a particular training group).

Letter Signoff

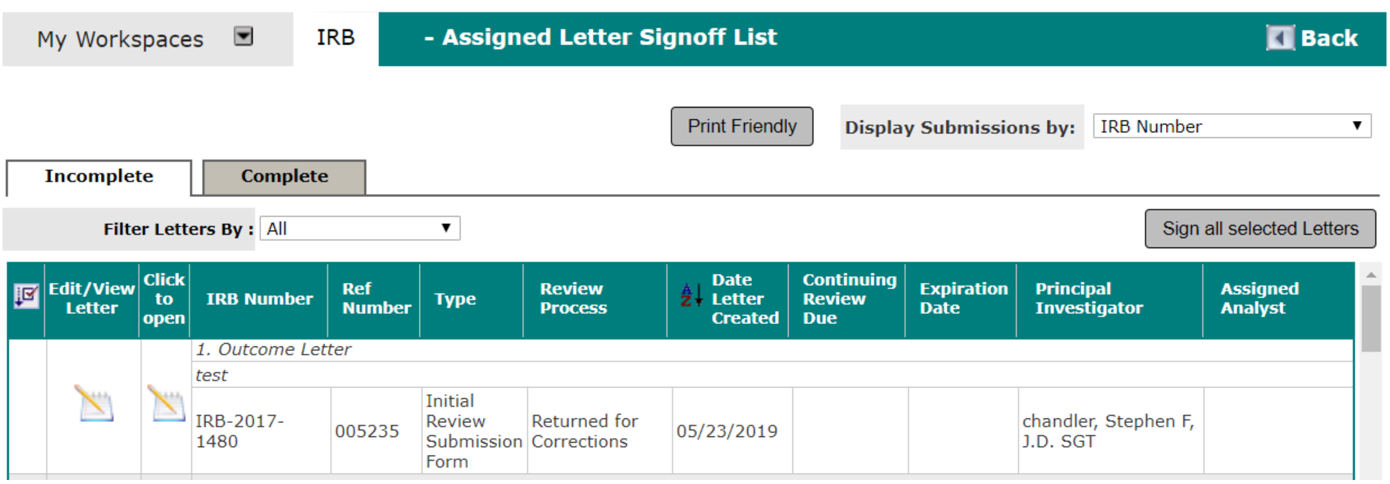
Letter Signoff allows you to electronically sign any outcome letters that have been routed to you for approval.



You may be assigned to electronically sign an outcome letter. From your homepage, select **Letter Signoff** from the **IRB Assistant** menu. Note: Signoff for individual letters can also be accessed through the tasks displayed on the home screen. The screen will open with two tabs: **Incomplete** and **Complete**. All submission letters that are awaiting your signature will be listed under the incomplete tab.

The submissions in the list can be displayed by the IRB Number or other Review Board Number, depending on which modules are set up in your instance of iRIS, by making a selection from the “Display Submissions by” dropdown box in the top right of the screen.

The IRB Number (or the number chosen to display by), Ref Number, Type, Review Process, Date Letter Created, Continuing Review Due, Expiration Date, PI, and Assigned Analyst of the submission will all display in the table. The list can be filtered by “Batched only” or “Non-Batched only” (batched or non-batched is a characteristic that is set when the letter itself is created, defining whether multiple letters can be signed at the same time) by changing the “Filter Letters By” dropdown menu to the desired option (as shown below).



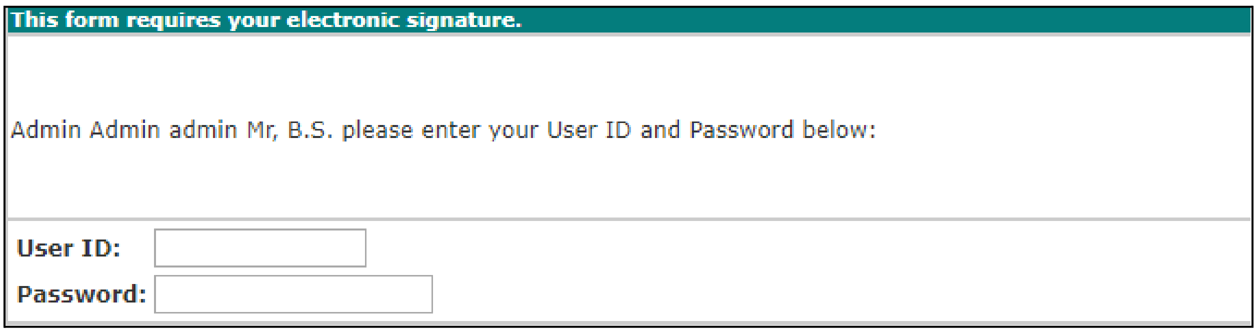
To review the submissions before signing these letters, select the icon in the “Click to open” column. The submission processing screens associated with the letter will open. If you are the IRB Coordinator, then all the tabs will be displayed. Otherwise, only the tabs your role has access to will be displayed.

You can apply your electronic signature using one of the following two methods:

1. **Batch: Review and sign off on all required items at once** (the quicker method). This option is available if, when the letter was created, you selected Yes to the question “Is batch signoff applicable?”

When you are ready to sign off on all the letters, select the letters’ checkboxes in the first column and click the **Sign all selected Letters** button. You will then be prompted with an alert message asking you to confirm that you would like to sign all the selected letters.

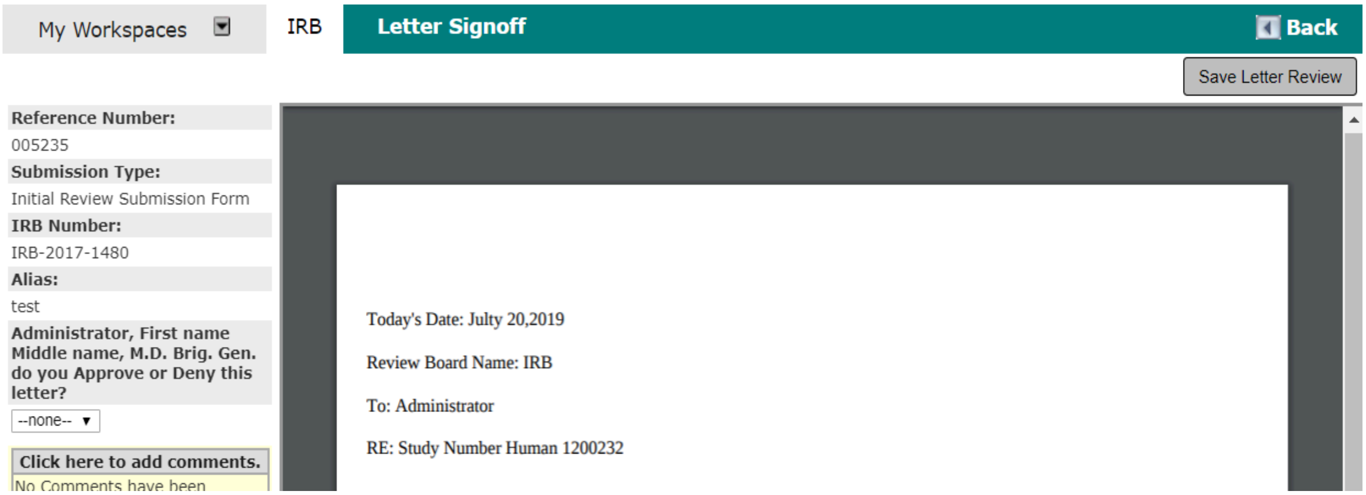
Select the **OK** button to confirm the signoff. The screen will be displayed as shown below.



Enter your iRIS UIN and Password (electronic signature) and select the **Save** button. The screen below will be displayed for a few moments; this screen will be displayed whether or not the letter is already in PDF form or if the letter still has to be routed around for signature.

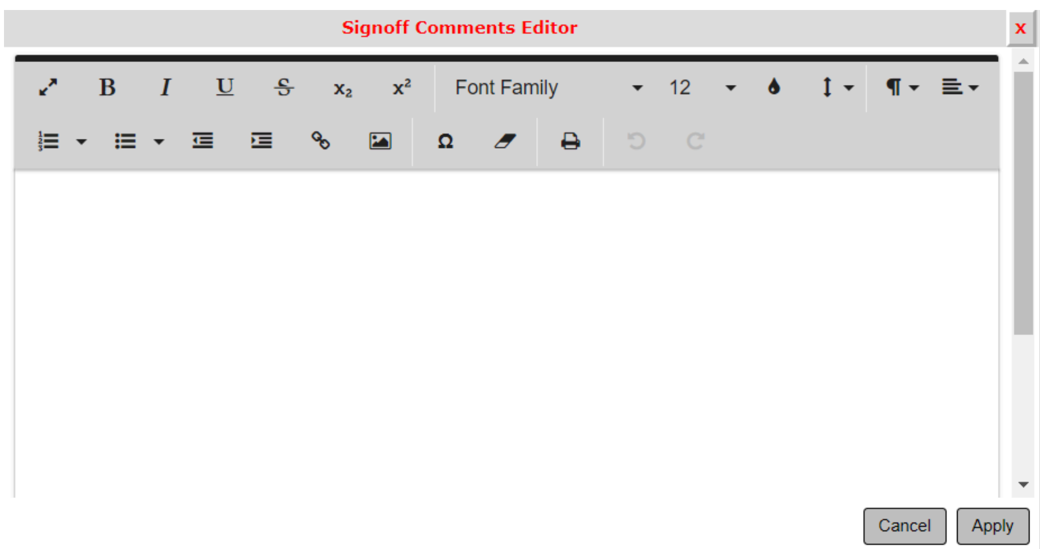
2. **Non-Batch Review and signoff item-by-item**.

Select the icon in the Edit/View Letter column and a screen similar to the screenshot below will be displayed.

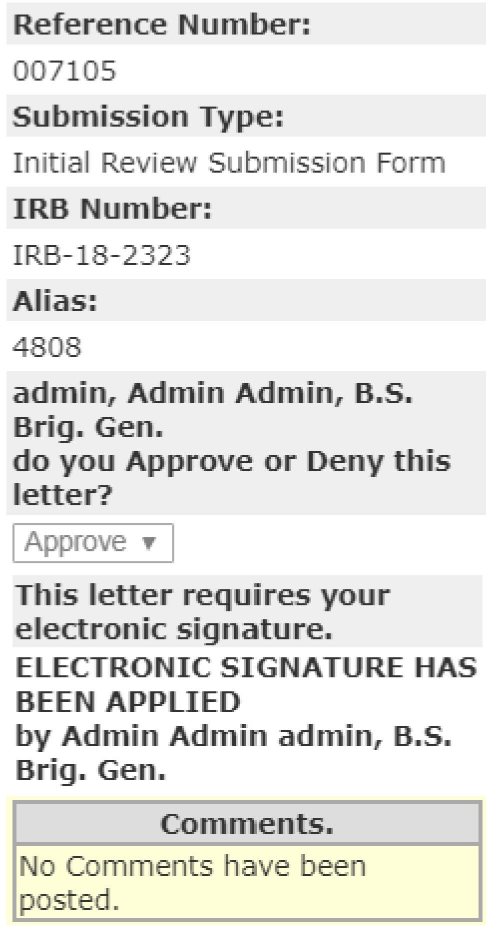


If you are allowed to change the content of the letter, the contents will appear in Word format; if not, the letter will appear in PDF format.

The submission information (**Reference Number**, **Submission Type**, and **Study Number**) will appear on the left side of the screen. You can select whether to Approve or Deny the letter from the dropdown menu. You will be allowed to add comments to the letter by selecting the **Click here to add comments** link. A popup window will be displayed (see below). Enter your comments and click the **Apply** button or **Cancel** to close the window without adding comments.

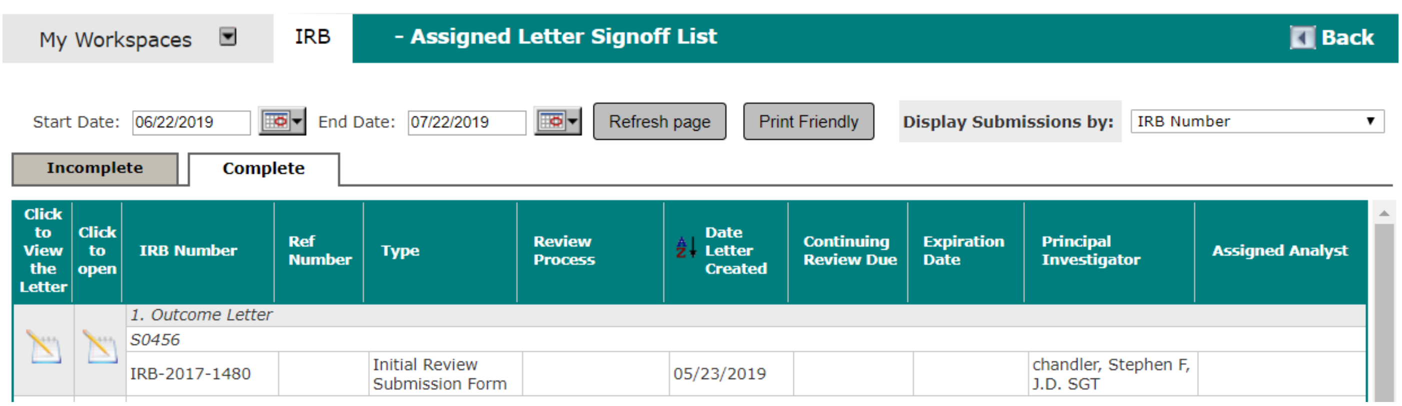


After you select whether to approve or deny the letter, a new field for your electronic signature will appear.



Enter your iRIS UIN and Password (electronic signature) and select the **Save Letter Review** button. After all the above operations are completed your main Assigned Letter Signoff List will read, "No Letters to Review and signoff."

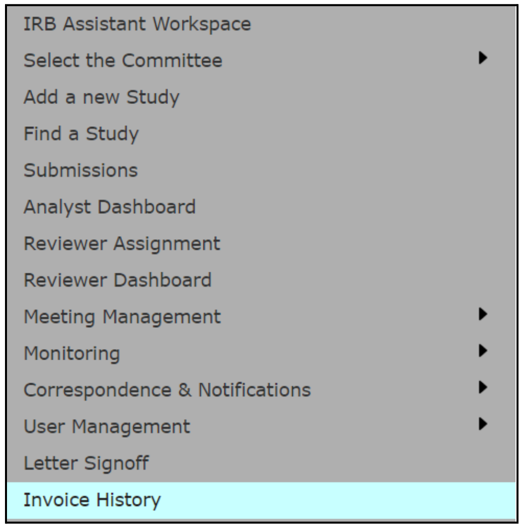
The **Complete** tab will display all the letters you have completed your signature for. This list can be filtered to a specific date range using the Start and End Date Fields. When the date range is set, click the **Refresh page** button to update the screen according to the filtered dates. You can choose whether to display the submissions by IRB Number or another type of Review Board Number, depending on which modules are setup in your instance of iRIS).



Invoice History

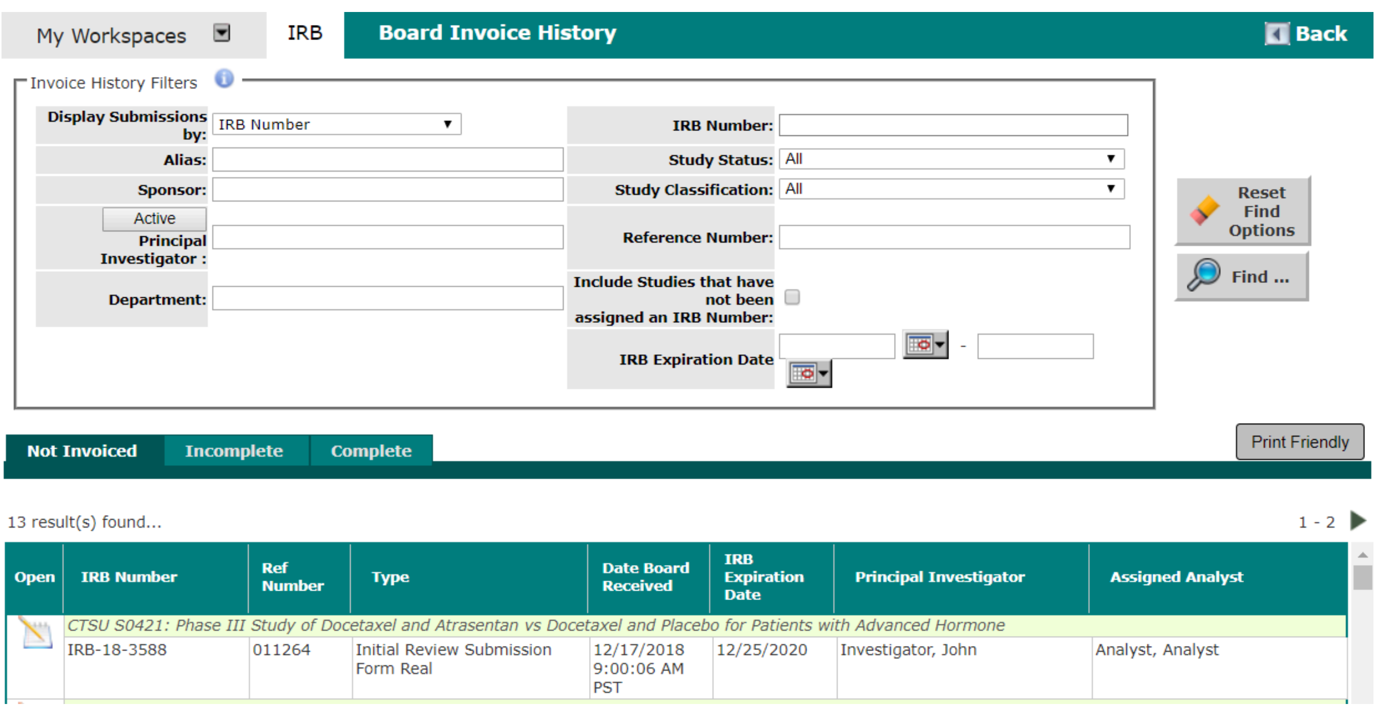
The **Invoice History** tool allows you to access "fee applied" submissions, complete and incomplete invoices, and you will have the ability to generate new invoices and track invoice payments made to the IRB. Please see the IRB Assistant – Invoicing manual for invoicing setup.

Click the Invoice History link within the IRB Assistant menu item.

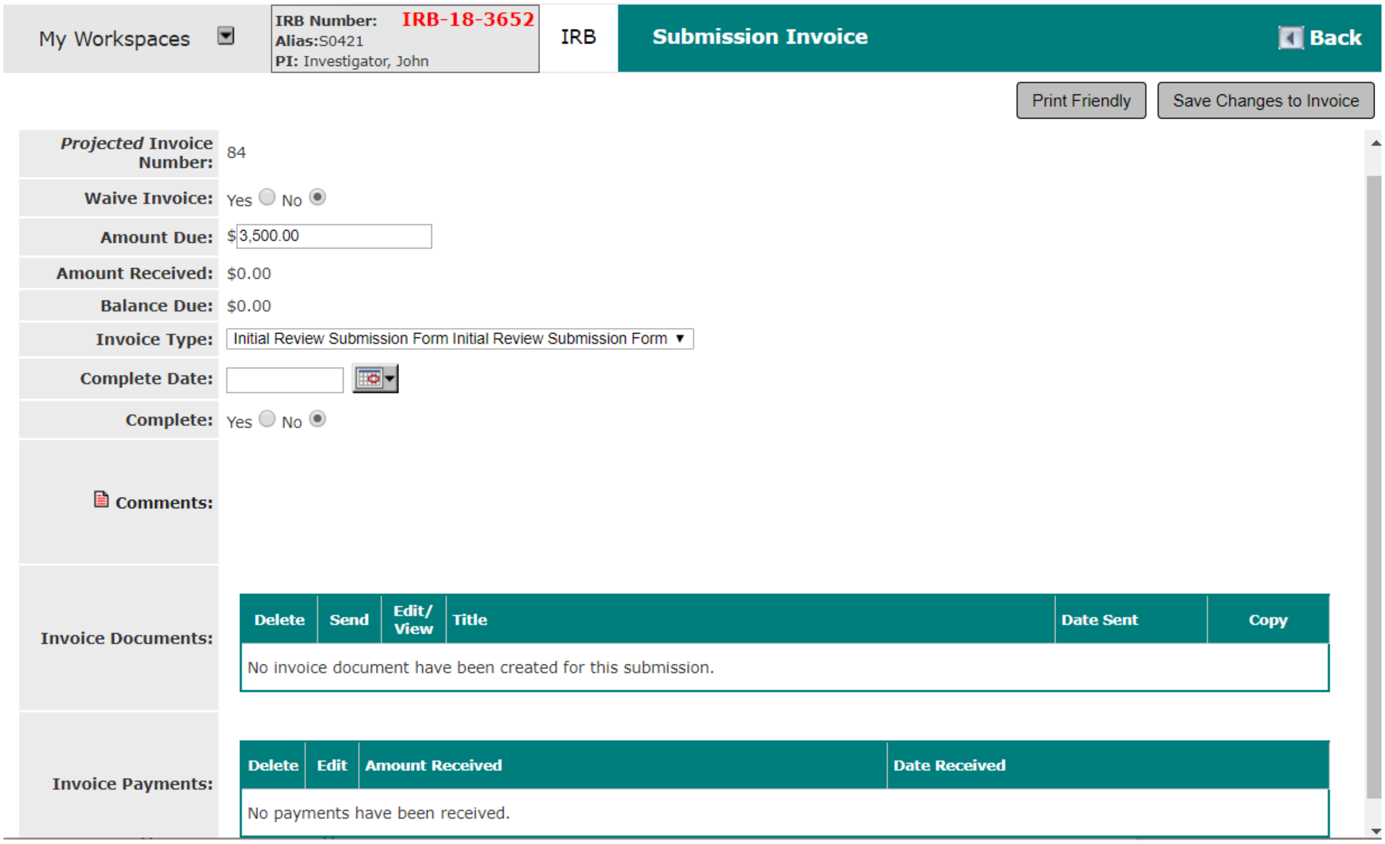


From within the invoice history screen you can view all of the IRB "apply fee for service" submissions. When accessing the invoice history, you will initially be directed to the **Not Invoiced** tab. You will also have access to the **Incomplete** tab and **Completed** tabs.

On the Not Invoiced tab, you will find all the study submissions that have not yet been invoiced.



Click the  icon in the Open column next to the invoice item to view invoice details.



The invoice page contains:

***Projected* Invoice Number** - The number that will be assigned if this is the next Invoice to be completed. Once an invoice number has been assigned, this field will display as **Invoice Number**.

Waive Invoice- Gives you the option to waive the invoice fee for this submission.

Amount Due- Cost of the review service fee.

Amount Received- Total dollar amount of all payments received for this submission.

Balance Due- The remaining balance for this submission.

Invoice Type- The submission type associated with the fee.

Complete Date- This is the date that all invoice payments have been received.

Complete- This flag will move the invoice item to the Complete tab within the Invoice History screen.

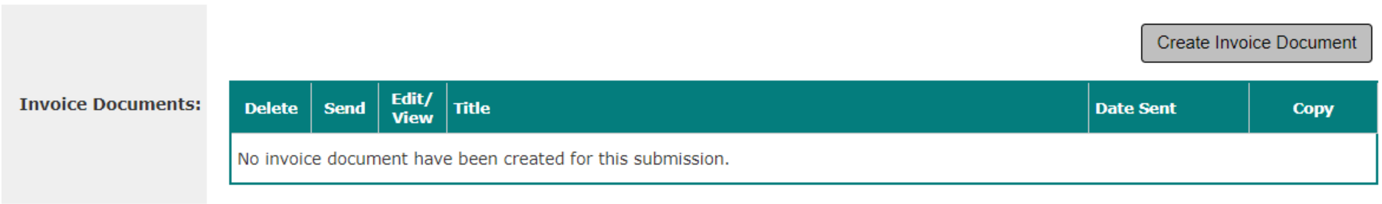
Invoice Documents-Where you can create and send an invoice document.

Invoice Payments- Where you can add received payments.

The Amount Due and Invoice Type should be adjusted before creating the invoice document. This will allow you to generate an accurate invoice document.

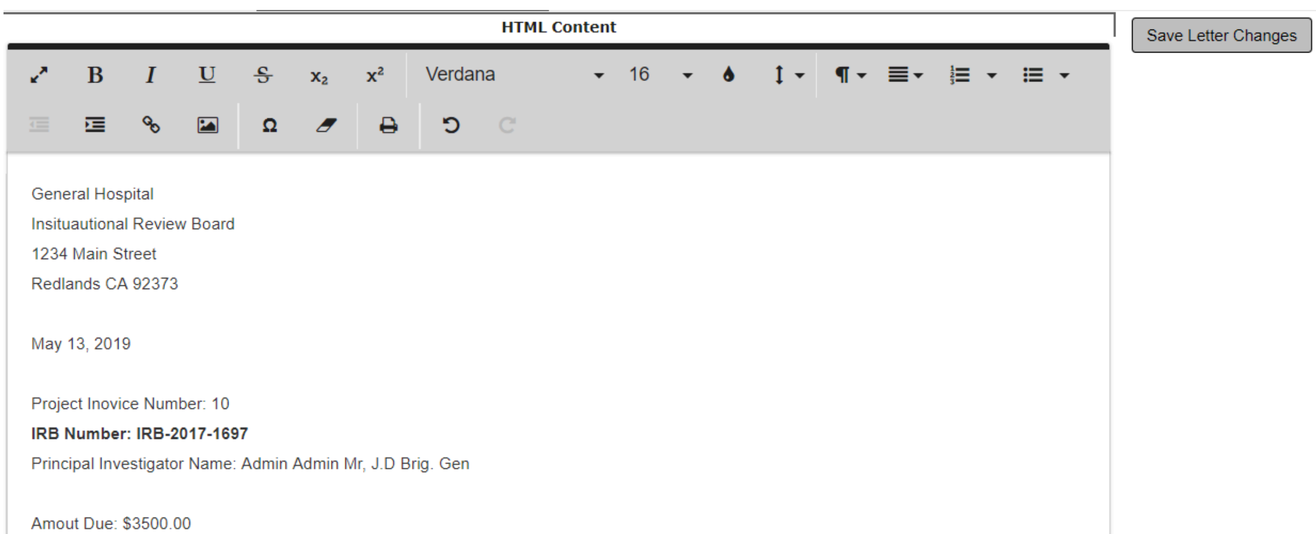
Click the **Save Changes to Invoice** to begin generating the invoice**.** This will create the ability to create invoice documents and add payments. The amount due and Invoice Type should be adjusted before creating the invoice document. This will allow you to generate an accurate invoice document.

Click the **Create Invoice Document** button to create the invoice.

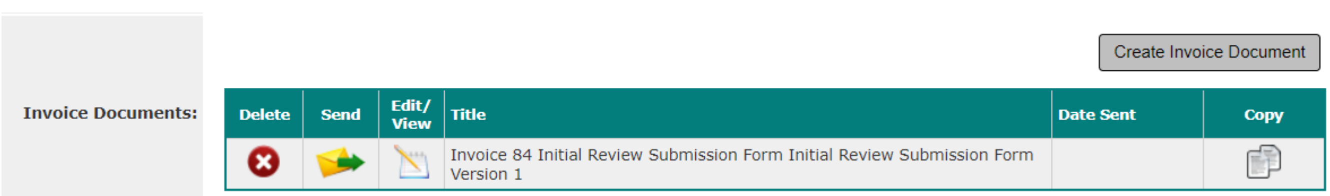


This will open your system's pre-configured invoice template. The Invoice Template is set up under Review Board Administration. These templates can include merge codes that will fill information particular to the study that the invoice is being generated for. You will be able to use the text editor to make any necessary changes to the document. Please see the IRB Assistant - RB Administration manual for Invoice Template setup.

Once you are done creating/making changes to the invoice template, click the **Save Letter Changes** button.



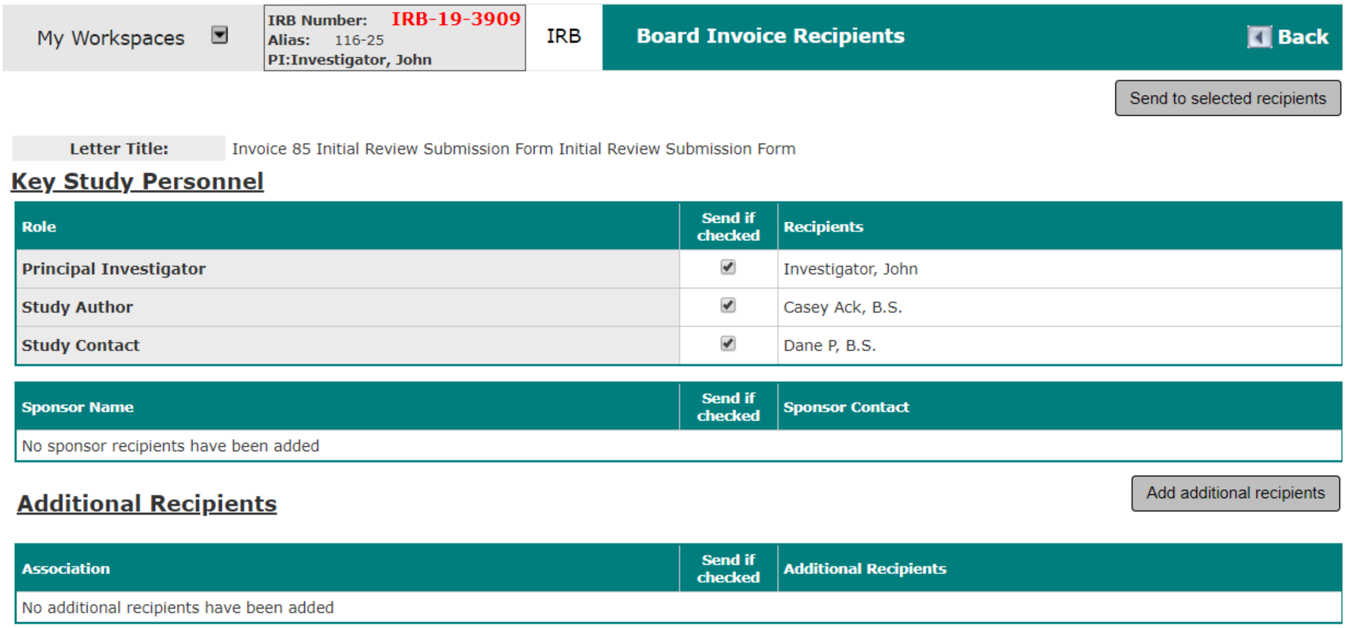
After saving the document, you will be returned to the invoice details page.



To delete an Invoice Document, click the icon in the Delete column.

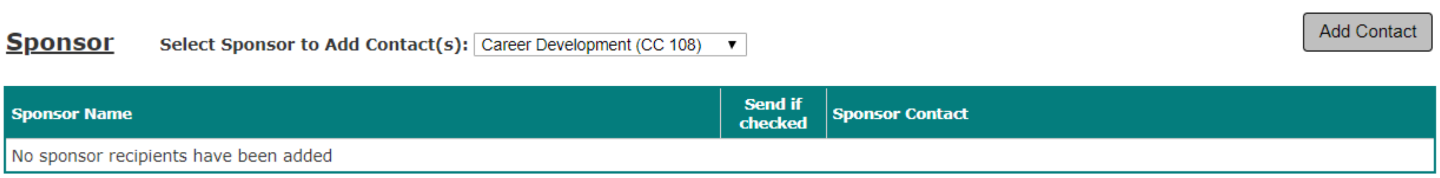
After saving the document, you will be returned to the invoice details page.

Click the **Send** button to select the recipients of the invoice document. One you have entered the page; all the Key Study Personnel will be defaulted to receive the invoice document. Click the "Send if checked" checkbox next to the recipient to include or remove them on the send-to list.



If the study is associated to a sponsor, you will be able to specify contacts associated to the sponsor. The Sponsor Contact will allow you to add as many contacts to the study for the sponsor as necessary.

Begin by clicking on the **Add Contact** button.

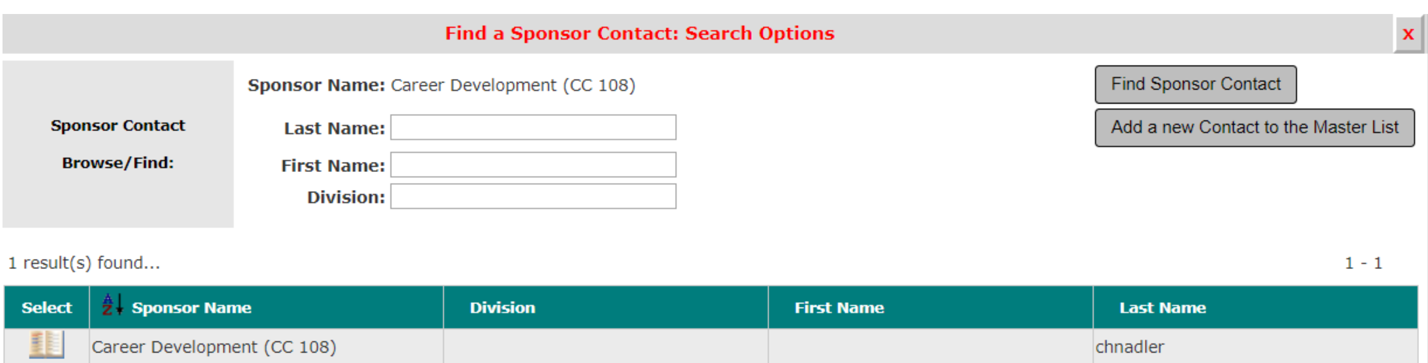


A popup window will open within your browser allowing you to search the system for the existing sponsor's contacts. If the sponsor contacts associated to the study exist, then they will be listed and can be selected.

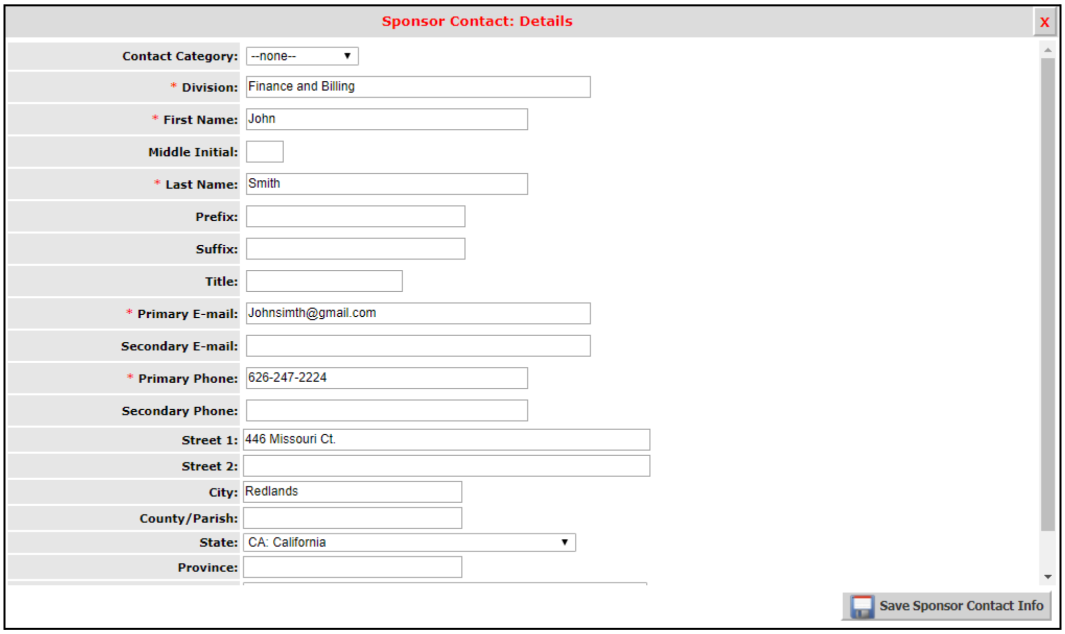
If the study does not have sponsor contacts that are associated to the study (see image above), you can click **Add a New Sponsor Contact** to search the master list of existing contact already setup in iRIS.

A new popup will display within the browser allowing you to search for existing sponsor contacts. Any contact already associated to the Sponsor can be searched using the Last Name, First Name and/or Division search fields. You can enter all or partial information in any of these fields or leave these fields blank and click the **Find Sponsor Contact** button to return all sponsor contacts associated to the sponsor you added to the study.

Select the Sponsor Contact from the list to add them to the send-to list.

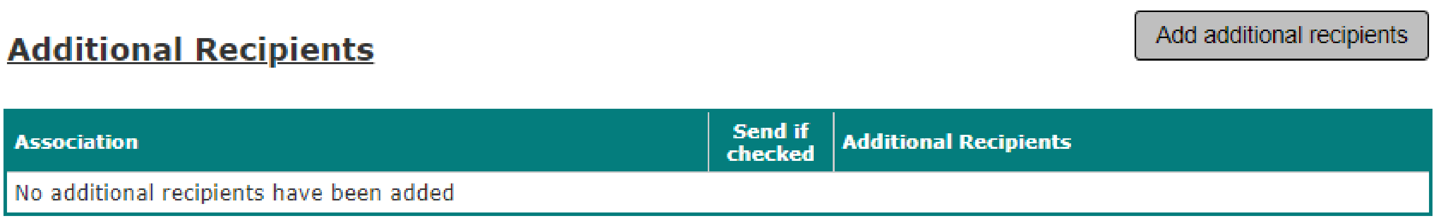


If you cannot find the sponsor contact in the list, you can add a new sponsor by clicking on the **Add a new Contact to the Master List** button.

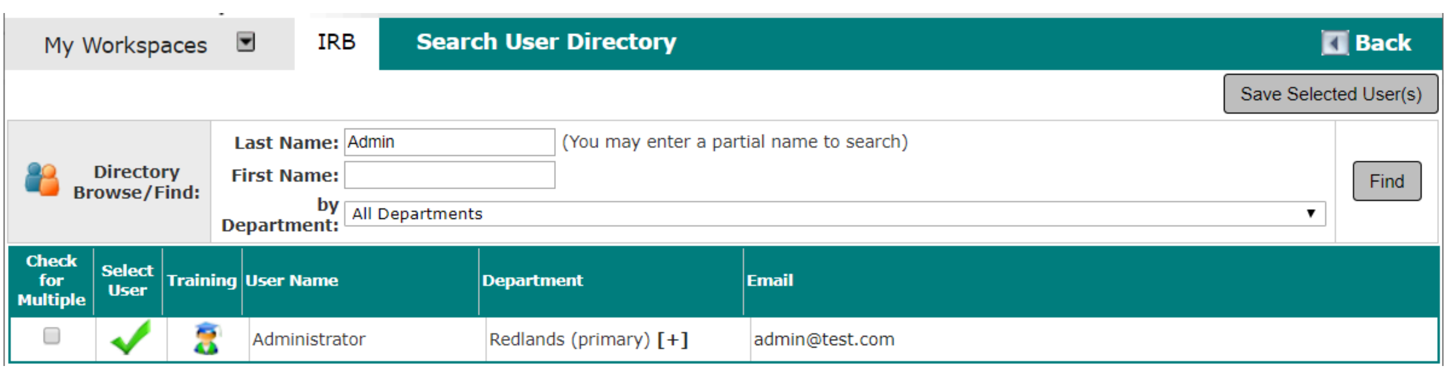


After you choose to add a new contact to the send-to list, the window will update, allowing you to specify the Contact Category, **Division** (required field), **First Name** (required field), Middle Initial, **Last Name** (required field) and information for the sponsor contact. When you are finished, click the **Save Sponsor and Contact Info** button. The system will take y

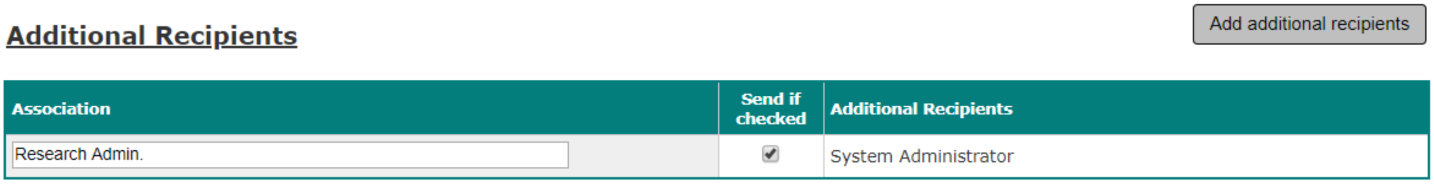
Note: If the study is not associated to a sponsor, you will not be able to add a sponsor contact.



You can click **Add additional recipients** to search the iRIS user directory for additional users to send the invoice to.



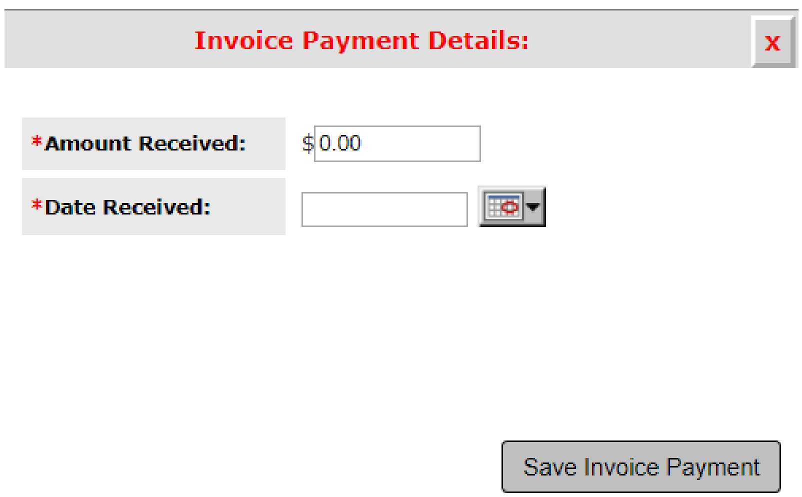
Once you have selected the appropriate recipients click the **'Save Selected User(s)'** button.



After sending the invoice document, you will be returned to the invoice details page.

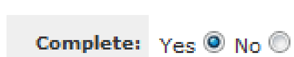
Click the **Add a New Payment** button to record payment entry.

When you enter Payments for the invoice, the Amount Received will be adjusted accordingly.

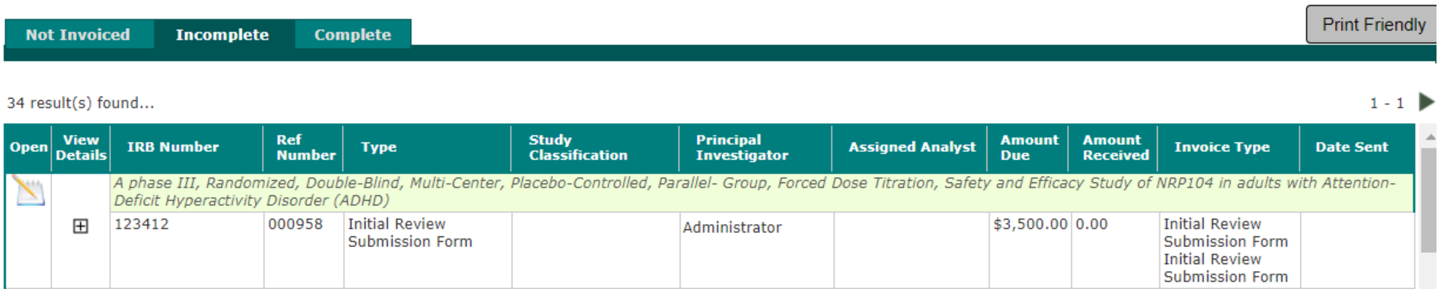


Enter the amount received and date received then click the **Save Changes to Invoice** button to save the payment entry.

Once the entire Amount Received equals the Balance Due, the Invoice is considered closed. You can now complete the invoice by selecting Yes for the Complete radio button. This will move the invoice entry to the Complete tab. Partial payments of the invoice should remain on the Incomplete tab.

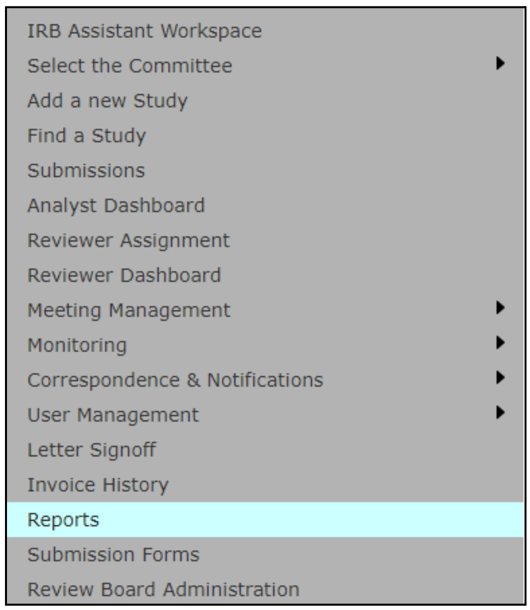


The Incomplete tab will house all of the open invoices within the review board. You can continue processing incomplete invoices until all payments have been received by the IRB.

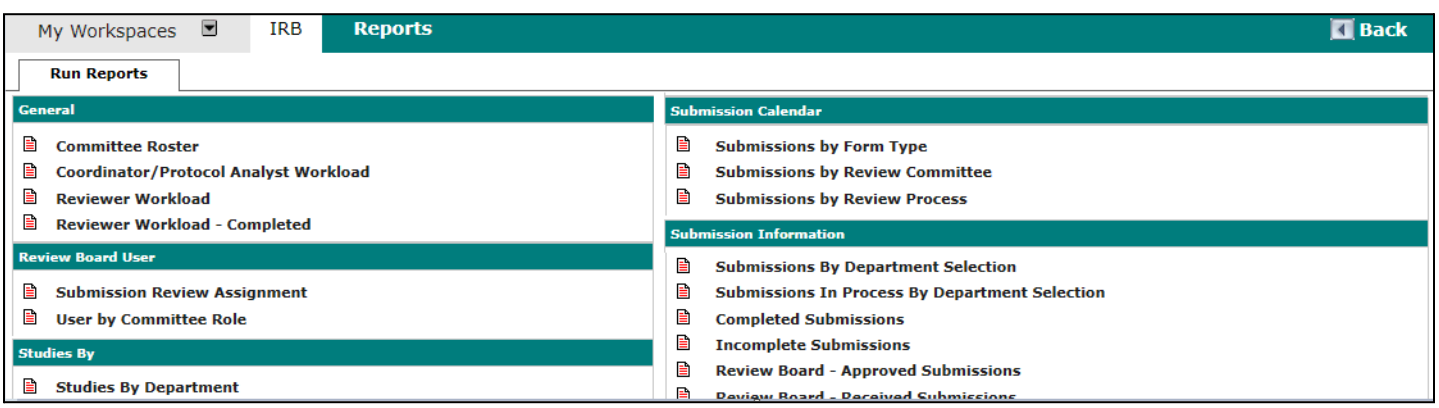


The **Completed** tab will house all completed invoice within the review board. You will have the ability to input date parameters to help narrow down results when you are searching for previously completed invoices.

Reports

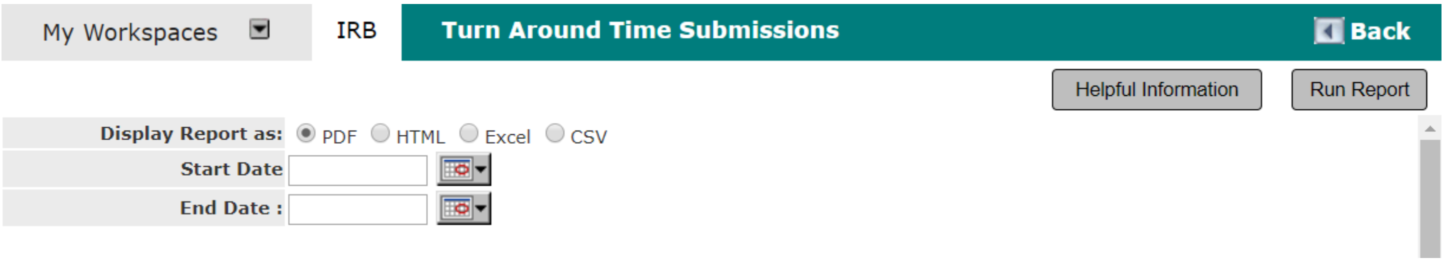


The **Reports** tool allows you to access and run the pre-canned reports that come with the IRB Assistant module. (See the IRB Assistant – Reports manual for more information)



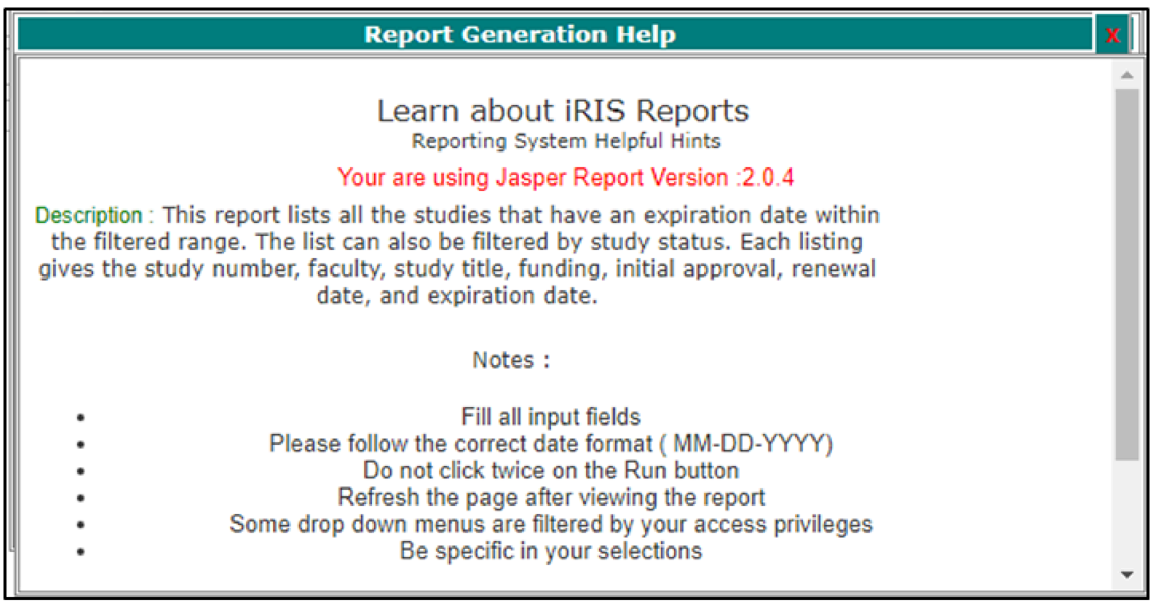
The Reports page lists the available reports grouped into a variety of categories. Clicking on a report link will allow you to set specific parameters and run the report. The parameters and filter options for each report will vary based on the requested information.

Within each report you will have the option to display the report in PDF, HTML, or Excel

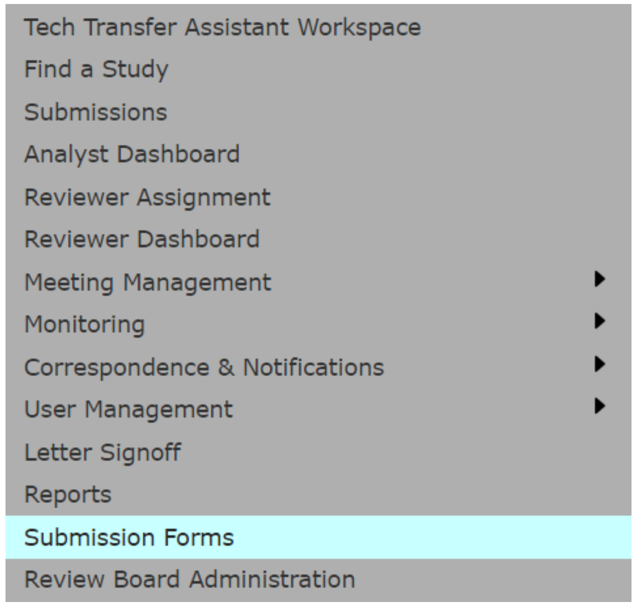


format.

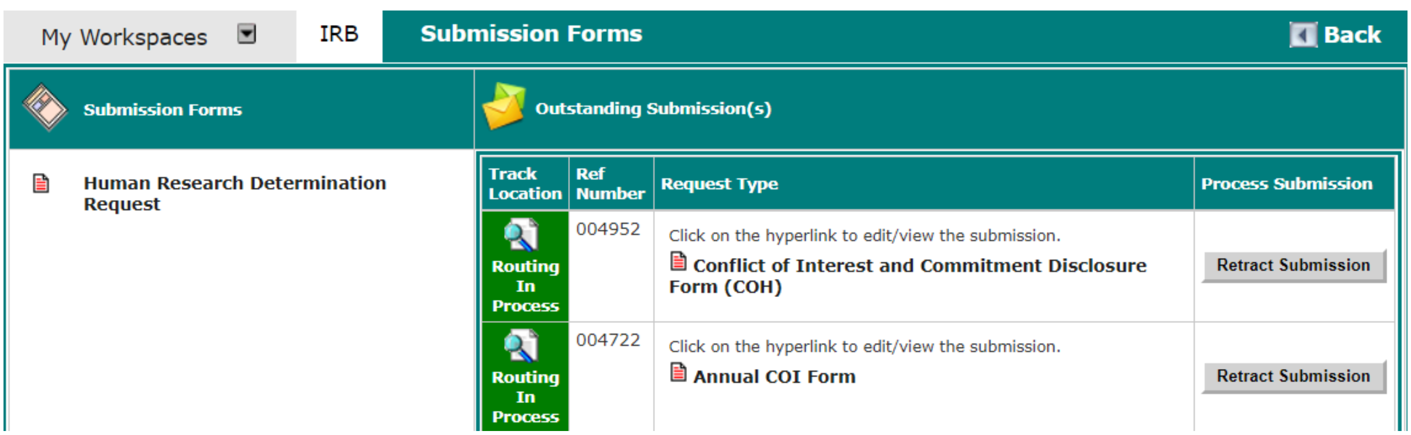
When you click the **Helpful Information** button, the Report Generation Help window will populate. The **Helpful Information** window displays notes that assist you in running the report and displays the description of the report.



Submission Forms



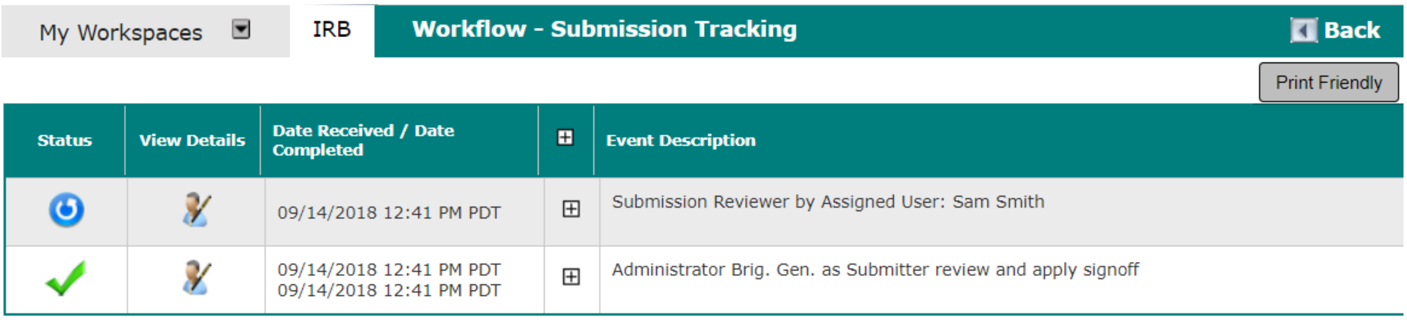
The **Submission Forms** section of IRB Assistant allows you to see all of the non-study submission forms accessible to the IRB as well as a list of Outstanding Submission(s) for these forms.



On the left side of the screen, you will see the Submission Forms section. If you click the name of a form in this list, you will be brought to the form library.

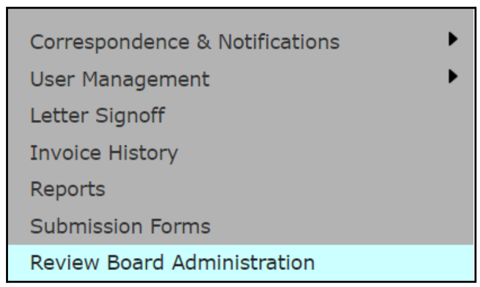
From this screen you can view all of the records of this form that have been submitted by different users in the system. You can also **Copy Form**, **Add a New Form**, **Compare Two Versions** if more than one version of a form is available, and **Delete Selected Form(s)** that haven't been submitted yet.

On the Outstanding Submission(s) side of the screen, you will see outstanding submissions of non-study submission forms in your system. Clicking **Routing in Progress** in the Track Location column will bring you to the Submission Tracking Workflow screen for the form.



Click **Back** to return to the Submission Forms screen. If you click the name of the form in the Request Type column, you can view a read-only copy of the form. If you need to edit the form, click the **Retract Submission** button and open the form again. Once you have made your desired edits, exit the form and click Send Submission to re-submit the form.

Review Board Administration



Review Board Administration allows you to configure many options related to the functioning of the board, set up configuration lists, define document templates including Outcome Letters, and Meeting Agendas and Minutes, and set up automatic review board-related notifications. Review Board Administration is typically reserved for Review Board Administrators. See the IRB Assistant - RB Administration manual for more information.