Conflict of Interest Assistant

COI Assistant Overview

Version 11.02

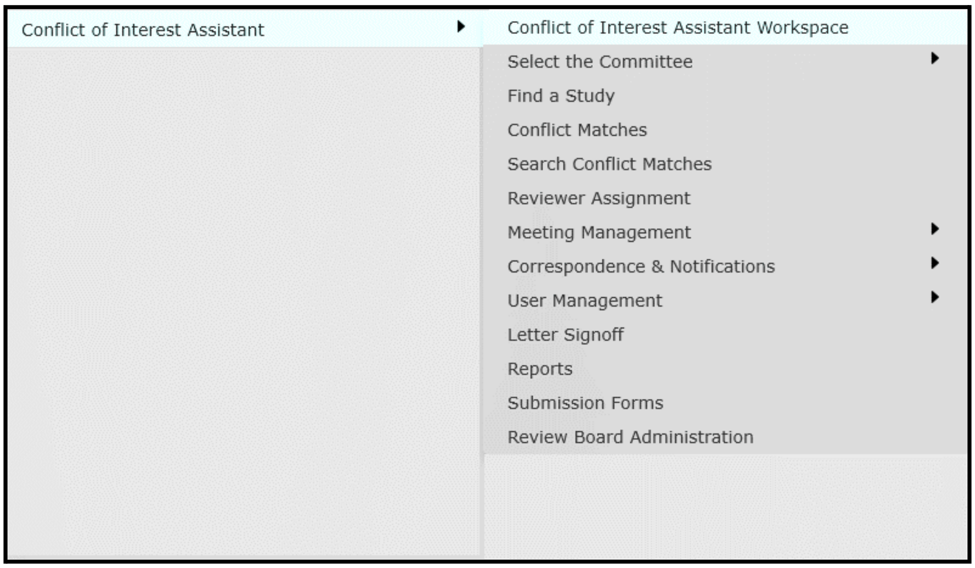
Contents

Conflict Of Interest Assistant Manual

Conflict of Interest Assistant Overview

The Conflict of Interest (COI) Assistant is available to streamline and assist in an institution's COI management. The COI Assistant works similarly to other review boards, but the main feature of this module is that it works in conjunction with the rest of the software to avoid financial and other types of conflicts of interest that may occur throughout the entire process of submission reviews, signoffs, member reviews, and so on.

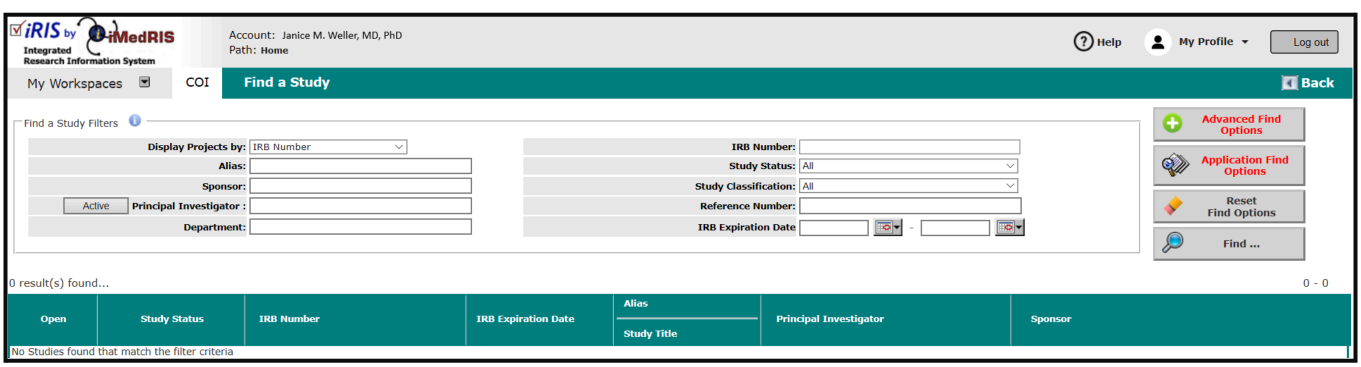
Whenever a submitted Annual COI or Study COI form has a conflict match, that match will populate in the Conflict Matches queue. Within the COI Assistant, you can manage these matches, search previously reviewed COI matches, and review management plans.



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.*

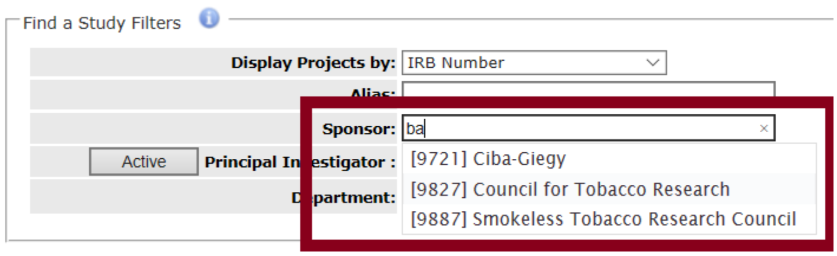
Find A Study

Use the **Find a Study** screen to look up studies. Click on this item in the main menu or click on the **Find A Study** icon in the **COI Assistant Workspace** to load the **Find A Study** search screen.



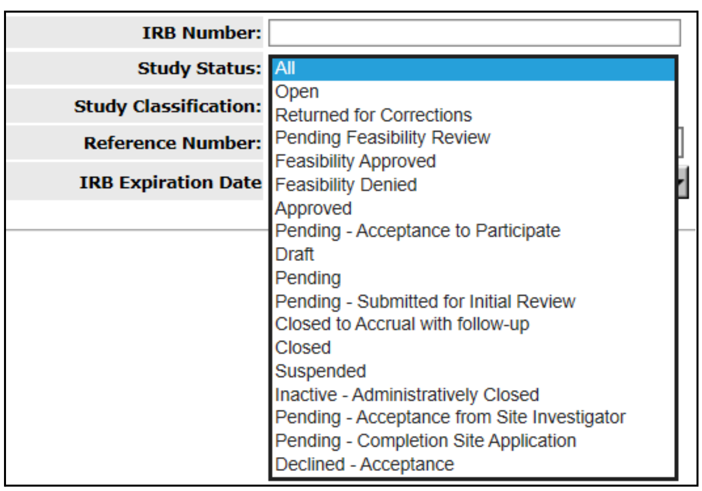
Using the dropdown lists and text fields, you can narrow your search using any known information. Depending on your system settings, studies can be displayed by the **IRB Number**, **Project Number**, **IACUC Number**, **IBC number**, or **Study Number**. Changing the **Display Projects by** field will update the table accordingly.

Some of the search fields are auto-populating fields. 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 toggle between Active and Inactive PIs. Inactive PIs are any user accounts in the system that have been flagged as Inactive that also are listed as Principal Investigators on studies. Active PIs are any user accounts that are flagged as Active and also are listed as Principal Investigators on studies.

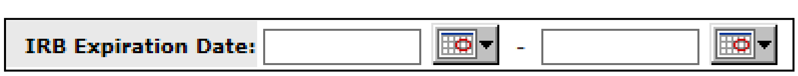
There are also dropdown lists of available **Study Status** and **Study Classification** you can choose from. ***Note:*** *Items shown in the lists will vary according to your specific configuration and custom Review Board Administration settings.*



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. Example, for a submission with Reference Number "000288," you would need to enter "000288" or "288" to filter the results correctly.

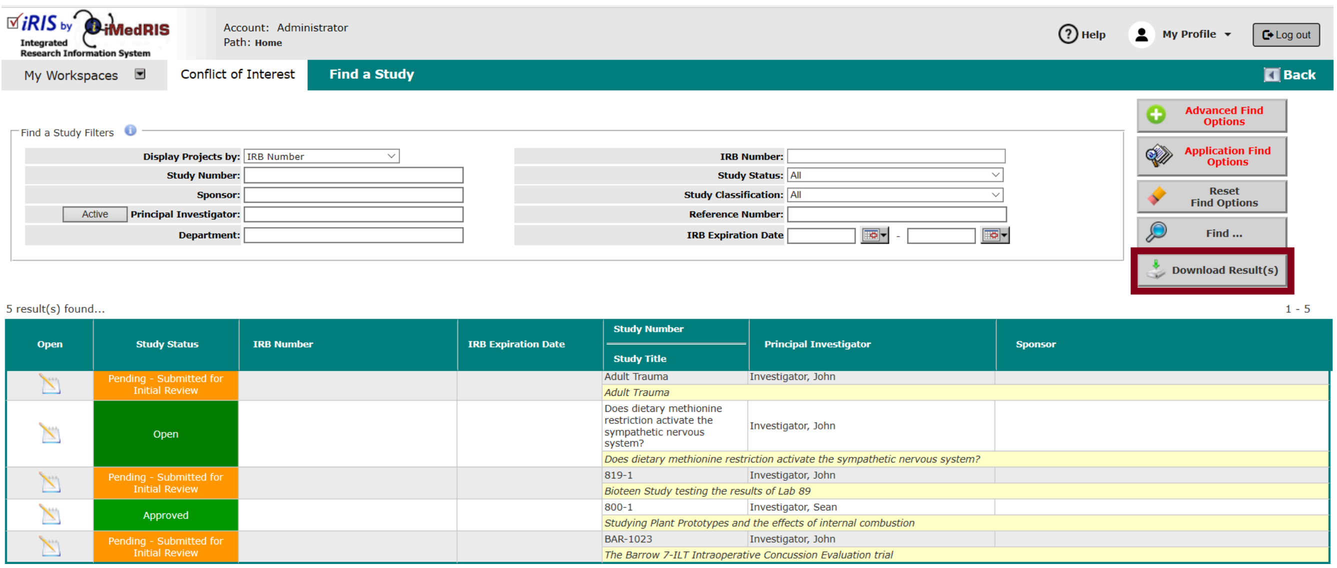
You can search by an expiration date range by entering in the appropriate information in the **Expiration Date** fields.



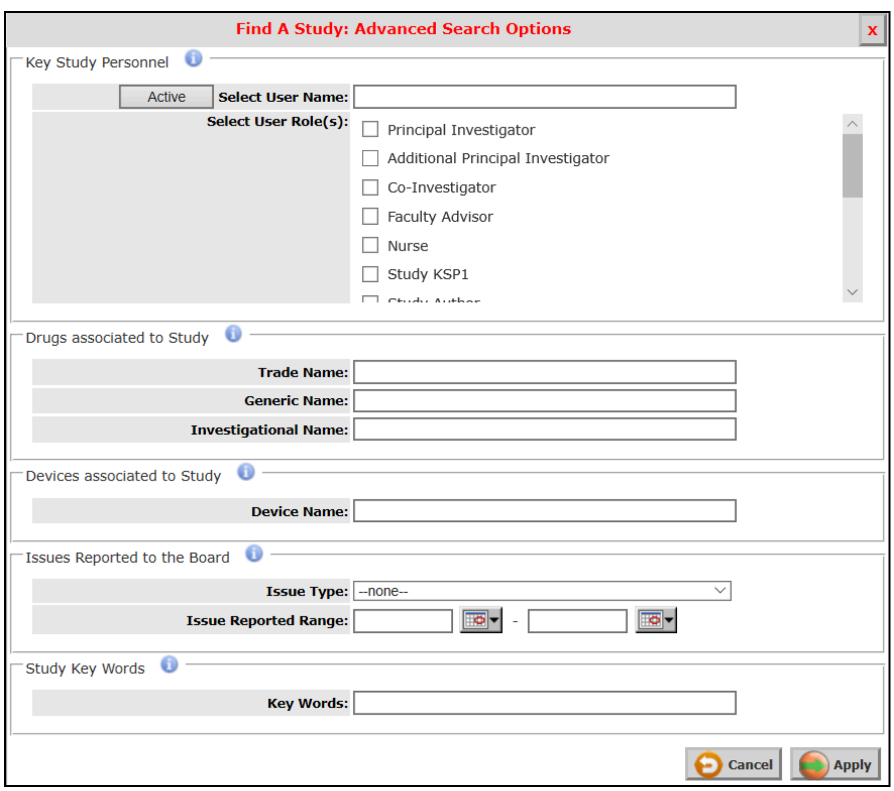
Reset Find Options – Click this button to reset the study filters and begin a new search.

When you click the **Find** button the system will return any matching studies, depending on the filters you selected.

Notice that once the **Find** button is clicked or search criteria have been applied, whether via the **Find a Study Filters** panel at the top of the **Find A Study** screen, the **Advanced Find Options** button/screen or **Application Find Options** button/screen, a **Download Result(s)** button will appear. Click this button to download the results list in .csv format.



For more search options, click on the **Advanced Find Options** button to open the **Advanced Search Options** form.

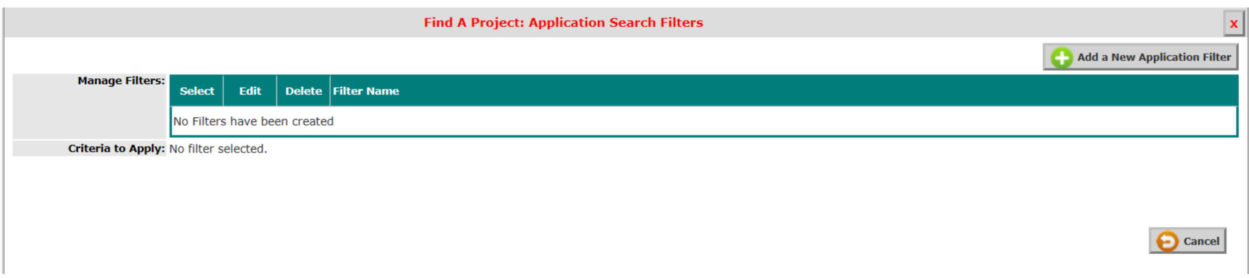


This form allows for filtering by study personnel, study drugs, devices, issue reports, and key words in the **Study Title**. You can choose to use one or all options in the **Advanced Search Options** form by selecting an item from a dropdown list and/or typing in the keywords. When you are finished, click the **Apply** button at the bottom right corner to apply the selected filters and view the result set in the **Find A Study** screen. Click the **Cancel** button to close the window without applying the filters.

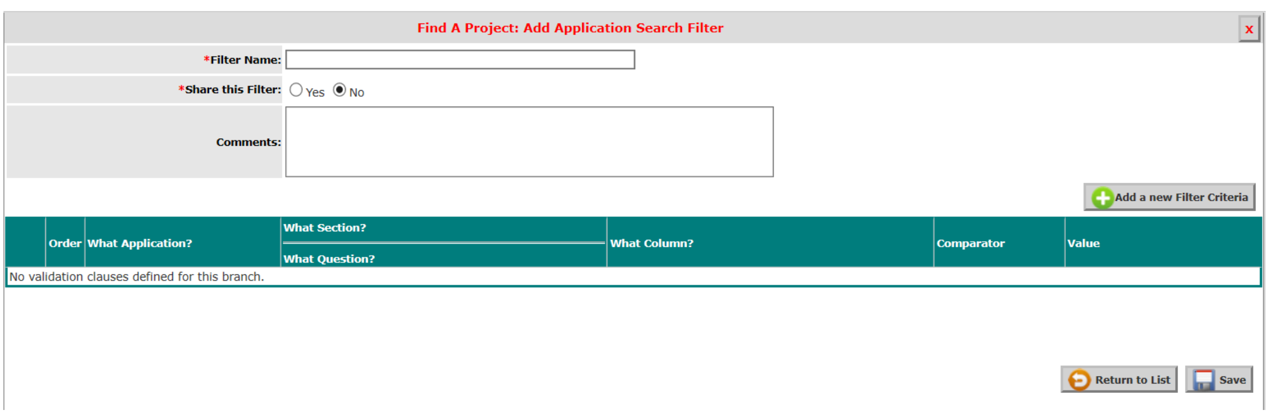
If you added **Advanced Find Options**, that button will update on the **Find A Study** screen with a yellow border to indicate extra filters are in use.

To remove **Advanced Find Options**, click on the button to open the associated form, clear its contents and click the **Apply** button.

For application-specific filters that can be saved and re-applied as needed, click on the **Application Find Options** button. This will open the **Application Search Filters** form. From here you can create and save new filters, or edit and apply previously created and saved filters.

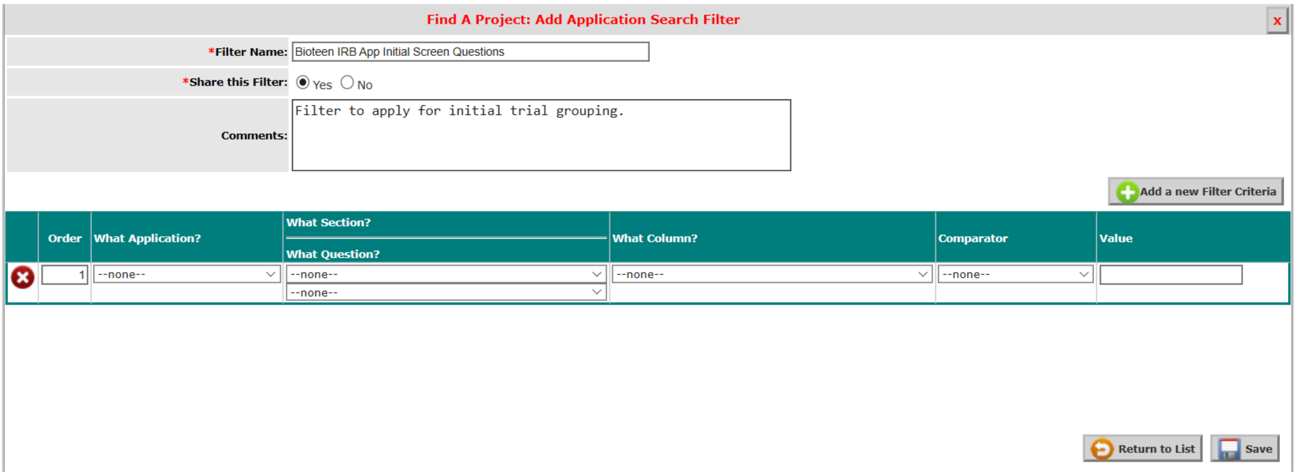


Click the **Add a New Application Filter** button to open the **Add Application Search Filter** form.

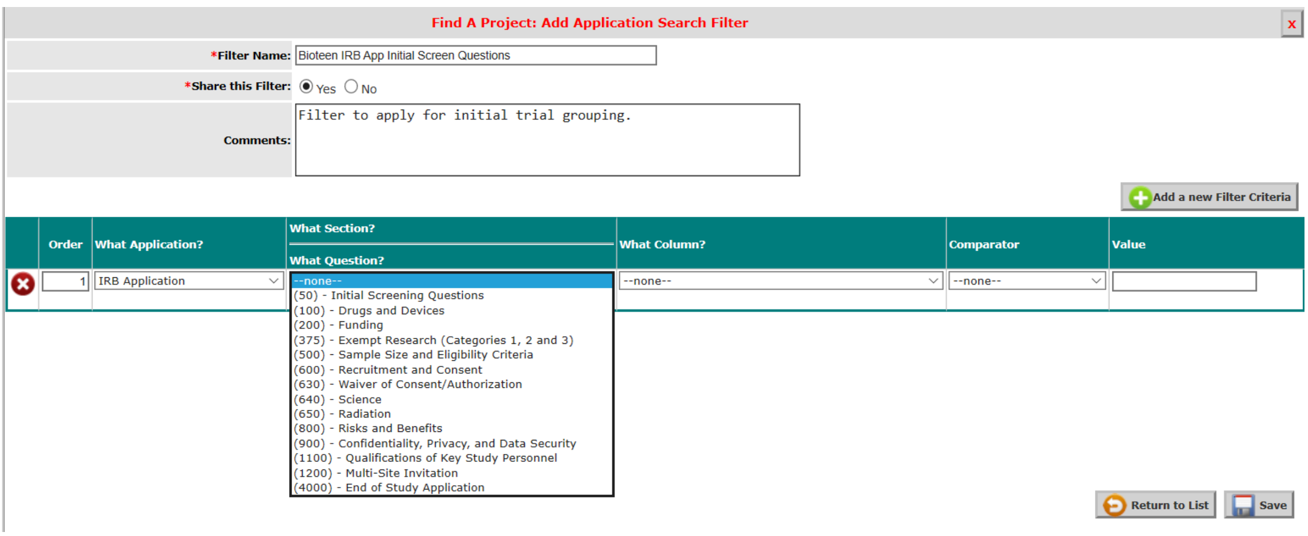


Enter a **Filter Name** and select **Yes** or **No** for **Share this Filter**. Selecting **Yes** will make the filter available for others to use, selecting **No** will keep the filter private to the person who created it. Optionally, you may also add comments.

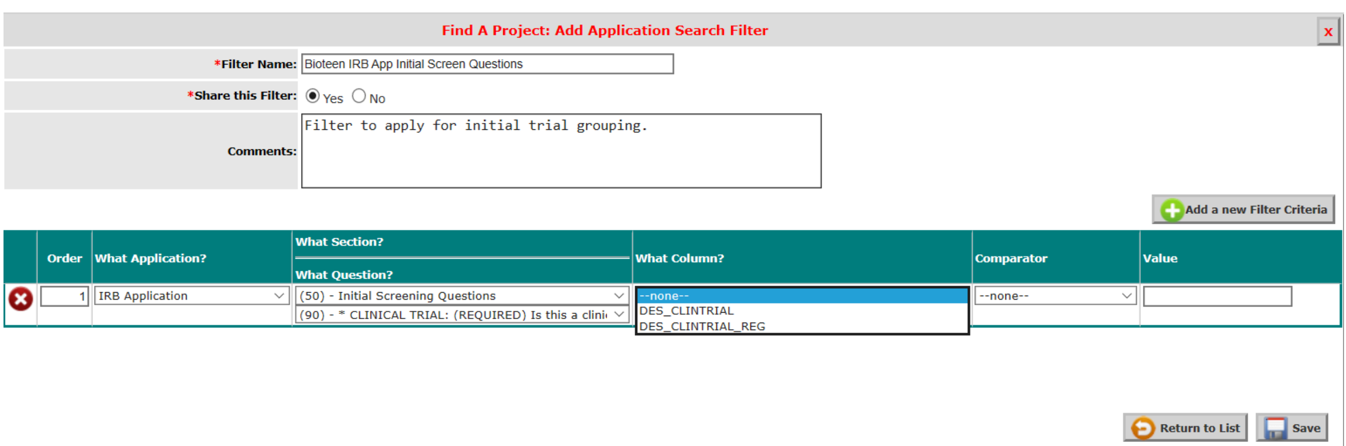
Click on the **Add a new Filter Criteria** button to add filter criteria. Available text entry fields and dropdown lists will be activated.



Select from the **What Application?** column to populate the **What Section?** and **What Question?** dropdown lists.

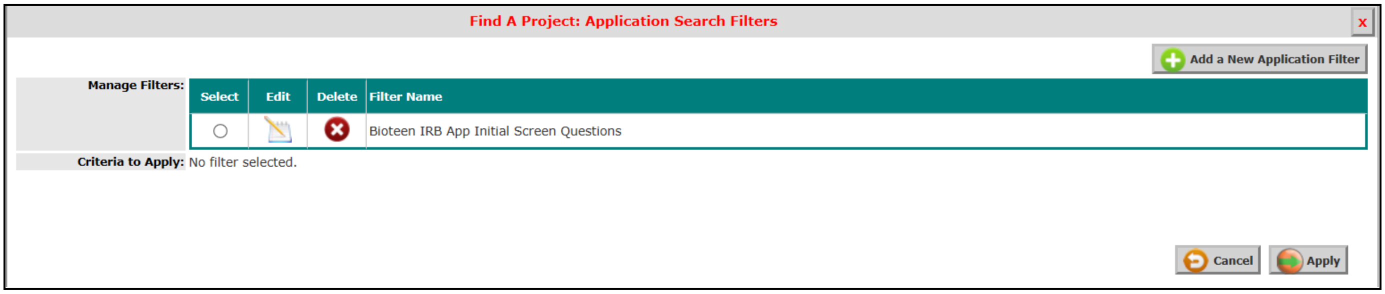


Make your selections in the **What Section?** and **What Question?** dropdown lists to populate the **What Column?** dropdown list and activate the **Comparator** dropdown list.



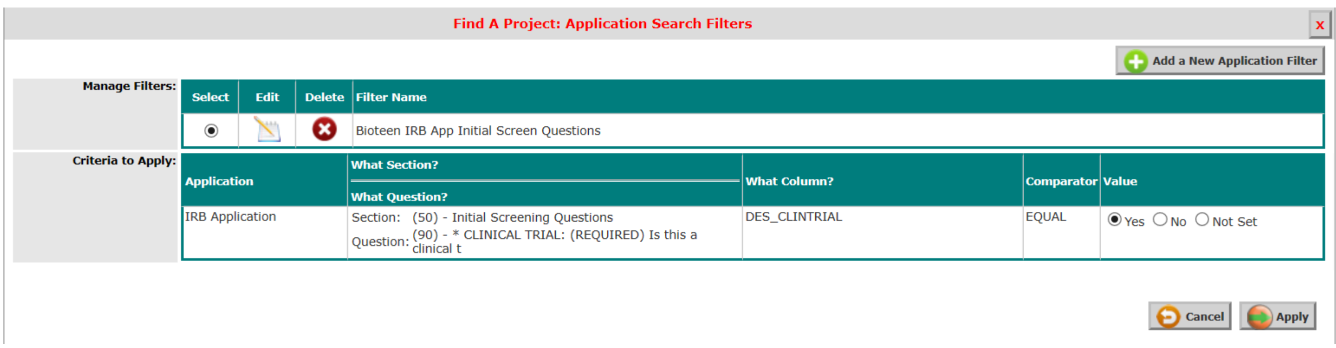
Select the desired **Comparator** and enter the desired **Value**. Click the **Save** button to save the filter and return to the **Application Search Filters** screen.

Alternatively, click the **Return to List** button to cancel and return to the **Add Application Search Filter** screen without saving any changes.



Repeat the **Add a New Application Filter** process to create additional filters and add them to the **Application Search Filters** list.

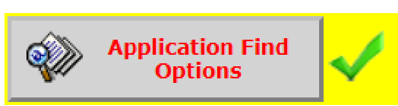
Click in the **Select** column of a filter in the list to view its **Criteria to Apply** details. You may change the default **Value** for a selected filter, and doing so will not change the default value in the underlying filter.



Click the icon in the **Edit** column to make and save changes to the underlying filter.

Click the **Apply** button to apply any selected filter(s) and view the filter results in the **Find A Study** screen.

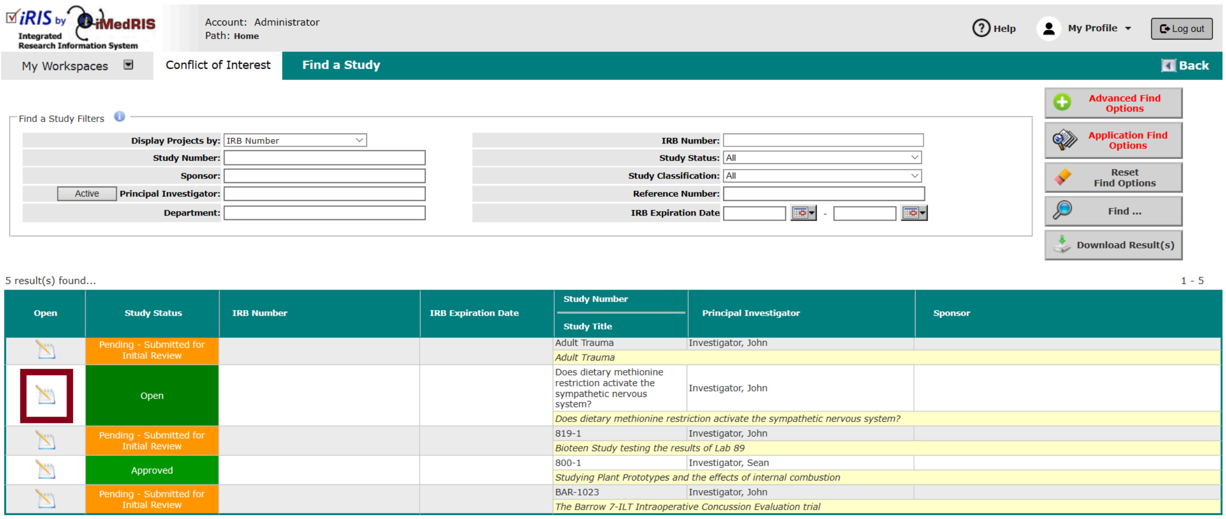
If you selected and applied any filters in the **Application Find Options**, the button will update with a yellow border to indicate extra filters are in use.



To remove **Application Find Options**, click on the button to open that form, clear the Select column for the filter you wish to remove and click the **Apply** button.

You may apply **Advanced Find Options**, filters from **Application Find Options**, or both.

Back on the **Find A Study** screen, once you find the study you are looking for, click the icon in the **Open** column to open the study record.



The other columns in the results section of the page are as follows:

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

IRB Number - If an IRB Number has been associated with a study, it will display here. This column will change to whatever you choose to display the studies 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.

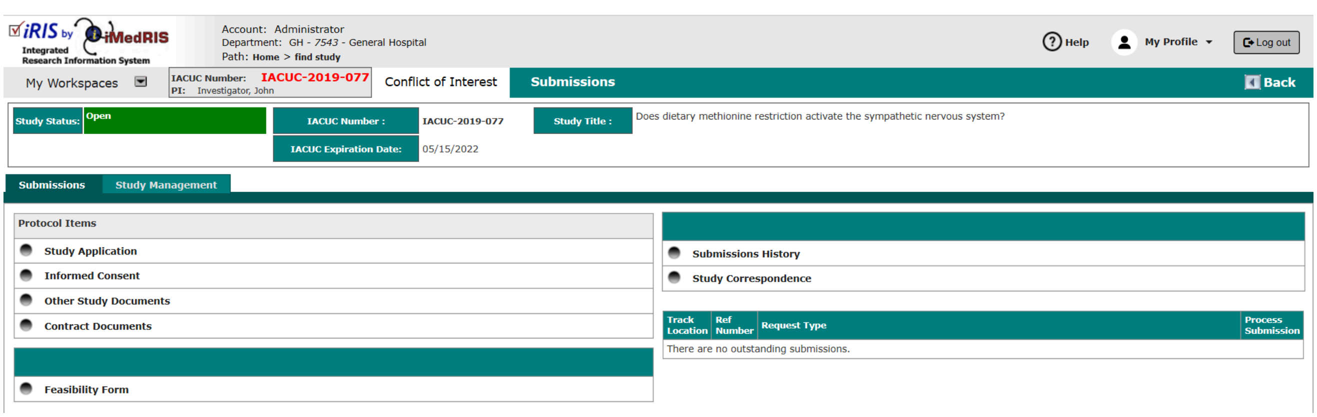
Study Number - This displays the Study Number/Nickname given to the study in the initial section of the Study Application.

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.

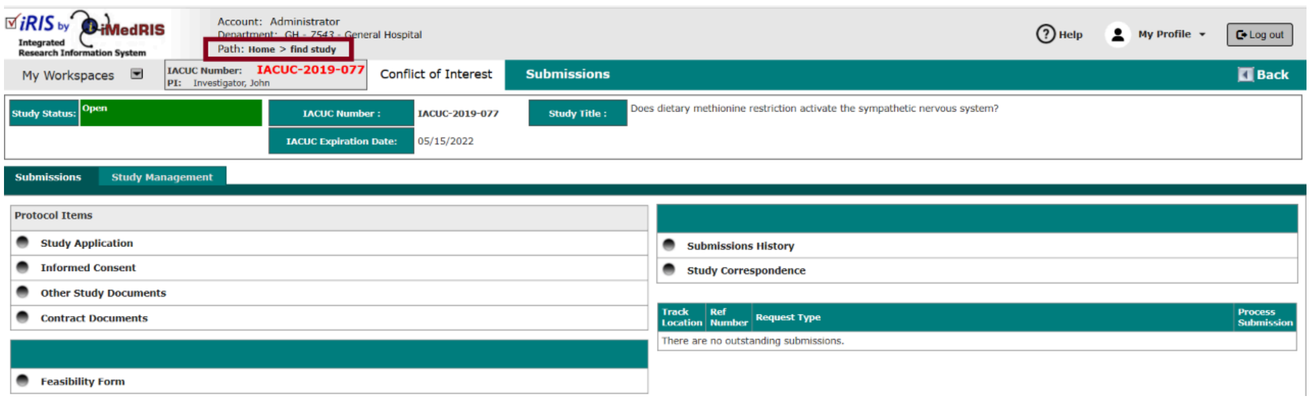
Clicking the icon in the **Open** column opens the **Study Management** page for the selected study. By default, this page opens to the **Submissions** tab. The menu items shown on this screen may vary according to your specific system configuration and role.



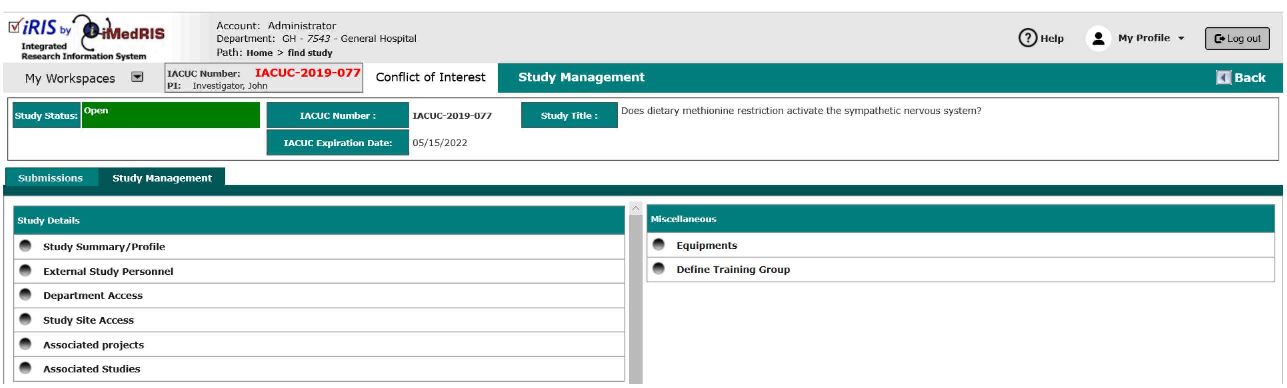
The **Submissions** tab in the lower part of the screen will display any forms available for viewing by the COI.

Notice the **Path** item at the upper left of the screen. This is a hyperlinked menu directory tree you can use to quickly navigate back through the path you've followed to get to your current location, and it appears on all screens that are nested one or more levels beneath the main **Conflict of Interest Assistant Workspace**.

In the example shown you are currently viewing the **Study Management** screen, and you can tell this screen is nested two levels beneath the main **COI Workspace** screen because there are two links available in the **Path**: **Home**, and **find study**. Clicking on **find study** in the **Path** will take you up one level in the directory tree, to the **Find A Study** screen. Clicking on **Home** in the **Path** will take you to the **COI Workspace**.

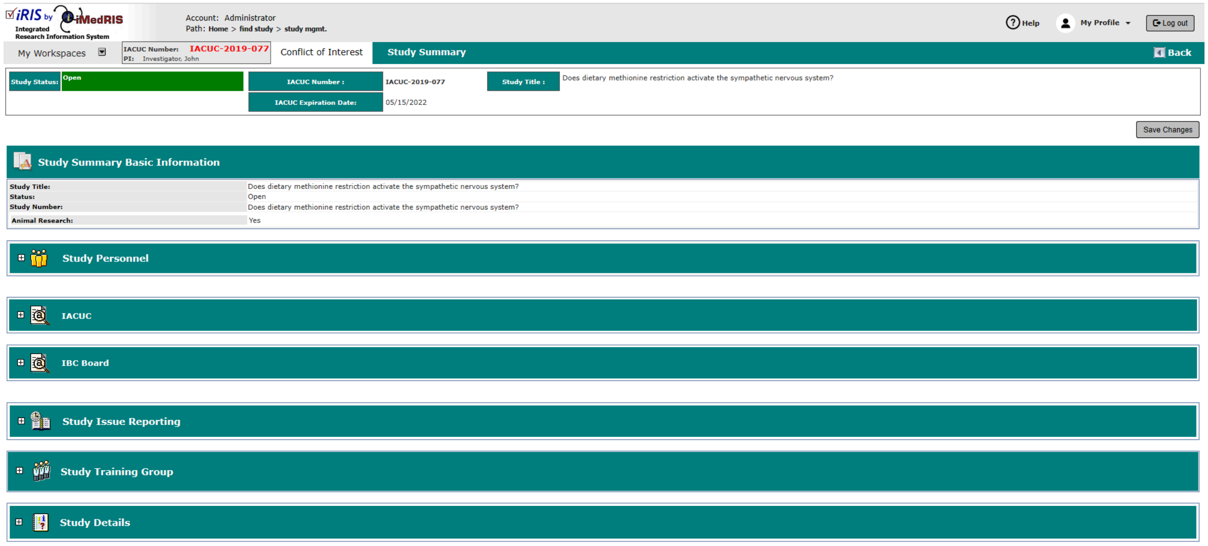


Clicking on the **Study Management** tab brings you to a screen where you can access all information regarding the study (with the exception of subject information).

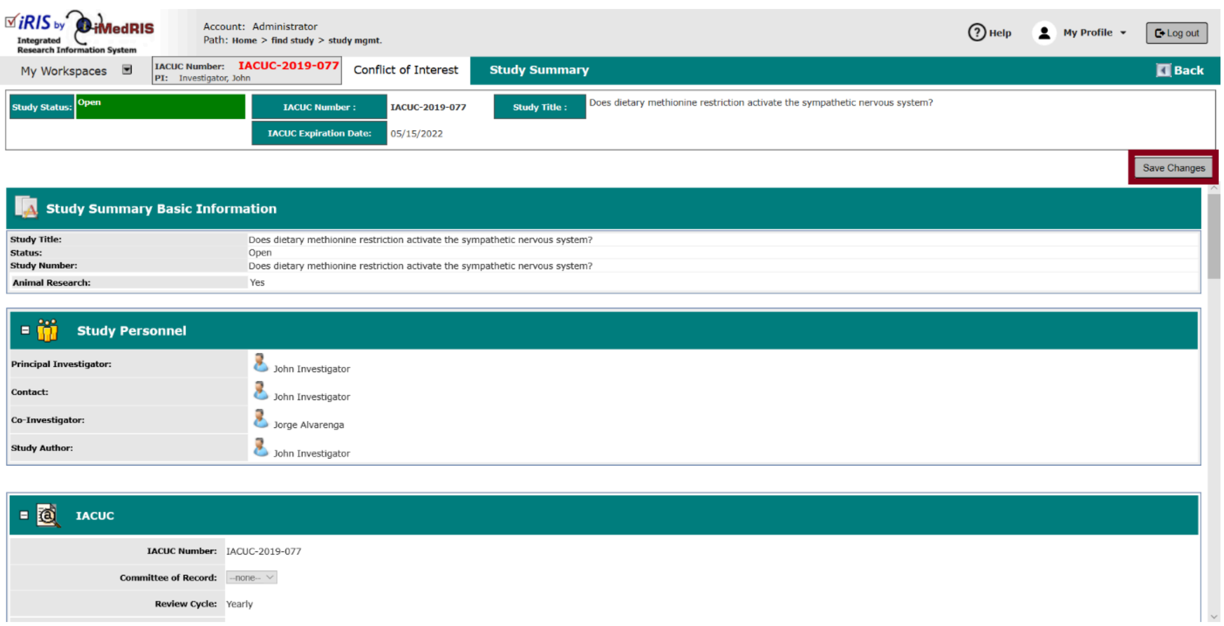


Depending on the COI's access to a study record in the system, you may or may not see the same links as shown in the screenshot above.

Click the **Study Summary/Profile** link in the **Study Details** column to open the **Study Summary** screen. This screen can contain any, or all of the sections shown in the following screenshot, according to your specific configuration and custom Review Board Administration settings.



By default, all available sections are opened in expanded view, as shown below. Some sections have editable fields. After making changes in any of those sections, click the **Save Changes** button at the upper right of the screen.



The **Study Summary/Profile** contains basic information about the study like personnel, review board information, study details, etc. The screenshot above 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 or off under Review Board Administration.

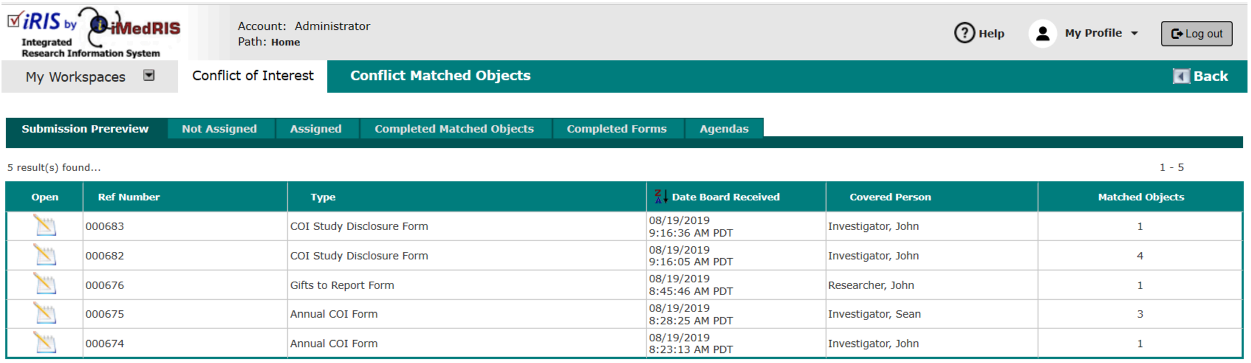
This area can be used to gather information about a specific study for COI purposes. Click the **Back** button at the upper right of the screen to return to the **Study Management** screen, or use the **Path** link labeled **study mgmt**.

Conflict Matches

The **Conflict Matches** link allows you to view and process all conflict matches generated as users filled out their disclosure forms.

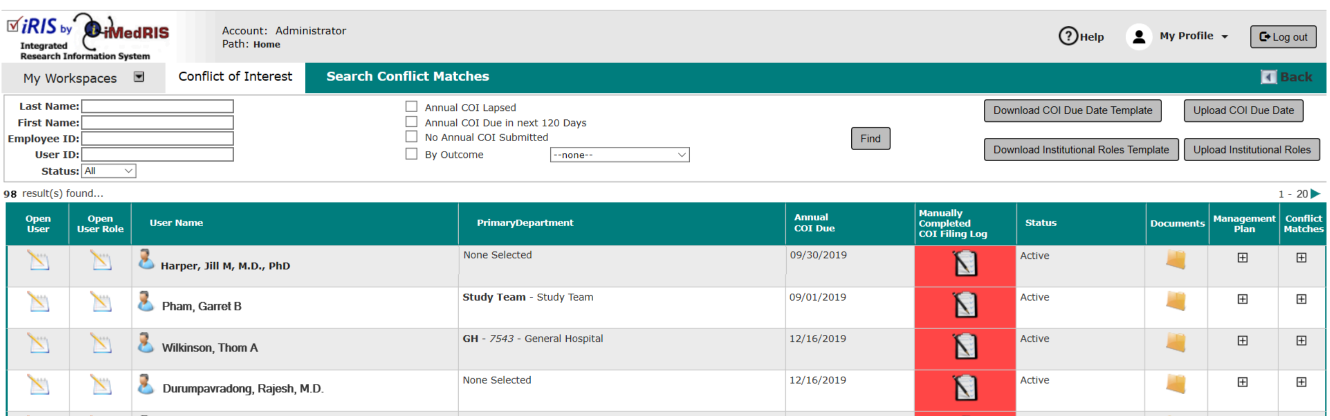
When you click on the **Conflict Matches** link a page will open to display all matches, divided into five tabs: **Submission Prereview**, **Not Assigned**, **Assigned**, **Completed**, and **Agendas**. Upon opening the link, the system will automatically default to the **Submission Prereview** tab.

See the COI Assistant - Match Processing manual for more information.



Search Conflict Matches

Search Conflict Matches is a tool for the COI Office to look up users in the system, see information about their submitted disclosures, and view or change their current COI Due Date, commitment reviewers, and Covered Person flag. Any previously submitted conflict match or related management plan can be accessed from this area, and documents uploaded within a Covered Person's match will populate here.



The **Search Conflict Matches** screen lists all users in iRIS™. Displayed in this table are the **Open User**, **Open User Role**, **User Name**, **Primary Department**, **Annual COI Due**, **Manually Completed COI Filing Log**, **Status**, **Documents**, **Management Plan** and **Conflict Matches** columns.

Annual COI Due is the date a user's Annual COI Form is due in the COI queue.

Status is the user's status in iRIS™. This can be either Active, meaning they have an active account in iRIS™, or it can be Inactive, which means the user is not active in the system and any COI due dates for this user will not be enforced.

Filters

The top of the page contains fields you can use to search for a particular user or search for users who have a COI Lapse or due date coming up.

You can search for a user by **Last Name**, **First Name**, **Employee ID**, **User ID**, or **Status**. Enter your desired parameters and click the **Find** button. Any users matching your search criteria will populate in the list.

You can also use a combination of filters to narrow down a list of users meeting certain criteria related to the COI due date, sponsors, and information from a processed Conflict Match. The items you can filter by are as follows:

Annual COI Lapsed – Any user who has a COI due date in the past that has not submitted the Annual COI form will populate in the list when this option is selected.

Annual COI Due in next 120 Days – Any user who has an Annual COI due date in the next 120 days will populate in the list when this option is selected.

No Annual COI Submitted – This filter will only display Covered Persons who have never submitted the Annual COI form with an Annual COI Due Date in the future.

By Outcome – Select an outcome type from the dropdown list to locate any user whose conflict match has been assigned the selected outcome.

You can use a combination of the search items to find a particular user or group of users.

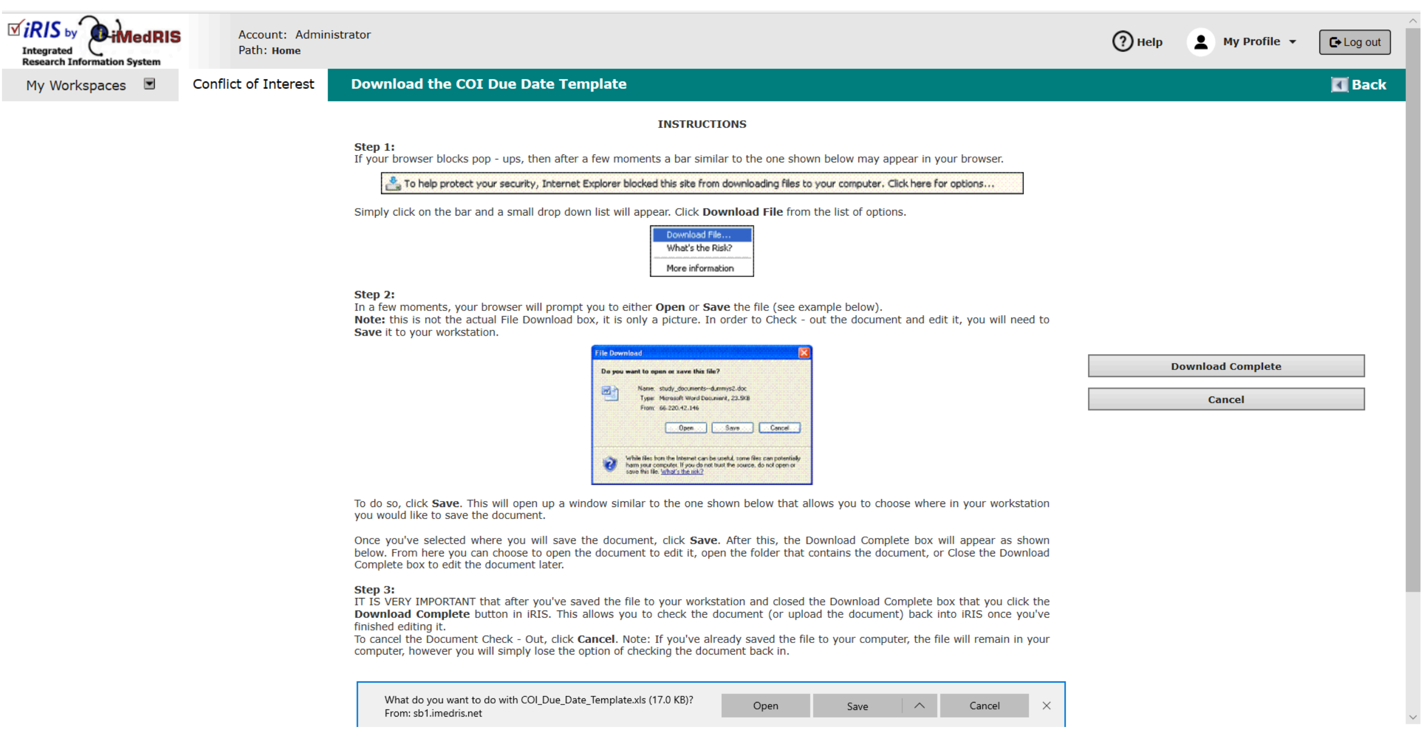
Download/Upload Templates

The **Search Conflict Matches** page contains options to download and upload spreadsheets that give you an easy way to enter multiple users' COI due dates or institutional roles.

COI Due Date Template

This is the template to use if you wish to upload COI due dates for multiple users to the system.

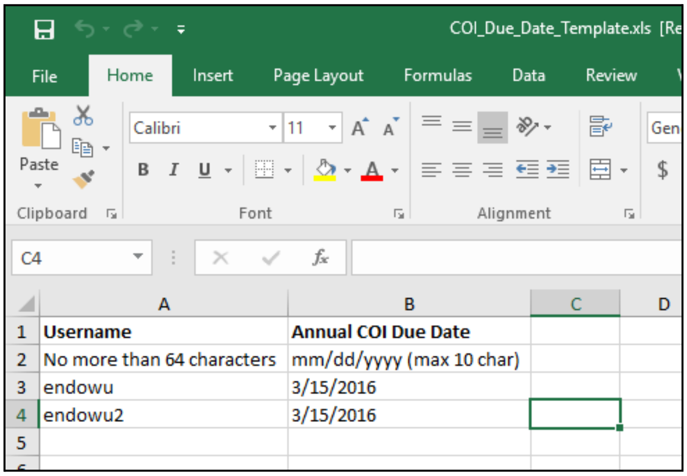
Click **Download COI Due Date Template** to start. A new screen will open with download instructions.



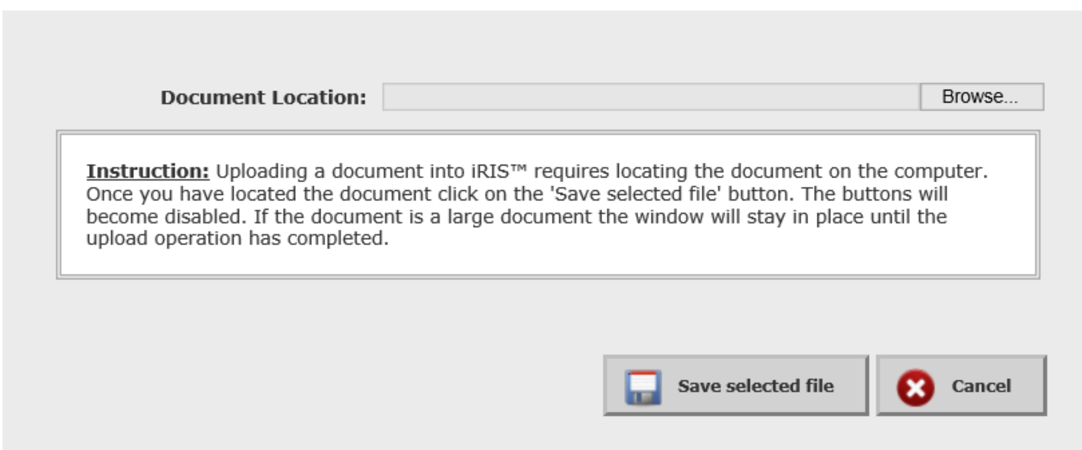
You will be prompted to select whether you wish to Open or Save the file. Be sure to save the file to a known location on your computer so you will be able to find and edit it.

Click **Download Complete** when you are finished downloading the template to return to the Search Conflict Matches screen, or **Cancel** to return without downloading the file. If you have not downloaded anything, you will also have to click the Cancel button in the download dialog box to close it.

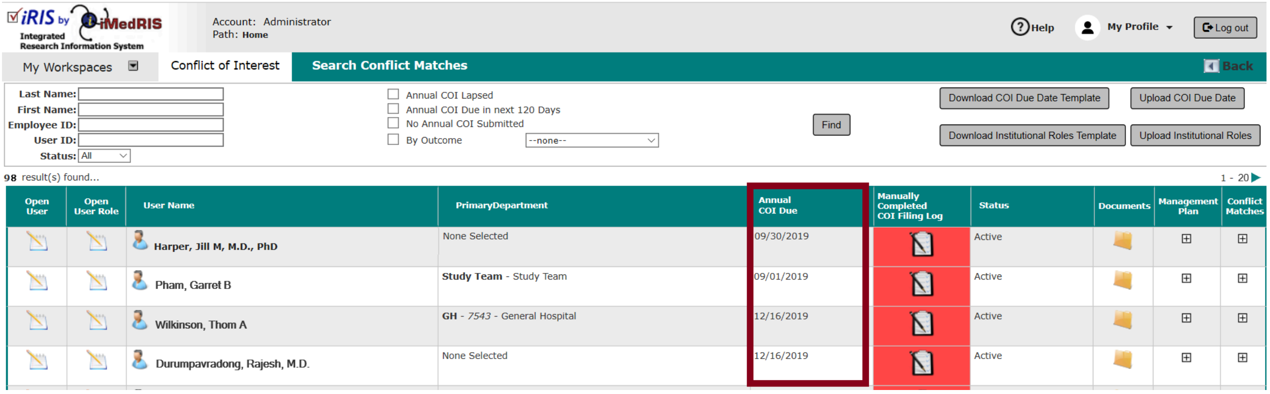
The template will appear as follows, and takes the form of an MS Excel spreadsheet. Instructions for proper formatting are included in the second row of the template spreadsheet.



When you are finished entering user names and Annual COI due date data, save your changes and return to the **Search Conflict Matches** screen. On that screen, click the **Upload COI Due Date** button. You will be prompted to browse for the file on your computer.



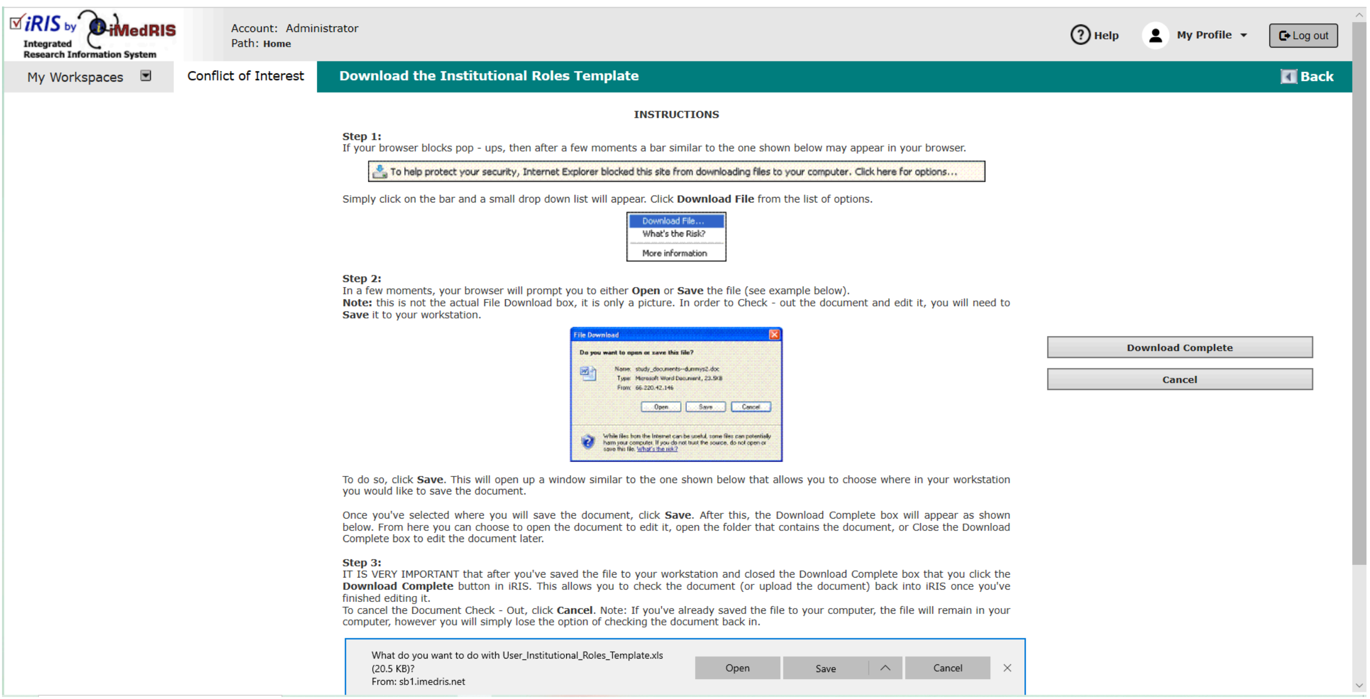
Click the **Browse** button to locate and select the file on your computer, then click **Save selected file** to select the file and upload it into iRIS™. Click **Cancel** to proceed without uploading a file. You can verify the uploaded users' **Annual COI Due** dates in the table of conflict matches.



Institutional Roles Template

This is the template to use if you wish to upload institutional roles for multiple users to the system.

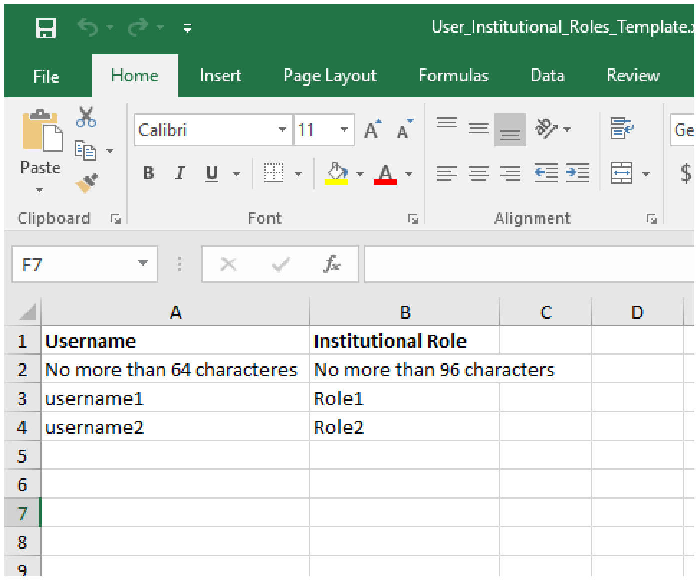
Click **Download Institutional Roles Template** to start. A new screen will open with download instructions.



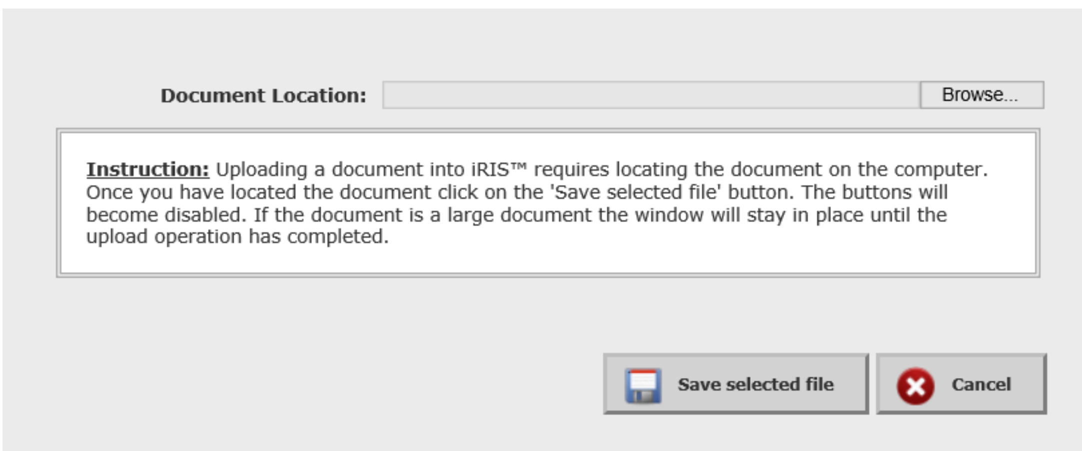
You will be prompted to select whether you wish to Open or Save the file. Be sure to save the file to a known location on your computer so you will be able to find and edit it.

Click **Download Complete** when you are finished downloading the template to return to the **Search Conflict Matches** screen, or **Cancel** to return without downloading the file. If you have not downloaded anything, you will also have to click the Cancel button in the download dialog box to close it.

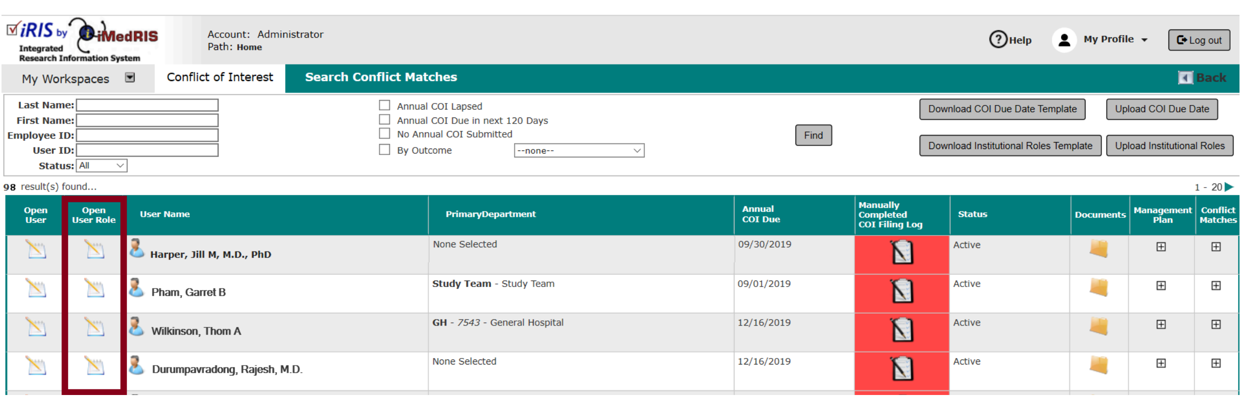
The template will appear as follows, and takes the form of an MS Excel spreadsheet. Instructions for proper formatting are included in the second row of the template spreadsheet.



When you are finished entering user names and institutional roles, save your changes and return to the **Search Conflict Matches** screen. On that screen, click the **Upload Institutional Roles** button. You will be prompted to browse for the file on your computer.



Click the **Browse** button to locate and select the file on your computer, then click **Save selected file** to select the file and upload it to iRIS™. Click **Cancel** to proceed without uploading a file. You can verify the users' **Institutional Role** data by clicking the icon in the **Open User Role** column next to the user's name.



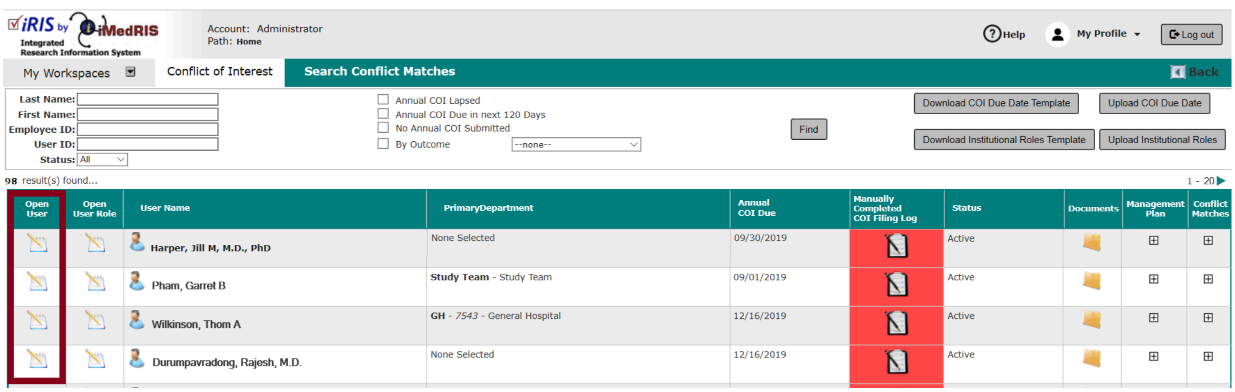
This will open the **Setup Institutional Role Assignment** form.

The column on the left displays roles to which this user is currently assigned. The column on the right displays all available roles, and will vary according to your system configuration and custom Review Board Administration settings.

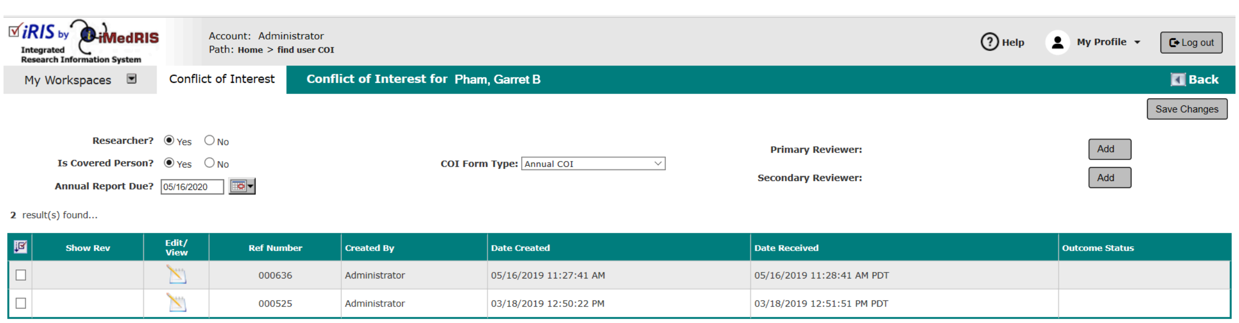
You can also assign roles to a user on this screen. To remove a role from the user's list, select the checkbox next to the role name and click the **Delete Role Assignment(s)** button. The column on the right displays other roles from the Institutional Role list that have not been assigned to this user. To add a new role for the user, select a role from the right-hand list and click the **Save Role Assignments** button.

Open User

In the list of users, the first column allows you to open specific, COI-related information about a user. From here, you can set Annual COI due dates, change commitment reviewers, and see any Annual COI forms sent to the office in the past.



Clicking on the icon in the **Open User** column will open a new page containing the user's specific COI-related information.



Researcher – If the user occupies a study personnel role on a study, this flag will be set to "Yes." If the user's Researcher status changes or the user should no longer have access to the **Study Assistant** tab for any reason, change the flag to

"No" and click **Save Changes** button. Note that setting the flag to "No" will restrict the user's ability to access studies on which they have a role.

Is Covered Person – If the user is a Covered Person, this flag will be set to "Yes." A user is typically set as a Covered Person at the time their account is created, but this flag can be set at any time. Once a user is flagged as a Covered Person, the system will include them in Annual COI due date assignment processing and will send notifications to the user about completing the form before the due date.

Annual Report Due – Use this date field to set or change the Annual COI due date for this user. The individual user's Annual Report Due date is the date that drives COI-related notifications (e.g., Annual COI Due, COI Past Due, COI Lapse notifications and tasks).

Note that it's also possible to set up a system-wide Annual COI due date in Conflict of Interest Assistant > Review Board Administration > Setup COI Annual Due. If the due date entered in this manner is in the future, any user in the system who is flagged as a Covered Person will update to the system-wide annual due date when it is set. However, it will still be possible to change individual users' Annual COI due dates on the user information screen described here (Conflict of Interest Assistant > Search Conflict Matches > Open User).

Primary Reviewer – If you are tracking Conflict of Commitment as well as Conflict of Interest, you can assign a primary reviewer to the user here. Click on the **Add** button to search the iRIS™ database for this user's commitment reviewer. When you add the reviewer, their name will be listed next to the **Primary Reviewer** label. Whenever an Annual COI form is submitted for this user and the user has indicated a conflict of commitment, the designated reviewer will be assigned to review this conflict.

Secondary Reviewer – If you are tracking Conflict of Commitment as well as Conflict of Interest, you can assign a Secondary Reviewer to the user here. Click on the **Add** button to search the iRIS™ database for this user's commitment reviewer. When you add the reviewer, their name will be listed next to the Secondary Reviewer label. Whenever an Annual COI form is submitted for this user and the user has indicated a conflict of commitment, the designated reviewer can be assigned to review this conflict.

If you are not using primary or secondary reviewers, you can set the system up so that it does not require you to provide a Primary and Secondary Reviewer for the Covered Person. This can be set in the system properties found under System Administration > System Configuration > COI Settings > system.coi_primary_reviewer_required.

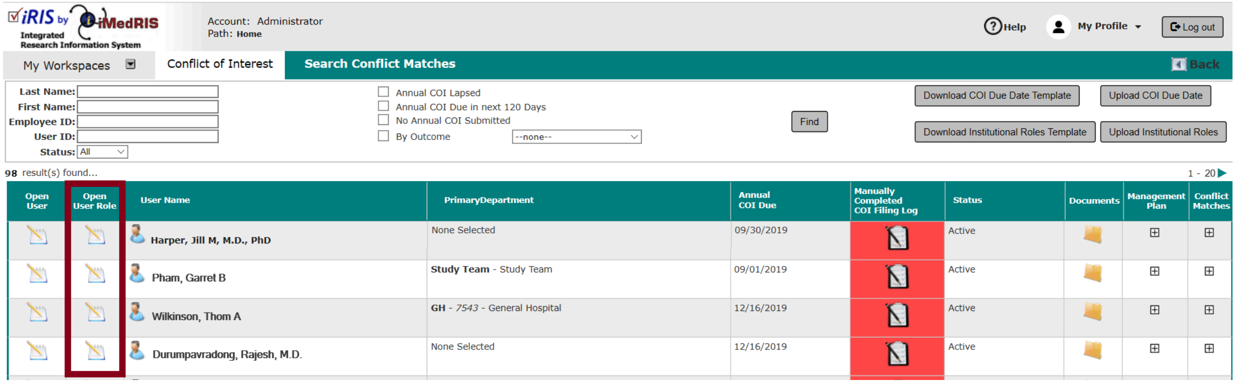
COI Form Type – From this dropdown list, you can select what type of forms you would like to display in the table of results. Select from between Annual COI and COI Miscellaneous.

Any COI forms submitted to the COI Office will display in the table below the settings information. You can view a form by clicking on its icon in the **Edit/View** column. The table also includes columns to display **Ref Number** (reference number) for the submission, **Created By**, **Date Created**, **Date Received** in the COI processing queue, and **Outcome Status**. The **Outcome Status** column will remain blank until an outcome has been entered for the form.

Be sure to **Save Changes** before navigating away from the screen.

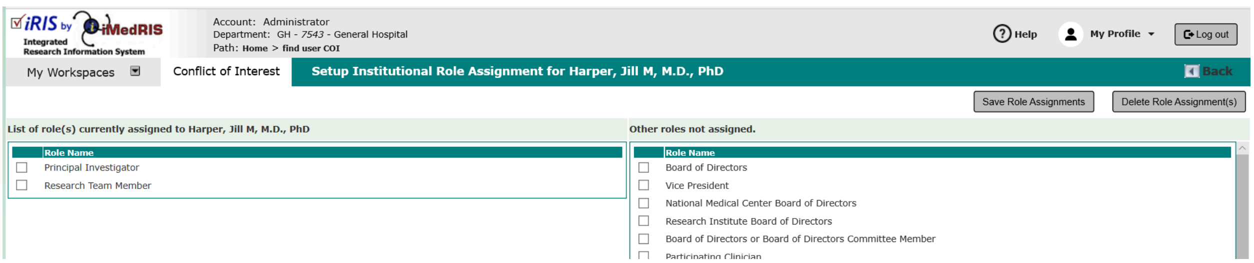
Open User Role

To view, add or change any institutional roles assigned to a user, click the icon in the **Open User Role** column.



Clicking the Open User Role icon opens the **Setup Institutional Role Assignment** screen, which allows for viewing and changing user roles.

The column on the left displays roles to which this user is currently assigned. The column on the right displays all available roles, and will vary according to your system configuration and custom Review Board Administration settings.

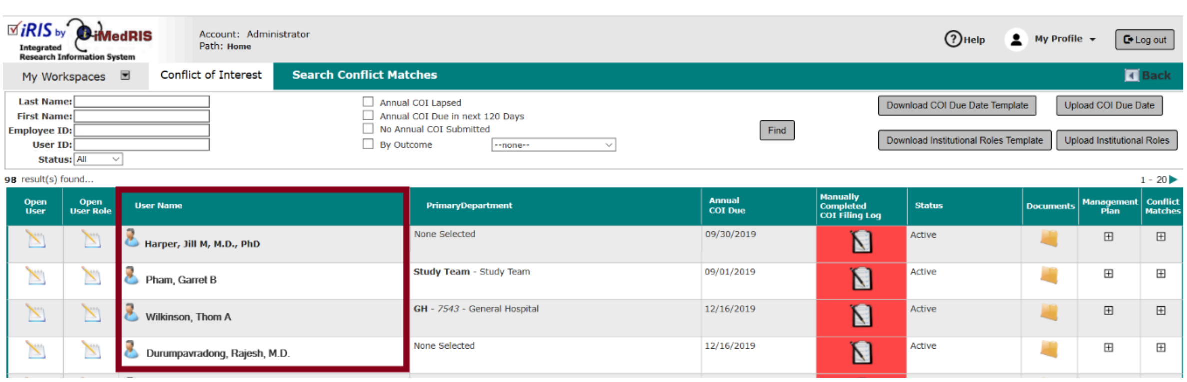


A user can be assigned to a role by selecting the role themselves in their Annual COI form (if that option is made available in the form). When they submit the form, the system will update this page to contain any of the roles they selected.

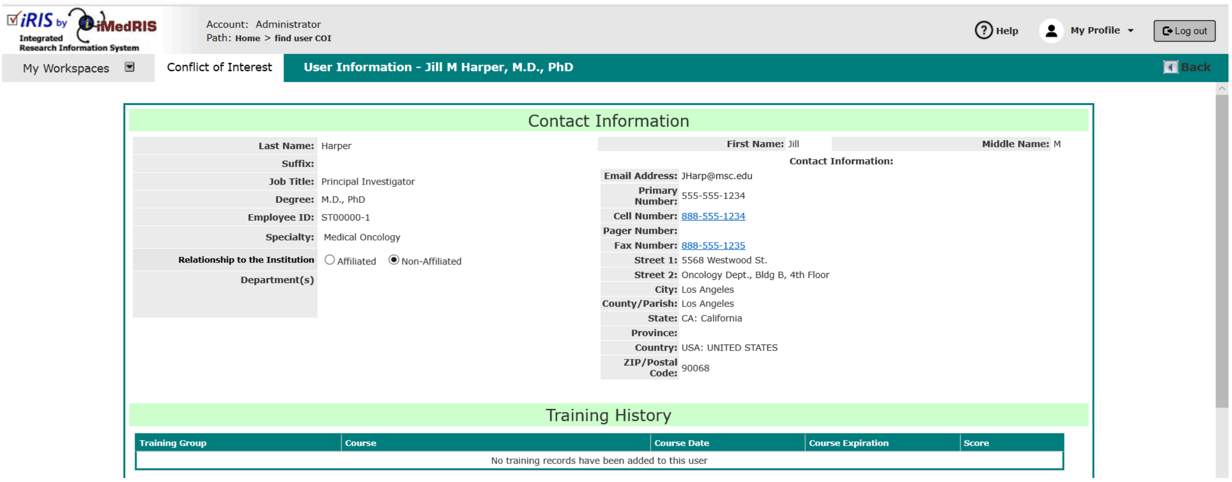
You can also assign roles to a user on this screen. To remove a role from the user's list, select the checkbox next to the role name and click the **Delete Role Assignment(s)** button. The column on the right displays other roles from the Institutional Role list that have not been assigned to this user. To add a new role for the user, select a role from the right-hand list and click the **Save Role Assignments** button.

User Details

You can look up user details like contact information, training information, licenses and CVs by clicking on the name of the user in the **User Name** column.



When you click on the user's name the **User Information** screen will open, displaying the user's information as it has been entered into their user account record.

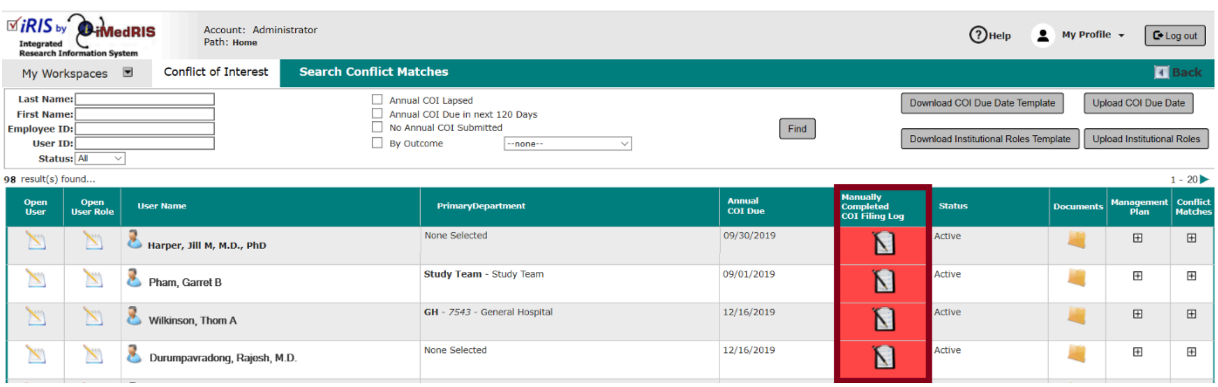


In addition to the **Contact Information** and **Training History** sections shown above, the screen also includes sections for **Disclosures**, **Medical Licenses** and **Curriculum Vitae** (resume).

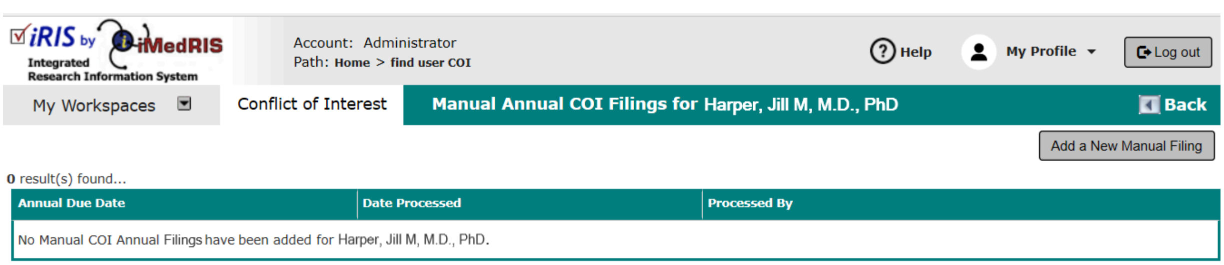
Manually Completed COI Filing Log

When a user's Annual COI filing will be due within 60 days, the system will send reminders and notifications to the user to encourage prompt completion of the filing. In cases where the affected user is unable to complete the standard Annual COI filing submission process for any reason, the system allows for manual processing.

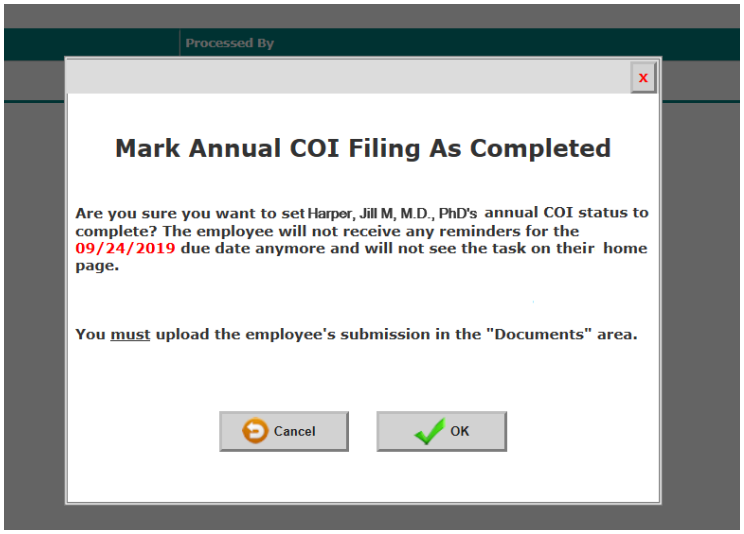
Locate the affected user in the **Search Conflict Matches** screen and click the icon in the **Manually Completed COI Filing Log** column for that user.



In the example shown below the user has no existing manual COI filings, but is within 60 days of the due date to file.

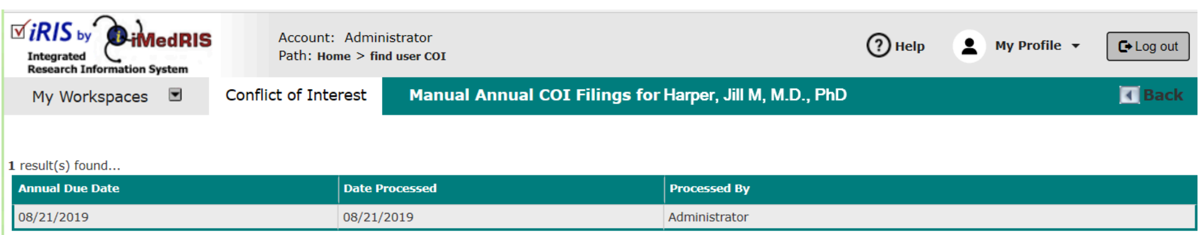


To add a manual filing for this user, click the **Add a New Manual Filing** button at the upper right of the screen. A warning box will display, reminding you that if you mark the Annual COI filing for this user as complete the user will receive no further notifications about their upcoming COI filing due date, which is shown in red, and that the user's filing document(s) MUST be manually uploaded to the user's Documents area to complete the manual filing.



Click **Cancel** to return to the **Search Conflict Matches** screen without making any changes.

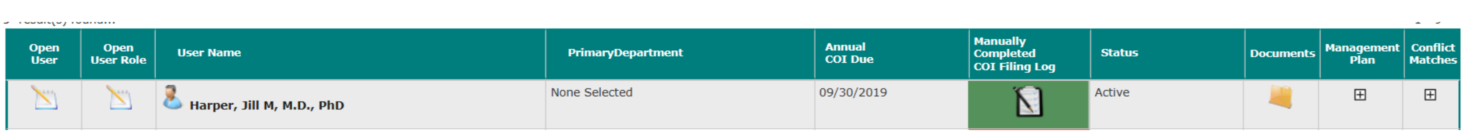
Click **OK** to set the user's COI filing status to complete. The manual filing is added to the list of manual filings for this user.



Annual Due Date	Date Processed	Processed By
08/21/2019	08/21/2019	Administrator

Back on the **Search Conflict Matches** screen this user's **Manually Completed COI Filing Log** column color has changed from red to green, indicating the user's manual filing has been set to complete.

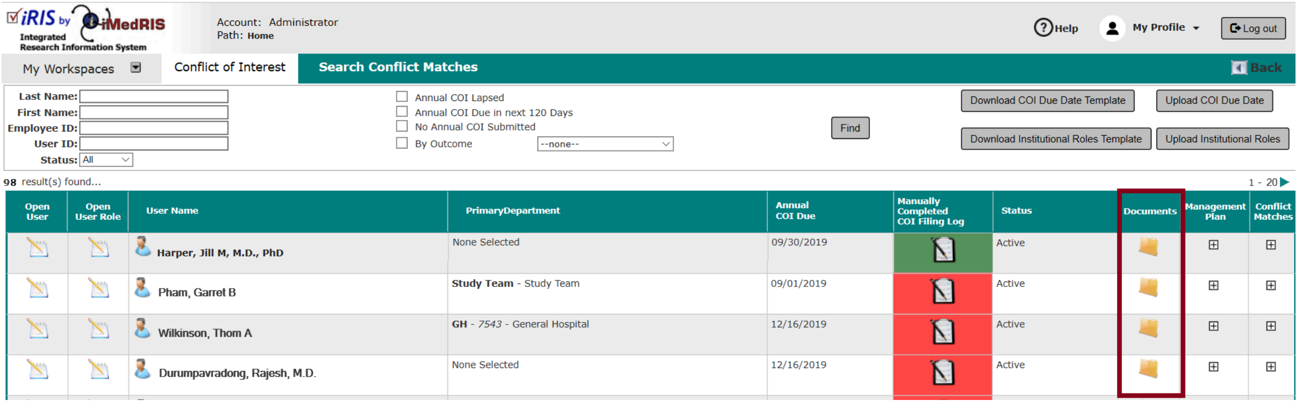
However, the user's filing document(s) MUST be manually uploaded to the user's Documents area to fully complete the manual filing.



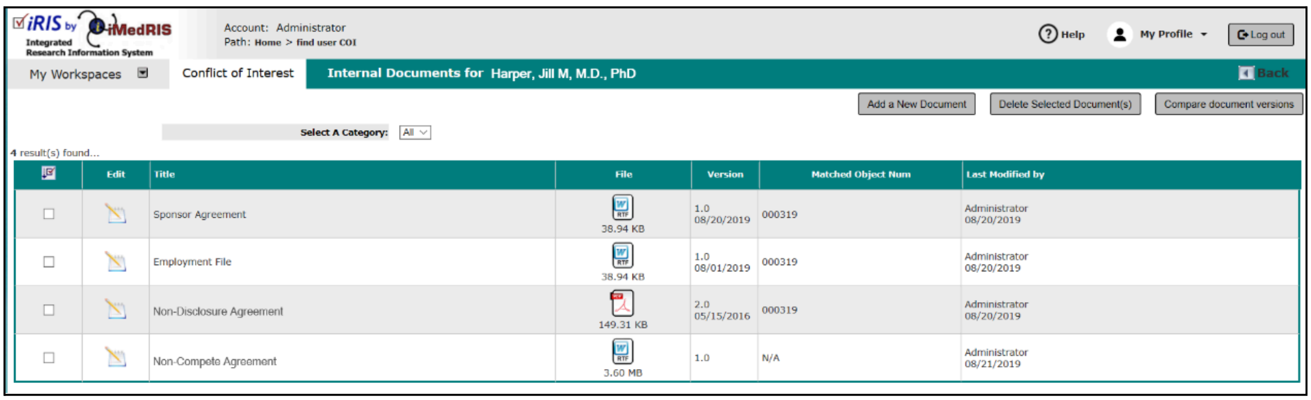
Open User	Open User Role	User Name	PrimaryDepartment	Annual COI Due	Manually Completed COI Filing Log	Status	Documents	Management Plan	Conflict Matches
		Harper, Jill M, M.D., PhD	None Selected	09/30/2019		Active		⊞	⊞

Documents

The **Documents** column within **Search Conflict Matches** provides the ability to look up any Internal Documents associated with the Covered Person within the match processing screens.



To view internal documents for a user, click the folder icon in the **Documents** column for that user. This opens the **Internal Documents** listing screen.



The Covered Person's document library stores any document you have attached to conflict matches or added through the library itself.

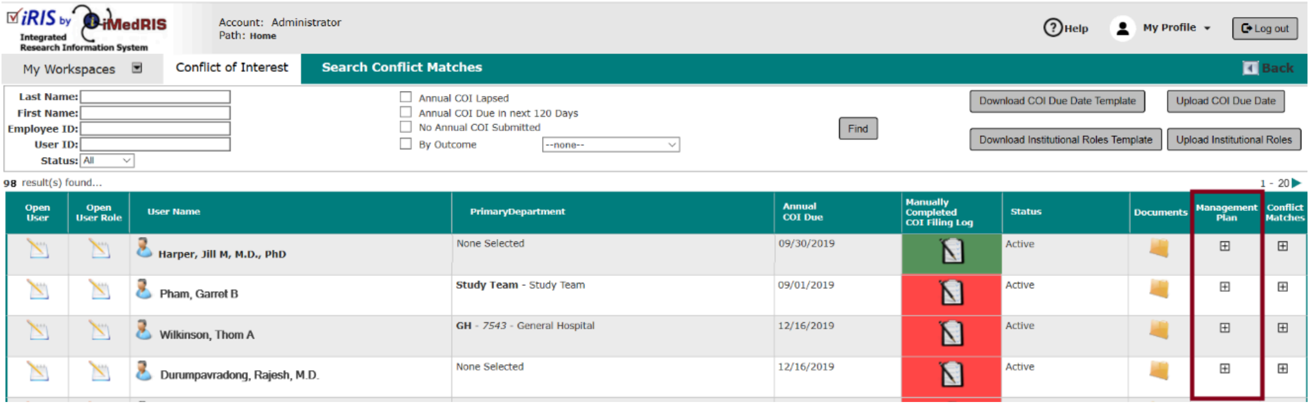
From this area, you can edit existing documents, add new documents, and compare documents. You can also filter the documents based on the Document Category assigned. The document category is defined within Review Board Administration > List Maintenance Setup tab > Internal Document Category.

The **Matched Object Number** column will only populate with data if the document was uploaded through Internal Documents within the conflict match processing screens. Any document added through this area will not be associated to a conflict match.

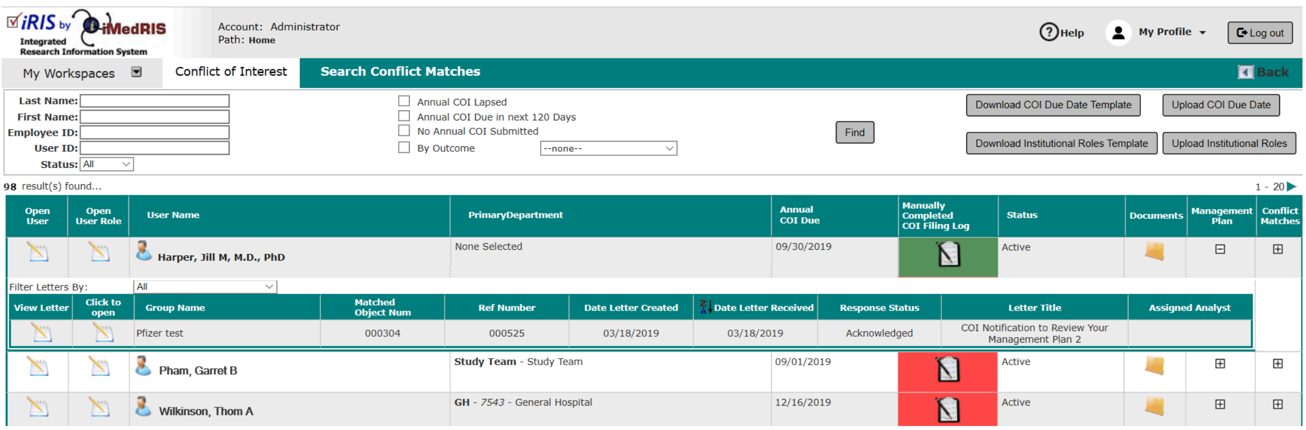
Management Plan

Management Plan Letters that have been generated and sent for a Covered Person are accessible via the **Management Plan** column within **Search Conflict Matches**.

To view available Management Plan Letters for the user, click on the plus sign icon for that user in the Management Plan column.



Expanding the details for the **Management Plan** column will display the Management Plans associated with the Covered Person.



You can filter the letters by selecting a status in the dropdown list.

Available filters:

> **All** –includes all letters regardless of status
>
> **Open Conflict Matches** – includes letters associated with conflict matches that are still in process
>
> **Conflict Processing Complete** – includes letters associated with conflict matches that have been completed within the COI Conflict Matches queue.

Some of the columns are sortable. You can click on the column header to sort by that field. The default sort is **Date Letter Received**, oldest to newest.

The columns shown in management plan details are as follows:

View Letter – This will open the letter in a separate window.

Click to Open - This will navigate you to the Match Review processing screens.

Group Name – If the letter is associated with grouped conflict matches, this column will populate with the assigned Group Name.

Matched Object Num – Displays the unique Matched Object Number with which the letter is associated.

Ref Number – Displays the Submission Reference Number associated with the form with which the Conflict Match was submitted.

Date Letter Created – Displays the date the letter was created.

Date Letter Received – Displays the date the letter was received by the Primary Recipient.

Response Status – Displays one of the following statuses:

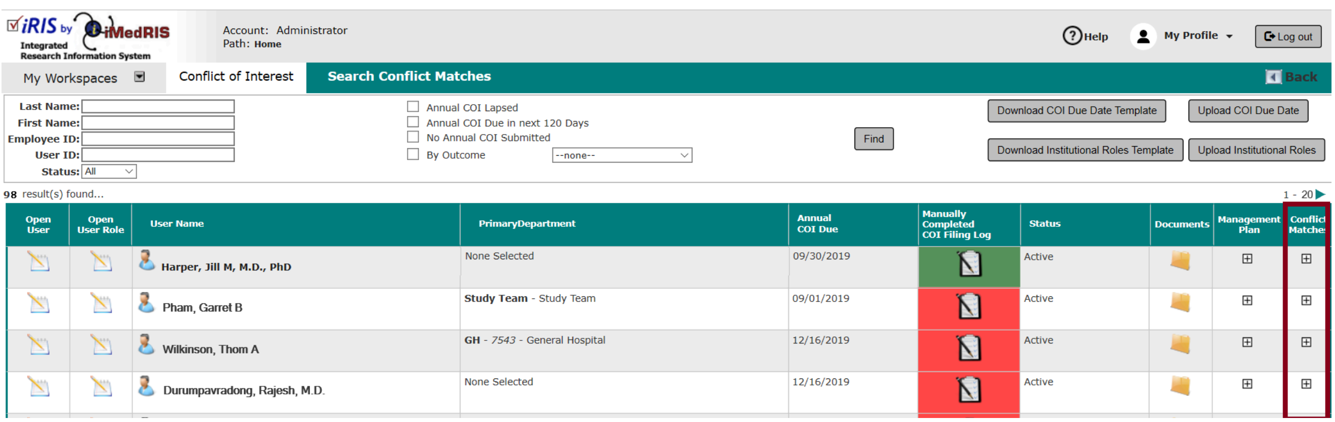
> **Open** –the Covered Person has not sent the response back to the COI yet
>
> **Acknowledged**–the Covered Person has returned the response to the COI but the match is still being processed by the board
>
> **Closed** –the board has closed the Conflict Match with which this letter is associated

Letter Title – Displays the title of the letter.

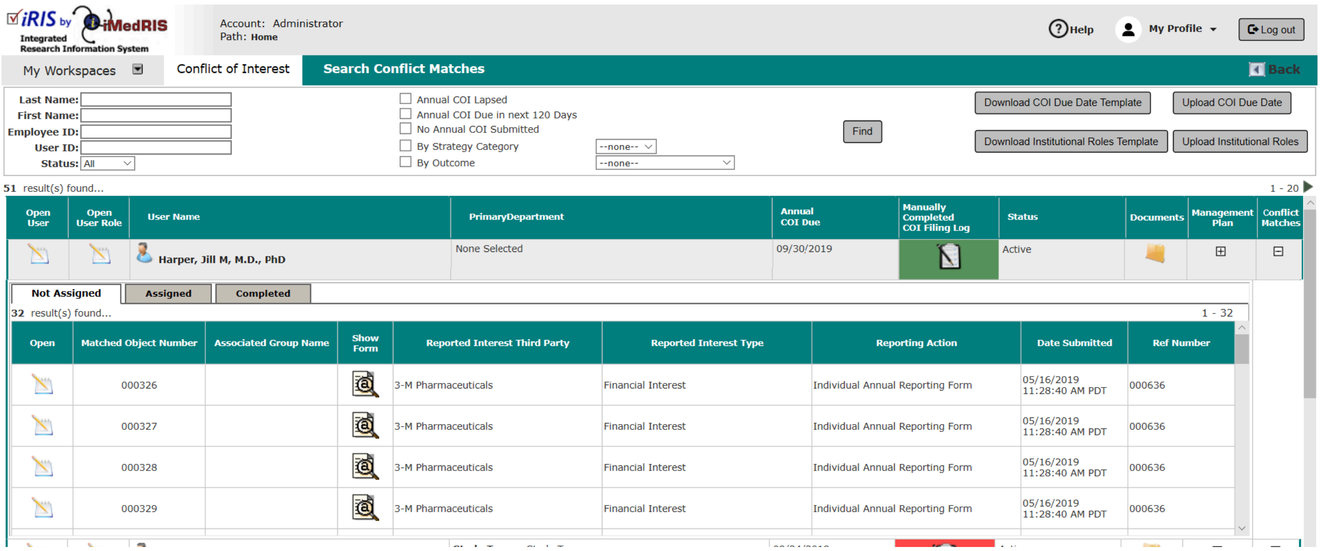
Assigned Analyst – Will display the Assigned Analyst, if one has been associated with the Conflict Match associated with this letter.

Conflict Matches

The **Conflict Matches** column allows you to look up any Conflict Match associated with Covered Persons.



Click on the plus sign in the **Conflict Matches** column for the Covered Person to view details of Conflict Matches associated with that person.



The **Conflict Match** records are sorted into three tabs: **Not Assigned**, **Assigned**, and **Completed**. These tabs follow the same logic as within the COI Conflict Matches queue, where unprocessed matches populate in the **Not Assigned** tab, matches assigned to a process that have not been completed populate in the **Assigned** tab, and any completed matches populate in the **Completed** tab.

Note that the detail panel includes a scroll bar at the right. The columns shown in the detail panel contain the following items and information:

Open – When this icon is clicked, it opens the Conflict Match processing screens.

Matched Object Number – Unique Matched Object Number for the match.

Group Name – If the letter is included in a conflict match group, this column populates with the assigned Group Name.

Show Form – When clicked to open, displays the submission form from which the Conflict Match originated, in a separate window.

Reported Interest Third Party – Name of the indicated third party interest (the sponsor with which the user indicated they have an interest).

Reported Interest Type – Depending on the specific conflict issue, this column populates with the type of interest noted within the form (e.g., Financial Interest, a Financial Commitment, Gifts from a Biomedical Company, etc.).

Reporting Action – Where the match has come from – whether via the Annual COI (Individual Annual Reporting Form), a Study COI, or a Miscellaneous Disclosure.

Date Submitted– The date the conflict form was submitted to the workflow.

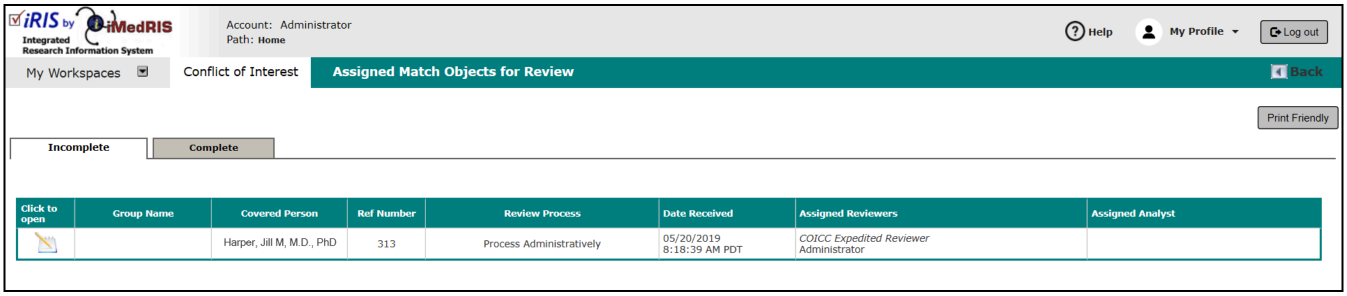
Ref Number – The reference number of the Study COI form.

Reviewer Assignment

The Reviewer Assignment function is used to access any open reviews to which you have been assigned. You can also access this area to view any of your previously completed reviews.

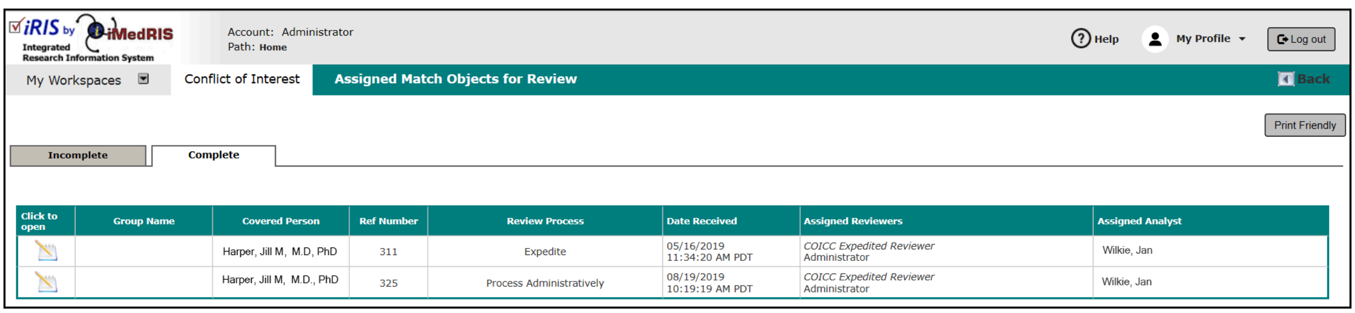
The **Assigned Match Objects for Review** screen is accessed via its link in the Conflict of Interest Assistant main menu, or its icon in the Conflict of Interest Assistant Workspace.

From this page, you can open the COI Submission Review Form (sometimes referred to as the Reviewer Checklist) by clicking the icon in the **Click to open** column.



You can toggle between the **Incomplete** and **Complete** tabs to cycle through your open reviews and closed reviews.

If you need to make changes to a closed review you can open that assignment by navigating to the **Complete** tab, locating your review, and clicking the icon in the **Click to Open** column. This will open the previously completed COI Submission Review Form, allowing you to make any necessary edits before saving and navigating back to the Reviewer Assignments page.



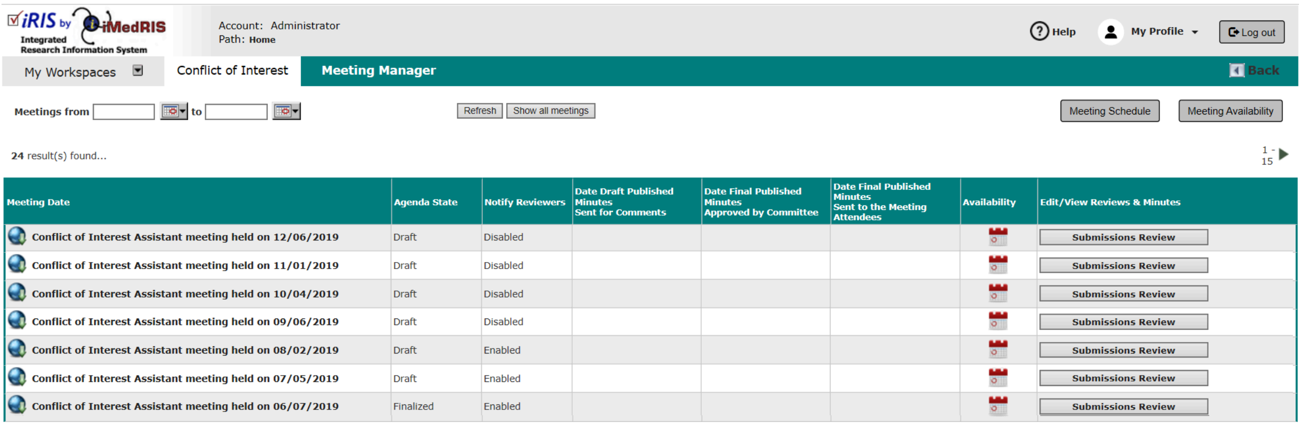
Meeting Management

The **Meeting Management** section of COI 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.

From here, 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.

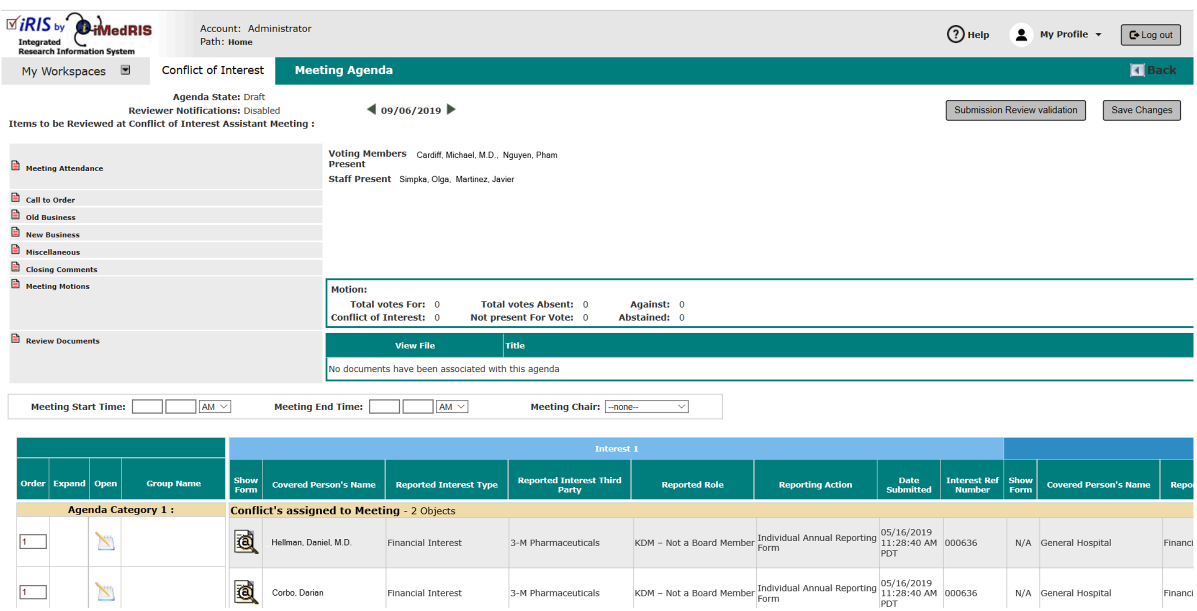


See the IRB Assistant - Meetings manual for more information.

Meeting Agenda

The **Meeting Agenda** screen allows you to view information related to specific meeting dates. You can access past and future meetings from this area.

Those in a review board administrator role can use this screen to prepare for an upcoming meeting. Others can view submissions placed on a particular meeting date in this screen. Read/write access for the meeting agenda is configured under Setup Role Access in Review Board Administration.



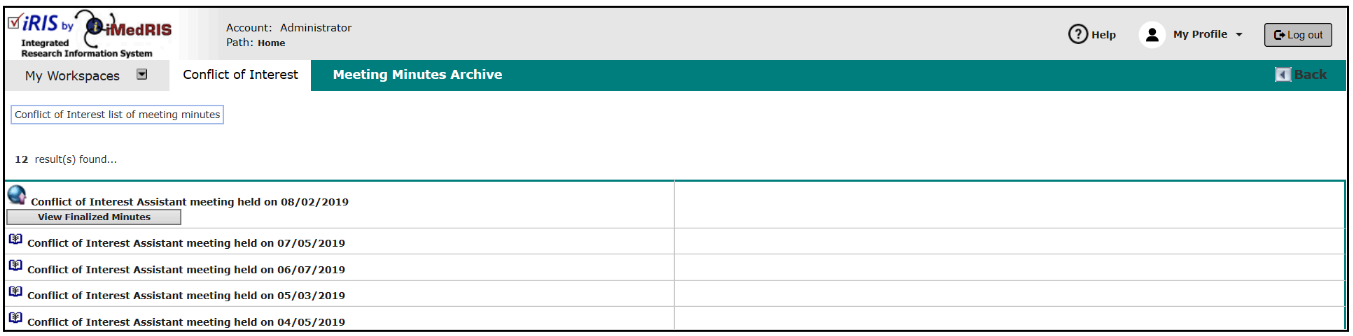
By default, the **Meeting Agenda** page will open to the next upcoming meeting. You can toggle to a different meeting date by clicking on the navigation arrows to the right and left of the meeting date at the top of the screen. See the COI Assistant - Meetings manual for more information

Meeting Minutes

Meeting Minutes allows access to published meeting minutes for any past meeting, and enables board members to pull minutes from a past meeting. The screen displays a table with a link for each board meeting that has been held, from newest to oldest. Clicking a meeting link opens the applicable Meeting Agenda screen.

If minutes have been generated and a Finalized version has been published, a **View Finalized Minutes** button will display for the applicable 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 yet been published, no button will display.

Click on the **View Finalized Minutes** or **View Draft Minutes** button to view the PDF document for that meeting.

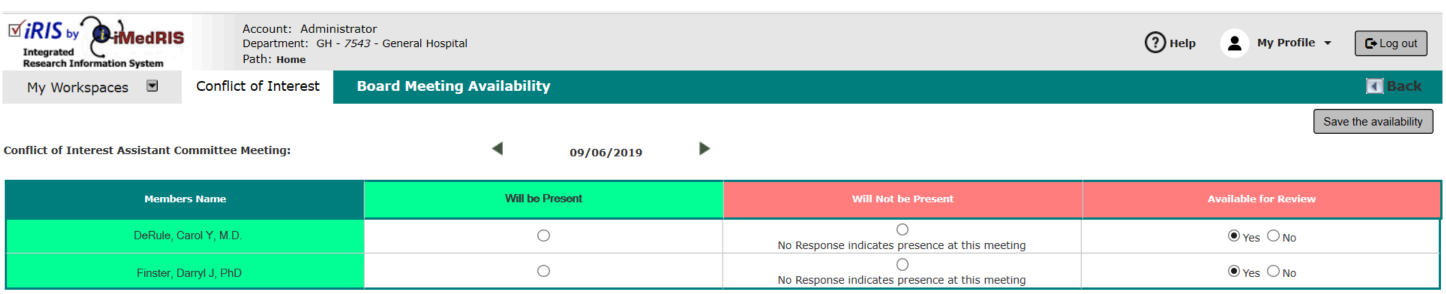


Draft or Finalized Minutes open in a new screen that displays the information entered from the meeting. The fields in the Minutes document will reflect what was defined in the Meeting Minutes Template. If the minutes are a draft version, a watermark will appear with the word **DRAFT** across the minutes.

See the COI Assistant - Meetings manual for more information.

Meeting Availability

The **Meeting Availability** menu option brings you the Board Meeting Availability screen. Here, COI administrators can scroll through meeting dates and set the availability for different board members for those dates.



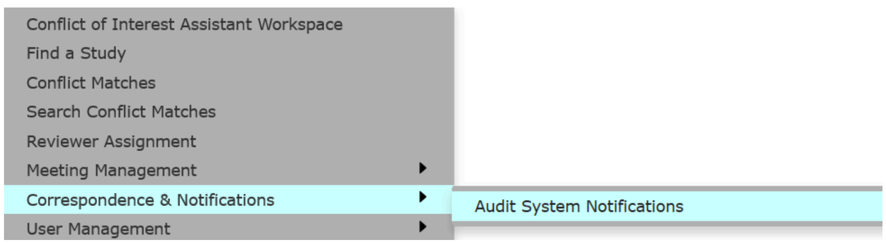
If you open the screen with a non-administrative role, you will be able to set your own availability for upcoming meetings via the View Calendar column.

Availability	Will be Present	Will Not be Present	Available for Review	View Calendar
Conflict of Interest Assistant September 06, 2019	No Response indicates your presence at this meeting		Yes No	
Conflict of Interest Assistant October 04, 2019	No Response indicates your presence at this meeting		Yes No	
Conflict of Interest Assistant November 01, 2019	No Response indicates your presence at this meeting		Yes No	
Conflict of Interest Assistant December 06, 2019	No Response indicates your presence at this meeting		Yes No	
Conflict of Interest Assistant January 03, 2020	No Response indicates your presence at this meeting		Yes No	
Conflict of Interest Assistant February 07, 2020	No Response indicates your presence at this meeting		Yes No	
Conflict of Interest Assistant March 06, 2020	No Response indicates your presence at this meeting		Yes No	

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

Correspondence and Notifications

The **Correspondence and Notifications** menu contains the Audit System Notifications sub-item.

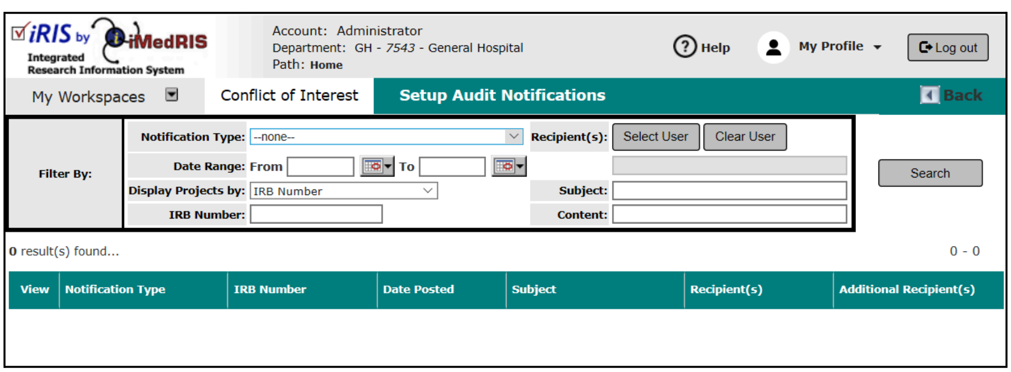


Audit System Notifications

The Audit System Notifications tool can be used by board administrators to search for a specific notification previously sent by the system.

The Audit System Notifications menu item is typically accessible by review board coordinators and administrators. Its accessibility can be provided to all roles via the Setup Role Access matrix found in Review Board Administration.

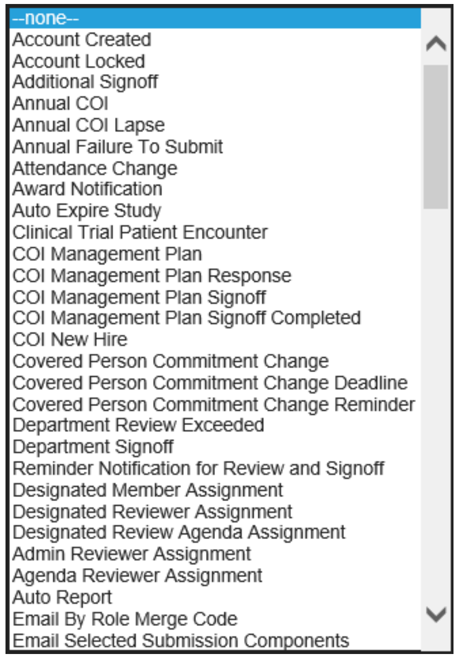
Every notification that is sent out by the iRIS™ system is logged, making it possible to track. Since the system automatically generates the notifications, this notification audit tool can be very useful for coordinators who need to check the status of a reviewer notification. All system notifications can be audited here to ensure they were sent.



Clicking on the Audit System Notifications link from the main Conflict of Interest Assistant menu opens the above Audit Notifications screen, which provides several filters to search for notifications you would like to see.

A list of found notifications will display with fifty items per page. Selections can be made using the **Filter By** fields:

Notification Type – Select a notification type from the dropdown list to filter the Notification Type. *Note that the items shown in the list will vary according to your specific system configuration and Review Board Administration settings.*



Recipient(s) – Use this field if you wish to perform an audit for a specific user within the system. Only user(s) with existing criteria who have received notifications will be displayed. When the **Select User** button is clicked, a new screen will be displayed (see below).

Enter your search criteria:

Last Name: part, or all of the last name of the user as entered in the system

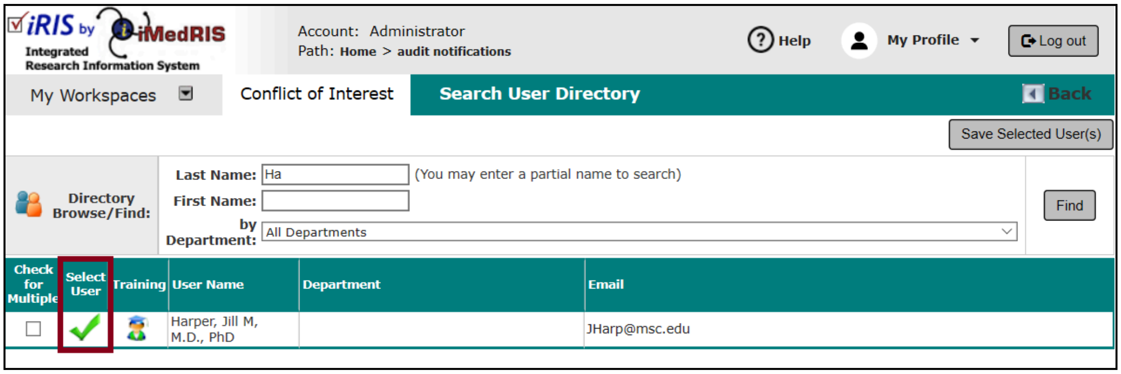
First Name: part, or all of the first name of the user as entered in the system

by Department: select a department from the drop down list to limit the search to that department.

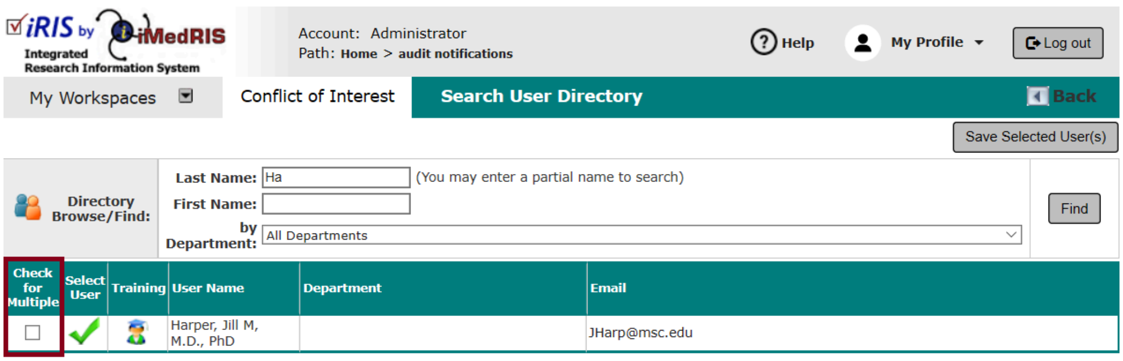
To clear the form, click the **Clear User** button.

Click the **Find** button to view search results.

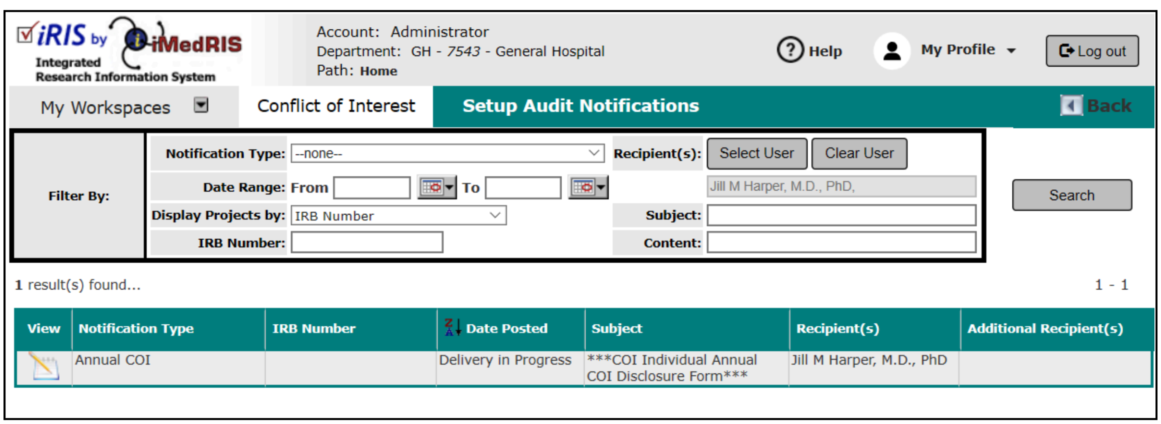
Click the **Select User** icon for to open the search results for that user.



If the search results include multiple users and you wish to include results for more than one of them in your search, click to select the **Check for Multiple** box next to each name you wish to include.



Click the **Save Selected User(s)** button to view the search results.



If the results include more than one record, use the **Filter By** fields at the top of the form to further limit the record set.

Date Range – When the notification was sent/processed.

Display Projects By: Select Study Number, IRB Number, IACUC Number or IBC Number from the list.

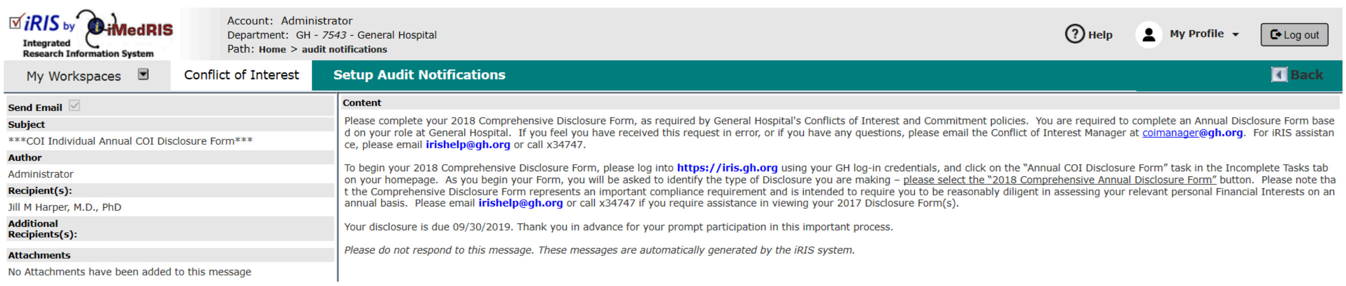
Subject – Enter a key word or phrase that would appear in the subject line of the notification. The wildcard “%” is available for this type of search.

Content – Enter a key word or phrase that would appear within the content section of the notification. The wildcard “%” is available for this type of search.

Use as many search fields as needed to narrow the search. Click the **Search** button to view results.

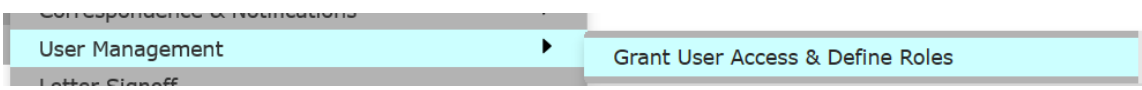
The results will be displayed with the most recent notification placed at the top of the page. You can sort the notification results by **Notification Type**, **[Study/IRB/IACUC/IBC] Number**, **Date Posted**, **Subject** or **Additional Recipient** in ascending or descending order by clicking on the respective column heading. Sort-by is not available for the **View** and **Recipient(s)** columns. When a sort is active, a sort-by icon will appear in the applicable column.

Click the **View** icon to view the entire body of the notification that was sent. Notification information shown is read-only, and will not have any document formatting applied.



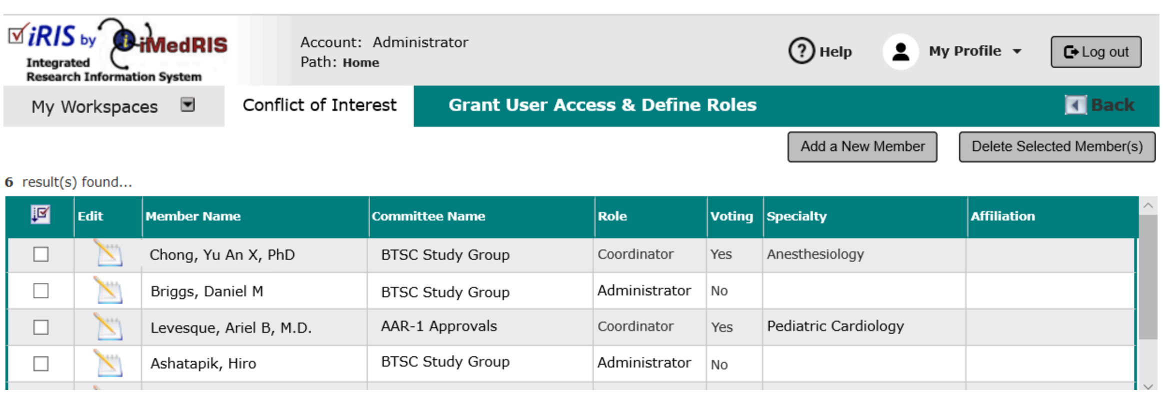
User Management

COI user management is accessed via the **User Management** > **Grant User Access & Define Roles** menu item, or the Grant User Access & Define Roles icon in the Conflict of Interest Assistant Workspace.



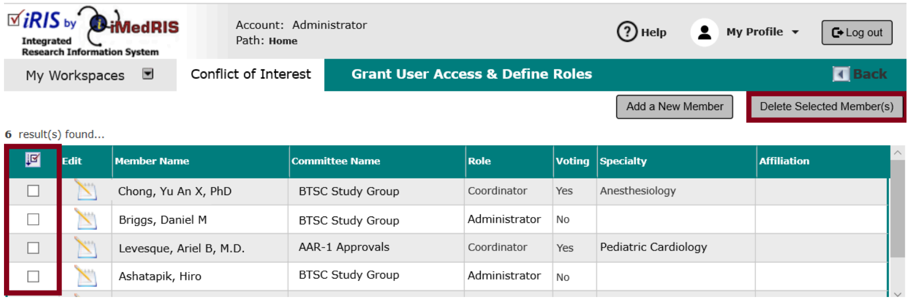
Grant User Access and Define Roles

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

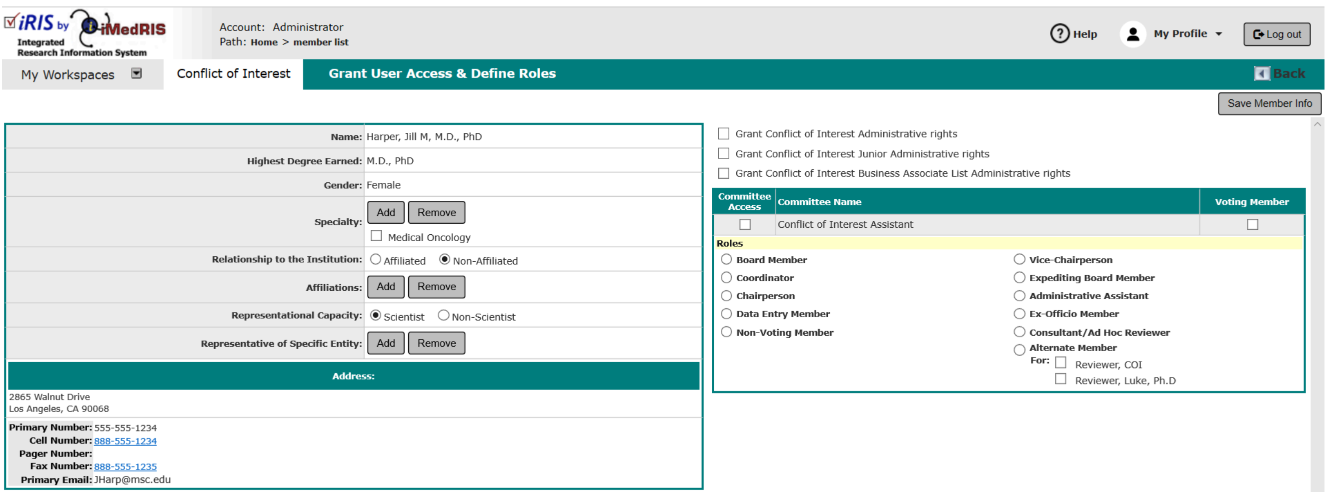


Any user who has a role on the COI Review Board will populate in this list. The list includes **Member Name**, board **Committee Name**, **Role**, **Voting** status, and where applicable, **Specialty** and **Affiliation**.

To delete Members, click the select box(es) to the left of the name(s) to be deleted and click the **Delete Selected Member(s)** button.

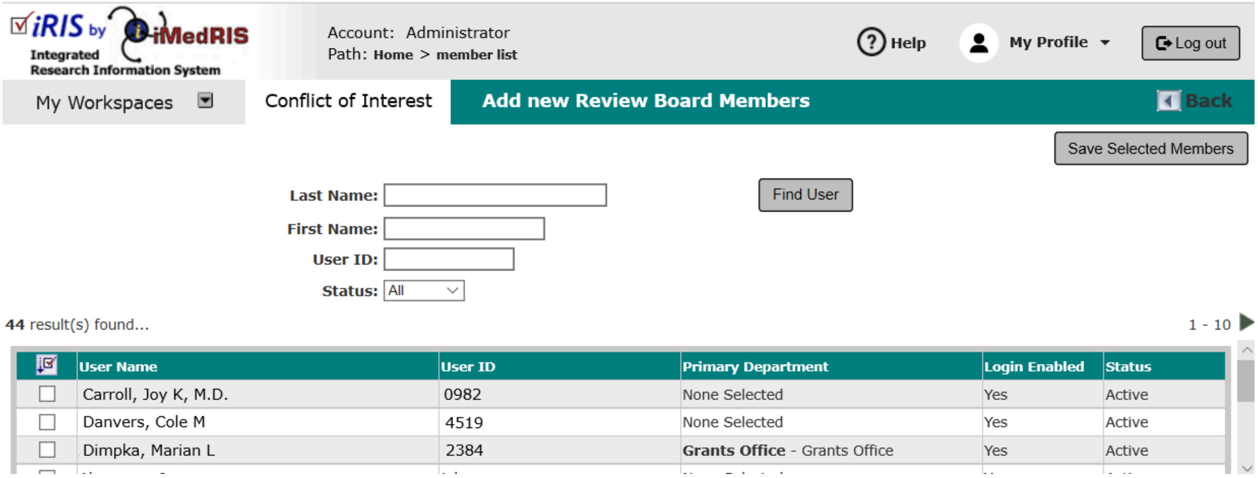


Change a user's access by clicking on the icon in the **Edit** column.



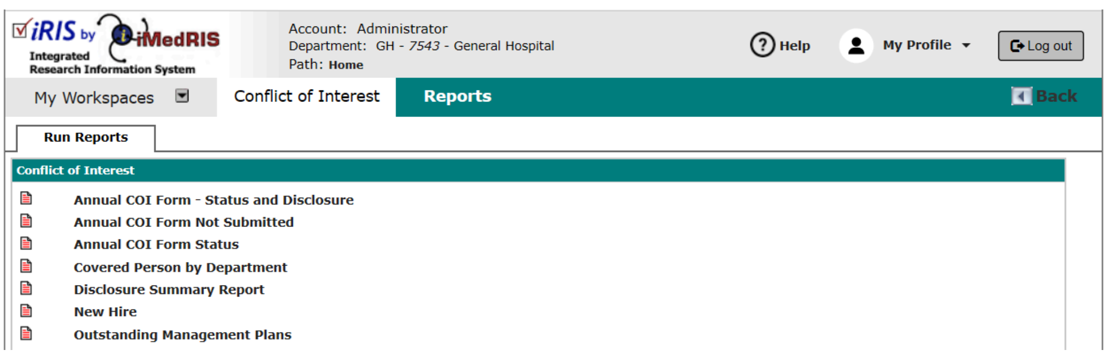
A screen listing contact information as well as role information will open. In this screen, you can Add or Remove user Speciality(ies), Add or Remove user Affiliations, Add or Remove the name of a Specific Entity the user represents, grant COI rights, or change the board member's role. Click on the **Save Member Info** button to save your changes before returning to the list.

To add a new member to the board click the **Add a New Member** button. This will open the Add new Review Board Members screen, which contains a searchable list of all users who do not have a role on the board. Use the search fields at the top of the form to filter by **Last Name**, **First Name**, **User ID**, and/or **Status**. Select a user from the list and click on the **Save Selected Members** button to add them to the board.



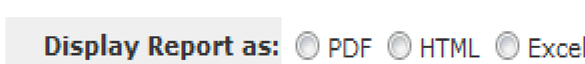
Reports

Boilerplate reports that come with the COI Assistant module are accessible via the Reports link from the Conflict of Interest Assistant main menu or workspace. The **Reports** screen lists all available reports.

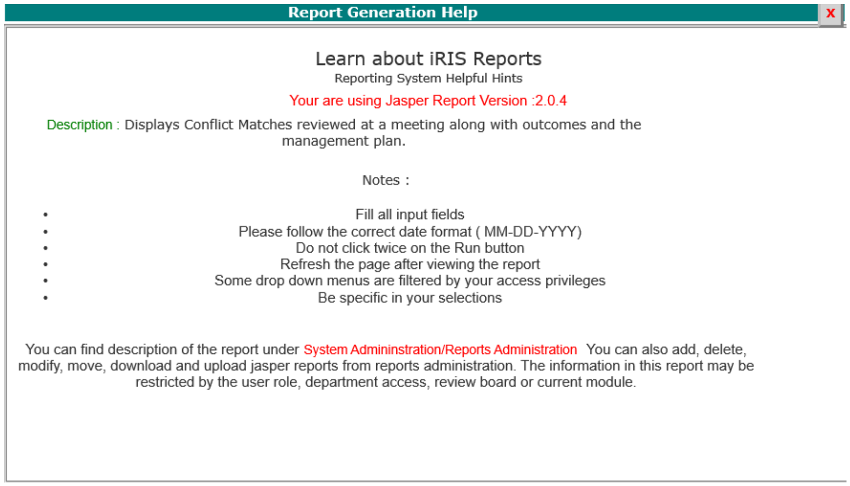


Clicking on a report link will allow you to set specific parameters and run the report. Available parameters and filter options for each report will vary.

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** popup window displays. The popup includes a description of the selected report and notes to assist you in running the report.



The reports that are available through the COI Assistant are as follows:

Annual COI Form – Status and Disclosure – This report will display the status of Annual COI forms and if a Covered Person has an active Disclosure.

Annual COI Form Not Submitted – This report will display Covered Persons who have not submitted their Annual COI form for the selected Annual COI Due Date Range.

Annual COI Form Status – This report displays a total number of Annual COI forms completed for the current Annual COI period by Department and Job Title.

Covered Person by Department – This report will display Covered Persons by their Primary Department.

Disclosure Summary Report – This report displays Conflict Matches reviewed at a meeting along with outcomes and the management plan.

New Hire – This report will display any New Hires within the dates selected.

Outstanding Management Plans – This report will display any Covered Person with an outstanding Management Plan that falls within the dates selected.

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, Meeting Agendas, and Meeting Minutes, and set up automatic review board-related notifications. Review Board Administration is typically reserved for Review Board Administrators. See the COI Assistant - RB Administration manual for more information.