Conflict of Interest Assistant

Conflict Match Processing

Version 11. 02

Contents

Conflict Match Processing

Introduction

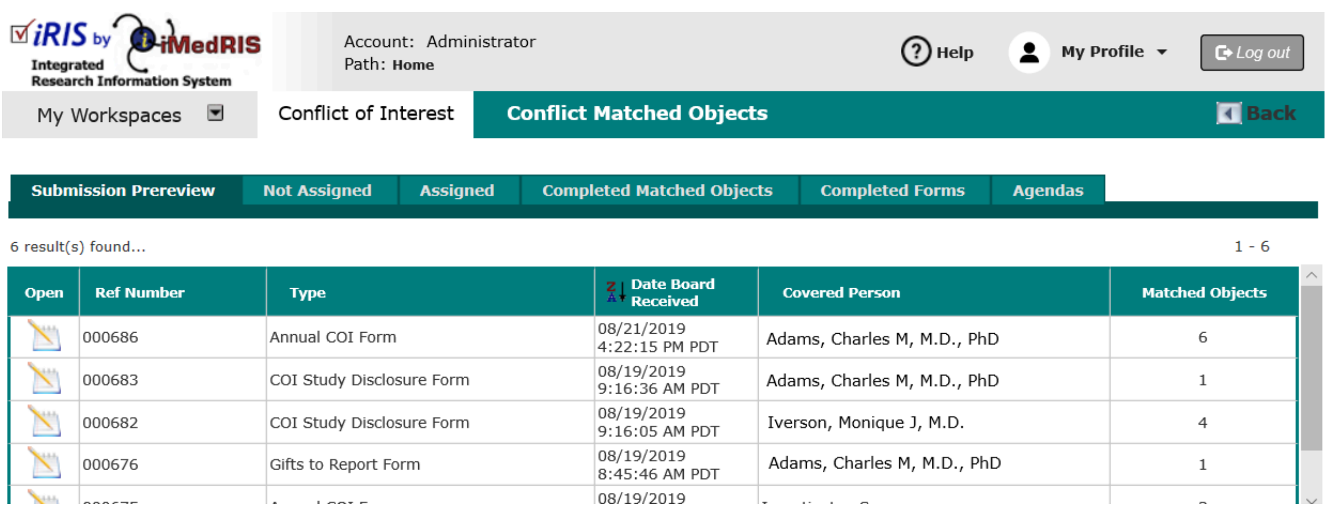
The Conflict of Interest Assistant allows for processing of iRIS™ user conflict matches that have been generated by answers on COI forms. From the Conflict Matches area of the system you can complete many tasks, including reviewing the match, adding documents, assigning reviewers, and sending out letters and Management Plans. This document covers steps to process Conflict Matches.

Conflict Matches

When a conflict match is found in an annual COI submission, it will be routed to the **Conflict Matched Objects** processing area of the Conflict of Interest Assistant.

This screen can be accessed via the Conflict of Interest Assistant > Conflict Matches menu link, or the Conflict Matches icon in the Conflict of Interest Workspace.

The Conflict Matched Objects screen lists any conflict match found in any form submitted to the COI Review Board. The COI submission queue is split up into six tabs: **Submission Prereview**, **Not Assigned**, **Assigned**, **Completed Matched Objects**, **Completed Forms**, and **Agendas**.



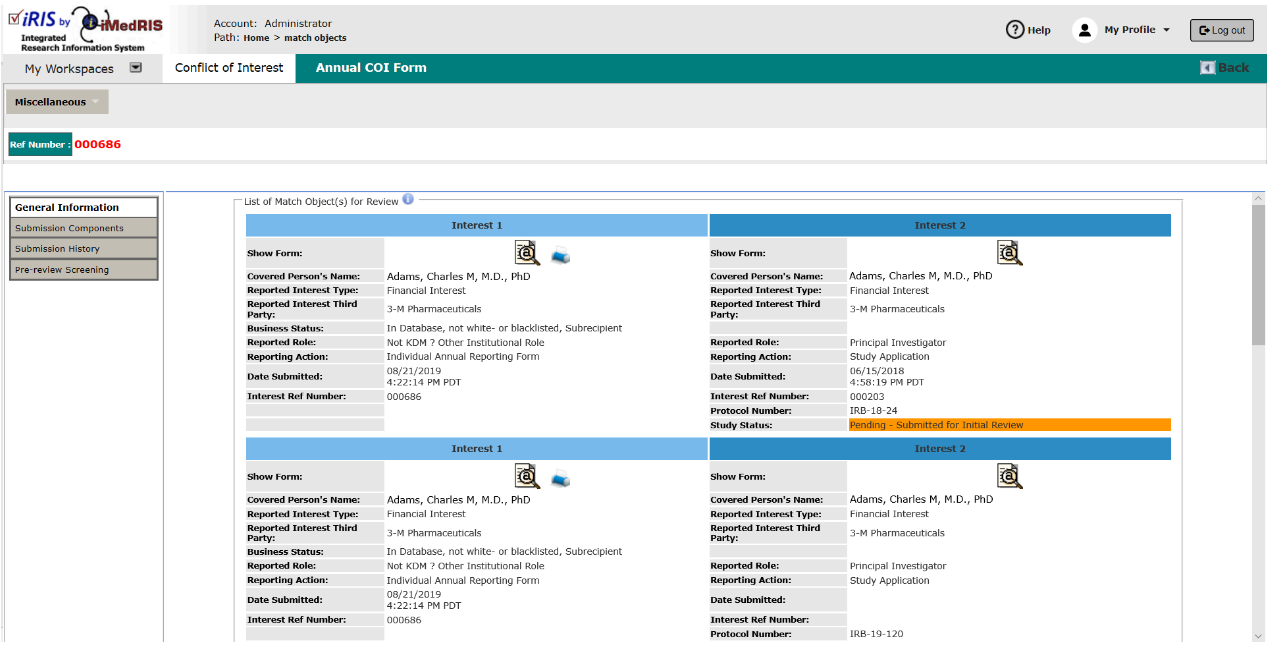
Submission Prereview

The screen initially loads with the **Submission Prereview** tab open. Here, you can get a summary view of conflict matches in the processing queue.

Clicking on the icon in the **Open** column for a match shown here will open the corresponding submission.

Open Form

When a form is opened from the **Open** column in the **Conflict Matched Objects** screen, **Submission Prereview** tab and a read-only version of the form loads in a new screen as shown below.



The different sections of the form are accessed via the menu tabs at left. By default, this screen loads with the **General Information** tab open.

Interest 1

Show Form—Where available, click on this icon to view the form where the conflict match has been identified. This will open the Annual COI or the Study COI form submitted. There may also be a **Print** icon next to the Show Form icon; if so, click it to view a print-friendly version of the information provided in the **List of Match Object(s) for Review** section.

Covered Person's Name—Name of the person who has indicated a conflict match

Reported Interest Type—Type of interest, as noted within the form (e.g., Financial Interest, Financial Commitment, Gifts from a Biomedical Company, etc.)

Reported Interest Third Party—Name of the indicated third party interest (the Sponsor with which the user indicated an interest)

Business Status—Indicates whether or not the business is in the database, whether it's a Sponsor, and whether it's white- or blacklisted

Reported Role—Role indicated by the Covered Person for this conflict match

Reporting Action—Where the match originated (e.g., COI Individual Annual Reporting Form, Study COI)

Date Submitted—Date the conflict form was submitted into the workflow

Interest Ref Number—Reference number of the COI form

Interest 2

This area will only populate with information if the specific conflict match has a matching study to display. If the Covered Person has a conflict with a certain sponsor, and has a role on a study with that same sponsor, information related to the study will populate in the Interest 2 area.

Show Form—Where available, click on this icon to view the form where the conflict match has been identified. This will open the Annual COI or the Study COI form submitted. There may also be a **Print** icon next to the Show Form icon; if so, click it to view a print-friendly version of the information provided in the **List of Match Object(s) for Review** section.

Covered Person's Name—Name of the person who has indicated a conflict match

Reported Interest Type—Type of interest, as noted within the form (e.g., Financial Interest, Financial Commitment, Gifts from a Biomedical Company, etc.)

Reported Interest Third Party—Name of the indicated third party interest (the Sponsor with which the user indicated an interest)

Reported Role—Role indicated by the Covered Person for this conflict match

Reporting Action—Where the match originated (e.g., COI Individual Annual Reporting Form, Study COI)

Date Submitted—Date the conflict form was submitted into the workflow

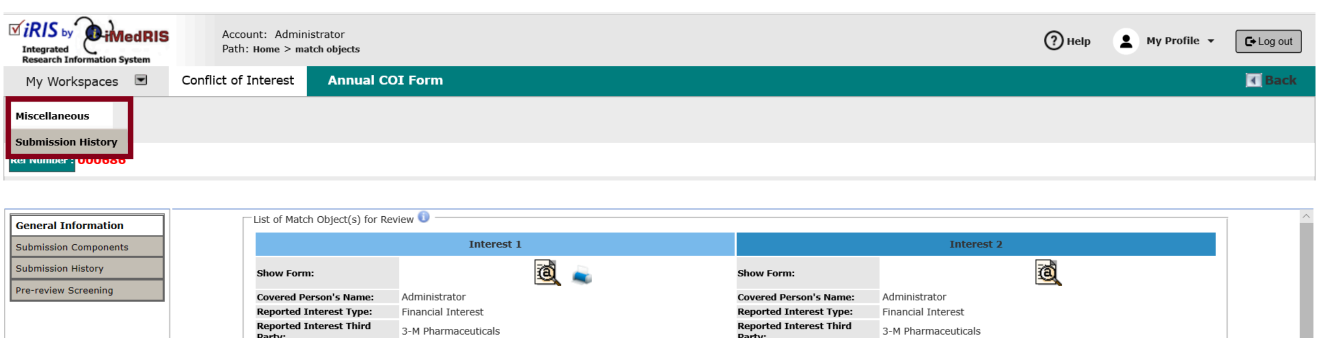
Interest Ref Number—Reference number of the COI form

Protocol Number—Protocol Number of the corresponding research study

Study Status—This field is visible and displays the current status of the corresponding research study, where applicable; where inapplicable, the field does not display

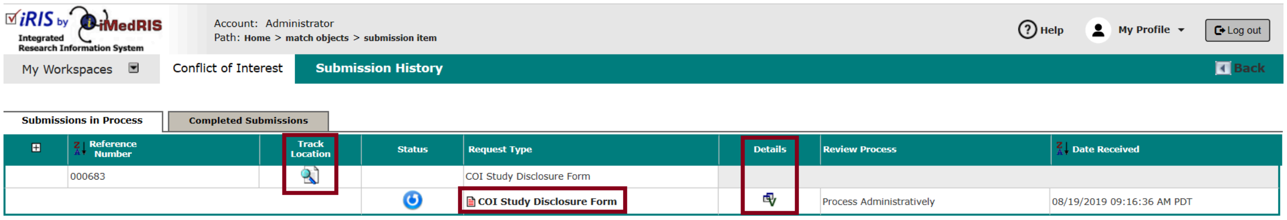
View Status Tracking Map

You can view a status tracking map for the submission, including previous rounds, via the **Miscellaneous > Submission History** dropdown item at the upper left.

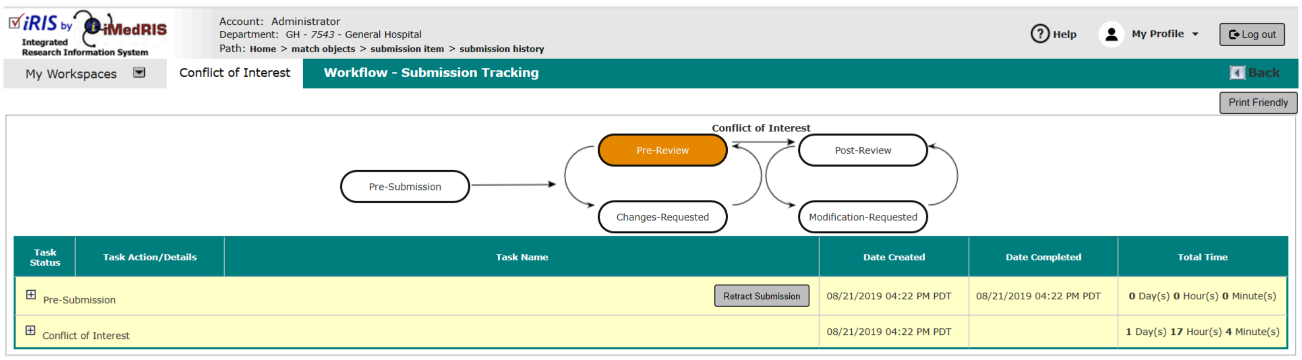


When the **Miscellaneous > Submission History** link is clicked, the **Submission History** screen displays. The screen has two tabs: **Submissions in Process** and **Completed Submissions**. Click either tab to toggle between them and view either completed submissions or those still in process.

The interactive elements on the tabs of this screen are **Track Location**, a link to view the form (**Request Type** column), and **Details**.



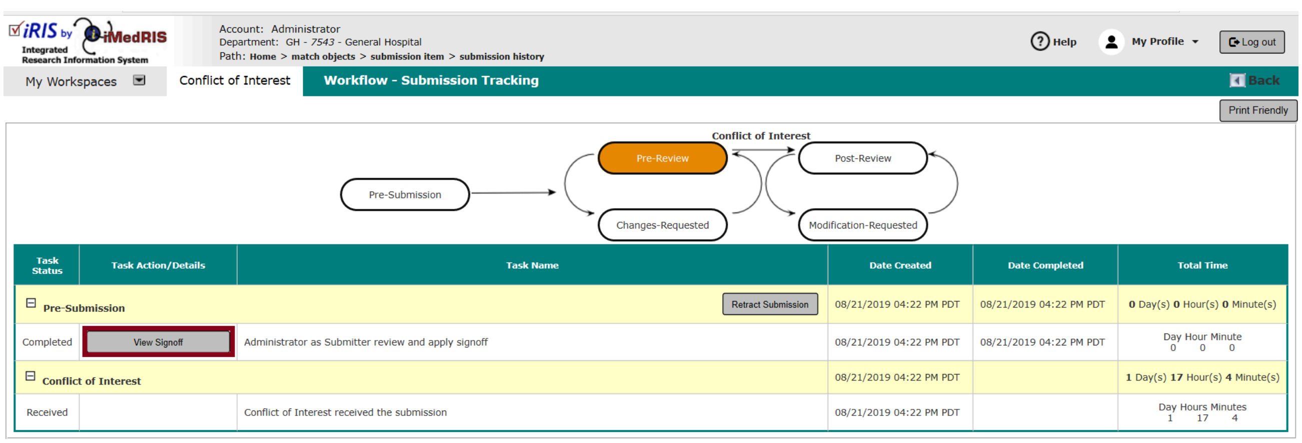
Click the icon in the **Track Location** column to open the **Workflow – Submission Tracking** screen, where you can view the location tracking map and summary information for the selected form.



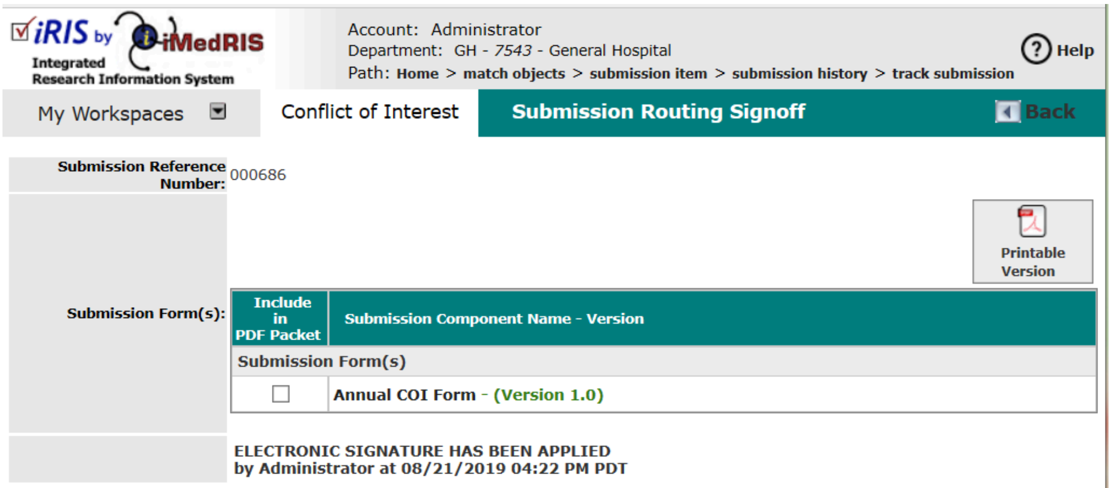
*Specific information and screen elements shown will vary according to the type of COI form under review, its current processing status, and any customizations made in Review Board Administration settings. For example, the **Retract Submission** button shown in the screenshot above will not be available for all forms at all stages of match processing.*

Click the plus signs at the far left to expand status details for each **Task Status** section. Alternatively, you can click any step in the workflow process diagram at top to expand details specific to that step.

In the following screenshot, all available sections have been expanded by clicking the plus signs.



Where a **View Signoff** button is present, click it to load the **Submission Routing Signoff** screen, where you can view and print signoff details. Click the **Include in PDF Packet** checkbox to select items, then click the **Printable Version** button.

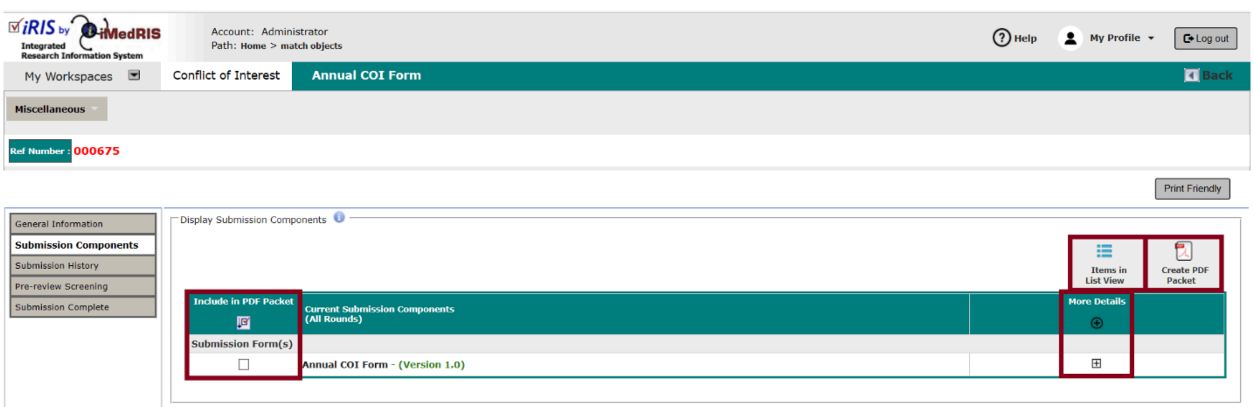


Note that at least one checkbox must be selected to print. If multiple items are selected, you will be given the opportunity to re-order them in the PDF packet before printing.

Where a **Retract Submission** button is present, you can click it to retract the submission. A confirmation popup will display, giving you the option to either **CONFIRM** or **CANCEL**.

Submission Components

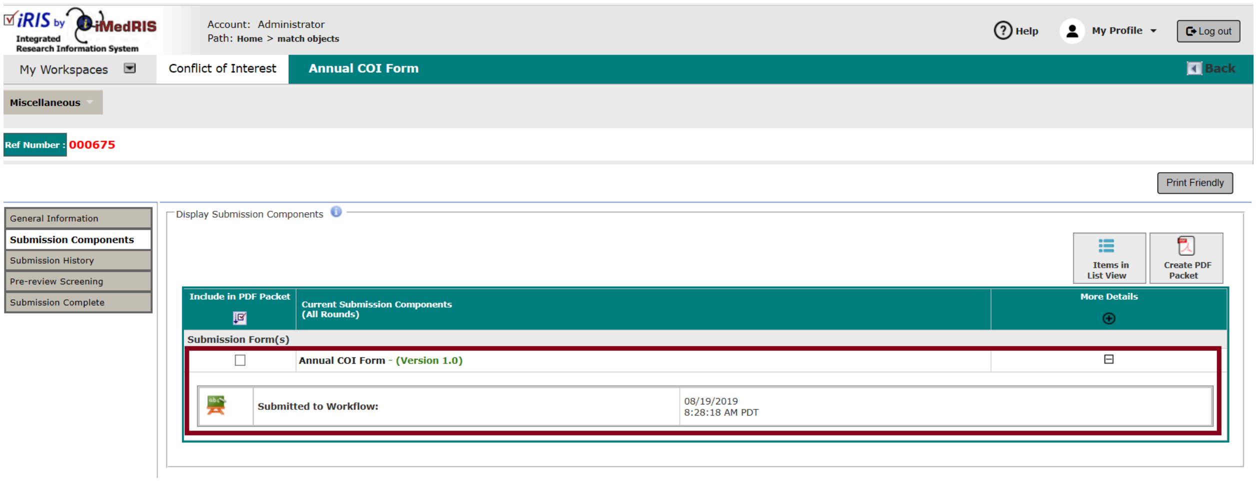
Back on the screen where a selected form is open (in the example below, it's an Annual COI Form), the second menu tab is **Submission Components**. On this tab, you can view details of forms and related documentation that comprise the submission.



Click the **Items in List View** button at the right to toggle between **Items in List View** and **Items in Folder View**. Folder View is only applicable where the submission includes grouped forms and/or documents.

To create a PDF packet, click the checkbox in the **Include in PDF Packet** column for items you wish to include, then click the **Create PDF Packet** button at the right. If you've made multiple selections, you will be given an opportunity to re-order them before printing the PDF Packet.

You can view details of a specific item in the list by clicking the plus sign icon in the **More Details** column for that item. To expand the details section for all items in the list, click the plus sign in the **More Details** column header.

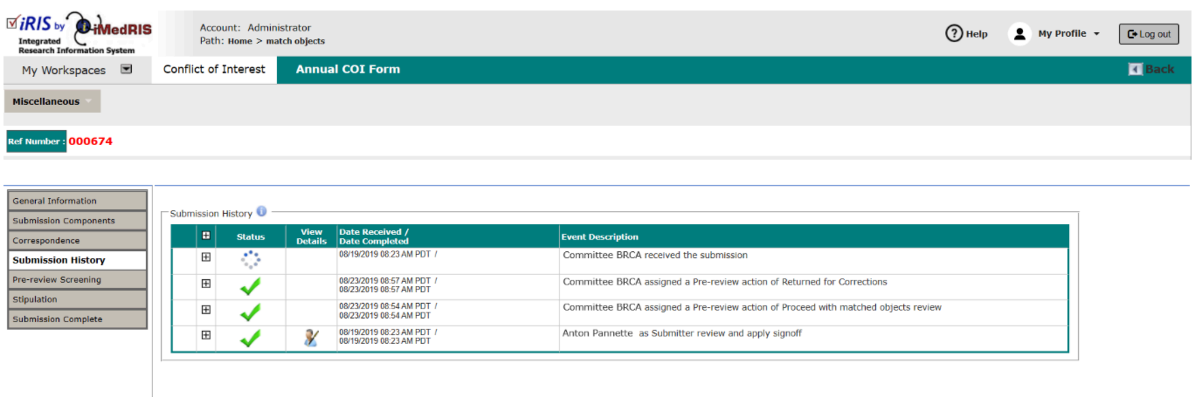


Use the **Print Friendly** button to open a simplified list in a new window.

Submission History

Back on the Open Form screen, click the **Submission History** tab to view submission history for the selected open form.

The **Status** column shows an icon representative of the associated item's current processing status. A green checkmark indicates the associated item is complete. The circle of fading dots indicates the associated item is still in process.

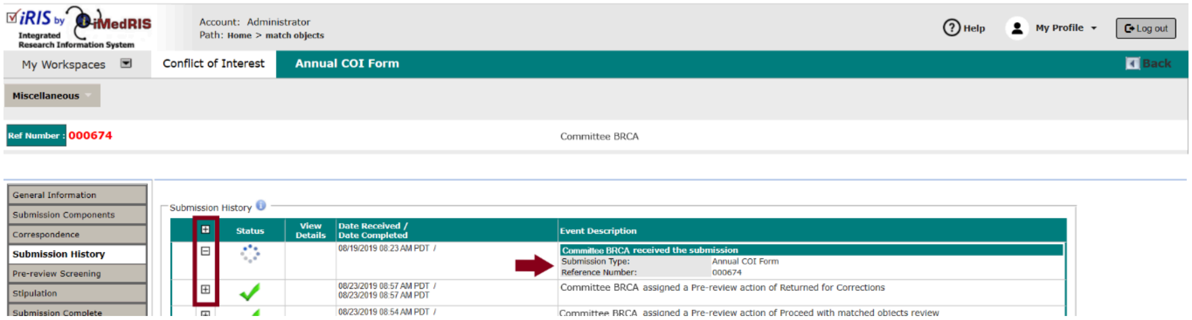


The **View Details** column will display an icon for items that have associated forms or related documentation. Where an icon is present, click it to view details of the form or associated documentation.

The **Date Received / Date Completed** column contains the date received for the item, followed by a forward slash, followed by the date completed for the item. If processing for the item is not yet complete, only a date received, and forward slash will be shown.

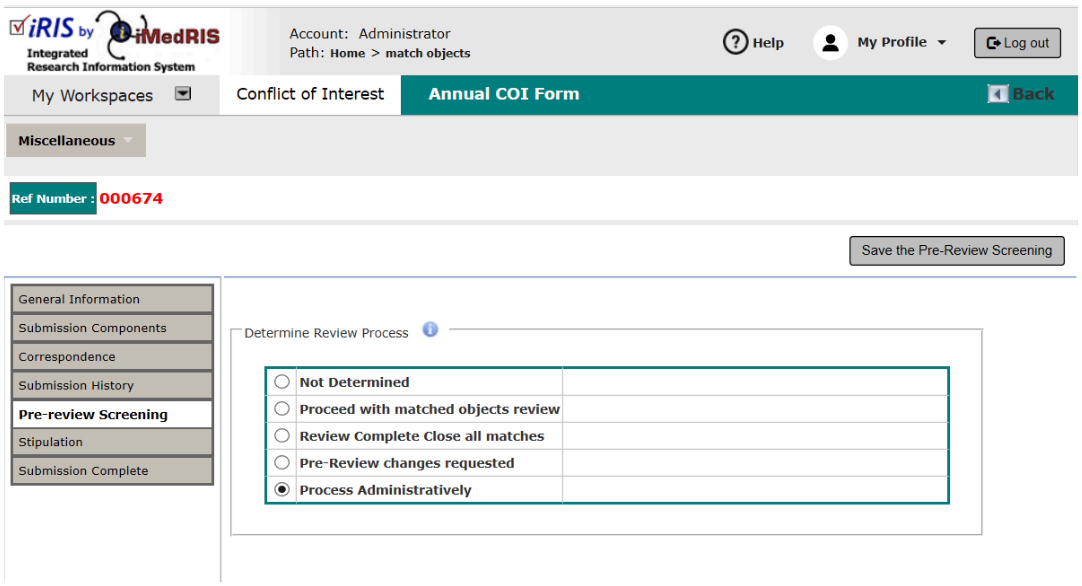
The **Event Description** column contains a brief description of the item.

Click the plus sign to the left of any item to view **Submission Type** and **Reference Number** for that item.



Pre-review Screening

Back on the Open Form screen, click the **Pre-review Screening** tab to enter the results of the screening.



The title of the form, document or object appears in the green header, and its **Ref Number** appears in red at the upper left of the screen.

Status options are as follows:

Not Determined—Keep the item in Pre-review Processing and make an entry to the file notating that decision.

Proceed with matched objects review—Move the item to the Not Assigned tab of the Conflict Matches home screen, where its matched objects can be assigned for further review.

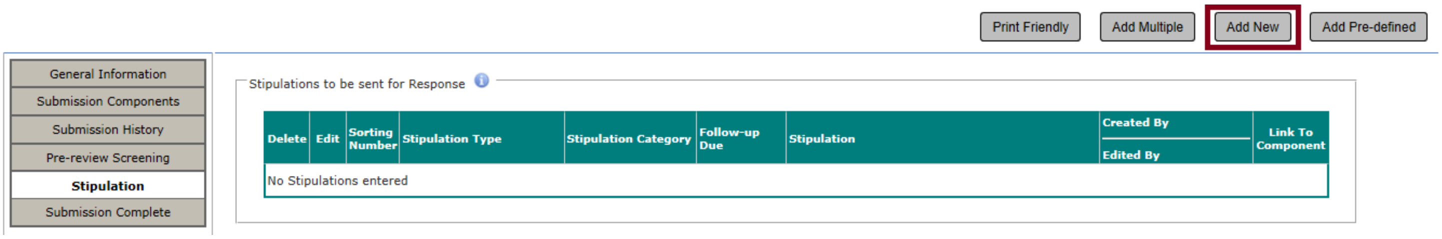
Review Complete Close all matches—Close all matches pertaining to this item and move the item to the Completed Matched Objects tab of the Conflict Matches home screen.

Pre-review changes requested—At least one change has been requested, processing cannot continue until the request has been addressed.

Process Administratively—Opens a special version of the Submission Complete screen with a Pre-Review Outcome dropdown box. See Submission Complete section later in this document for more information.

Stipulation

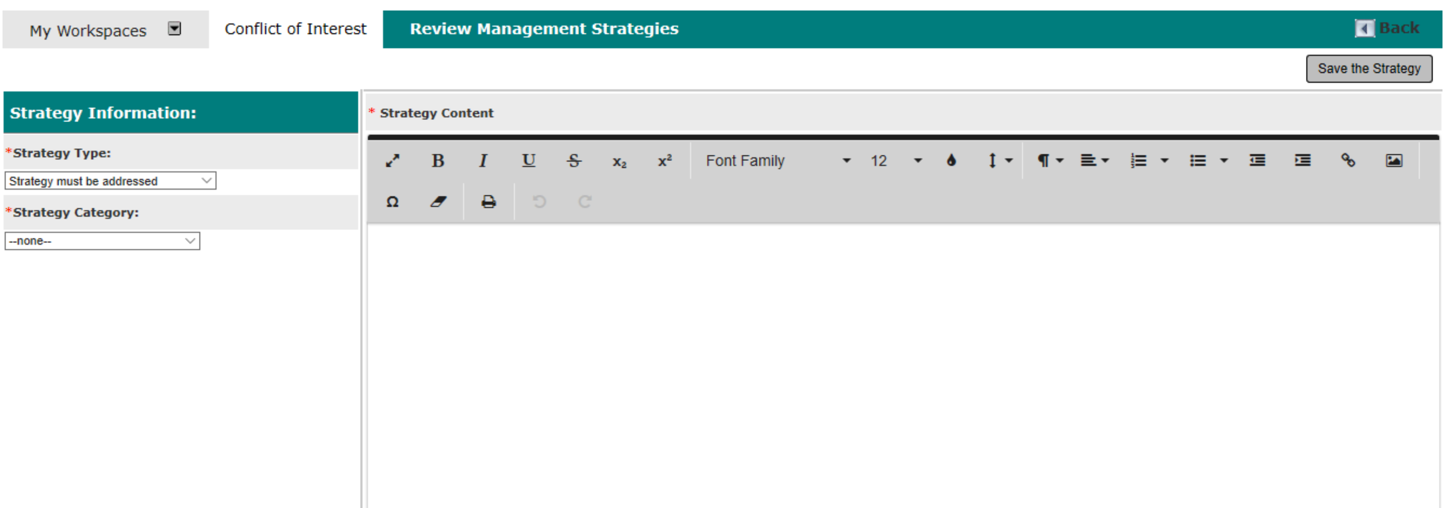
Back in the Open Form screen, the next tab is **Stipulation**. There are three ways to add stipulations: **Add Multiple**, **Add New** and **Add Pre-defined**.



Add New Stipulation

Click the **Add New** button to manually enter a stipulation line item.

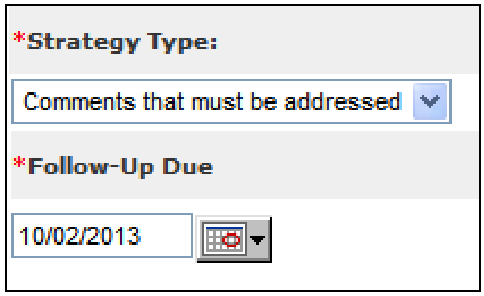
The **Review Management Strategies** screen opens, allowing you to type or paste in text for the stipulation in a rich text editor.



Select a **Strategy Type** and **Strategy Category** at left, then click the **Save the Strategy** button to add the strategy to the stipulations list.

There are three **Management Strategy Type**s:

> **Strategy must be addressed—** The covered person must follow the strategy and respond to the COI office with an acknowledgement.
>
> **Comments that must be addressed—** When you select this type from the dropdown list the screen will refresh, adding a field to specify a follow-up due date. The Covered Person must respond to the item before the specified date, outside of the main management plan follow-up due date (this is assigned when you are sending the management plan to the Covered Person, which is covered later in this document).



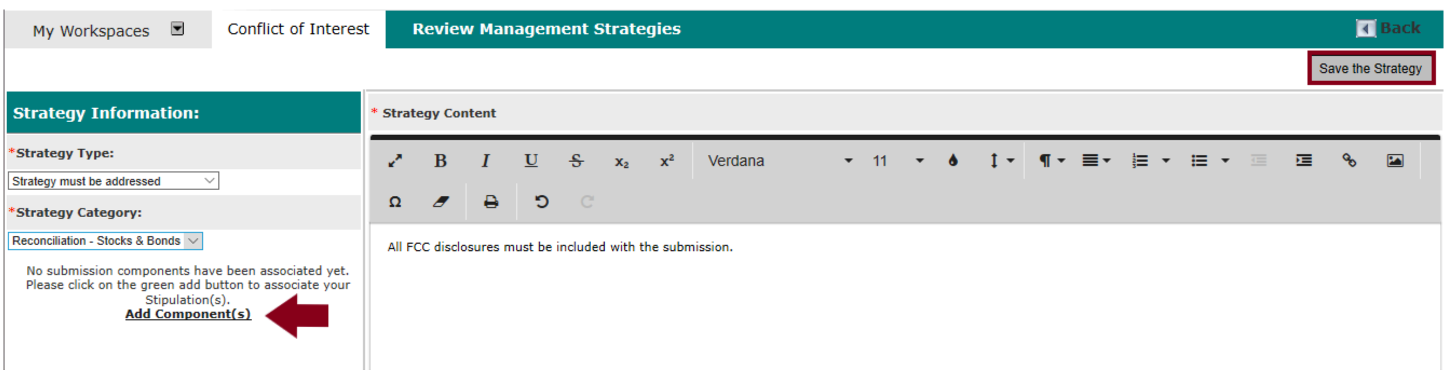
Comments— Adds recommendations for the Covered Person. The comments are merged into the Management Plan and require acknowledgement from the Covered Person.

Strategy Category is a configurable list set up in Review Board Administration, and its contents will vary according to the entries added here for your system.

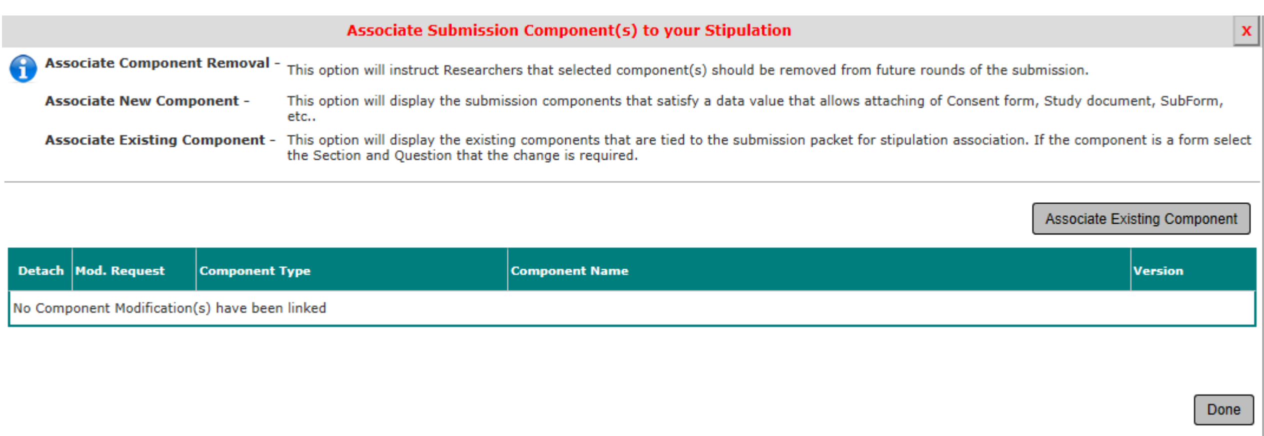
Associate Component(s)

If there are submission components available for the matched object (e.g., COI Study Disclosure Form), an **Add Component(s)** link will be available at the lower left of the text editor page where stipulations are added (red arrow in the screenshot below).

Submission components are associated where possible in order to provide reviewers with a link to the item referenced by a stipulation, so they can more quickly complete their review.

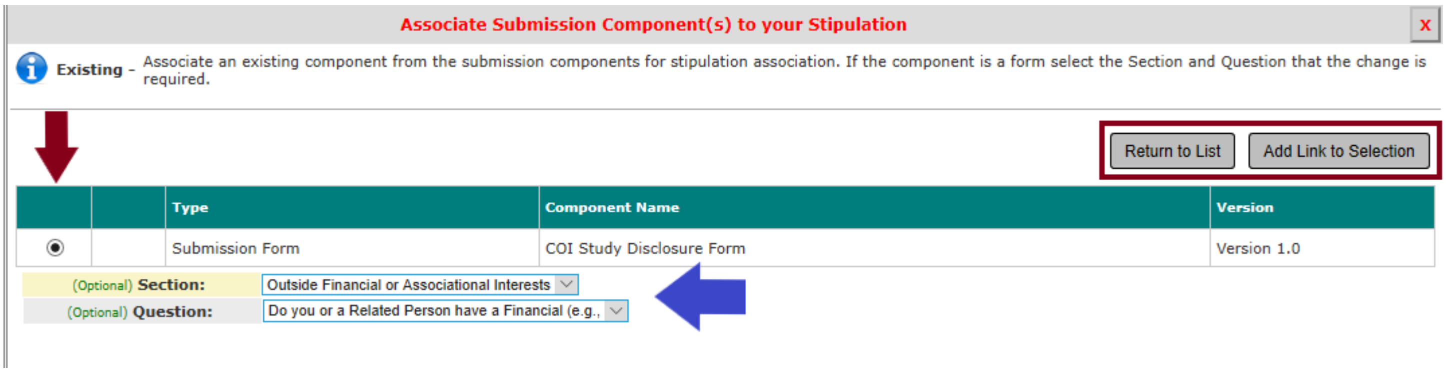


Click the **Add Component(s)** link to associate the applicable component with the stipulation. This will open the **Associate Submission Component(s) to your Stipulation** screen.



Buttons shown on this screen will vary according to the matched object under review, its available components and stage of processing.

In the screenshot below, the **Associate Existing Component** button has been clicked. The **Associate Submission Component(s) to your Stipulation** screen opens, listing components available for association.

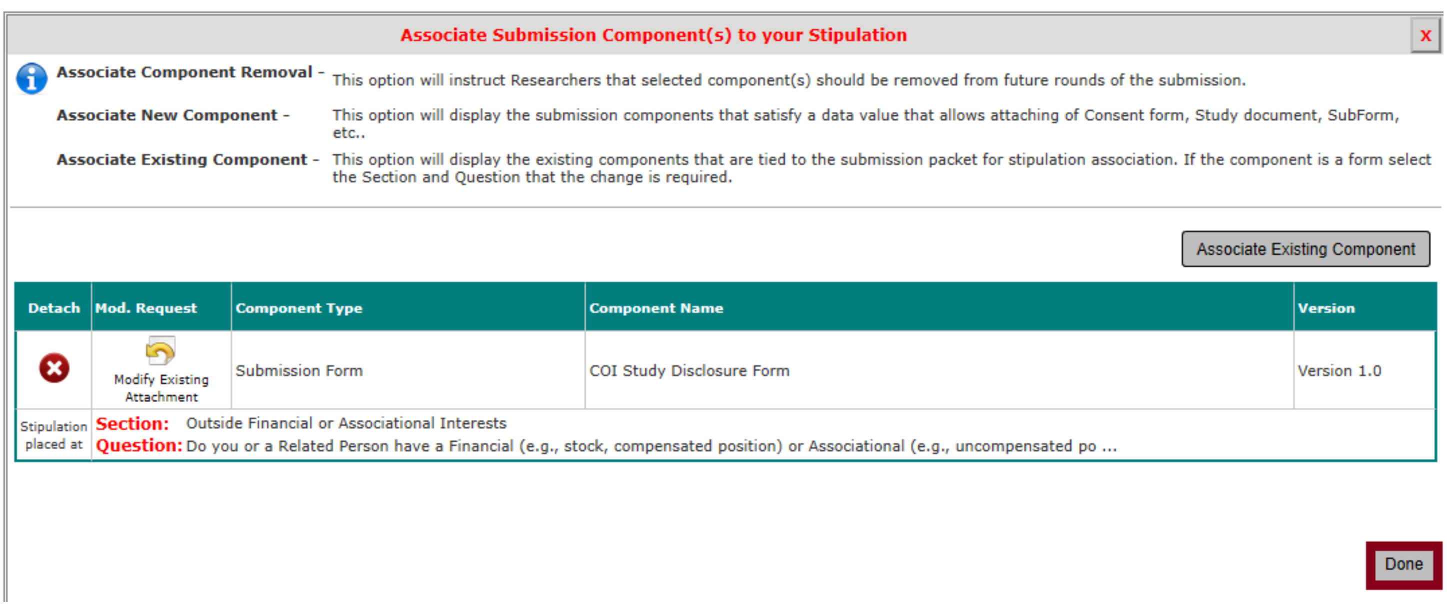


Click the select icon for the item you wish to associate with your stipulation (red arrow in screenshot above).

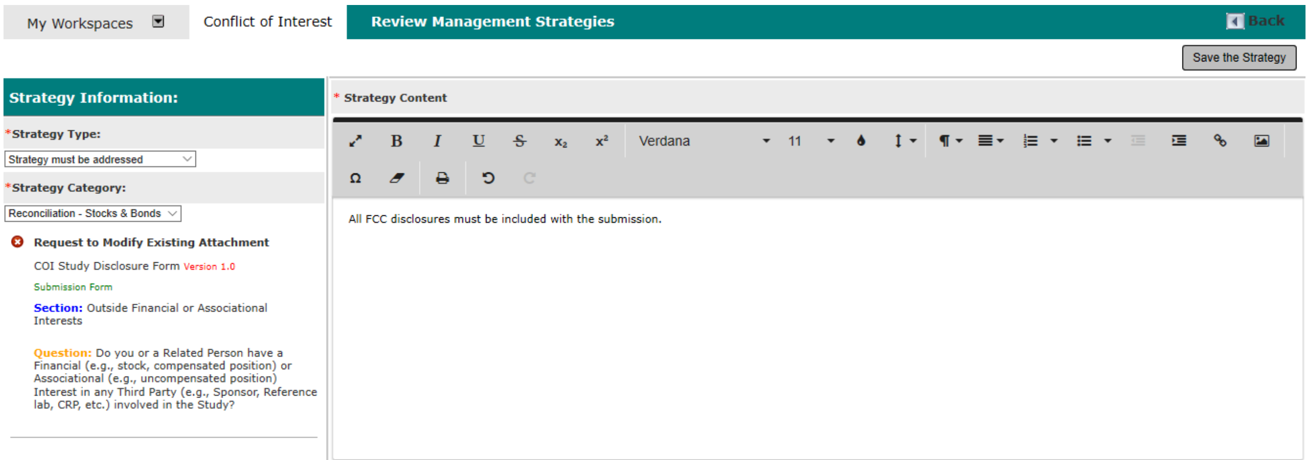
Depending on the type of item, one or more dropdown lists may appear for you to specify a location in the associated submission component (blue arrow in screenshot above). Populating these dropdowns, where available, will open the item to the specific section and/or question associated with the stipulation when the reviewer clicks the component link provided with the stipulation.

Click the **Return to List** button to close the form without saving changes.

Click the **Add Link to Selection** button to associate the selected submission component. The dialog box updates with details of the component associated with the stipulation.



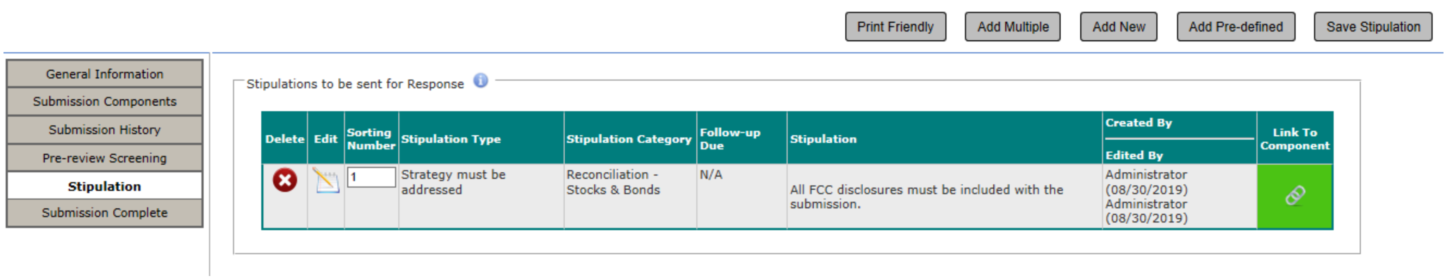
Click the **Done** button to confirm the association and return to the Review Management Strategies text editor, where your stipulation is still in draft form.



The screen updates at the left side to include details of the associated submission component. Click the red **Delete** icon in that section to remove the associated component.

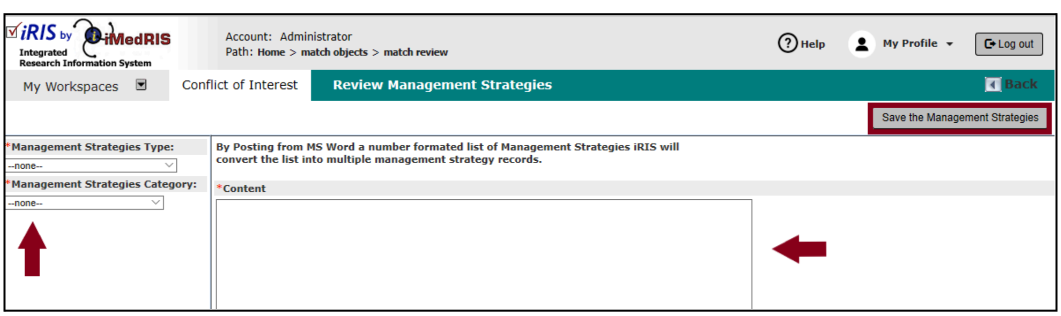
Click the **Save the Strategy** button to save the stipulation.

The **Stipulation** tab updates with the added stipulation.



Add Multiple Stipulations

Click the **Add Multiple** button in the Stipulation tab to add multiple stipulations at once.



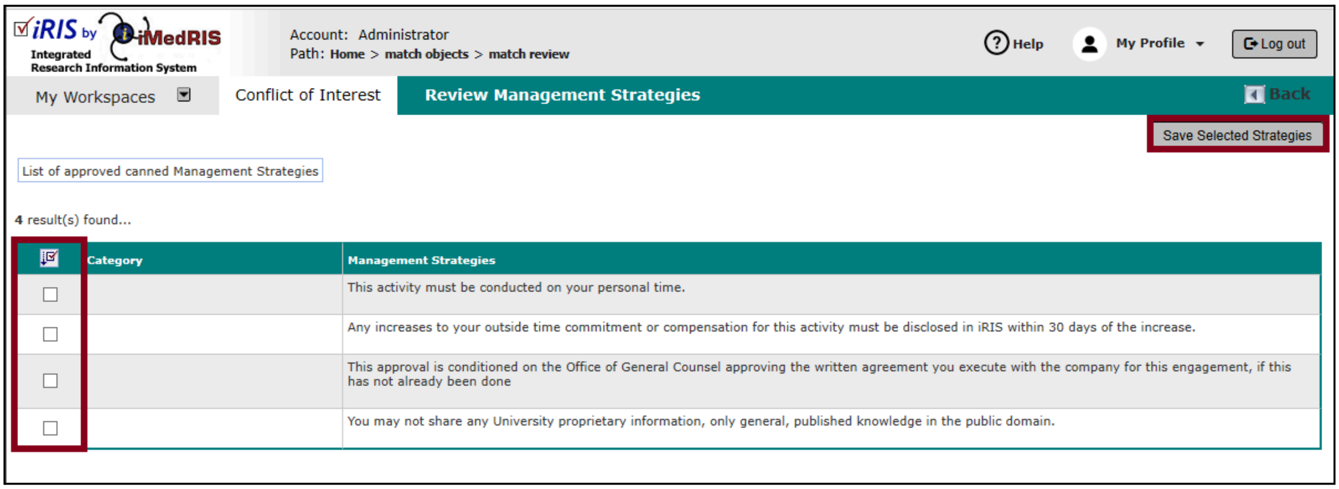
Copy stipulations that have been formatted as a numbered list in a Word document, then paste the copied, numbered list into the text editor box. Select a **Management Strategies Type** and **Management Strategies Category** at left, then click the **Save the Management Strategies** button to add the pasted list of strategies to the list of stipulations on the Stipulations tab.

Add Pre-defined Stipulations

If certain stipulations are commonly applied, you can save them to the Pre-defined Strategies list under Review Board Administration > List Maintenance Setup > Predefined Strategies.

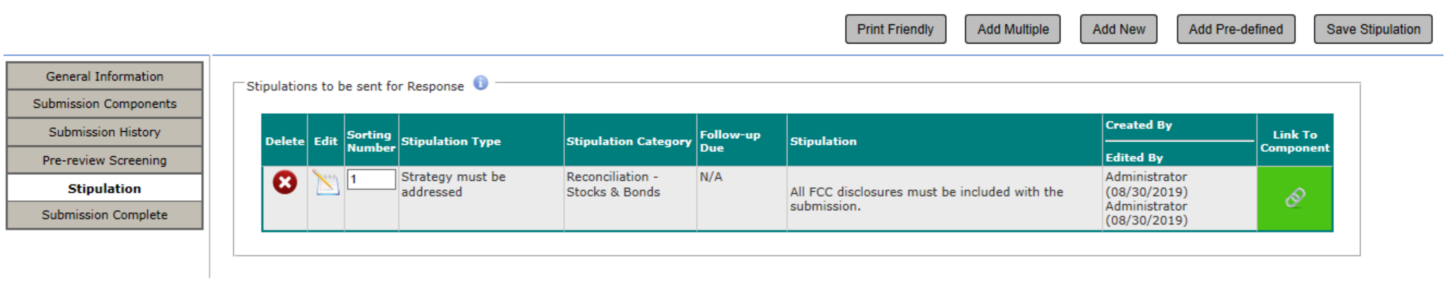
Note that this single Strategies list is used for both stipulations and management strategies.

When you click the **Add Pre-defined** button in the Stipulation tab, a screen listing all the predefined strategies will open. You can select a strategy or multiple strategies, then click the **Save Selected Strategies** button.



The stipulation(s) will be added as a "Strategy must be addressed" type.

All stipulations added, regardless of the method used to add them, will appear in the **Stipulations to be sent for Response** table in the Stipulation tab.



Click the **Delete** icon next to the appropriate stipulation to delete that item.

Click the icon in the **Edit** column next to the appropriate stipulation item to open it for modifications.

Stipulations are displayed in the order you added them. If you would like to reorder them, you can change the numbering in the **Sorting Number** column. Numbering starts at one (1) and continues in descending order (e.g., 2, 3, 4, etc.). Change the numbers to re-order the stipulations as desired, and then click the **Save Stipulation** button.

Submission Complete

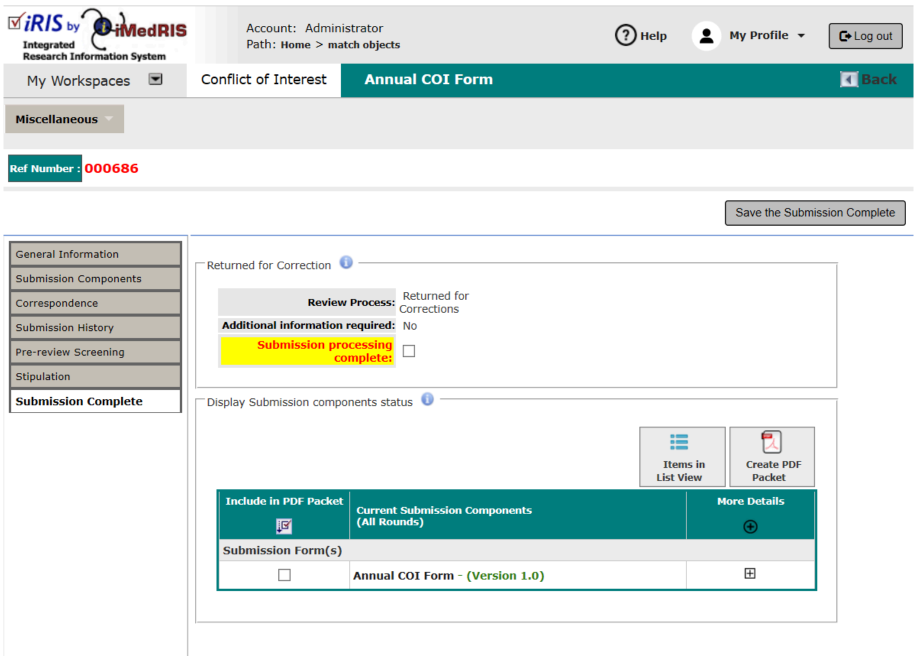
Back on the Open Form screen, click the **Submission Complete** link to set status to complete for the item currently under review.

The **Ref Number** for the form, document or object under review is shown in red at the upper left. The top section title reflects the most recent status update on the item. In the example shown below, the title is **Returned for Correction**. This section contains the following fields:

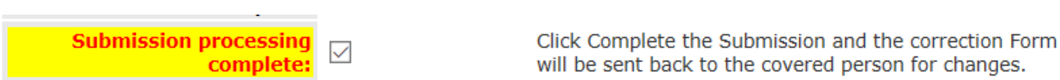
Review Process—Reflects the most recent status of the item.

Additional Information required—Displays Yes if more information is required, No if no additional information is required.

Submission processing complete—Check this box to set processing status to 'complete' for the form, document or other object identified by the **Ref Number**.



When the **Submission processing complete** box is checked a message will display, reminding the user to click the **Save the Submission Complete** button and describing what will happen to the object next as a result of being marked complete.

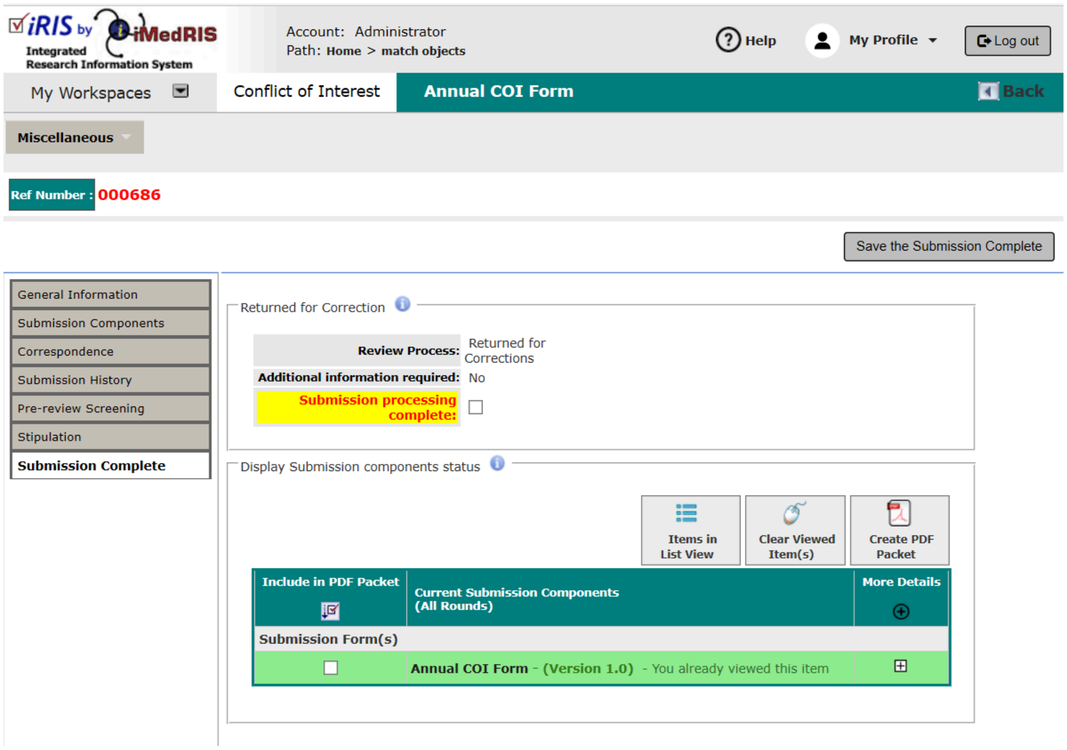


Use the **Display Submission components status** section in the lower half of the form to view, comment on, or package listed items into a PDF.

If there are any grouped items in the list, click the **Items in List View** button to toggle between List and Folder view.

Click the checkbox next to items you'd like to include, then click the **Create PDF Packet** button to generate a PDF Packet of the selected items. Note that if you've selected multiple items, you will be given the opportunity to re-order them in the PDF Packet.

Click on the name of an item in the list, shown in the **Current Submission Components (All Rounds)** column, to open it for review in a read-only version. Depending on the item, you may be able to add comments to it. After an item is viewed the Submission Complete screen updates with the addition of visual and text cues demonstrating the item has been viewed, as well as a **Clear Viewed Item(s)** button:



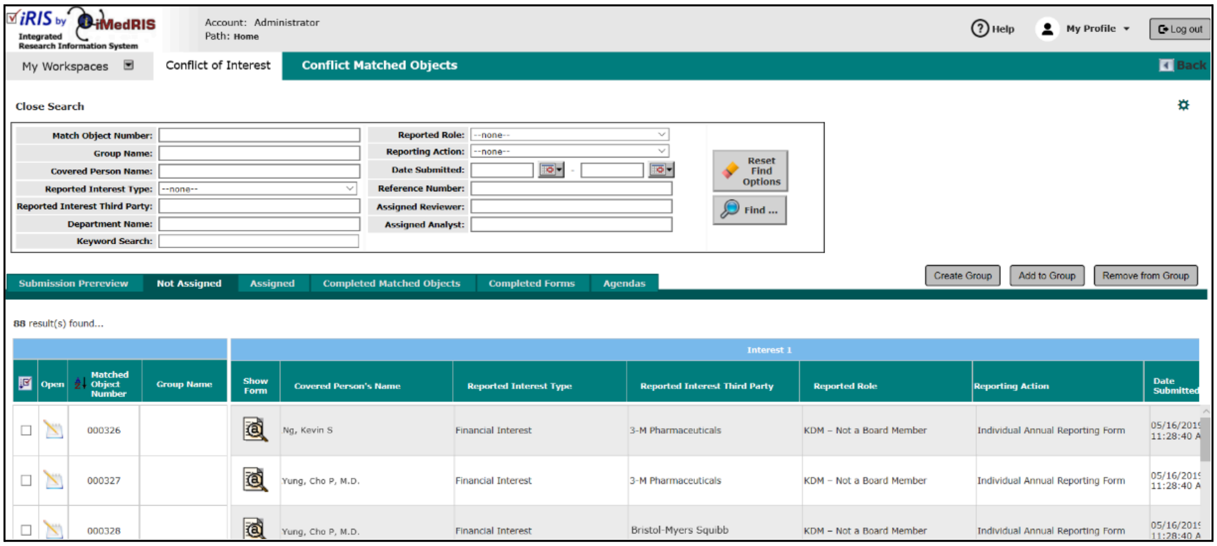
In cases where there are numerous items listed here, these changes make it easy to see at a glance which items have been viewed and which have not. Click the **Clear Viewed Item(s)** button to clear the green highlight bar(s) and **You already viewed this item** message(s).

Click the **More Details** plus sign to the right of an item name to view its submission details.

If there are any grouped items in the list, click the **Items in List View** button to toggle between List and Folder view.

Not Assigned

Any new match that is unprocessed will populate within this tab. There can be multiple conflict matches within each Annual COI form submitted to the Conflict of Interest submission queue. Each match is broken out into its own separate entry within the queue, as opposed to being contained within a single form.



By default, the Not Assigned tab loads with a search form at the top. You can use the fields in this form to filter the list of records by **Match Object Number**, **Group Name**, **Covered Person Name**, **Reported Interest Type**, **Reported Interest Third Party**, **Department Name**, **Keyword Search**, **Reported Role**, **Reporting Action**, **Date Submitted** range, **Reference Number**, **Assigned Reviewer** or **Assigned Analyst**.

Click the **Close Search** link at the upper left to close the search form.

Notice how, in the previous screenshot image of the Not Assigned tab, the columns under the blue header labeled ***Interest 1*** *are truncated at the right. This is because there are more data elements to display than will fit in a single screen. Use the scrollbars at the right and bottom of the form to view the rest of the* ***Interest 1*** *column and the* ***Interest 2*** *column (not shown in screenshot).*

The columns listed in the **Not Assigned** tab are as follows.

 **—**Use the checkbox to select matches and add them to a group. Conflict Match Groups will be discussed in more detail later in this document.

Open—Click this icon to open a match for processing.

Matched Object Number—Each conflict match in iRIS™ is assigned its own unique reference number, which is used to identify the individual match or match Group (see **Creating Groups** section that follows). Note that this is not the same reference number used with submission forms in iRIS™.

Group Name—After adding matches to a group, the name of the group will display in this column.

Interest 1

Show Form—Where available, click on this icon to view the form where the conflict match has been identified. This will open the Annual COI or the Study COI form submitted. There may also be a **Print** icon next to the Show Form icon; if so, click it to view a print-friendly version of the information provided in the **List of Match Object(s) for Review** section.

Covered Person's Name—Name of the person who has indicated a conflict match

Reported Interest Type—Type of interest, as noted within the form (e.g., Financial Interest, Financial Commitment, Gifts from a Biomedical Company, etc.)

Reported Interest Third Party—Name of the indicated third party interest (the Sponsor with which the user indicated an interest)

Reported Role—Role indicated by the Covered Person for this conflict match

Reporting Action—Where the match originated (e.g., Annual COI Individual Annual Reporting Form, Study COI)

Date Submitted—Date the conflict form was submitted into the workflow

Ref Number—Reference number of the COI form

Interest 2

This area will only populate with information if the specific conflict match has a matching study to display. If the Covered Person has a conflict with a certain sponsor, and also has a role on a study with that same sponsor, information related to the study will populate in the Interest 2 area.

Show Form—Where available, click on this icon to view the form where the conflict match has been identified. This will open the Annual COI or the Study COI form submitted. There may also be a **Print** icon next to the Show Form icon; if so, click it to view a print-friendly version of the information provided in the **List of Match Object(s) for Review** section.

Covered Person's Name—Name of the person who has indicated a conflict match

Reported Interest Type—Type of interest, as noted within the form (e.g., Financial Interest, Financial Commitment, Gifts from a Biomedical Company, etc.)

Reported Interest Third Party—Name of the indicated third party interest (the Sponsor with which the user indicated an interest)

Reported Role—Role indicated by the Covered Person for this conflict match

Reporting Action—Where the match originated (e.g., Annual COI Individual Annual Reporting Form, Study COI)

Date Submitted—Date the conflict form was submitted into the workflow

Ref Number—Reference number of the COI form

Proposal Number—Proposal Number of the corresponding research study

Project Status— Status of the corresponding project

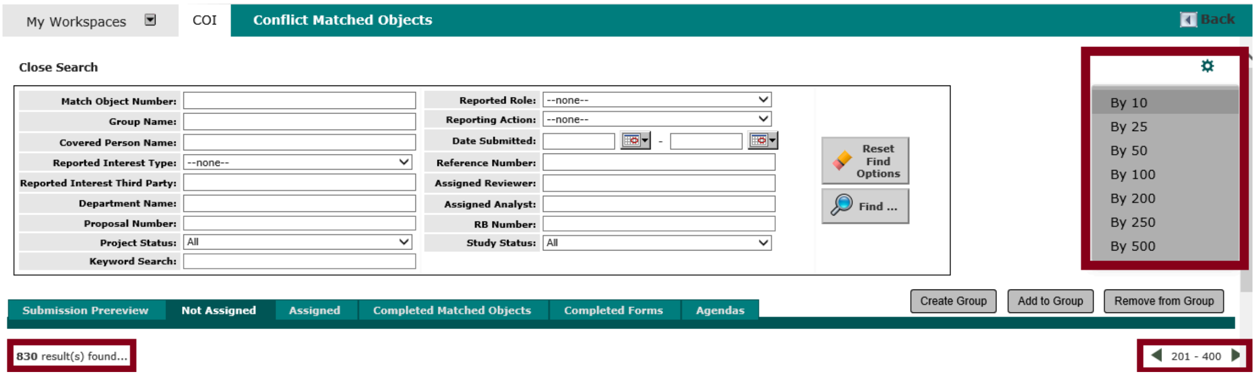
Protocol Number—Protocol Number of the corresponding research study

Study Status—Status of the corresponding research study (e.g., Draft, Pending – Submitted for Initial Review, Approved, etc.)

Reporting Action PI—The Principal Investigator of the corresponding research study

All SSF Comp?—Flag to indicate when all Study Specific Forms have been completed

All PSF Comp?—Flag to indicate when all Project Specific Forms have been completed



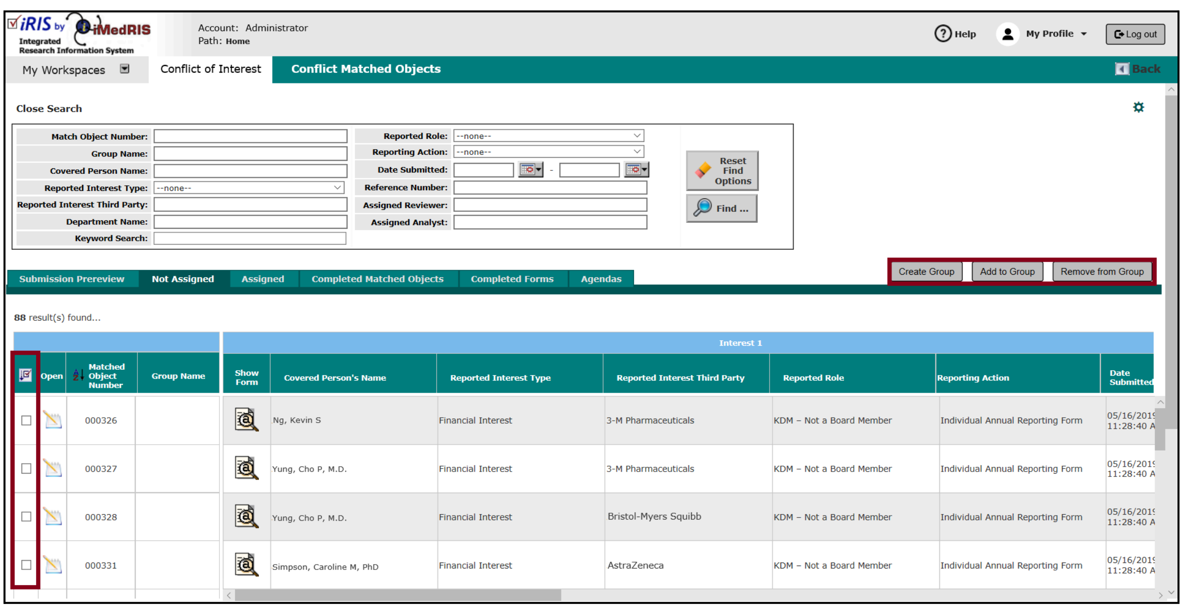
If the quantity of matches shown is large a small gear icon will appear at the upper right hand of the screen, as shown in the previous screenshot. Click the icon to set the number of records you wish to display per screen.

Grouping Matches

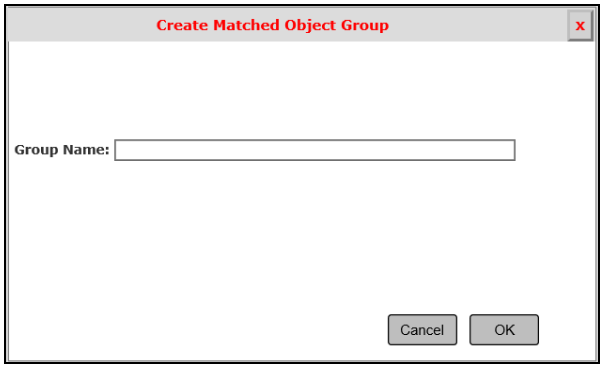
Conflict matches that populate in the Conflict of Interest submission queue can be grouped together to be processed as a group instead of individually on the Not Assigned tab. This can be done for any conflict match, but is typically used to group matches for the same Covered Person.

Create Group

To create a Group for future use without adding any matches to it, ensure none of the checkboxes at the far left of the match list are selected and click the **Create Group** button.



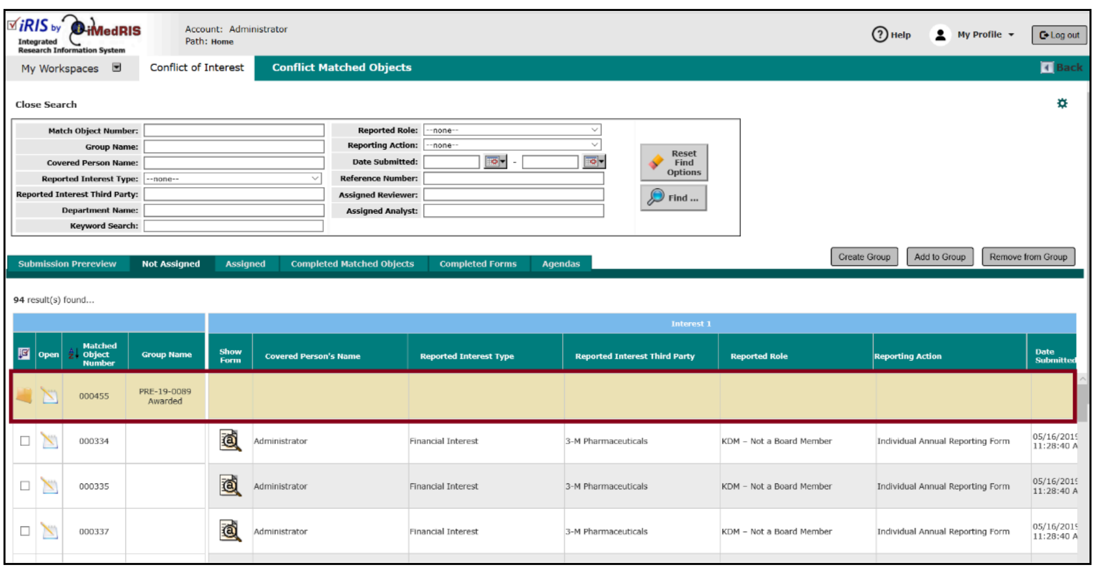
The Create Matched Object Group dialog displays, prompting you to enter a Group name and click the OK button to save the Group.



To create a Group and simultaneously add records to it, click the checkboxes next to the records you wish to add to the Group and click the **Create Group** button. The **Create Matched Object Group** dialog will open.

After you've entered a **Group Name** and clicked the **OK** button, the selected items will be added to the newly created Group and the Not Assigned tab display will update to reflect the new grouping.

In the example that follows the first two records in the list were selected and the Create Group button was clicked. In the Create Matched Object Group dialog the **Group Name** "PRE-19-0089 Awarded" was entered and the OK button was clicked.

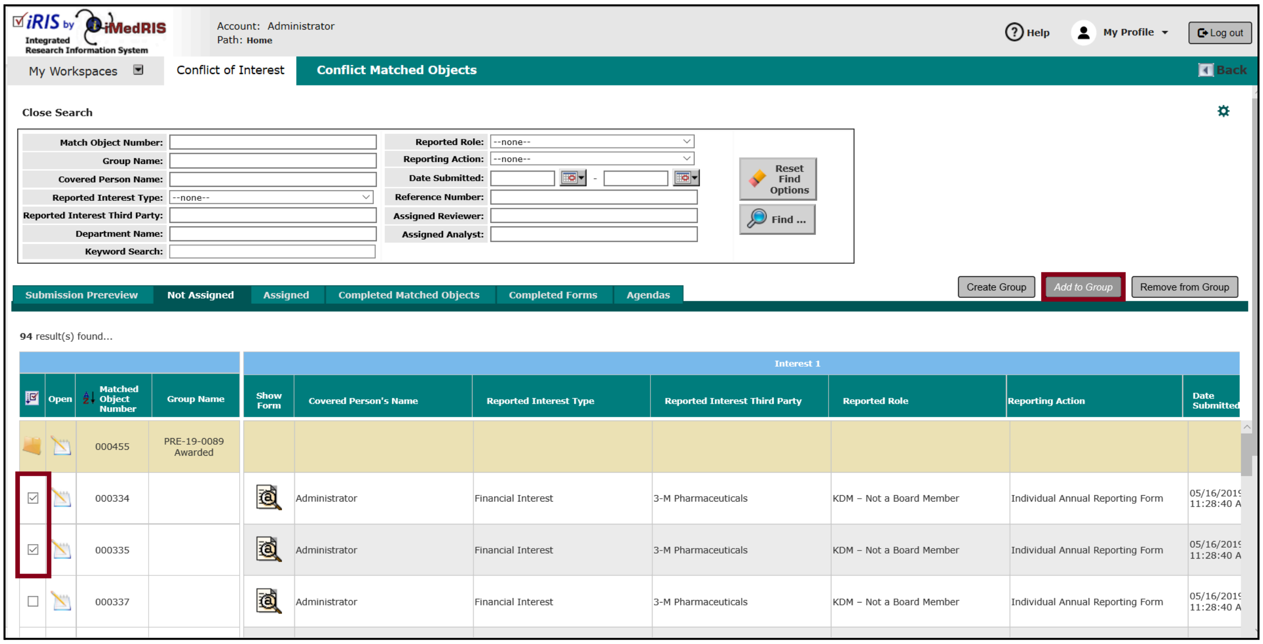


The **Matched Object Number** for the first item added to the Group is now the **Matched Object Number** for the entire Group. You can view the matches within a Group by clicking on the yellow folder icon. The items within the Group can now be processed together.

All Groups created via the Create Matched Object Group dialog are added to the Groups list (see Add to Group, next section).

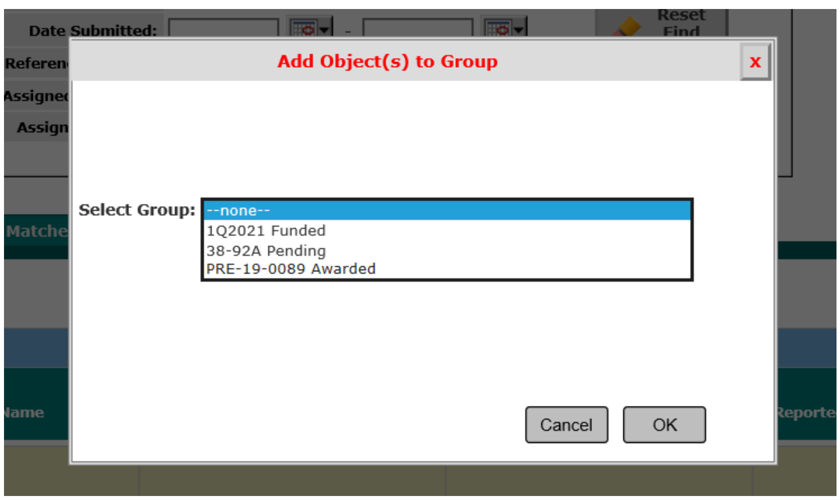
Add to Group

After a Group has been created, you can add other matches to it.



Select the checkboxes for records you wish to add to a Group and click the **Add to Group** button.

The **Add Object(s) to Group** dialog displays. Select a Group from the dropdown list and click the **OK** button to add the selected matched objects to that Group.

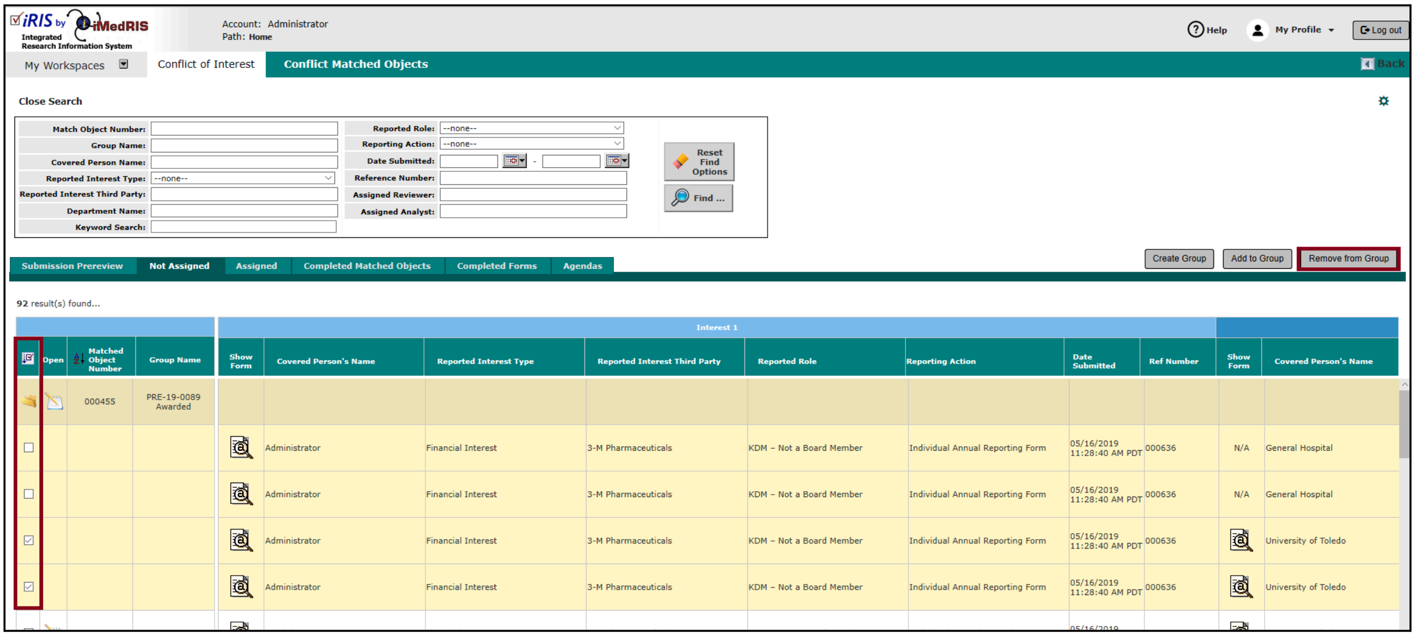


Back on the Not Assigned tab the selected items will no longer display as individual line items but will be included in the assigned Group.

Note that match items can only be part of one Group at a time. If you wish to change the Group assignment for a given item, you must remove it from the current Group and then add it to the desired Group (see next Section, Remove from Group).

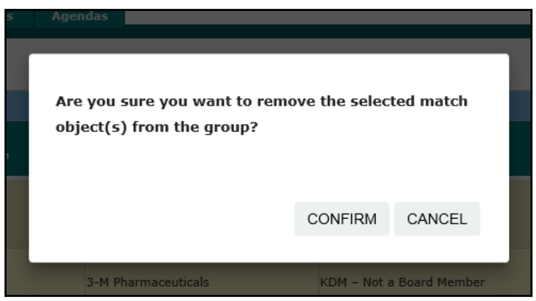
Remove from Group

If an item was added to a Group by mistake or needs to be moved to a different Group, you can remove the item from its current Group. Once removed, the item can be added to a different Group if desired. Start by clicking to open the yellow folder for the Group to view all matches within the Group.



Select the record(s) to remove and click the **Remove from Group** button.

A confirmation dialog will display. Click **Confirm** to continue to remove the item from the group.



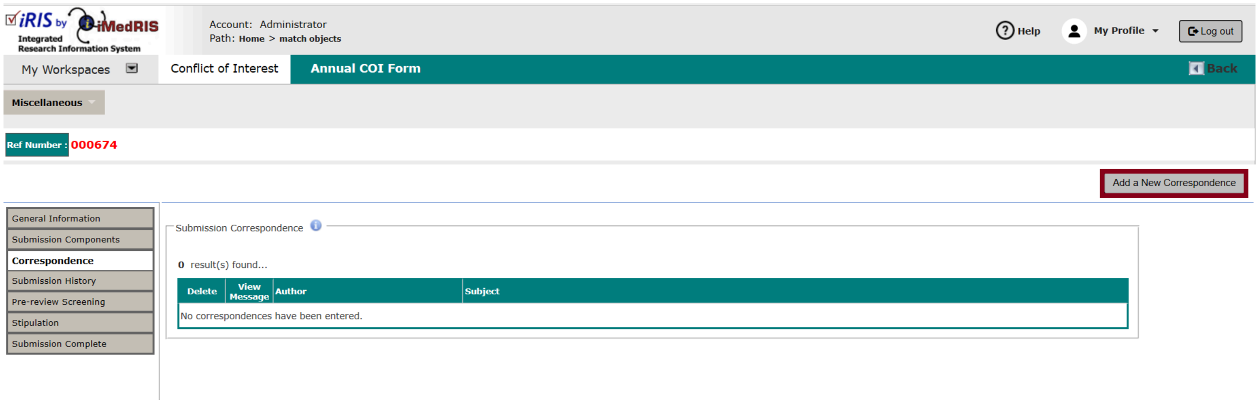
The matched objects you removed from the Group now display as individual line items on the Not Assigned tab. To confirm your item(s) have been removed, click on the applicable Folder icon to open it and verify the removal.

Click **Cancel** in the confirmation dialog to return to the Not Assigned tab without making any changes.

Correspondence

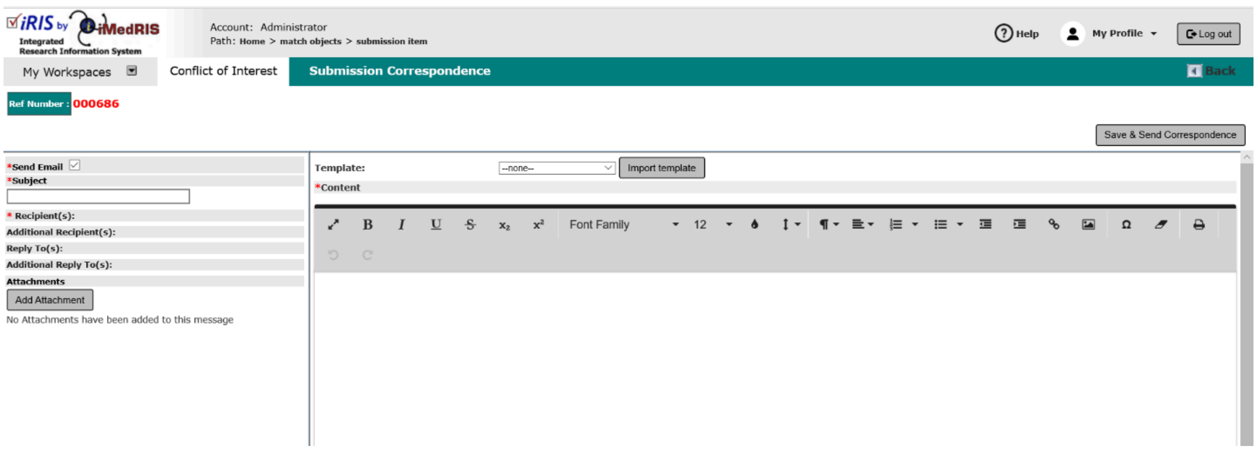
Within the Not Assigned, Assigned and Completed Matched Objects tabs, depending on the form or object under review, when the form or object is open a **Correspondence** menu tab may be added to the navigation menu at left.

The Correspondence tab is where you can view, add, reply to, or forward Correspondence items attached to the open form or object.



Add a New Correspondence

Click the **Add a New Correspondence** button at the upper right (shown above) to open the **Submission Correspondence** form (shown below). This form is used to process correspondence attached to the selected, open form.

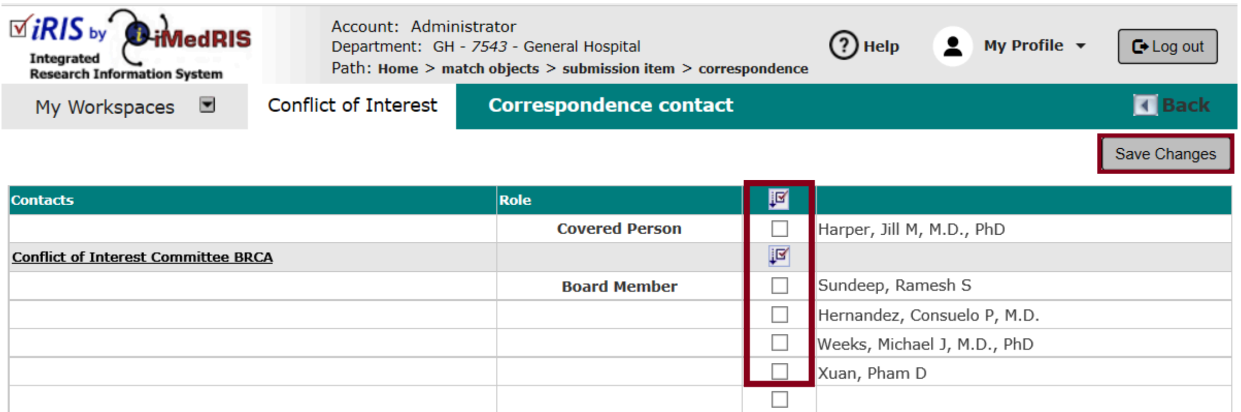


This screen includes the following elements:

Send Email—Selected by default. Leave the box checked if the email will be sent to at least one recipient when you are finished composing it. Uncheck the box if you wish to create and save a draft correspondence but will not yet be sending it.

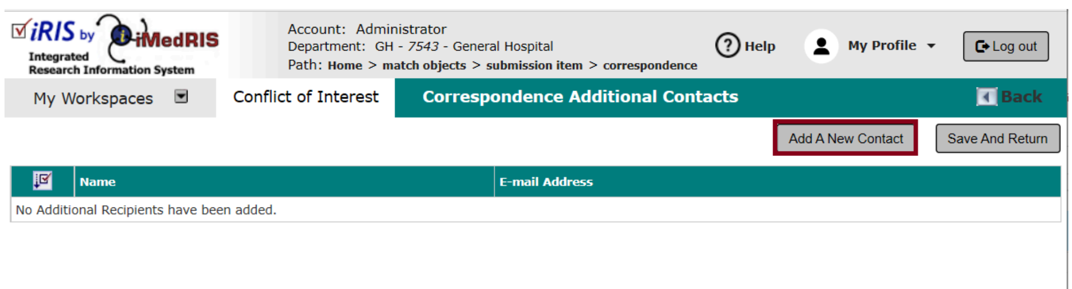
Subject—The subject line for your email message.

Recipient(s) / Reply To(s) —Click on these links to open a list containing the names of everyone assigned by the system as eligible to receive Correspondence related to the selected, open form (see screenshot below).



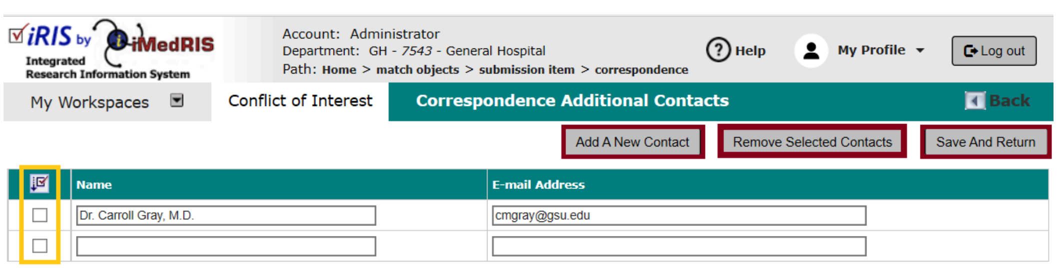
When adding a recipient or reply-to, click to select the checkbox(es) next to the name(s) you wish to add to distribution for the message, then click the **Save Changes** button to return to the Submission Correspondence screen.

Additional Recipient(s) / Additional Reply To(s)—If you wish to add more email recipients or reply recipients, click on either of these links to open the **Correspondence Additional Contacts** form, shown below.



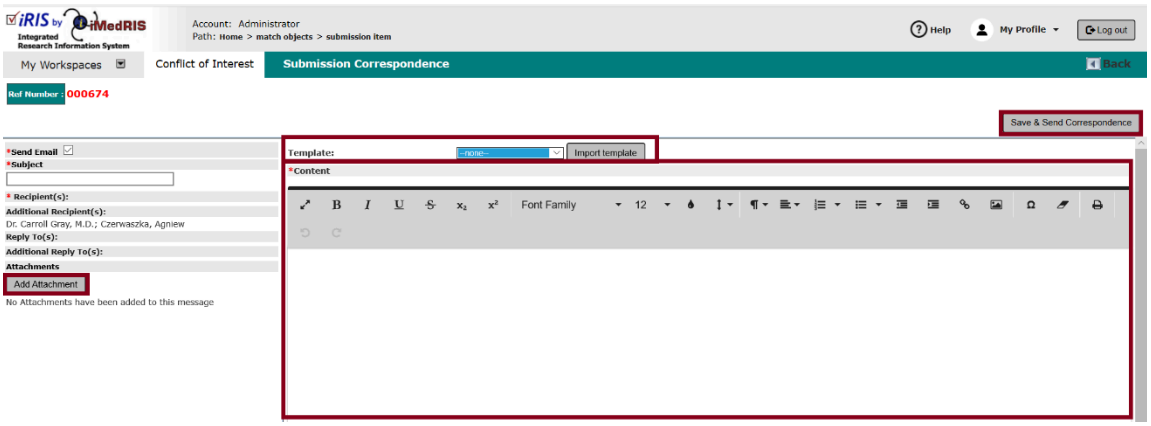
Click the **Add A New Contact** button to add a name and email address to the list. The form will load an editable **Name** and **E-mail Address** field, and a **Remove Selected Contacts** button will be added to the form. You can add as many additional recipients as you like on this form.

In the example shown below, **Add A New Contact** was clicked to load **Name** and **E-Mail Address** fields in the first row. After the desired text was entered in each field, the **Add New Contact** button was clicked again to add another row, where another **Name** and **E-Mail Address** can be entered.



After all desired names and email addresses are added, click the **Save and Return** button. The names saved here will be available for selection as **Additional Recipient(s)** or **Reply To(s)** for as long as they remain in the list.

If you wish to delete any names from the Additional Contacts list after they've been saved, click the checkbox(es) next to the name(s) to be removed (area indicated by a yellow box in the screenshot above) and click the **Remove Selected Contacts** button.



Attachments—Click this button to add attachments to the email message.

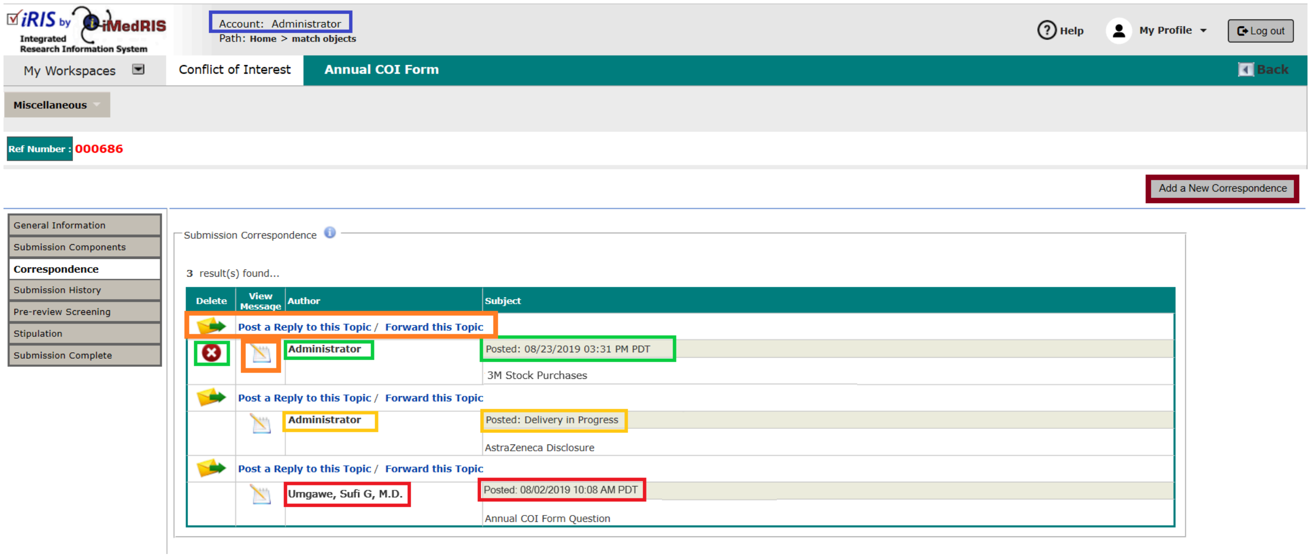
Template—If your system has pre-configured email correspondence templates set up, you can select the desired email template for your message from the Template dropdown list. Those with the necessary access rights can also use the **Import template** button to import new, pre-formatted message templates.

Content—The Content area is where you will compose your email message, and it works the same as any standard email program. You can use the icons on the toolbar at the top of the Content area to apply formatting, insert images or links, insert special characters, or print the message.

Save & Send Correspondence—When you're finished composing your message, click this button to save a copy of the message to the file and send a copy to everyone included in the **Recipient(s)** and **Additional Recipient(s)** lists. Names specified as **Reply To(s)** or **Additional Reply To(s)** will be included in the list of people who will receive replies to your message.

Managing Correspondence

After one or more correspondence items have been created, you can return to the Correspondence tab to manage those items.



To open a correspondence item in order to view it, reply to it or forward it, you can click on any of the items highlighted by orange boxes in the screenshot above: **Forward Email icon** (envelope with green arrow), **Open icon** (notepad with pencil), **Post a Reply to this Topic** link, or **Forward this Topic** link.

If you are the author of an email listed here, AND that email is either still in draft form or has been delivered by the mail system, you will see a **Delete** icon available for that email (highlighted by green boxes in the screenshot above).

There is a **Delete** icon next to the first email in the list (highlighted with green boxes in the screenshot above) because “Administrator” is the logged-in user (highlighted with a blue box in the screenshot), AND “Administrator” is the author the first email (green box), AND that email has been delivered (see **Posted** details, second green box).

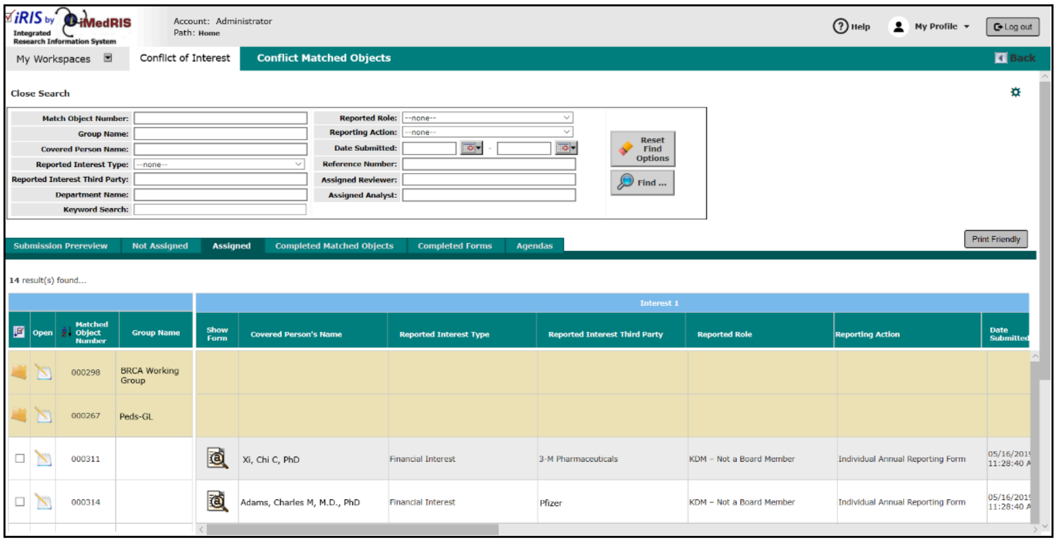
There is no Delete icon next to the second email authored by “Administrator” (highlighted by a yellow box in the screenshot), because that email has not yet been delivered to all recipients (see **Posted** details, second yellow box).

There is no Delete icon next to the third email because, while **Posted** details show that email was delivered, the email author was someone other than “Administrator” (highlighted by red boxes in the prior screenshot).

Note that while deleting an item here removes it from the list, a permanent record of any correspondence that has been sent from within the system will be retained with the associated form or document (item opened from the main Conflict Matches screen).

Assigned

After a process is assigned to a Conflict Match, the record will move from the **Not Assigned** tab to the **Assigned** tab and can be accessed from this tab until Conflict Match processing is completed.

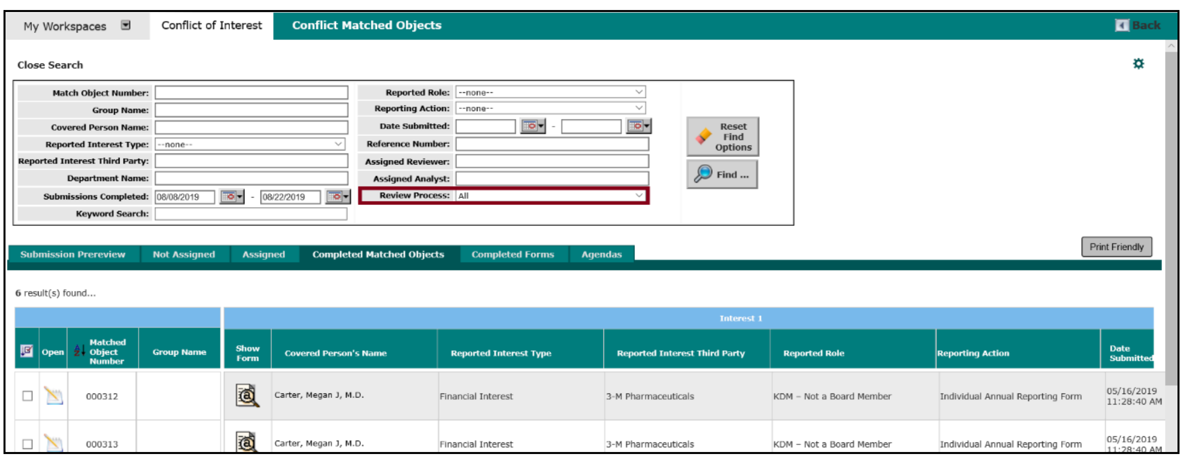


This screen contains the same columns, information, and interactive screen elements as the Not Assigned tab, with the exception of the Grouping buttons.

On this screen the Grouping buttons have been removed and a **Print Friendly** button appears in the same screen location. Click it to view a print friendly version of the matched objects list.

Completed Matched Objects

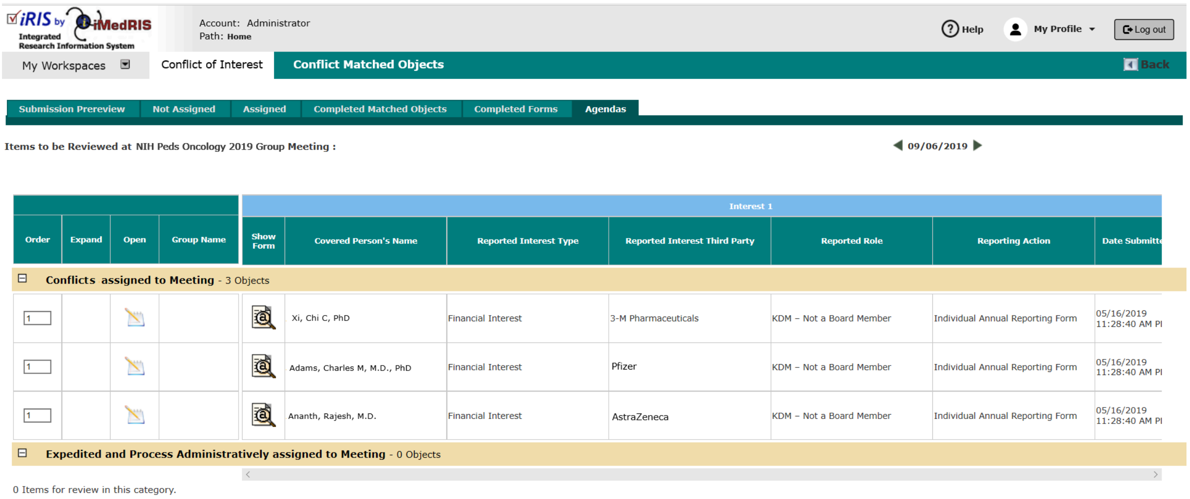
Matches for which processing is complete are listed in the **Completed Matched Objects** tab. This tab contains the same columns, information, and interactive screen elements as the **Assigned** tab, with one exception.



The search panel now includes a **Review Process** (e.g., Expedited, Processed Administratively, etc.) search option. Items shown in the **Review Process** dropdown list will vary according your specific installation and Review Board Administration settings.

Agendas

The **Agendas** tab opens to the next scheduled meeting of the COI Office and lists any conflict reviews assigned to that meeting date.



There are two categories on the screen: **Conflicts assigned to Meeting** for full board conflicts and **Expedited and Process Administratively assigned to Meeting** for items processed Expedited or Administratively which have also been placed on the meeting agenda.

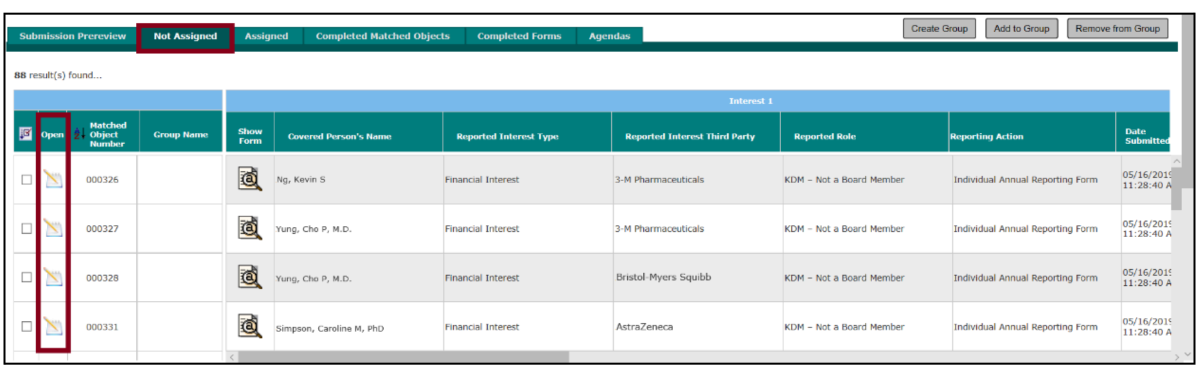
You can select a different meeting date by clicking the green previous and next arrows on either side of the meeting date, at the upper right of the screen.

The Coordinator can use the **Order** column to set the order for items to appear on the meeting agenda. Numbering begins with one (1) and continues in descending order (e.g., 2, 3, 4, etc.).

If you are looking for a specific match review to be referenced in a meeting, locate the corresponding line item and then open the match review by clicking the icon in the **Open** column.

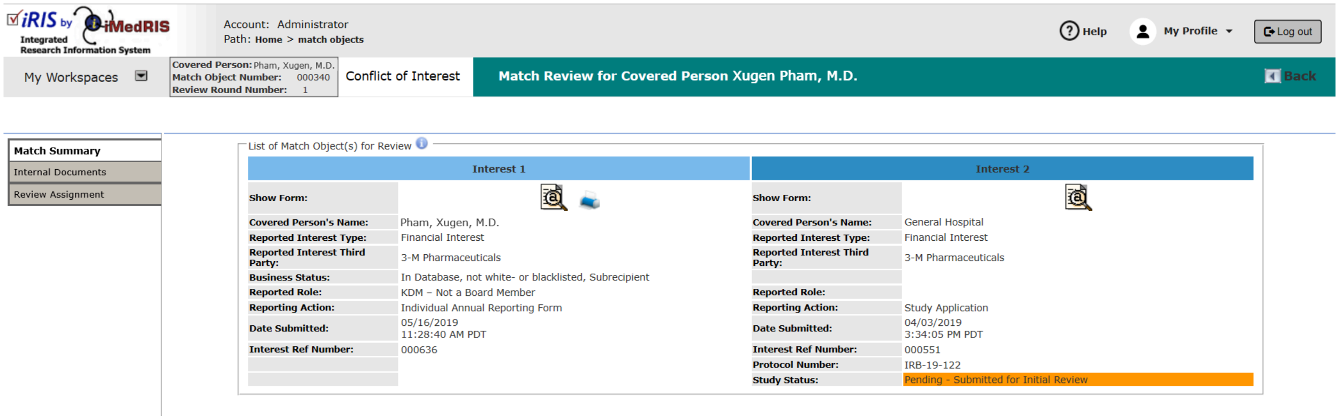
Processing Matches

When you open a Conflict Match from the Not Assigned tab, you will open the Conflict of Interest – Match Review processing screens, which contain information and tools to process a conflict match.



Match Summary

The first match processing screen is the **Match Review** screen. Tabs available on the left will vary depending on the processing steps required for the specific item under review.

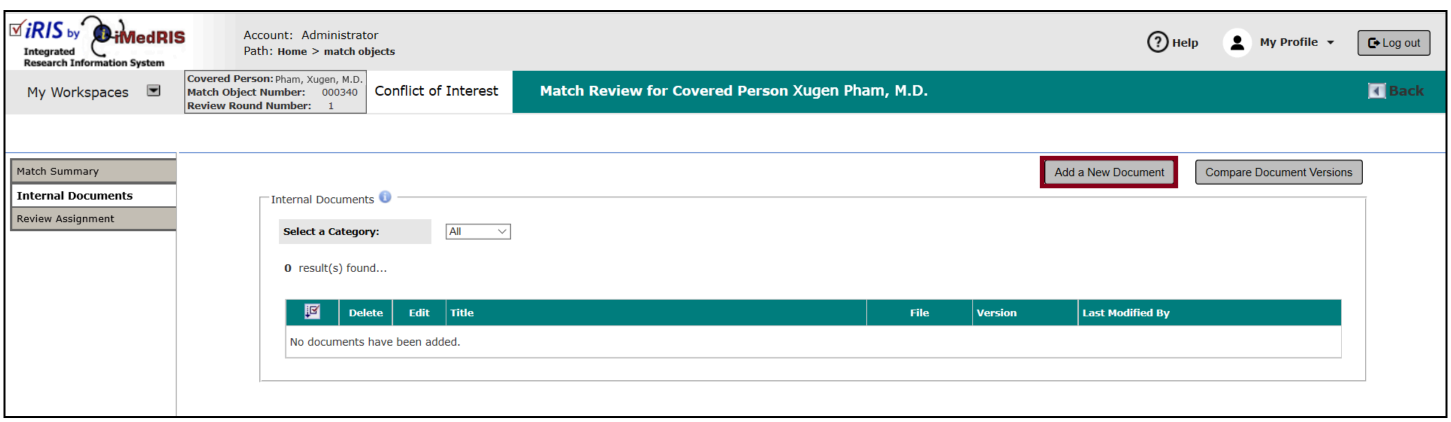


The screen opens to the **Match Summary** tab by default. This tab lists brief details about the match being viewed.

If you are processing a Group of matches, each match will be listed on this screen and you can scroll down to see each match in detail. The summary details on this screen consist of the same information and screen elements shown when viewing matched objects from within the Not Assigned, Assigned and Completed tabs.

Internal Documents

The Internal Documents tab allows you to upload documents related to the Covered Person and the Conflict Match being processed.



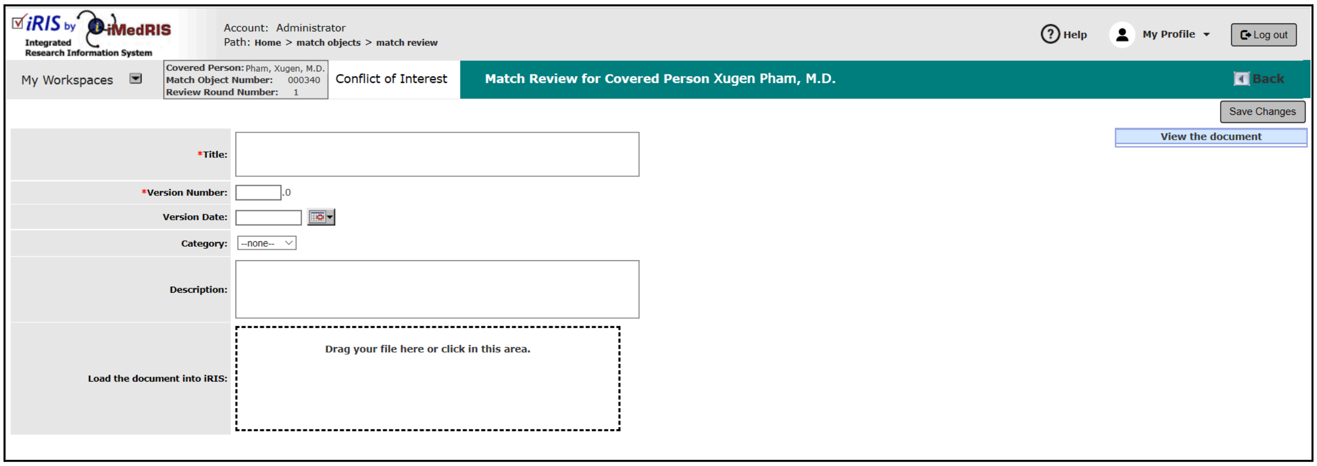
Any documents previously uploaded will populate in this screen. Click the **Add a New Document** button to add a document to this review.

Add Documents

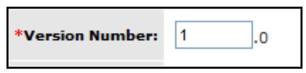
When the **Add a New Document** button is clicked in the **Internal Documents** tab, a new screen will open to allow for entry of details about the document and upload of the document file.

Fields presented on this screen are as follows:

Title—Enter the title of the document to be uploaded.



Version Number —Enter the number at which you wish to start versioning for the document to be uploaded. This can be any character or number.

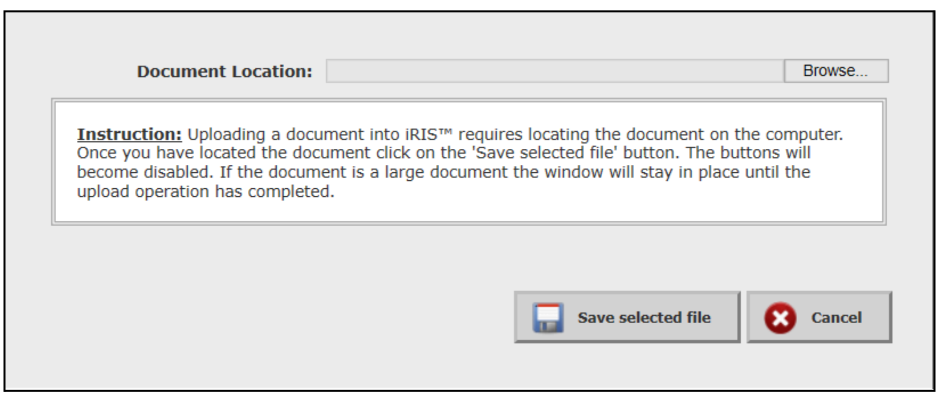


Version Date—Enter or select the date of the manually-entered version number, typically the date the document was uploaded to the system.

Category—Use this configurable dropdown list to group documents into categories (e.g., Checklist).

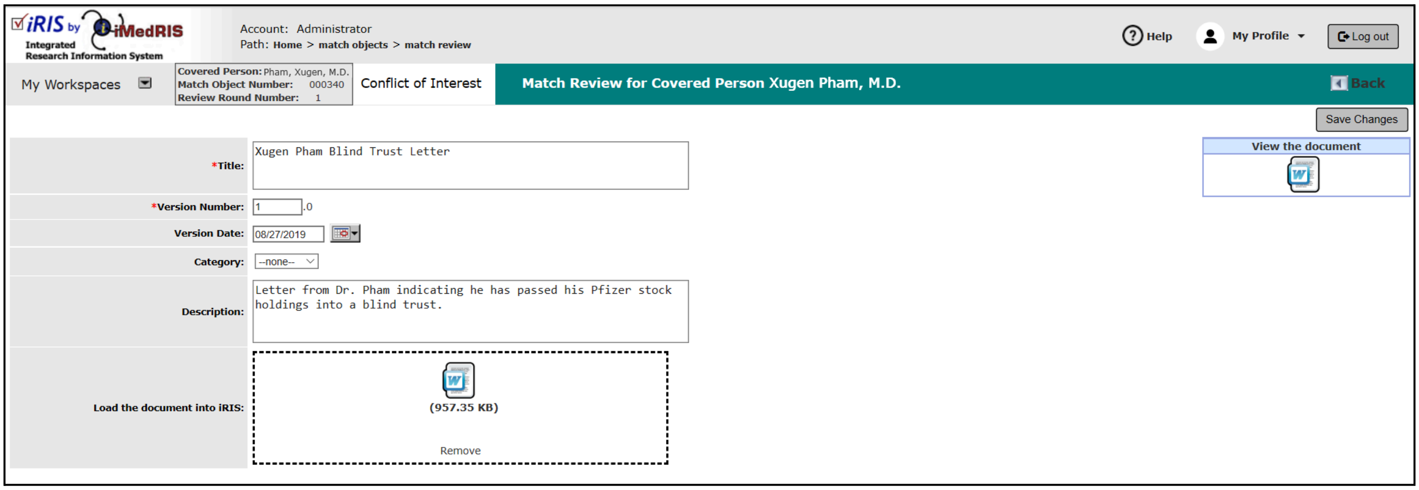
Description—Enter a brief description of the document to be uploaded.

Load the document into iRIS—After entering the required information, drag the document file from your computer into this box to start the upload. To browse for the file to be uploaded, click inside the box to open the upload dialog.



Click the Browse button at top right to locate the document file on your computer. After a file has been selected and its location is shown in the Document Location field of the upload dialog, click the **Save selected file** button.

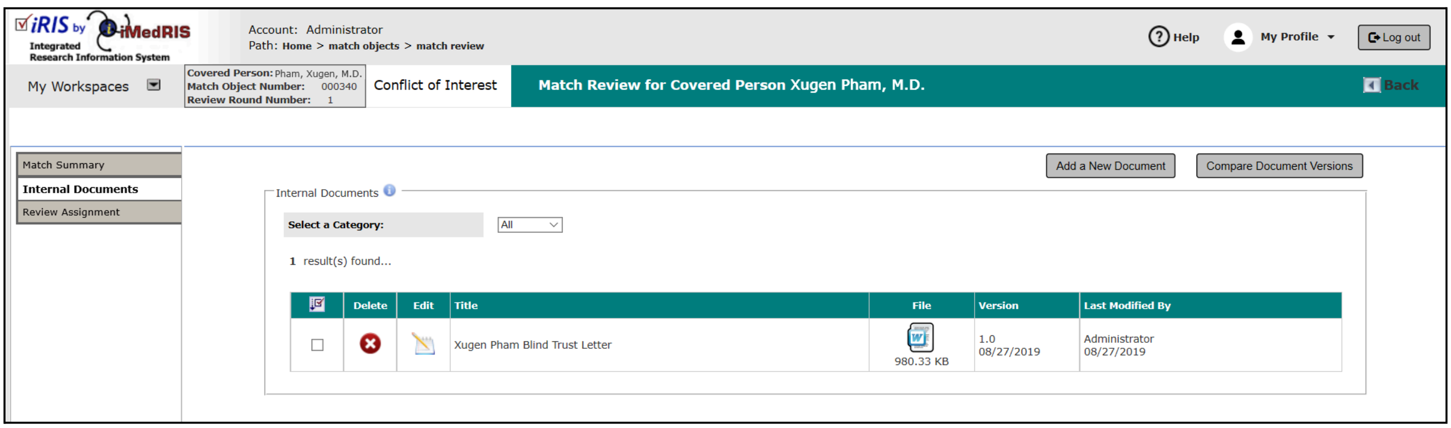
The system will return you to the previous screen. The document has been uploaded and will appear as an icon next to the document information, as shown in the screenshot below.



Click the **Remove** link in the **Load the document into iRIS** box to remove the document.

Click the document icon in the **View the document** panel at the upper right to view the uploaded file.

Click the **Save Changes** add the document to Internal Documents for the matched object.



Any document record you add will be appended to the list at the bottom of the Internal Documents screen and will populate within Search Conflict Matches -> Documents for the Covered Person.

Documents can be compared to other uploaded documents. Click the checkboxes next to two different versions of the same document and click the **Compare Document Versions** button.

Any uploaded document can be removed by clicking the icon in the **Delete** column.

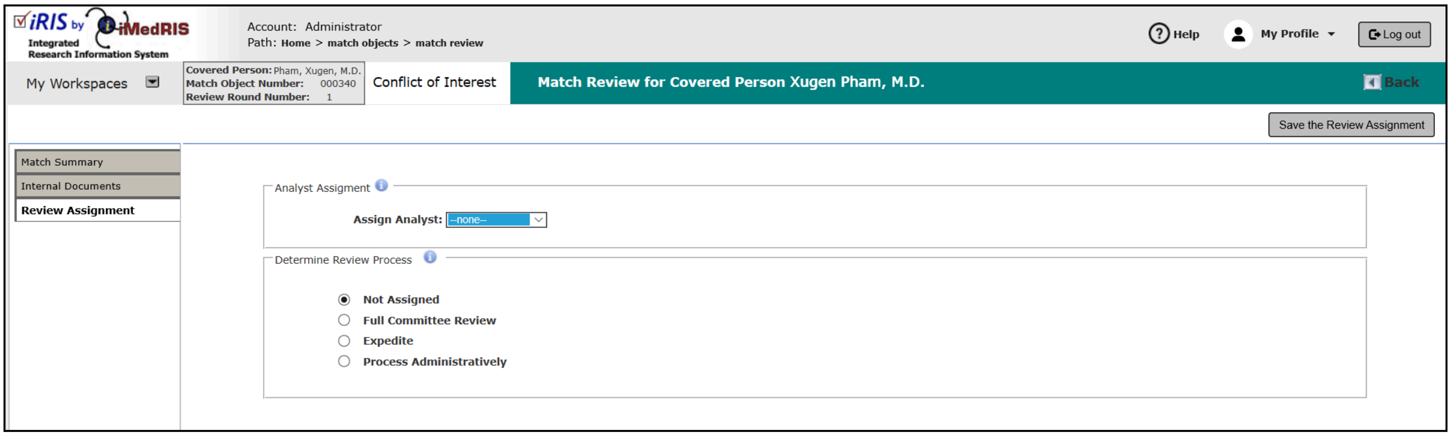
To edit an uploaded document, click the icon in the **Edit** column.

You can view the document by clicking on the icon in the **File** column.

Note: Access to Internal Documents can be set for each COI Review Board Role within Setup Role Access in Review Board Administration, in the COI Disclosure Document row. The Document Category can be set up using the Internal Document Category configuration under Review Board Administration > List Maintenance Setup.

Review Assignment

The **Review Assignment** tab is where an Analyst is assigned to review the matched object.



Analyst Assignment

The **Assign Analyst** dropdown list is populated with the names of users whose Conflict of Interest role has been set to Coordinator in System Administration.

Select a name from the list to assign an Analyst. When the review assignment is saved, the assigned Analyst will receive a task on their home screen related to this Conflict Match.

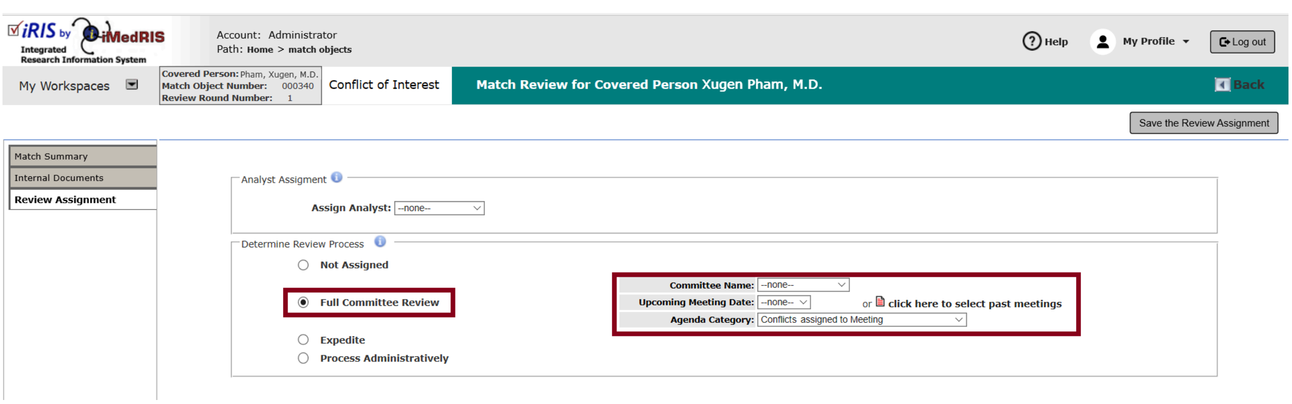
Determine Review Process

Use the selections presented here to process the Conflict Match.

Not Assigned - Conflict matches default to this status when first submitted to the Conflict Match queue. This indicates that a Review Process has not yet been assigned and causes the conflict to populate in the Not Assigned tab.

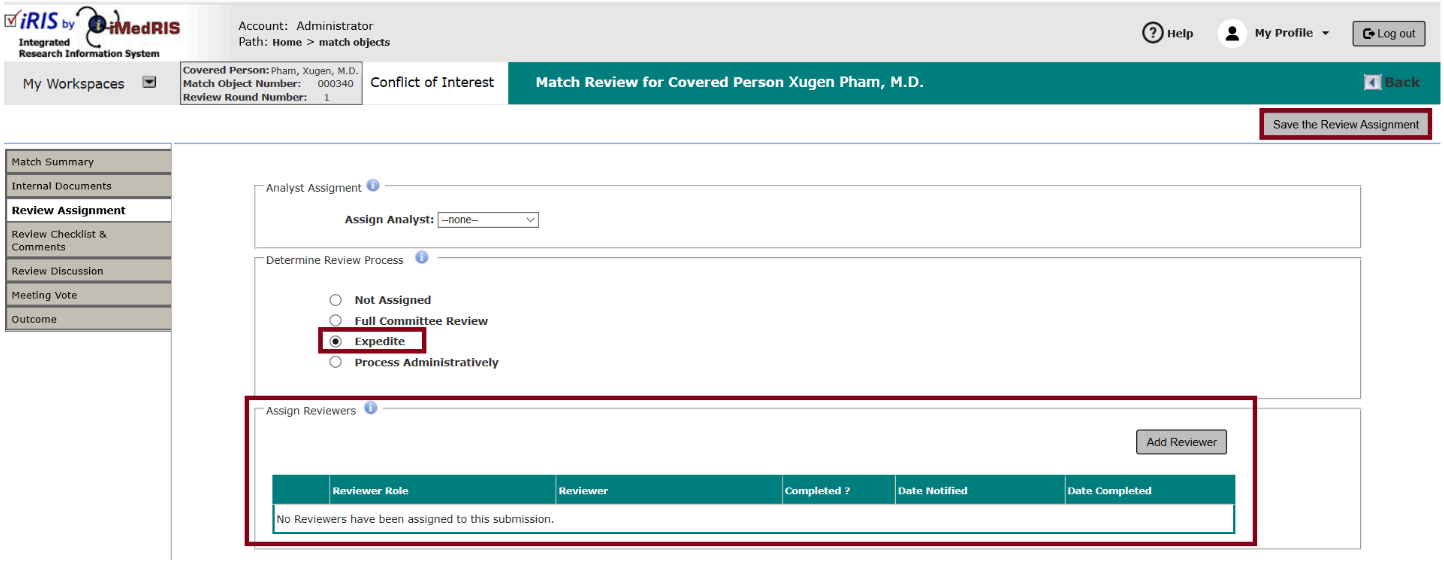
Full Committee Review – This option allows you to assign the match to a committee meeting. After this option is selected, committee and meeting selection items will be displayed to the right.

The Full Committee Review option can be turned on or off in Review Board Administration settings (see the Review Board Administration manual for more details).



Expedite – If this option is selected and saved by clicking the **Save the Review Assignment** button the screen will populate an **Assign Reviewers** section, as shown in the following screenshot, provided the reviewer option is turned on for this processing type in Review Board Administration settings (see the Review Board Administration manual for more details). After making reviewer selections click the **Save the Review Assignment** button again.

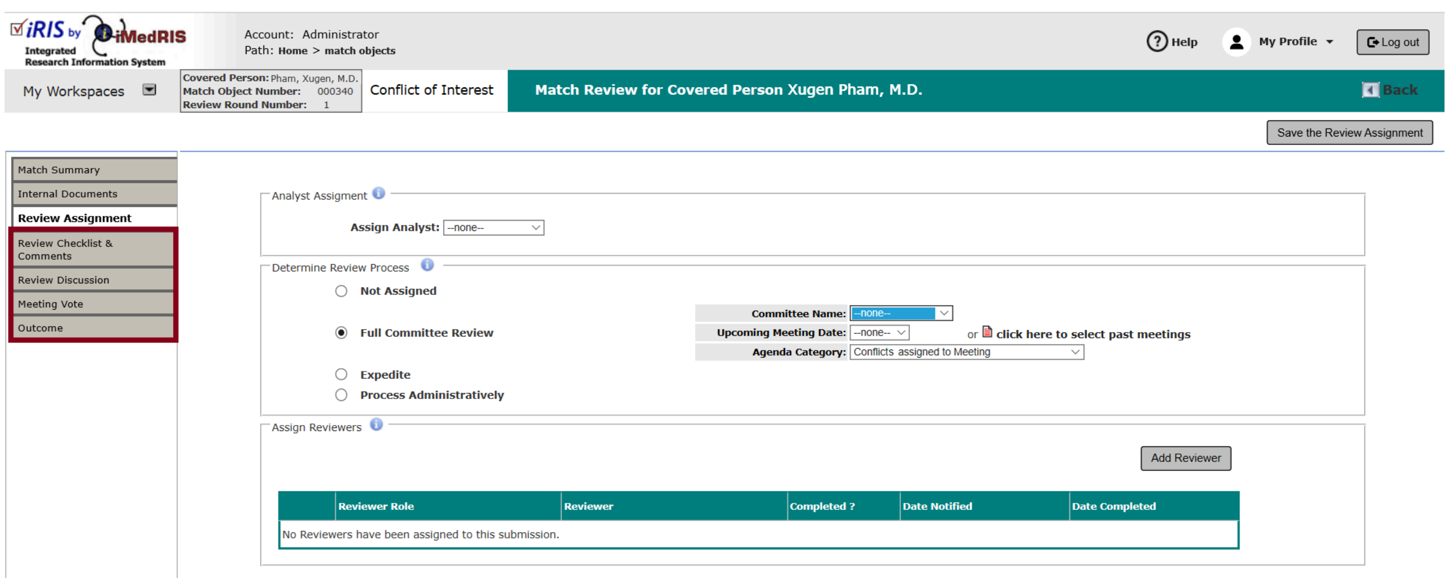
The Expedite processing option can be turned on or off in Review Board Administration settings (see the Review Board Administration manual for more details).



Process Administratively – This process is a useful action for matches that need to be processed through the office but not reviewed.

Selecting **Process Administratively** and clicking the **Save the Review Assignment** button will also populate an **Assign Reviewers** section, as described above for Expedited processing, if the reviewer option is turned on for this processing type in Review Board Administration settings (see the Review Board Administration manual for more details).

After making and saving any selection other than Not Assigned or clicking the link to select a past meeting when the Full Committee Review option is selected, four new tab options will be displayed at the left: **Review Checklist and Comments, Review Discussion, Meeting Vote** and **Outcome.** These tabs provide easy access to the most commonly used match processing functions and information.

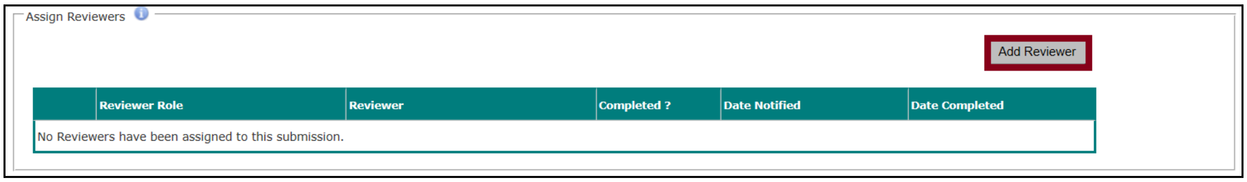


These tabs will continue to be accessible when processing this match unless a different review process option is selected and saved.

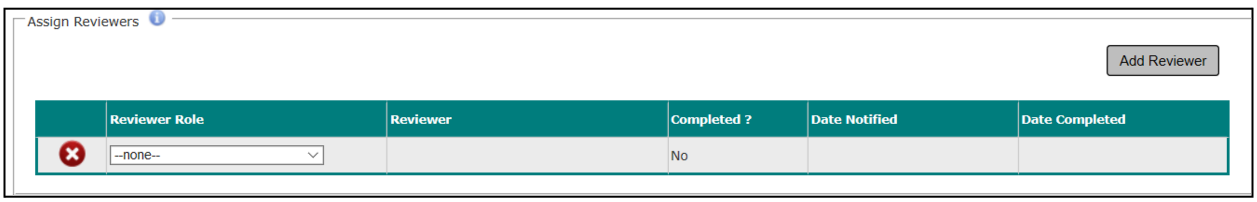
Assign Reviewers

This option is available for Conflict Matches that have been assigned a review process. This area can be turned completely off in Review Board Administration (see the Review Board Administration manual for more details). This section allows the coordinator or administrator to assign a user within the COI Office to review a conflict match.

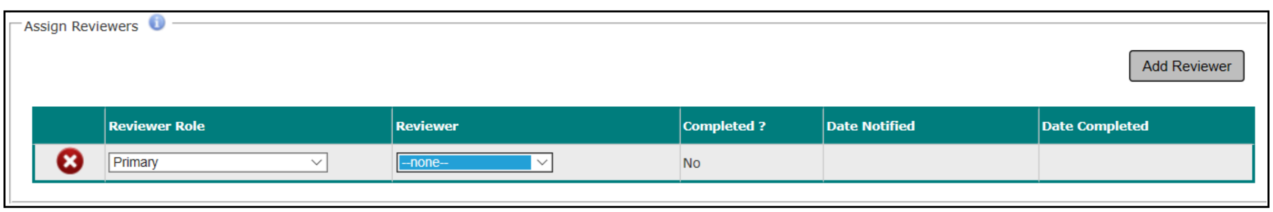
To add a Reviewer, click the **Add Reviewer** button in the Assign Reviewers section.



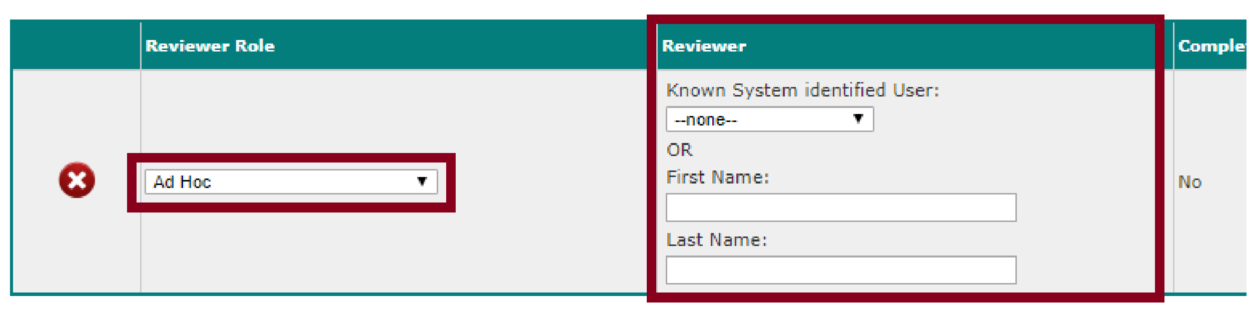
As shown below, the first row of the reviewers table will populate with a **Delete** icon, a dropdown **Reviewer Role** list, and a default **Completed?** status of "No".



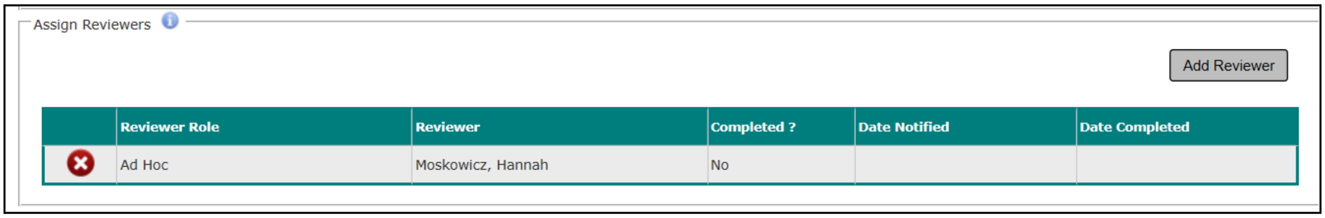
After any **Reviewer Role** other than Ad Hoc is selected, the screen will refresh to allow you to select from a dropdown list of Reviewers who occupy your selected role.



If the Ad Hoc **Reviewer Role** is selected the screen will refresh, allowing you to either manually enter the Reviewer's name or select it from a **Known System identified User** list.



After selecting and/or entering the correct data, select the **Save the Review Assignment** button. The screen will refresh with the assigned Reviewer's information (see below).



You may add as many Reviewers as needed. Click the **Add Reviewer** button to add more Reviewers.

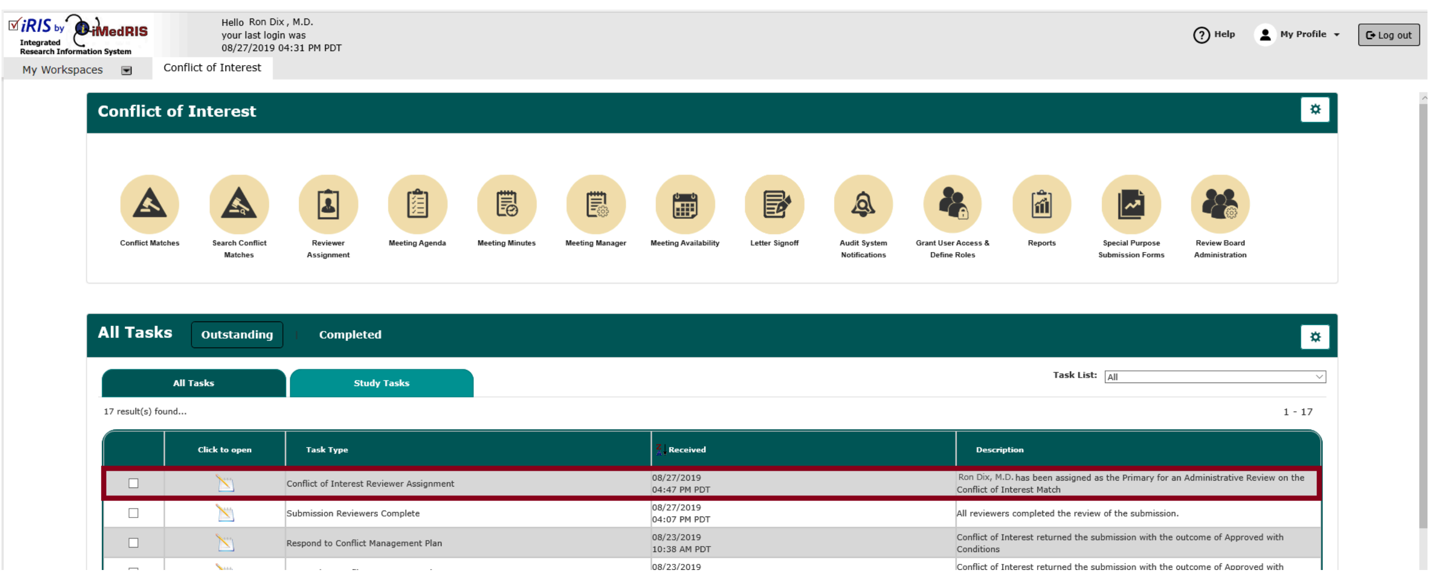
A Reviewer can be deleted from the list by clicking the **Delete** icon next to the applicable Reviewer name. A confirmation dialog will open with **OK** and **Cancel** buttons. Click **OK** to confirm the deletion or **Cancel** to exit without deleting.

Assigned Reviewers will receive a notification advising them that a Conflict Match is waiting for their review, and the assignment will also appear as a task on the assigned Reviewer's home screen. Notification options are set up under Review Board Administration (see the Review Board Administration manual for more details).

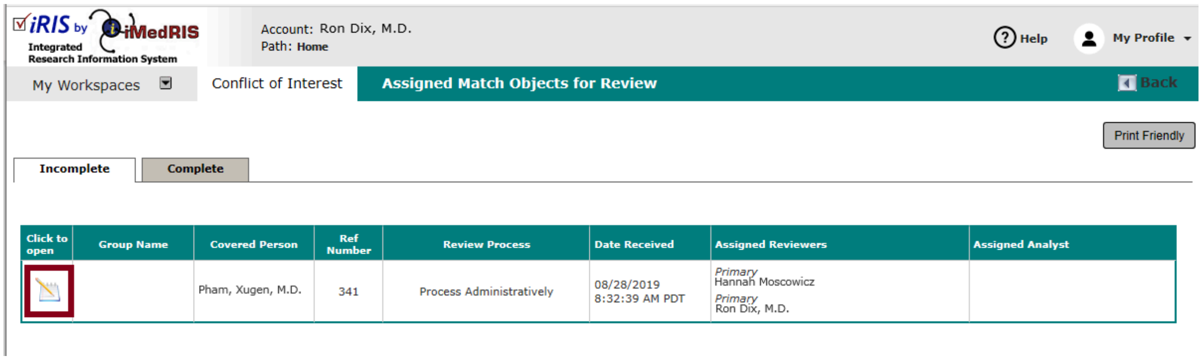
If the Review Process is assigned to Review Committee Agenda, the reviewer will not receive a notification until the coordinator enables the reviewer notifications for that meeting date.

Reviewer Assignments

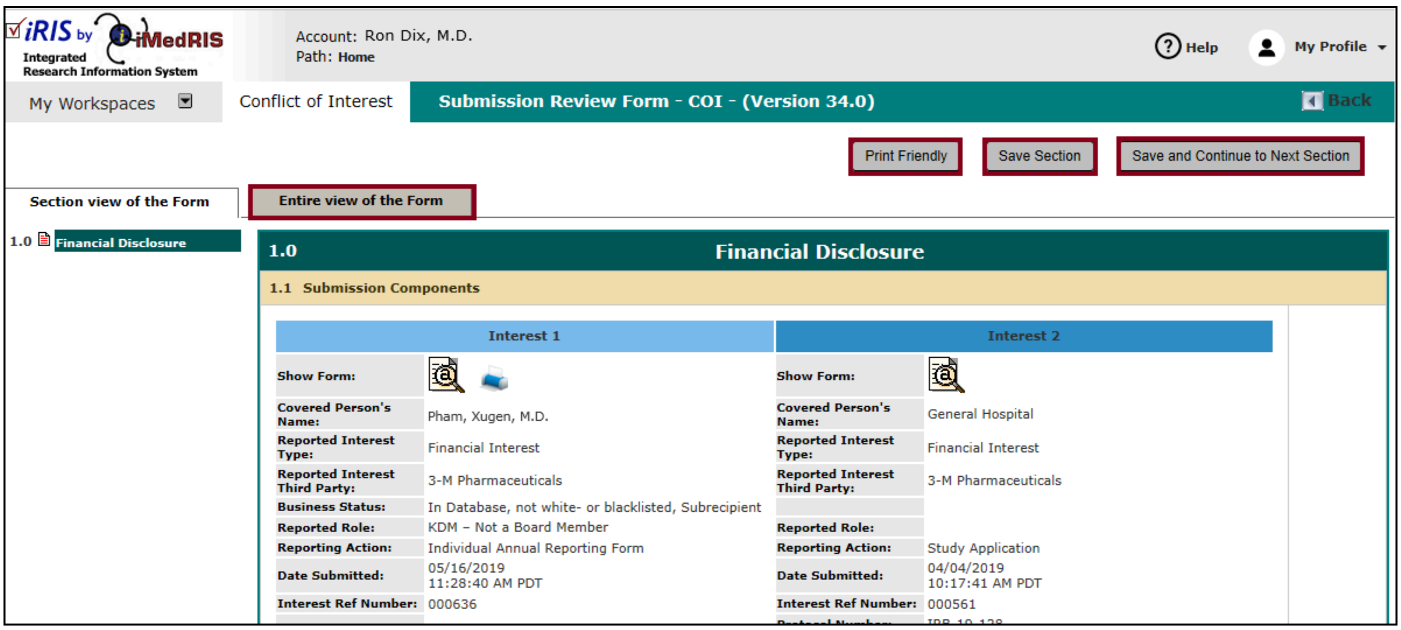
When you assign a Reviewer to a conflict match, the Reviewer will get a notification from iRIS™ to alert them to the task. When the Reviewer logs in to iRIS™ the review task will be shown in the **All Tasks** list on the Reviewer's home page.



The Reviewer task will also be added to the Incomplete tab of the **Assigned Matched Objects for Review** screen for the assigned Reviewer.



The Reviewer can click the icon in the **Click to open** column to review the assigned matched object.



The previous screenshot shows the Reviewer checklist, open to the first section of the conflict match that's under review.

The Reviewer can click on the **Show Form** icon in the columns for Interest 1 and Interest 2 (if applicable) to see the actual form submitted by the Covered Person.

The Reviewer can click on the printer icon in the column for Interest 1 to view a print friendly version of the entire form in HTML or PDF format. A dialog will pop up, prompting the Reviewer to choose the desired format.

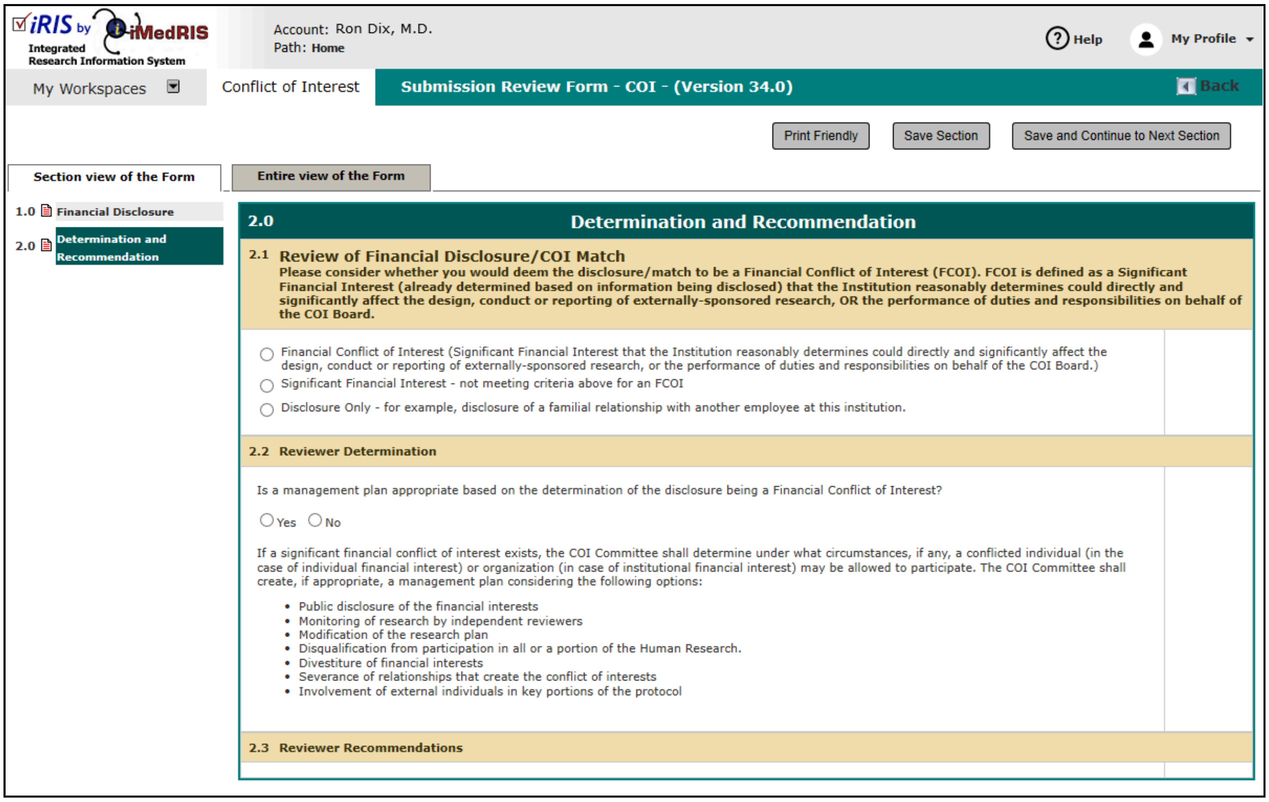
Note that the reviewer checklist form is defined in the System Form Designer and can contain any number of questions for the reviewer to fill out.

After the completing the review of the first section, the Reviewer can click either the **Save Section** or **Save and Continue to Next Section** button.

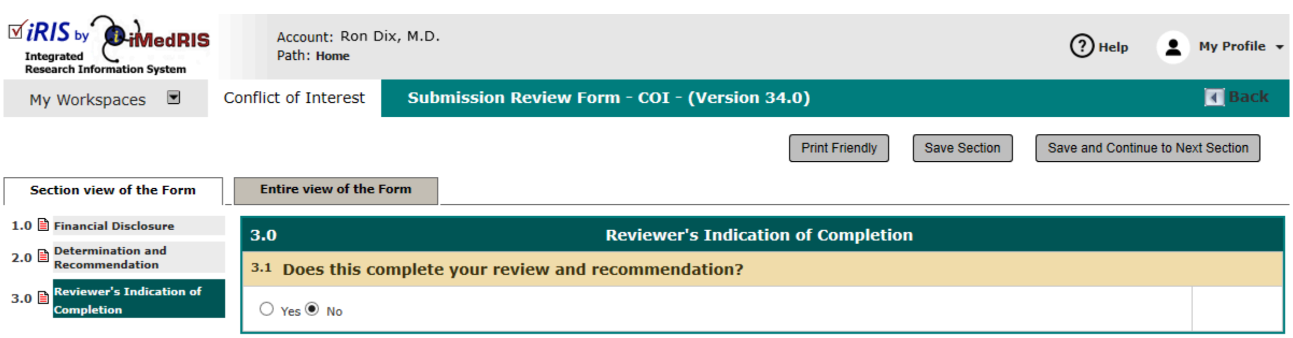
The **Save Section** button would be applicable in cases where the Checklist or associated Form has been configured to include editable fields for the Reviewer in any sections. The Reviewer would click **Save Section** after making a change in a section when the Reviewer does not need to view any other sections.

Otherwise, when review of the active section is complete the Reviewer clicks the **Save and Continue to Next Section** button.

The **Entire view of the Form** tab dynamically builds a reviewed copy of the form. When clicked this tab shows a version of the form containing only those sections that have been reviewed and saved, providing an easy way to check progress on the review at a glance.



As the Reviewer progresses through the form, the navigation menu at the left of the form will dynamically add tabs for each section. The Reviewer can click on any section shown in the menu to return to that section.

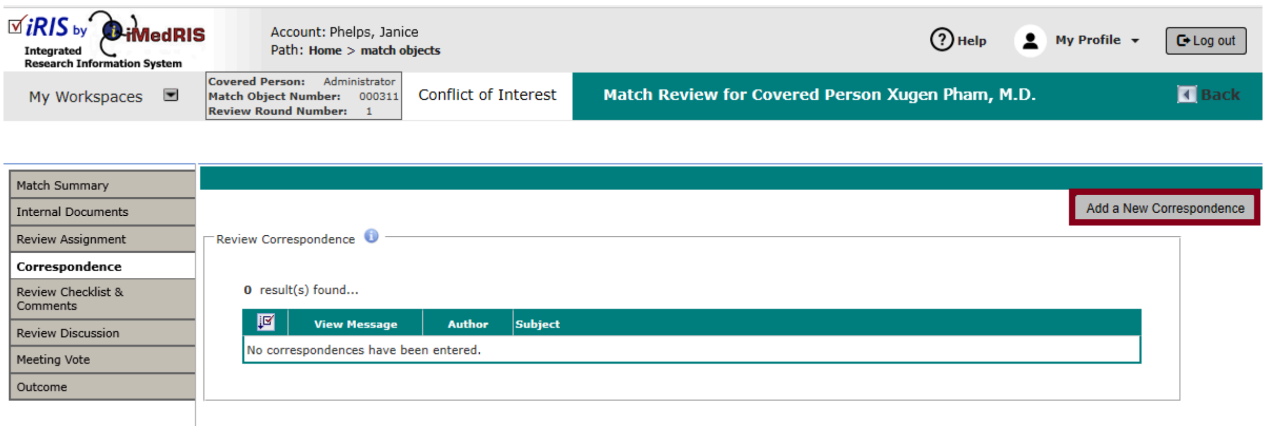


At the end of the reviewer checklist the reviewer will indicate that they are finished with the review and click the **Save and Continue** button. A confirmation message will display. Indicating "Yes" in this section flags the review as complete.

The incomplete Reviewer task will be removed from the home screen and the Analyst assigned to this conflict match will receive a notification and home screen task indicating the Reviewer is finished with the review.

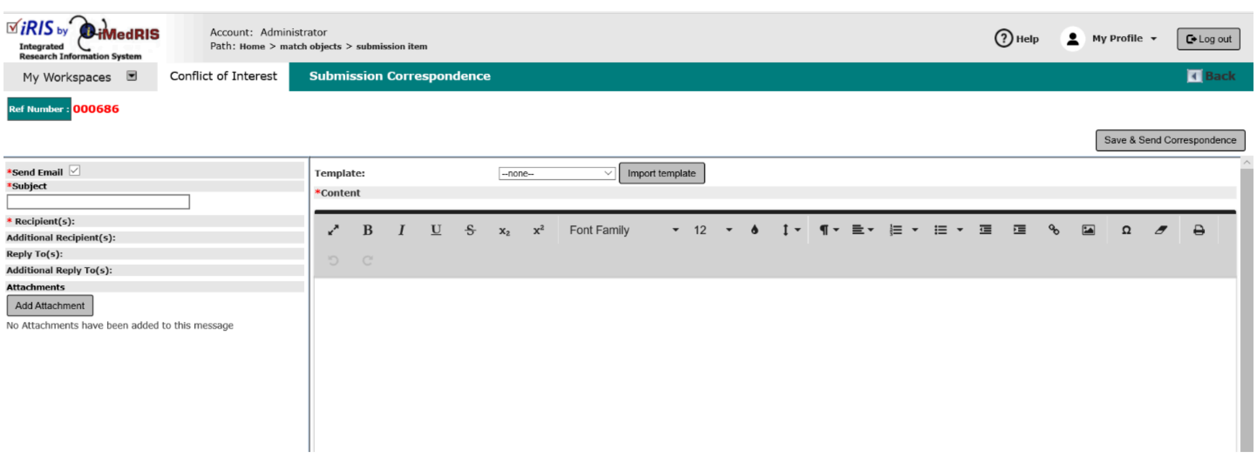
Correspondence

Depending on their stage of processing, matched objects opened from within the Not Assigned, Assigned or Completed Matched Objects tab of Match Processing may include a Correspondence link in the menu at the left side of the screen.



Add a New Correspondence

Click the **Add a New Correspondence** button at the upper right (shown above) to open the **Submission Correspondence** form (shown below). This form is used to process correspondence attached to the selected, open form.



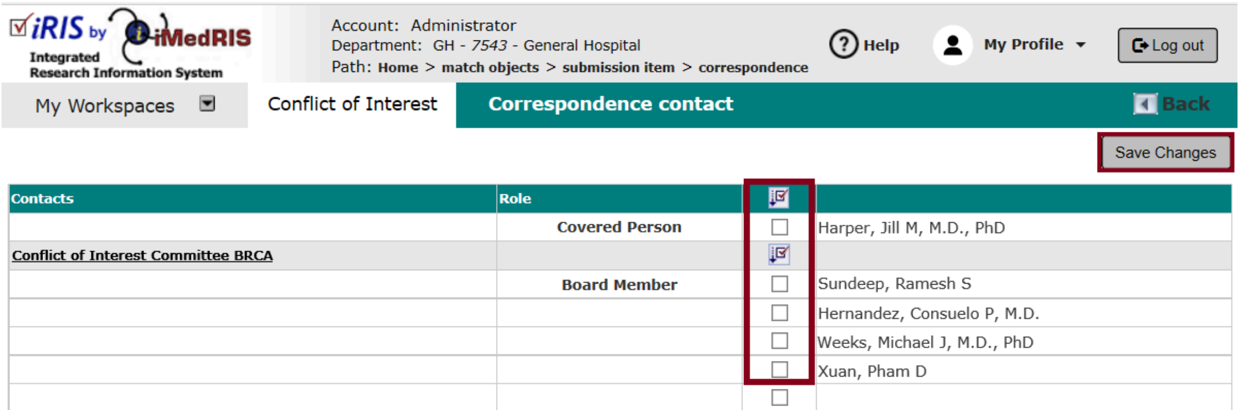
This screen includes the following elements:

Send Email—Selected by default. Leave the box checked if the email will be sent to at least one recipient when you are finished composing it. Uncheck the box if you wish to create and save a draft correspondence but will not yet be sending it.

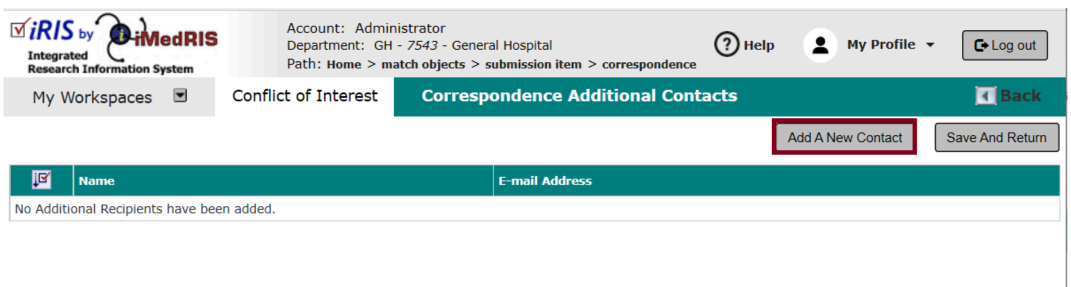
Subject—The subject line for your email message.

Recipient(s) / Reply To(s) —Click on these links to open a list containing the names of everyone assigned by the system as eligible to receive Correspondence related to the selected, open form (see screenshot below).

When adding a Recipient, click to select the checkbox(es) next to the name(s) you wish to add to distribution for the message, then click the **Save Changes** button to return to the Submission Correspondence screen. Adding a **Reply To** name works the same way.

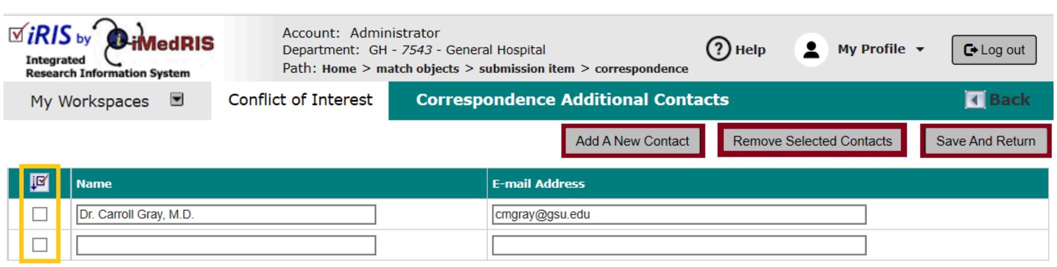


Additional Recipient(s) / Additional Reply To(s)—If you wish to add more email recipients or reply recipients, click on this link to open the **Correspondence Additional Contacts** form, shown below.



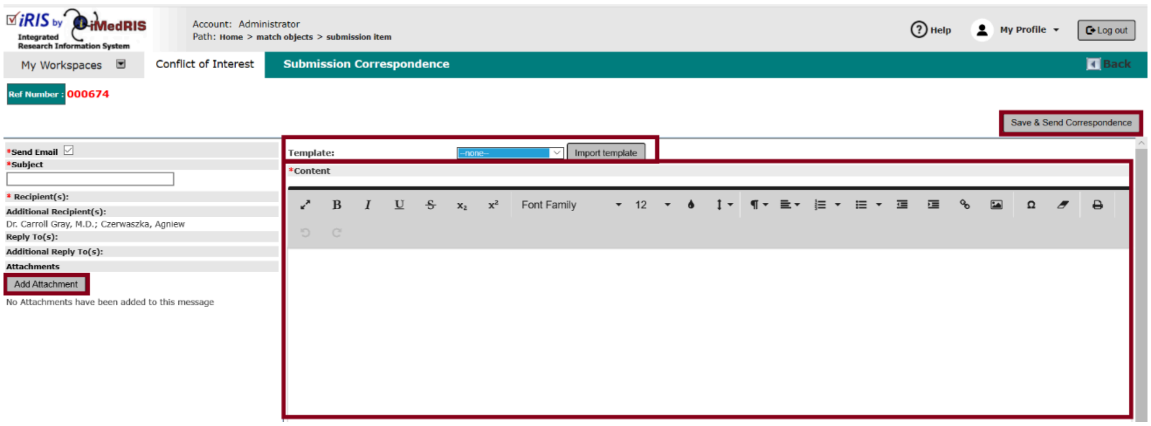
Click the **Add A New Contact** button to add a name and email address to the list. The form will load an editable **Name** and **E-mail Address** field, and a **Remove Selected Contacts** button will be added to the form. You can add as many additional recipients as you like on this form.

In the example shown below, **Add A New Contact** was clicked to load **Name** and **E-Mail Address** fields in the first row. After the desired text was entered in each field, the **Add New Contact** button was clicked again to add another row, where another **Name** and **E-Mail Address** can be entered.



After all desired names and email addresses are added, click the **Save and Return** button. The names saved here will be available for selection as **Additional Recipient(s)** or **Reply To(s)** for as long as they remain in the list.

If you wish to delete any names from the Additional Contacts list after they've been saved, click the checkbox(es) next to the name(s) to be removed (area indicated by a yellow box in the screenshot above) and click the **Remove Selected Contacts** button.



Attachments—Click this button to add attachments to the email message.

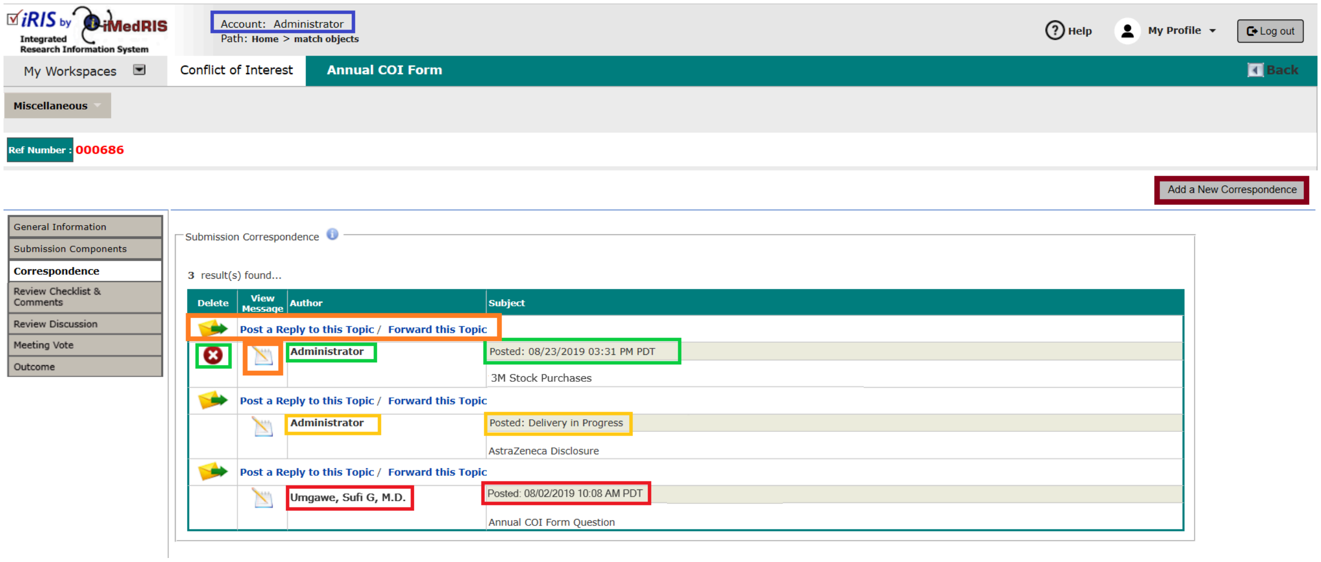
Template—If your system has pre-configured email correspondence templates set up, you can select the desired email template for your message from the Template dropdown list. Those with the necessary access rights can also use the **Import template** button to import new, pre-formatted message templates.

Content—The Content area is where you will compose your email message, and it works the same as any standard email program. You can use the icons on the toolbar at the top of the Content area to apply formatting, insert images or links, insert special characters, or print the message.

Save & Send Correspondence—When you're finished composing your message, click this button to save a copy of the message to the file and send a copy to everyone included in the **Recipient(s)** and **Additional Recipient(s)** lists. Names specified as **Reply To(s)** or **Additional Reply To(s)** will be included in the list of people who will receive replies to your message.

Managing Correspondence

After one or more correspondence items have been created, you can return to the Correspondence screen to manage those items.



To open a correspondence item in order to view it, reply to it or forward it, you can click on any of the items highlighted by orange boxes in the screenshot above: **Forward Email icon** (envelope with green arrow), **Open icon** (notepad with pencil), **Post a Reply to this Topic** link, or **Forward this Topic** link.

If you are the author of an email listed here, AND that email is either still in draft form or has been delivered by the mail system, you will see a **Delete** icon available for that email (highlighted by green boxes in the prior screenshot). There is a **Delete** icon next to the first email in the list (highlighted with green boxes in the prior screenshot) because "Administrator" is the logged-in user (highlighted with a blue box in the screenshot), AND "Administrator" is the author the first email (green box), AND that email has been delivered (see **Posted** details, second green box).

There is no Delete icon next to the second email authored by "Administrator" (highlighted by a yellow box in the screenshot), because that email has not yet been delivered to all recipients (see **Posted** details, second yellow box).

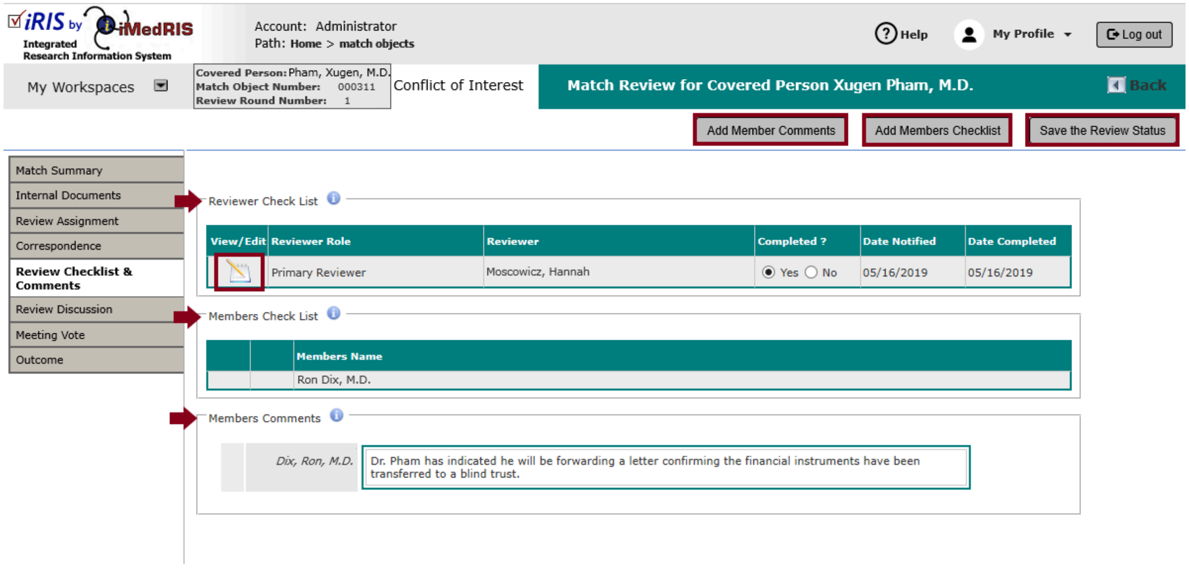
There is no Delete icon next to the third email because, while **Posted** details show that email was delivered, the email author was someone other than "Administrator" (highlighted by red boxes in the prior screenshot).

Note that while deleting an item here removes it from the list, a permanent record of any correspondence that has been sent from within the system will be retained with the associated form or document (item opened from the main Conflict Matches screen).

Review Checklist and Comments

The **Review Checklist and Comments** screen contains three sections: **Reviewer Check List**, **Members Check List** and **Members Comments**.

At the upper right, there are also three buttons: **Add Member Comments**, **Add Members Checklist**, and **Save the Review Status**.



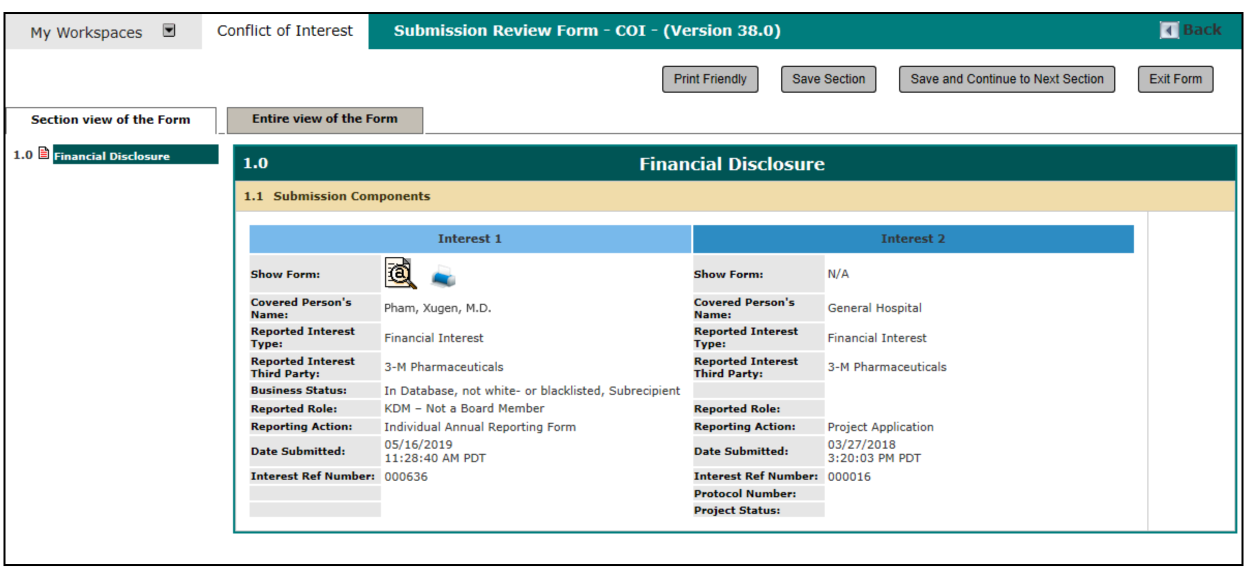
The **Reviewer Check List** section lists assigned Reviewers by name and role, and includes links to reviewed objects and documents associated with the respective Reviewer. To open an object or document, click its icon in the View/Edit column.

If you are logged in as the Reviewer, you will be able to edit the checklist by clicking on the icon in the **View/Edit** column. You can also status your review as complete by changing the “Yes/No” value in the **Completed?** column and clicking the **Save the Review Status** button.

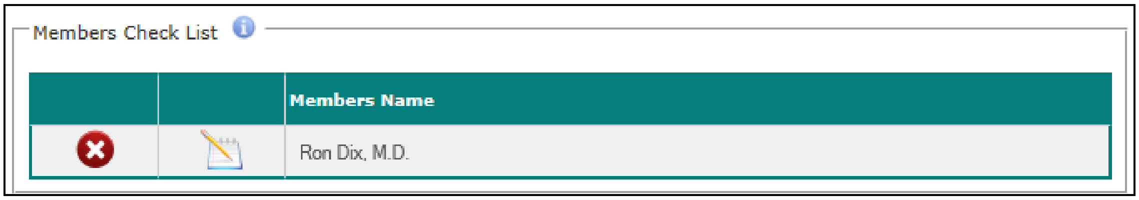
The **Members Check List** section lists the names of Board Members who have added their own Members Checklist to the matched object.

The **Members Comments** section displays comments added to the file by Board Members.

Board Members and Analysts can create a Members Checklist by clicking on the **Add Members Checklist** button at the top right of the screen.

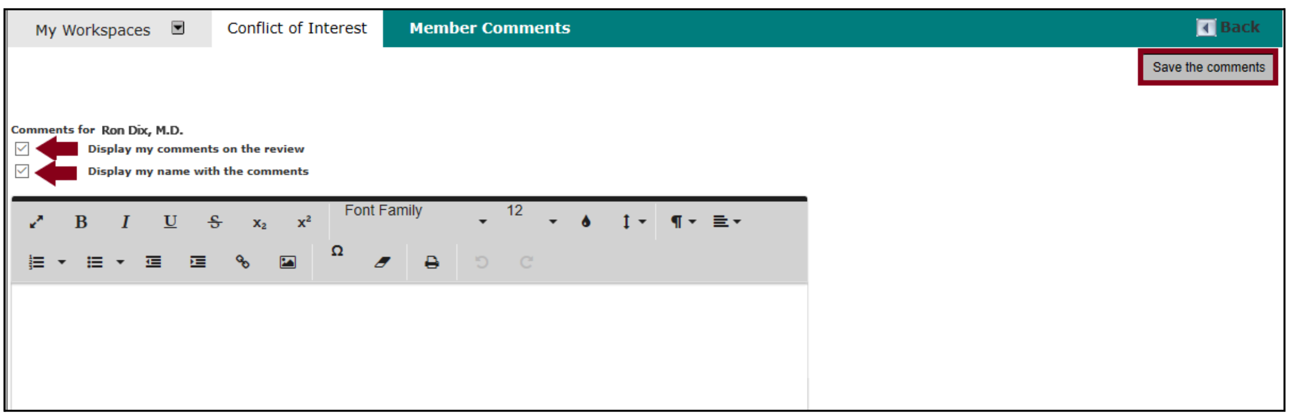


This will open a Member checklist, which is the same form the Reviewer filled out. The Board Member or Analyst can answer the same questions but will not have to indicate completion because this is not a Reviewer task. Rather, the Board Member or Analyst is adding a checklist as supplemental documentation.



When the form is finished and the Board Member or Analyst returns to the Review Checklist and Comments screen, the Members Check List table populates with an entry. The Board Member or Analyst can access their checklist by clicking on the **Edit** icon, or Delete the checklist by clicking the icon corresponding to the record. Only the Board Member or Analyst who added the Members Checklist can delete it.

Board Members can add comments to the conflict match by clicking on the **Add Member Comments** button. A new screen will open, allowing the Board Member to add comments in a rich text editor.

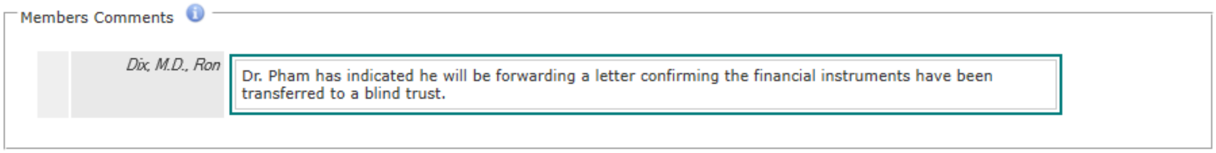


Above the text editor are two checkboxes, both selected by default.

If the Member wishes to keep the comments hidden from other Board Members, the **Display my comments on the review** checkbox should be deselected.

If the Board Member wishes to post their comments for other Board Members, but wants to keep the comments anonymous, the **Display my name with the comments** checkbox should be deselected.

Once comments are entered, click the **Save the comments** button to save the comments and return to the Reviewer Checklist and Comments screen. The Board Member comment will be shown if **Display my comments on the review** was selected at the time the comment was saved. The Board Member name will also be shown if **Display my name with the comments** was selected at the time the comment was saved.

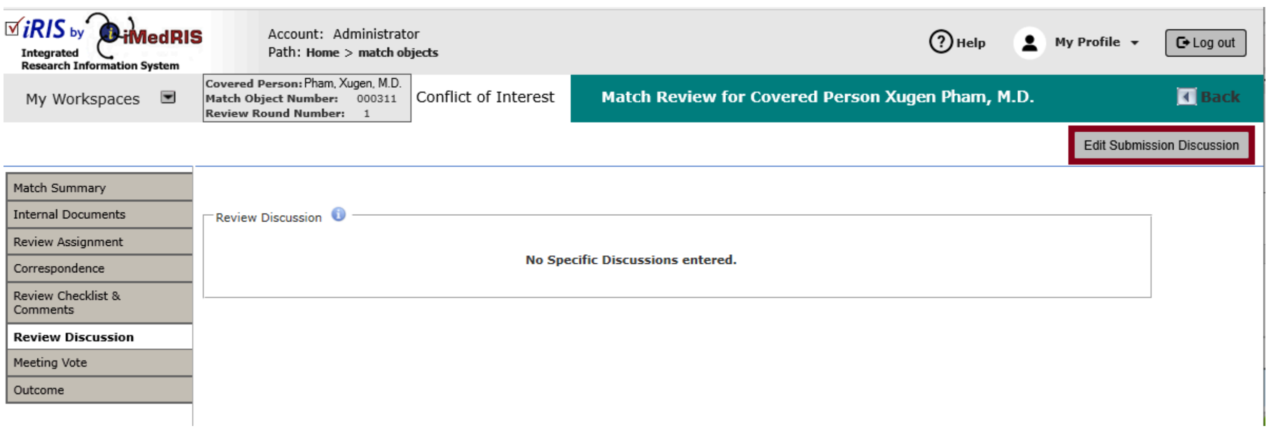


If the comments had been flagged as anonymous or hidden by de-selecting those checkboxes at the time the comment was saved, only the user who added the comments would see their name and/or the comments displayed on this screen.

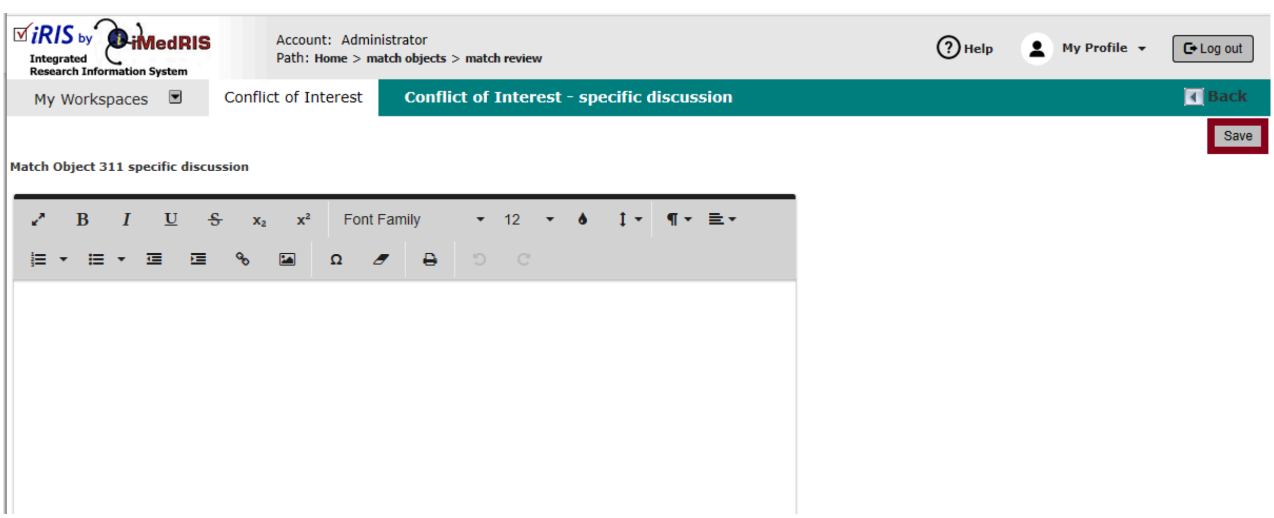
Review Discussion

The **Review Discussion** tab can be used to capture information related to the match review. These can be notes from the analyst or any discussion about the conflict that take place during a meeting. Items from the Reviewer Checklist can also be merged into the Review Discussion. The Review Discussion can then in turn be merged into letters and meeting minutes.

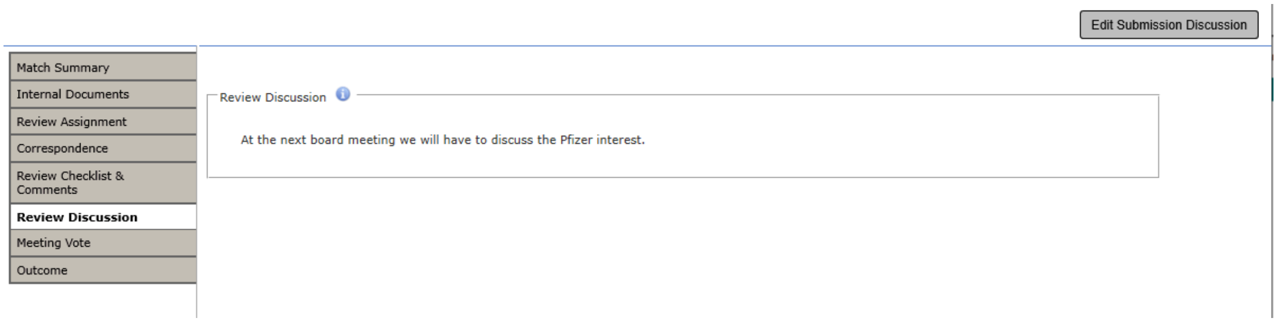
To add information to the **Review Discussion**, click the **Edit Submission Discussion** button.



A new screen will open, containing a rich text editor where you can type in or copy and paste your information. When you are finished, click the **Save** button.



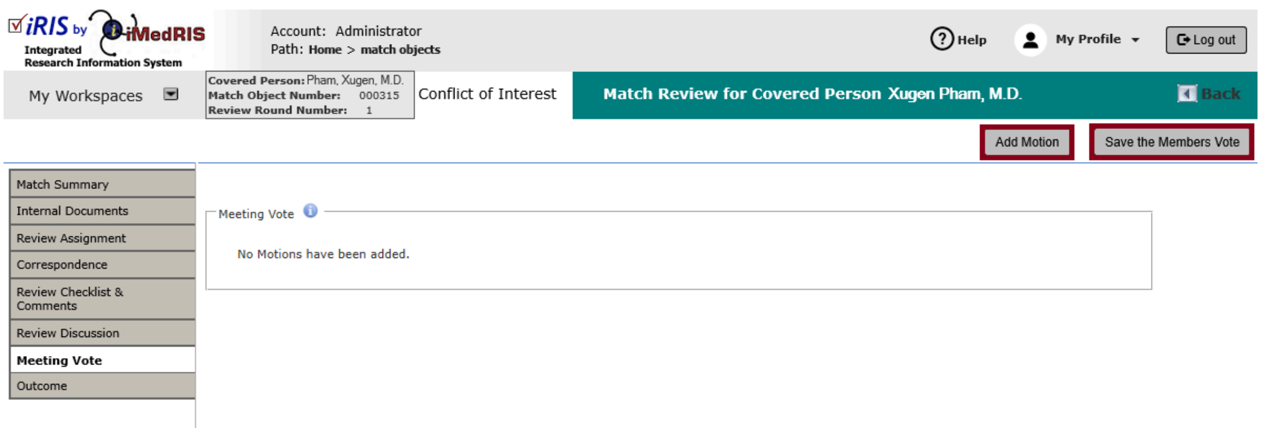
Your text will be displayed in the **Review Discussion** table. You can click the **Edit Submission Discussion** button to add to the discussion, if needed.



Meeting Vote

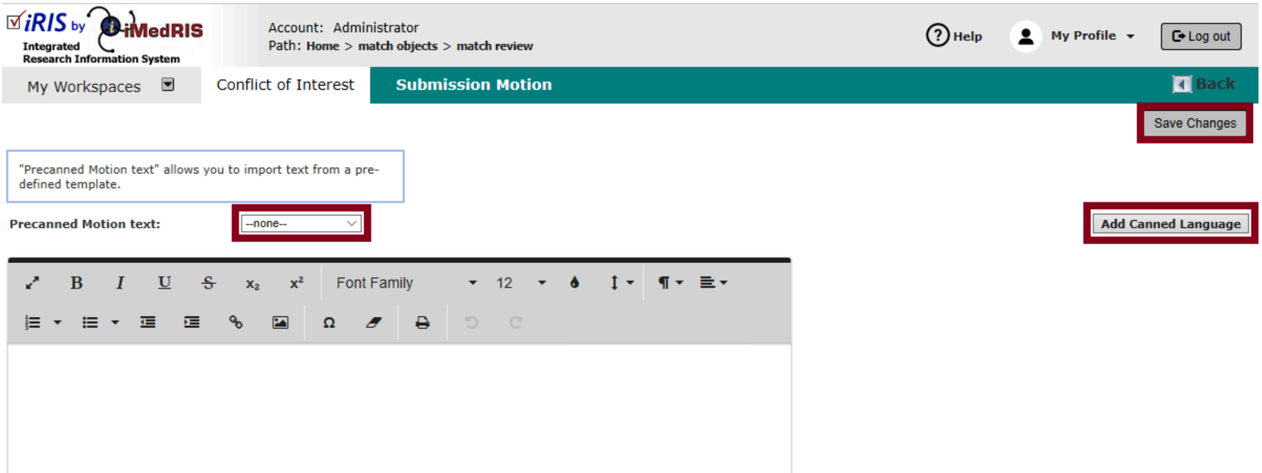
This tab will only populate for your match review if you selected a full board meeting review type.

Use this tab to capture votes for the match review. You can capture the vote at the time of the meeting, or any time afterward, but before match review processing is complete. Start by clicking the **Add Motion** button.

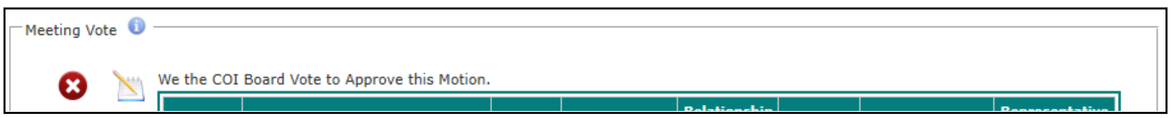


A new screen will open with a text editor where you can type in or copy and paste a motion.

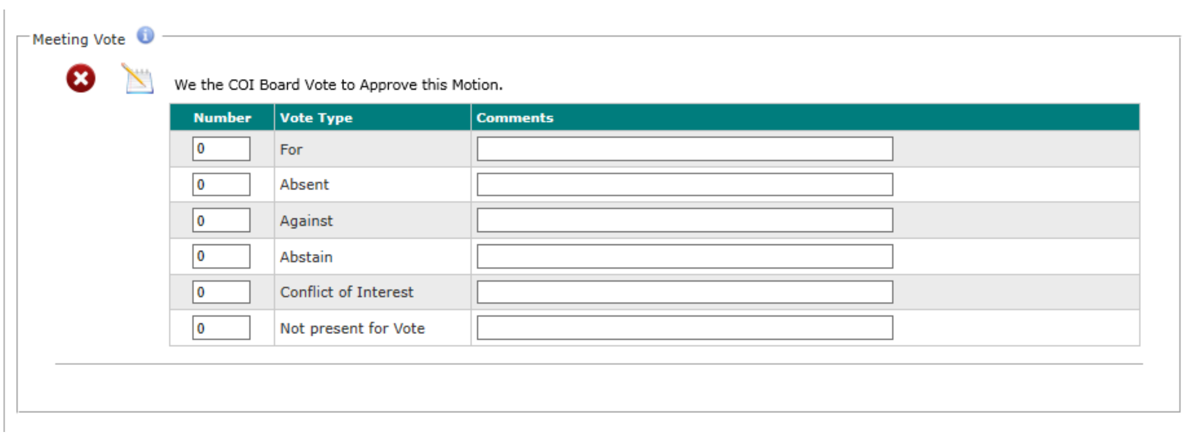
You can also use precanned motions by selecting a template from the **Precanned Motion text** dropdown list. With your selection highlighted in the dropdown list, click the **Add Canned Language** button. Precanned language for use in these motions is set up in Review Board Administration > System Setup > Setup Canned Motion.



Once your motion is defined in the text editor, click on the **Save Changes** button. the added motion text will appear at the top of the Meeting Vote section as shown below. Click the Delete icon to delete the added motion text. Click the Edit icon (pad and pencil) to revise the added motion text.



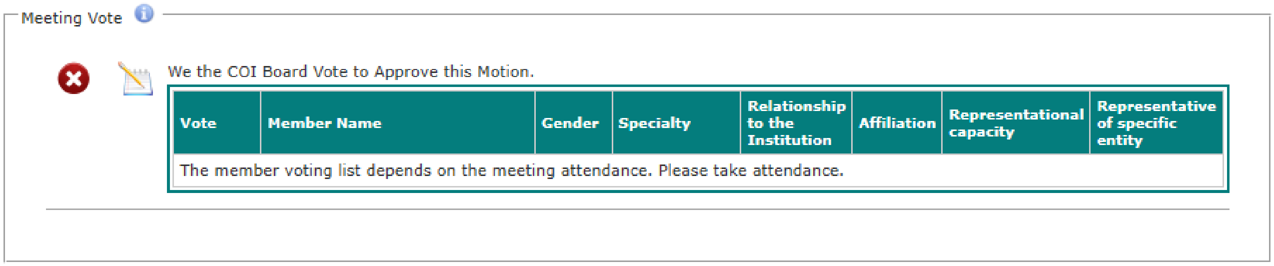
Depending on your review board configuration, the motion you added may or may not be set for anonymous voting. If it is anonymous voting (vote summary), then the screen will appear similar to the screenshot below.



Enter the number of members that voted for each **Vote Type** in the **Number** text field corresponding to each **Vote Type**. After entering the votes, click the **Save the Vote Summary** button.

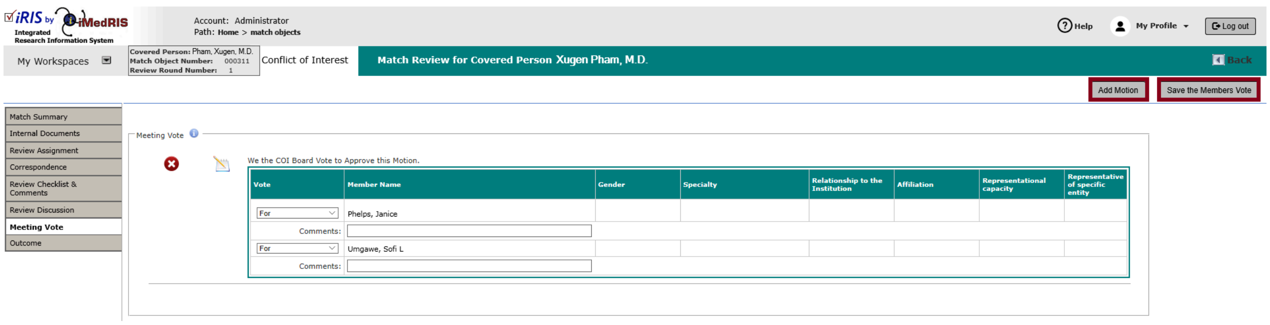
The Anonymous Voting option is toggled off or on in Review Board Administration. For more details on this setting, please refer to the COI Assistant - Properties manual.

If Anonymous Voting is toggled off in your system, attendance will need to be set before voting can take place. If attendance has not been set, the below screen shot will be displayed.



Attendance is taken under Conflict of Interest Assistant > Meeting Management > Meeting Manager. There, the responsible Coordinator or Board Member can look up and select the current meeting and mark attendance.

If attendance has been set and taken, the list of members present will be displayed as shown in the screenshot below.



The vote type can be selected in the **Vote** column next to each **Member Name**. Each member's Gender, Specialty, Relationship to the Institution, Affiliation, Representational Capacity, and Representative of Specific Entity information can also be found under the corresponding columns, as provided in the member's user profile.

A **Comments** line is provided to enter any comment the member wishes to have notated with their vote.

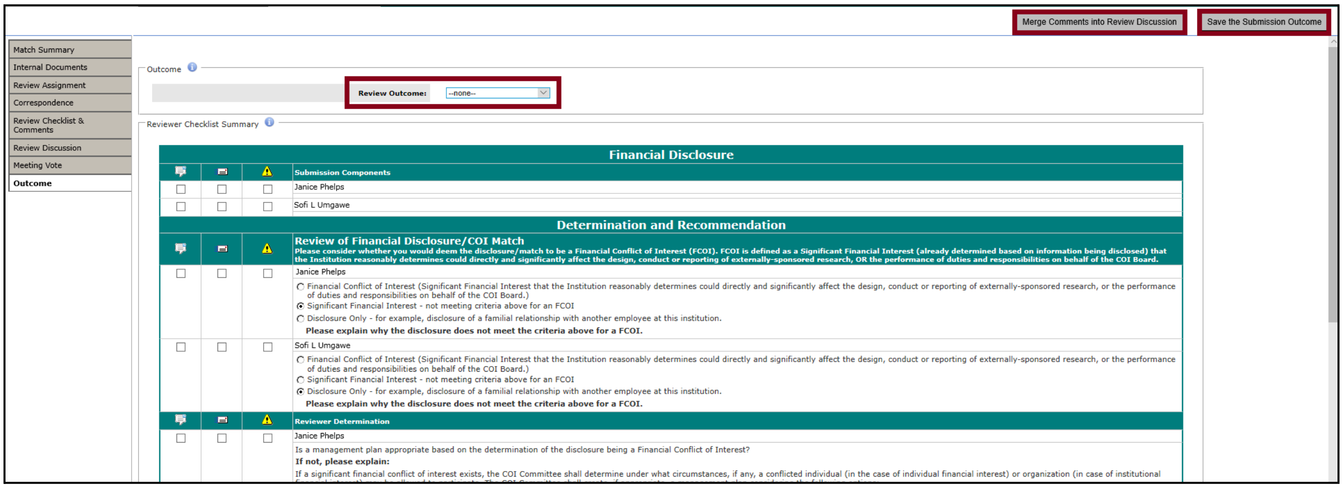
After the votes for the motions have been set click the **Save the Members Vote** button. The votes will be saved and can be used to merge into outcome letters (see the COI Assistant – Administration Manual for more information).

Use the **Add Motion** button to add more motions to the **Meeting Vote**.

Outcome

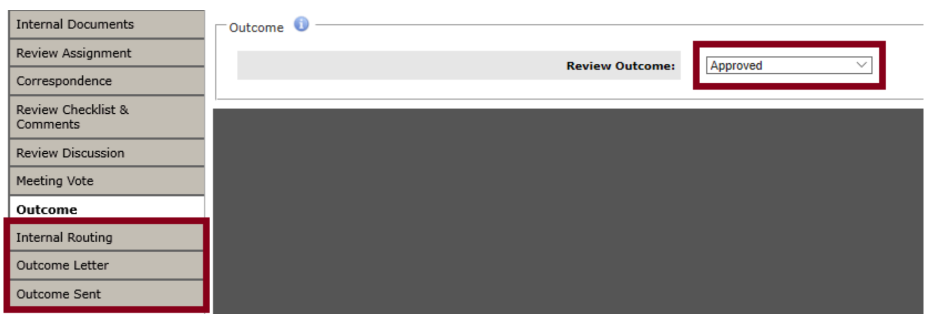
The **Outcome** tab is where an outcome is set for the match review and is typically reserved for COI Coordinators. Here, the Coordinator can select certain items from a reviewer checklist and merge them into management strategies or pull the information into outcome/response letters or meeting minutes.

After reviews are complete for a conflict match the **Outcome** tab will include a summary screen of all reviewer checklists and member checklists as well.



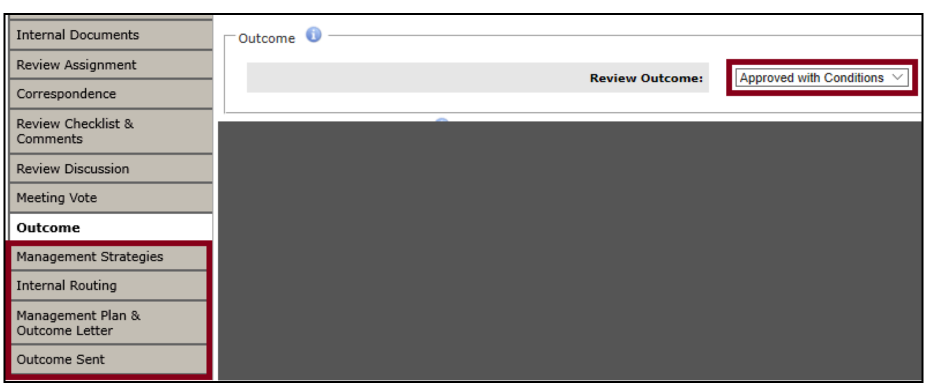
Select the desired outcome from the **Review Outcome** dropdown list at the top of the screen. The outcomes in the list are configurable and can be set up under Review Board Administration > List Maintenance Setup tab > Review Outcome/Outcome Configuration List. The outcome selected from this dropdown list determines whether the conflict match is acceptable to the COI Office as-is, or a management strategy must be put in place.

If any **Review Outcome** *other* than **–none--** or **Approved with Conditions** is selected the screen will refresh, and three additional tabs are added to the menu at left: **Internal Routing**, **Outcome Letter** and **Outcome Sent**.



If you select a Review Outcome of **Approved with Conditions** the screen will refresh, and four additional tabs are added to the menu at left: **Management Strategies**, **Internal Routing**, **Management Plan & Outcome Letter** and **Outcome Sent.**

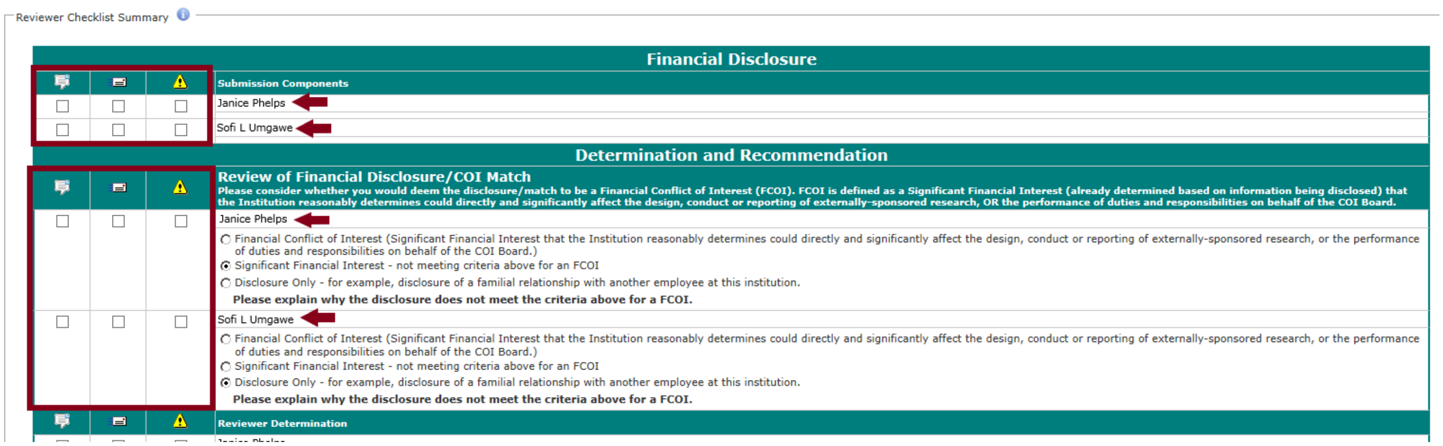
*Note: The label shown on the **Outcome Letter** tab depends on the outcome selected. Where a Management Plan is required the label reads **Management Plan & Outcome Letter**. Otherwise it reads **Outcome Letter**.*



You will be able to define any management strategies before sending the management plan to the Covered Person.

Note: The Covered Person will receive a task on their home screen regarding the management plan; see the COI Assistant – For Covered Persons manual for additional details on how this process functions from their side.

In the **Reviewer Checklist Summary** table, a list will populate containing the questions from the checklist and the names of reviewers and Board Members who completed the checklist. The answers to questions from the checklist appear underneath the Reviewer/Board Member names.



To the left of the Reviewer/Board Member name are three checkboxes that can be used to merge that reviewer/member's answer into a certain place in the system.

 - A checkmark in the first column will merge the item into the **Review Discussion** tab when the **Merge Comments into Review Discussion** button is clicked (shown previously in full screenshot of the Outcome tab, buttons are at the upper right), minus the reviewer/member name.

Anything that is merged into the discussion can be pulled into the meeting minutes, provided the Submission Specific Discussion merge code is used in the meeting minutes template (this is discussed in further detail later in this document).

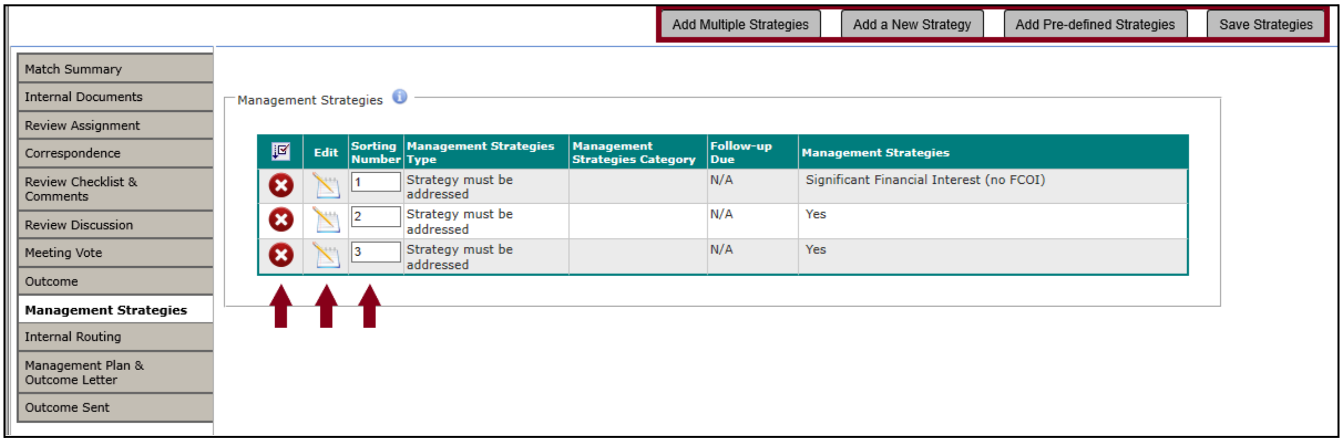
 - A checkmark in the second column will merge the item into an Outcome Letter when it is generated, provided the Submission Review Summary merge code is used in the outcome letter template.

 - A checkmark in the third column will take the answer to the question and create a Management Strategy on the **Management Strategies** tab when the **Merge Comments into Management Strategies** button is clicked (shown previously in full screenshot of the Outcome tab, buttons are at the upper right).

After setting the outcome and merging the desired items in the checklists, click the **Save the Submission Outcome** button (shown previously in full screenshot of the Outcome tab, buttons are at the upper right).

Management Strategies

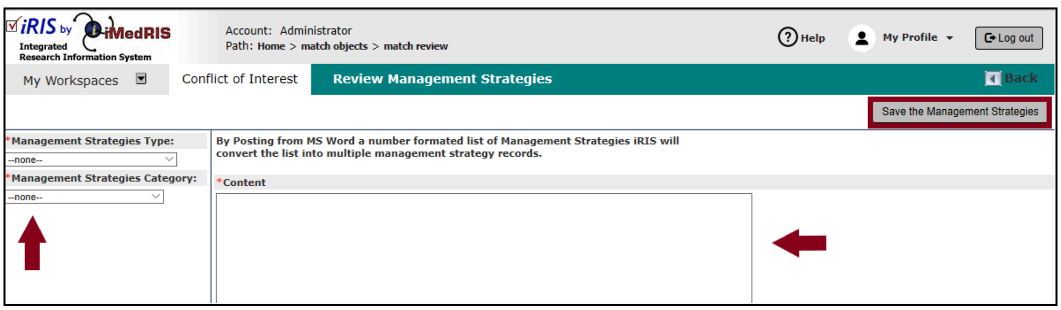
If the Covered Person associated with the conflict match needs to adhere to a management plan, the **Management Strategies** tab will populate in the menu. From this screen, you can create the strategies that you want to merge into your management plan. Each strategy will be added to the list as a separate line item.



There are four ways to populate the screen with management strategies.

1. Strategies merged from the Outcome tab. The screenshot above shows strategies that were merged in from the **Outcome** tab.

2. Add Multiple Strategies – Click this button to add multiple strategies at once.

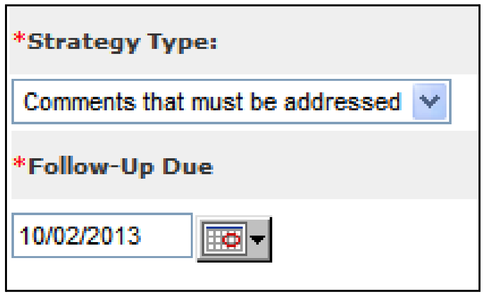


Copy strategies that have been formatted as a numbered list in a Word document, then paste the copied, numbered list into the text editor box. Select a **Management Strategies Type** and **Management Strategies Category** at left, then click the **Save the Management Strategies** button to add the pasted list of strategies to the **Management Strategies** list.

There are three **Management Strategy Type**s:

Strategy must be addressed— The covered person must follow the strategy and respond to the COI office with an acknowledgement.

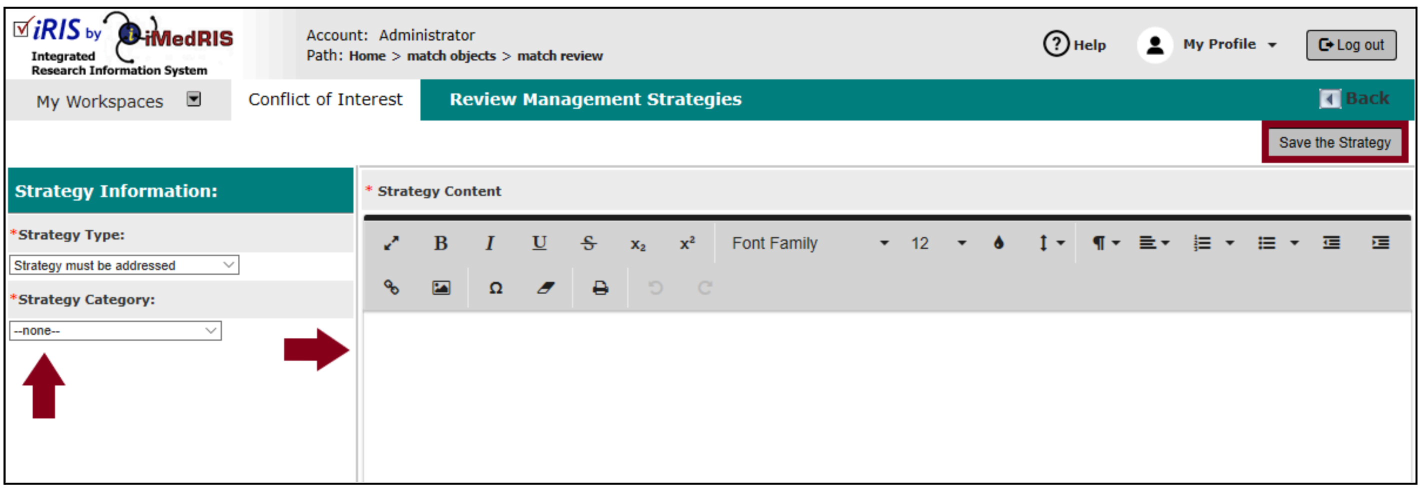
Comments that must be addressed— When you select this type from the dropdown list the screen will refresh, adding a field to specify a follow-up due date. The Covered Person must respond to the item before the specified date, outside of the main management plan follow-up due date (this is assigned when you are sending the management plan to the Covered Person, which is covered later in this document).



Comments— Adds recommendations for the Covered Person. The comments are merged into the Management Plan and require acknowledgement from the Covered Person.

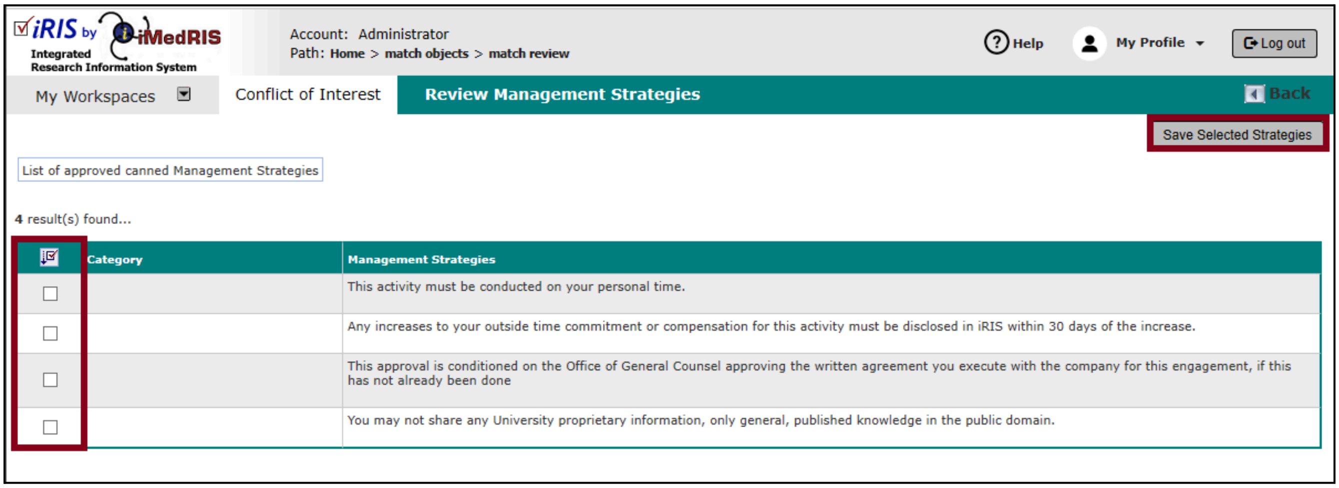
3. Add a New Strategy – Click this button to manually enter a strategy line item.

When you click this button a new screen opens, allowing you to type or paste in text for the management strategy in a rich text editor. Select a **Strategy Type** and **Strategy Category** at left, then click **Save the Management Strategies** to add the strategy to the **Management Strategies** list.



4. Add Pre-defined Strategies – If certain strategies are commonly applied, you can save them to the Pre-defined Strategies list under Review Board Administration > List Maintenance Setup > Predefined Strategies.

When you click the **Add Pre-defined Strategies** button, a screen listing all the predefined management strategies will open. You can select a strategy or multiple strategies, and then click the **Save Selected Strategies** button.



The strategy will be added as a "Strategy must be addressed" type.

All strategies added, regardless of the method used to add them, will appear in the Management Strategies table.

Click the **Delete** icon next to the appropriate strategy record to delete that strategy item.

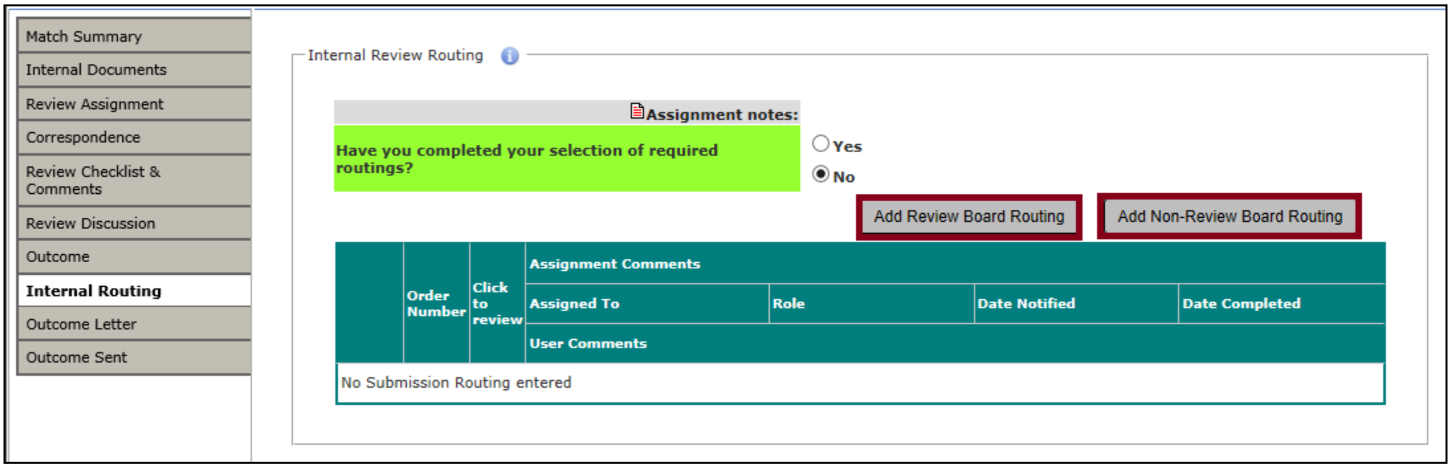
Click the icon in the **Edit** column next to the appropriate strategy record to open the strategy item for modifications.

Strategies are displayed in the order you added them. If you would like to reorder them, you can change the numbering in the **Sorting Number** column. Change the numbers, and then click the **Save Strategies** button.

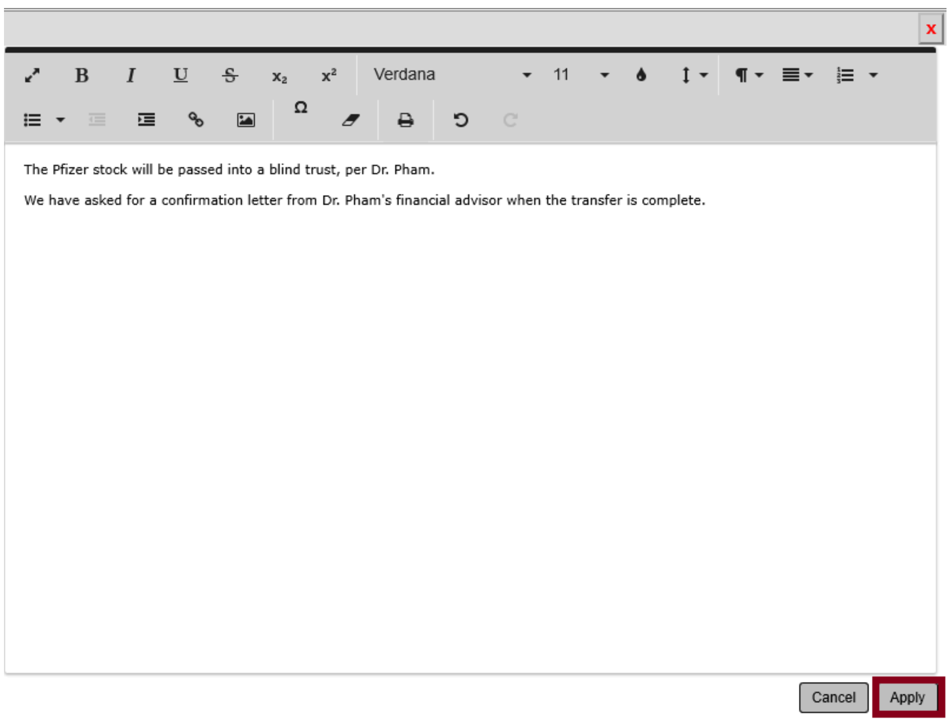
Note: The Covered Person will receive a task on their home screen regarding the management plan; see the COI Assistant – For Covered Persons manual for additional details on how this process functions from their side.

Internal Routing

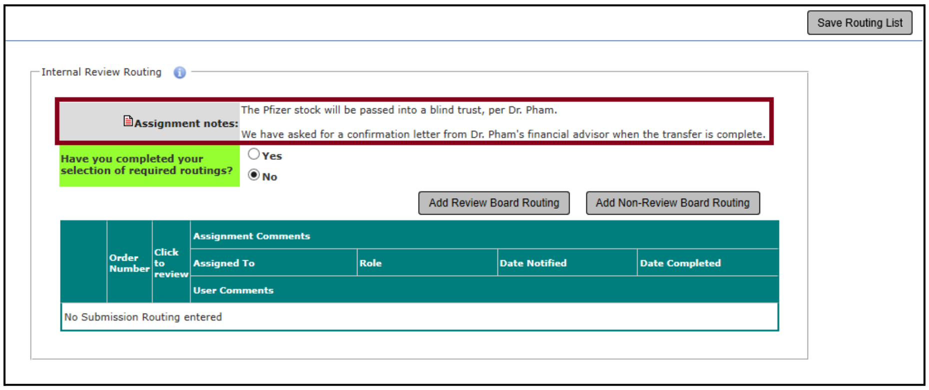
The Internal Submission Routing tab within a submission is a very useful tool for COI Analysts, who can use this tab to route the conflict match internally, any number of times, all at once. Internal Routing can be used to show a Chairperson a specific match review or to have a specialty reviewer view the conflict match.



The **Internal Routing** tab allows for routing notes on the match. Click the **Assignment notes** link to add these notes.

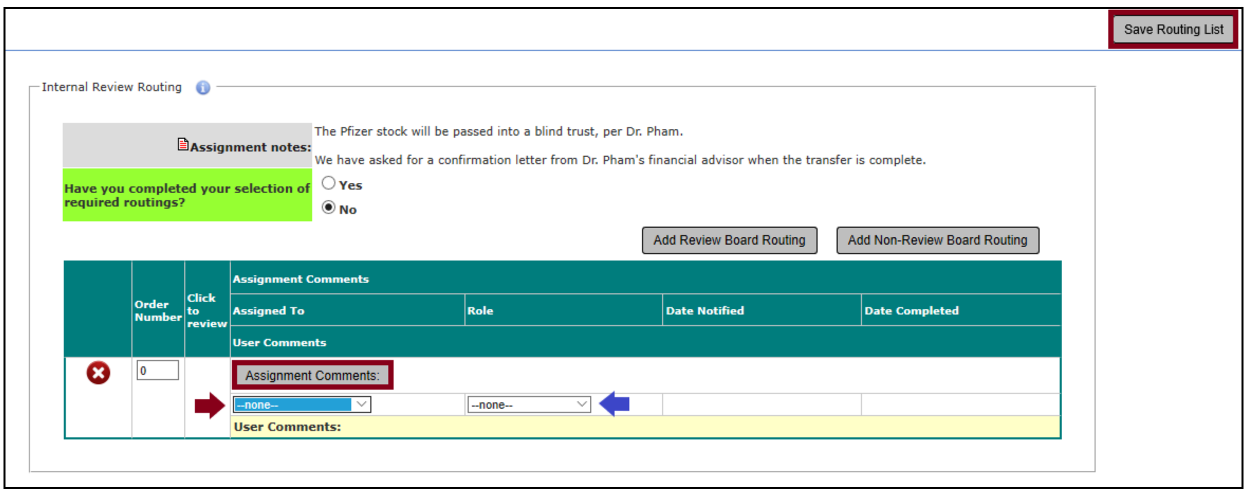


The **Assignment Notes** are added to the **Internal Routing** screen and will be included when Submission items are routed.



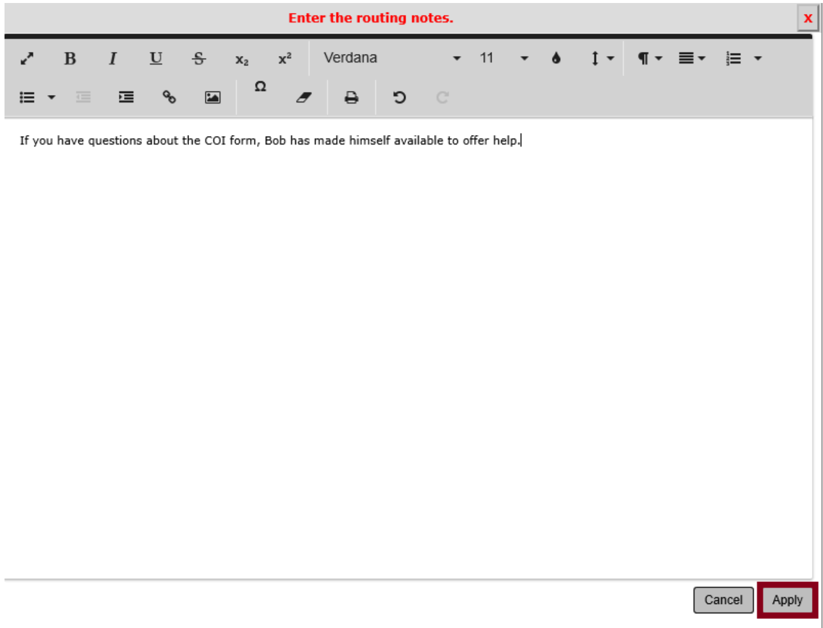
This screen is used to create the list of users whose reviews are needed to complete an internal signoff on the Conflict Match.

Review Board Members can be added by clicking the **Add Review Board Routing** button. This will create a row that allows you to choose a Board Member from a dropdown list (red arrow in screenshot below) and optionally et a Role for the Board Member (blue arrow in screenshot below). Use the **Save Routing List** button to save your additions.

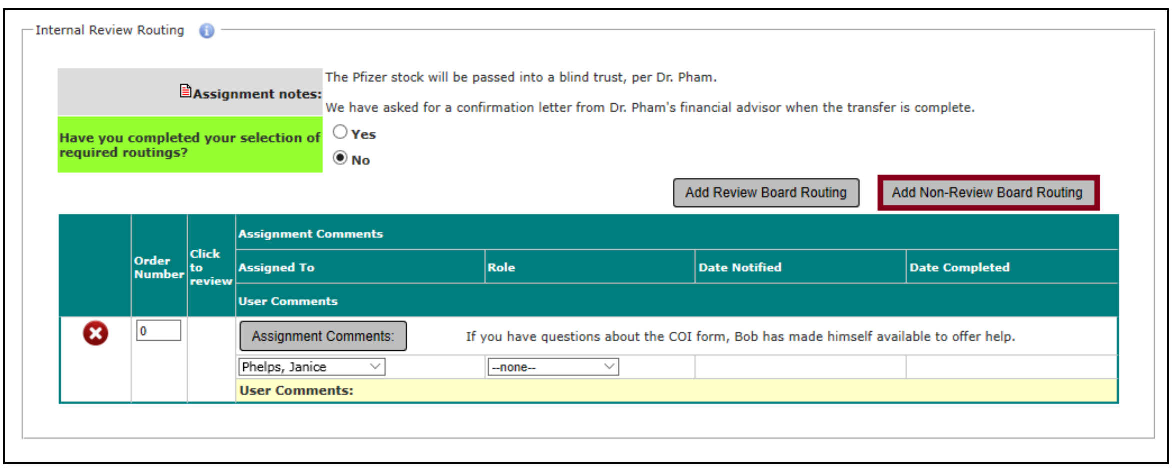


To enter reviewer-specific assignment notes (optional), click the **Assignment Comments** button above the user's name.

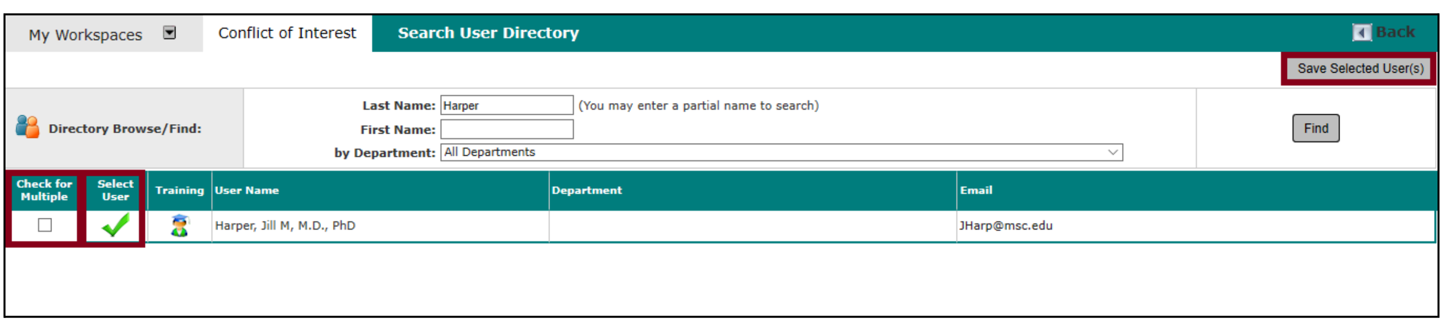
A text editor will open. Enter your comments and click the **Apply** button to save changes and return to the Internal Routing screen. Click the **Cancel** button to close the text editor and return to the Internal Routing screen without adding comments.



Your comments will populate to the right of the **Assignment Comments** link. These comments are specific to the user and will populate in the assignment when the user opens their task.

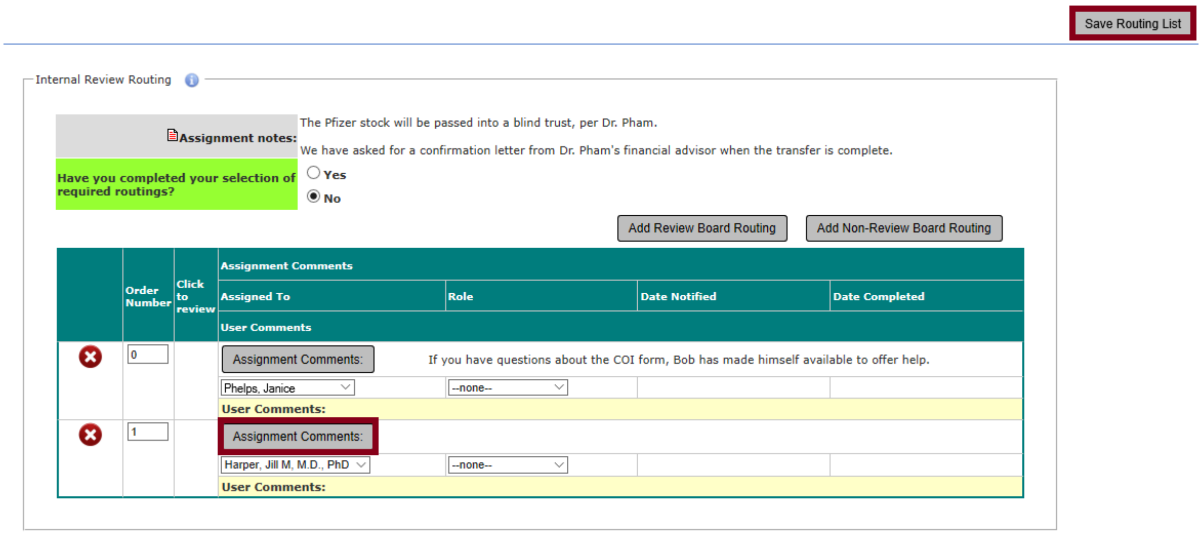


Click the **Add Non-Review Board Routing** button to add someone who is not a Review Board Member to Internal Routing. A new screen will open, allowing you to use the Search User Directory screen to look up the desired person by **Last Name**, **First Name**, **Department**, or any combination of all three.



Click either the **Save Selected User(s)** button or click the **Select User** icon (green checkmark in the **Select User** column) to add an individual person to Internal Routing.

If your search has returned multiple users you wish to add to Internal Routing, next to each name to be included, click the box in the **Check for Multiple** column and then click the **Save Selected User(s)** button to add the names and return to the Internal Routing screen.



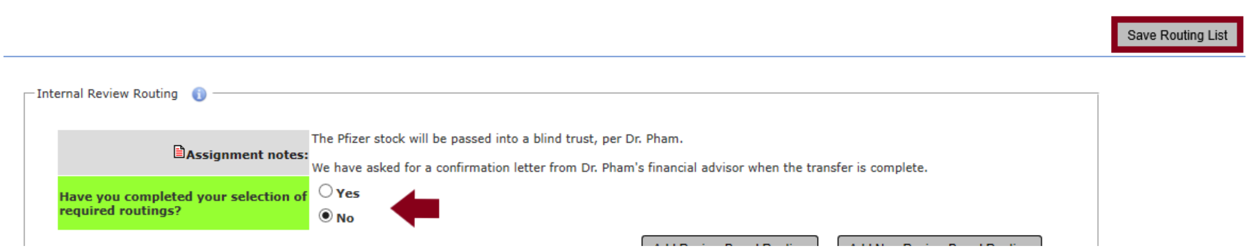
Each name added will be in a separate row and will have the same **Assignment Comments** button available for you to add comments specific to each person.

Routing will occur in the order indicated by the numbers entered in the **Order Number** column, with the lowest number (zero) being first in the routing order. One (1) will be next, followed by two (2), and so on.

When the user with the lowest order number completes the assigned routing, the next user in the order on the list will be notified for signoff. This process will continue until the list is completed. Users with the same order number will receive the notification at the same time.

You can re-order the list by changing the numbers in the **Order Number** column. If a user that has already been notified is subsequently deleted, the user with the next highest order number will be notified. This keeps the submission moving in the event a user does not sign off in a timely manner.

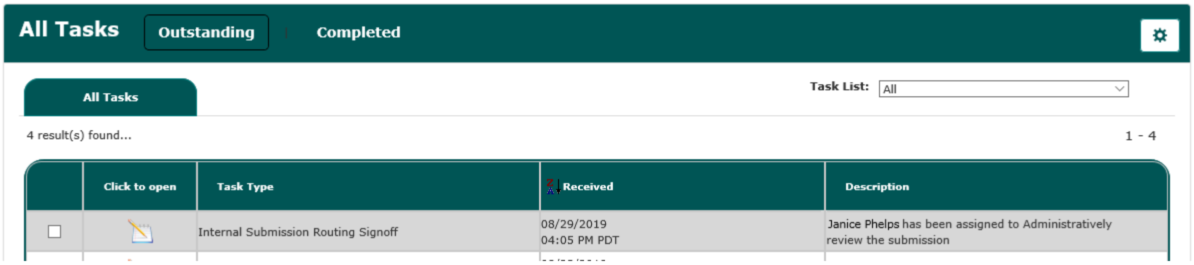
Beneath the assignment notes display there is a Yes/No question (red arrow in screenshot below): **Have you completed your selection of required routings?** The default answer selection is **No**.



When your changes to the routing list are complete, click the **Yes** selection and click the **Save Routing List** button.

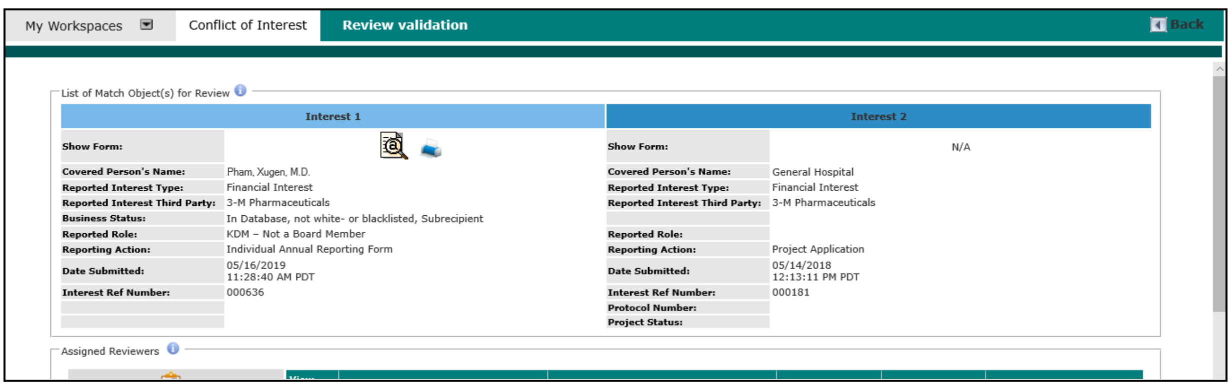
Internal Routing Task

When a user has been notified of an Internal Submission Routing Signoff assignment, upon logging into iRIS they will find an **Internal Submission Routing Signoff** task on their COI Workspace home screen.

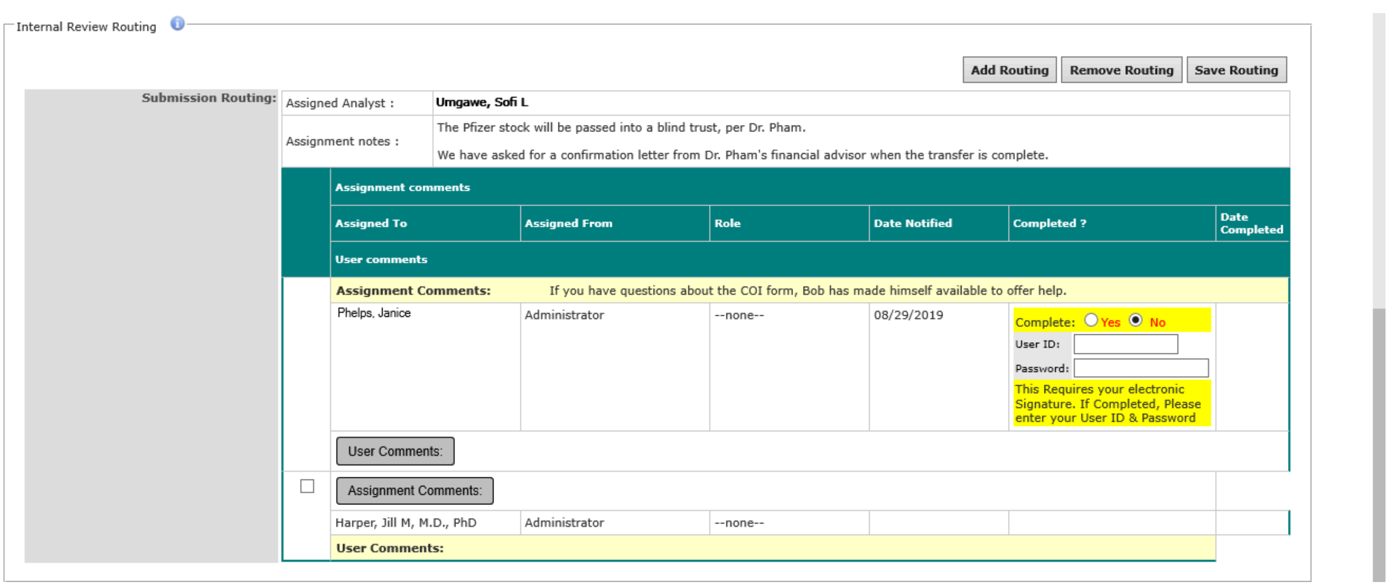


To complete their review, the user clicks the icon in the **Click to Open** column to open a **Review validation** screen.

The screen includes sections for Match Object(s) under review, **Assigned Reviewers**, **Management Plan Document** details (if applicable), **Response Letter** details (if applicable), and **Outcome**. Only the first section is shown in the screenshot below.



After completing their review of each applicable section and object, the user scrolls down to the **Internal Submission Routing** block at the bottom of the form.

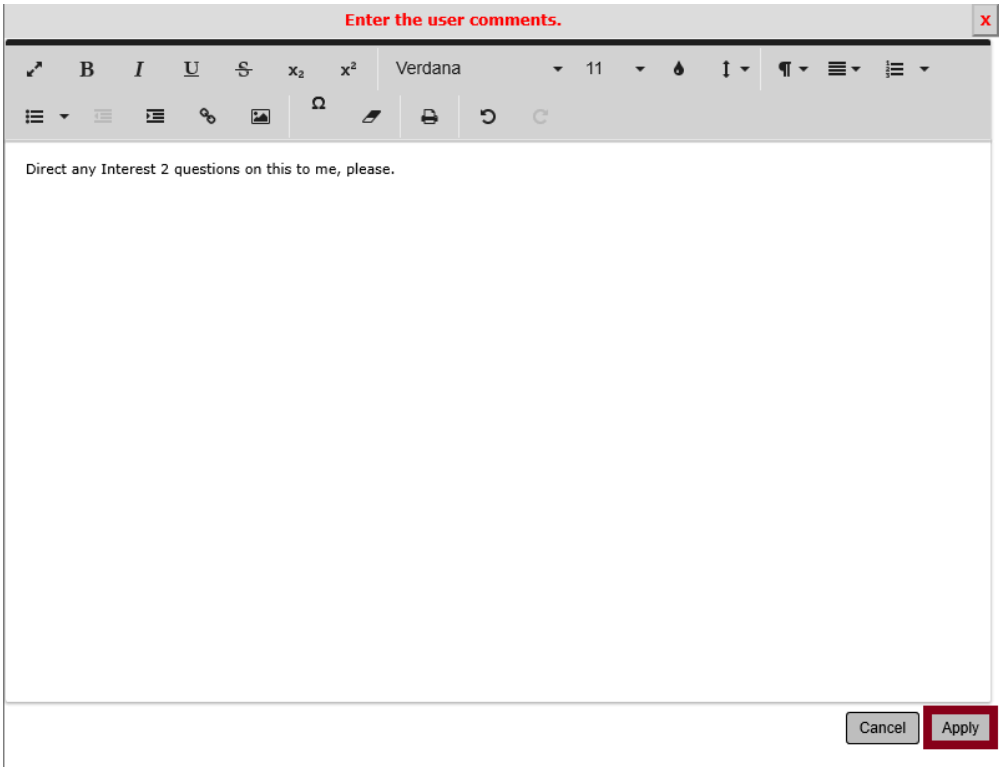


From this area, the user can indicate whether they are finished with the review.

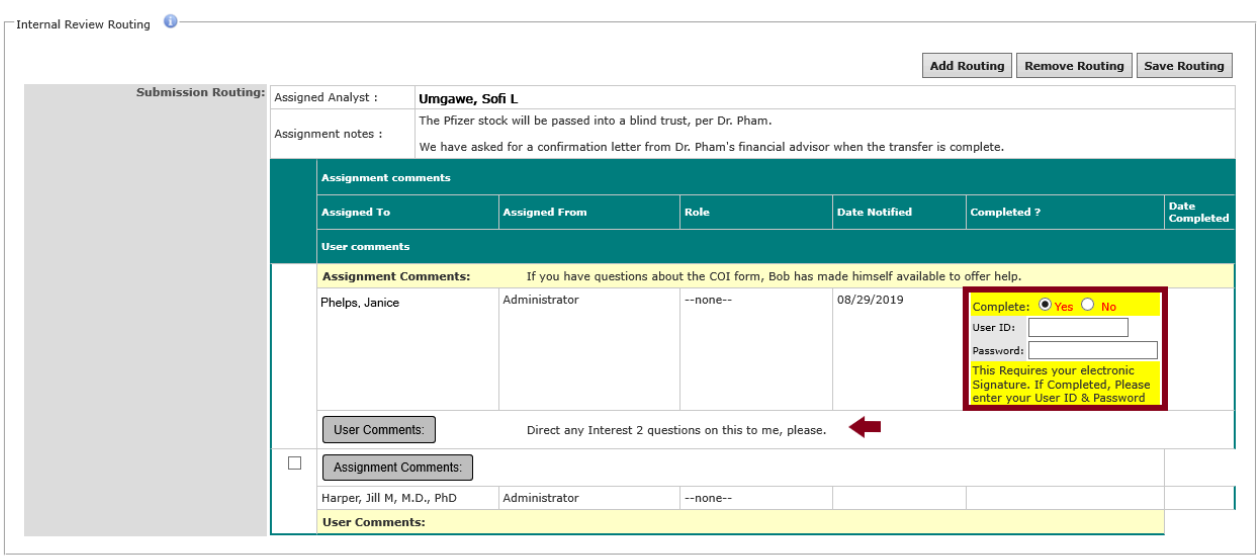
The user can add more routing tasks, if needed, by clicking the **Add Routing** button.

The user can remove a routing task by selecting the checkbox to the left of the routing item and clicking the **Remove Routing** button.

If the user needs to comment back to the Analyst, they can click on the **User Comments** button to open the text editor.

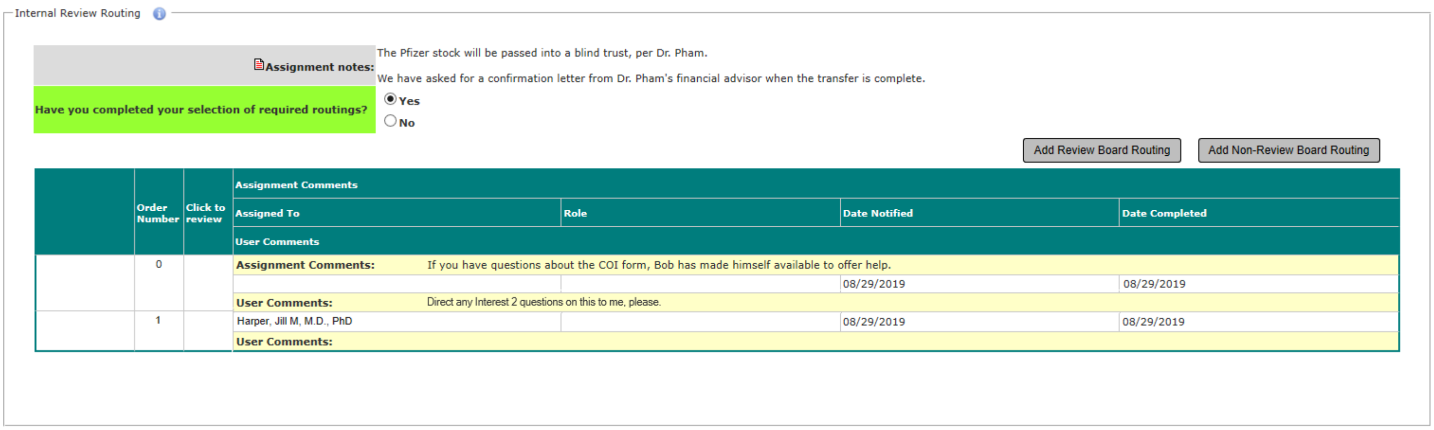


Any user comments added will be reflected in the **User Comments** area of **Submission Routing**, as shown below (red arrow).



Before the task can be removed from the user's home screen, the user must indicate "Yes" in the **Complete** box, enter their login credentials (if required) and click on the **Save Routing** button.

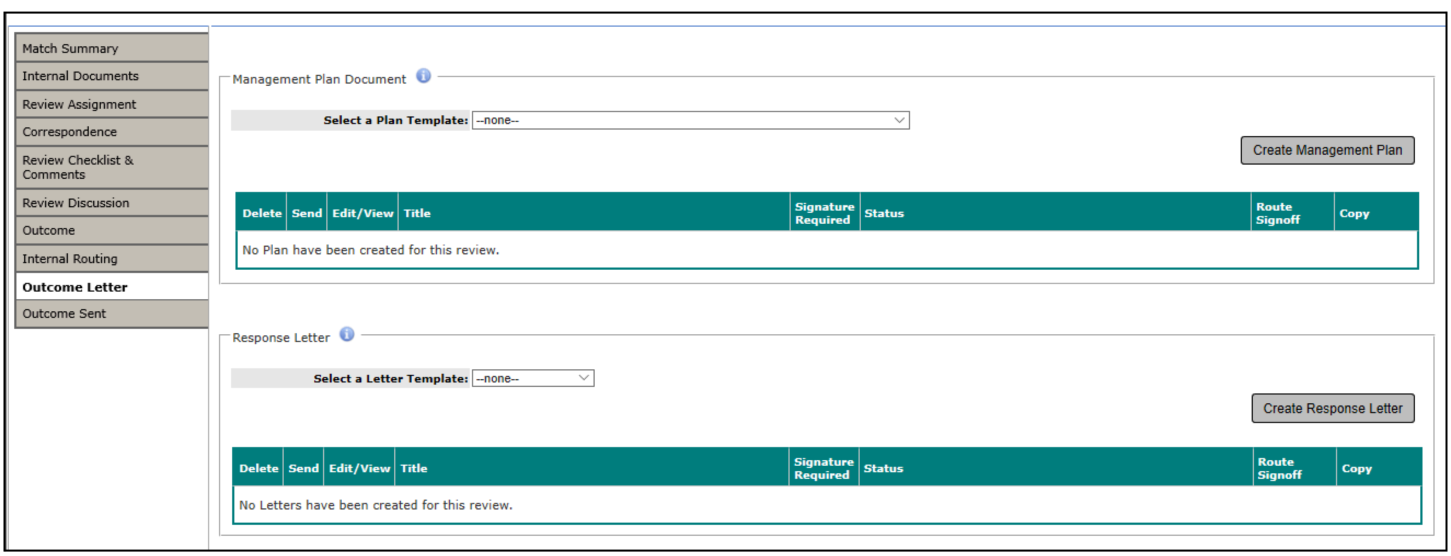
When all users assigned to the Internal Routing have completed their routing assignments, the Analyst for the match review will receive a notification from the system as well as a home screen task. When the task is opened, the Analyst will be returned to the **Internal Routing** tab.



From here the Analyst can see when the users completed their assignments and if they have included any comments. The Analyst can also use the **Add Review Board Routing** or **Add Non-Review Board Routing** buttons to add more routing tasks.

Outcome Letter

This tab allows the Analyst to create a Management Plan and/or an Outcome Letter to send to the Covered Person or other individuals as needed. Depending on the outcome assigned, the tab may read **Management Plan & Outcome Letter** or just **Outcome Letter**.



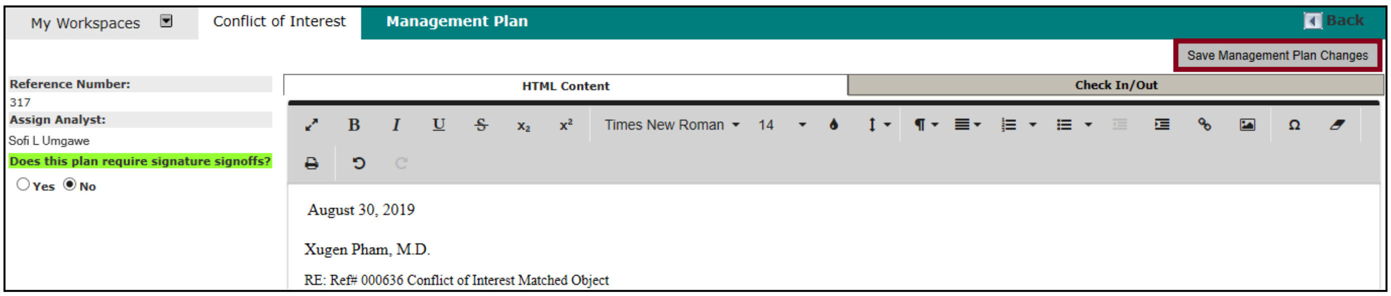
This screen is broken up into two parts, **Management Plan Document** and **Response Letter**.

The **Management Plan Document** can be created to pull in the Management Strategies added earlier.

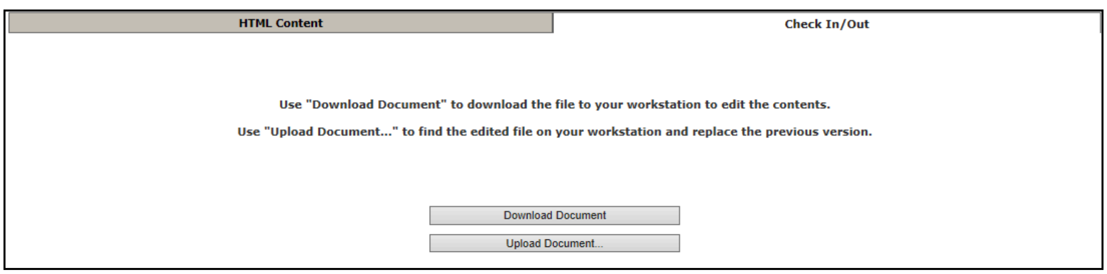
To create the Management Plan, begin by selecting a template from the **Select a Plan Template** dropdown list in the **Management Plan Document** area. After the template is selected, click the **Create Management Plan** button.

Management plan templates are created under Review Board Administration > System Setup > Setup Management Plan. There is no limit to the number of templates that can be defined there.

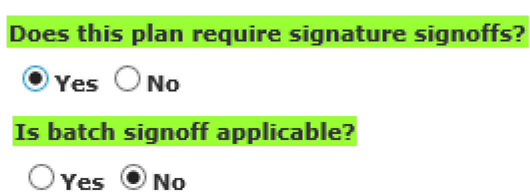
After the **Create Management Plan** button is clicked, a text editor screen is displayed. The text editor contains an editable version of the management plan.



When changes in the text editor are complete, click the **Save Management Plan Changes** button. When the plan has been saved, the **Check In/Out** tab will populate with **Download Document and Upload Document** buttons the Analyst can use to complete editing of the plan offline, then upload a revised version to the iRIS™ system later.

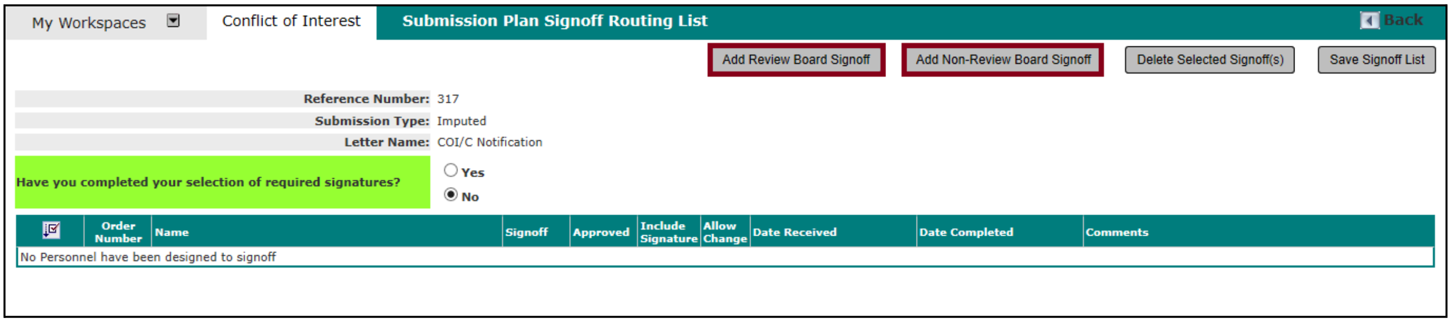


To the left of the text editor screen is the match information (**Reference Number** and **Assigned Analyst**). To require signature signoffs for this letter, select "Yes" under **Does this plan require signature signoffs?** When this is done, another field will populate as shown below:



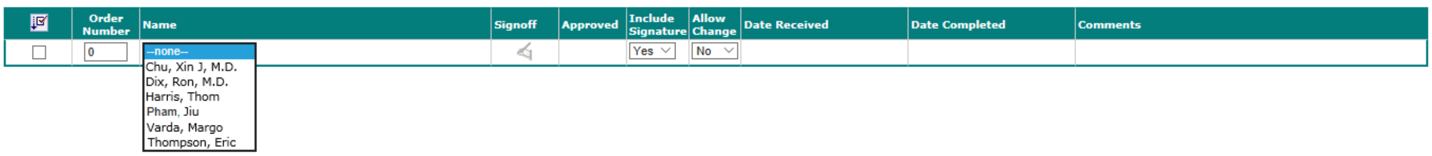
Batch signoff allows a user to sign more than one letter at a time. If this is applicable, select "Yes."

If the signature signoff was set to "Yes," you will be redirected to the Submission Plan Signoff Routing List screen when the **Save Management Plan Changes** button is clicked.

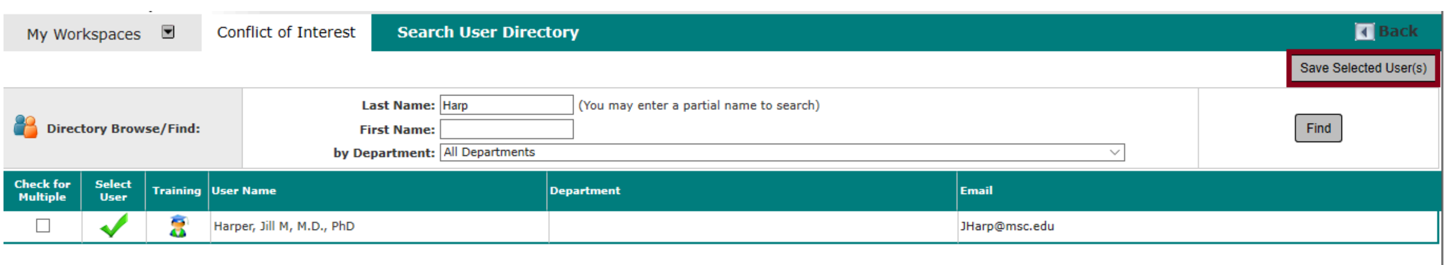


There are two ways to add a user to approve and signoff on the letter: via the **Add Review Board Signoff** button or the **Add Non-Review Board Signoff** button.

When clicked, the **Add Review Board Signoff** button adds a row to the signoff block enabling the user to choose any COI Board Member.

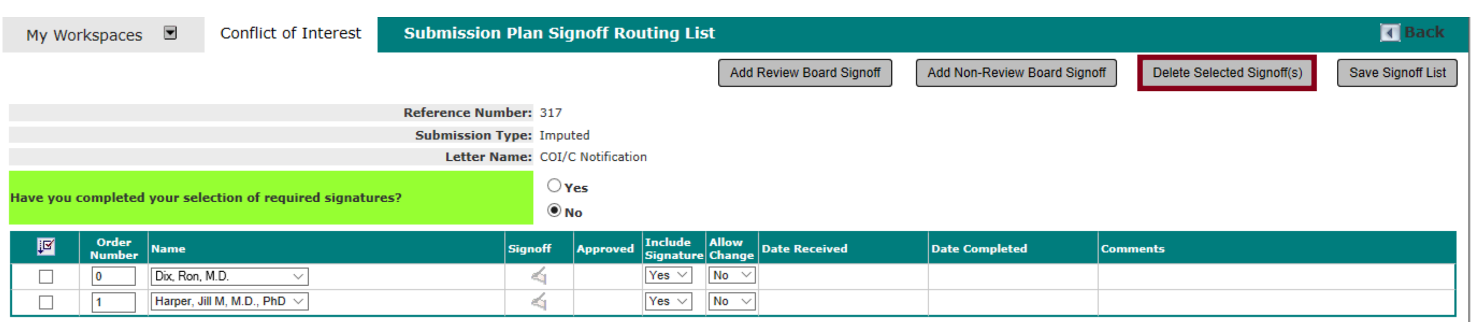


When clicked, the **Add Non-Review Board Signoff** button opens the **Search User Directory** form, enabling the Analyst to choose any user in the iRIS™ database and add their name for signoff, regardless of Board Member status.



Selecting a user from the list in the search form and clicking the **Save Selected User** button adds a row to the signoff block with the selected user's name.

After selecting the users required to sign off, their records will appear as shown in the screen shot below.



Order Number—Specifies who will receive the signoff task first. Users with the same order number will both receive the task at the same time.

Name—This is the name of the user (selected from the dropdown menu) who must sign the outcome letter.

Signoff—This column is only useful for the currently logged-in user. If you have been selected for signoff and you are the logged in user, the writing hand icon next to your name will darken ( )and you will be able to sign off on the letter by clicking this icon.

Approved—This area will display the status of the letter after the user has approved or denied it.

Include Signature—If this field is set to "Yes," the user's electronic signature will be required when they approve the letter.

Allow Change—If this is set to "Yes," the user designated for signoff will be allowed to edit the letter.

Date Received—This is the date that the user receives the letter for signature.

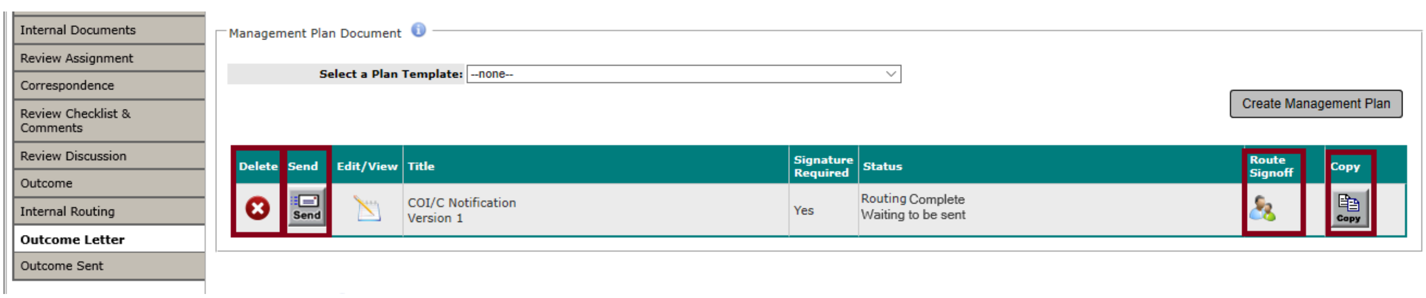
Date Completed—This is the date that the user applies their electronic signature.

Comments—Any comments the user may have entered upon sig off.

To delete a user previously added to the signoff block click to select the checkbox next to the name, then click the **Delete Selected Signoff(s)**.

Once all selections are made, click "Yes" in the **Have you completed your selection of required signatures?** Field and click the **Save Signoff List** button. This will send a notification to the first user selected for signoff.

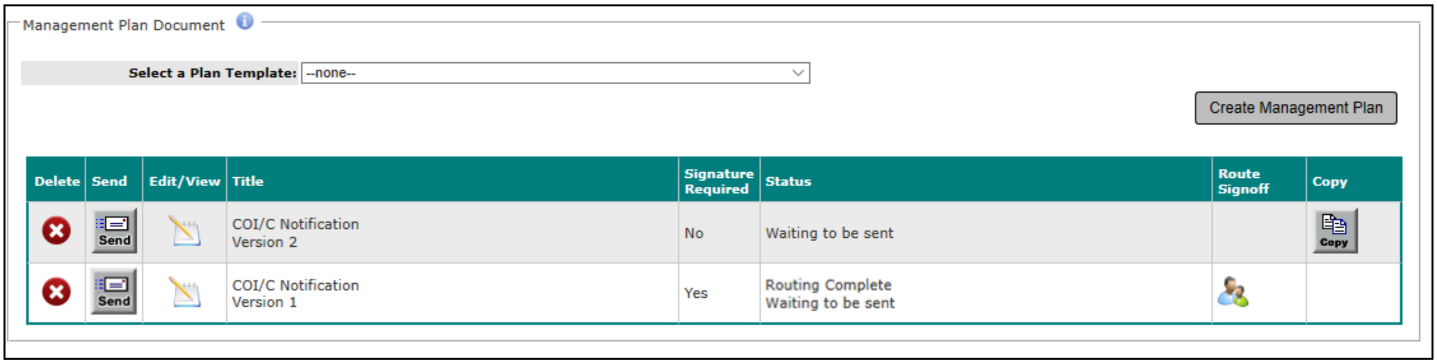
Navigating back to the **Outcome Letter** tab, you will see the Management Plan that you just created in the list.



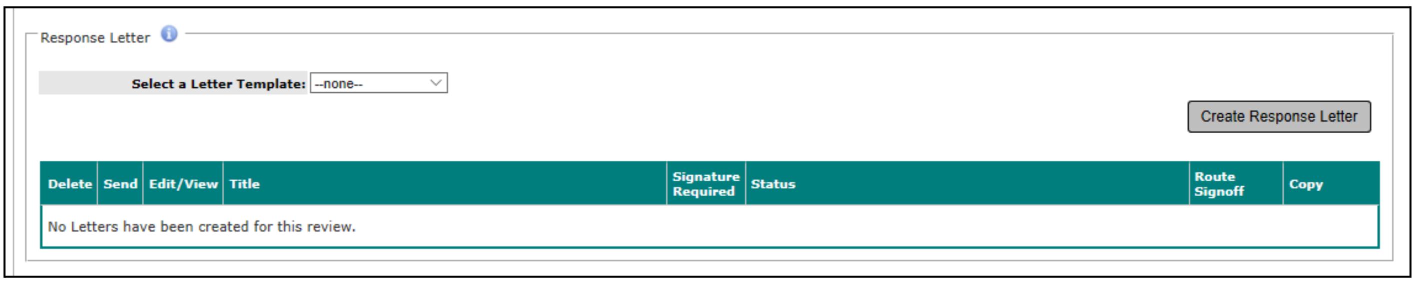
Other outcome letters can be added in a similar fashion. The **Send** button is dimmed until routing signoff is complete. In the example shown above signoff is complete so the **Send** button is lit and accessible.

A letter can be deleted by clicking the icon in the **Delete** column for that letter. Additionally, the letter can be routed for further signoff by clicking the **Route Signoff** icon. It can also be copied.

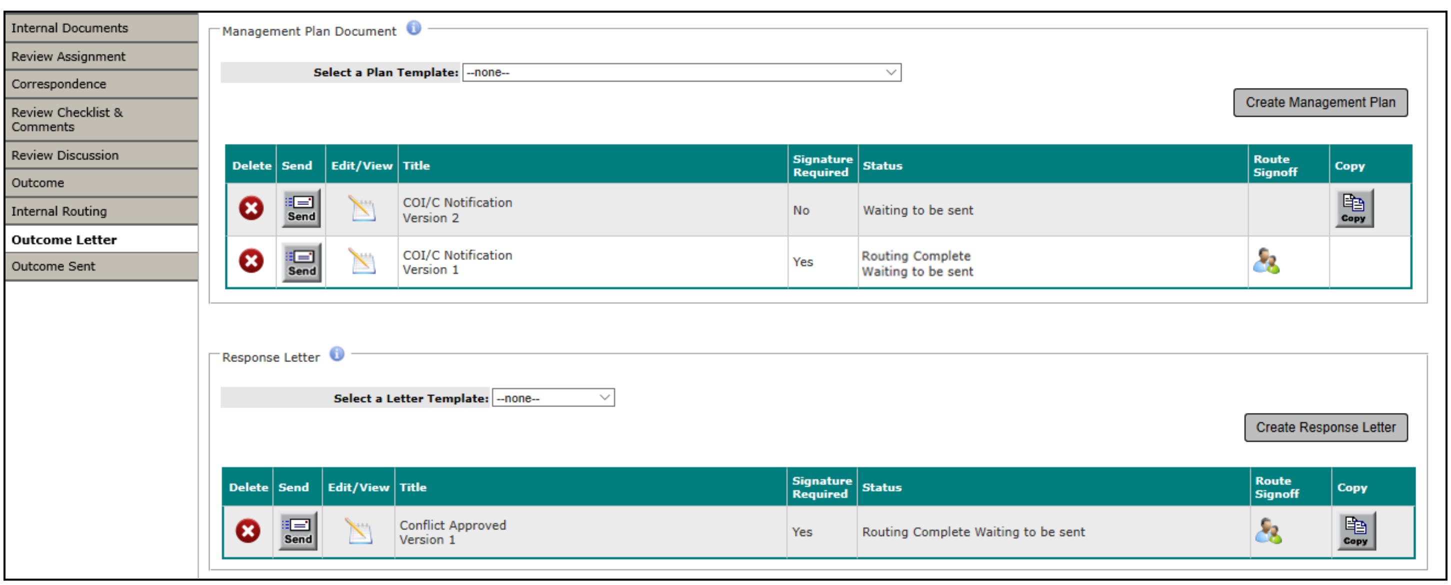
When a letter is copied it defaults to require no signatures for signoff, so any desired routing must be manually added. In addition, the **Send** button is lit and accessible for the copy and its status is set to **Waiting to be Sent**.



You can also generate an Outcome Letter using the dropdown menu in the **Response Letter** area of the Outcome Letter tab. The templates available in the **Select a Letter Template** dropdown list are configured within Review Board Administration > System Setup > Setup Outcome Letter Templates.



Outcome Letters are generated the same way that the Management Plan Document is created and can also be routed for signatures.

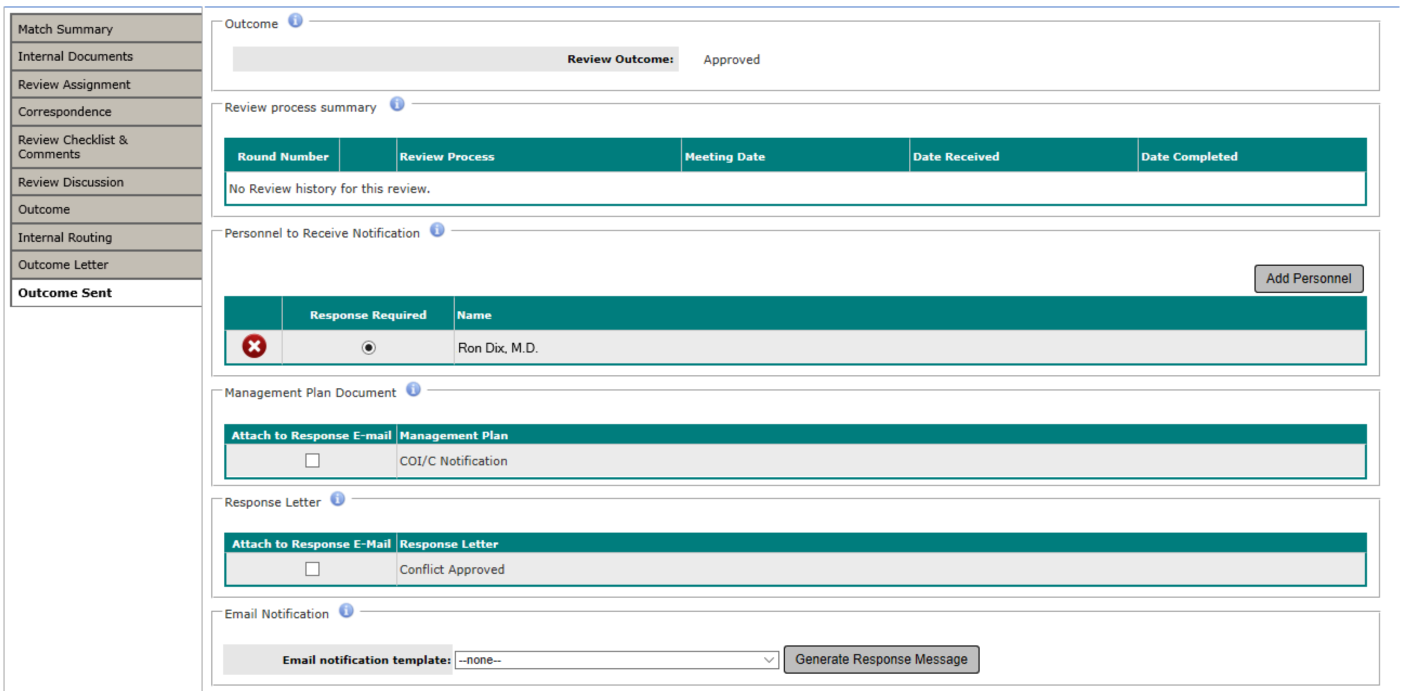


You can send the Management Plans and letters from this screen, or you can bundle these items when you send the Management Strategies to the Covered Person in the next tab.

Note: If you send the Management Plan Document and Outcome Letter from this screen you will not be able to include them in the bundle, this is an either-or selection.

Outcome Sent

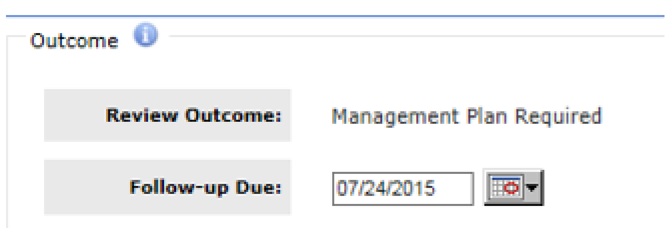
Once you have completed the review process for the conflict match, you will need to use the **Outcome Sent** tab to send the Management Plan and any other letters to the Covered Person along with any Management Strategies.



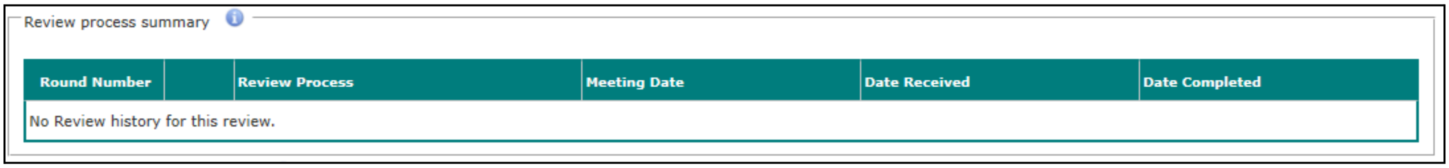
The Outcome you selected on the **Outcome Letter** tab displays in the **Outcome** section at the top of the page.

If the **Outcome** does not require a management plan no **Follow-up Due** date field will appear in the **Outcome** section, as shown in the previous screenshot.

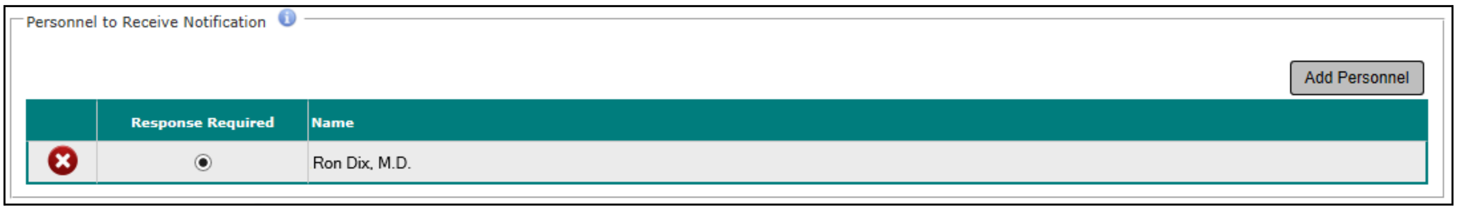
If the **Outcome** requires a management plan a **Follow-up Due** date field will be added to the **Outcome** section, as shown below.



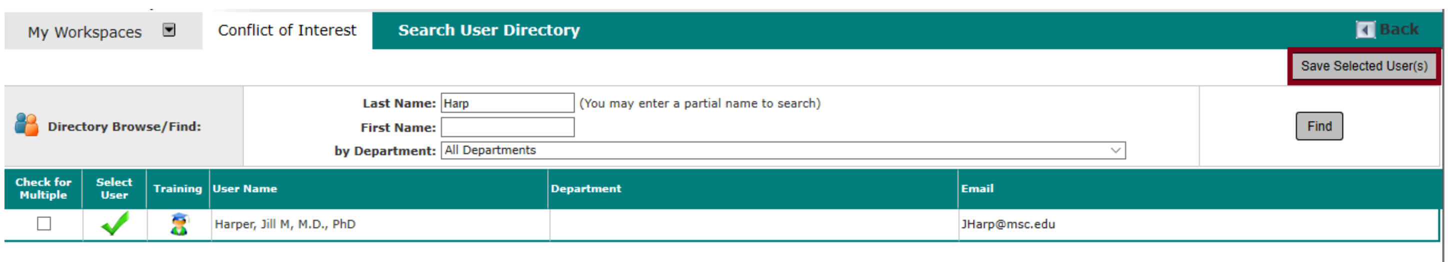
The **Review process summary** table section is next, beneath the **Outcome** section. If this is the first round for the conflict match, this table will not populate with any information. Later, if you determine it needs to be reviewed again after a response to management strategies is received. this table will populate with information from the previous round.



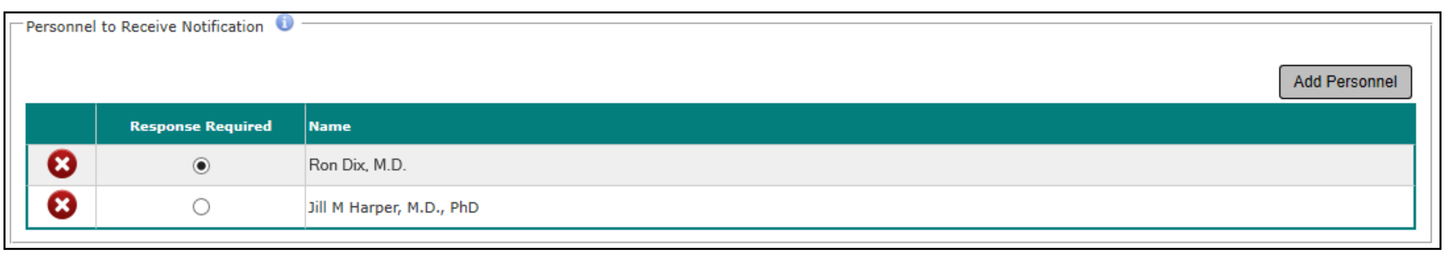
The **Personnel to Receive Notification** section is next, beneath the **Review process summary** section. Here, you can specify a user or users who will receive the management plan or outcome letter. The system will auto-populate the Covered Person and flag them as "Response Required" if the outcome is to send a Management Plan. If the outcome is approved, the Covered Person will default as the primary recipient.



Click the **Add Personnel** button to add more recipients for the Management Plan Letter and/or Outcome Letter. The **Search User Directory** screen will open, allowing you to search the iRIS database for a user to add. Search and find the user, and then click the **Select User** icon (green checkmark in the Select User column).



Back on the **Outcome Sent** tab, the user will be added to the table of **Personnel to Receive Notification** section.

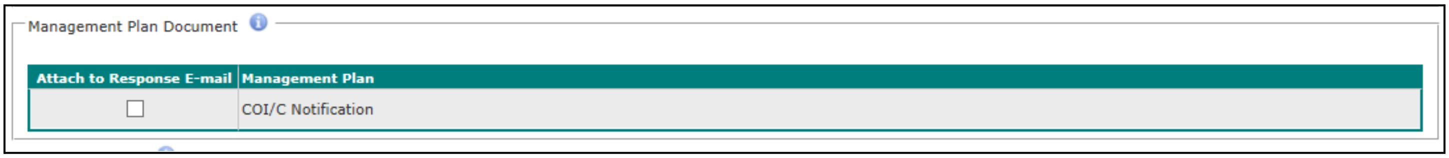


You can select more than one user to receive the letter when you save the Outcome Sent tab, but you only indicate that a response is *required* from one user. This means that the system will create a task on the user's home screen allowing them to respond to the management plan.

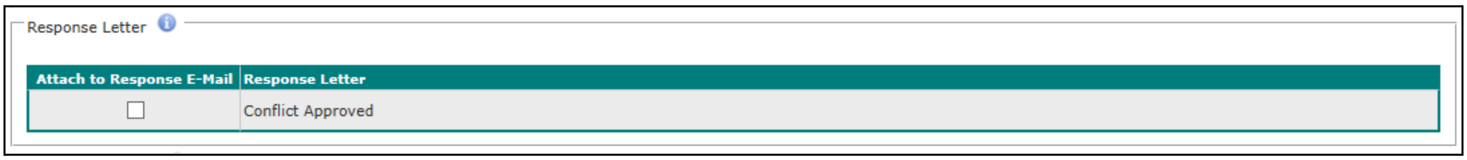
Any other user listed here will receive a notification from the system, but not a task. You would typically indicate that the response is required of the Covered Person.

You can remove a user from the table by clicking the **Delete** icon in the far left column.

Any Management Plan Documents created in the **Outcome Letter** tab will populate in the **Management Plan Document** area. Click the **Attach to Response E-Mail** checkbox next to the document to include it in the response.



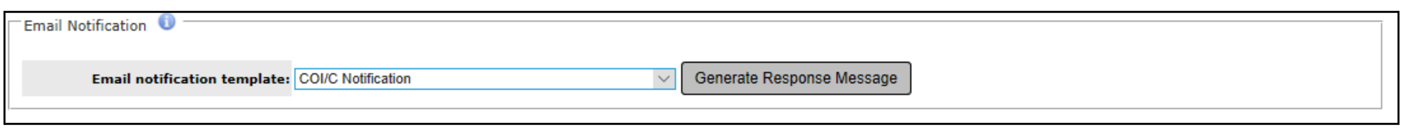
Any Response Letters created in the Outcome Letter tab will populate in the Response Letter area. Click the **Attach to Response E-Mail** checkbox next to the document to include it in the response.



If you have already sent the Management Plan or Outcome Letter from the Management Plan and Outcome Letter tab you will not be able to attach it to the response back to the Covered Person.

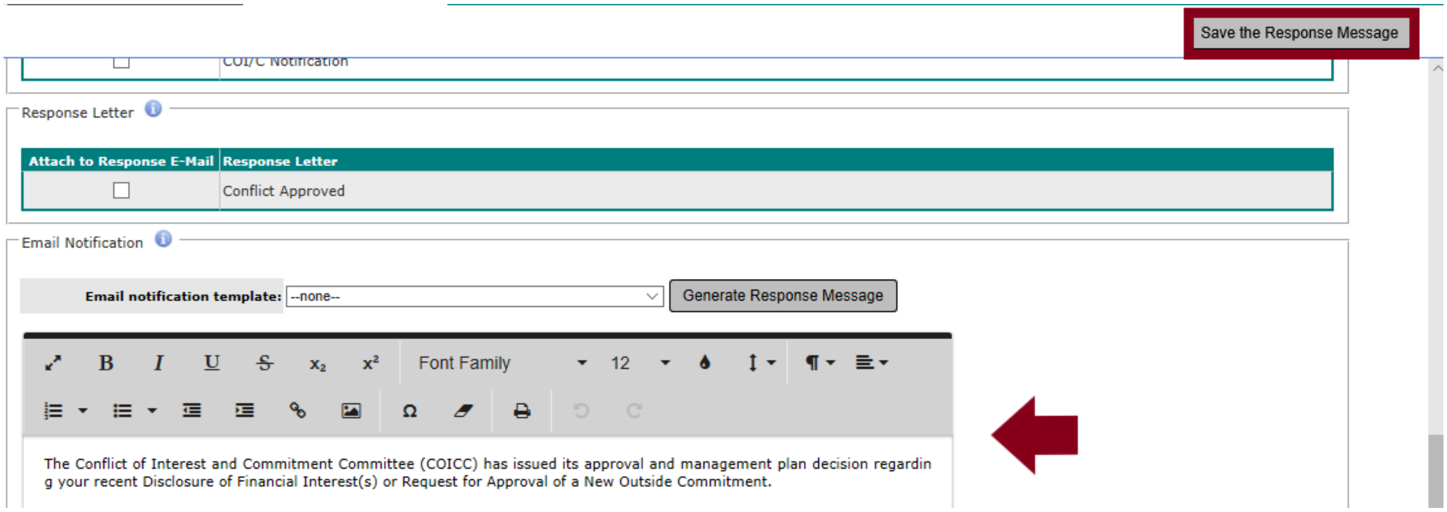
The last section on the **Outcome Sent** tab is **Email Notification**. Select a template from the **Email notification template** dropdown list.

The templates in this dropdown list are configurable and are set up under Review Board Administration > Review Board Notification Setup > Response Notifications. There is no limit to the number of templates that can be added, but only one can be selected to generate a response message for each match.

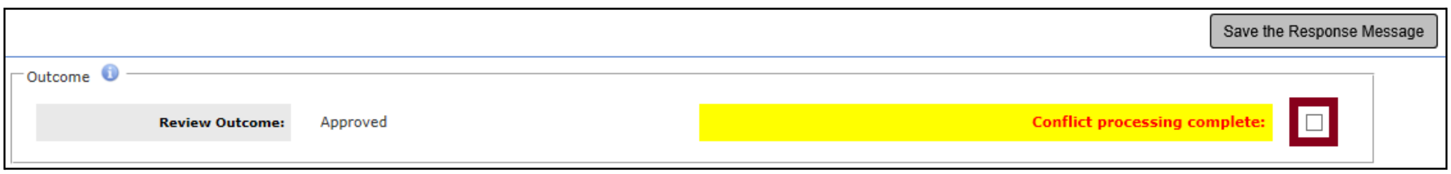


After selecting a template from the list, click the **Generate Response Message** button. The rich text editor opens, containing the contents of the selected template. This template can contain merge codes that will pull in information related to the specific match you are processing.

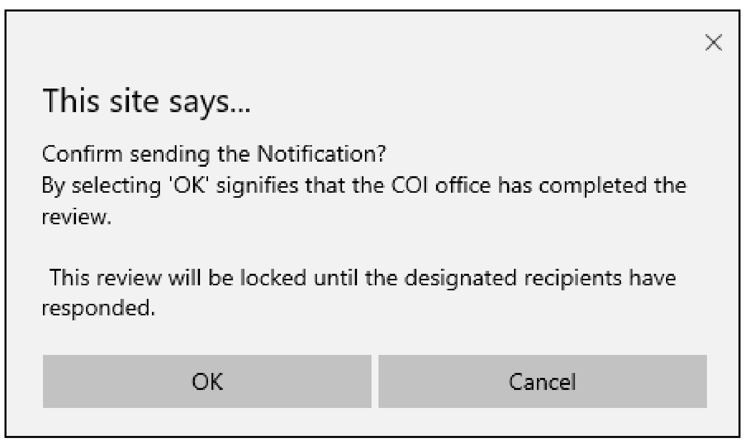
The text pulled in with the template can be modified as desired in the text editor.



When any changes to the notification are complete, click the **Save the Response Message** button at the upper right of the screen. The response can now be completed back in the **Outcome** section at the top of the Outcome Sent tab.



A confirmation prompt message dialog will appear.



Click **OK** to send the response. Click **Cancel** to return to the Outcome Sent tab without sending the response.

The system will attach any Management Strategies and the Outcome Letter to the email template you generated. The email will be sent to anyone you selected in the **Personnel to Receive Notification** table.

The conflict match will become locked and you will no longer be able to edit it.

If you indicated that a management plan is required in the Outcome tab, a new Management Plan Response tab will populate beneath the Outcome Sent tab (see next section).

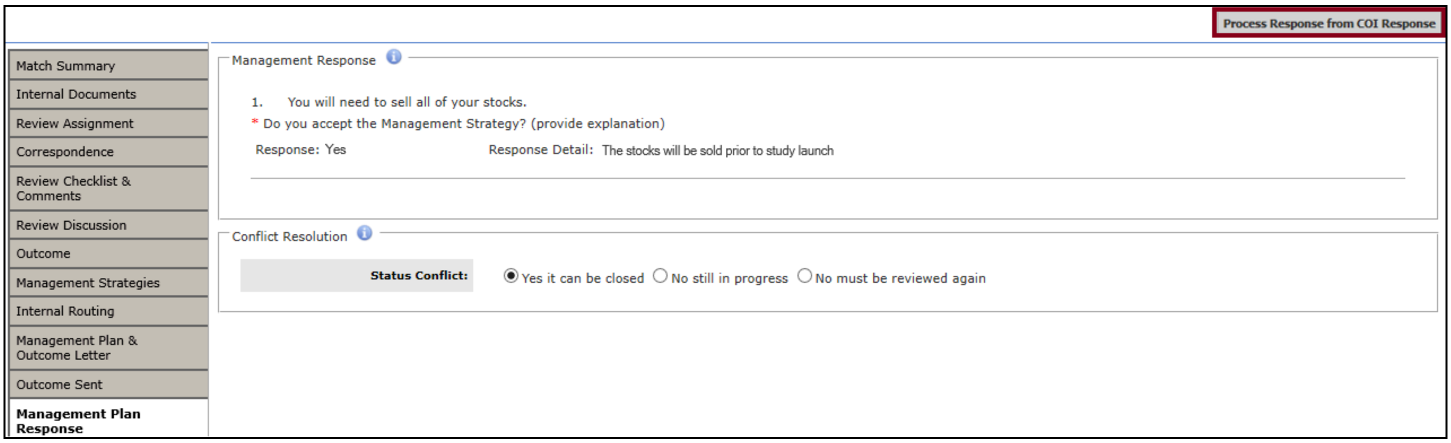
If the conflict match is approved, the screens will be read-only and the review is complete in iRIS™.

Note: In some cases, you will be able to undo the completion of the conflict match: if the match is assigned to a full board review and the meeting minutes for that meeting date have not been finalized, or if the conflict match has been processed Expedited or Administratively Processed, you will be able to uncheck the **Conflict Processing complete** checkbox. Setting the match back to an editable state should only be used for certain cases, as when you complete the process, the letters and response message will bundle to the selected recipients again.

Management Plan Response

When the Covered Person has replied to the Management Plan Response, the assigned Analyst will receive a Conflict Response Complete task on their home screen.

Opening this task opens the **Management Plan Response** tab for the conflict match.



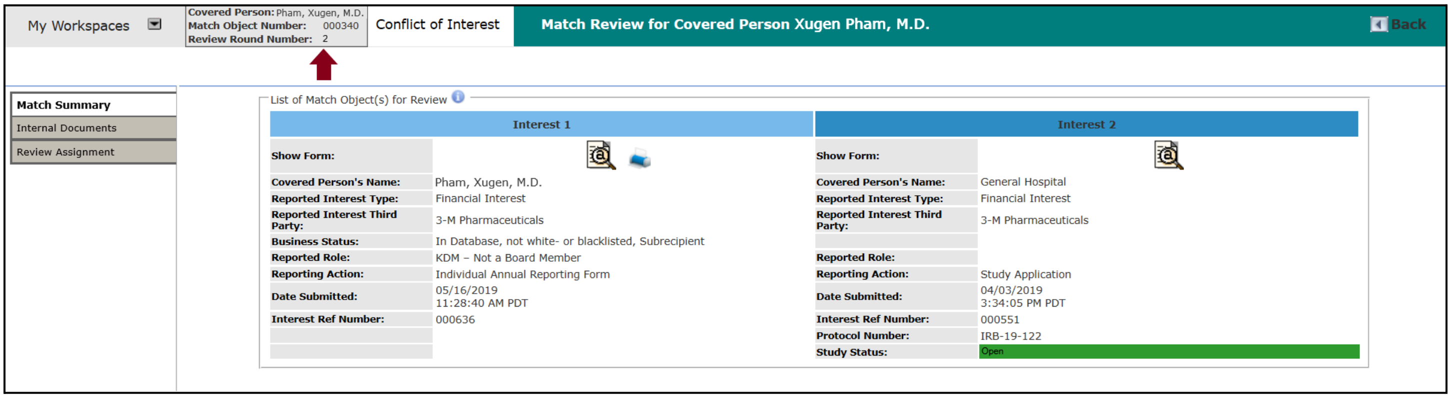
This screen will summarize the response from the Covered Person in the Management Response table. Any Management Strategies will be listed out, along with how the Covered Person responded to each strategy and any details provided.

After reviewing the Covered Person's response, you can specify how to further process the match review. Specify this process in the Conflict Resolution table. If the response from the Covered Person is satisfactory, select the first radio button, "Yes it can be closed." If you need more time to review the response, leave the selection for "No still in progress". If you need to further process the conflict match, select the "No must be reviewed again" selection. After you make your selection, you must click the **Process Response from COI Response** button.

If your status the conflict to be closed, the system will close out the processing for this match review. No further action is necessary.

If you leave the status to still in progress, the processing will stay with the Management Plan Response tab until you status the conflict differently.

If you indicate that the status must be reviewed again the system will reopen a new round of reviews for the conflict match. The system will direct you to the Match Summary tab of a new review round, or you will be able to find the match review on the Assigned Tab by looking up the Reference Number.



When you open the match review, it will open to the Match Summary tab.

At the top of the screen, the Review **Round Number** reads 2, meaning this is the second round of review for this Conflict Match.

You can further process the match review as needed by going to the Review Assignment tab and assigning a review process and reviewers if needed.

In that case, processing continues from here as with the first round of review.