Conflict of Interest Assistant

Review Board Administration

Version 11.02

Contents

COI Assistant – Review Board Administration

Introduction

Within Review Board Administration, you can set up configuration lists, define Outcome Letter and Management Plan templates, define Meeting Agenda and Minutes templates, and set up automatic review board notifications. Due to this high level of control, the Review Board Administration section of the Conflict of Interest Assistant module is typically reserved for review board administrators.

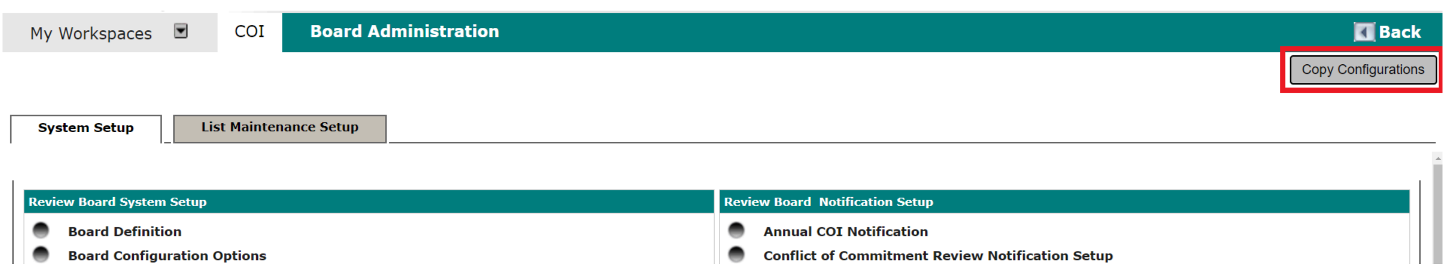
System Setup

The first section of Review Board Administration is the System Setup tab. This section allows review board administrators to manage the general setup for the COI Assistant module. As a review board administrator, you can define review board details, set up review board roles, and define board member access in iRIS. You can also create the templates for Outcome Letters, Management Plans, Minutes, and Agendas, as well as set up your institution's annual COI Due Date and change labels within the COI module.

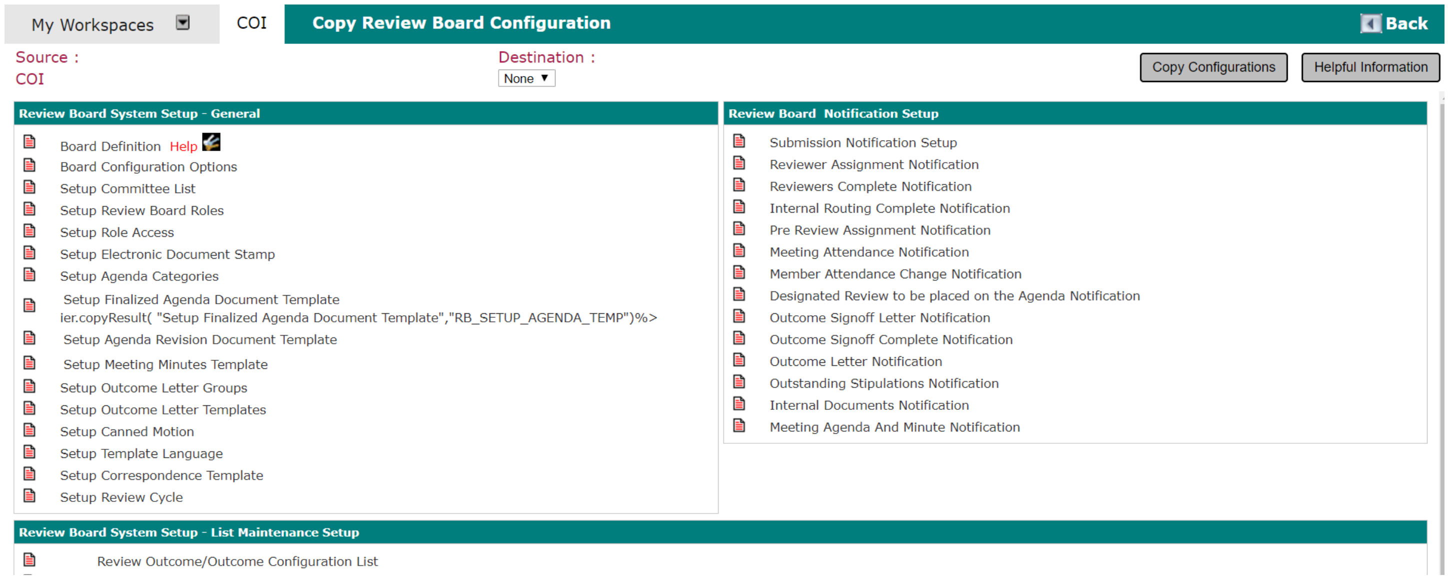
Copy Configurations

*Prior to reviewing the Copy Configurations section of Review Board Administration, note that Copy Configurations is a tool designed to assist with the initial setup of iRIS. It is not recommended that this tool be used once your organization's Review Boards have been set up in IRIS, or once your system has gone live. Also, this tool must be used in conjunction with other COI review boards to secure optimal functionality.

You can copy configurations by clicking on the **Copy Configurations** button, as long as the Review Boards are of the same type (e.g., COI to COI, IRB to IRB, or IACUC to IACUC). Please note that configurations cannot be copied from review boards that are of different types (e.g., COI to IRB or IRB to IACUC); configurations can only be copied to review boards that are of the same type.



Click on the **Copy Configurations** button to get started.

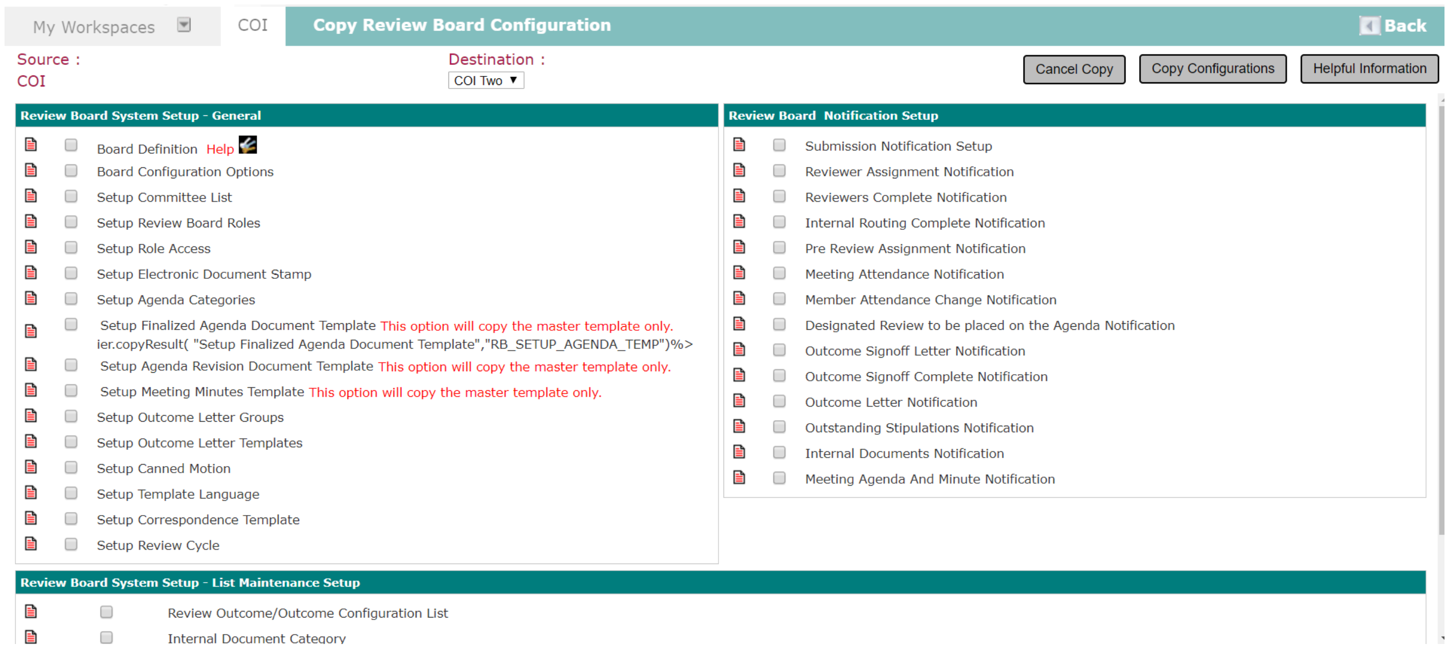


A new screen will open, displaying all available configurations that can be copied to another review board.

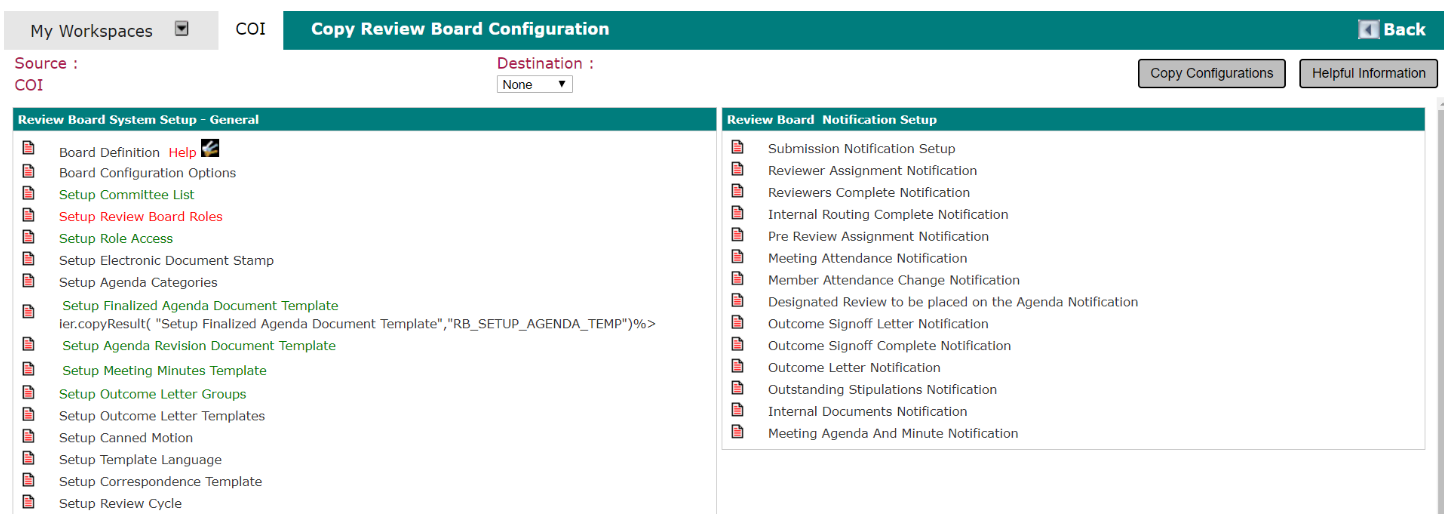
At the top-left corner of the page, the Source is listed. The source indicates the review board you are currently in. You will need to select a copy-destination review board from the Destination drop-down list. Only review boards of the same type will populate in the Destination drop-down list. When a destination is selected, checkboxes will populate next to each configuration option, allowing you to select the configurations you wish be copied to the selected destination.

*Note: certain configurations of the COI Review Board cannot be copied. These include:

- Setup Review Board Roles
- Setup Electronic Document Stamp
- Setup Management Plan
- Setup Correspondence Template
- Setup COI Annual Due
- Annual COI Form Label Configuration List
- Annual COI Notification
- Conflict of Commitment Reviewer Notification Setup
- New Study/Project Conflict of Interest Notifications Setup
- Management Plan Notification
- Study Status Configuration List
- Configure COI Lists



Select the checkboxes next to the configuration items you wish to copy to your destination review board. If you do not wish to proceed, click the **Cancel Copy** button to return to the Review Board Administration list. To proceed with the copy, click the **Copy Configuration** button.



As shown above, the screen will refresh and update. Any items successfully copied will be color-coded green, and items that did not copy successfully will be color-coded red. An item will not copy over if there is no data to copy, or if the corresponding field is not turned on in the destination review board.

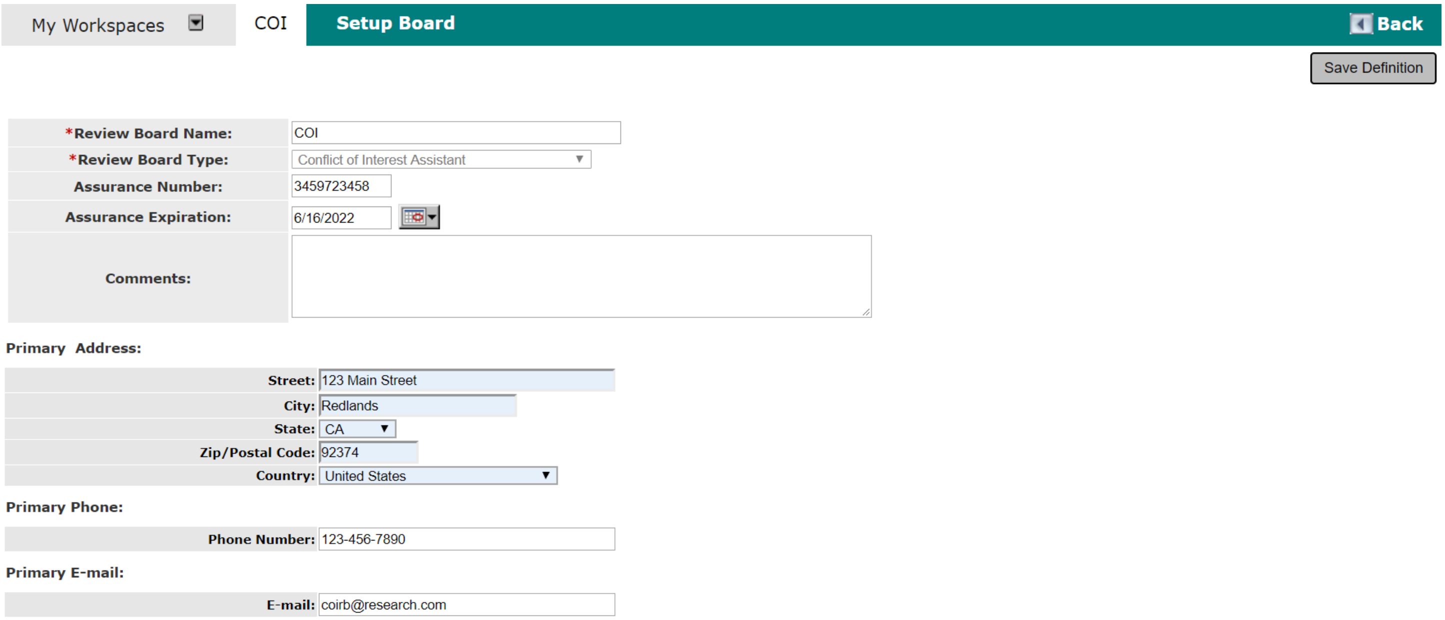
Note: When performing a review board configuration copy from one board to another, fields that were originally pre-populated in the destination board will be overwritten with the copied source board's data.

Good practices for successful board configuration copying:

- Have each item in the source review board completely configured so you will only need to copy one time.
- iMedRIS recommends performing a board configuration copy function only once to a destination review board.

Board Definition

The first item in the Review Board System Setup list is Board Definition.

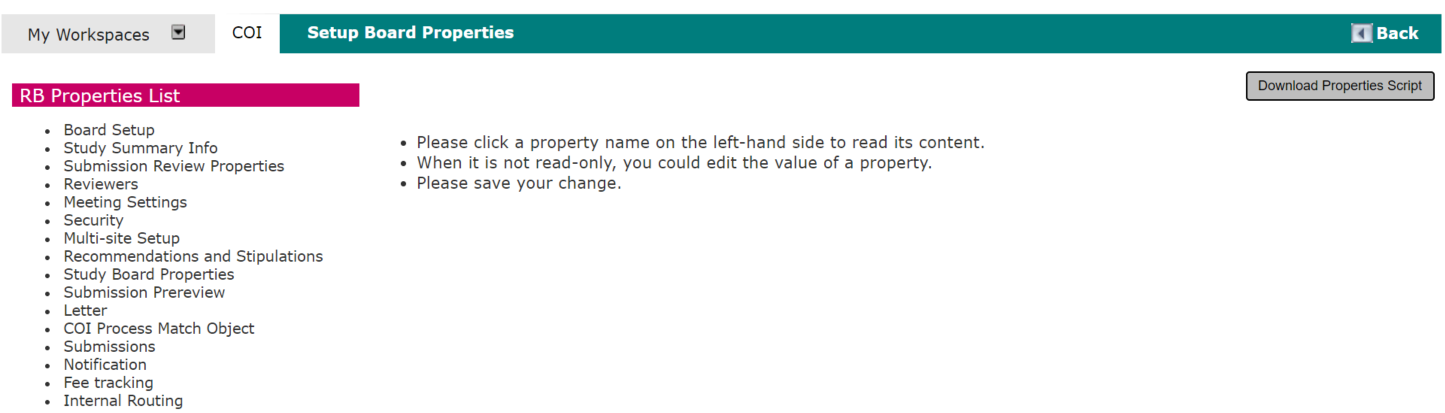


This page allows you to specify details regarding the review board. There are two required information fields: **Review Board Name** and **Review Board Type**. The **Review Board Type** is a list of predefined board types as specified in your contract with iMedRIS Data Corporation. The drop-down list will be disabled on this page, as the review board type has already been pre-defined in System Administration.

Fill in or change the information you need to update, then click the **Save Definition** button on the top right of the page. Click the **Back** button when you are done to return to the Copy Configuration page.

Board Configuration Options

The second item in the Review Board's System Setup list is Board Configuration Options. This page lists the properties that the Administrator can set within the Review Board module. Before changing these properties, it is a good idea to determine the property settings that will best align with your organization's preferences, and, when in doubt, it is a good idea to verify your needed changes with iMedRIS personnel.



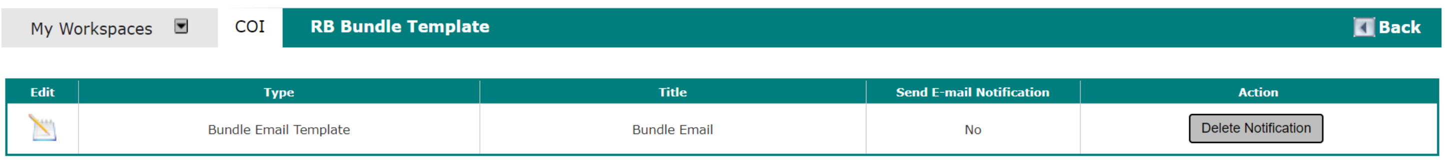
The Review Board properties are organized into categories, displayed on the left panel of the screen. To view the properties in a category, simply click on the category in the left panel and all the properties related to that category will appear in the rest of the screen. Yes/No radio buttons indicate that the properties can be set "on" or "off" and a property with any other value indicates that the property is a variable.

See the COI Assistant - Properties manual for more information on each individual property.

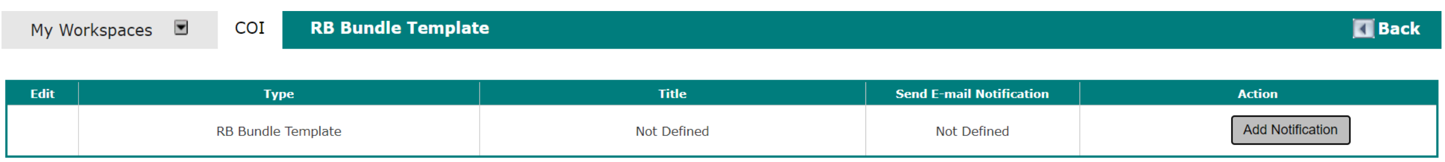
You can use the **Download Properties Script** button to download a SQL script containing the configurations for the review board properties, which can be used to import the configurations into another iRIS system.

Setup Bundle Email Template

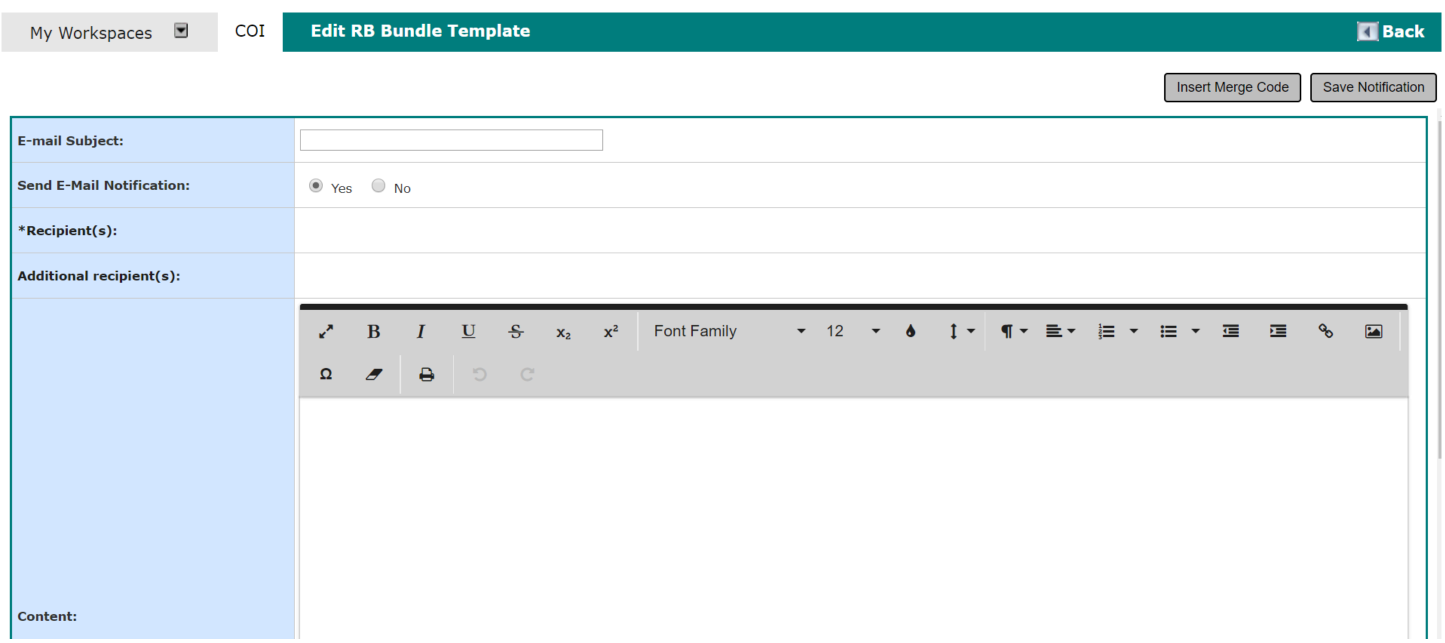
This option allows you to create an email template to be included with bundle emails sent from the Submission Complete tab of the submission processing screens. Clicking this link will open the RB Bundle Template screen, where you can click the icon to open and edit the template. You can click **Delete Notification** to delete the existing template.



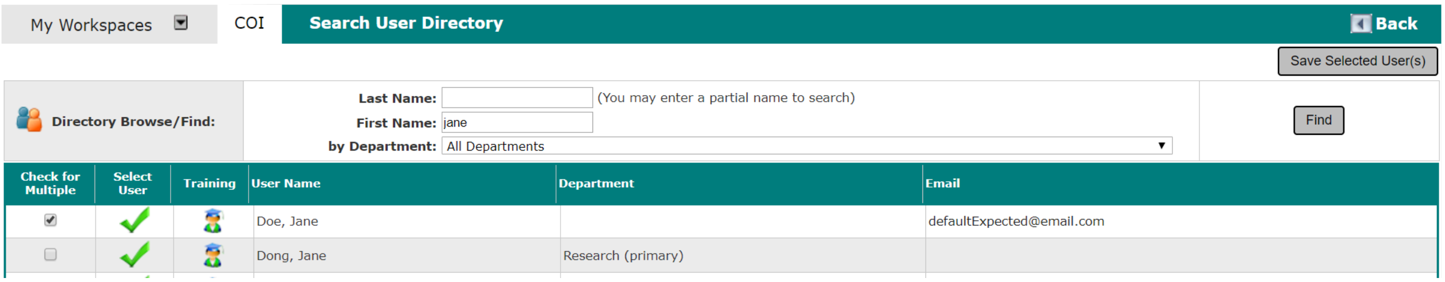
If no template has been added, click **Add Notification**.



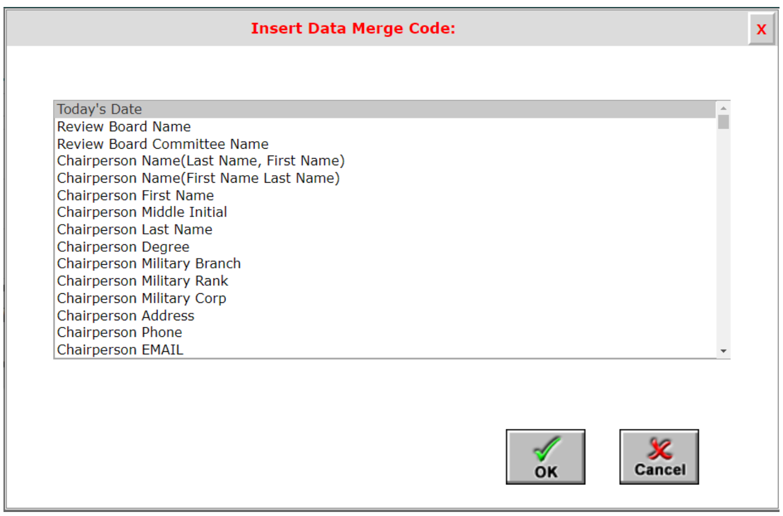
When editing the bundle email template, first, enter a subject in the E-mail Subject field. You can use the Send E-Mail Notification flag to determine whether an email will be sent along with the notification.



Click the **Recipient(s)** link to open a screen where you can search for users in your iRIS system to whom you can send the email or click **Additional recipient(s)** to add non-iRIS users and their email addresses. To delete a recipient, check the box next to their name and click **Delete**.

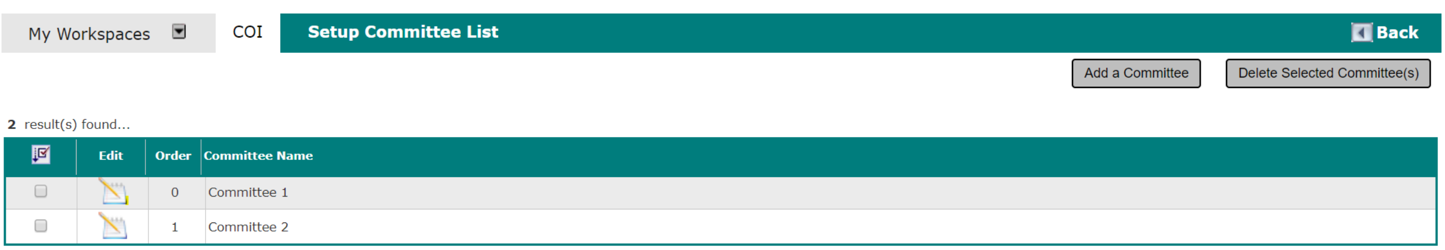


Enter email content in the Content field, and enter merge codes, if desired, by clicking the **Insert Merge Code** button. Click **Save Notification** to save your changes.



Setup Committee List

Committee Setup lists the current committees for the review board and allows you to delete or edit these committees. New committees can be added here as well.



Opening the Committee List page will display a list of current committees in your review board. This is a list of the committees only. Access to committees is defined in a user's account.

Most systems are not set up for Committee Submissions; rather, all matches arrive in the review board's Matched Objects Queue, where all committees are included. If your review board is set up for Committee Submissions (when property *rb.use_submission_by_committee* is set to "Yes"), the system will be set up to route conflict matches to individual committees and not to the review board as a whole. At this point, the committees found in the Committee

Setup list are the committees you can route the COI match to. When your review board is setup for Committee Submissions, members of one committee will not be able to access matches that were not sent specifically to their committee.

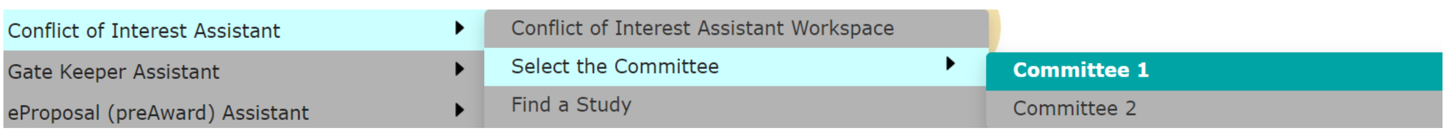
When processing a match, the match is placed on the appropriate committee's meeting date. Each committee will have its own set of meeting dates.

Committees can be added and removed and renamed from the Committee Setup area. To delete a committee, select the checkbox next to the committee name, and then click on the **Delete Selected Committee(s)** button.

To rename a committee, click on the **Edit** icon next to the committee name.

A new page will open. You can modify the name of the committee by changing its Description. Click the **Save Committee** button to save your changes. The changes will display in the list of committees.

Adding a committee is a similar process. Click the **Add a Committee** button, enter the committee name in the Description, and then click the **Save Committee** button.



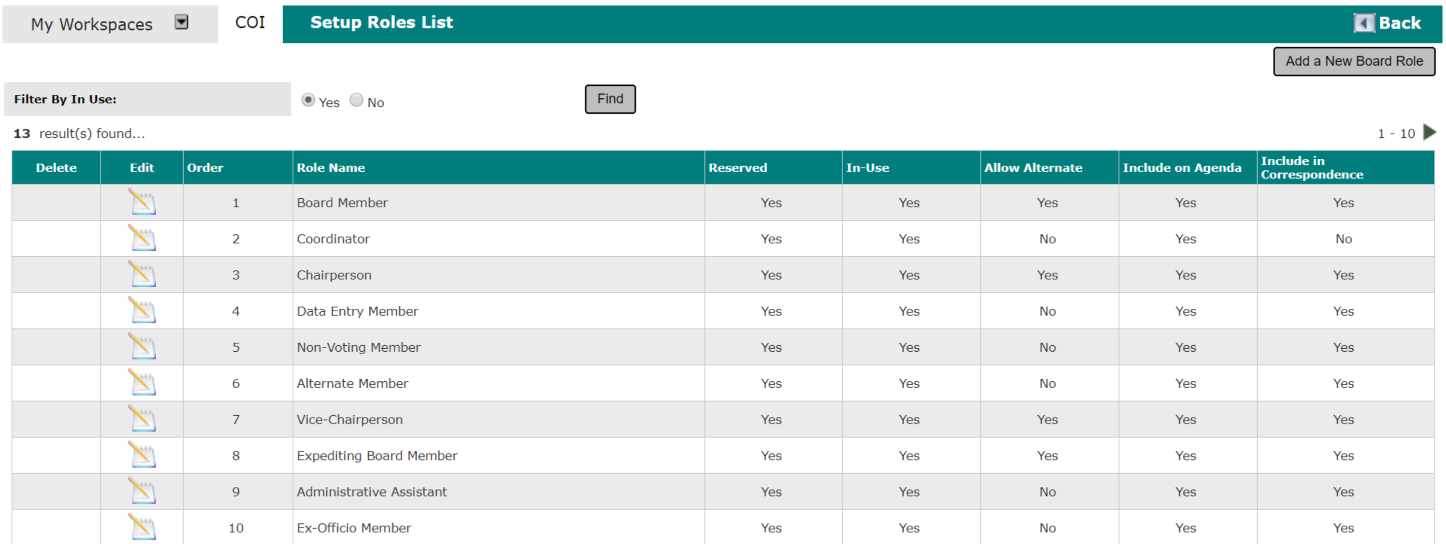
If your account has been assigned to more than one committee within the review board, you will be able to flip between committees by selecting a committee from the review board assistant menu.

Flipping to a certain committee will show you details for that particular committee when you click on certain screens in the review board assistant menu – Meeting Agenda, Meeting Minutes, and Meeting Manager will only display information for the committee you are currently in.

If your system is set up with Committee Submissions, the Conflict Matches queue will only contain matches sent to the committee in which you are currently logged in.

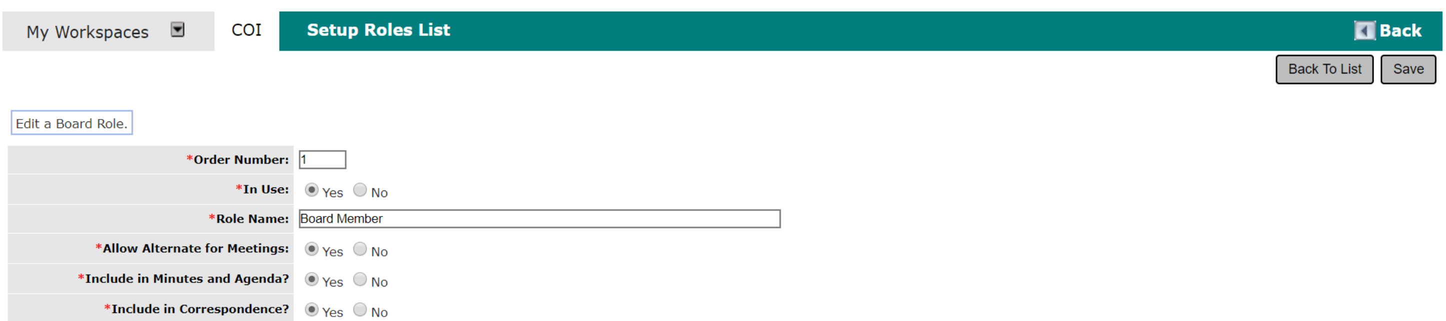
Setup Review Board Roles

The COI review board will be preset with review board roles that you can associate to review board members. These roles are listed in the Setup Review Board Roles section. From here, you can rename existing review board roles or add new roles. Each role you define in this list can be given permissions in Setup Role Access, where access to certain screens can be provided.



Delete	Edit	Order	Role Name	Reserved	In-Use	Allow Alternate	Include on Agenda	Include in Correspondence
		1	Board Member	Yes	Yes	Yes	Yes	Yes
		2	Coordinator	Yes	Yes	No	Yes	No
		3	Chairperson	Yes	Yes	Yes	Yes	Yes
		4	Data Entry Member	Yes	Yes	No	Yes	Yes
		5	Non-Voting Member	Yes	Yes	No	Yes	Yes
		6	Alternate Member	Yes	Yes	No	Yes	Yes
		7	Vice-Chairperson	Yes	Yes	Yes	Yes	Yes
		8	Expediting Board Member	Yes	Yes	Yes	Yes	Yes
		9	Administrative Assistant	Yes	Yes	No	Yes	Yes
		10	Ex-Officio Member	Yes	Yes	No	Yes	Yes

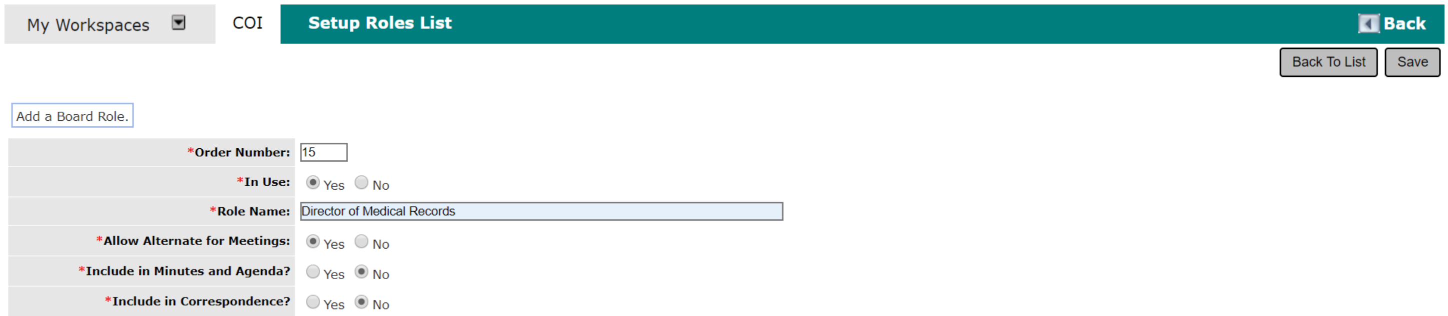
Opening the page will provide a list of all available roles for your organization's review board. These are iRIS predefined review board roles, which you can rename if needed; however, you cannot delete any of the predefined roles. The predefined iRIS roles are identifiable with "Yes" in the "Reserved" column and they will not contain a delete icon next to them. To change an existing role name or change the order in which they are displayed, click the **Edit** icon.



A new page will open. From here you can change the Order Number and Role Name. Also displayed are the **In Use**, **Allow Alternate for Meetings**, **Include in Minutes and Agenda,** and **Include in Correspondence** flags. Read more about these items below.

When you are finished making changes, click the **Save** button. To return to the list of roles without making changes, click on the **Back to List** button.

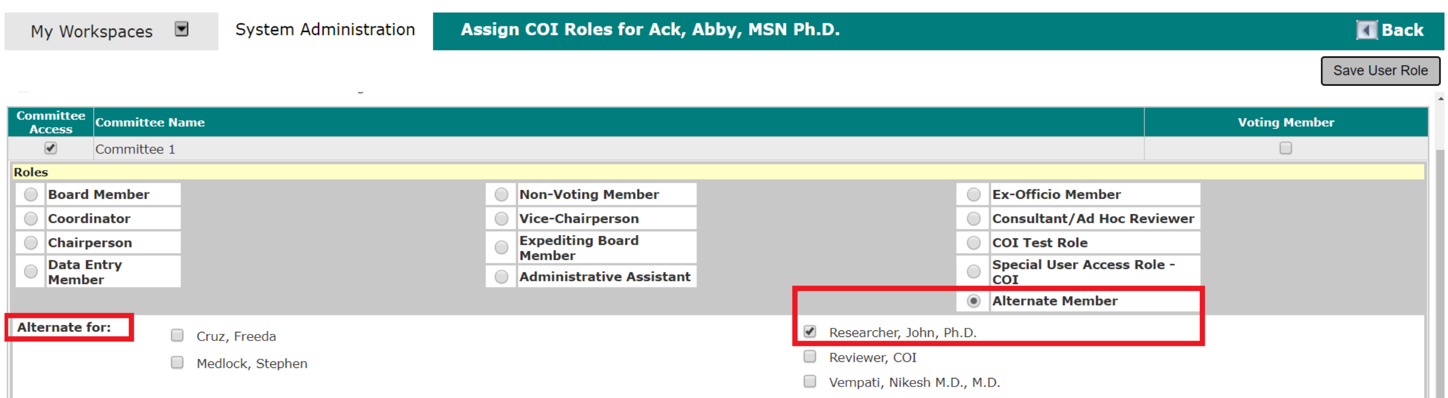
Adding a new role is a similar process. Click on the **Add a New Board Role** button.



Enter the Order Number and Role Name.

In Use - When adding a brand-new role to the review board, you will be able to specify if the role is in use or not in use. This tells the system whether to activate the role or not. If “In Use” is set to “Yes,” you will be able to assign a user to this role. If “In Use” is set to “No,” you won’t be able to assign this role to a user. The reason for this functionality is to discourage deleting a role that has been used and is already assigned to users. Rather than deleting the role, you can set the “In Use” option to “No,” leaving the history of this role intact in the system, but not allowing the role to be used moving forward. If a role that has been used in the past were to be deleted, links and historical records associated to that role would not display properly.

Allow Alternate for Meetings - Set this flag to “Yes” to allow members assigned this role to be assigned as an alternate at a meeting. Any user given the Alternate Member role or a role with this flag set to “Yes” will be included in the Alternate For list within Grant User Access & Define Roles, as shown in the screenshot below.

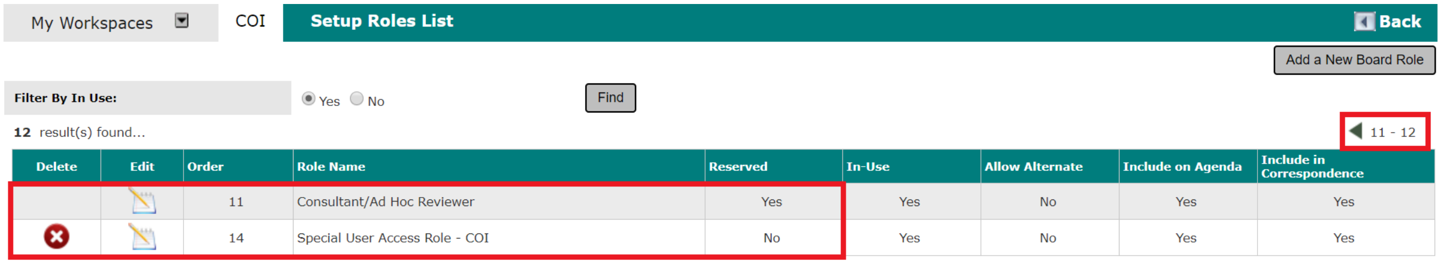


Include in Minutes and Agenda? – If this option is set to “Yes,” the user assigned this role will be selectable in the list of Attendees for a meeting date. If this is set to “No,” the user assigned this role will not display on the Meeting Attendance page. Note: Any role with this flag set to “No” will also not be included in notifications related to the meeting (i.e., Meeting Minutes and Agenda notifications, Meeting Attendance notifications).

Include in Correspondence? – If this option is selected, this role will be available in the list of roles to send correspondence to. If it is not selected, users will not be able to send correspondence to this role.

When you are finished adding the details, click on the **Save** button to save and to return to the previous screen.

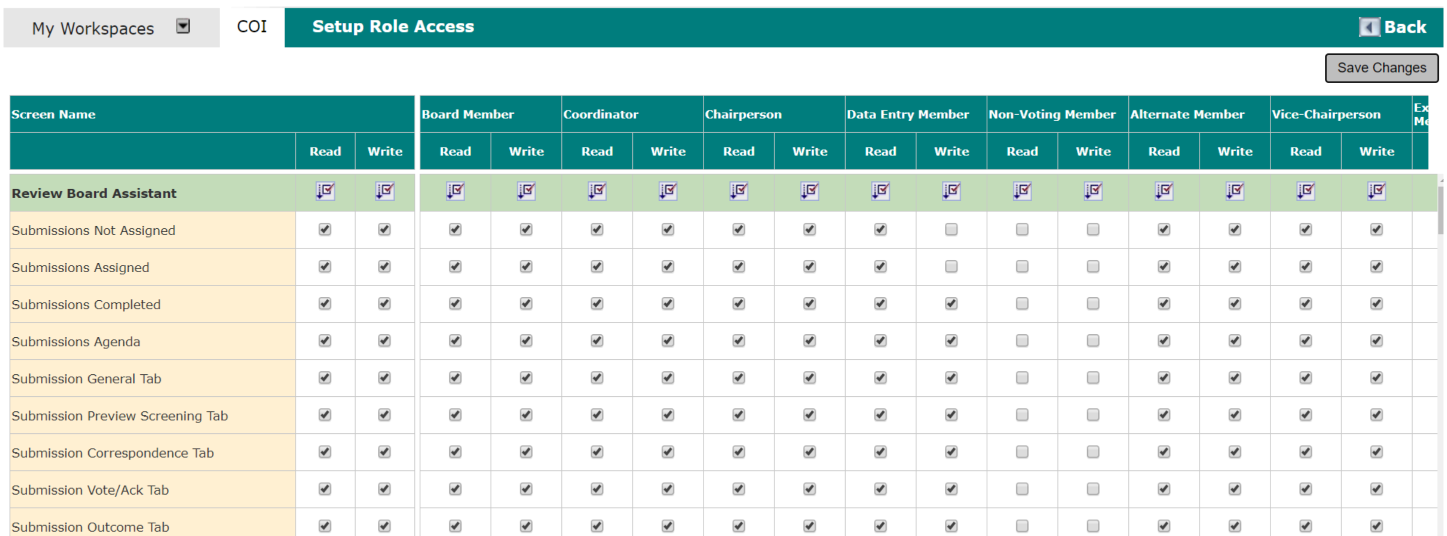
If there are more than ten roles in the list, you will need to use the page navigator, located at the top-right of the table. You can click on the green arrow adjoining the page navigator to view the next or previous page.



Outside of the pre-existing roles, custom roles will read “No” in the Reserved column and will have the red X icon in the Delete column.

Setup Role Access

The Define Role Access feature gives the system administrator the ability to assign review board members read-only access or full-writing privileges within certain iRIS screens.



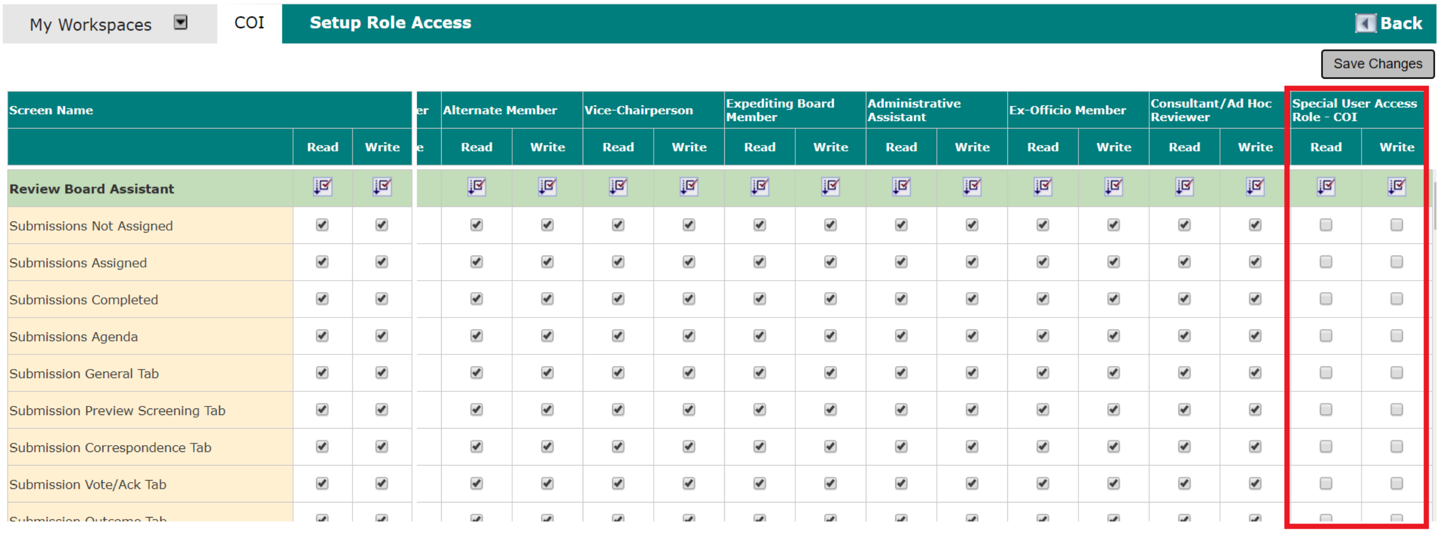
The above page lists all available iRIS screens on the left side of the matrix, while the column headers of the matrix display all review board roles. Within each role are two columns with optional checkboxes used to assign “Read” and “Write” privileges to each board member within each iRIS screen. If the Read and Write checkboxes are both selected, this means that the user has full access to that particular screen in the system, allowing the user to both view the page and update records on the page.

If “Read” is selected but “Write” is not selected, this means that the user has read-only privileges to that particular screen in the system – to view the page but not to modify records on the page.

You cannot give a user Write access to a page without Read access.

The first set of Read and Write columns are to turn on/off a screen in general. If you remove Read and Write access at this top level, none of the roles on the review board will have access to that screen. This is recommended for use if you do not want to see a particular screen within your system’s review board.

There are vertical and horizontal scroll bars available at the bottom and right of the screen, allowing you to navigate and view other roles and screens available listed on this page.

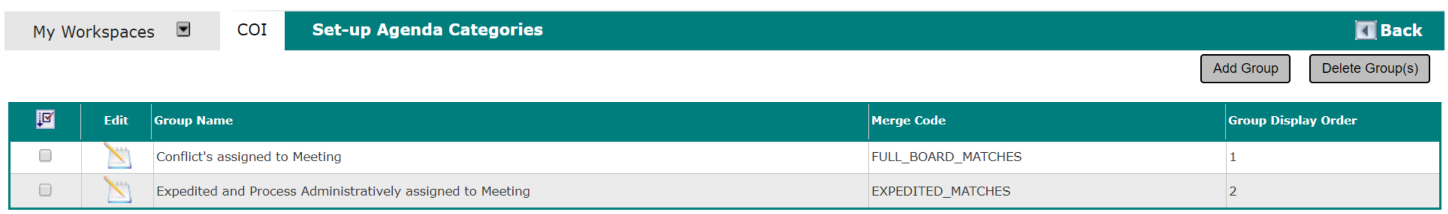


If you set up a new role in Setup Review Board Roles, you would also need to set up that new role's system access in the Role Matrix. Any roles added to Review Board Roles will populate with a column in the Role Matrix (at the end of the list's predefined roles). iRIS will default all Read and Write cells to be unchecked for new roles. You will need to review and set up the appropriate Read and Write access for the new roles.

After making any changes to this screen, be sure to click the **Save Changes** button to save your work.

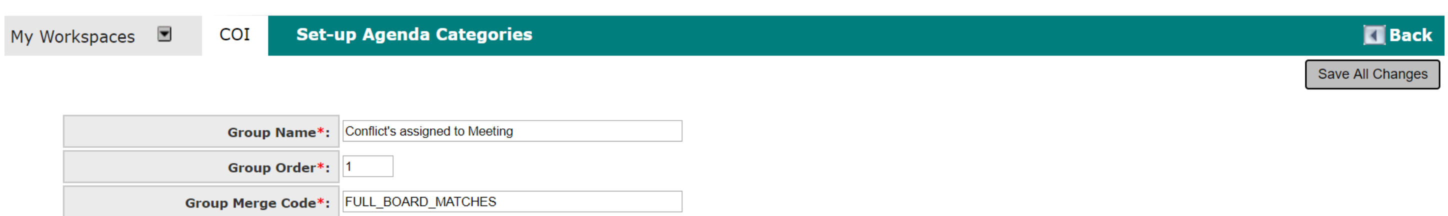
Setup Agenda Categories

This system functionality allows you to set up categories where conflict matches can be placed on your meeting agenda.



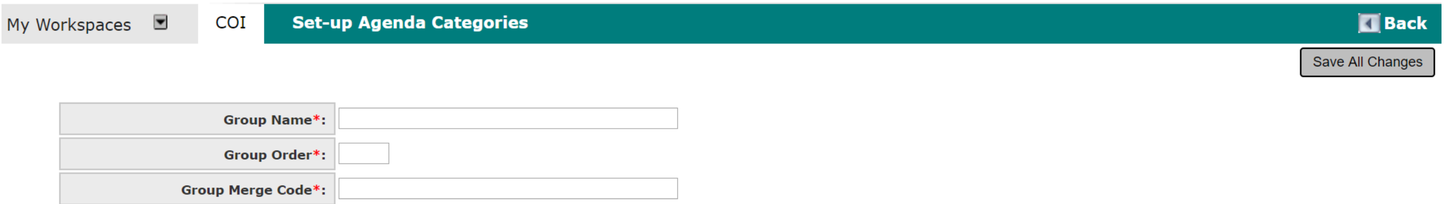
In the screenshot above, you will see that two groups have already been created in this example. To edit an existing group, click the icon in the **Edit** column.

From the next screen, you will be able to edit the Group Name, Group Order, and Group Merge Code. The Merge Code will be used when setting up your agenda template, which will be described further below.



When you are finished making edits, be sure to click the **Save All Changes** button.

To add a new agenda category, click the **Add Group** button. You will be prompted to enter a Group Name, Group Order, and Group Merge Code.

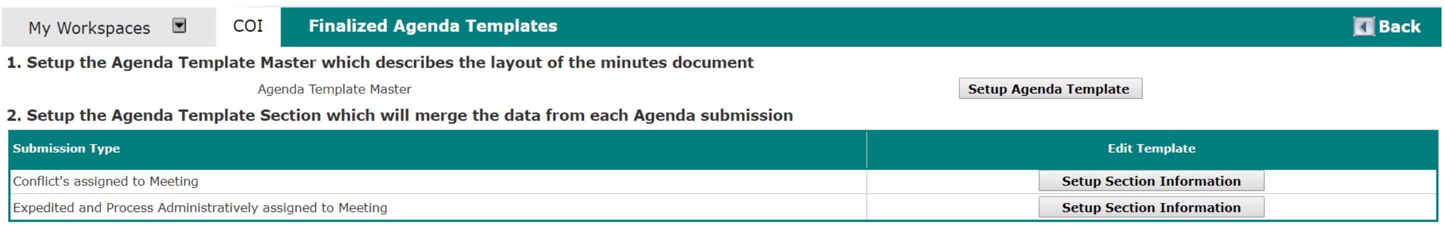


Click **Save All Changes** to preserve your edits and add the new agenda category to the list of records.

To delete an agenda category, check the box next to the record and click **Delete Group(s)**.

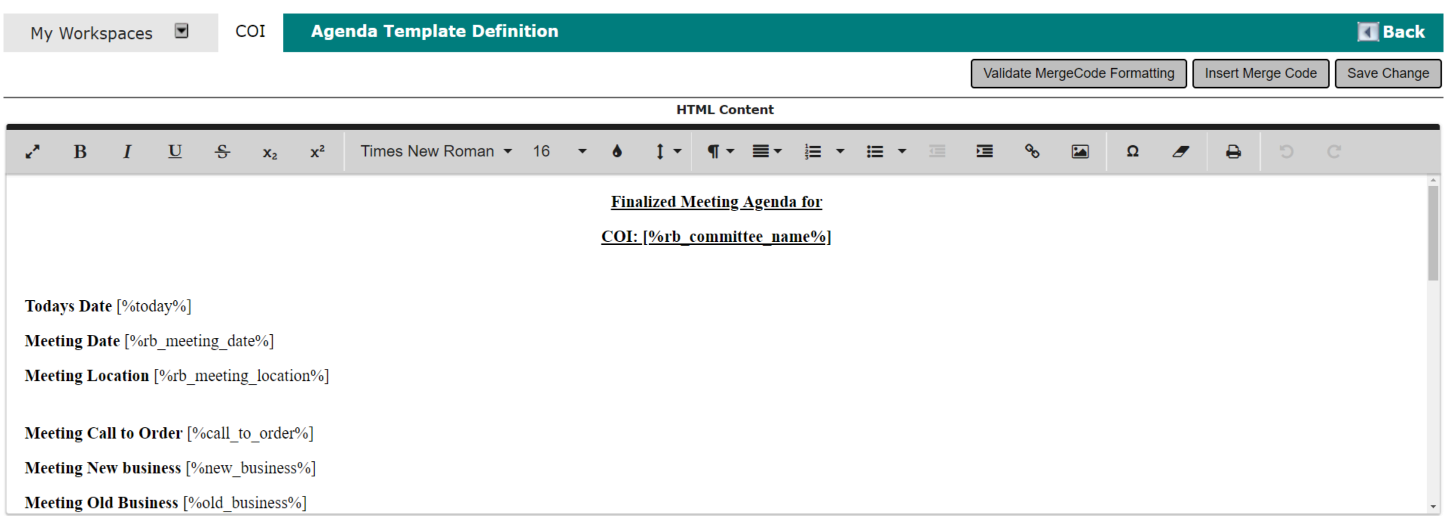
Setup Finalized Agenda Document Template

You can create a master template for your Meeting Agenda document. This template will store your meeting agenda outline with data merging features that will auto-populate specific information into the agenda when it is generated for a meeting. See documentation on the Meeting Manager for instructions on how to generate the agenda for a specific meeting.



The Finalized Agenda Templates screen displays the Agenda Template Master's outline. This screen depicts the general layout of an agenda's document and shows the different sections that can be added to your master agenda template (for Full Board Conflict Matches and Expedited/Administratively Processes Conflict Matches, or any other custom agenda categories you created). You can set up the master agenda template using the data merge sections available via the Setup Agenda Template button, from which you can select the desired data that is to be merged from individual Conflict Matches to the Master Agenda Template.

To begin, you will need to first define the content of the Agenda Template Master. Click on the **Setup Agenda Template** button.

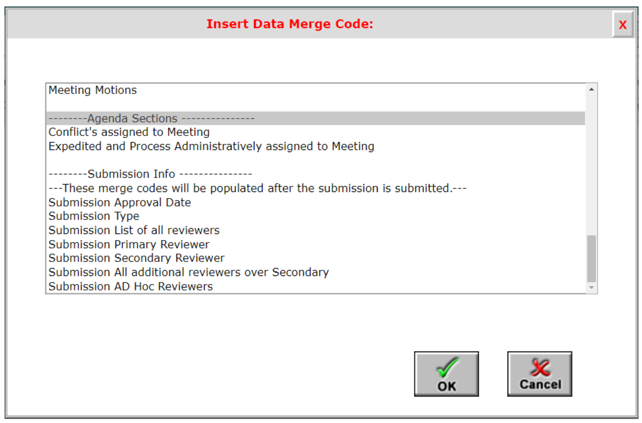


A new page will open, containing an embedded Word editing program. If the template master has already been created, it will be displayed similarly to the example in the above screenshot. If the master was not created, this is where it can be created using the features provided in the text editor and the available merge codes. To insert a merge code, first, insert your cursor where you would like the merge code to go. Then, click the **Insert Merge Code** button located at the top of the screen. A window will pop up listing the available merge codes. Highlight the merge code to insert and click the **OK** button.

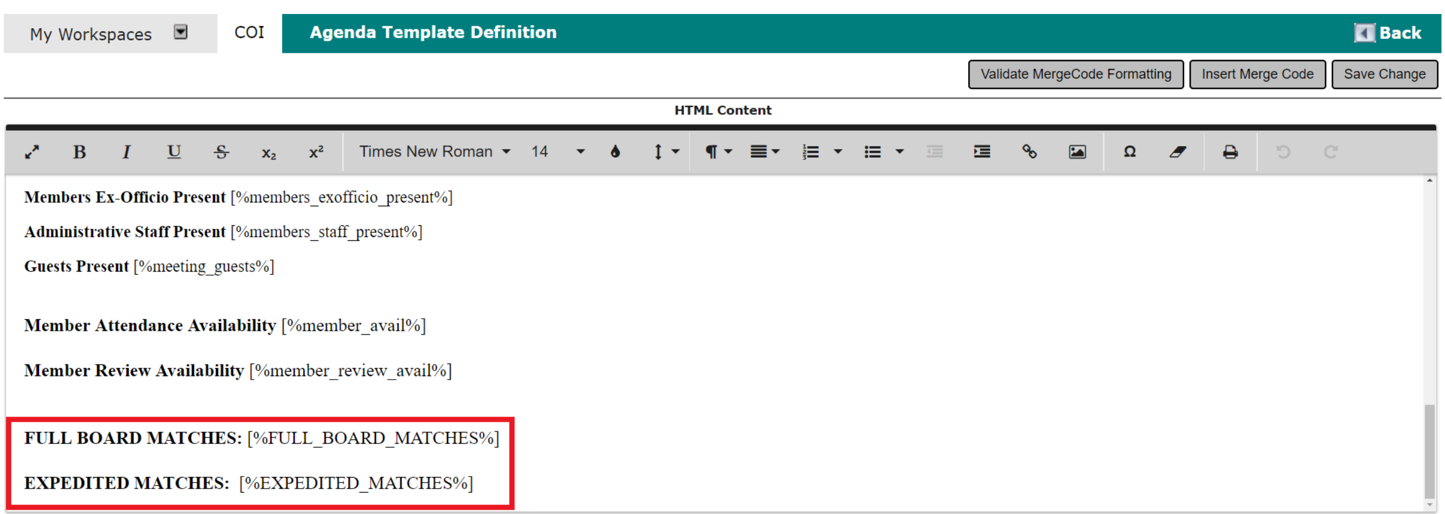
A merge code is a programmed label that will pull information into the document when the document is generated. When the Agenda is generated for a specific meeting date, the merge code %rb_meeting_date% will populate with the date of the meeting.

You can set up your Agenda template using the tools available in the Word editor and the list of merge codes.

The Agenda Sections merge codes, which you will find useful for your Agenda Template, are found towards the bottom of the list of merge codes.



These codes, "Conflicts Assigned to Meeting" and "Expedited and Process Administratively Assigned to Meeting," represent your agenda sections. You will use such merge codes to pull in specific information about the Conflict Matches up for review at a particular meeting. You must first add these merge codes to the master template, and then you will define the information that each merge code will pull into the document when setting up section information, which will be described further in this document.

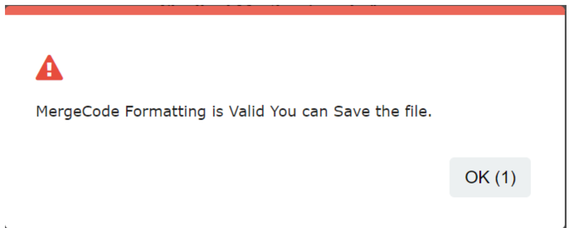


When finished editing or creating the template master, click on the **Save Changes** button, located at the top of the screen.

Validate Merge Code Formatting

Validate Merge Code Formatting is a functionality that allows you to test whether the merge codes in your template contain invalid RTF content that will prevent them from populating correctly in your documents. For example, if the text in part of a merge code, but not the entire merge code, is bolded, this is the type of error that Validate Merge Code Formatting will correct.

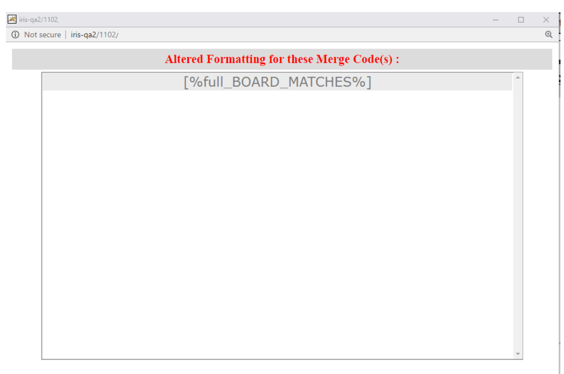
When you click Validate Merge Code Formatting, one of three things will occur. If all of the merge code formatting in your template is valid, you will see the following message:



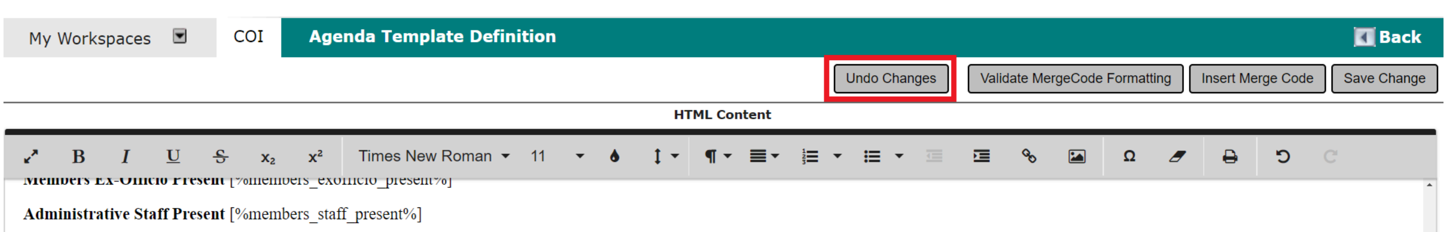
If any of your merge codes contain invalid content, as seen below, you will get a popup message displaying the merge codes that the system was able to correct for you.

FULL BOARD MATCHES: [%FULL_BOARD_MATCHES%]
FULL BOARD MATCHES: [%***full***_BOARD_MATCHES%]

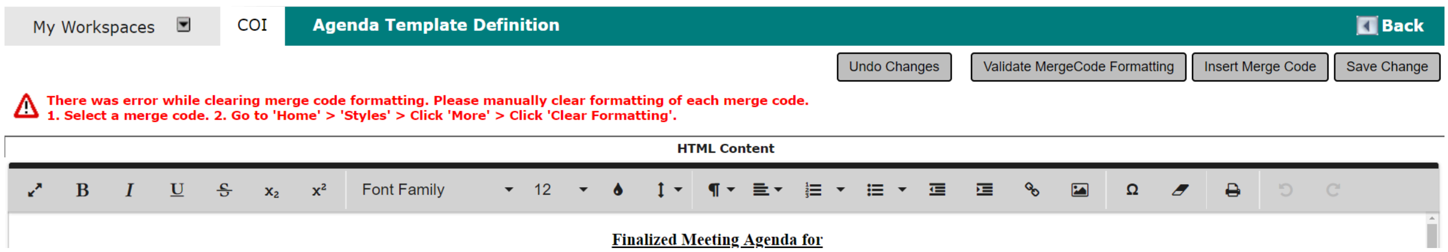
In the example given, you can see that part of one merge code is bolded and the other is partially italicized. When you click Validate Merge Code Formatting, you will see the following popup:



When you look at the document again, the merge codes are corrected. If you need to, you can click the **Undo Changes** button to revert to the previous version of the merge codes.

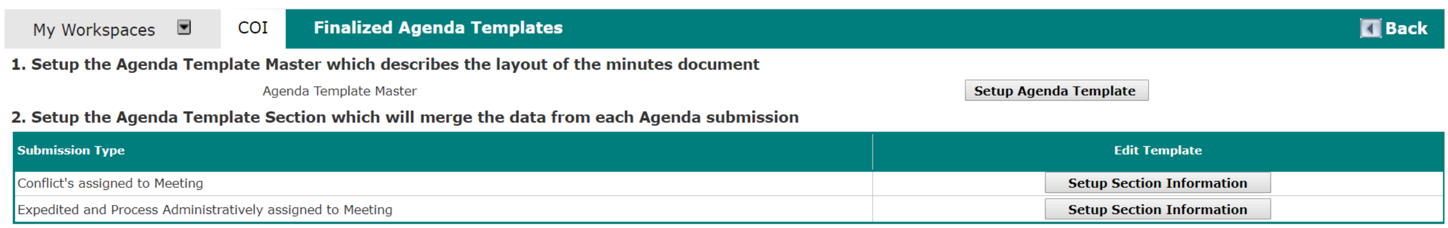


If there is an incorrect merge code that cannot be validated, the system will return an error message. For example, if ”[%” or “%]” is entered in the template with no other associated merge code content, you will receive the following error:



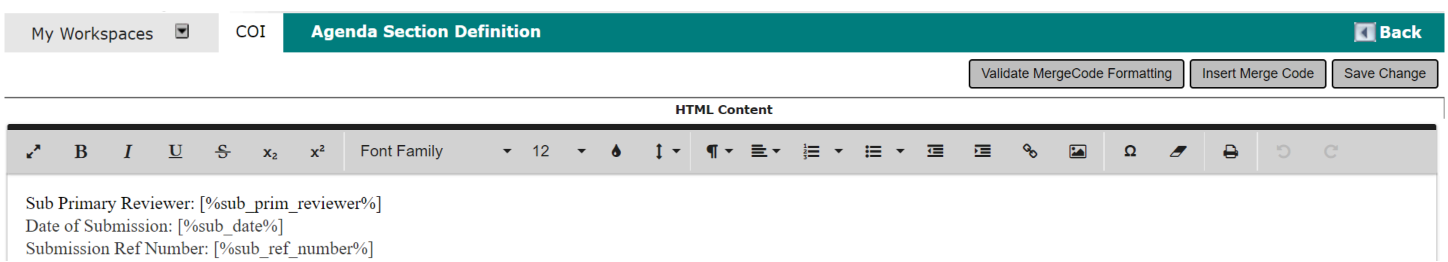
You can go in and remove any incorrect merge code data as described above or follow the instructions in the error message to manually clear merge code formatting.

Setup Section Information



When a Meeting Agenda is generated for the review board, the general information will display that you have added to the Agenda Template Master. Then, the agenda will list each of the matches assigned to the meeting based on the section merge codes you set up in the Agenda Template Master.

You will set up what the Agenda Template Master should display for each Conflict Match in the appropriate Section Definition. To edit a submission type template, click on the **Setup Section Information** button.

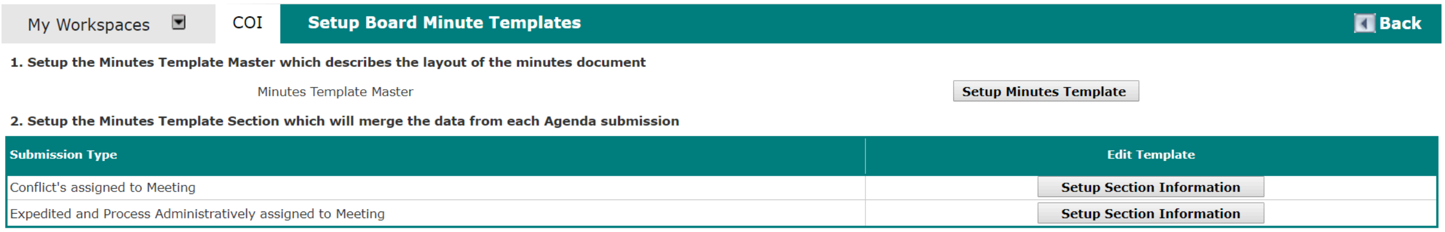


Continue to edit or create this section as explained in creating/editing the Agenda Template Master, except this information will be specific to the Conflict Match, not the general Meeting Agenda information.

When you generate a Meeting Agenda on a specific meeting date, the system will generate one document using the three sections of the template: The Agenda Template Master and the two subsections for Full Board and Expedited/Administratively Processed Conflict Matches.

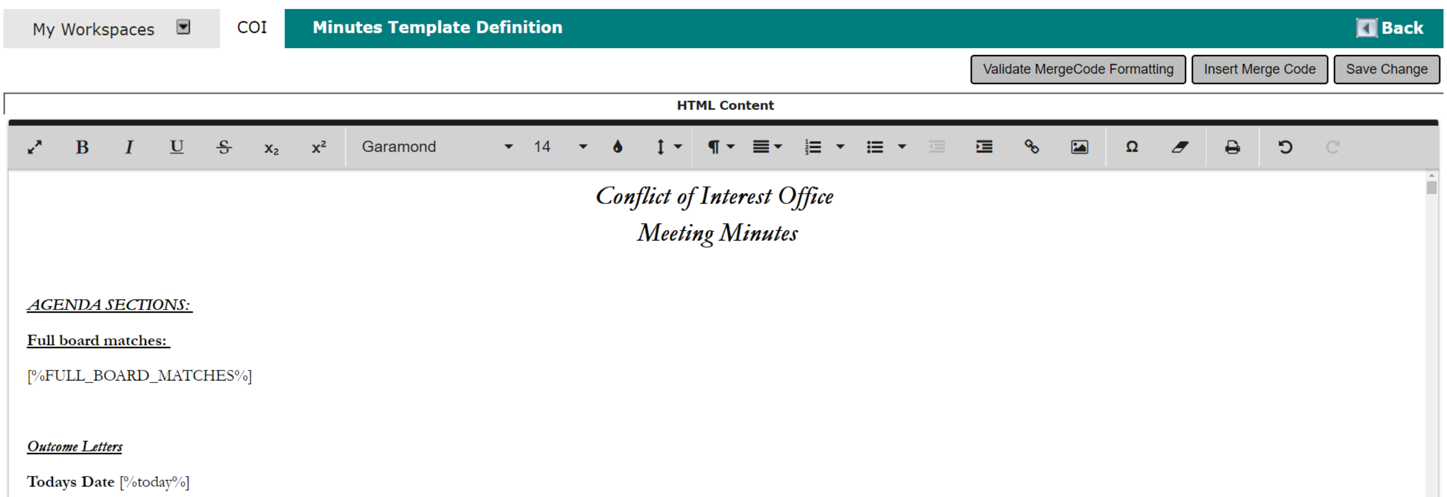
Setup Meeting Minutes Template

You can create a master template for your Meeting Minutes document. This template will store your meeting minutes outline, and, with the use of merge codes, will pull in specific information regarding a meeting when you generate the minutes for that particular meeting. See the COI Assistant – Meetings manual for instructions on how to generate the minutes for a specific meeting.



The Minutes Templates page lists the Minutes Master Template, which describes the general layout of the Minutes document, and the different sections that can be added to the master template (such as Full Board Conflict Matches and Expedited/Administratively Processed Conflict Matches). You can setup the template for these sections, which will merge data from each Conflict Match into the Master Minutes Template.

First, you will define the content of the Minutes Template Master. Click on the **Setup Minutes Template** button.

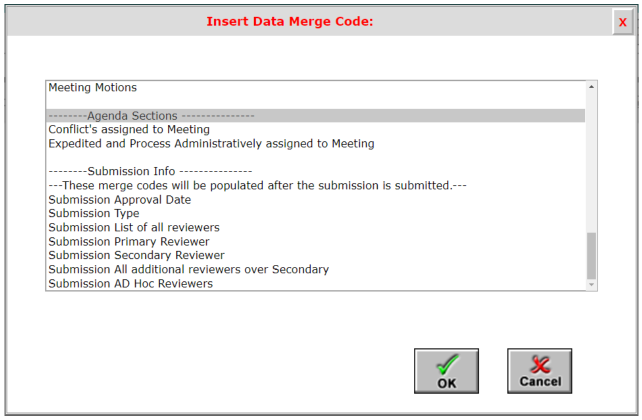


A new page will open, containing an embedded Word editor (please note that the Word editor will only work in Internet Explorer). If the template master has already been created, it will display similarly to the example in the above screenshot. If the master was not created, this is where it can be created using the features provided in the text editor and the available merge codes. To insert a merge code, position your cursor in the document, and then click the **Insert Merge Code** button, located at the top of the screen. A window will pop up listing the available merge codes. Highlight the merge code you wish to insert and click the **OK** button.

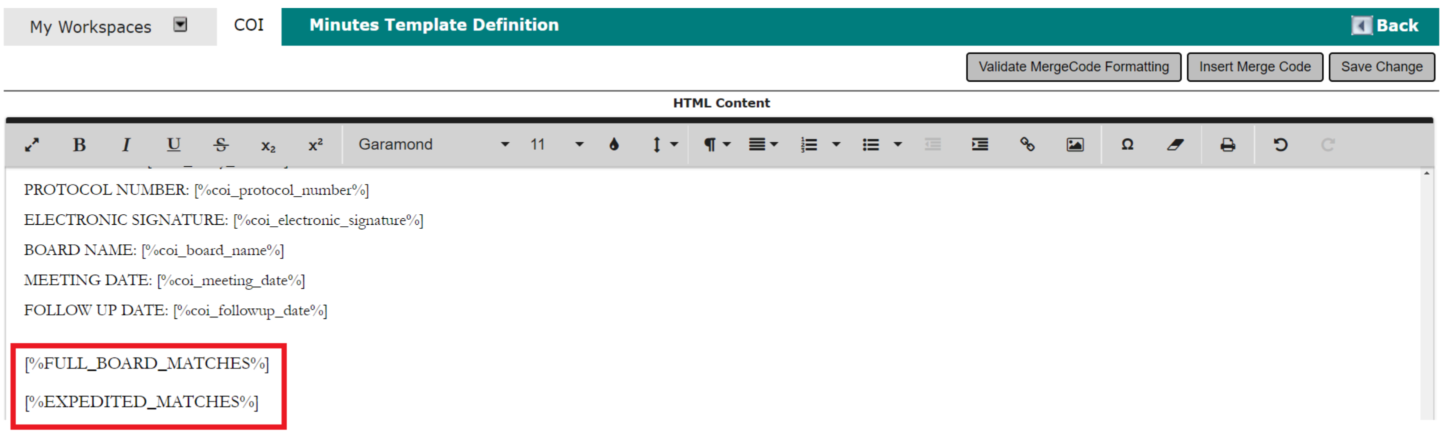
A merge code is a programmed label that will pull information into the document when the document is generated. When the Minutes document is generated for a specific meeting date, the merge code for %meeting_date% will populate with the date of the meeting.

You can set up your Minutes template using the tools available in the Word editor and the merge codes list.

Merge codes you will find useful for your Minutes Master Template are found near the bottom of the list of merge codes.

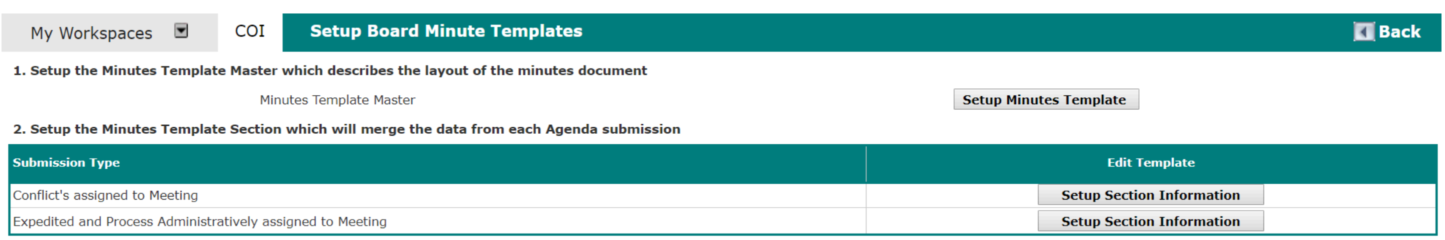


These codes are “Conflicts Assigned to Meeting” and “Expedited and Process Administratively Assigned to Meeting”. These two merge codes are used to tell the Minutes Template Master to pull in specific information about Conflict Matches that were reviewed at a particular meeting.



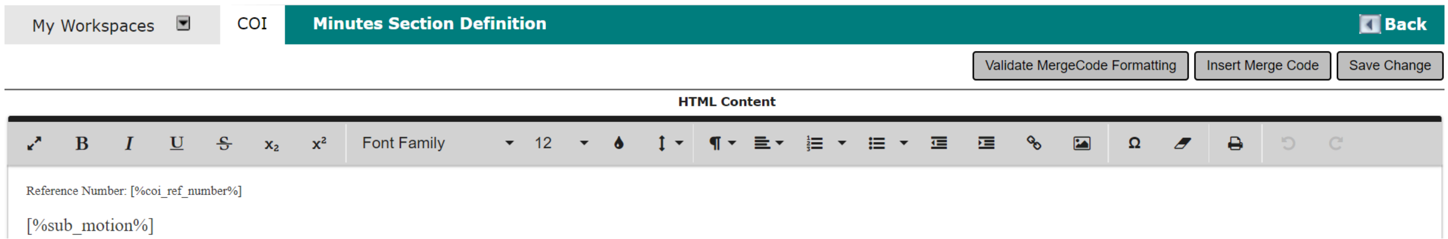
These two merge codes are entered into the Minutes Master Template and will pull in information that has been entered into the Section Information.

When finished editing or creating the template master, click the **Save Change** button, located at the top of the screen.



When Meeting Minutes are generated for the review board, general information from the Minutes Template Master will display. The document will also list each of the matches assigned to the meeting based on the section merge codes you set up in the Minutes Template Master and the information entered into the Section Information.

To set up or edit what should be displayed in the Minutes Template Master for each Conflict Match in the appropriate Section definition, click on the **Setup Section Information** button.

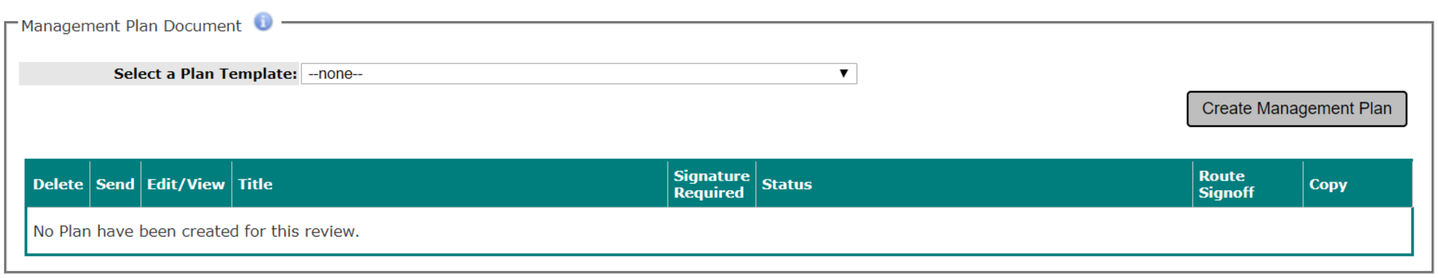


Edit or create this section as you created/edited the Minutes Template Master, except this information will be specific to the Conflict Match, not the general Meeting Minutes information.

When you generate Meeting Minutes for a specific meeting date, the system will generate one document using all the sections of the template.

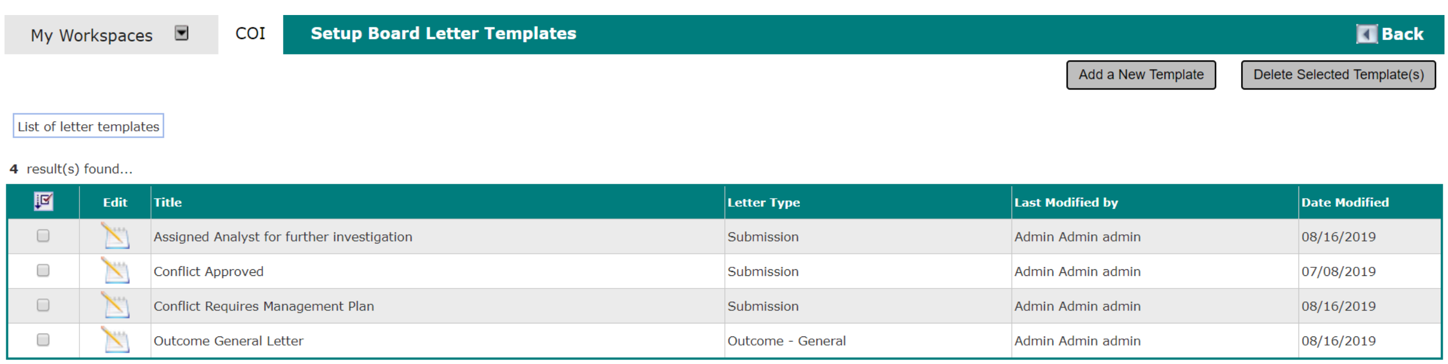
Setup Management Plan

You can set up Management Plan templates using this functionality. This feature works similarly to the Setup Outcome Letter Templates functionality as described below. Note: Management Plan templates added here will be available to select within the Management Plan and Outcome Letters tab within the Conflict Match processing screens.

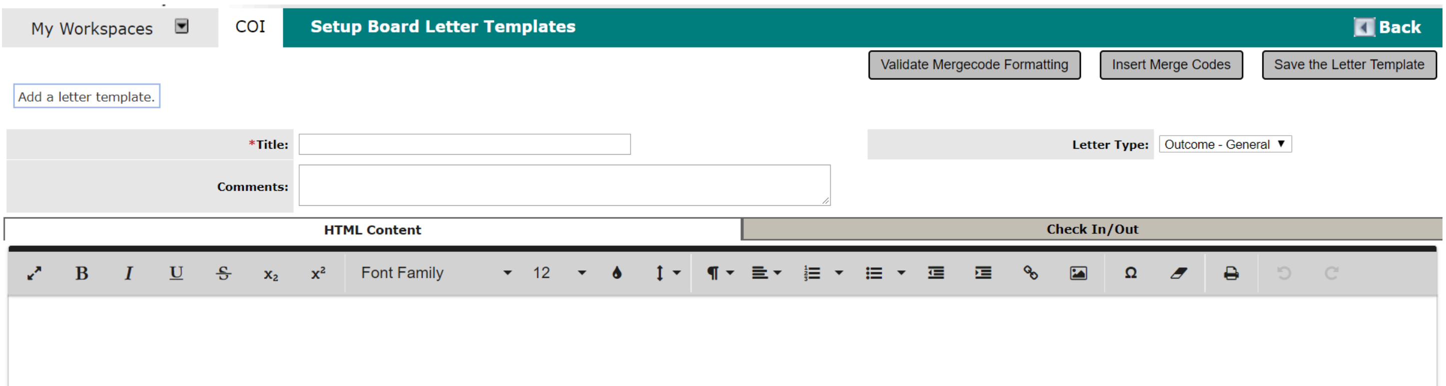


Setup Outcome Letter Templates

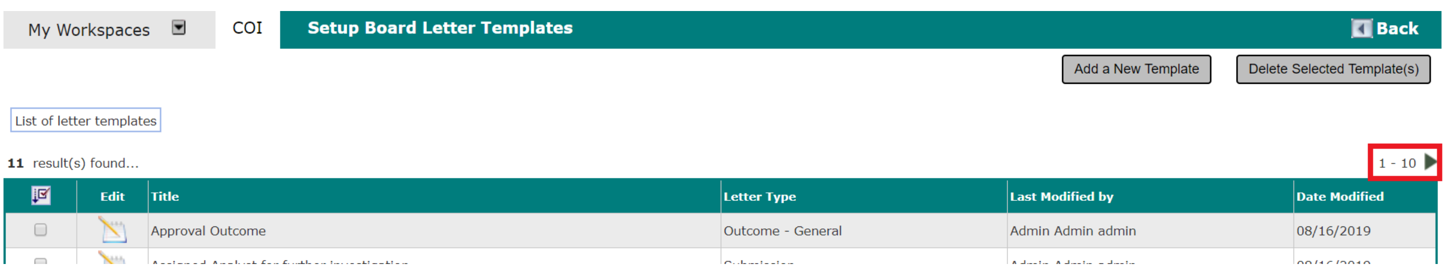
Using this functionality, you can set up the review board's Outcome Letter templates. Letter templates are created using merge codes that will pull in information specific to the Conflict Match when the letter is generated.



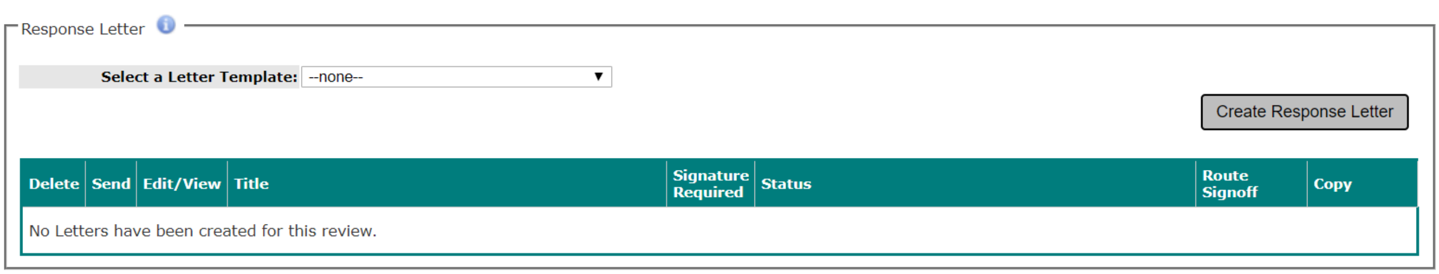
When you open the page, any letter already defined for the review board will list on the page, displaying the Title, Letter Type, Last Modified By, and Date Modified information. You can edit an existing letter by clicking on the **Edit** icon or you can add a brand-new letter by clicking on the **Add a New Template** button.



If the number of letter templates exceeds ten results, a small **green arrow** will display at the top right of the letter templates table. Click this arrow to move to the next page of letter templates.



When you add a new letter template, a page will open containing a blank embedded Word editor. If you chose an existing template, the Word editor would contain the contents of the existing letter template. Enter the Title of the template and select a Letter Type from the dropdown list. There are two types listed in the dropdown list: Submission and Outcome – General.



Selecting the Submission type from the dropdown list will cause the letter template to be listed among the templates available in the Outcome Letter tab in the Conflict Match processing screens.

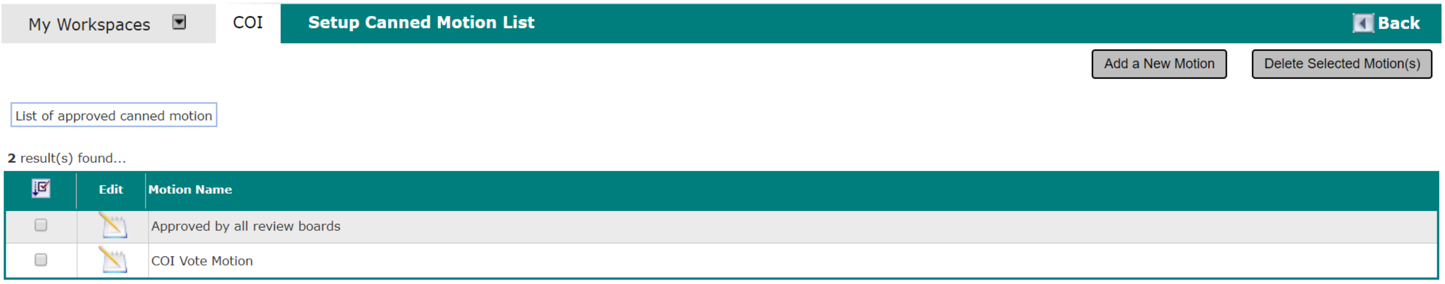
You can use the Outcome – General letter type if you have been using a template you no longer want to appear in the list of available letters, but you do not want to delete it from the system.

Add content to the template by inserting merge codes using the **Insert Merge Code** button and by using the features available in the embedded Word editor.

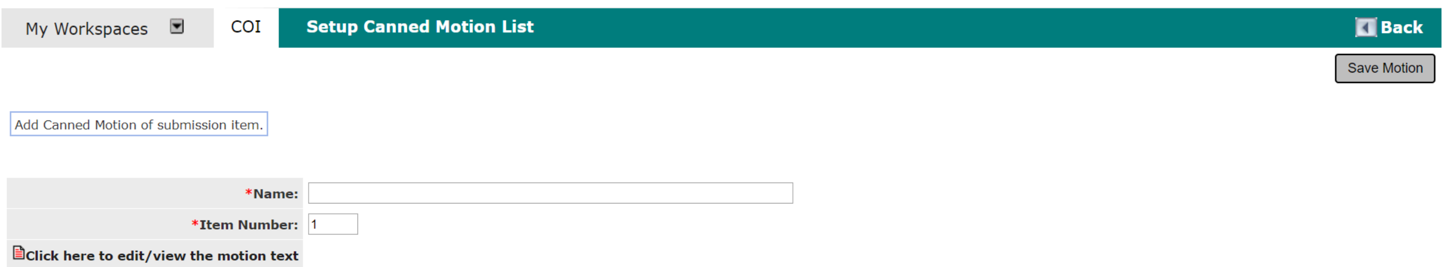
When you are finished creating the template, click the **Save the Letter Template** button to save.

Setup Canned Motion

You can set up a list of canned motion text that can be used to pull into a motion for a conflict match. You can have any number of canned motions in this list.



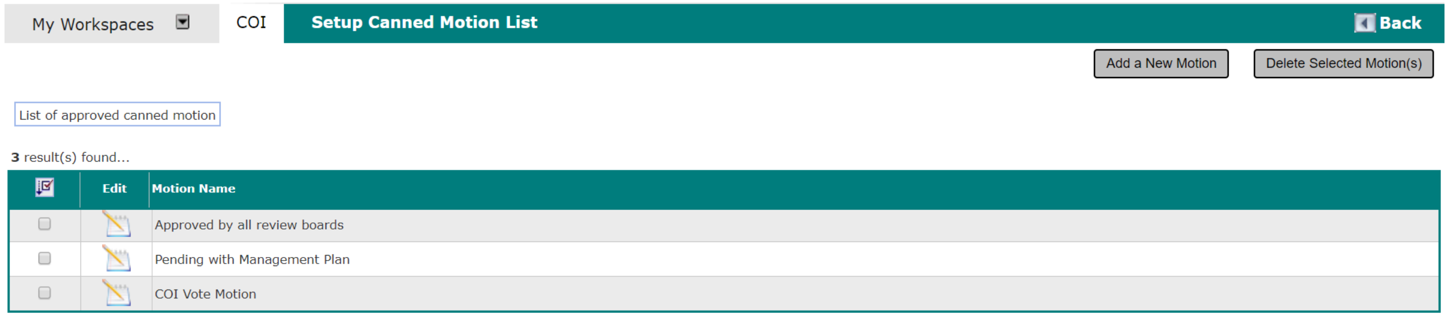
When you open the page, a list of any canned motions will display. If canned motions have not yet been added, this page will not list any records. You can click the **Add a New Motion** button to add a new canned motion to the list.



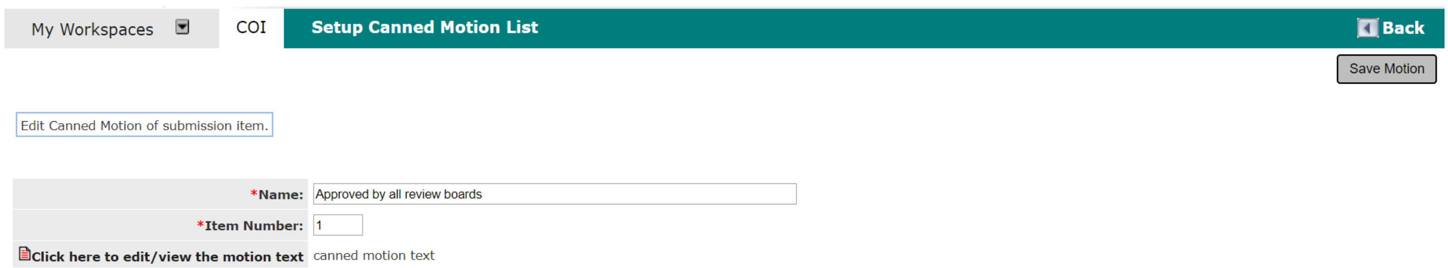
When you add a new canned motion, you will need to provide the **Name** of the motion and the **Item Number** (order in which the canned motion should be displayed). To add the content of the canned motion, click on the link "**Click here to edit/view the motion text.**"

This will open a new page containing an embedded rich text editor. You can copy and paste or type in your canned motion to the rich text editor. Click the **OK** button when you are ready to add the text to your motion.

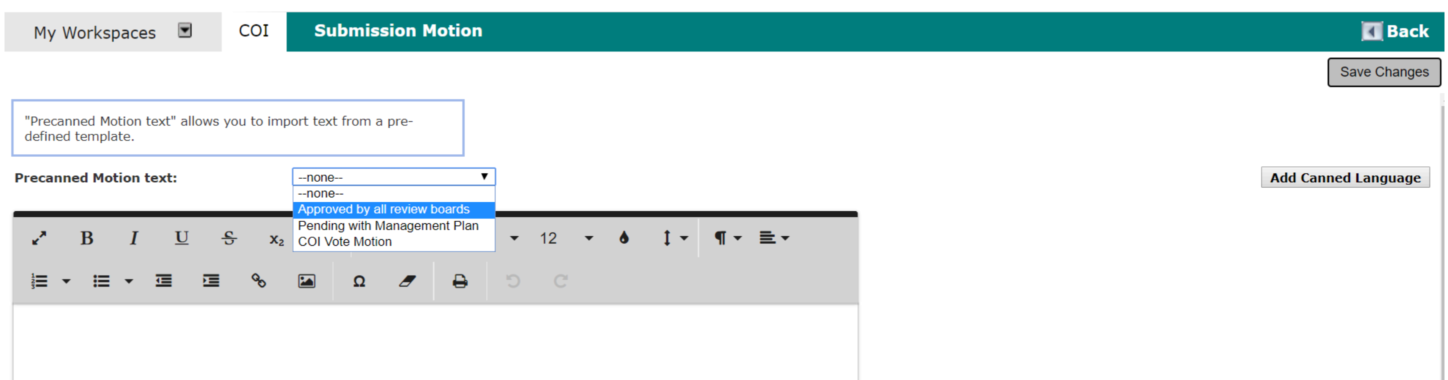
After adding the Name, Item Number, and text for the canned motion, click on the **Save Changes** button for the record to be added to the list of canned motions.



Canned motions can be edited by clicking on the **Edit** icon next to the name of the motion. This will open a new page allowing you to modify the Name, Item Number, and text for the canned motion.



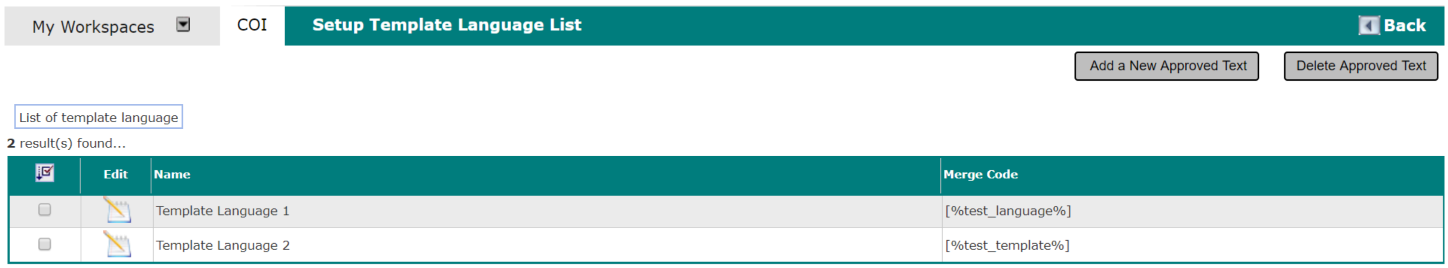
You can delete a canned motion by selecting the checkbox next to the appropriate canned motion and clicking on the **Delete Selected Motion(s)** button.



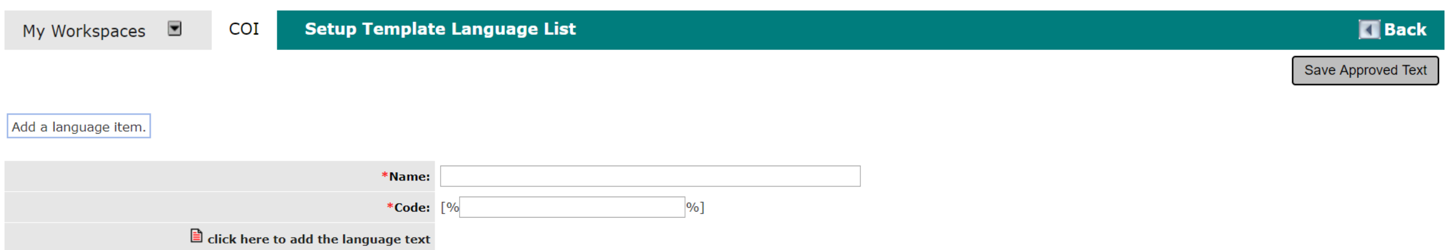
Any canned motion added will display in the **Precanned Motion text** dropdown list when you are adding a motion to a Conflict Match on the Meeting Vote tab found in the Conflict Match processing screens.

Setup Template Language

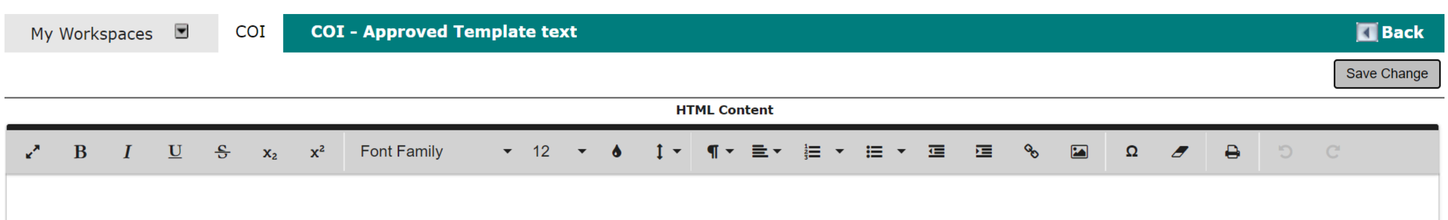
When you generate Minutes, Agendas, and Outcome Letters you have the ability to merge in template language. This is in the case you have specific language you want to pull into a document that is easily accessible. You can set up a list of template language in Setup Template Language and pull template language into your Minutes, Agenda, or Outcome Letters as needed.



When you open the page, a list of defined template language entries will display. If templates have not yet been added, the page will not list any records. You can click the **Add a New Approved Text** button to add a new template language to the list.

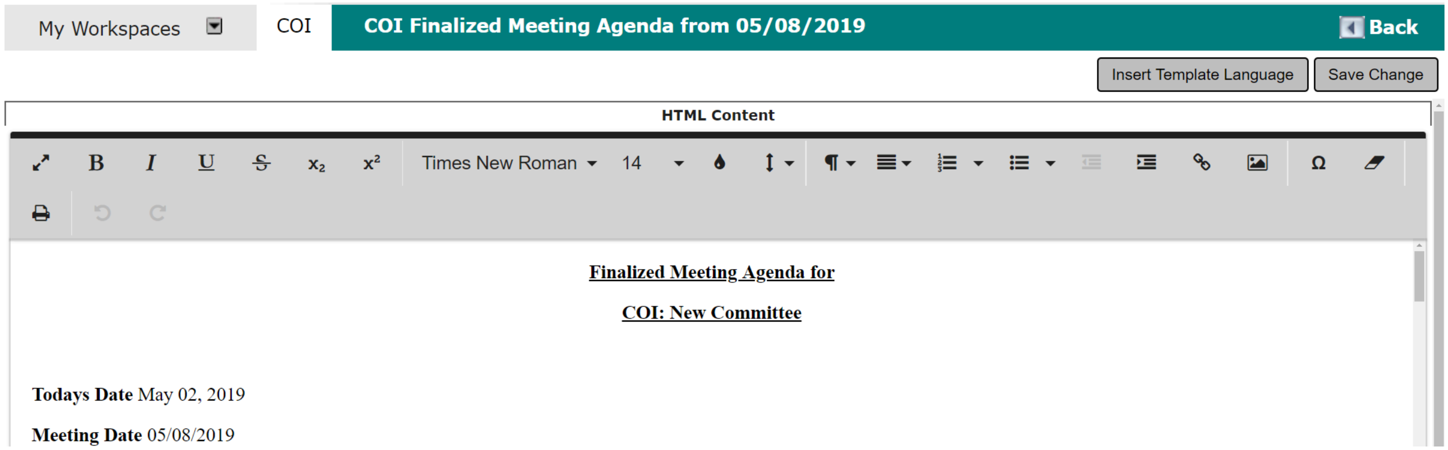


When you add new template language, you will need to provide a Name for the template language and a Code to define the merge code iRIS will use to insert the language into a document. The Code must be alpha-numeric and cannot contain spaces or special characters. To add the content of the template language, click on the **Click here to add the approved consent language** link.

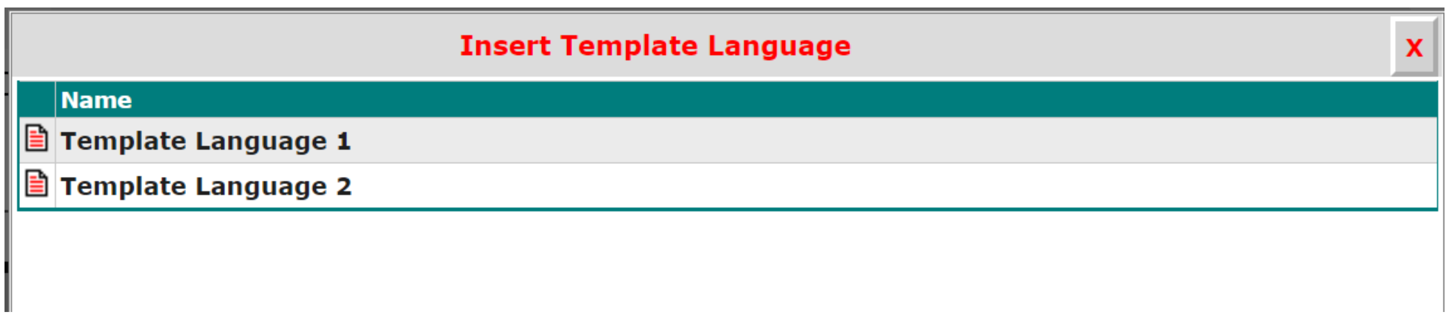


This will open a new page containing an embedded Word editor (please note, the embedded editor will only work in Internet Explorer). You can copy and paste or type in your canned motion text. Click the **Save Change** button when you are ready to add the text to your template language.

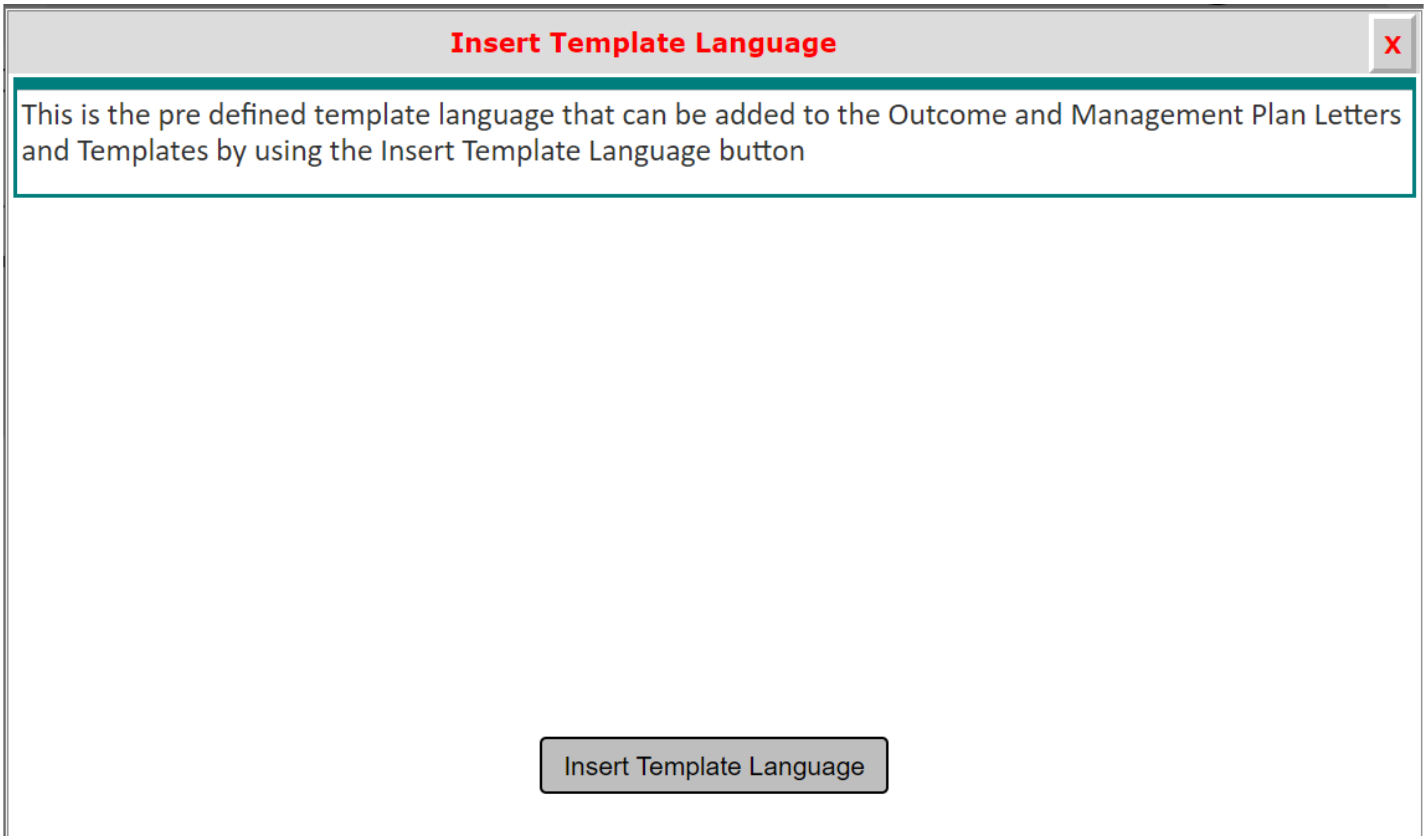
After adding the Name, the Code, and text for the template language, click the **Save Approved Text** button and the record will be added to the list of template language.



Template Language can be inserted into Outcome Letters, Meeting Minutes, and Meeting Agendas. Above the embedded Word editor of the generated letter, agenda, or minutes you will see an **Insert Template Language** button. First, position your mouse cursor in the document where you would like to insert the language.



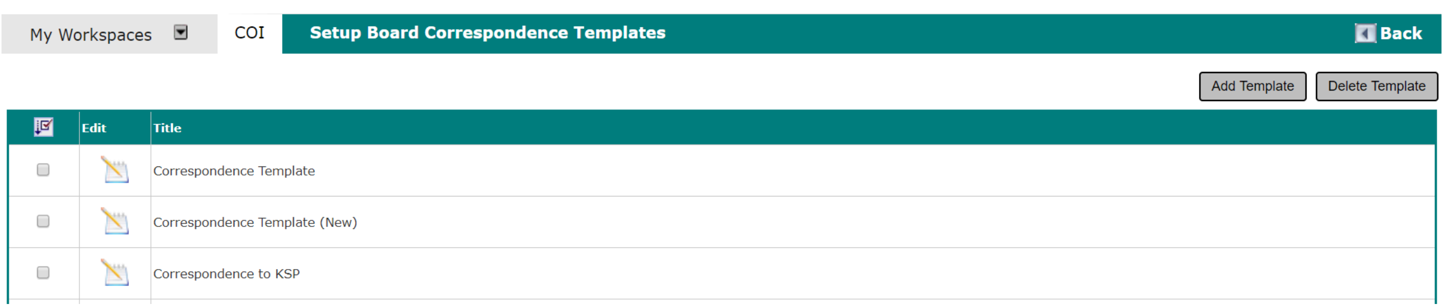
Clicking the **Insert Template Language** button will open a small popup window that will link to your list of template languages. Click on the language you wish to insert into the document.



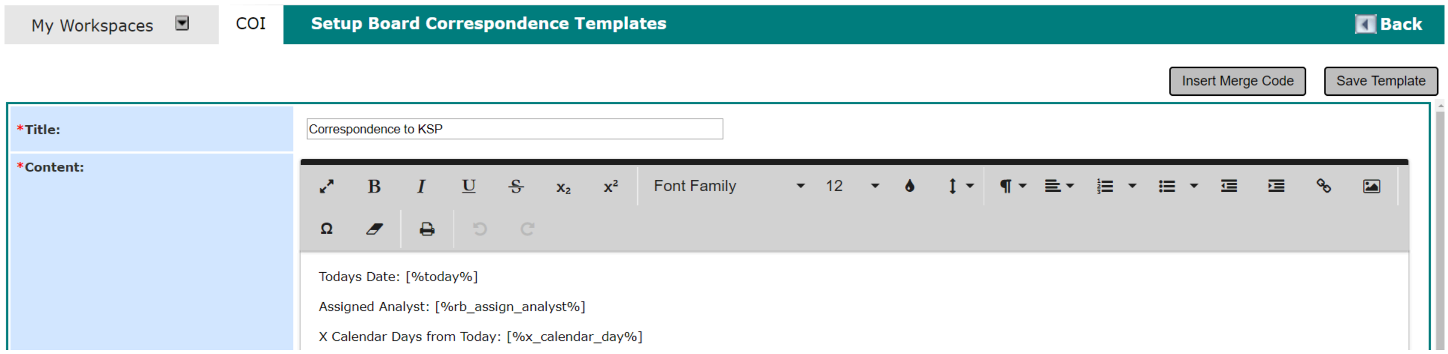
The popup will refresh, displaying the text of the template language. You can highlight the text of the language and copy and paste it into your document, or you can click on the **Insert Template Language** button. Doing this will close the pop-up window and insert your language into the document.

Setup Correspondence Template

You can set up templates that you can pull into Correspondence generated for a Conflict Match. You can have any number of templates and pull any template into correspondence within the Conflict Match processing screens.

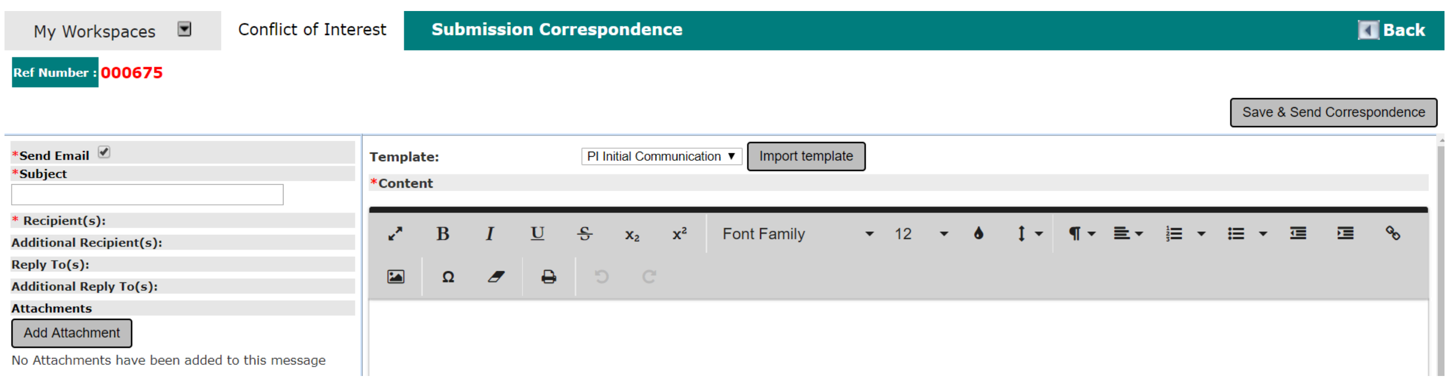


When you open the page, a list of any correspondence templates defined will display. If templates have not yet been added, this page will not list any records. You can click the **Add Template** button to add a new template to the list.



When you add a new correspondence template, you will first need to provide the **Title**. Beneath the Title field is an embedded rich text editor where you can copy and paste or type in the content of your correspondence template. You can also insert merge codes that will pull in specific information when the correspondence template is added to a specific Conflict Match. Click on the **Insert Merge Code** button for a list of available merge codes. To insert a merge code, position your mouse cursor in the document where you would like the code to be inserted, click the **Insert Merge Code** button, and then click the code you want to insert.

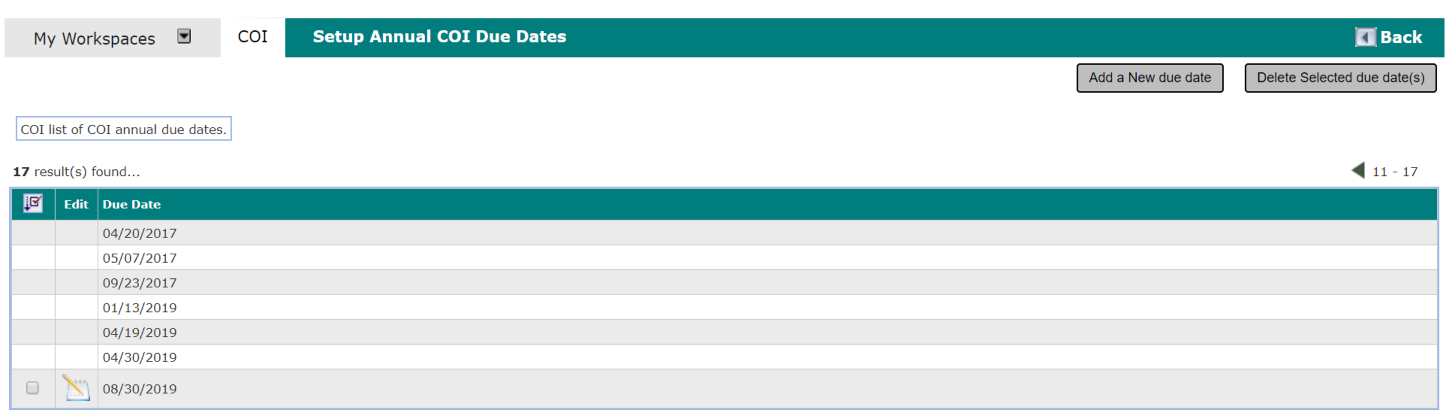
When you are finished adding content to the correspondence template, click the **Save Template** button.



Correspondence Templates are used when you create a correspondence record for a Conflict Match in the Conflict Match processing screens. Above the embedded editor, you will find a dropdown list that contains the available templates.

Setup COI Annual Due

Set up your institution's due date for receiving the Annual COI Form, which will be a future date that defines when existing Covered Persons in the system are to submit their Annual COI Form.



The page will list any Annual COI Due Dates that have been set up. Dates that fall in the past will not be editable and cannot be deleted. Future dates can be modified and can be deleted as needed.

Click the **Add a New due date** button to add a new date to the system.

A new page will open, containing a date field. Enter the Annual COI Due Date in this field and click the **Save due date** button to add the date to the system.

Preexisting users in the system will update to a future Annual COI date when their existing Annual COI Due Date has passed. For example, if a user has a COI due date of 1/1/2019 and the next Annual COI Due Date in the system is scheduled for 1/1/2020, after 1/1/2019 has passed, the system will update the user's account with the COI due date of 1/1/2020, in anticipation of next year's Annual COI Due Date.

New hires to the institution will receive a separate Annual COI due date, five days after their account creation. Once that date passes, the system will update their account with the next upcoming Annual COI Due Date, as defined in this configuration section of iRIS.

You may override the Annual COI Due Date for any user by accessing their information and manually changing their individual COI due dates in the Search Conflict Matches menu section, found within the COI Assistant module.

*Note: The COI Due Date Notifications will trigger based on the individual user's assigned COI Due Date and not the Annual COI Due Date setup in this configuration section of iRIS. The Annual COI Due Date is set up so that the system can assign one date to multiple Covered Persons, instead of needing to manually assign a due date to each individual.

Annual COI Form Label Configuration List

If your Annual COI Form is using iRIS predefined data values for gathering conflict information, you can use this area to modify the labels within the data values. The different categories of lists are labeled in bold on the left before the new section of COI labels.

My Workspaces | COI | **Setup COI Labels** | Back

List of Labels for Investment BioMedical

Edit	Predefined Name	Alternate Name	Description
	You just indicated that you or a Related Person have an investment interest(s) in a Biomedical third party. Complete a separate entry for every investment you or a Related Person have.	You just indicated that you or a Related Person have an investment interest(s) in a Biomedical third party. Complete a separate entry for every investment you or a Related Person have.	
	Who engaged in the activity?	Who engaged in the activity?	
	Provide the name of the Biomedical third party:	Provide the name of the Biomedical third party:	
	If Other, please enter the name of the Biomedical third party:	If Other, please enter the name of the Biomedical third party:	
	Select the estimated current value of the investment:	Select the estimated current value of the investment:	
	If > $100,001, please specify the amount of the Investment:	If > $100,001, please specify the amount of the Investment:	
	Select the current estimated ownership percentage:	Select the current estimated ownership percentage:	
	If > 5.0%, please specify your estimated percentage ownership:	If > 5.0%, please specify your estimated percentage ownership:	

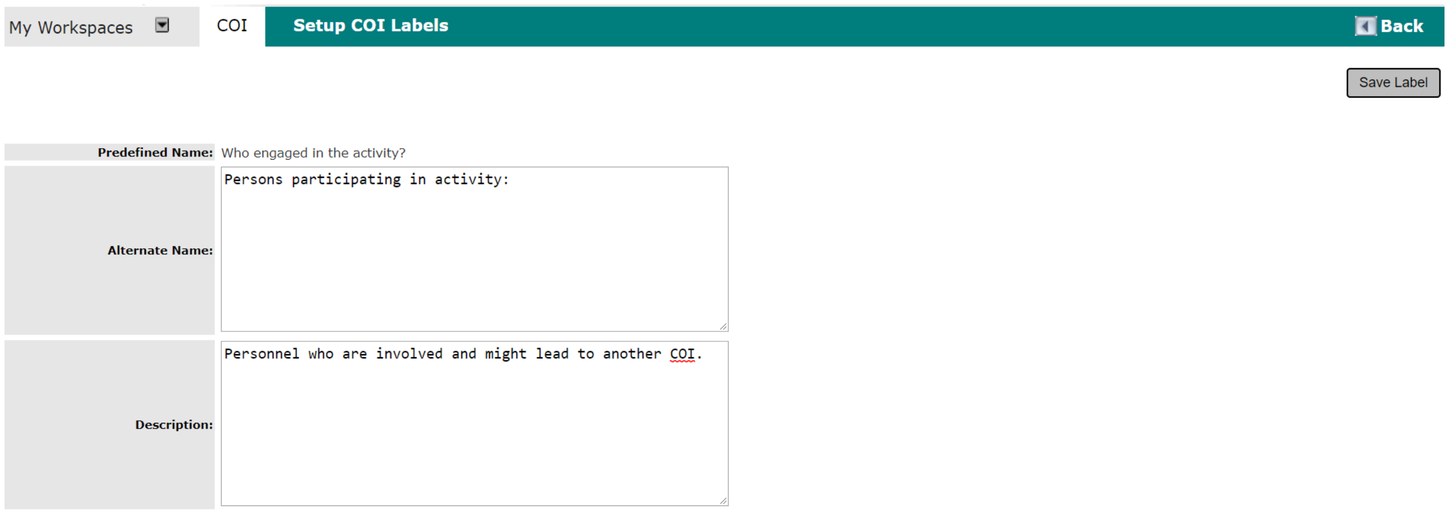
Within the Annual COI Form, you can use any of iRIS's predefined data values, shown above. Each of these data values has a corresponding area in the Annual COI Label Setup that you can use to change the labels within the data values.

My Workspaces | COI | **Setup COI Labels** | Back

List of Labels for Investment NonBioMedical

Edit	Predefined Name	Alternate Name	Description
	You just indicated that you or a Related Person have an investment interest(s) in a non-Biomedical third party. Complete a separate entry for every investment you or a Related Person have.	You just indicated that you or a Related Person have an investment interest(s) in a non-Biomedical third party. Complete a separate entry for every investment you or a Related Person have.	
	Who engaged in the activity?	Who engaged in the activity?	
	Provide the name of the non-Biomedical third party:	Provide the name of the non-Biomedical third party:	
	Select the estimated current value of the investment:	Select the estimated current value of the investment:	
	If > $100,001, please specify the estimated current value of the investment:	If > $100,001, please specify the estimated current value of the investment:	
	Select the current estimated ownership percentage:	Select the current estimated ownership percentage:	
	If > 5.0%, please specify the current estimated ownership percentage:	If > 5.0%, please specify the current estimated ownership percentage:	

Each of the data values found in the Annual COI form sections also have their own section within the Annual COI Form Label Configuration List. Shown in the screenshot above are the labels for the Investments with Biomedical Third Parties. You may change any label by clicking the **Edit** icon next to the appropriate label.

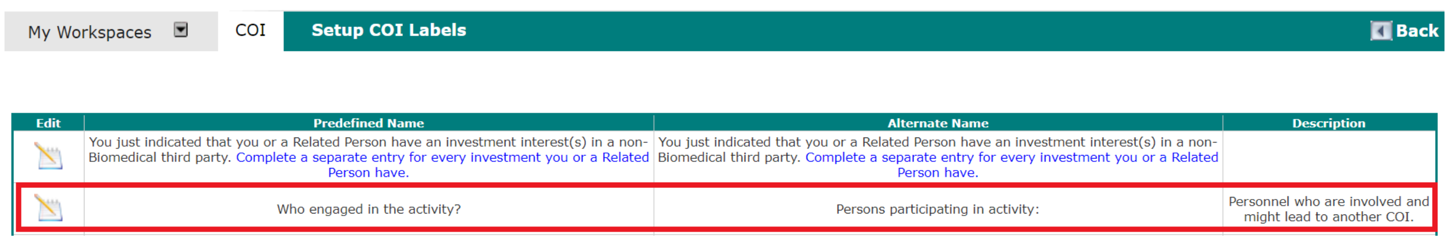


A new page will open, allowing you to change the label. Listed on this page is **Predefined Name**, which is the original label and cannot be changed. The Predefined Name section is provided for reference only, so that you will know what the original label was.

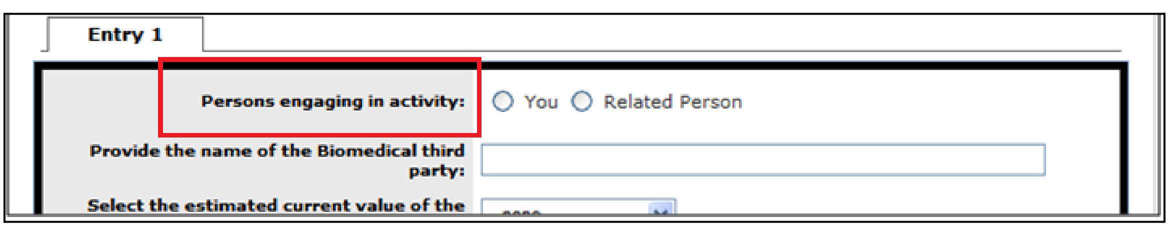
Alternate Name: This is where you can change the label to what you want displayed within this data value.

You can also add a **Description** that can be used to note why the change was made.

Click on the **Save Label** button to save your changes.



The Annual COI Label Setup page will reflect any changes you make to the labels.

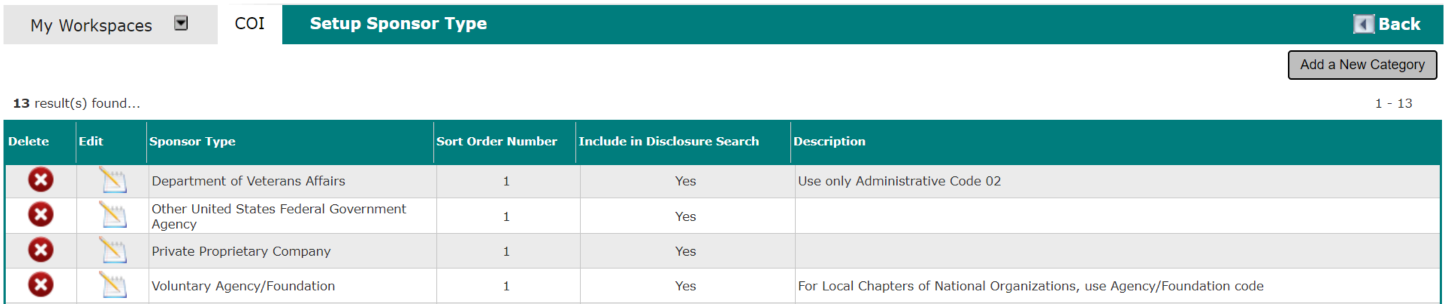


Any label changes you make will update the appropriate data value within the Annual COI Form.

Setup Business Associate Type

This is a list of available Business Associate Types that you can associate to a Business Associate (Sponsor) record.

After selecting this link, the master list of existing Sponsor Types will display. You can edit the existing records, as well as add new categories and delete categories.



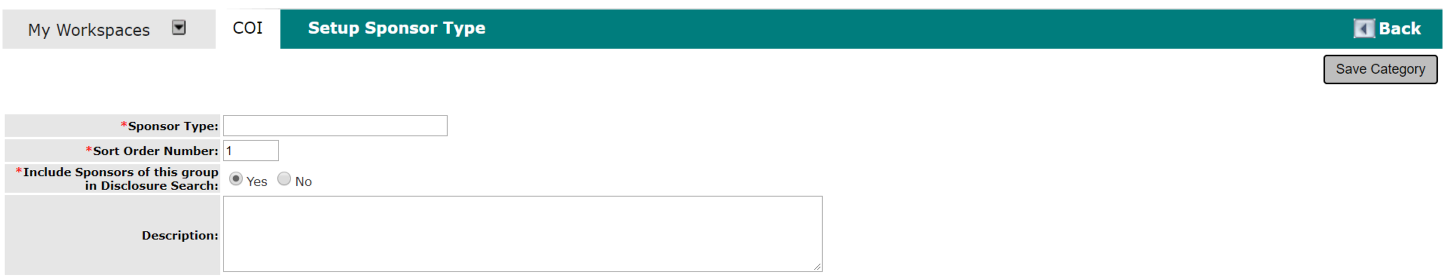
My Workspaces | COI | Setup Sponsor Type | Back

Add a New Category

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

Delete	Edit	Sponsor Type	Sort Order Number	Include in Disclosure Search	Description
		Department of Veterans Affairs	1	Yes	Use only Administrative Code 02
		Other United States Federal Government Agency	1	Yes	
		Private Proprietary Company	1	Yes	
		Voluntary Agency/Foundation	1	Yes	For Local Chapters of National Organizations, use Agency/Foundation code

Clicking the **Add a New Category** button will direct you to the following screen:



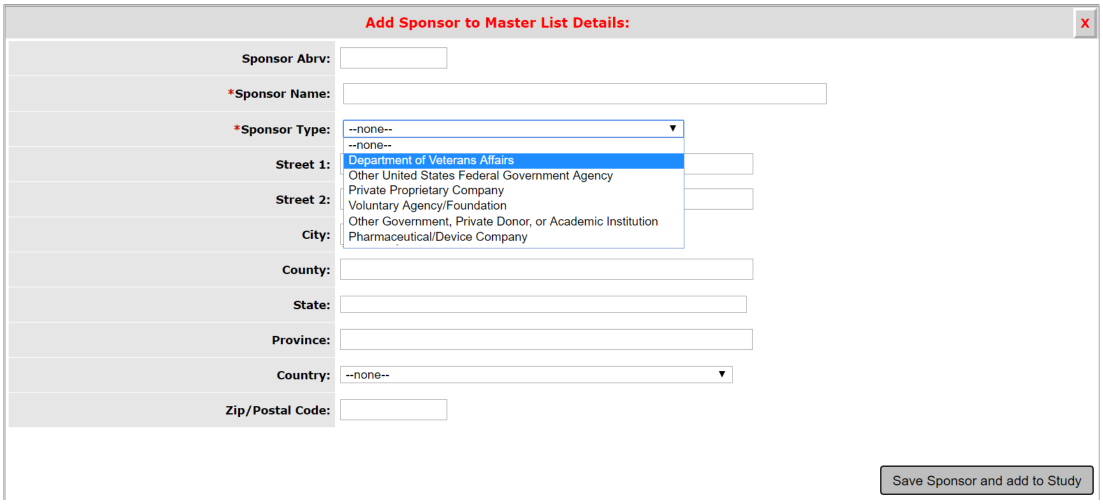
Sponsor Type – In this field, you are required to designate the display name for the Sponsor Type record.

Sort Order Number – Enter a number to set the order in which you want the Sponsor Types to display.

Include Sponsors of this group in Disclosure Search – This setting is used for the COI module. Any sponsor associated to a Sponsor Type with this flag set to Yes will be included in the conflict of interest check. This means when a Covered Person submits a conflict of interest form with a conflict match listing a sponsor with this type, the system will flag a COI match and report it to the Conflict of Interest board.

Description – You can enter a description of the Sponsor Type here. This field is for internal purposes and will not be displayed to end users.

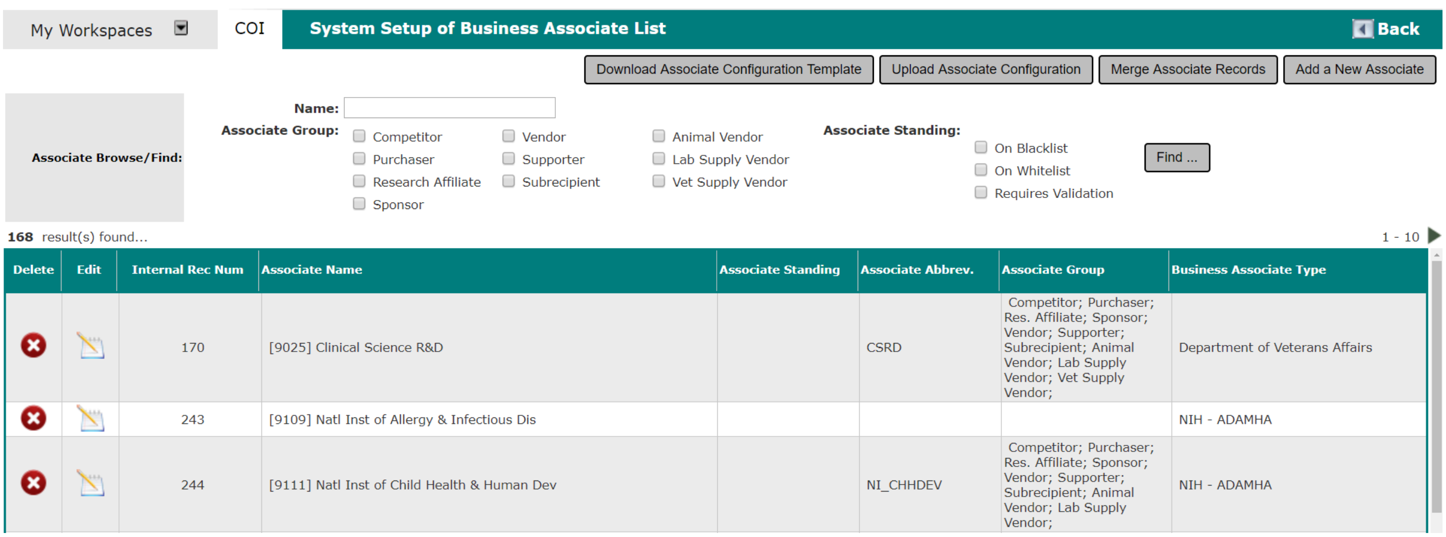
Click **Save Category** to add the Sponsor Type to the master list and make it available to be applied to sponsors in the system.



To delete an existing Sponsor Type, click the icon next to the corresponding record in the list of Sponsor Types.

Setup Business Associate List

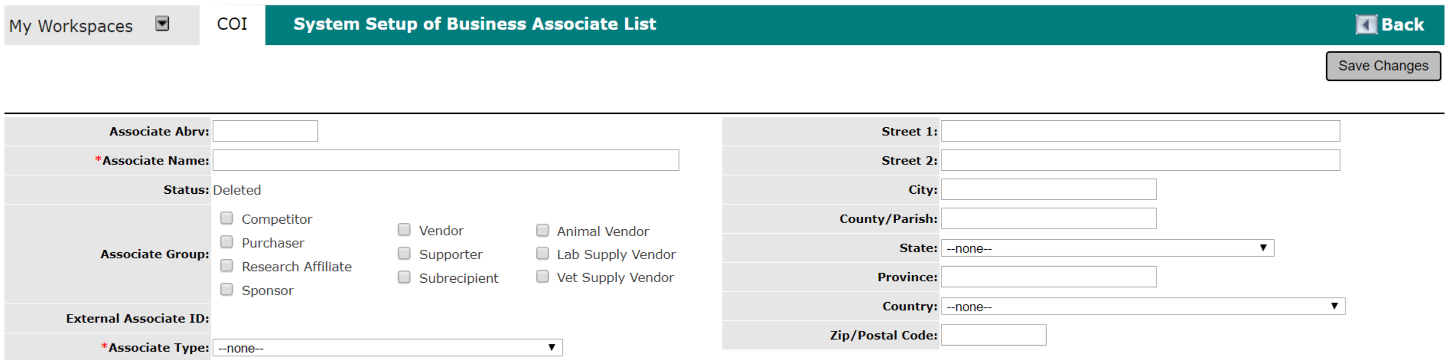
The Business Associate List contains a list of institutions you may need to track as a Sponsor, Subrecipient, Vendor, etc. Records added to the Business Associate list can be used in a variety of ways in the system. They can be added as a study sponsor, as a third party for a conflict of interest, and as a sponsor or subrecipient on a study.



Clicking the Business Associate List link will populate the existing Associates in the system. You will have the ability to **Download Associate Configuration Template,** a template that will allow you to add multiple business associates at one time, **Upload Associate Configuration,** a template to add the associates to the system, **Merge Associate Records**, **Add a New Associate,** and delete and edit the existing business associates**.** Additionally, this page contains search filters that will allow you to search for a specific record.

Add a New Associate

Selecting **Add a New Associate** will prompt you to enter the below fields. Saving this information will add the record to the list of Associates/Sponsors within iRIS.



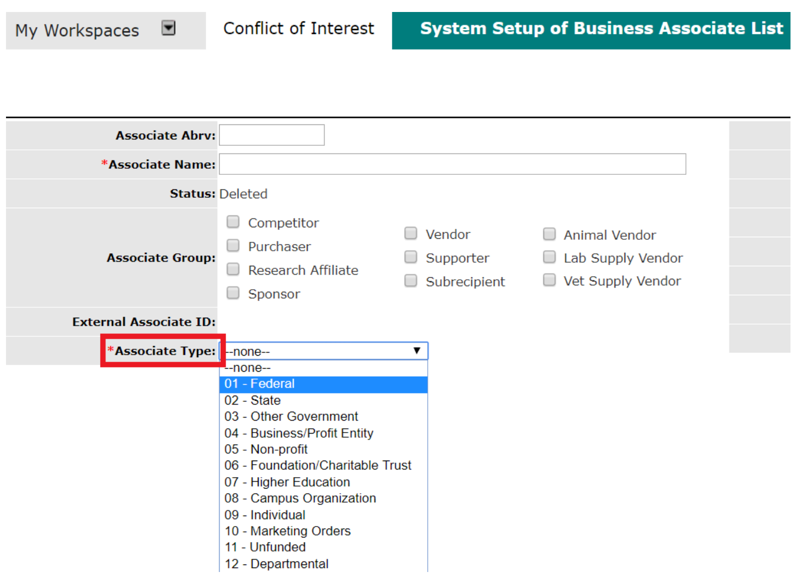
Associate Abrv – Allows the designation of an abbreviation for the particular associate.

Associate Name – In this required field, you must specify the business associate's name.

Status – Displays the internal status of the record. Once the record is saved, this status will change to "Active."

Associate Group – Allows the designation of the group the associate should be labeled as. Depending on the answer given in this list, additional fields will populate below. Note: The Associate Group list is a configurable list.

Associate Type – Shows the configured options from the **Setup Business Associate Type** in the drop-down.

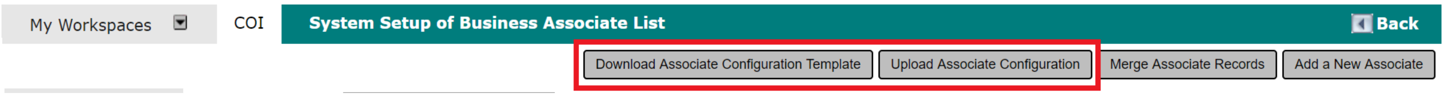


Street 1 & 2, City, County/Parish, State, Province, Country, Zip/Postal Code – Allows the input of the Associate/Sponsor's address or location information.

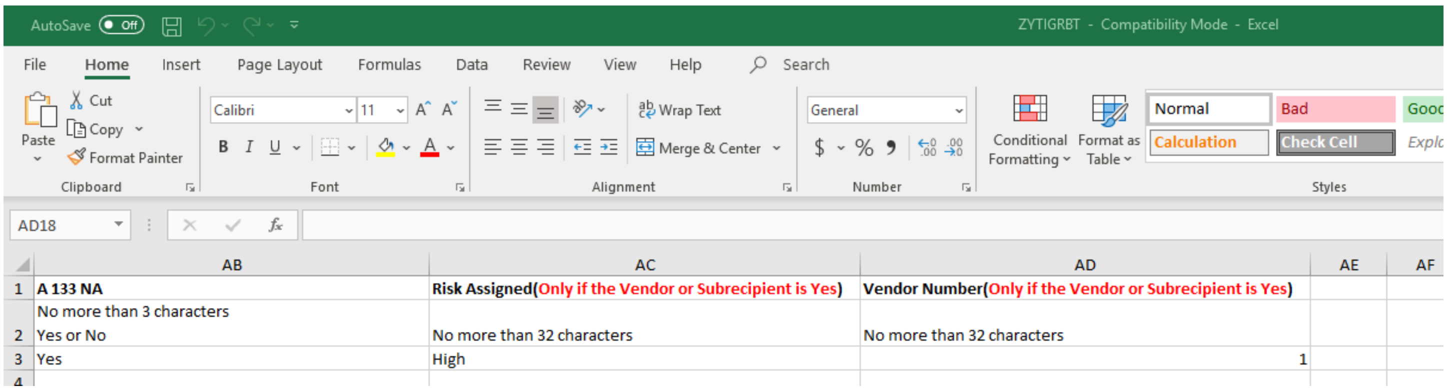
Clicking **Save Changes** will add the new Business Associate to the master list.

Download/Upload Associates

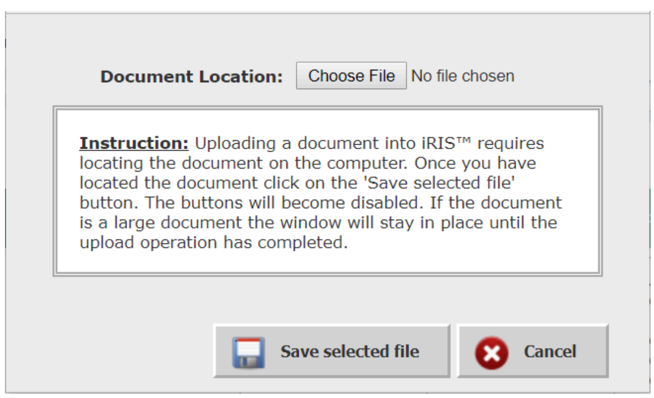
The **Download/Upload Associate** features give you the ability to upload an Excel file with as many business associate records as needed at one time.



Download Associate Configuration Template – This feature will allow you to download an Excel spreadsheet template. This template is set up in the proper format for uploading business associate records, with instructions for the input of data in each field. When downloading, be sure to **Save** the file to a known location on your computer, so the data can be input and saved for future uploading. Below you will find a screenshot of this spreadsheet template.

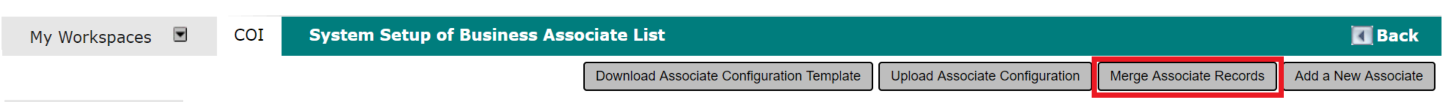


Upload Associate Configuration – Selecting to upload will open a pop-up window, where you will be able to browse for the correct Excel file containing the business associate records you wish to upload.

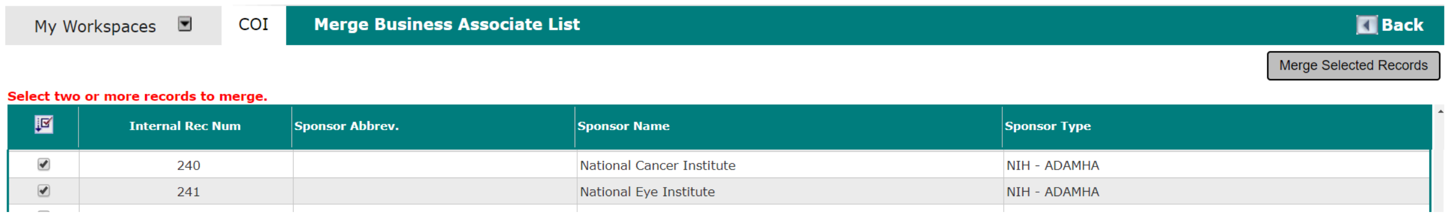


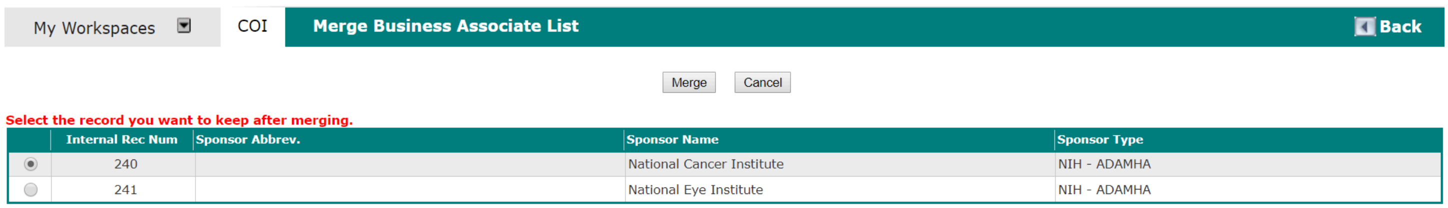
Merge Associate Records

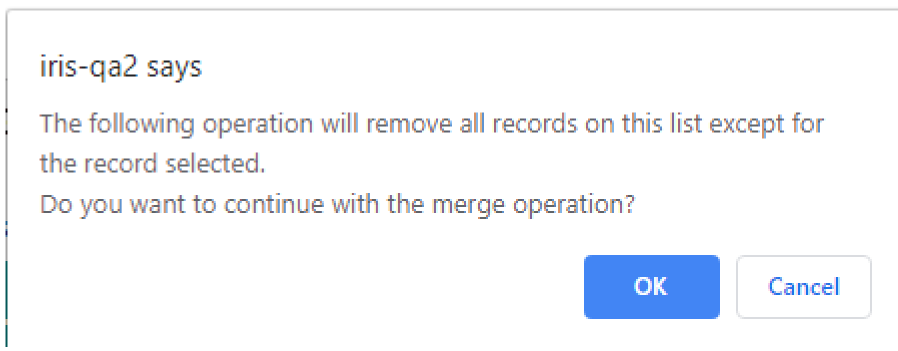
Selecting to **Merge Associate Records** allows you to merge duplicate records within the system.



After making this selection, a list of the existing records will populate. Selecting two or more records will allow you to merge the records and select the record that you wish to keep.







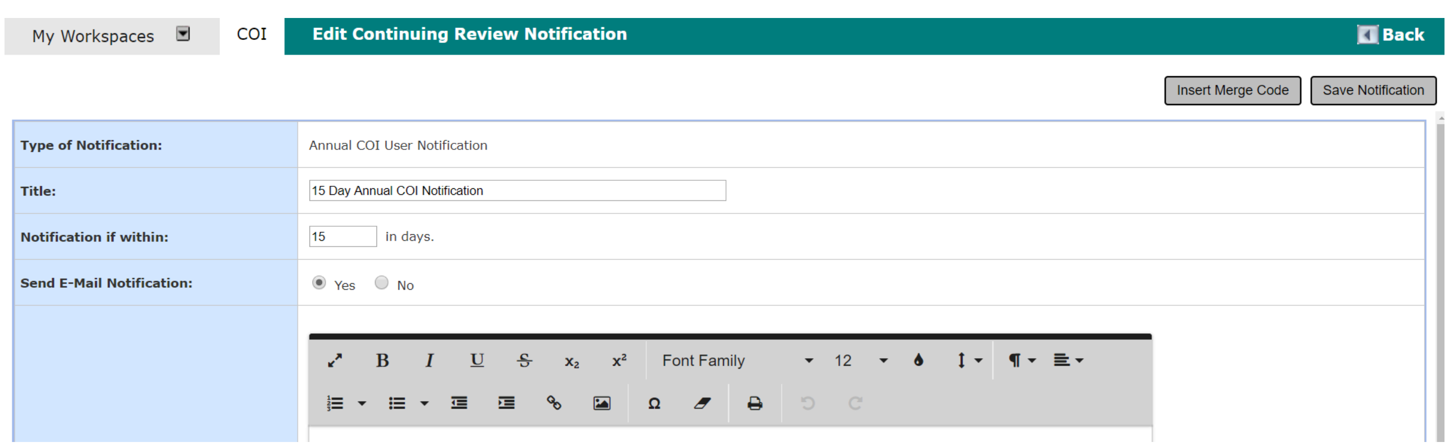
Note: For records already existing on studies, the record that was kept will replace the deleted record within the study.

Once a Business Associate/Sponsor has been added to the master list, they become available for selection when reporting activities in a COI form.

Review Board Notification Setup

Review Board Notifications can be set up to send notifications to Covered Persons as well as to members of the board. These notifications range from notices of Annual COI Due Dates, to Reviewer Assignments and Meeting Agenda and Minutes notifications.

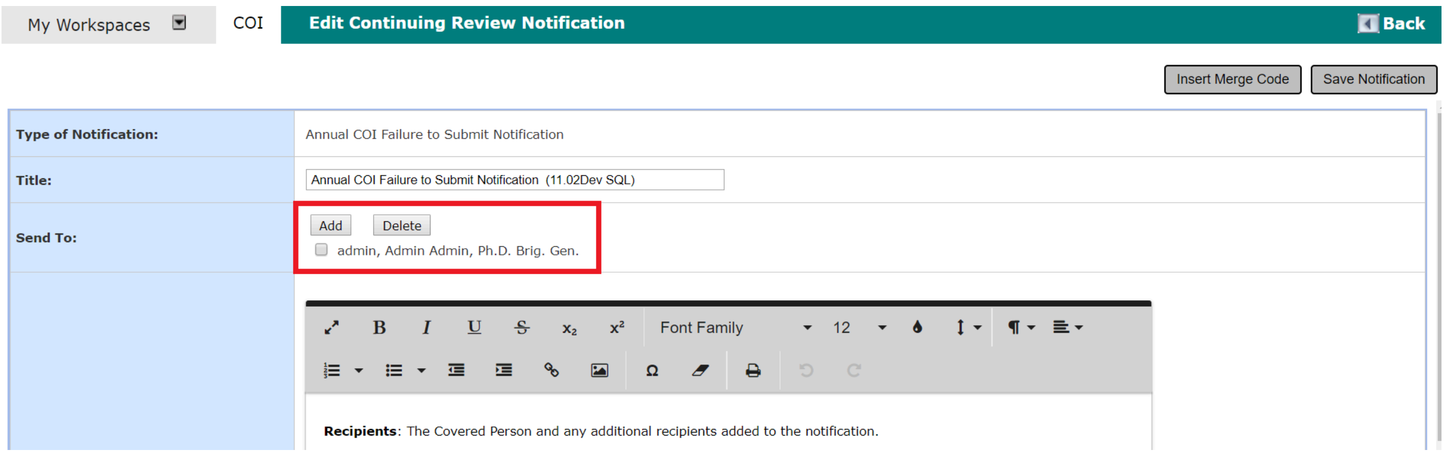
Review Board Notifications can be set up by entering the content of the email and using merge codes to pull in specific information. Start by clicking the button to add a new notification.



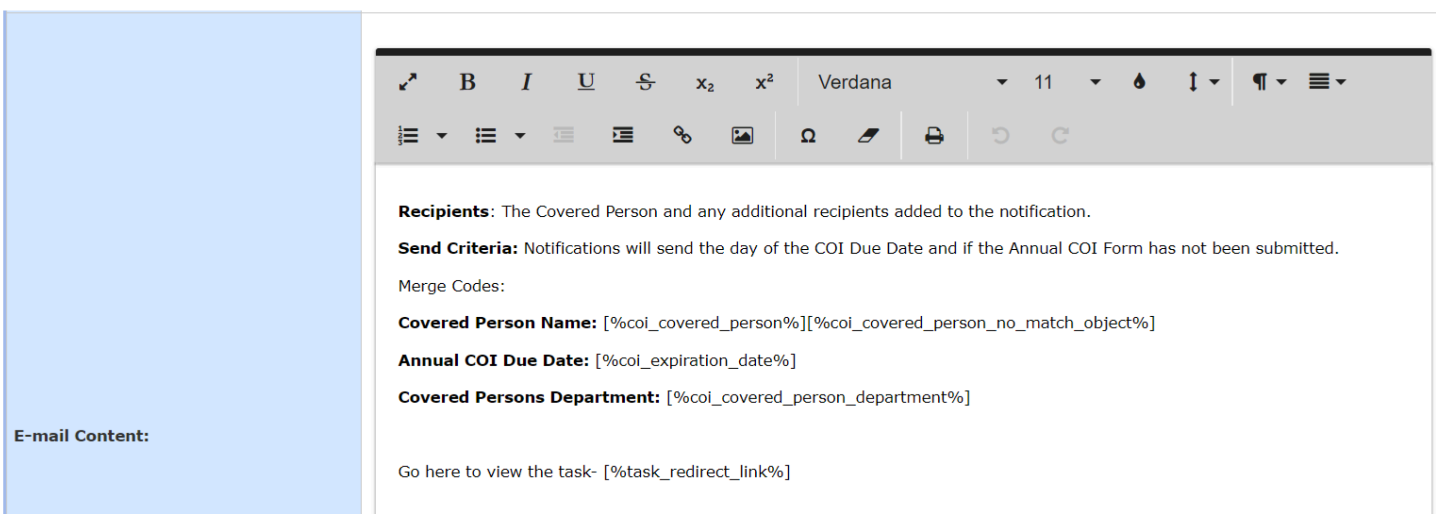
All notifications will require a Title. This will be the subject line of the email.

Certain notifications will require a number of days. This is typically how many days prior to a certain date you want the notification to send.

You will also be able to specify whether or not to send the email notification by selecting "Yes" or "No" in the **Send E-Mail Notification** field. If "Yes" is set, the notification will send to the recipient. If "No" is set, the notification will not send. You would set a notification to "No" if you do not want the notification to send out but you also do not want to delete it from the system.



Some notifications will allow you to select additional recipients if there is a **Send To** column. Click the **Add** button and you will be able to search the database for a user to add as a recipient. You can have any number of additional recipients for the notification. To remove an additional recipient, click the checkbox next to their name, and then click the **Delete** button.



Within the **E-Mail Content** portion of the notification you can enter the body of the email. You can type in or copy and paste text, and use the system's merge codes to pull in specific information when the notification is generated. Click the **Insert Merge Code** button and a small pop-up window will open, allowing you to select the merge code you wish to use.

Annual COI Notification

These notifications send to Covered Persons (and, where appropriate, a system administrator) to alert them of upcoming Annual COI Due Dates, Lapses in submitting the Annual COI Form, and New Hire Notifications.

Annual COI User Notifications

You can set up any number of notifications that will send to a covered person on a certain number of days prior to their COI Due Date.

Add a New Notification | Delete Notification(s)

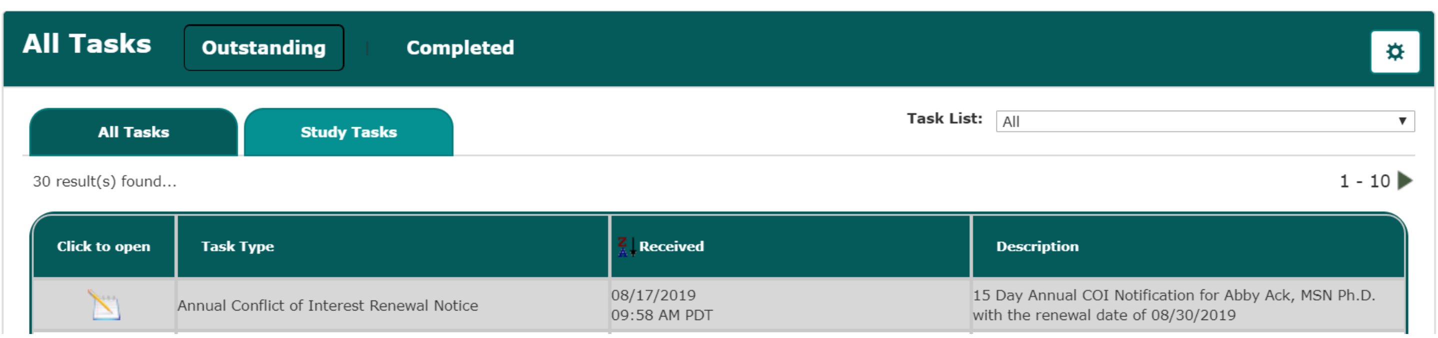
List of Annual COI User Notifications

	Edit	Type	Title	Notification prior to expiration date	Send E-mail Notification
		Annual COI User Notification	Annual COI User Notification in 30 days	30 Days	Yes
		Annual COI User Notification	15 Day Annual COI Notification	15 Days	Yes
		Annual COI User Notification	10 Day Annual COI Notification	10 Days	Yes
		Annual COI User Notification	Annual COI 1 Day Notification	1 Days	Yes

You can set up any number of notifications that will send X amount of days prior to the Covered Person's COI Due Date.

Recipients: Covered Person.

Send Criteria: Notification will send x amount of days prior to the COI Due Date



The first notification to trigger and send to the Covered Person will also cause an Annual Conflict of Interest Renewal Notice task to populate on the Covered Persons homepage. This task will remain on the user's homepage until the Annual COI Form is completed and submitted to the COI Office.

Annual COI Lapse Notifications

Here, you can set up any number of notifications that will send to Covered Persons who have not yet submitted their Annual COI Form on a specified amount of days after the COI Due Date. If the Covered Person submits the form, these notifications will not trigger.

Add a New Lapse Notification | Delete Lapse Notification(s)

List of Annual COI User Lapse Notifications

	Edit	Type	Title	Notification X days after to Annual Due date	Send To
		Annual COI Lapse Notification	Annual COI Lapse Notification	3 Days	Doe, Jane

Recipients: The Covered Person and any additional recipients added to the notification.

Send Criteria: Notifications will send x amount of days after the COI Due Date if the Annual COI Form has not been submitted.

Annual COI Failure to Submit Notification

One notification will send to a Covered Person on their COI Due Date if the Annual COI Form has not been submitted.

List of Annual COI Failure To Submit Notifications

Edit	Type	Title	Send To	Action
	Annual COI Failure to Submit Notification	Annual COI Failure to Submit Notification	Doe, Jane	Delete Failure Notification

You can only have one notification defined. This notification will send on the day of the COI Due Date as long as the Covered Person has not yet submitted their Annual COI Form.

Recipients: The Covered Person and any additional recipients added to the notification.

Send Criteria: Notifications will send the day of the COI Due Date if the Annual COI Form has not been submitted.

New Hire Annual COI Notifications

When a new user account is created and that account is flagged as a Covered Person, the system will assign that user a COI Due Date five days after their account creation, which will trigger a notification to alert the new hire of his or her Annual COI Form.

List of New Hire Annual COI Notifications

Edit	Type	Title	Every ? days after account created	Send To	Action
	Annual COI New Hire Notification	Annual COI New Hire Notification	2 Days	Hart, Jane	Delete New Hire Annual COI Notification

You can only have one notification defined. This notification will send based on the number of days specified after the account is created.

Recipients: The Covered Person and any additional recipients added to the notification.

Send Criteria: Notifications will send x amount of days after user account is created.

Conflict of Commitment Review Notification Setup

Set up notifications that will to send to Commitment Reviewers for review assignments and acknowledgements.

Level 1 Commitment Reviewer Notifications

Level 1 Commitment Reviewer Notifications will only send to Level 1 Commitment Reviewers. The first notification will send when the reviewer receives a new commitment to review. The second two notifications will send to the reviewer a specified number of days after receiving the initial notification, serving as reminders of the review.

Level 1 Commitment Reviewer Notifications

Edit	Type	When to Notify	Title	Send E-mail Notification	Action
	Level 1 Reviewer Notice to review a reported Commitment		Level 1 Reviewer Notice to review a reported Commitment	Yes	Delete Notification
	Level 1 Reviewer Reminder to review a reported Commitment	Notify when reviewer has not been completed within 1 Days	Level 1 Reviewer Reminder to review a reported Commitment	Yes	Delete Notification
	Level 1 Reviewer Deadline Missed reminder to review a reported Commitment	Notify recurring when reviewer has not been completed within 2 Days	Level 1 Reviewer Deadline Missed reminder to review a reported Commitment	Yes	Delete Notification

Recipient: Level 1 Commitment Reviewer.

Send Criteria: These notifications will send when (1) The task is first received/assigned, (2) X amount of days from which the reviewer task was received/assigned but has not yet been completed, and (3) Every recurring x amount of days from which the task was received/assigned but is not yet completed.

Level 2 Commitment Reviewer Notifications

These notifications will send to Level 2 Commitment Reviewers. The first notification will send when the reviewer receives a new commitment to review. The second two notifications will send to the reviewer a certain number of days after receiving the initial notification, serving as reminders of the review.

Level 2 Commitment Reviewer Notifications

Edit	Type	When to Notify	Title	Send E-mail Notification	Action
	Level 2 Reviewer Notice to review a reported Commitment		Level 2 Reviewer Notice to review a reported Commitment	Yes	Delete Notification
	Level 2 Reviewer Reminder to review a reported Commitment	Notify when reviewer has not been completed within 1 Days	Level 2 Reviewer Reminder to review a reported Commitment	Yes	Delete Notification
	Level 2 Reviewer Deadline Missed reminder to review a reported Commitment	Notify recurring when reviewer has not been completed within 3 Days	Level 2 Reviewer Deadline Missed reminder to review a reported Commitment	Yes	Delete Notification

Recipient: Level 2 Commitment Reviewer.

Send Criteria: These notifications will send when (1) The task is first received/assigned, (2) X amount of days from which the reviewer task was received/assigned but has not yet been completed, and (3) Every recurring x amount of days from which the task was received/assigned but is not yet completed.

Covered Person Commitment Review Acknowledgement Notifications

Commitment review acknowledgement notifications will send to the Covered Person with commitment changes made by the reviewer.

Covered Person Commitment Review Acknowledgement Notifications

Edit	Type	When to Notify	Title	Send E-mail Notification	Action
	Covered Person notice to acknowledge a change of Commitment		Covered Person notice to acknowledge a change of Commitment	Yes	Delete Notification
	Covered Person reminder to acknowledge a change of Commitment	Notify when reviewer has not been completed within 2 Days	Covered Person reminder to acknowledge a change of Commitment	Yes	Delete Notification
	Covered Person deadline to acknowledge a change of Commitment	Notify recurring when reviewer has not been completed within 7 Days	Covered Person deadline to acknowledge a change of Commitment	Yes	Delete Notification

Recipient: Covered Person.

Send Criteria: These notifications will send when (1) The task is received/assigned, (2) X amount of days from which the acknowledgement was received/assigned but has not yet been completed, and (3) Every x amount of days from which the acknowledgement task was received/assigned but is not yet completed.

New Study Conflict of Interest Notifications Setup

If you are using the Study COI Form, the New Study/Project Conflict of Interest notifications can be set up to alert KSP on a study when the system requires them to fill this form out.

Notifications specific for case

Edit	Type	When to Notify	Title	Send E-mail Notification	Action
	Key Study Personnel Conflict of Interest Initial Notification		Study COI Form Notification	Yes	Delete Notification
	Key Study Personnel Conflict of Interest Reminder Notification	Notify when reviewer has not been completed within 2 Days	Study COI Form Incomplete	Yes	Delete Notification
	Key Study Personnel Conflict of Interest Deadline Notification	Notify recurring when reviewer has not been completed within 7 Days	Study COI Form Deadline Missed	Yes	Delete Notification

Recipient: Covered Person.

Send Criteria: These notifications will send when (1) The task is first received/assigned, (2) X amount of days from which the acknowledgement was received/assigned but has not yet been completed, and (3) Every recurring x amount of days from which the acknowledgement task was received/assigned but is not yet completed.

Multiple notifications specifically configured, or the different study forms will be listed here.

New Project Conflict of Interest Notifications Setup

If you are using the Project COI Form, the New Project Conflict of Interest notifications can be set up to alert KSP on a project when the system requires them to fill this form out.

Notifications specific for 700U2 Disclosure Form

Edit	Type	When to Notify	Title	Send E-mail Notification	Action
	Key Project Personnel Conflict of Interest Initial Notification		Project COI Form Notification	Yes	Delete Notification
	Key Project Personnel Conflict of Interest Reminder Notification	Notify when reviewer has not been completed within 2 Days	Project COI Form Incomplete	Yes	Delete Notification
	Key Project Personnel Conflict of Interest Deadline Notification	Notify recurring when reviewer has not been completed within 7 Days	Project Study COI Form Deadline Missed	Yes	Delete Notification

Recipient: Covered Person.

Send Criteria: These notifications will send when (1) The task is first received/assigned, (2) X amount of days from which the acknowledgement was received/assigned but has not yet been completed, and (3) Every recurring x amount of days from which the acknowledgement task was received/assigned but is not yet completed.

Multiple notifications specifically configured, or the different study forms will be listed here.

Review Response Notification Setup

The Review response, or submission notifications, will generate and send to the study when a review board returns a submission for changes. You can also define reminder notifications to be sent when the study does not respond within a certain amount of time to these changes.

List of Response Types

Edit	Type	Title	Send E-mail Notification
	Submission Correction	Submission Correction	Yes
	Review Response	Review Response	Yes

Response Types

These two notifications will generate and send when the review board requests changes. The Submission Correction will generate and send when the review board indicates there are pre-review changes. The Review Response will generate and send when the review board adds stipulations and sets the Submission Outcome to an outcome that will return to the study. These notifications will send x amount of days after the Submission Correction/Review Response has been sent, if the study has not responded.

List of Submission Correction Reminder Notifications

Add a New Reminder Notification | Delete Reminder Notification(s)

	Edit	Type	Notification after ? Days	Title	Send E-mail Notification
		Submission Correction Reminder Notification	30 Days	COI Correction Reminder	Yes

List of Review Response Reminder Notifications

Add a New Reminder Notification | Delete Reminder Notification(s)

	Edit	Type	Notification after ? Days	Title	Send E-mail Notification
		Submission Response Reminder Notification	30 Days	Submission Response Reminder	Yes

Reviewers Notification Setup

Reviewers Notifications are programmed to send to assigned reviewers of a Conflict Match. There is also a notification you can set up to let the assigned analyst of a Conflict Match know when reviewers have completed their review.

Reviewers Complete Notification

The Reviewers Complete notification will trigger and send to the assigned analyst when reviewers are complete with their reviews on a Conflict Match.

List of RB Reviewers Complete Notifications

Edit	Type	Title	Send E-mail Notification	Action
	RB Reviewers Complete Notification	RB Reviewers Complete Notification	Yes	Delete Notification

Recipient: Assigned Analyst.

Send Criteria: This notification will send when reviewer assignments on a Conflict Match are complete.

Reviewer Assignment Notifications

Reviewer Assignment notifications will generate and send to an assigned reviewer based on the review process of the conflict match. You can also set up a notification to send to the reviewer if they have been removed from the review.

List of Reviewer Assignment Notifications

Edit	Type	Title	Send E-mail Notification	Action
	Agenda Reviewer Assignment Notification	Reviewer Agenda Assignment Notification	Yes	Delete Notification
	Expedited Reviewer Assignment Notification	COI - Expedited Reviewer Assignment Notification	Yes	Delete Notification
	Process Administrative Reviewer Assignment Notification	Review a COI Process Administratively Test for a COI	Yes	Delete Notification
	Reviewer Unassignment Notification	Notification for Reviewer	Yes	Delete Notification

Agenda Reviewer Assignment Notification

This notification will send to a full board reviewer. Note that you must also have Enable Reviewer Notifications set to "Yes" under the Meeting Date within Meeting Manager before full board review notifications will send.

Recipient: Assigned Reviewer.

Criteria: This notification will send when the Review Process of Assign to Review Committee Agenda is set, a reviewer is assigned to the Conflict Match, and Enable Reviewer Notifications is set to Yes.

Expedited Reviewer Assignment Notification

The Expedited Reviewer notification will send to a reviewer when a Conflict Match for review is assigned a Review Process of Expedited.

Recipient: Assigned Reviewer.

Send Criteria: This notification will send when the Review Process is set to Expedited and a reviewer is assigned to the Conflict Match.

Process Administrative Reviewer Assignment Notification

The Process Administrative Reviewer Assignment notification will send to a reviewer when a Conflict Match for review is assigned a Review Process of Process Administratively.

Recipient: Assigned Reviewer.

Send Criteria: This notification will send when a Review Process of Process Administratively is set and a reviewer is assigned to the Conflict Match.

Reviewer Unassignment Notification

The Reviewer Unassignment notification will send if you delete a reviewer assignment task.

Recipient: Assigned Reviewer.

Send Criteria: This notification will send upon a reviewer's removal from reviewing a Conflict Match.

Reviewer Assignment Pending Reminder

You can set up a Reviewer Assignment Pending Reminder notification that will send out a specified number of days after a review assignment to remind the reviewer of his or her task.

List of Reviewer Assignment Reminders

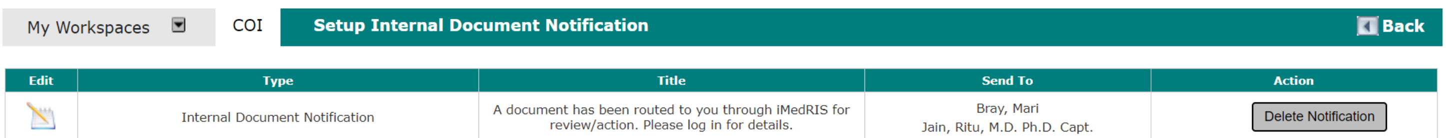
Edit	Type	When to Notify	Title	Send E-mail Notification	Action
	Reviewer Assignment Pending Reminder	Notify every 1 Days	Reviewer Assignment Pending Reminder	Yes	Delete Notification

Recipient: Assigned Reviewer.

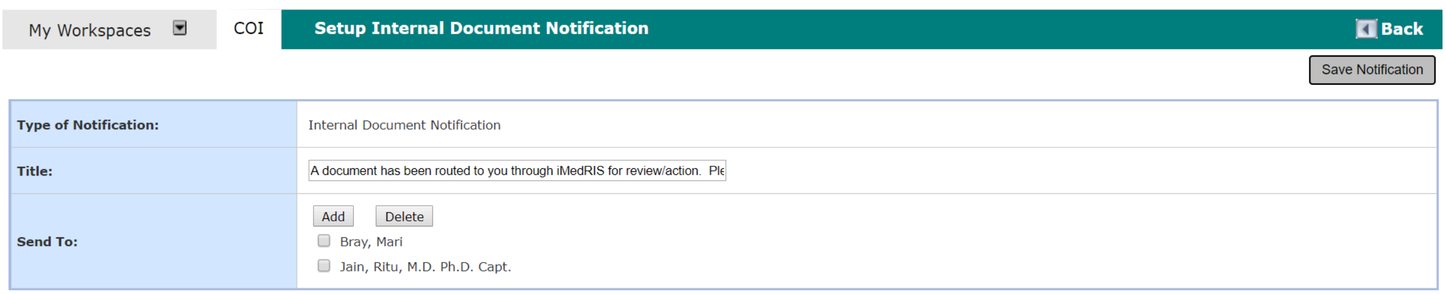
Send Criteria: This notification will send every x amount of days after the initial assignment notification is sent and the reviewer has not yet completed his or her review.

Internal Documents Notification

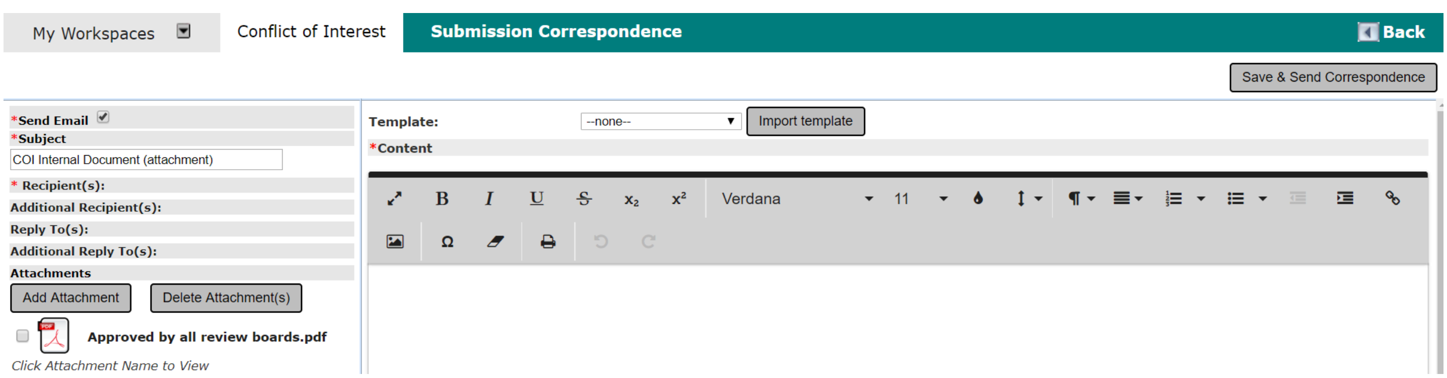
The review board can upload documents to a study record specific to the study and internal to the review board. When documents are uploaded, you have the ability to email that document to another user of the system.



Notifications defined here will attach the uploaded document and send to the selected recipient.



The contents of the notification contain a title and recipients. You do not need to specify content for the notification.



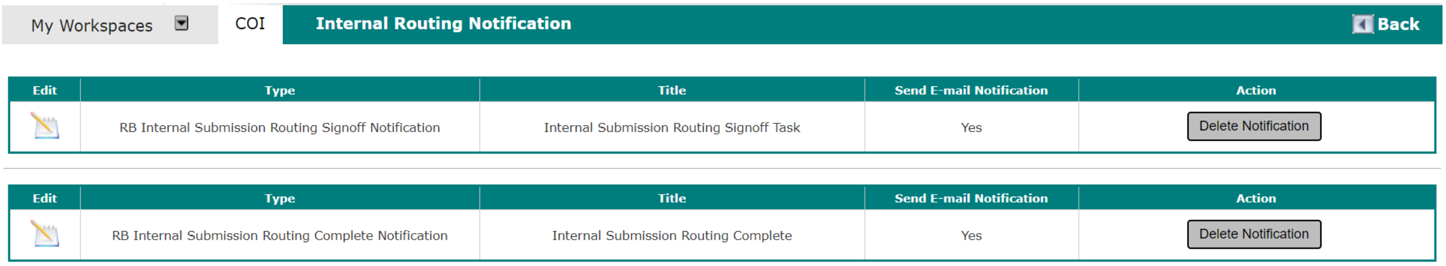
Recipients: Any user specified within the notification template, or any additional recipients manually added at the time you send the notification. The screenshot above shows an example of a template about to be sent from a study within the COI board. The Recipients column pulled in the recipient as defined in the notification setup, and you can also manually add additional recipients here.

Send Criteria: The notification will send when you access Review Board Internal Documents within a study record of the COI board. Select the checkbox next to the document you wish to send, then click the **Send Email** button.

This will cause the Internal Documents Correspondence page to open. You can type in content for the notification, change the recipient list or change the Subject line for the email. When you are done and ready to send the notification, click on the **Save & Send Correspondence** button.

Internal Routing Notification

Internal Routing notifications will send to both the user assigned an Internal Routing task and the assigned analyst when an Internal Routing task is completed.


My Workspaces | COI | Internal Routing Notification | Back

Edit	Type	Title	Send E-mail Notification	Action
	RB Internal Submission Routing Signoff Notification	Internal Submission Routing Signoff Task	Yes	Delete Notification

Edit	Type	Title	Send E-mail Notification	Action
	RB Internal Submission Routing Complete Notification	Internal Submission Routing Complete	Yes	Delete Notification

Internal Routing Assignment Notification

Internal Routing Assignment notifications are sent to users who are assigned an Internal Routing task.

Recipient: User assigned a routing task from the Internal Routing tab within the Conflict Match processing screens.

Send Criteria: This notification will send as soon as the user is assigned, and you indicate “Yes” to the question: Have you completed your selection of required routings?

Internal Routing Complete Notification

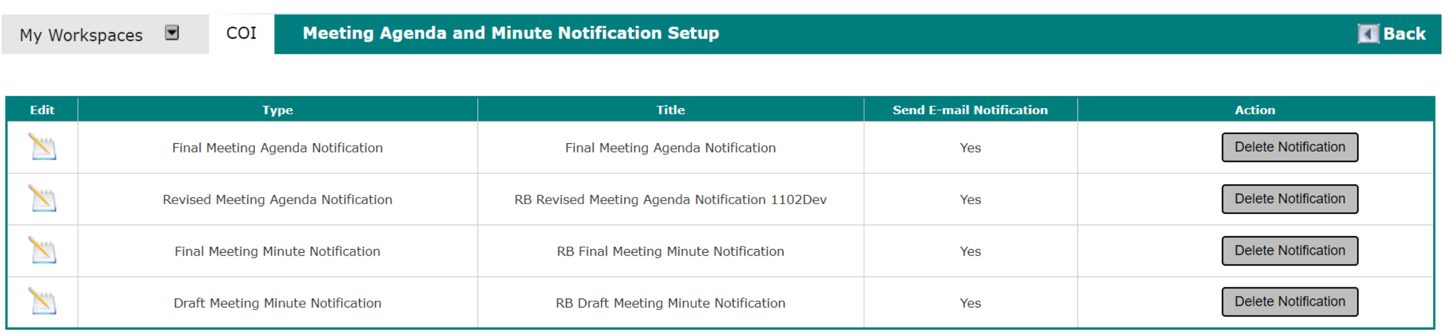
The Internal Routing complete notification will send to the Assigned Analyst when all assigned users have completed their Internal Routing tasks for a Conflict Match.

Recipient: Assigned Analyst.

Send Criteria: This notification will send when all users have completed their Internal Routing tasks for a Conflict Match.

Meeting Agenda and Minute Notification

The Meeting Agenda and Minutes notifications send out to board members when you generate, publish, and indicate to the system to send out the agenda template or a Minutes template for a specific meeting date in the Meeting Manager. These notifications generate with the PDF-published versions of the appropriate document attached. They will send to all board members or to members present at a specific meeting, depending on what notification is being sent out.


My Workspaces | COI | Meeting Agenda and Minute Notification Setup | Back

Edit	Type	Title	Send E-mail Notification	Action
	Final Meeting Agenda Notification	Final Meeting Agenda Notification	Yes	Delete Notification
	Revised Meeting Agenda Notification	RB Revised Meeting Agenda Notification 1102Dev	Yes	Delete Notification
	Final Meeting Minute Notification	RB Final Meeting Minute Notification	Yes	Delete Notification
	Draft Meeting Minute Notification	RB Draft Meeting Minute Notification	Yes	Delete Notification

Final Meeting Agenda Notification

Final Meeting Agenda notifications will generate when you send the published Meeting Agenda for a specific meeting date within the Meeting Manager. The notification will attach a PDF Meeting Agenda.

Recipient: All members of the committee.

Send Criteria: Clicking **Send The Finalized Agenda Document To All Members** within a meeting date in the Meeting Manager will send this notification.

Revised Meeting Agenda Notification

The Revised Meeting Agenda notification will generate when you send a published Revised Meeting Agenda for a specific meeting date in the Meeting Manager. The notification will attach a PDF Meeting Agenda Revision. ***Not applicable to COI.**

Recipient: All members of the committee

Send Criteria: Clicking **Send The Revised Agenda Document To All Members** within a meeting date in the Meeting Manager will send this notification.

Final Meeting Minute Notification

The Final Meeting Minute notification will generate when you send the published Meeting Minutes for a specific meeting date in the Meeting Manager. The notification will attach a PDF copy of the Meeting Minutes.

Recipient: Users marked present at the meeting.

Send Criteria: Clicking **Send Out A Final Copy Of The Minutes To The Meeting Attendees** within a meeting date in the Meeting Manager will send this notification.

Draft Meeting Minutes Notification

The Draft Meeting Minutes notification will generate when you send a copy of the Draft Meeting Minutes for a specific meeting date in the Meeting Manager. The notification will attach a PDF copy of the Draft Meeting Minutes.

Recipient: Users marked present at the meeting.

Send Criteria: Clicking **Send Out A Copy Of The Draft Minutes To The Meeting Attendees** within a meeting date in the Meeting Manager will send this notification.

Meeting Attendance Notification Setup

You can set up notifications that will send to board members a certain amount of days prior to a meeting date, asking them to log in to the system and set their meeting availability. You can also setup a notification that will send to COI Coordinators if any member changes their availability within a certain amount of time prior to a meeting date.

My Workspaces COI **Meeting Attendance Notification Setup** Back

Add a New Notification Delete Notification(s)

List of Meeting Attendance Notifications

	Edit	Type	Notification prior to expiration date	Title	Send E-mail Notification
		Meeting Attendance Notification	30 Days	Member Attendance Notification	Yes

List of Member Attendance Change Notification

Edit	Type	Title	Send E-mail Notification	Action
	Member Attendance Change Notification	Member Attendance Change Notification	Yes	Delete Member Attendance Change Notification

Meeting Attendance Notifications

If you would like to send notifications to board members notifying them to set their availability for upcoming meetings, you can set these reminders in the Meeting Attendance Notifications section. These notifications will send to Board Members a certain amount of days prior to a meeting date to let the member know they need to set their availability for that particular meeting. You can have any number of meeting attendance notifications set up.

Recipients: Members of the committee.

Send Criteria: These notifications will send x amount of days prior to a meeting date.

Member Attendance Change Notification

The Member Attendance Change notification will send to COI Coordinators a certain amount of time prior to the meeting date if any member has changed their availability.

Recipients: COI Coordinators.

Send Criteria: The notification will send x amount of days prior to a meeting date only if a member changes attendance in the specified amount of time before the meeting.

Outcome Letter Notification

Notifications related to Outcome Letters are set up here. These notifications send to Outcome Letter recipients, to users assigned to sign an Outcome Letter, and to alert analysts that signoffs on letters have been completed.

Outcome Letter Notification

The notification that will generate and send to selected recipients when you send an Outcome Letter is set up in the Outcome Letter Notification section. This notification will attach a PDF Outcome Letter.

List of RB Outcome Letter Notifications

Edit	Type	Title	Send E-mail Notification	Action
	RB Outcome Letter Notification	Outcome Letter Notification	Yes	Delete Outcome Letter Notification

Recipients: Selected recipients, designated when the Outcome Letter is created.

Send Criteria: This notification will send when the "Send" option is clicked for an Outcome Letter.

Outcome Signoff Letter Notification

The Outcome Signoff Letter notification is generated and sent to a user assigned to sign off on an Outcome Letter.

List of Outcome Signoff Letter Notifications

Edit	Type	Title	Send E-mail Notification	Action
	RB Outcome Signoff Letter Notification	Outcome Signoff Letter	Yes	Delete Outcome Signoff Letter Notification

Recipients: Any user assigned to sign the Outcome Letter.

Send Criteria: This notification will send when "Have you completed your selection of required signatures?" is set to Yes within the Letter Signoff Routing List.

Outcome Signoff Complete Notification

The Outcome Signoff Complete notification generates and sends to an assigned analyst when all signoff tasks for the letter have been completed.

List of Outcome Signoff Complete Notifications

Edit	Type	Title	Send E-mail Notification	Action
	RB Outcome Signoff Complete Notification	RB Outcome Signoff Complete Notification	Yes	Delete Outcome Signoff Complete Notification

Recipients: Assigned Analyst.

Send Criteria: This notification will send when all assigned users have completed their Outcome Letter signoff tasks.

Management Plan Notifications

Notifications related to Management Plan Letters are set up in the Management Plan Notifications section. These notifications send to Management Plan Letter recipients, to users assigned to sign a Management Plan Letter, and to alert analysts that signoffs on letters have been completed.

My Workspaces | COI | **RB Management Plan Notification** | **Back**

List of RB Management Plan Notifications

Edit	Type	Title	Send E-mail Notification	Action
	COI Management Plan Notification	New Management Plan Yeah	Yes	Delete Management Plan Notification

List of Management Plan Signoff Notifications

Edit	Type	Title	Send E-mail Notification	Action
	COI Management Plan Signoff Notification	COI Management Plan Signoff Notification	Yes	Delete Plan Signoff Notification

List of Management Plan Signoff Complete Notifications

Edit	Type	Title	Send E-mail Notification	Action
	COI Management Plan Signoff Completed Notification	COI Management Plan Signoff Completed Notification	Yes	Delete Plan Signoff Complete Notification

Management Plan Notification

The Management Plan notification generates and sends to selected recipients when you send a Management Plan. This notification will attach a PDF Management Plan Letter.

Recipients: Selected Recipients.

Send Criteria: This notification will send when Send is clicked for a Management Plan.

Management Plan Signoff Notification

The Management Plan Signoff notification will generate and send to a user assigned to sign off on a Management Plan.

Recipients: Any user assigned to sign the Management Plan.

Send Criteria: This notification will send when “Have you completed your selection of required signatures?” is set to Yes within the Letter Signoff Routing List.

Management Plan Signoff Complete Notification

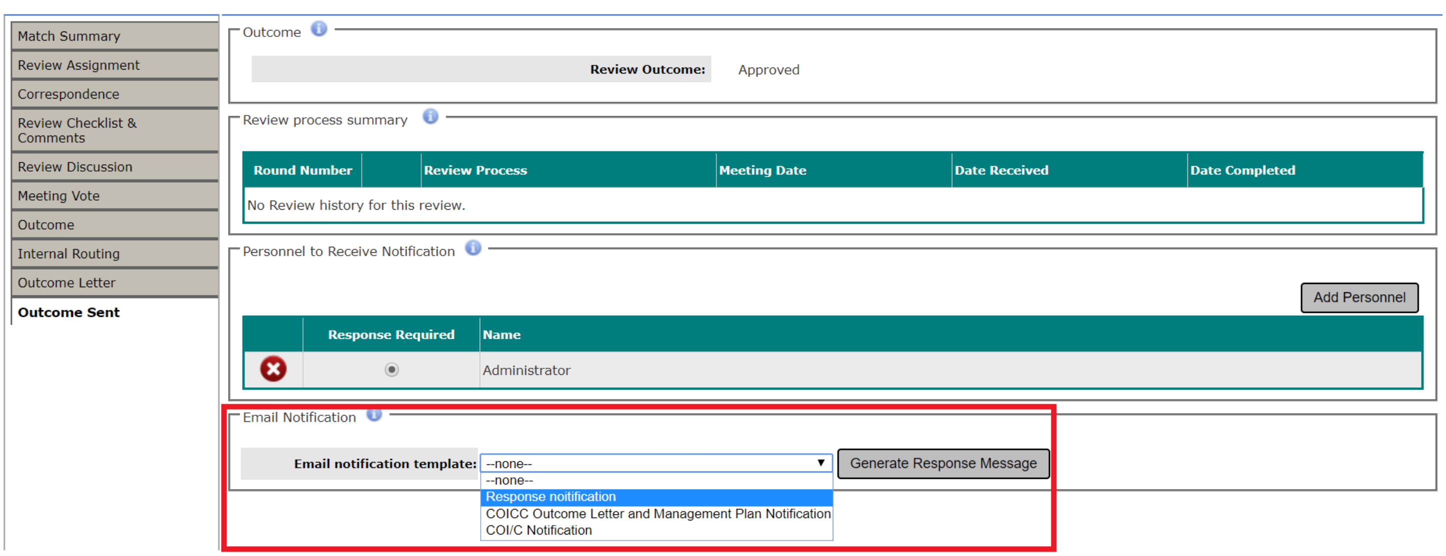
The Management Plan Signoff Complete notification generates and sends to an assigned analyst when all signoff tasks for the letter have been completed.

Recipients: Assigned Analyst.

Send Criteria: This notification will send when all assigned users have completed their Management Plan Signoff tasks.

Response Notifications

When you are ready to complete processing a match within the Conflict Match processing screens, the next step is to generate a response to the Covered Person, which will bundle any Management Strategies and Letters associated to the Conflict Match.



Before you can complete processing a Conflict Match, you must select an Email Notification to send to the Covered Person. The list of email notification templates available in the dropdown list are set up under Response Notifications.

The Response Notifications are templates you can select when you are sending a response to the Covered Person.

Response Notification

Add a Template | Delete Template(s)

List of Response Notification Templates

	Edit	Title
		All Conflicts Approved with Dept Merge Code in it
		Approved Disclosure
		Management Plan Required

You can set up any number of Response Notifications. These notifications are generated in the Outcome Sent tab of the Conflict Match processing screens where you can also use merge codes to pull in information specific to the Conflict Match.

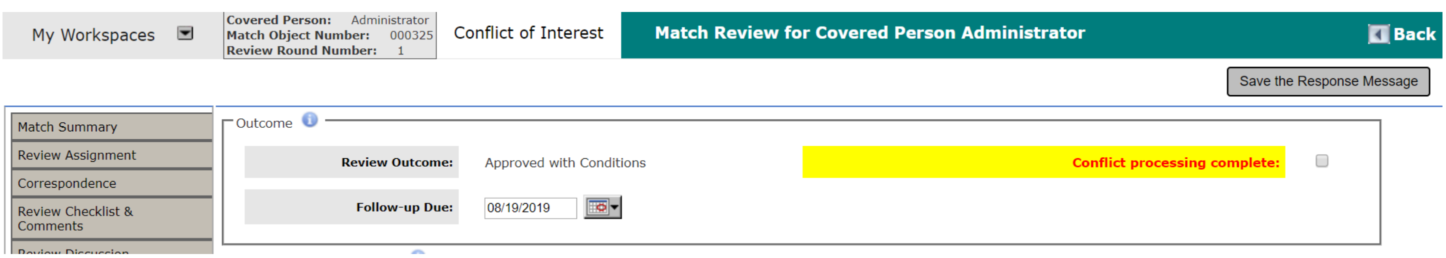
Personnel to Receive Notification

Add Personnel

	Response Required	Name
		Administrator
		John Investigator

Recipients: Any user added to the Personnel to Receive Notification list (see above) on the Outcome Sent tab, within the Conflict Match processing screens.

Send Criteria: Notification will send when the Conflict Processing Complete flag is set in the Outcome Sent tab, located in the Conflict Match processing screens.



Response Reminder Notifications

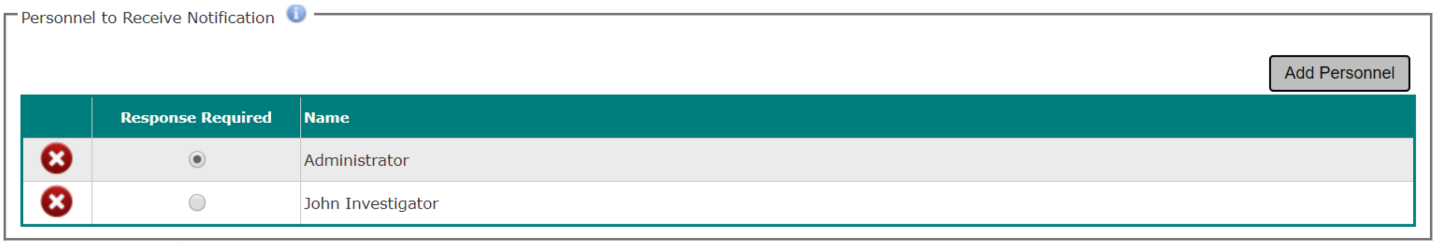
If you send a Management Plan to a Covered Person and indicate a Follow-Up Due date in the Outcome Sent tab of the Conflict Match processing screens, you can set up reminder notifications that will send to the Covered Person a designated number of days after the follow up was due.

List of Response Reminders Notifications

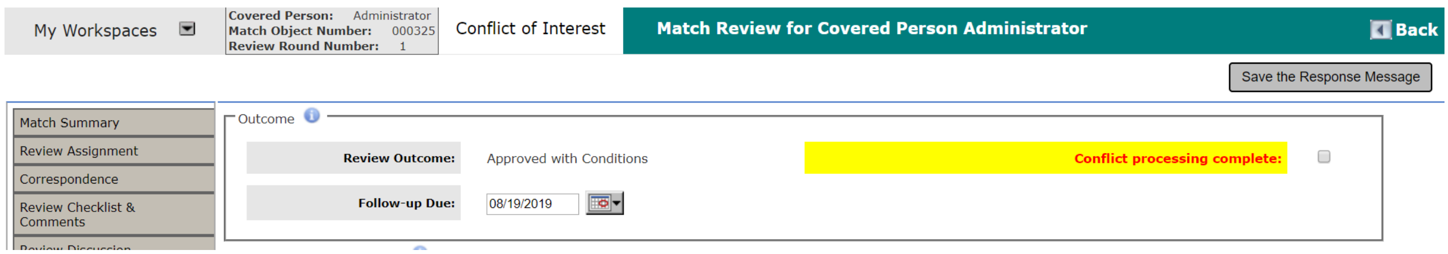
Add a New Response Reminders Notification | Delete Response Reminders Notification(s)

	Edit	Type	Notification after ? Days	Title	Send E-mail Notification
		COI Response Reminder Notification	1 Days	COI Response Reminder	Yes

You can set up any number of reminder notifications.



Recipients: A user flagged with "Response Required" in the Personnel to Receive Notification table of the Outcome Sent tab within the Conflict Match processing screens. The recipient is typically the Covered Person.



Send Criteria: The notification will send x amount of days after the indicated Follow-up Due date if the Management Plan has not been responded to.

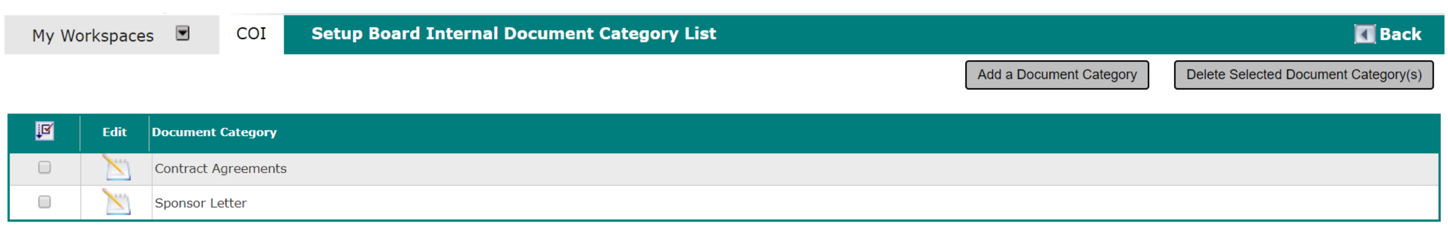
List Maintenance Setup

List Maintenance Setup contains the configurable dropdown lists available for you to set up. The left column contains lists related to study lists and system-wide lists. The right column contains lists related to Conflict of Interest drop-down lists that are mapped to panels in the COI Forms.

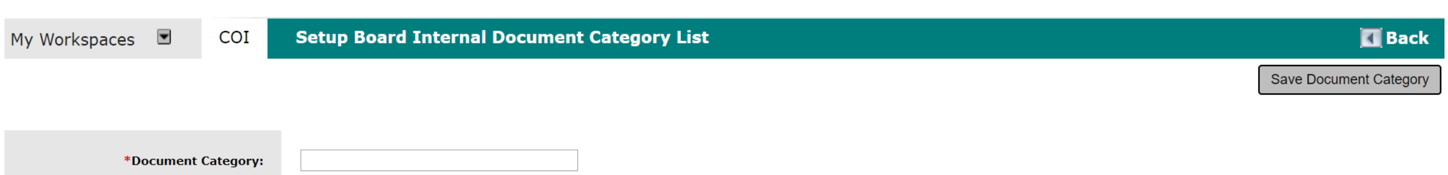
Review Board Lists

Internal Document Category

You can create categories for any Internal Documents you upload to a study within the COI board.

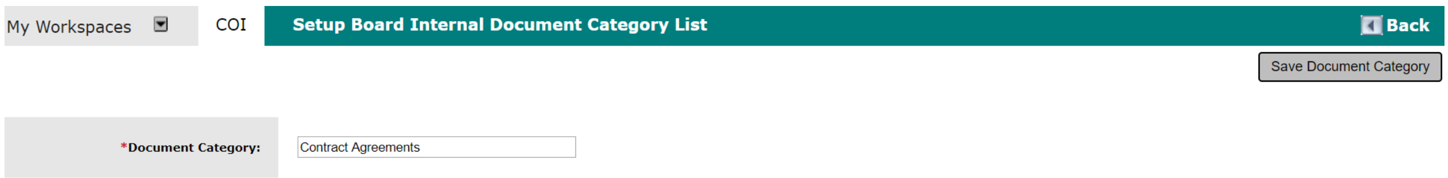


When you open the Internal Document Category page, a list of all categories will display. If you have not set up any categories, the page will be blank. You can add a category by clicking on the **Add a Document Category** button.

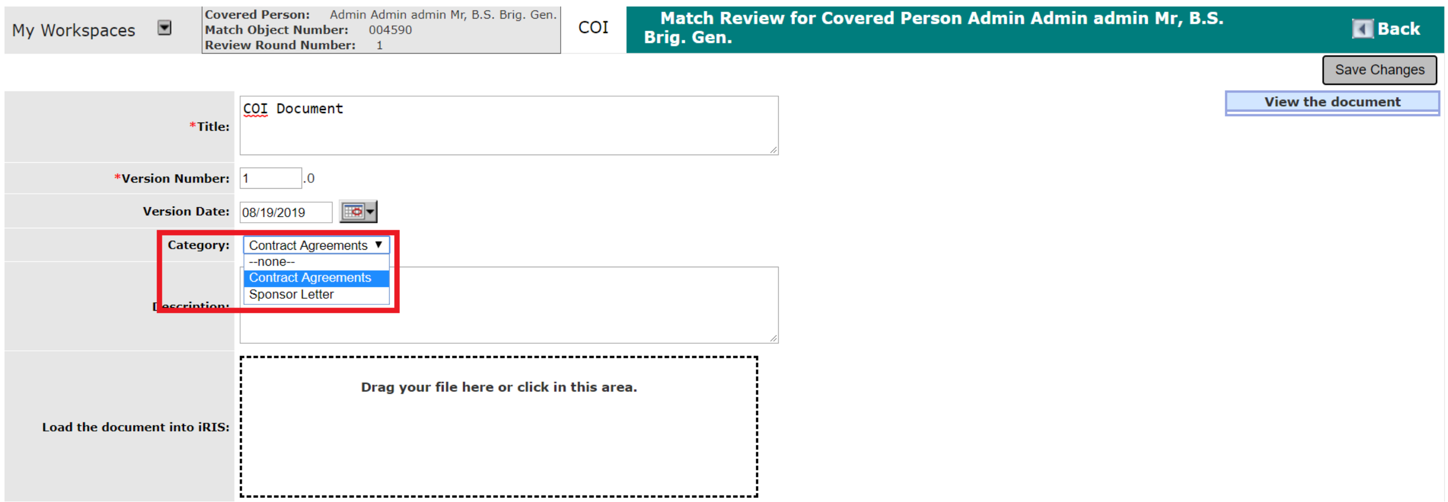


Type in the **Document Category** name, and then click the **Save Document Category** button to add the category to the list.

You can edit existing categories by clicking the **Edit** icon next to the category name. This will open a page that will allow you to modify the name.



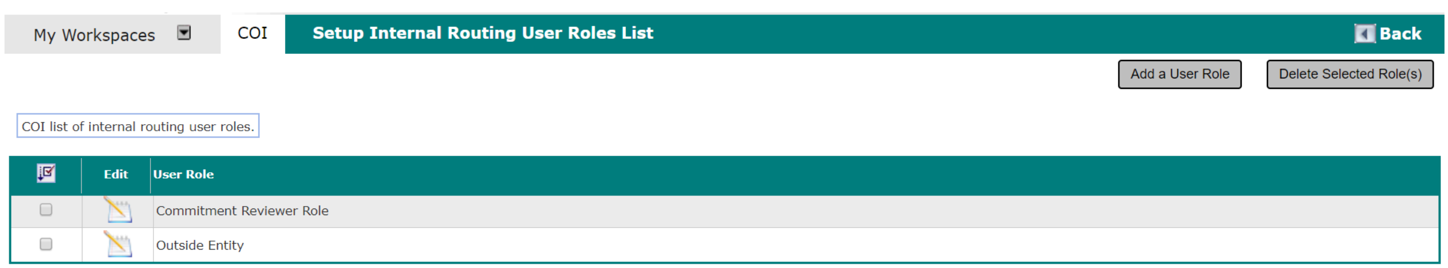
Note: The Internal Document Category is a shared list between the Review Board Internal Study Documents and the Covered Person Internal Documents.



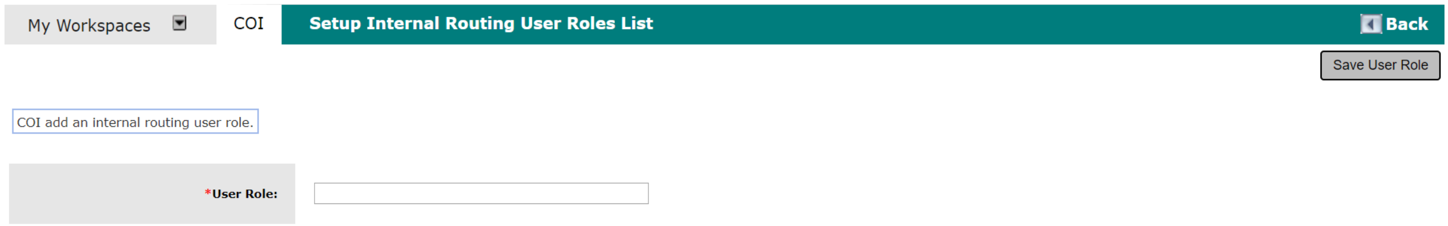
Any category you add to the list will populate in the Category dropdown list when you are uploading a document in the Review Board Internal Documents area after accessing a study from the COI board side. The categories also populate in the **Category** dropdown list when you are adding a document to a Covered Person within Internal Documents in the Conflict Match processing screens or within Search Conflict Matches.

Internal Routing User Roles

When you are assigning a user to an Internal Routing task, you can specify a role for that user. To use the user roles feature, the review board property rb.useReviewRouting_user_role must be set to "Yes."

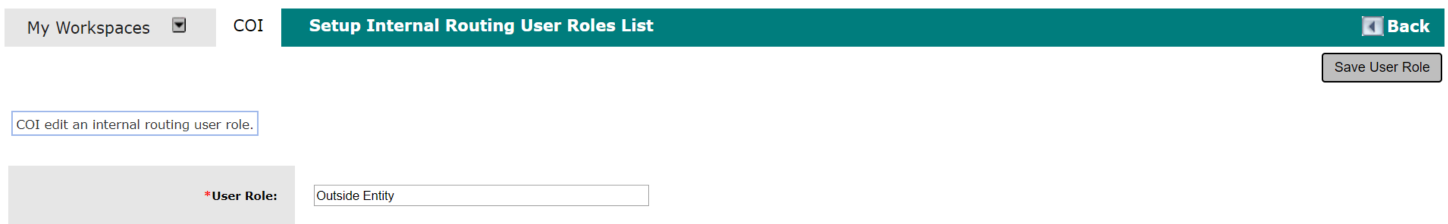


When you open the Internal Routing User Roles page, a list of roles will display. If you have not set up any roles, the page will not list any records. You can add a new role by clicking on the **Add a User Role** button.

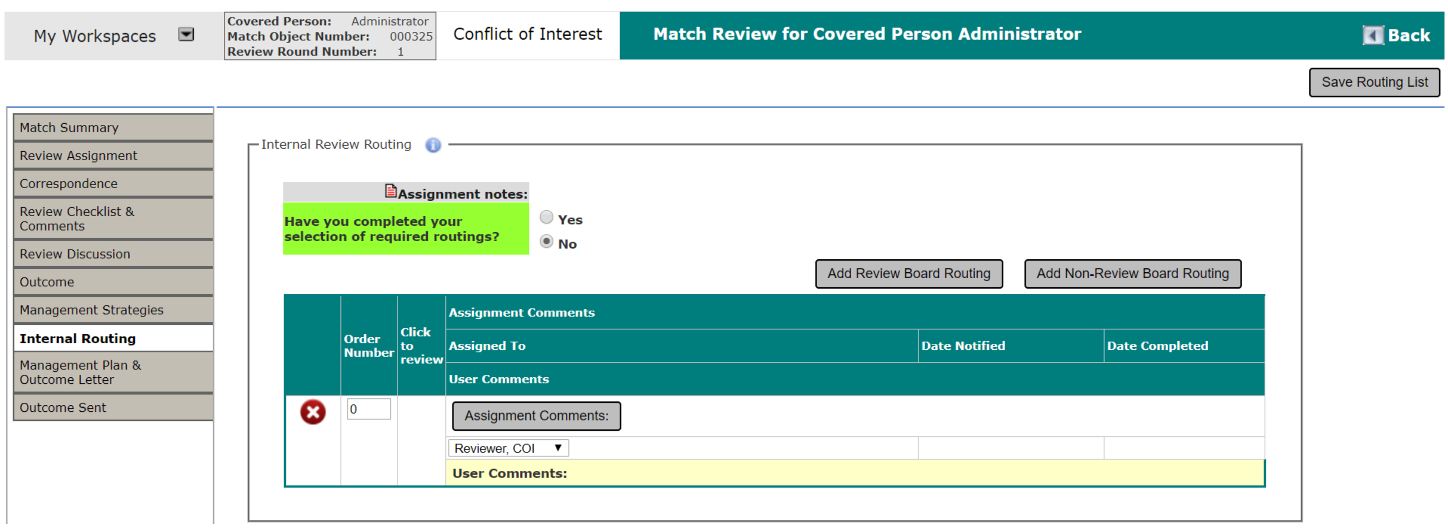


Type in the **User Role** name, and then click the **Save User Role** button to add the new role to the list.

You can edit existing roles by clicking the **Edit** icon next to the role name. This will open a page that will allow you to modify the role's name.

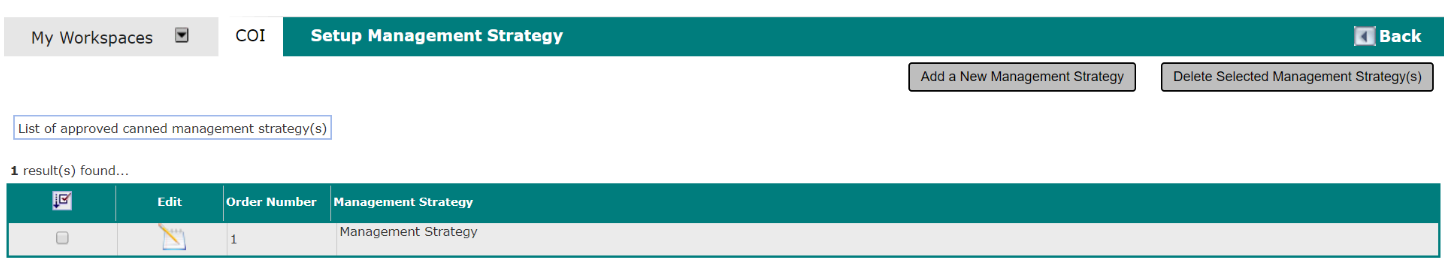


Any role you add to the list will populate in the dropdown list next to the user assignment when you are making an Internal Routing assignment for a Conflict Match.

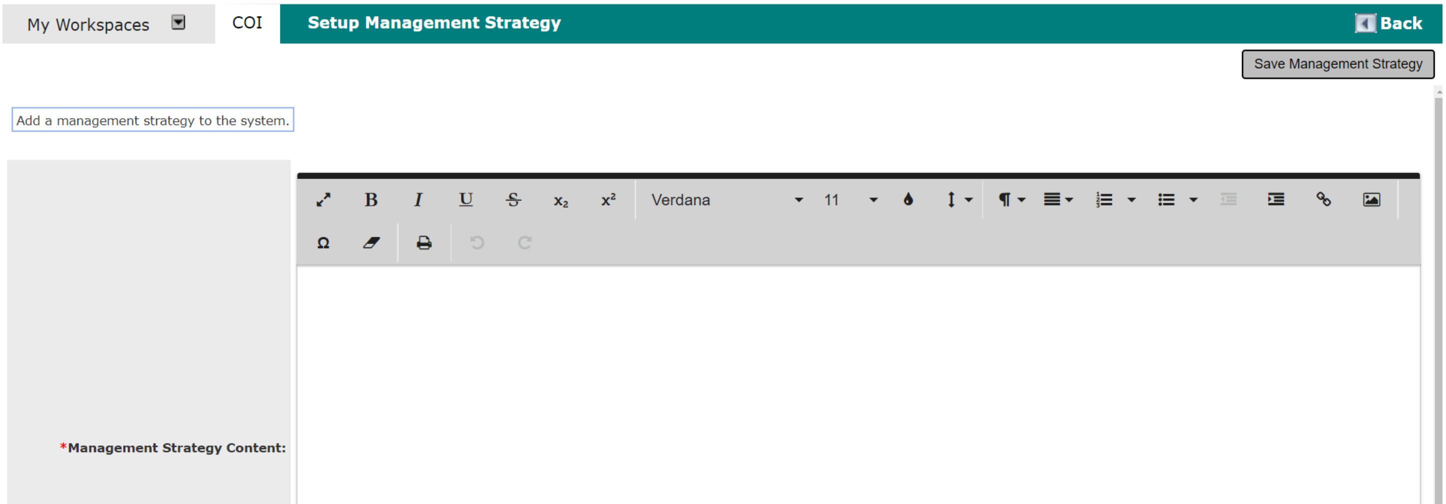


Predefined Strategies

If you have a list of commonly used Management Strategies, you can set them up under Predefined Strategies and pull them into Conflict Matches as needed.



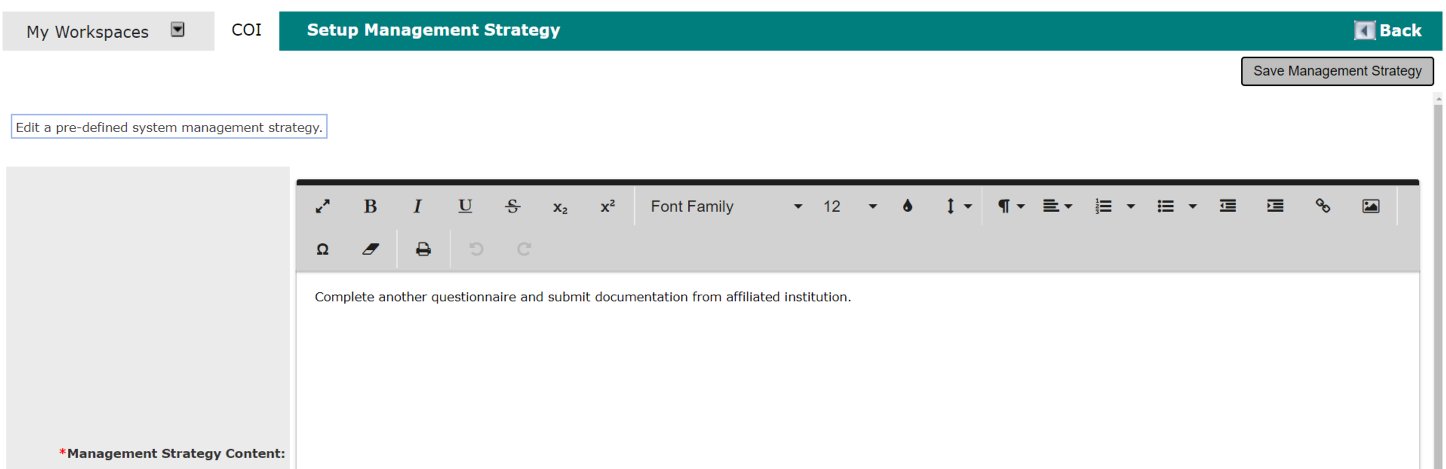
When you open the Predefined Strategies page, a list of predefined strategies will display. If you have not set up any strategies, the page will not list any records. You can add a new predefined strategy by clicking on the **Add a New Management Strategy** button.



If you have set up your system to use Strategy Categories, the **Category** field will populate at the top of the page containing the list of categories you have created. You can choose the category to which you wish to associate the Predefined Strategy from the dropdown list. If you have not set up your system to use Strategy Categories, it will not display, as seen in the screen above.

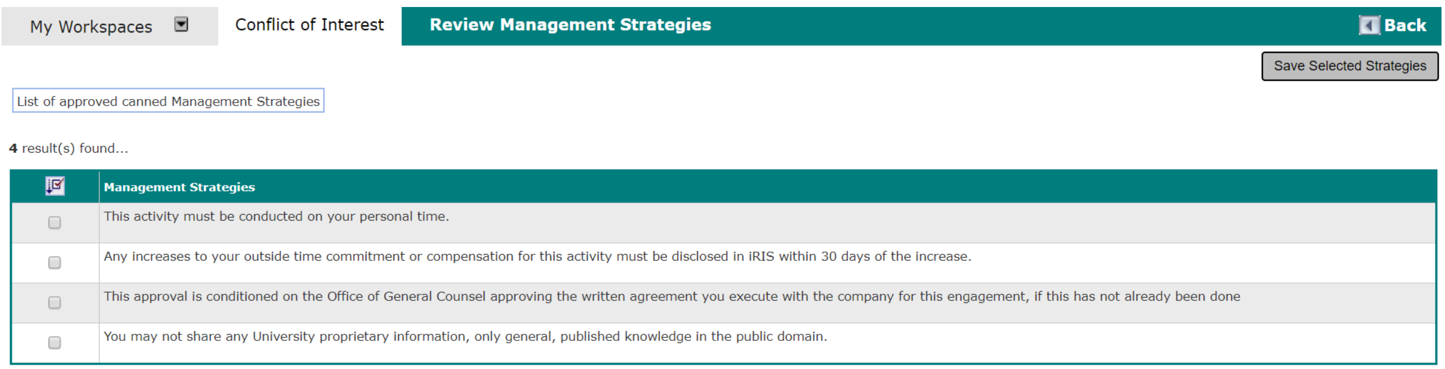
Type in the **Management Strategy Content** specify an **Order**, and then click the **Save Management Strategy** button to add the predefined strategy to the list.

You can edit existing strategies by clicking the **Edit** icon next to the record. This will open a page that will allow you to modify the **Category**, **Management Strategy Content,** and the **Order**.



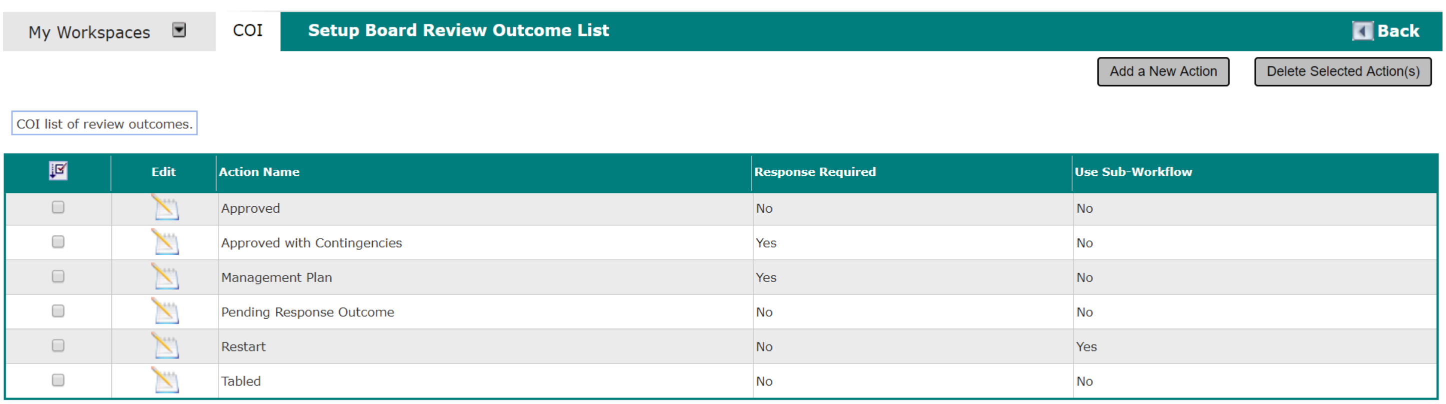
When you are creating a management strategy for a Conflict Match, you will be able to select the option to **Add Pre-defined Strategies**.

When you do, a new page will open listing any predefined strategy(ies) you may have added to the configuration list.

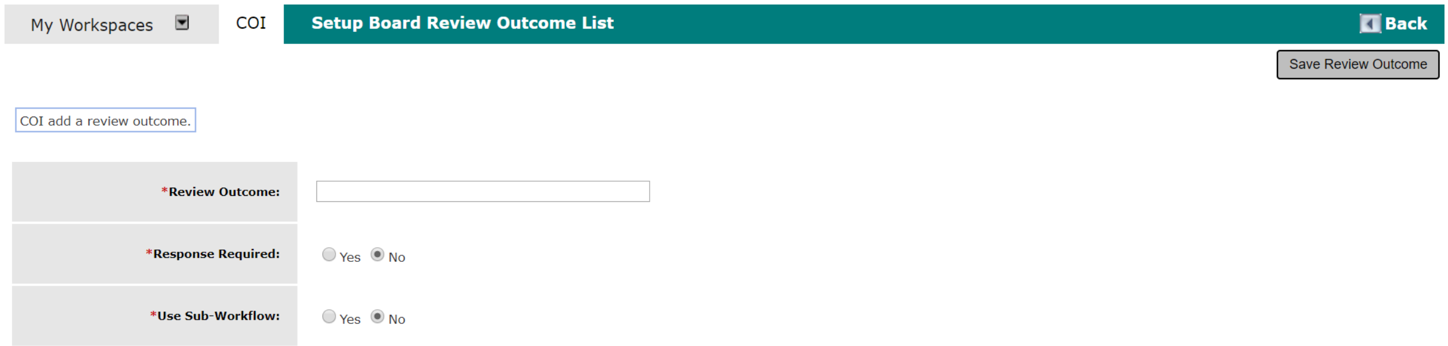


Review Outcome/Outcome Configuration List

Setup the Outcome List for Conflict Matches here.

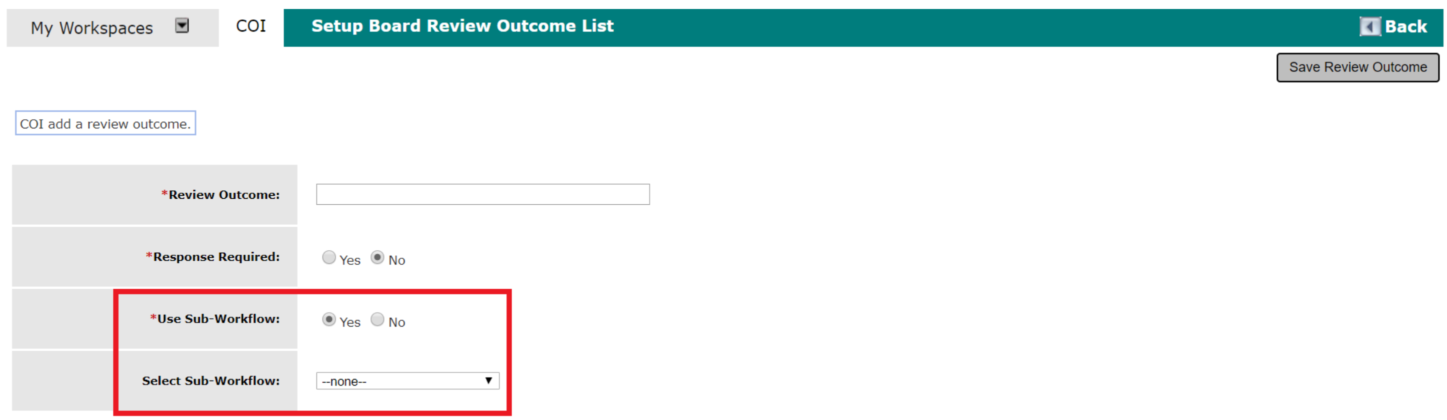


When you open the page, a list of review outcomes will display. If you have not set up any review outcomes, the page will not list any records. You can add a new review outcome by clicking on the **Add a New Action** button.



Type in the **Review Outcome,** specify **Response Required**, and **Use Sub-Workflow.**

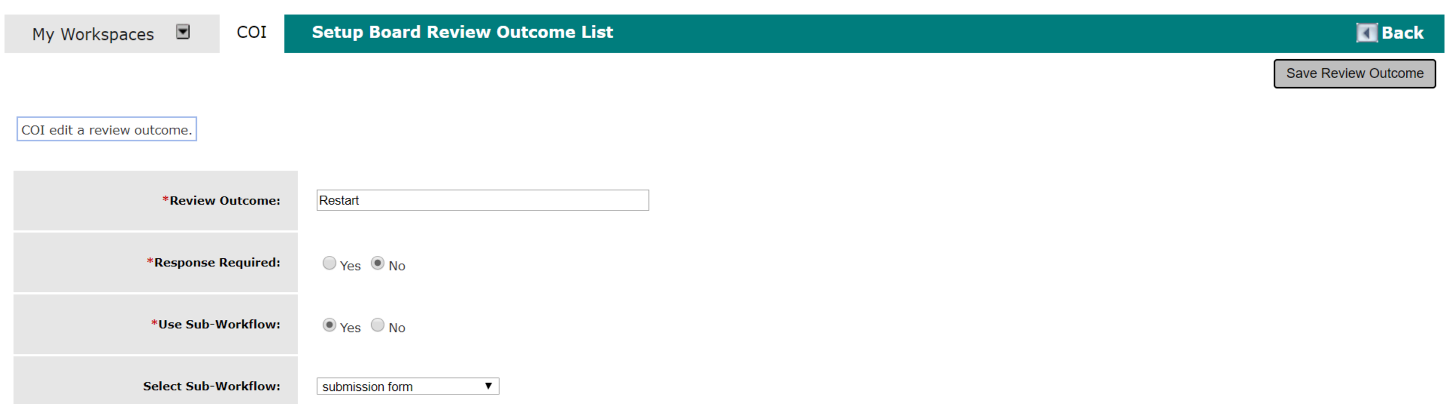
If **Use Sub-Workflow** is set to “Yes”, then the option **Select Sub-Workflow** will appear with the dropdown options.



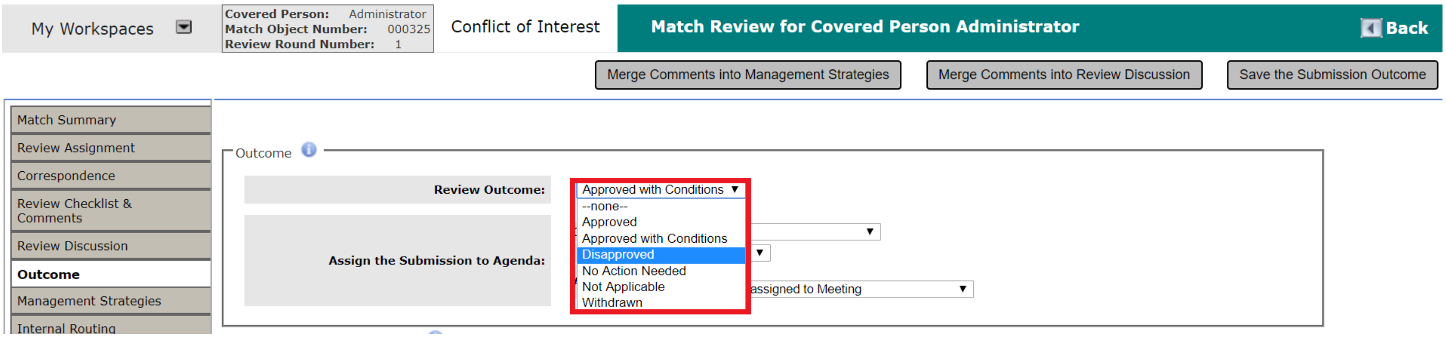
If **Use Sub-Workflow** is set to “No”, then the option **Select Sub-Workflow** will not display.

Click **Save Review Outcome** button to add the review outcome to the list.

You can edit existing review outcomes by clicking the **Edit** icon next to the record. This will open a page that will allow you to modify the **Review Outcome**.

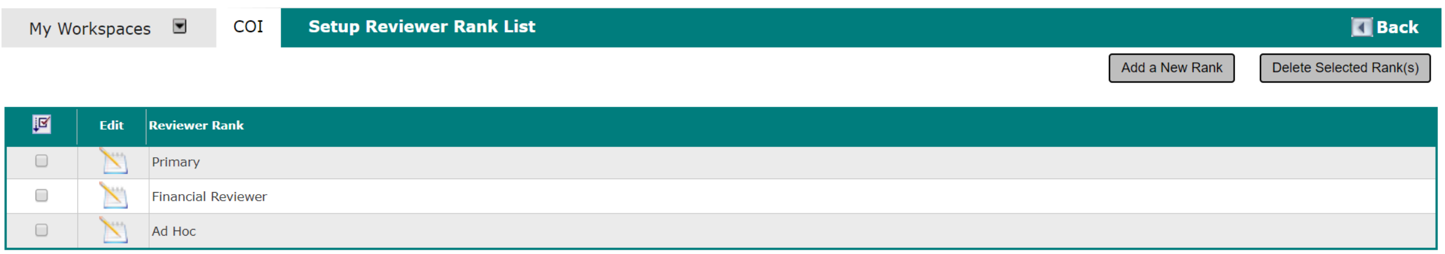


The list of Review Outcomes will populate in the Review Outcome list within the Outcome tab of the Conflict Match submission processing screens.



Reviewer Rank Configuration List

Define your reviewer ranks within the Reviewer Rank Configuration List.

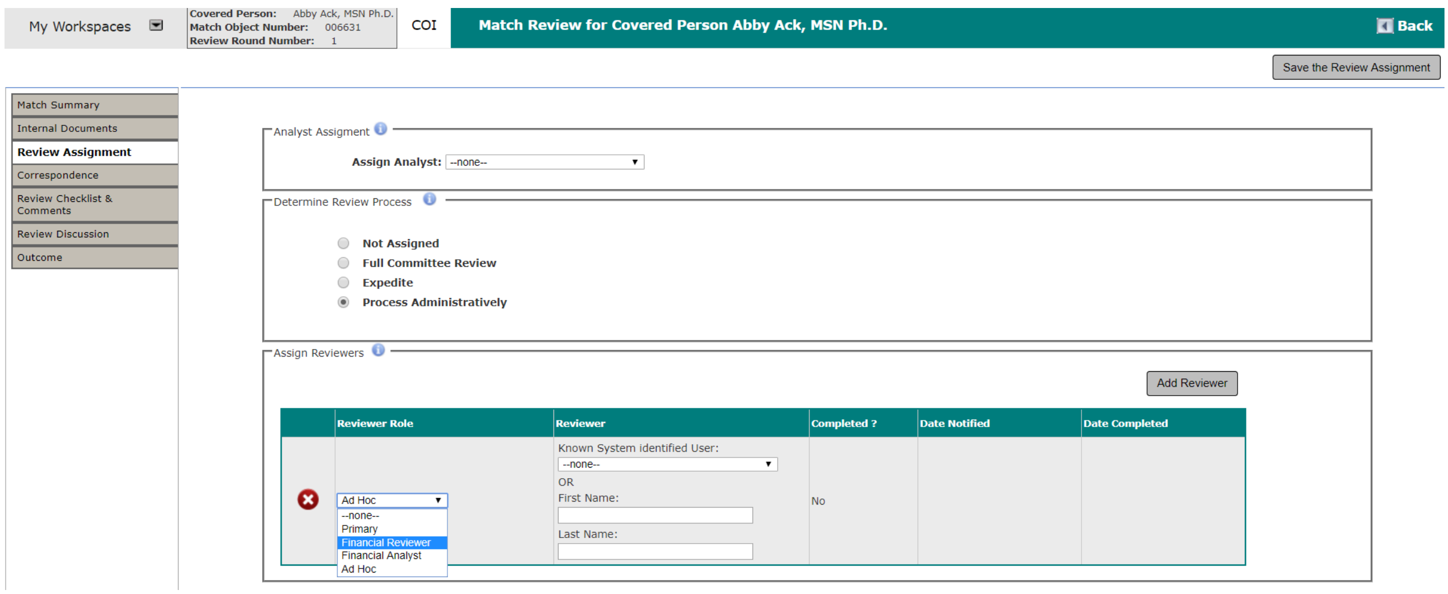


When you open the page, a list of reviewer ranks will display. If you have not set up any reviewer ranks, the page will not list any records. You can add a new reviewer rank by clicking on the **Add a New Rank** button.

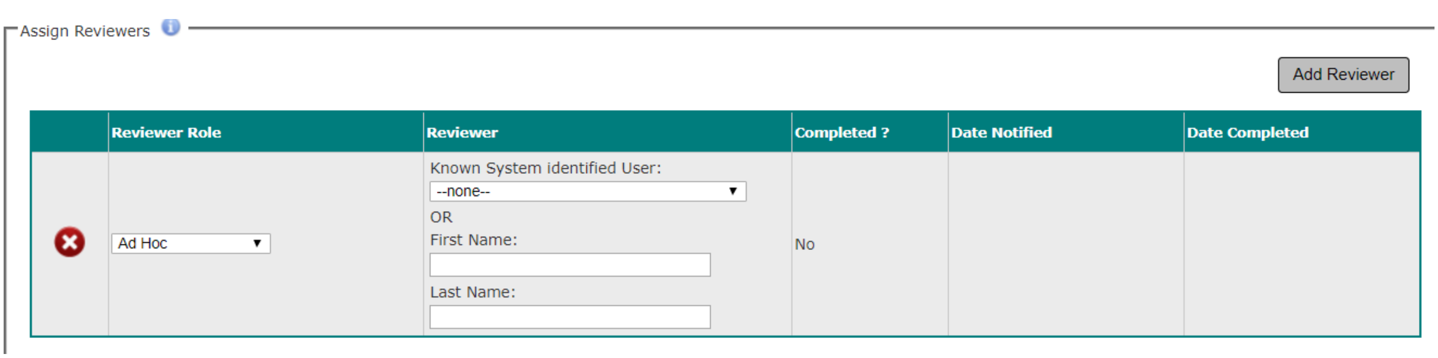
Type in the **Reviewer Rank** name and specify whether the rank represents a Financial Analyst reviewer by selecting Yes or No. Indicating Yes will tell the system to treat this role as an Ad Hoc reviewer. You must also enter a number to specify a rank, using rank numbers 1, 2, 3, or 0. The rank numbers will tell the system how to treat the reviewer ranks, with 1 indicating a Primary Reviewer in the system, 2 indicating a Secondary Reviewer, 3 indicating any other reviewer level, and 0 indicating an Ad Hoc reviewer. Click the **Save Reviewer Rank** button to add the record to the list.

You can edit existing reviewer ranks by clicking the **Edit** icon next to the record. This will open a page that will allow you to modify the record.

Reviewer ranks populate in the Reviewer Role column, as shown in the image above, when you are assigning a reviewer to a Conflict Match.

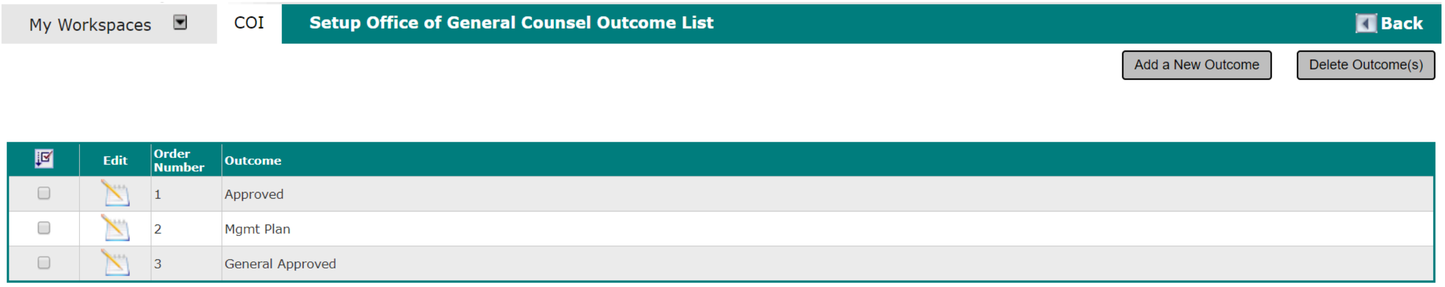


If the reviewer rank you selected is an Ad Hoc rank, you will be able to select a Board Member from the drop-down list in the Reviewer column, or you can type in the first name and last name of the user (for specialty reviewers who do not have a user account in iRIS).

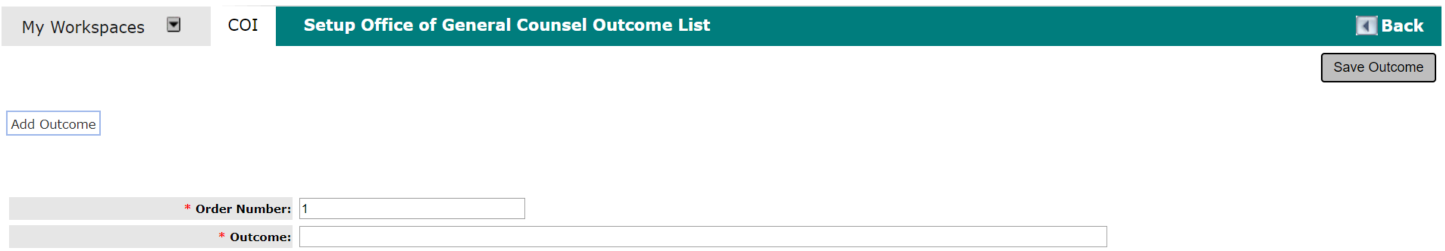


Office of General Counsel Outcome List

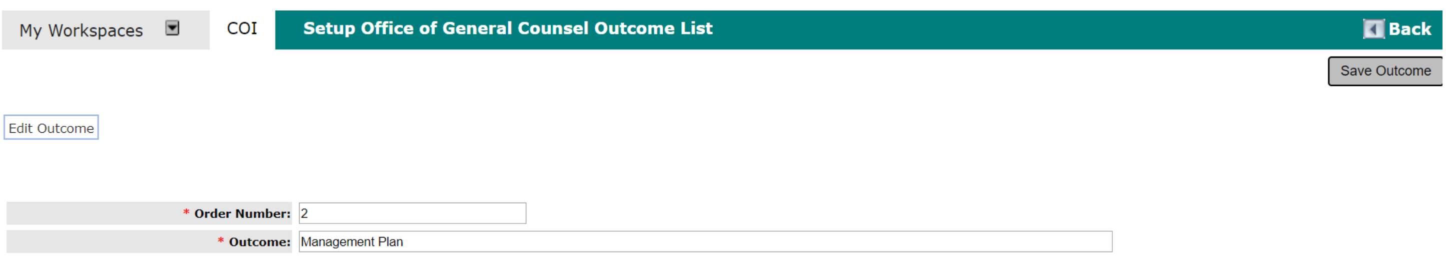
You can select Office of General Counsel Outcomes on the Outcome tab of the Conflict Match processing screens. When you first open this page, any outcomes that have already been configured will display. If you have not configured any outcomes yet, the page will not display any records.



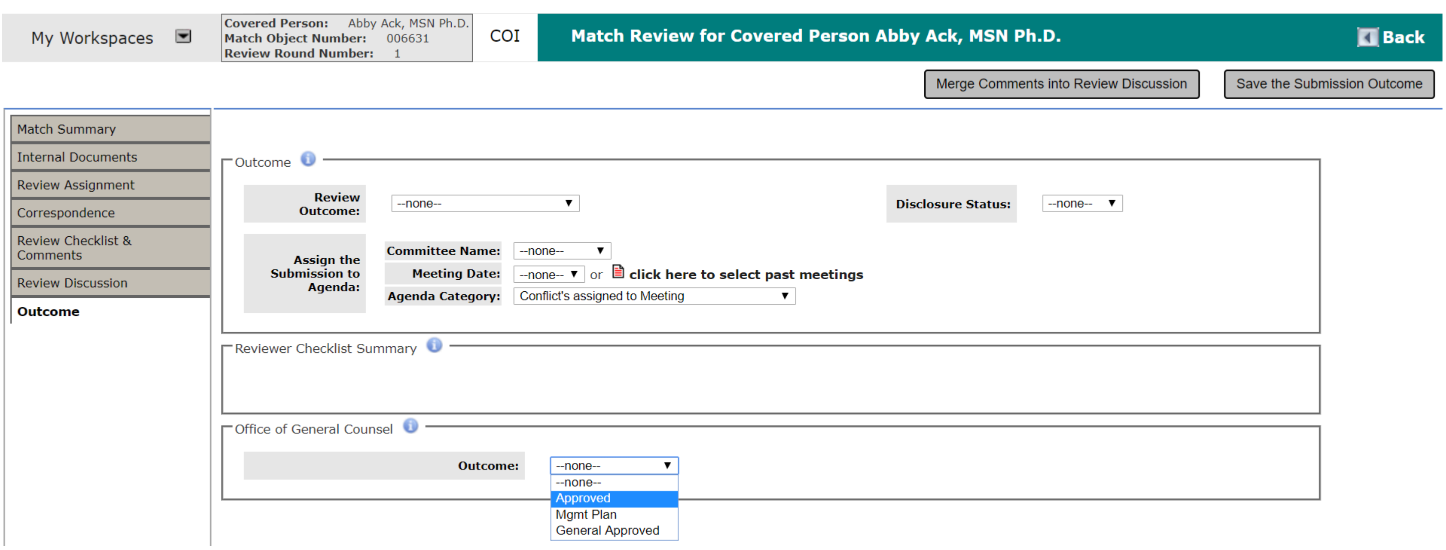
Click **Add a New Outcome** to add a new Office of General Counsel Outcome. On the page that opens, you can enter an Order Number (sets the order in which the outcomes will be displayed) and an Outcome.



When you are finished entering information, click **Save Outcome** to proceed. If you need to edit an outcome, click the icon in the **Edit** column. You will be brought back to the screen shown above, where you can edit the Order Number and Outcome.

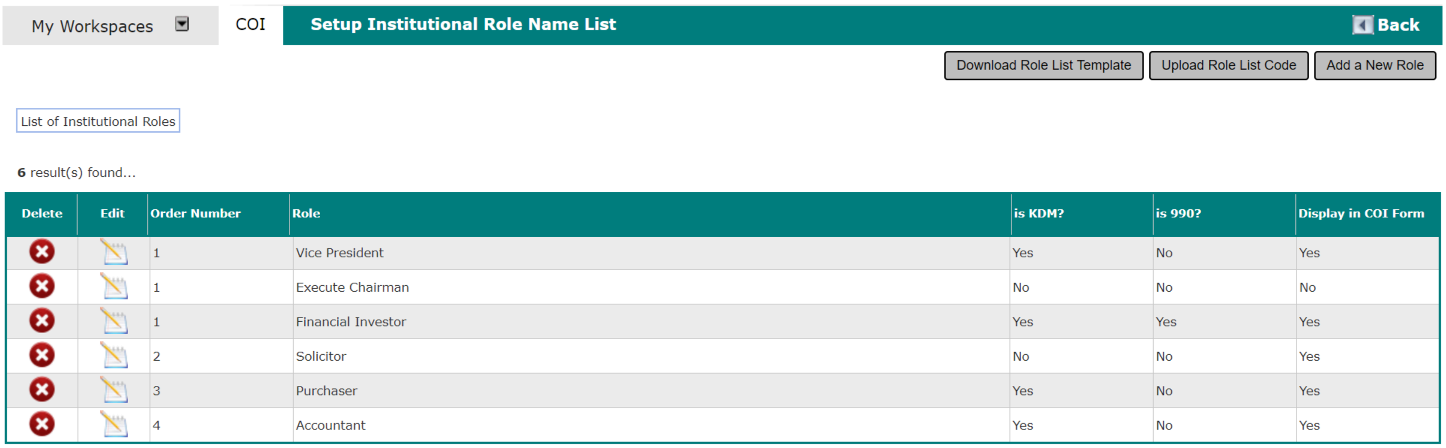


You can select an Outcome from the Office of General Counsel section of the Outcome tab of the Conflict Match processing screens.



Setup Institutional Role Name list

The Institutional Role Name List is used in the Annual COI Form and in a Covered Person's record. Institutional Roles can be set up so the system can flag a certain user if they have a role that indicates a KDM or a 990 requirement.



Delete	Edit	Order Number	Role	is KDM?	is 990?	Display in COI Form
		1	Vice President	Yes	No	Yes
		1	Execute Chairman	No	No	No
		1	Financial Investor	Yes	Yes	Yes
		2	Solicitor	No	No	Yes
		3	Purchaser	Yes	No	Yes
		4	Accountant	Yes	No	Yes

The **Delete** column contains Delete icons that can be used to delete a role. When you select one of these icons, you will receive a message confirming that you wish to delete the item. Click **OK** to proceed or **Cancel** to cancel the deletion.

Edit- Contains an icon that you can click to open, view, and edit information about an existing role.

Order Number- Determines not only how the roles are to be grouped in this list, but also the order in which they are to appear within the Annual COI Form's list of roles when you are given the option to assign a role to a user.

Role – Contains the name of the role that has been defined.

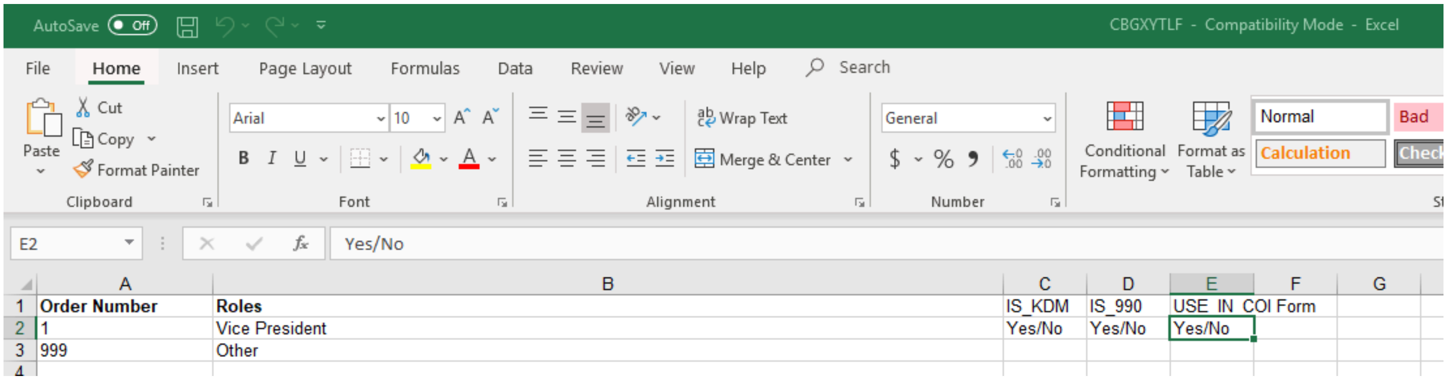
Is KDM?- Indicates whether or not the role is a Key Decision Maker.

Is 990?- Indicates whether or not the role falls under the 990 criteria.

Display in COI Form – Indicates whether the role should display within the Institutional Roles data value, which is located within the Annual COI Form. This will allow a user to select their institutional roles.

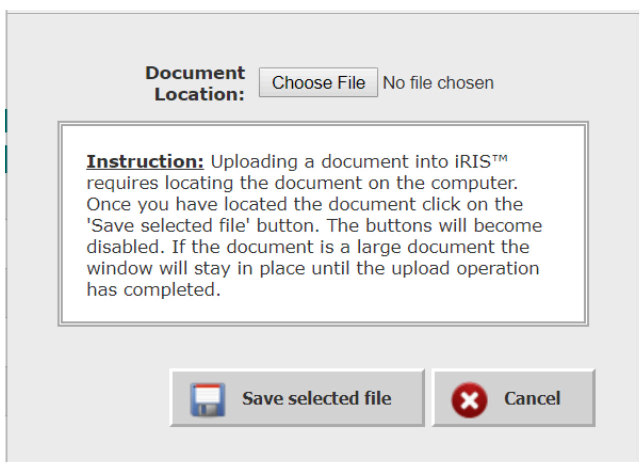
If your list of roles is extensive, rather than entering them one-by-one, you can upload them. Click the **Download Role List Template** button.

You will want to make sure you save the document to a location on your computer that you will remember. The document should automatically download (this also depends on the browser that you are using – different browsers will behave differently).



The Excel download is a simple template where you can enter (or copy and paste) role order numbers and role definitions, and indicate “Yes” or “No” in columns C, D, and E. When you are finished entering information, save the file and return to the Institutional Role configuration list.

Click the **Upload Role List Code** button.

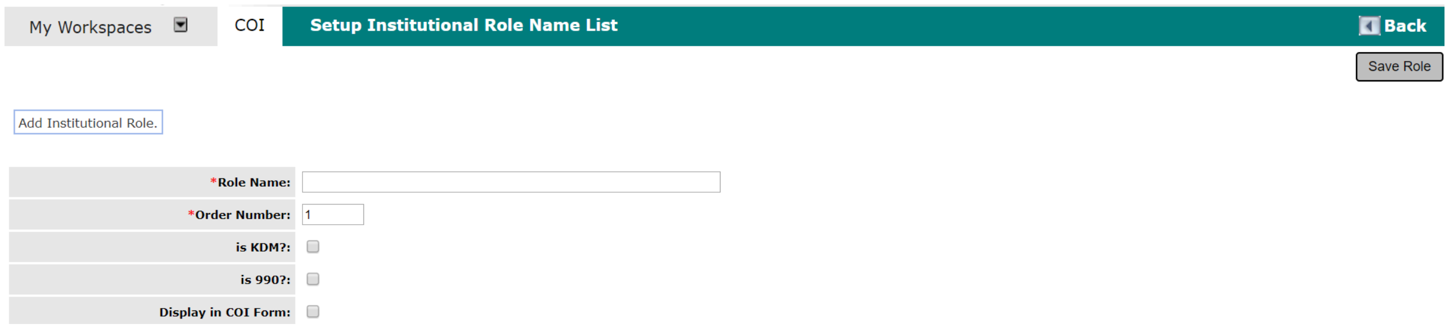


Browse your machine for the edited Excel file’s location. Click **Save selected file** when you have located the file. You can click the **Cancel** button to cancel the upload.

When the roles are successfully uploaded, the system will alert you with a message. If for any reason the upload fails, the pop-up will inform you. Possible reasons for failure would be leaving any of the columns blank or adding extra columns to the spreadsheet.

Any roles you uploaded will now appear in the list of roles.

You can manually add a new role to the list by clicking on the **Add a New Role** button.

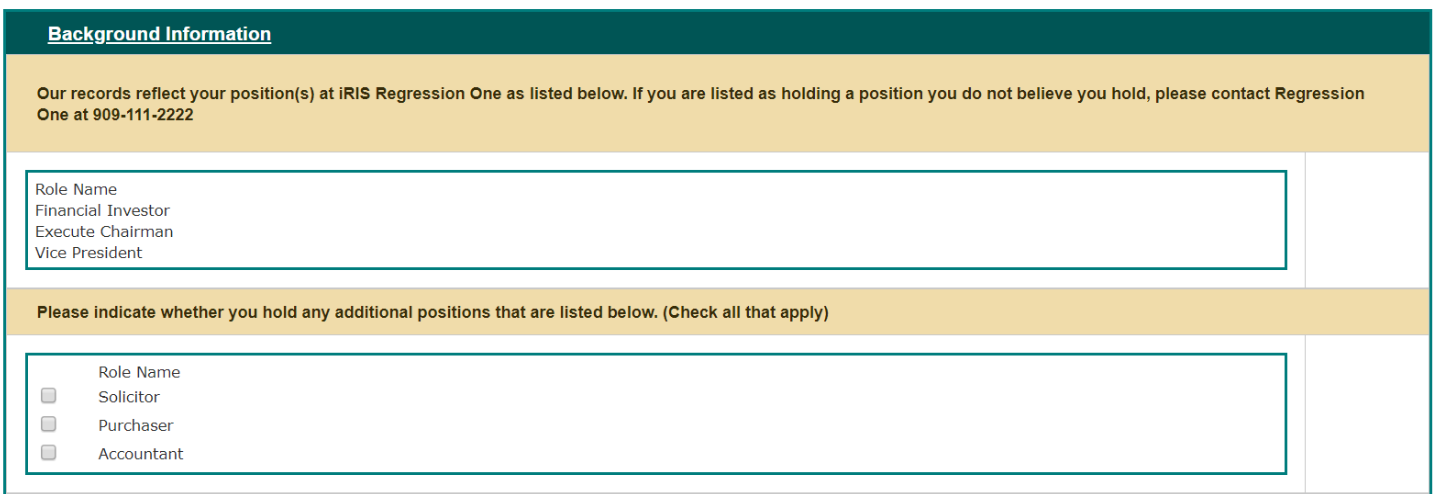


A new page will open. Enter the **Role Name** and specify an **Order Number**.

You can also set flags for the role:

Is KDM? – Indicates whether or not the role is a Key Decision Maker. If a user has a KDM role, certain triggers in the system can be set, including COI triggers and Conflict of Commitment triggers. You can then program branching in your COI Forms to branch down a certain path if the user filling out the form has a role with KDM flagged.

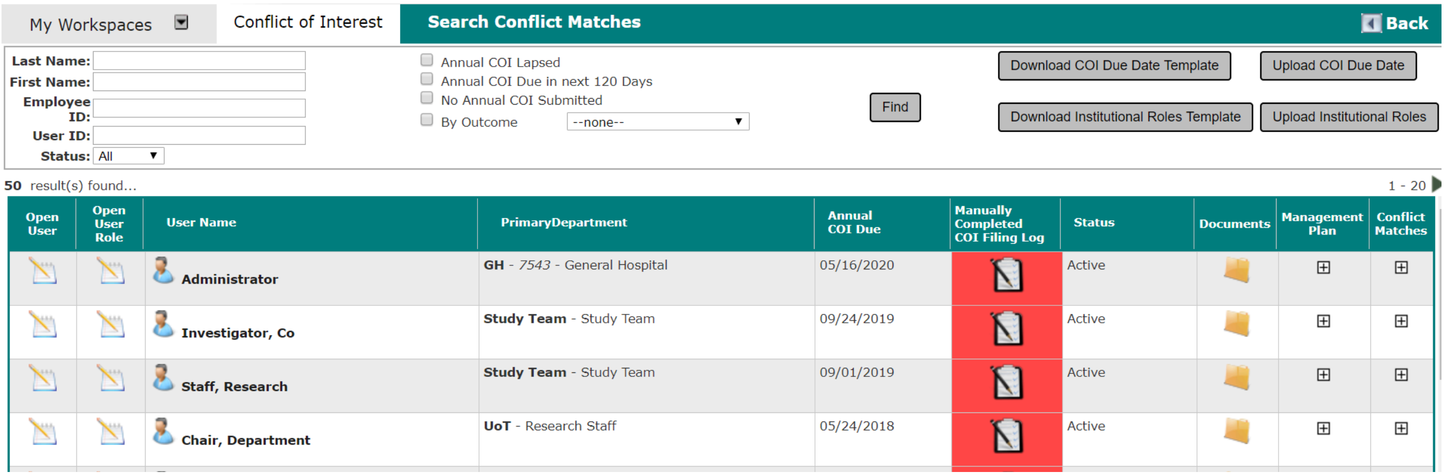
Is 990? – Indicates whether or not the role falls under 990 criteria. You can also program branching in your COI Forms when the user filling out the form has a role with 990 flagged.



Display in COI Form – Indicates whether the role should display in the Institutional Roles data value, located within the Annual COI Form (see the above screenshot). This will allow a user to select their institutional roles.

When you are finished adding the details for the role, click the **Save Role** button and your role will be added to the list.

Once you have entered your institutional roles, you will be able to assign institutional roles to users within the Search Conflict Matches menu item within the COI Review Board Assistant.

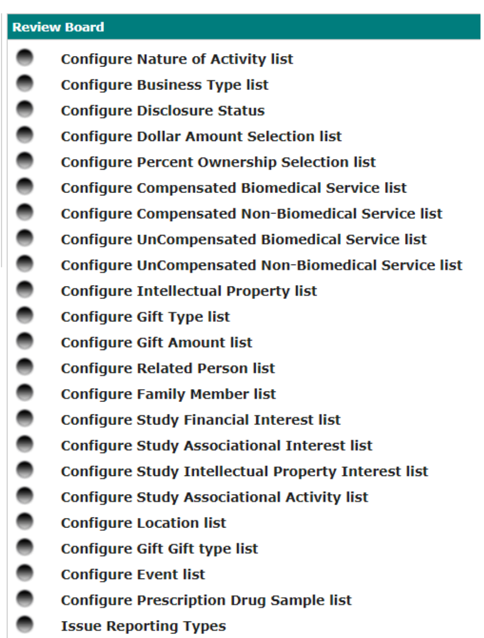


Click the icon in the **Open User Role** column to view role assignment information.

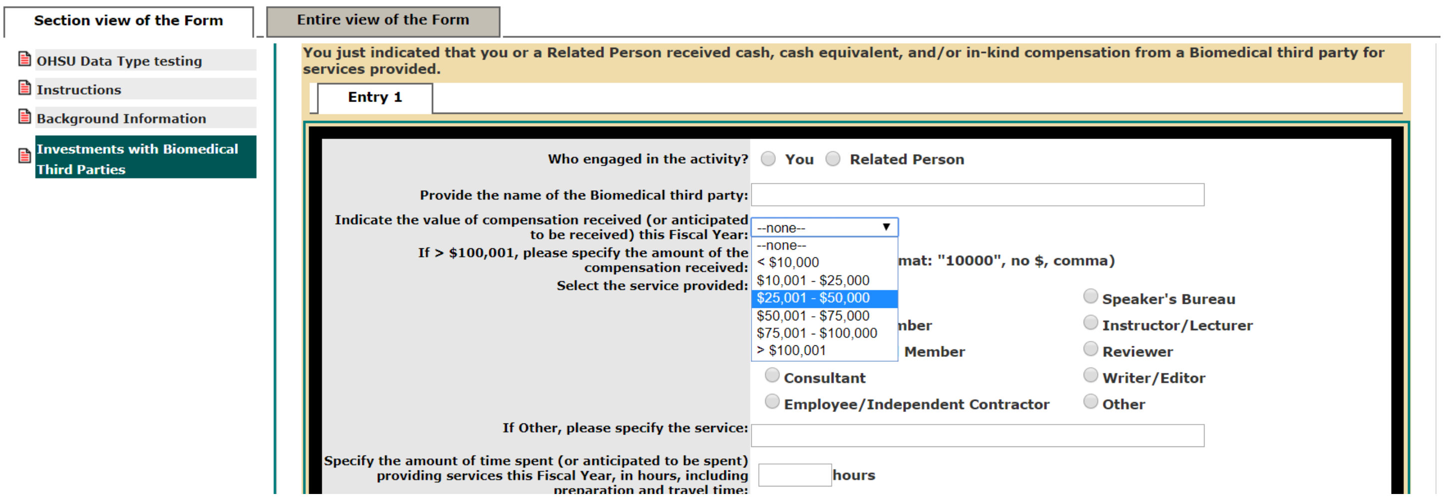
This will open a page that lists the assigned Institutional Roles, from which you can assign additional roles to the selected user.

COI Configuration Lists

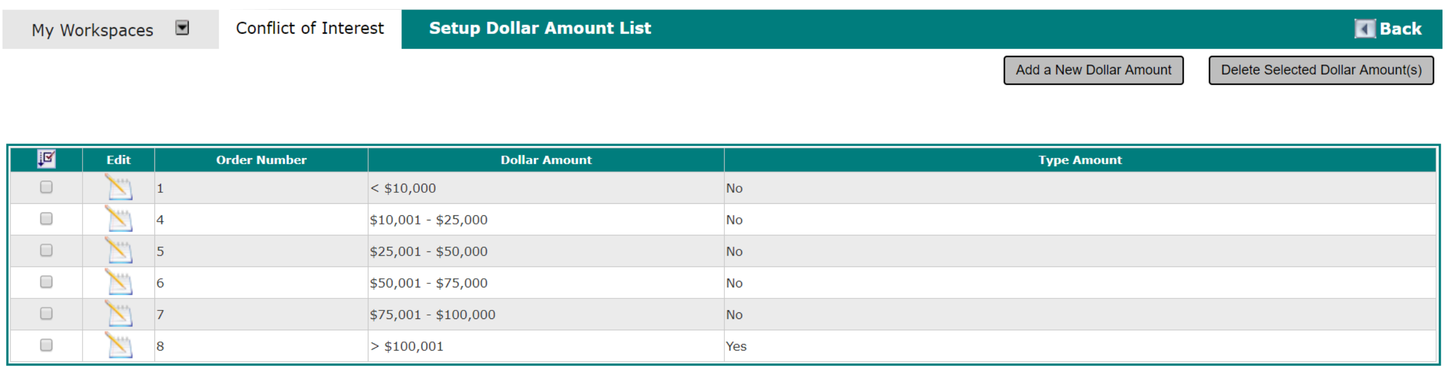
These configuration lists consist of drop-down lists that are made available throughout the panels of the COI Form.



You can either use iRIS predefined panels or you can build custom panels for your institution's COI form, to which you can add any of the drop-down lists available.



This portion of the manual will discuss how to create records within each of the configuration lists available.



	Edit	Order Number	Dollar Amount	Type Amount
		1	< $10,000	No
		4	$10,001 - $25,000	No
		5	$25,001 - $50,000	No
		6	$50,001 - $75,000	No
		7	$75,001 - $100,000	No
		8	> $100,001	Yes

Each configuration list will display any records created. The example used here is the Dollar Amount configuration list and will serve as a general example for a common setup.

The first column contains checkboxes. These checkboxes are used to delete a record. To delete a record, click the **checkbox** next to the record you wish to modify, and then click the **Delete Selected Dollar Amount(s)** button, located on the top right of the screen. Alternately, you may see the red X Delete icons. You can delete a record by clicking on its corresponding Delete icon.

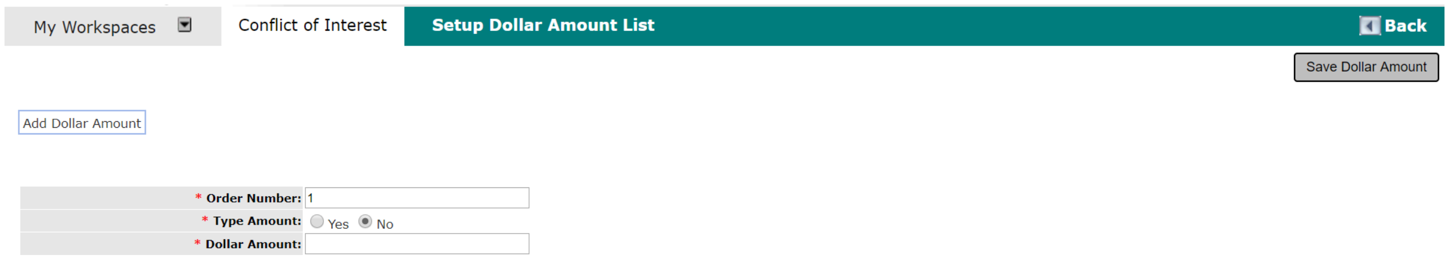
The **Edit** column contains an icon that you can click to open, view, and edit information about a selected record.

The **Order Number** column determines not only how the records are grouped in this list, but also the order in which they are to appear within the Annual COI Form.

Dollar Amount – Represents the column that contains the name of the record.

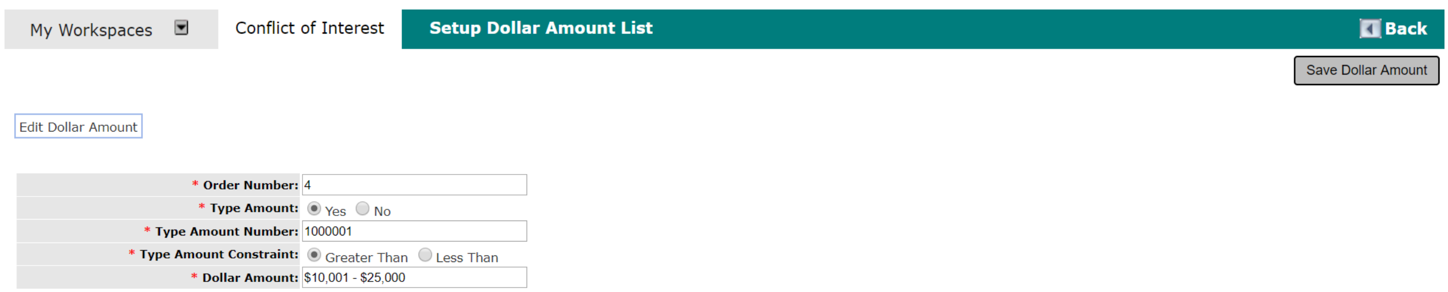
Type Amount – This indicates whether a user will be prompted for additional information if a record is selected from the dropdown list.

A new record can be created by clicking on the **Add a New Dollar Amount** button.

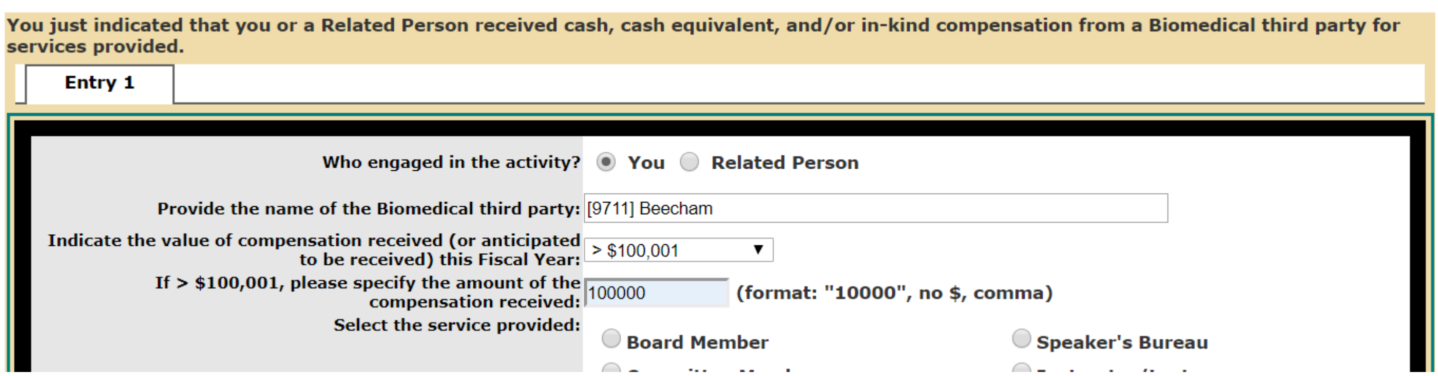


A new page will open, allowing you to specify an **Order Number** and give the record a name using the **Dollar Amount** field. Some of the configuration lists will have a column for **Type Amount**.

After entering the details, click the **Save Dollar Amount** button.



When you indicate "Yes" to Type Amount, the page will refresh. You will be prompted to specify the **Type Amount Number** and **Type Amount Constraint.** These values will cause the system to validate a user's response in the COI Form.

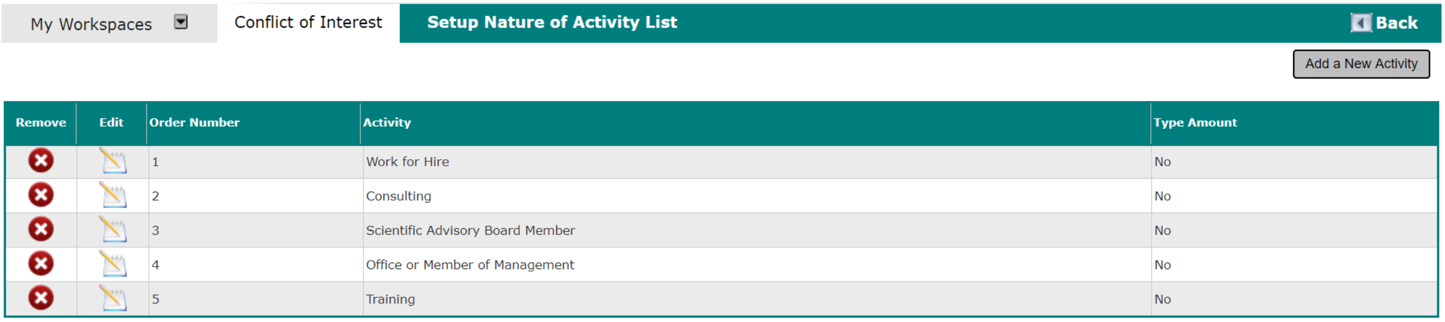


The example in the screenshot above shows that >$100,001 has been selected from the Dollar Amount drop-down list within a panel in the Annual COI Form. Selecting this option caused another field to populate below that field, asking the user to specify the exact dollar amount. The user had entered "100000", but based on the logic setup in the Dollar Amount configuration list, the user now needs to specify an amount greater than 100,001. The system will not allow the user to proceed until they change the amount in the dropdown list or change the dollar amount in the field below the Dollar Amount drop-down list.

The following describes each configuration list and where they are used in the Annual COI Form.

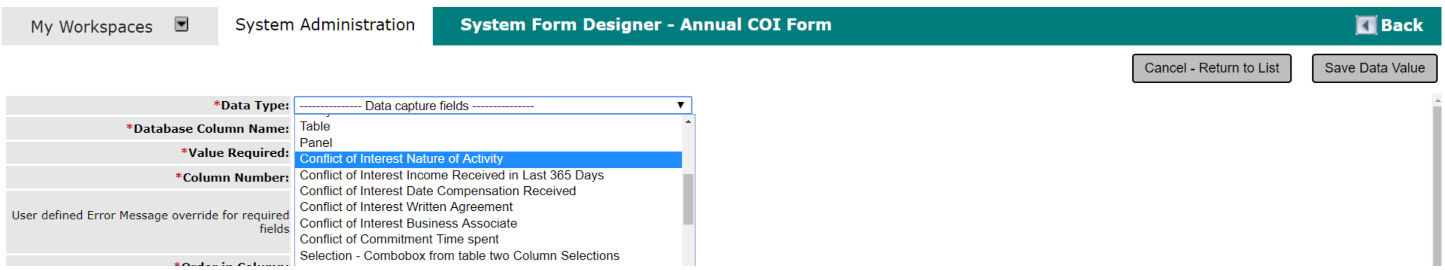
Configure Nature of Activity List

From this screen, you can configure the Nature of Activity drop down list available within the Annual Disclosure form.



Remove	Edit	Order Number	Activity	Type Amount
		1	Work for Hire	No
		2	Consulting	No
		3	Scientific Advisory Board Member	No
		4	Office or Member of Management	No
		5	Training	No

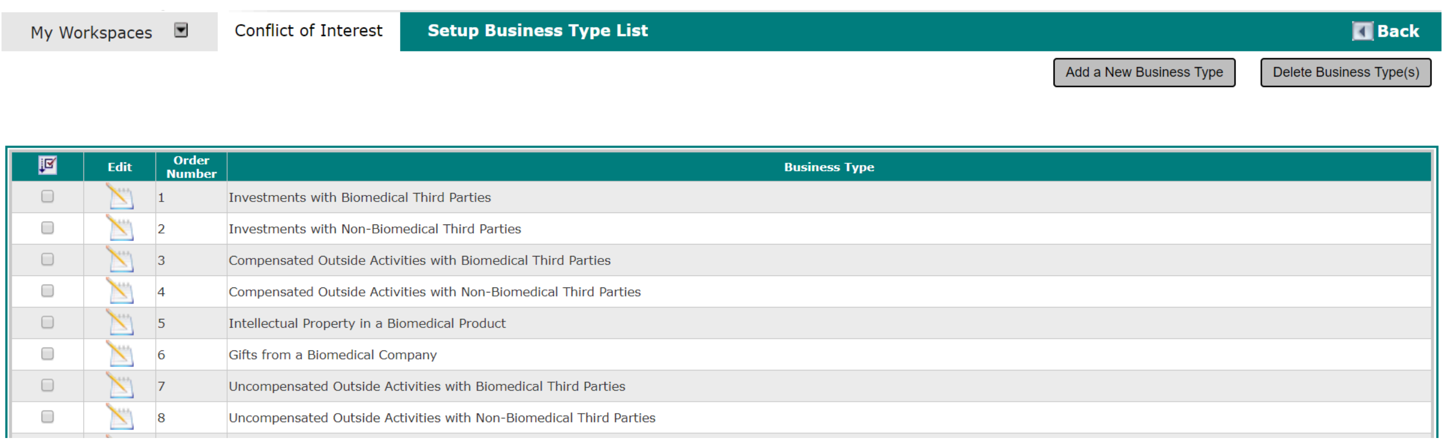
Nature of Activity records can be included as a Data Type in the Panels defined within the Annual COI Form.



The Nature of Activity data value is only available as a data value within the Panel Data Type.

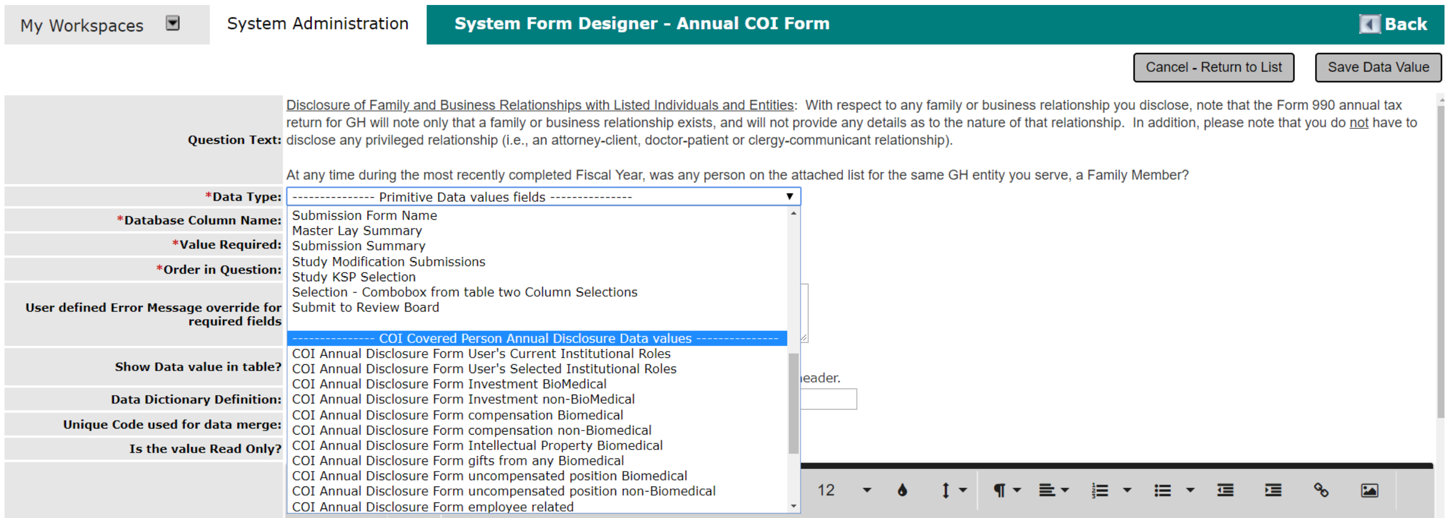
Configure Business Type list

The Configure Business Type list contains standard business types that are commonly used, but you can create additional business types as needed.



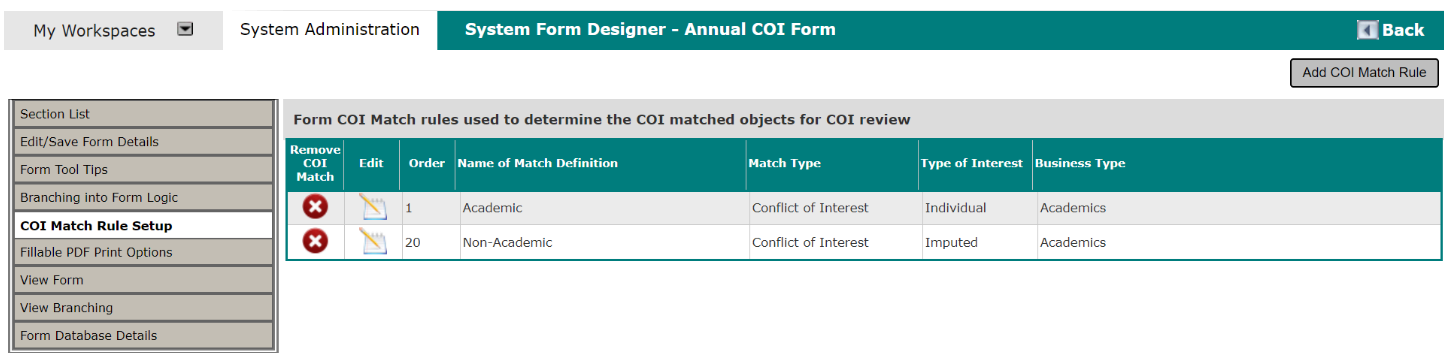
	Edit	Order Number	Business Type
		1	Investments with Biomedical Third Parties
		2	Investments with Non-Biomedical Third Parties
		3	Compensated Outside Activities with Biomedical Third Parties
		4	Compensated Outside Activities with Non-Biomedical Third Parties
		5	Intellectual Property in a Biomedical Product
		6	Gifts from a Biomedical Company
		7	Uncompensated Outside Activities with Biomedical Third Parties
		8	Uncompensated Outside Activities with Non-Biomedical Third Parties

Business Types are associated to the predefined iRIS data values in the Annual COI Form.

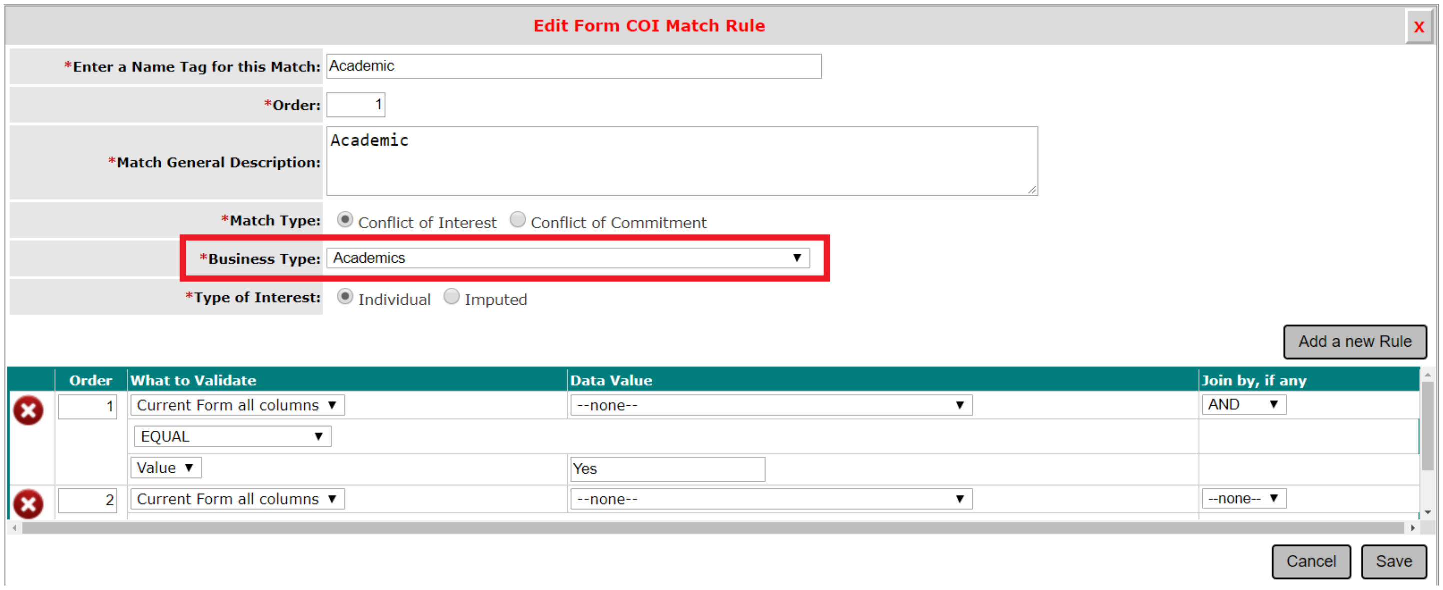


If you are using iRIS' predefined values for capturing conflict matches, you will want to keep the original records for the Business Type list. These records map to the corresponding data values in the forms designer (please see image above). When a user fills out the form and indicates a conflict within one of the data values, the Reported Interest Type will populate with the corresponding Business Type.

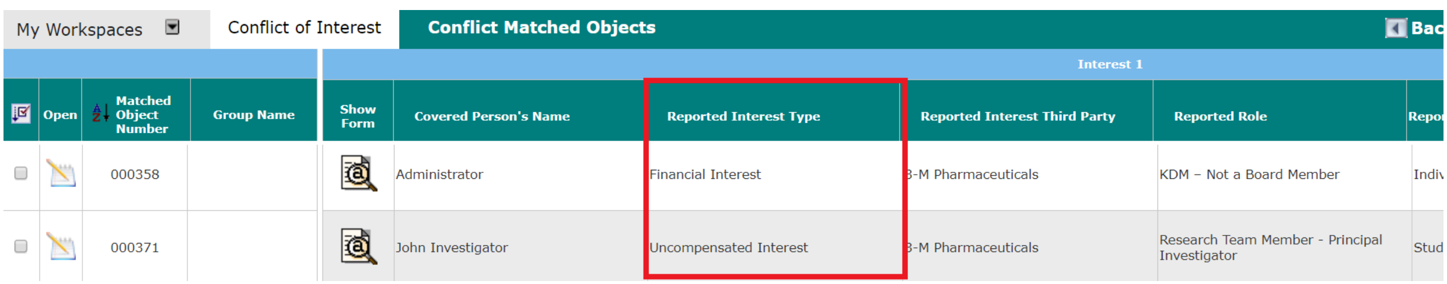
If you are using your own custom COI form panels, you will be able to specify Match Rules within the COI Form.



When creating a Match Rule, you will be able to select a Business Type from a dropdown list. This dropdown list pulls from the Business Type configuration list.

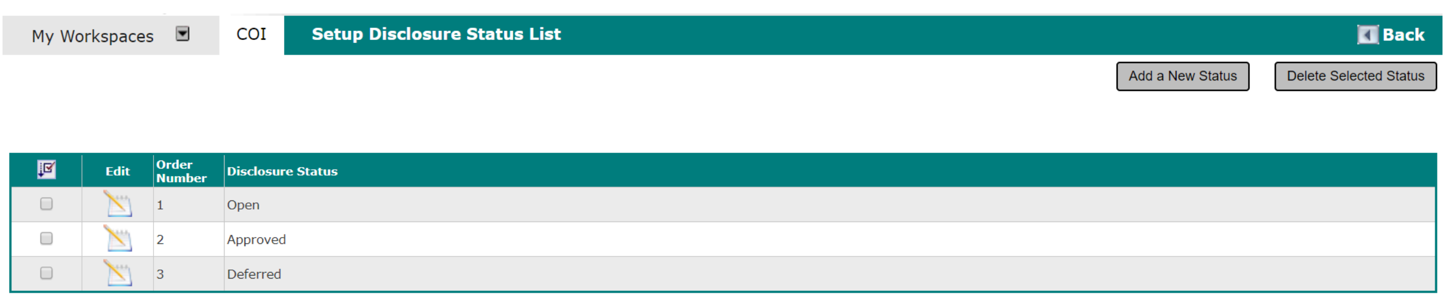


Any COI Match triggered, whether using iRIS predefined data values or custom panels, will populate the appropriate Business Type in the Reported Interest Type column.

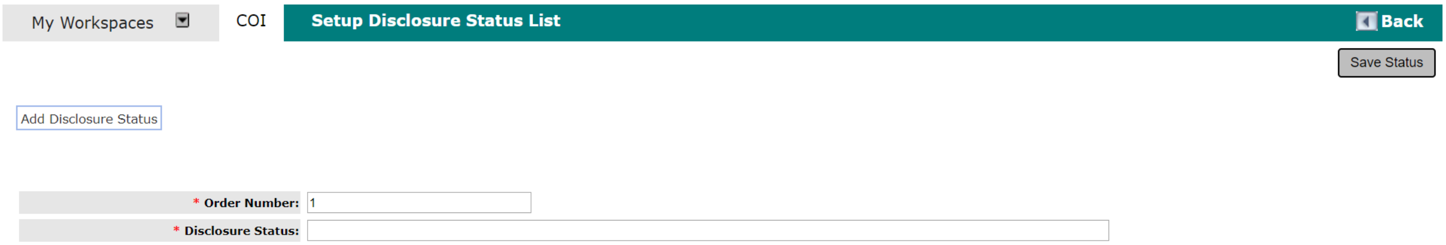


Configure Disclosure Status

The Configure Disclosure Status configuration list allows you to set up a list of disclosure statuses that can be selected on the Outcome tab of the Conflict Match processing screens. When you first open this screen, you will see a list of any disclosure statuses that have already been added to the system, if any.

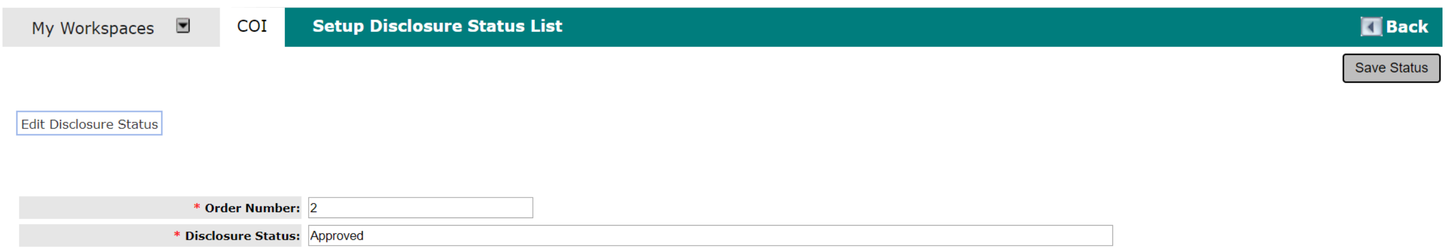


To add a new disclosure status, click **Add a New Status**. You will be brought to a screen where you can enter the Order Number, representing its order both in the list of records and in the dropdown list on the Outcome tab, and the name of the Disclosure Status.



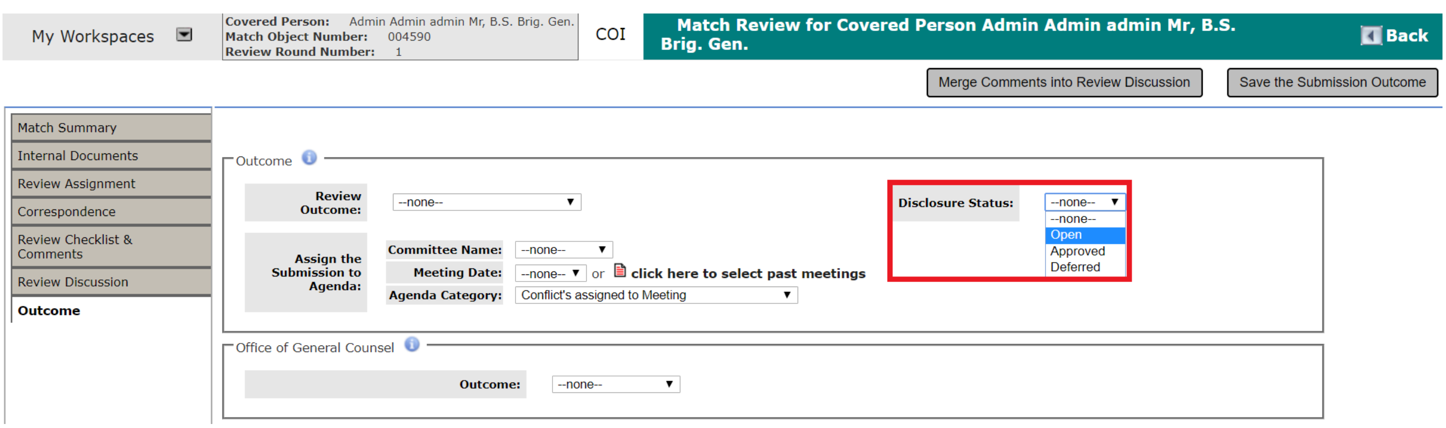
Click **Save Status** when you are done entering information to save what you have added and return to the main list of records.

Click the icon in the Edit column to edit an existing disclosure status. You will be able to edit the Order Number and Disclosure Status name.



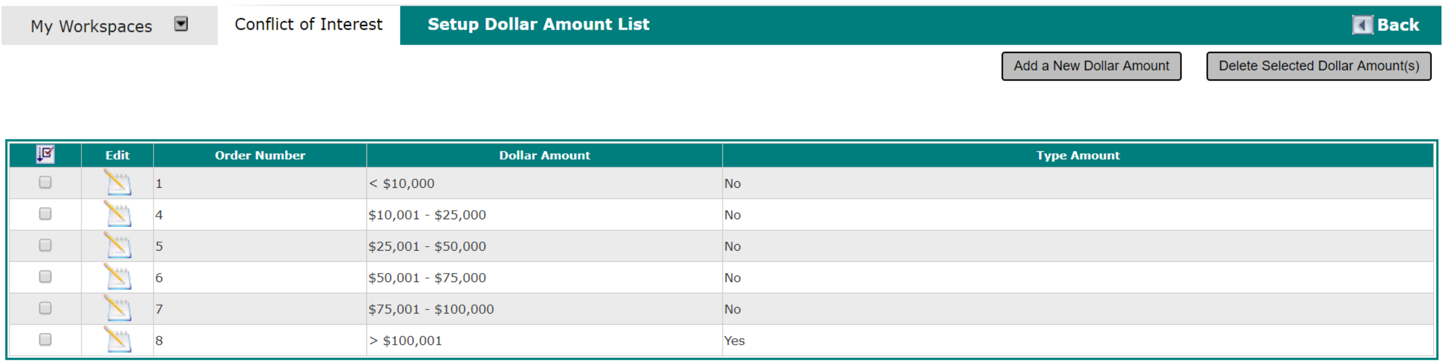
To delete a Disclosure Status, check the box next to the record and click **Delete Selected Status**.

The Disclosure Status dropdown menu appears on the Outcome tab of the Conflict Match processing screens.

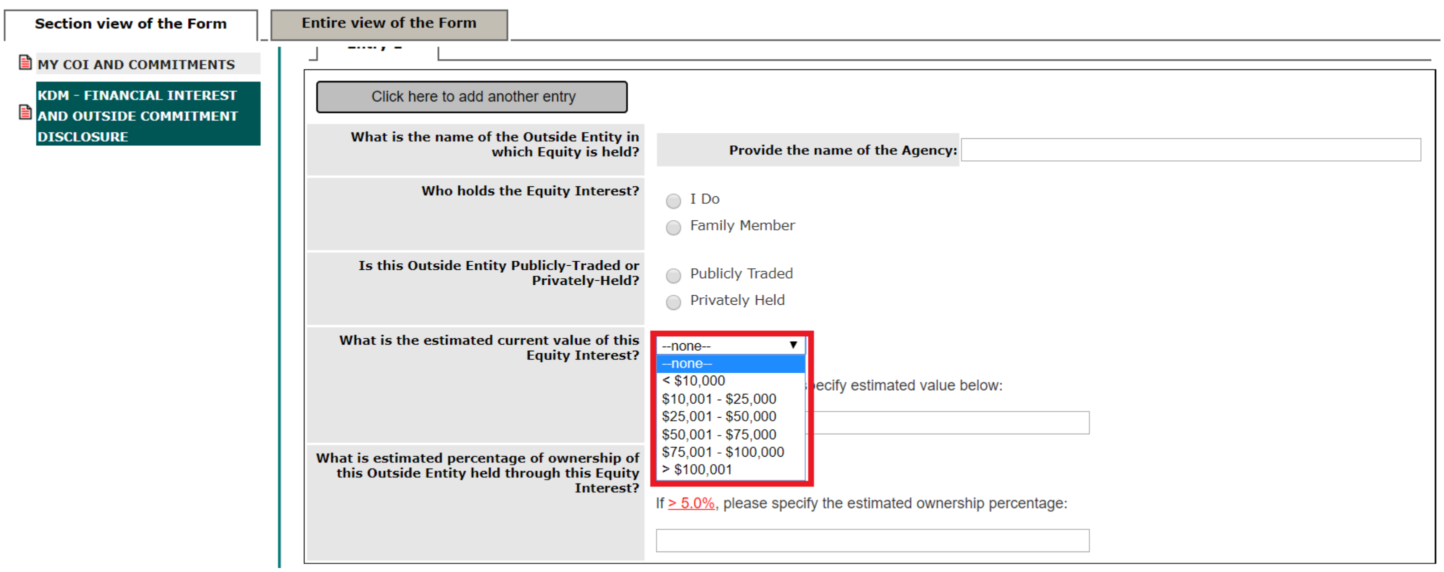


Configure Dollar Amount Selection list

The Dollar Amount dropdown list allows you to set up ranges of dollar amounts for users to select from within a panel.

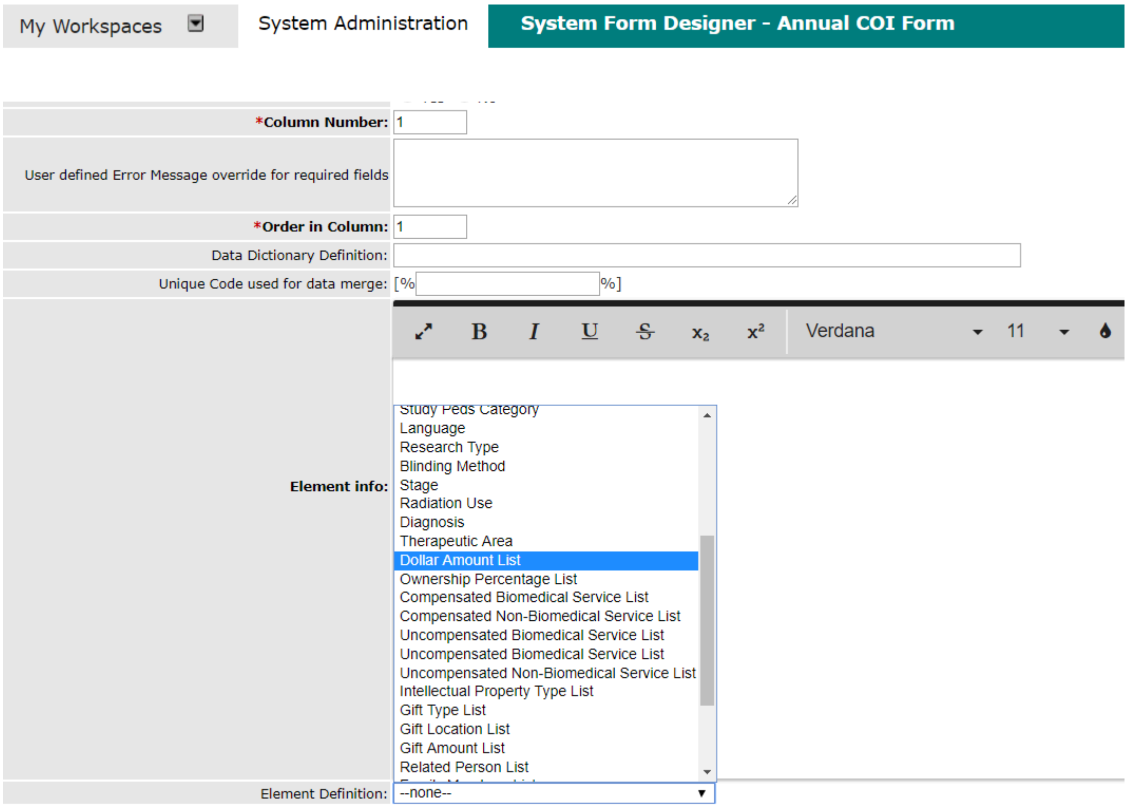


The configuration list allows you to specify the Order Number, Dollar Amount, and Type Amount (for cases where you would like the user to specify the exact amount if over/under a certain amount), that should show on your organization's COI form.



The Dollar Amount drop-down list will appear in the following data values:

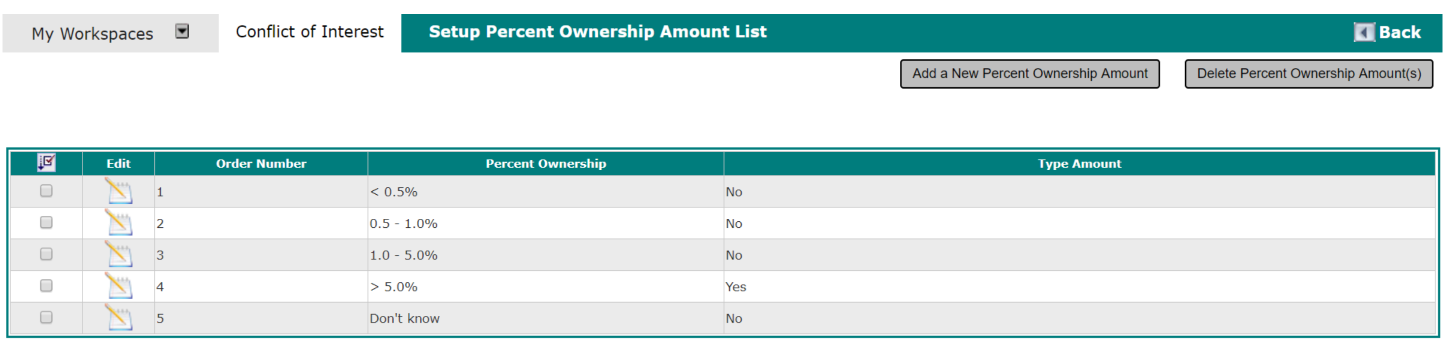
- COI Annual Disclosure Form Investment BioMedical
- COI Annual Disclosure Form Investment non-BioMedical
- COI Annual Disclosure Form Compensation Biomedical
- COI Annual Disclosure Form Compensation non-Biomedical



The Dollar Amount configuration list can also be pulled into a custom panel while designing your institution's COI Form in the System Form Designer. The configuration list is available when you choose a Data Type of Selection - Configuration List data type. The configuration list to select is Dollar Amount List.

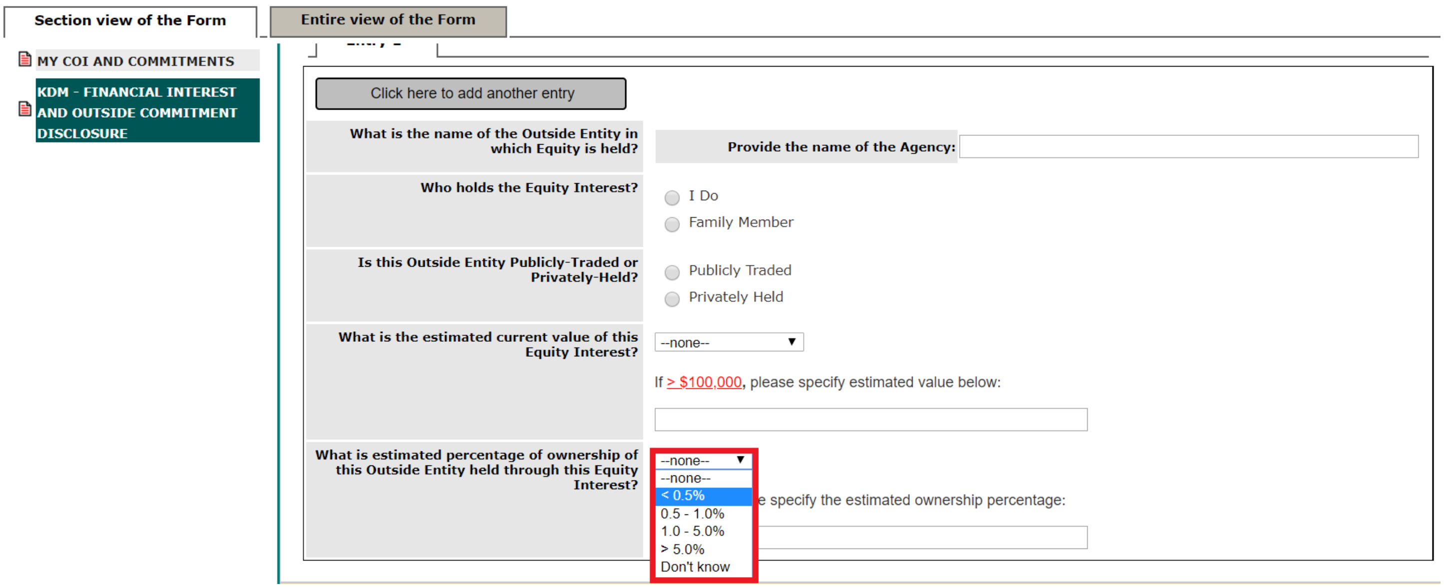
Configure Percent Ownership Selection list

The Percent Ownership dropdown list allows you to set up a range of percentages to select from within a COI form.



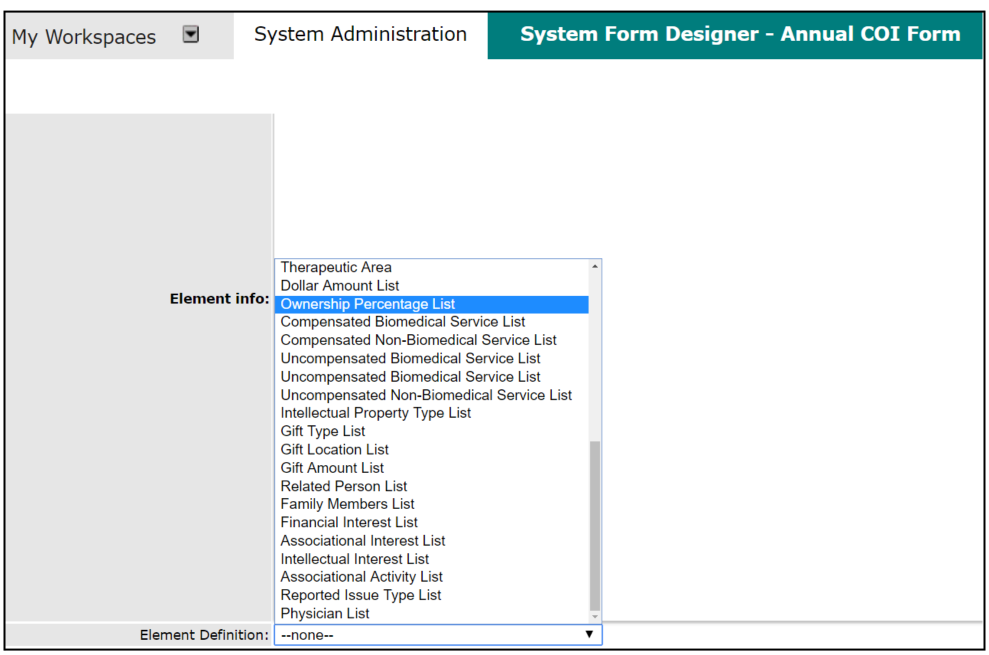
	Edit	Order Number	Percent Ownership	Type Amount
		1	< 0.5%	No
		2	0.5 - 1.0%	No
		3	1.0 - 5.0%	No
		4	> 5.0%	Yes
		5	Don't know	No

The configuration list allows you to specify the Order, Percent Ownership, and whether "Type Amount" should be activated (for cases where you would like the user to enter the exact percentage amount).



The Percent Ownership drop-down list will appear in conjunction to the following data values:

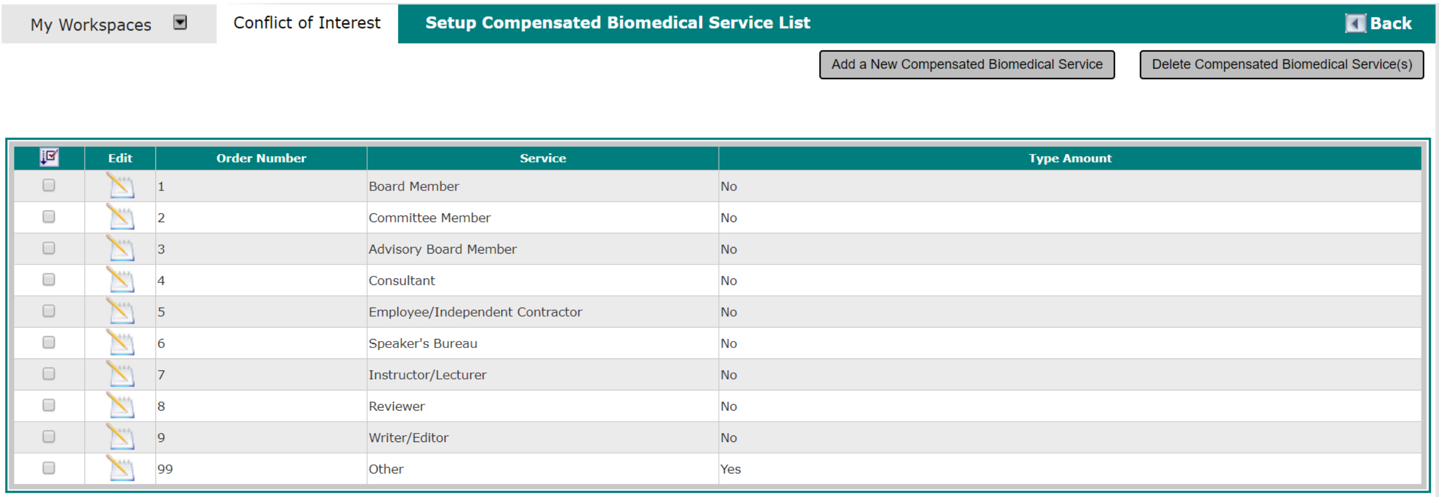
- COI Annual Disclosure Form Investment BioMedical
- COI Annual Disclosure Form Investment Non-BioMedical



The Percent Ownership configuration list can also be pulled into a custom panel. The configuration list is available when you use the "Selection – Configuration List" data type. The configuration list to select within this category is "Ownership Percentage List."

Configure Compensated Biomedical Service list

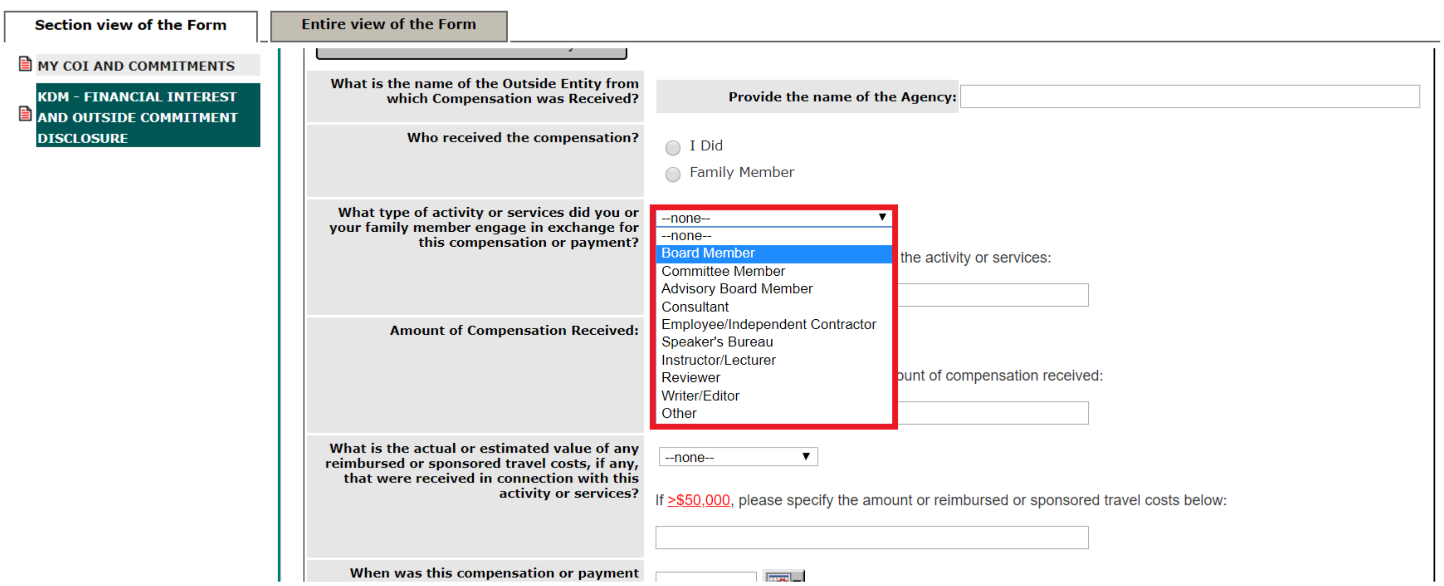
The Compensated Biomedical Service list allows you to set up different services to select from when indicating the service provided to an outside entity.


My Workspaces | Conflict of Interest | Setup Compensated Biomedical Service List | Back

Add a New Compensated Biomedical Service | Delete Compensated Biomedical Service(s)

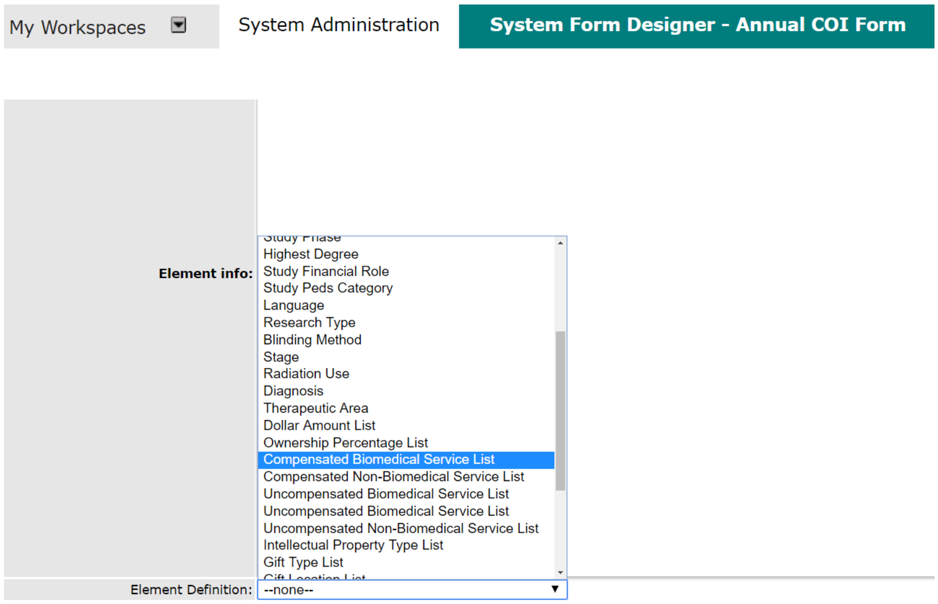
	Edit	Order Number	Service	Type Amount
		1	Board Member	No
		2	Committee Member	No
		3	Advisory Board Member	No
		4	Consultant	No
		5	Employee/Independent Contractor	No
		6	Speaker's Bureau	No
		7	Instructor/Lecturer	No
		8	Reviewer	No
		9	Writer/Editor	No
		99	Other	Yes

The configuration list allows you to specify the Order Number, Service, and whether “Type Amount” should be activated (for cases where you would like the user to specify additional information, e.g. “Other”).



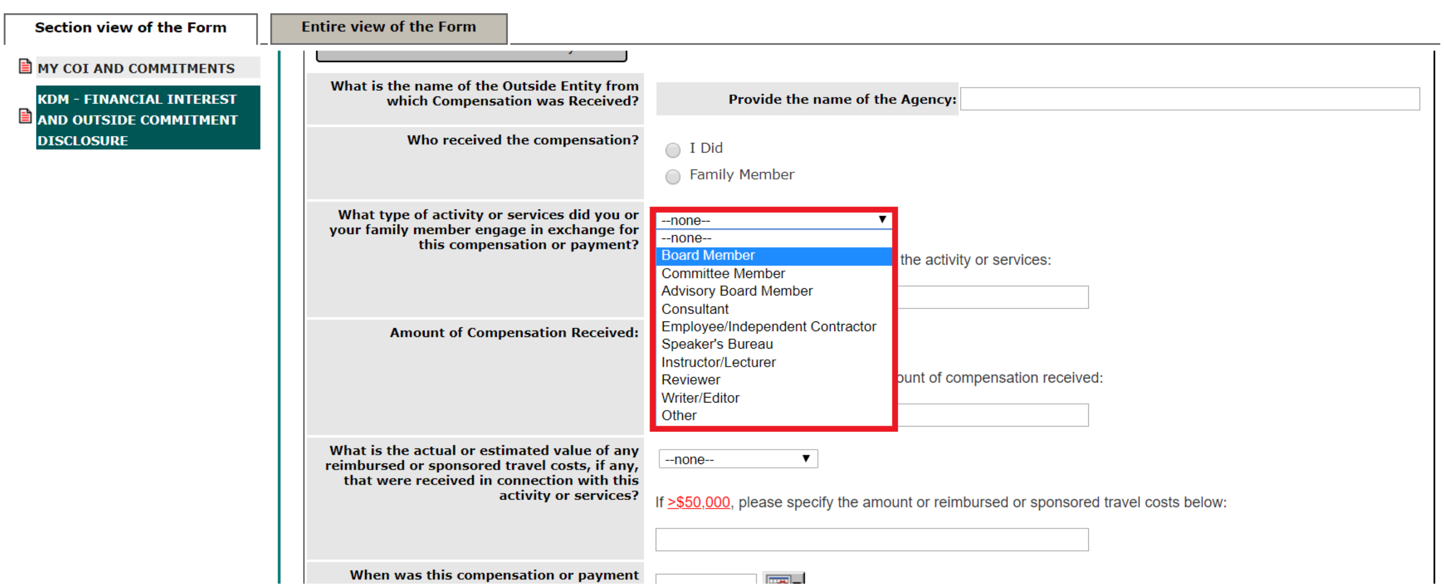
The Biomedical Service List will appear in the following data values:

- COI Annual Disclosure Form Compensation Biomedical



The Biomedical Service List can also be pulled into a custom panel. The configuration list is available when you use the “Selection – Configuration List” data type. The configuration list to select within this category is “Compensated Biomedical Service List”.

If using this data value in a custom panel, the data will be presented to the user in a drop-down list. Note: if an item with “Type Amount” set to “Yes” is selected, the user will not be prompted to specify additional information. This option will only work in the predefined panels.



Configure Compensated Non-Biomedical Service list

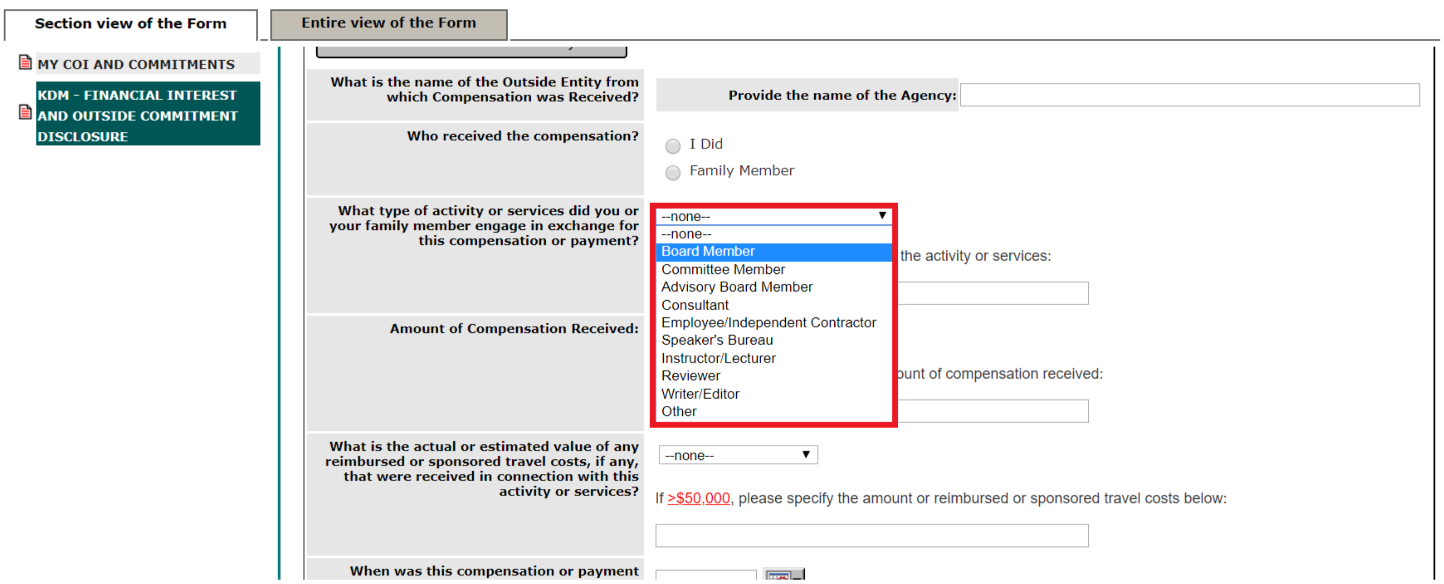
The Compensated Non-Biomedical Service list allows you to set up services for users to select from within a panel.

My Workspaces | Conflict of Interest | **Setup Compensated Non-Biomedical Service List** | Back

Add a New Compensated Non-Biomedical Service | Delete Compensated Non-Biomedical Service(s)

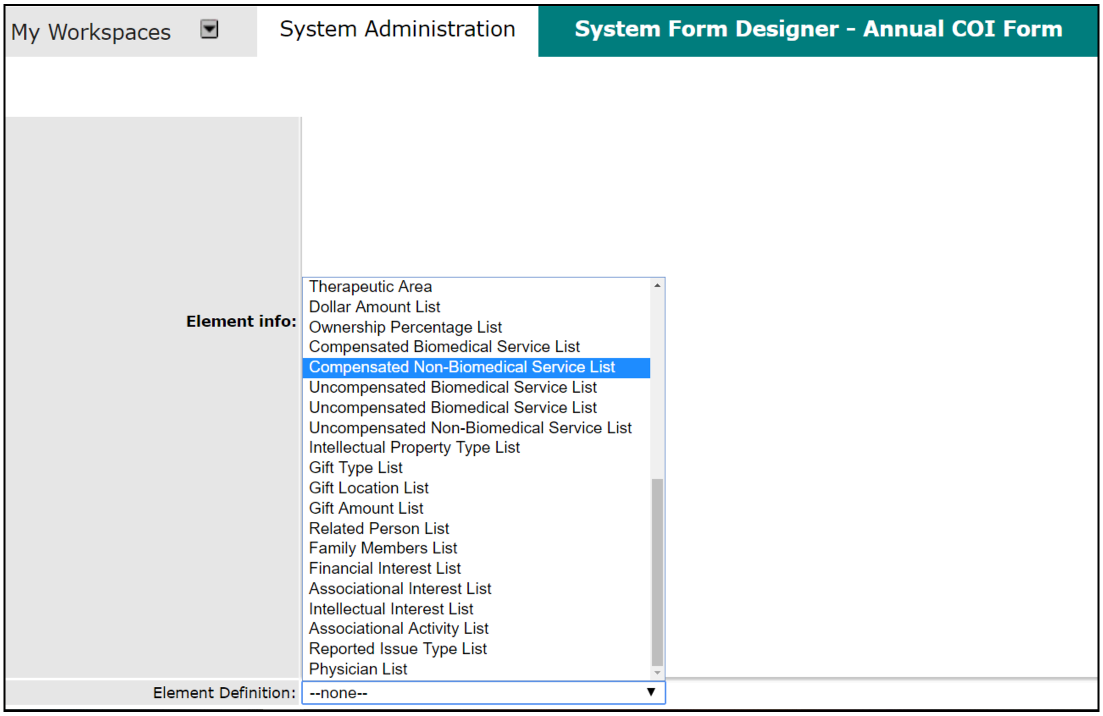
	Edit	Order Number	Service	Type Amount
		1	Board Member	No
		2	Committee Member	No
		3	Advisory Board Member	No
		4	Consultant	No
		5	Employee/Independent Contractor	No
		6	Speaker's Bureau	No
		7	Instructor/Lecturer	No
		8	Reviewer	No
		9	Writer/Editor	No
		99	Other	Yes

The configuration list allows you to specify the Order Number, Service, and whether “Type Amount” is applicable (for cases where you would like the user to specify additional information, e.g. “Other”).



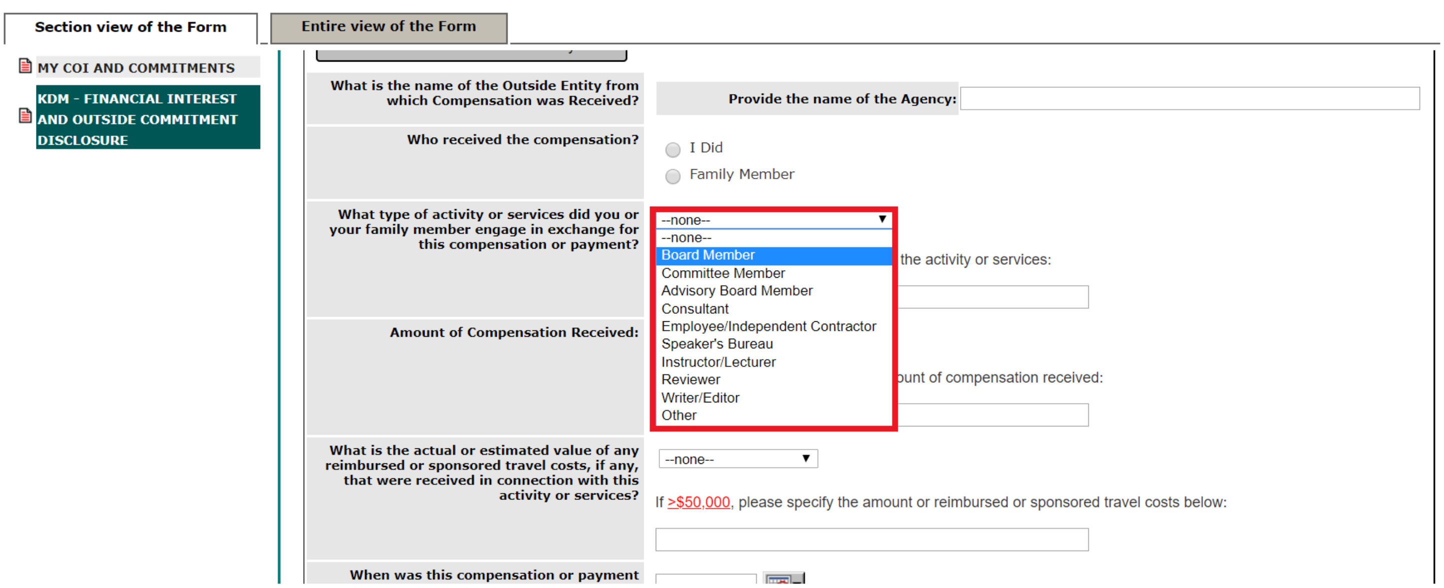
The Non-Biomedical Service List will appear in the following data values:

- COI Annual Disclosure Form compensation non-Biomedical



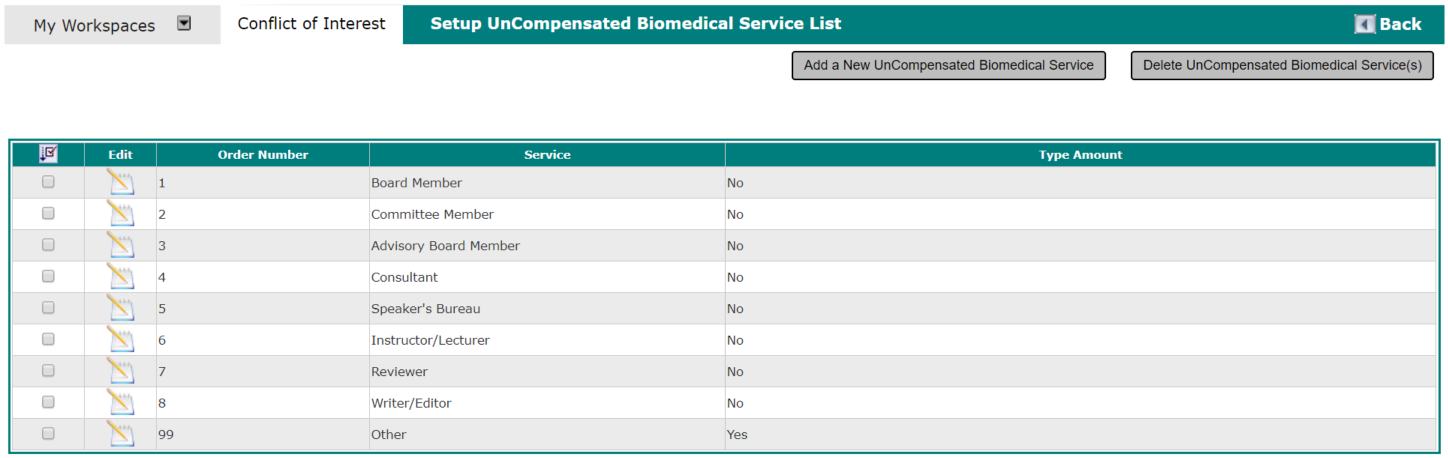
The Non-Biomedical Service List can also be pulled into a custom panel. The configuration list is available when using the “Selection – Configuration List” data type. The configuration list to select is “Compensated Non-Biomedical Service List”.

If using this data value in a custom panel, the data will be presented to the user in a dropdown list. Note: if an item with “Type Amount” set to “Yes” is selected, the user will not be prompted to specify additional information. This will only work in the predefined panels.



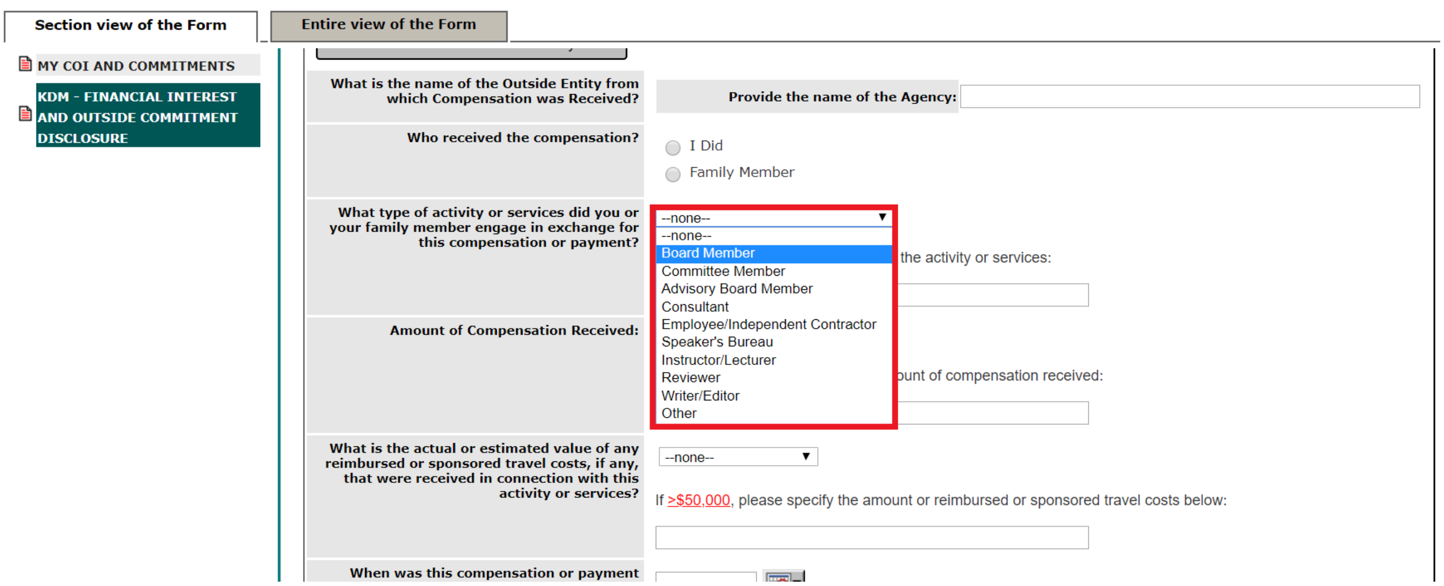
Configure Uncompensated Biomedical Service list

The Uncompensated Biomedical Service list allows you to set up services to select from within a panel.



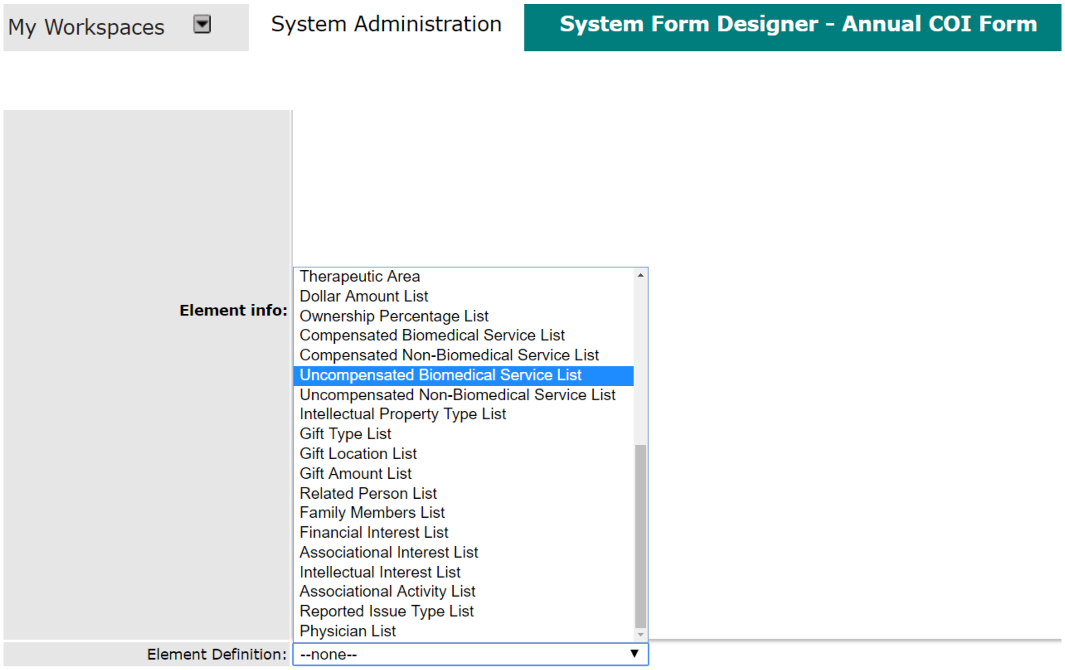
	Edit	Order Number	Service	Type Amount
		1	Board Member	No
		2	Committee Member	No
		3	Advisory Board Member	No
		4	Consultant	No
		5	Speaker's Bureau	No
		6	Instructor/Lecturer	No
		7	Reviewer	No
		8	Writer/Editor	No
		99	Other	Yes

The configuration list allows you to specify the Order Number, Service, and whether "Type Amount" should be activated (for cases where you would like the user to specify additional information, e.g. "Other").

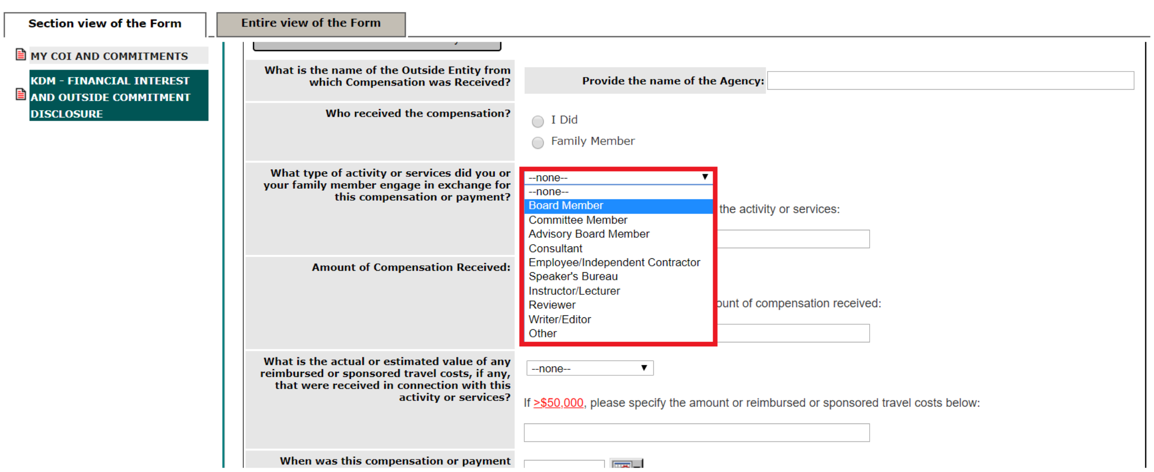


The Uncompensated Biomedical Service List will appear in the following data values:

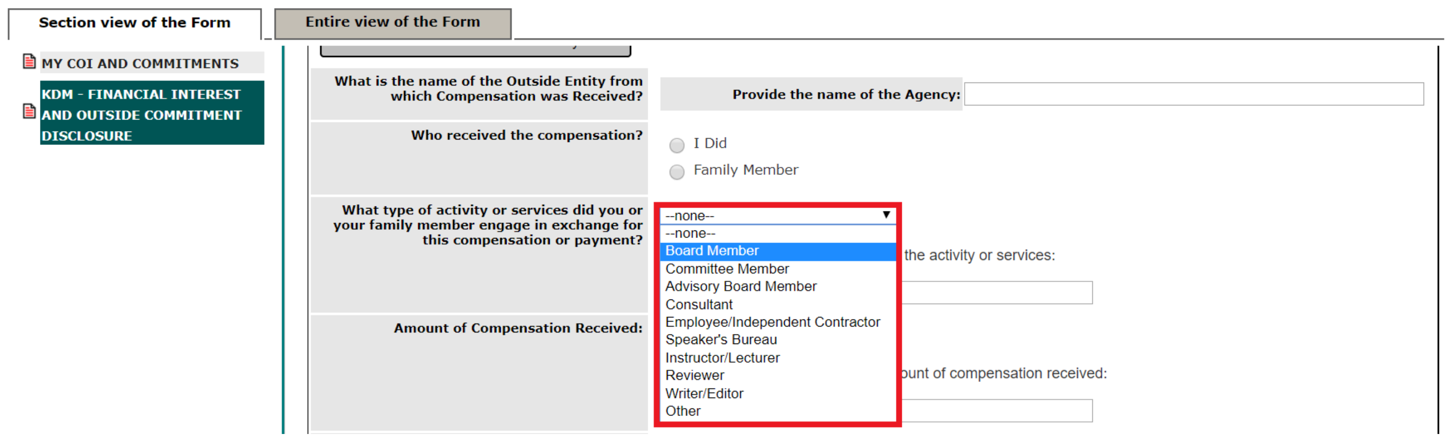
- COI Annual Disclosure Form Uncompensated Biomedical.



The Uncompensated Biomedical Service List can also be pulled into a custom panel. The configuration list is available in the “Selection – Configuration List” data type and the configuration list to select from this category is “Uncompensated Biomedical Service List”.

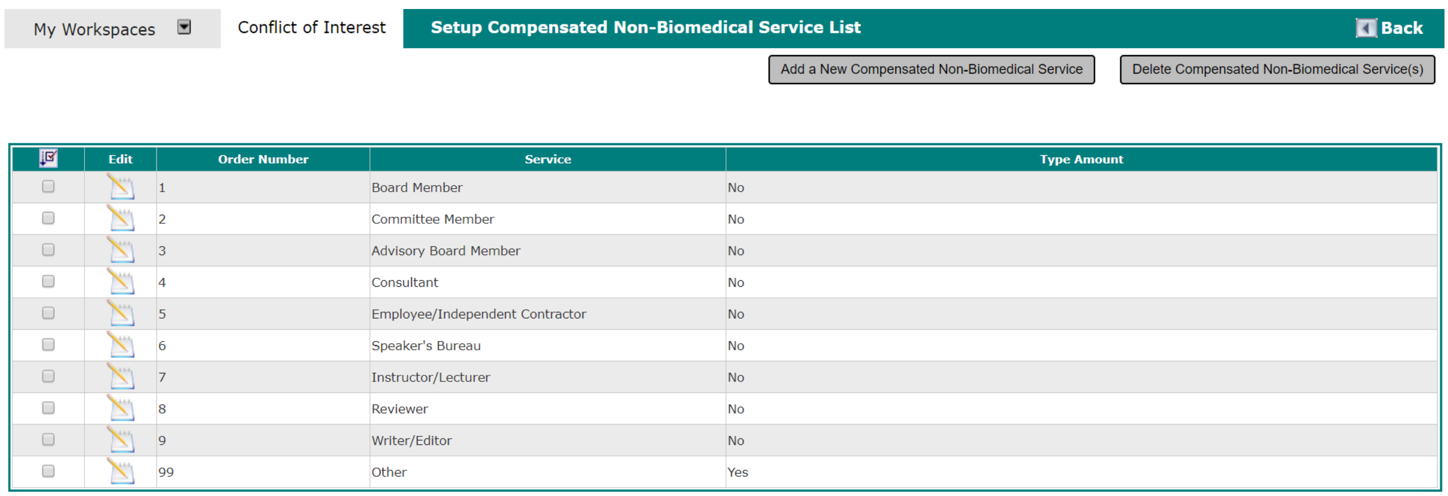


If using this data value in a custom panel, the data will be presented to the user in a drop-down list. Note: if an item with “Type Amount” set to “Yes” is selected, the user will not be prompted to specify additional information. This will only work in the predefined panels.



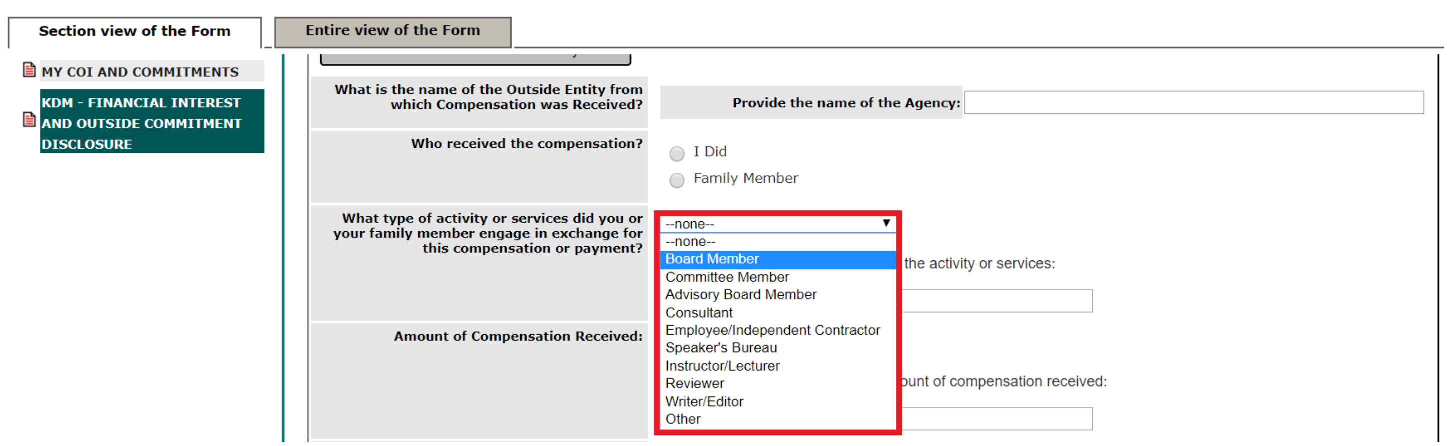
Configure Uncompensated Non-Biomedical Service list

The Uncompensated Non-Biomedical Service list allows you to set up services for users to select from within a panel.



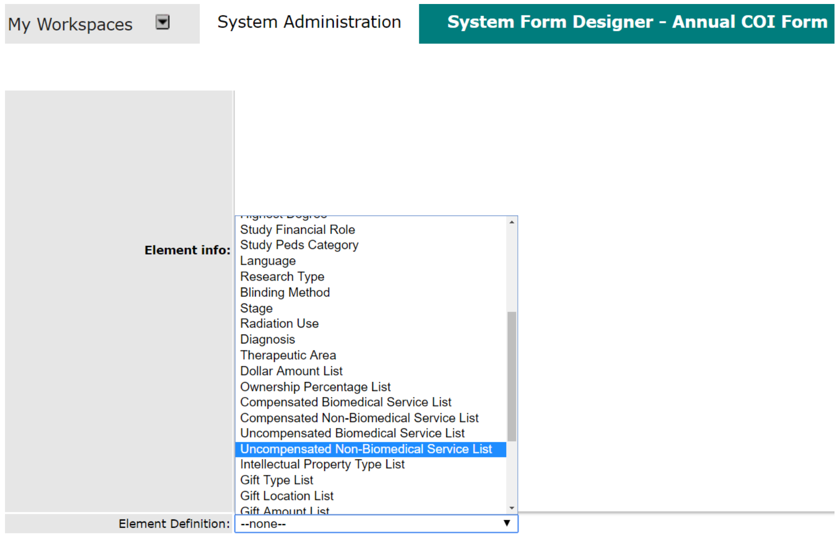
	Edit	Order Number	Service	Type Amount
		1	Board Member	No
		2	Committee Member	No
		3	Advisory Board Member	No
		4	Consultant	No
		5	Employee/Independent Contractor	No
		6	Speaker's Bureau	No
		7	Instructor/Lecturer	No
		8	Reviewer	No
		9	Writer/Editor	No
		99	Other	Yes

The configuration list allows you to specify the Order Number, Service, and whether "Type Amount" should be activated (for cases where you would like the user to specify additional information, e.g. "Other").

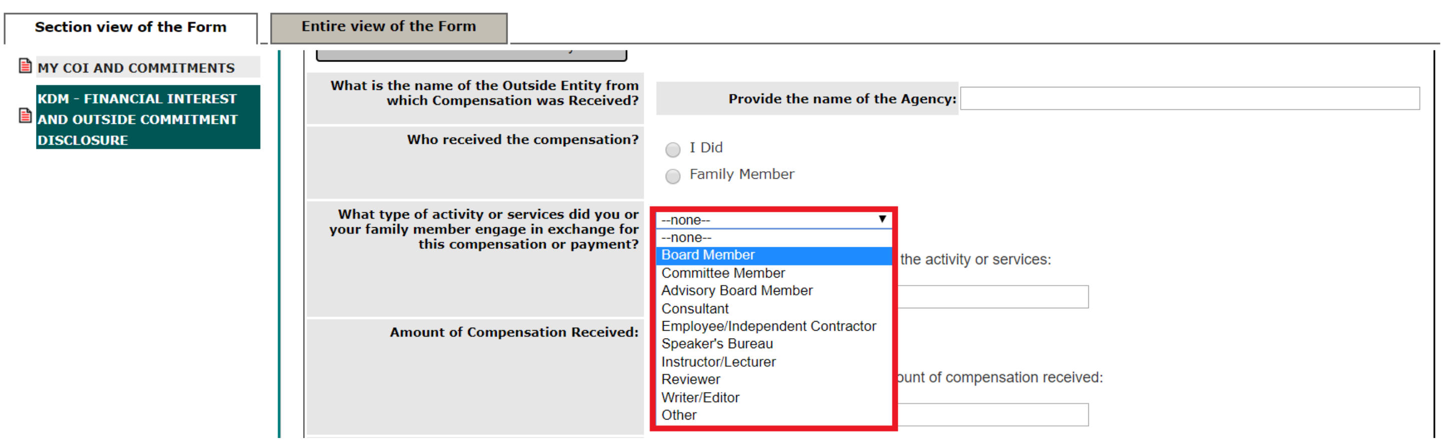


The Uncompensated Non-Biomedical Service List will appear in the following data values:

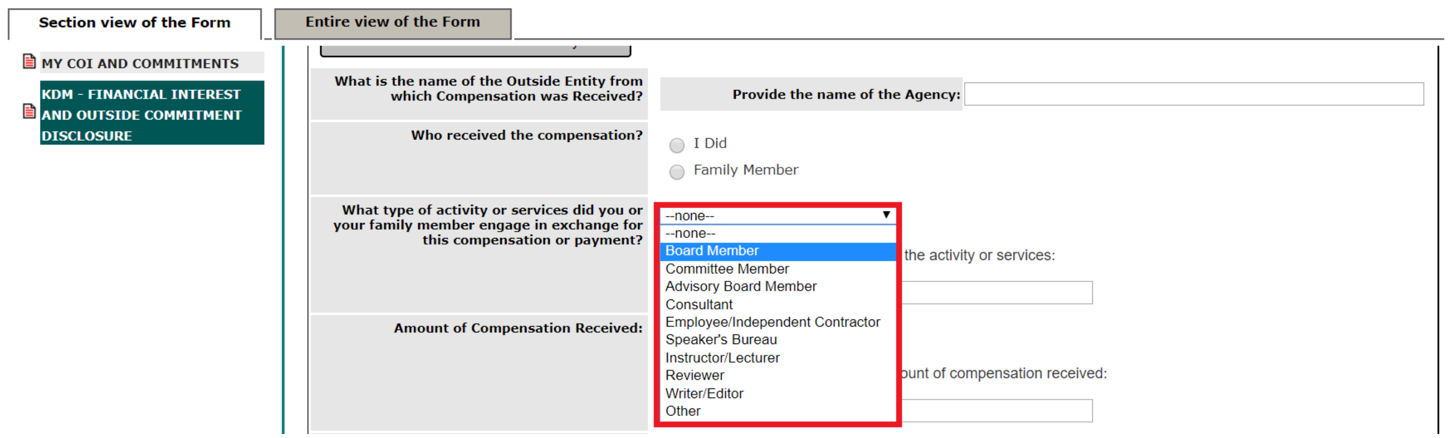
- COI Annual Disclosure Form Uncompensated Position non-Biomedical



The Uncompensated Non-Biomedical Service List can also be pulled into a custom panel. The configuration list is available when you use the “Selection – Configuration List” data type, and the configuration list to select is “Uncompensated Non-Biomedical Service List”.

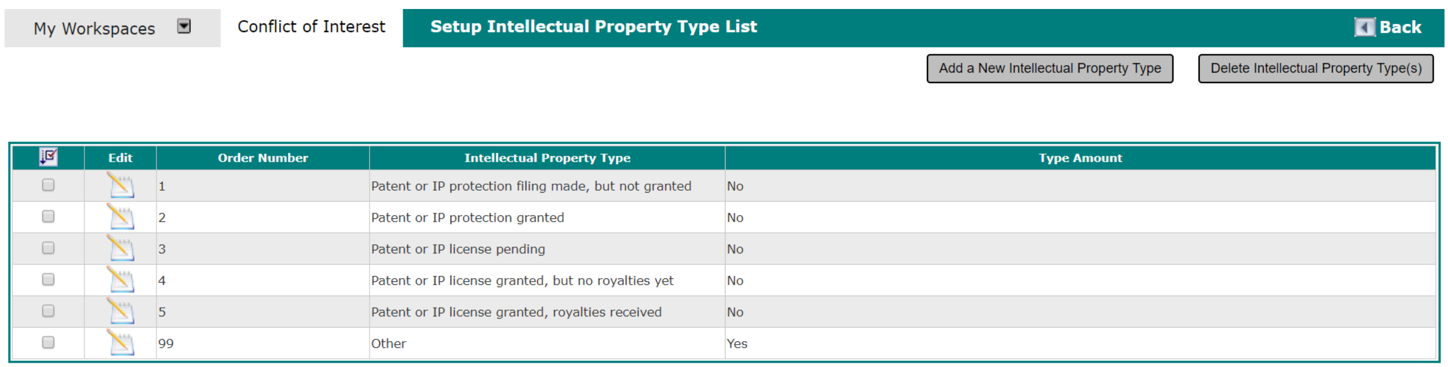


If using this data value in a custom panel, the data will be presented to the user in a drop-down list. Note also, if an item with “Type Amount” set to “Yes” is selected, the user will not be prompted to specify additional information. This will only work in the predefined panels.



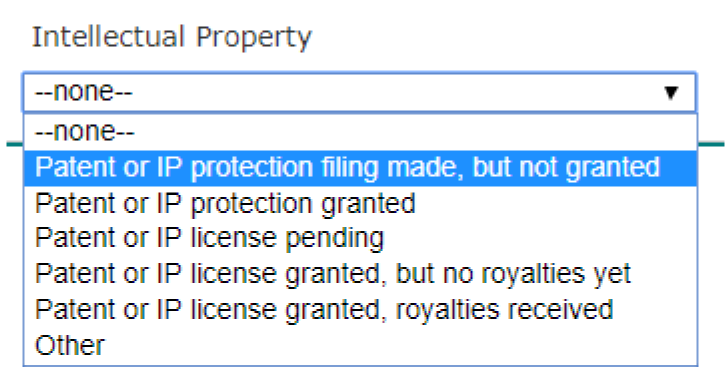
Configure Intellectual Property list

The Intellectual Property Type list allows you to set up a list for users to select from within a panel.



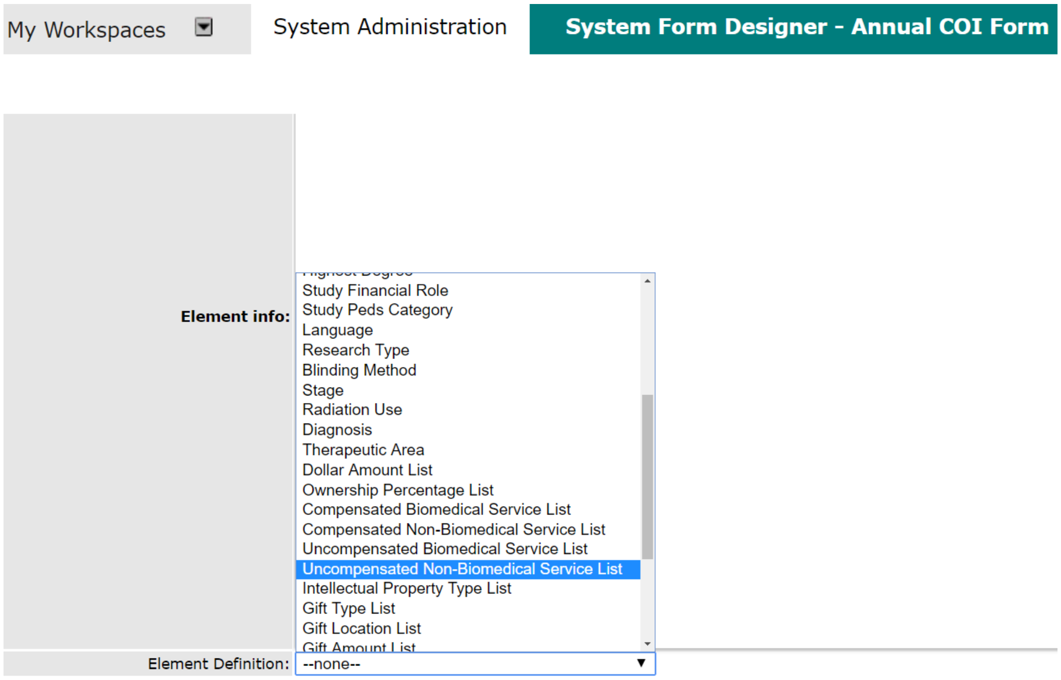
	Edit	Order Number	Intellectual Property Type	Type Amount
		1	Patent or IP protection filing made, but not granted	No
		2	Patent or IP protection granted	No
		3	Patent or IP license pending	No
		4	Patent or IP license granted, but no royalties yet	No
		5	Patent or IP license granted, royalties received	No
		99	Other	Yes

The configuration list allows you to specify the Order Number, Intellectual Property Type, and whether "Type Amount" should be activated (for cases where you would like the user to specify additional information, e.g. "Other").

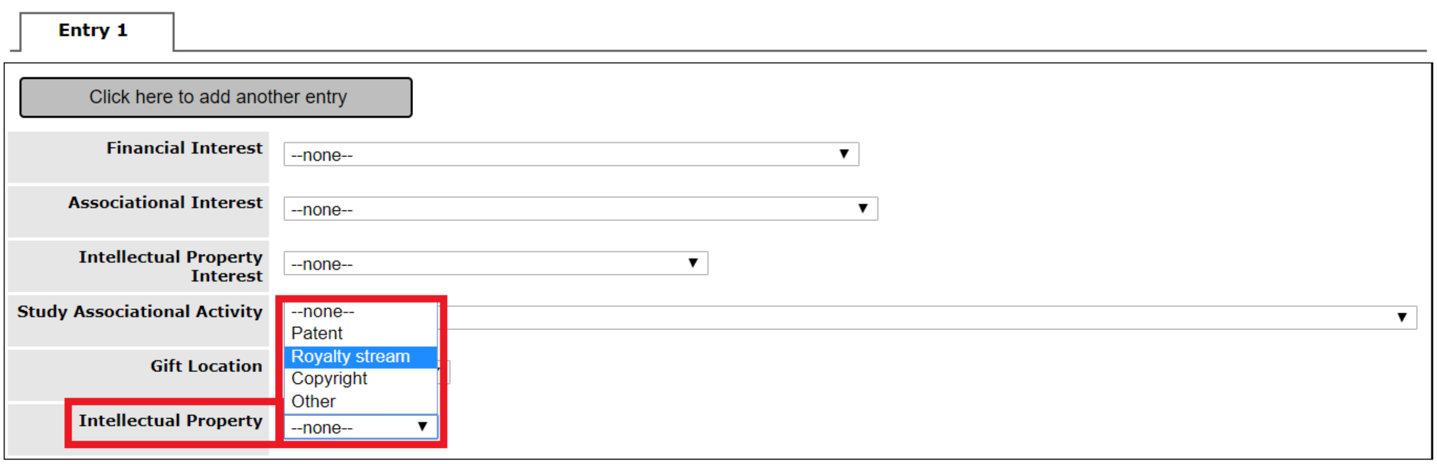


The Intellectual Property Type List will appear in the following data values:

- COI Annual Disclosure Form Intellectual Property Biomedical



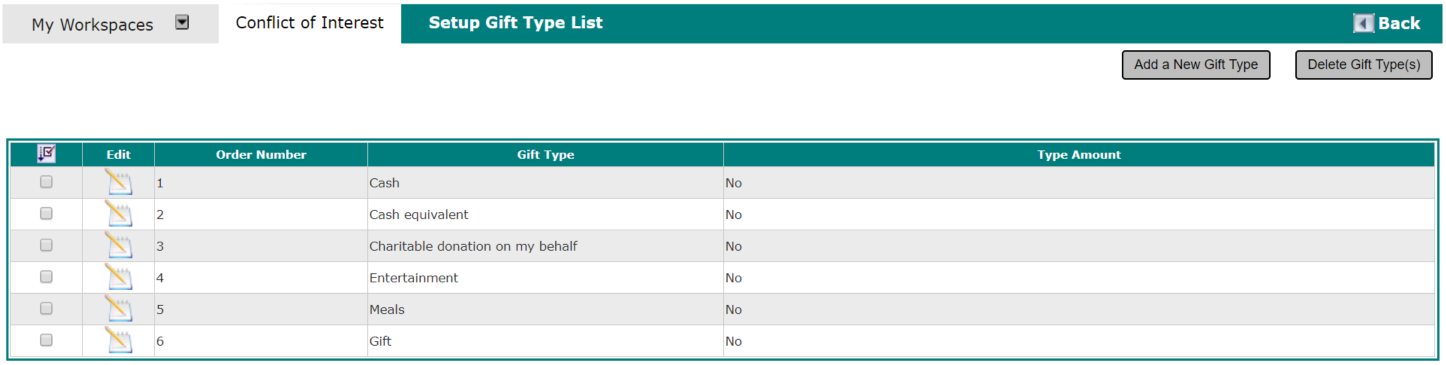
The Intellectual Property List can also be pulled into a custom panel. The configuration list is available when you use the "Selection – Configuration List" data type and the configuration list to select is "Intellectual Property Type List."



If using this data value in a custom panel, and if an item with "Type Amount" set to "Yes" is selected, the user will not be prompted to specify additional information. This option will only work in the predefined panels.

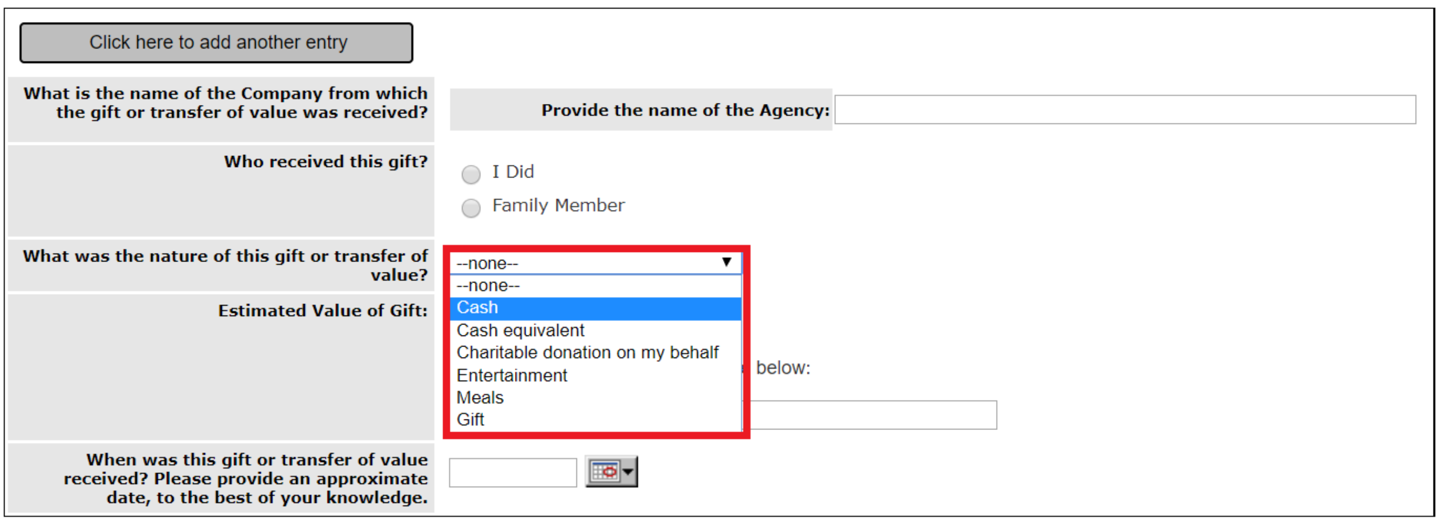
Configure Gift Type List

The Gift Type list allows you to set up different gift types for users to select from within a panel.



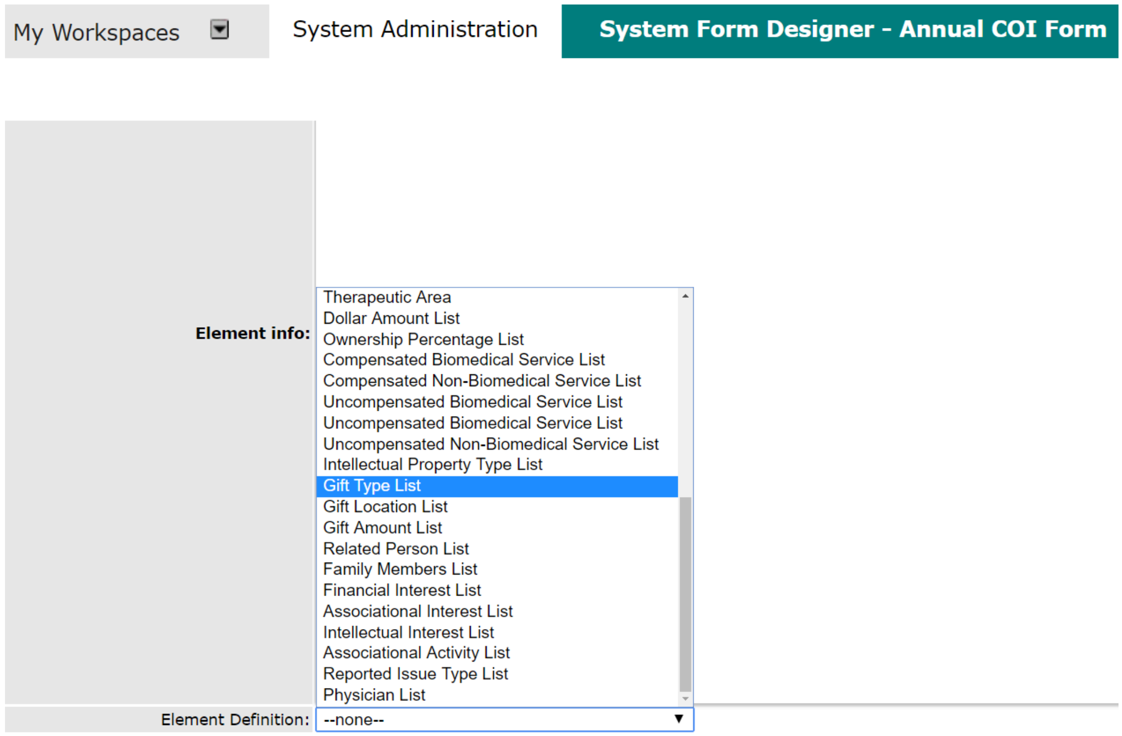
	Edit	Order Number	Gift Type	Type Amount
		1	Cash	No
		2	Cash equivalent	No
		3	Charitable donation on my behalf	No
		4	Entertainment	No
		5	Meals	No
		6	Gift	No

The configuration list allows you to specify the Order Number, Gift Type, and whether "Type Amount" should be activated (for cases where you would like the user to specify additional information, e.g. "Other").



The Gift Type List will appear in the following data values:

- COI Annual Disclosure Form gifts from any Biomedical

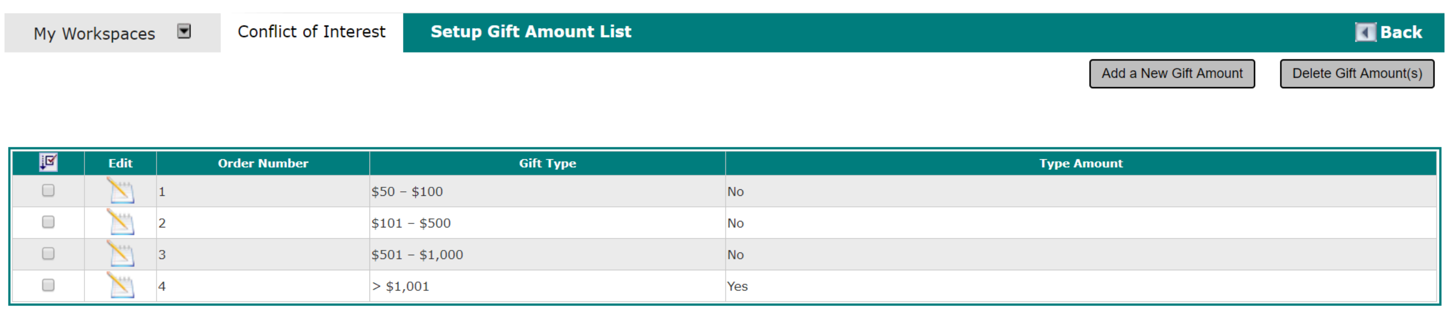


The Gift Type List can also be pulled into a custom panel. The configuration list is available when you use the “Selection – Configuration List” data type. The configuration list to select from this category is “Gift Type List”.

If using this data value in a custom panel, and if an item with “Type Amount” set to “Yes” is selected, the user will not be prompted to specify additional information. This will only work in the predefined panels.

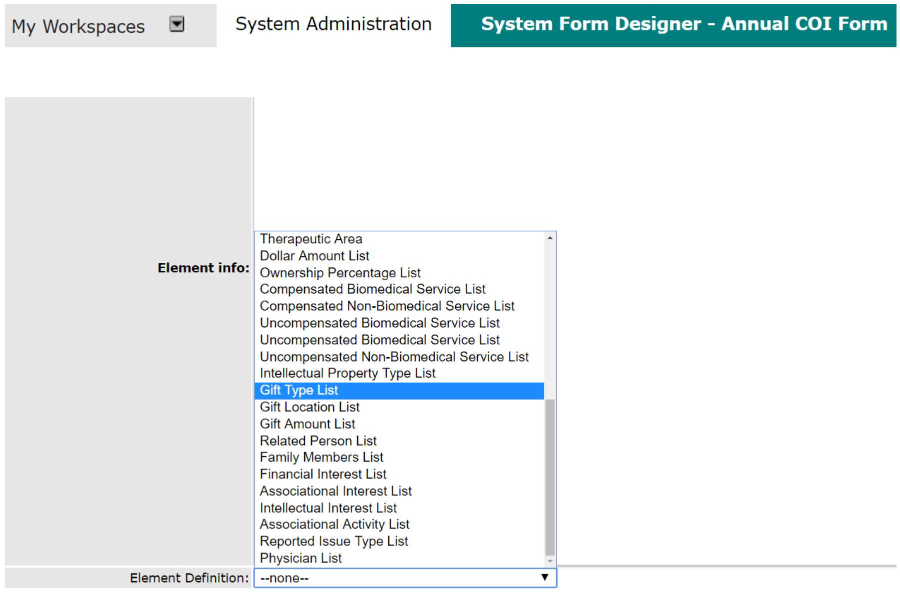
Configure Gift Amount list

The Gift Amount list allows you to set up gift amounts for users to select within a panel.

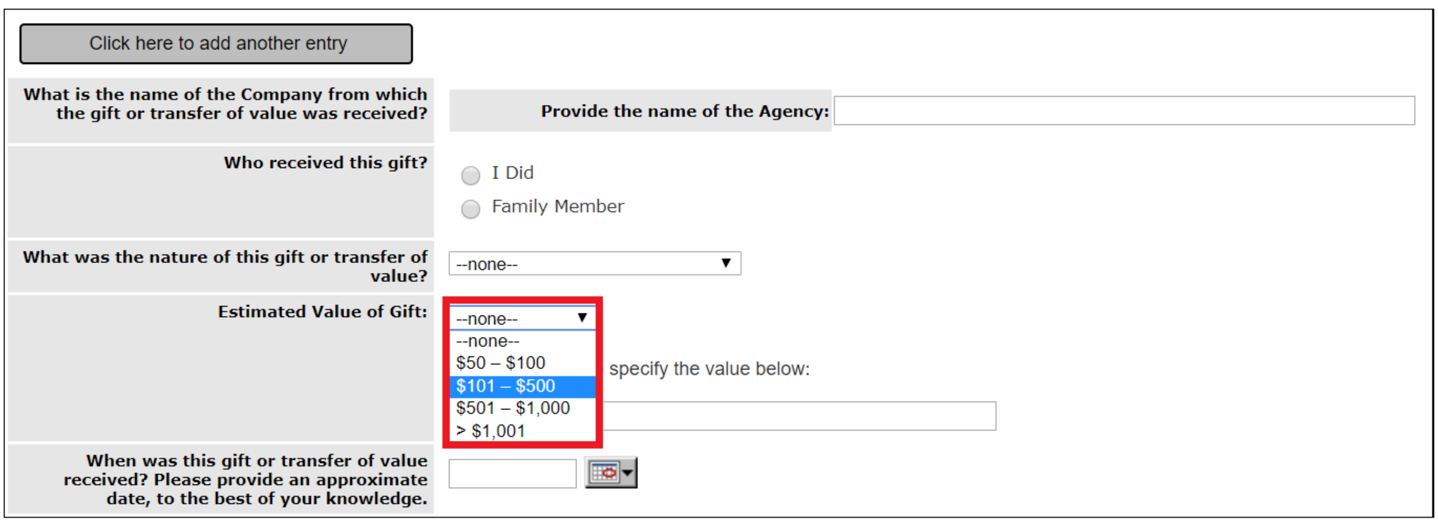


	Edit	Order Number	Gift Type	Type Amount
		1	$50 – $100	No
		2	$101 – $500	No
		3	$501 – $1,000	No
		4	> $1,001	Yes

The configuration list allows you to specify the Order Number, Gift Amount, and whether “Type Amount” should be activated (for cases where you would like the user to enter the exact amount if over or under a certain percentage); however, note that Type Amount is not applicable to the Gift Amount list because it is only for use within custom panels.



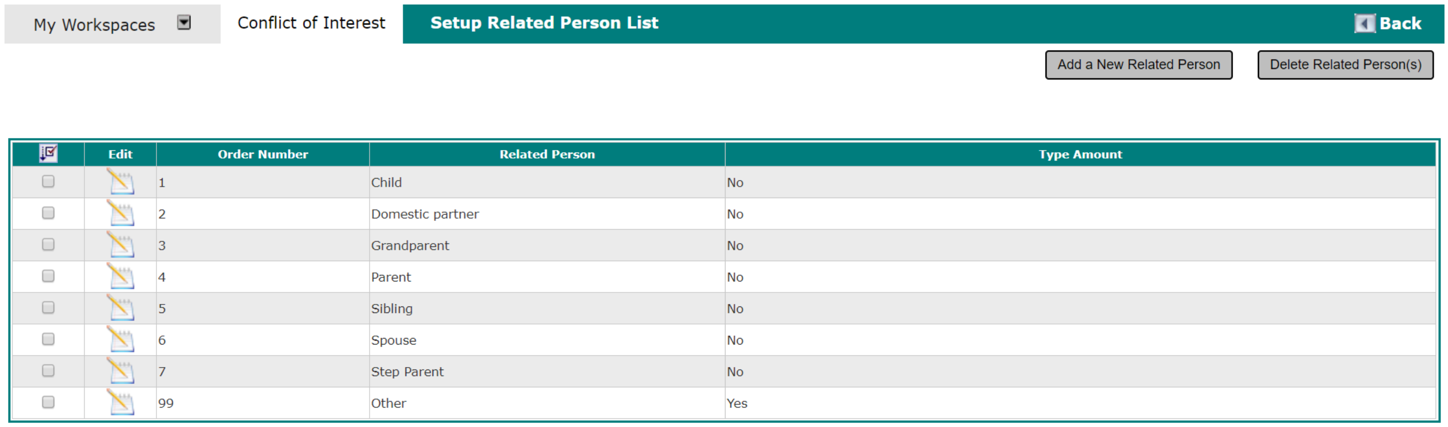
The configuration list is available when you use the "Selection – Configuration List" data type. The configuration list to select is "Gift Amount List".



If using this data value in a custom panel, and if an item with "Type Amount" set to "Yes" is selected, the user will not be prompted to specify additional information. This will only work in the predefined panels.

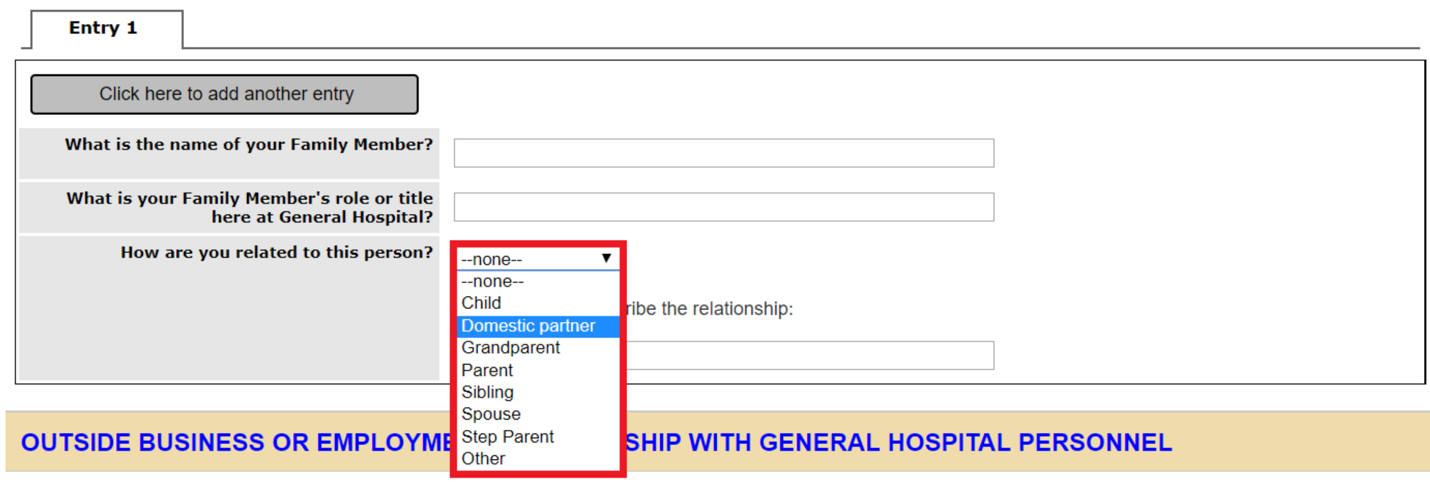
Configure Related Person list

The Related Person list allows you to setup different related persons for users to select from within a panel.



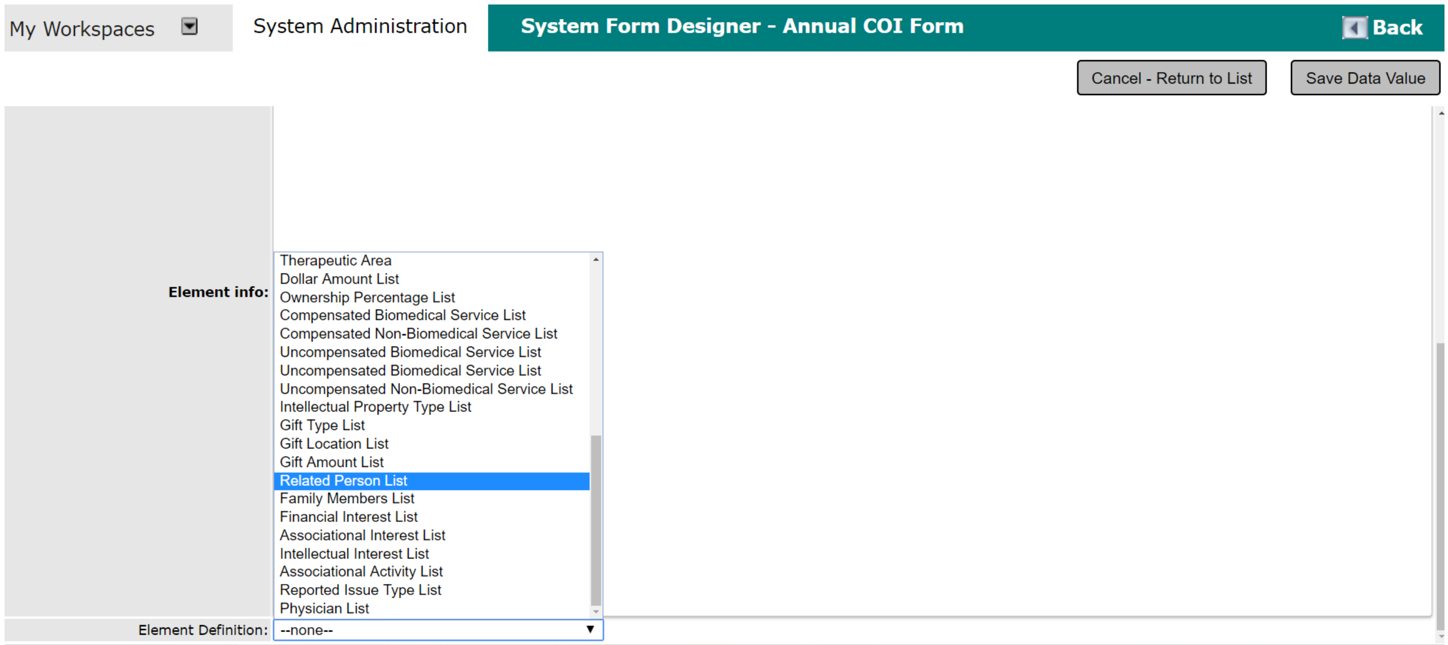
	Edit	Order Number	Related Person	Type Amount
		1	Child	No
		2	Domestic partner	No
		3	Grandparent	No
		4	Parent	No
		5	Sibling	No
		6	Spouse	No
		7	Step Parent	No
		99	Other	Yes

The configuration list allows you to specify the Order Number, Related Person, and whether “Type Amount” should be activated (for cases where you would like the user to specify additional information, e.g., “Other”).



The Related Person List will appear in the following data values:

- COI Annual Disclosure Form - employee related

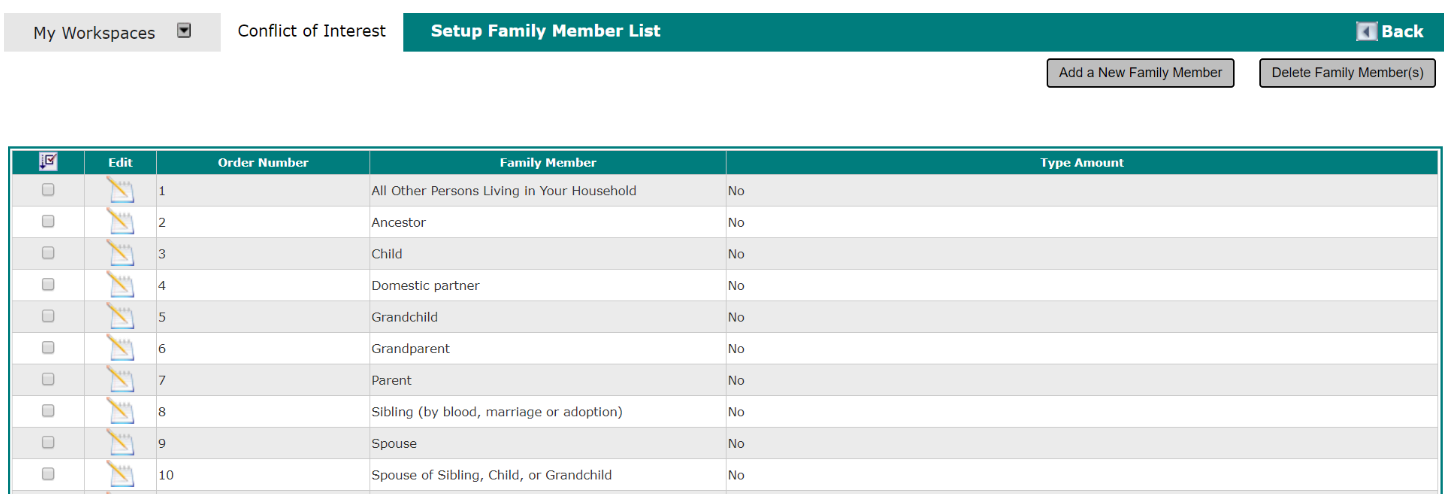


The Related Person List can also be pulled into a custom panel. The configuration list is available when using the "Selection – Configuration List" data type. The configuration list to select is "Related Person List".

If using this data value in a custom panel, and if an item with "Type Amount" set to "Yes" is selected, the user will not be prompted to specify additional information. This option will only work in the predefined panels.

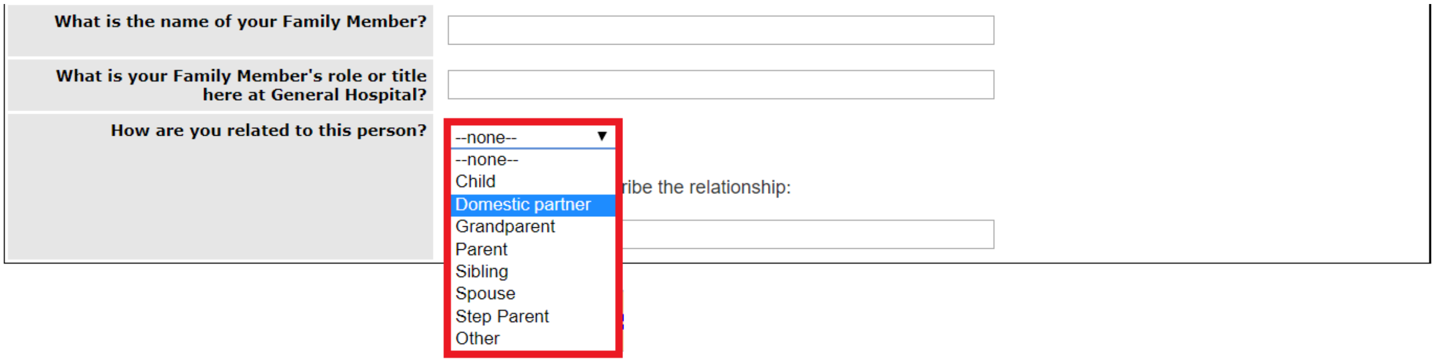
Configure Family Member list

The Family Member list allows you to setup different family member roles for users to select from within a panel.



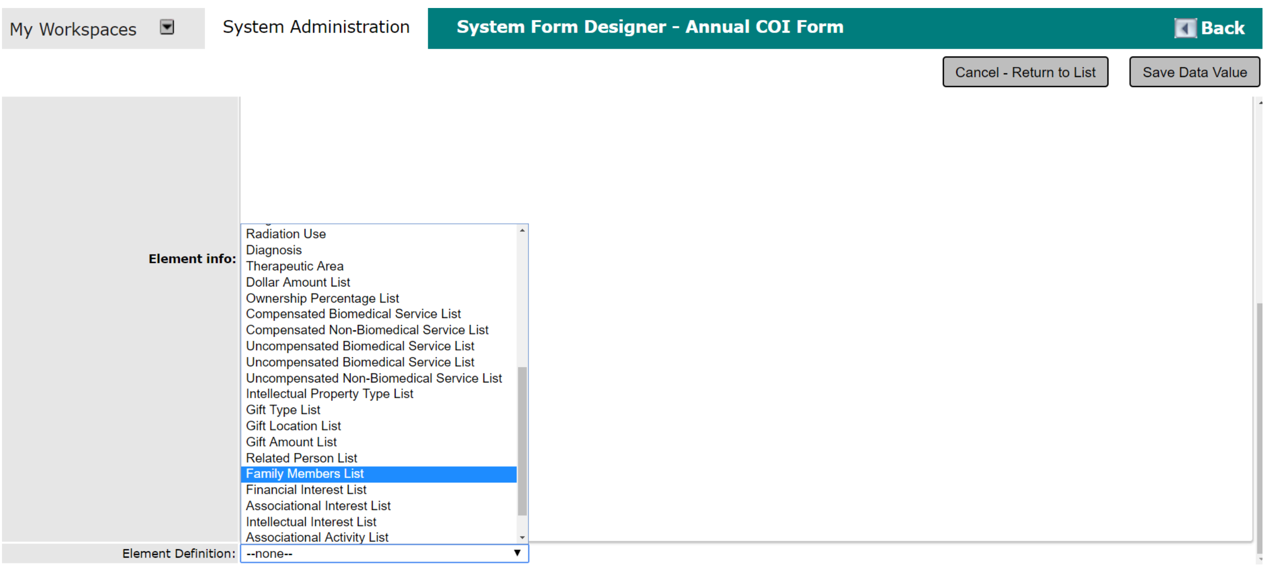
	Edit	Order Number	Family Member	Type Amount
		1	All Other Persons Living in Your Household	No
		2	Ancestor	No
		3	Child	No
		4	Domestic partner	No
		5	Grandchild	No
		6	Grandparent	No
		7	Parent	No
		8	Sibling (by blood, marriage or adoption)	No
		9	Spouse	No
		10	Spouse of Sibling, Child, or Grandchild	No

The configuration list allows you to specify the Order Number, Family Member, and whether "Type Amount" should be activated (for cases where you would like the user to specify additional information, e.g., "Other").



The Family Member List will appear in the following data values:

- COI Annual Disclosure Form relation of Family with Listed Persons

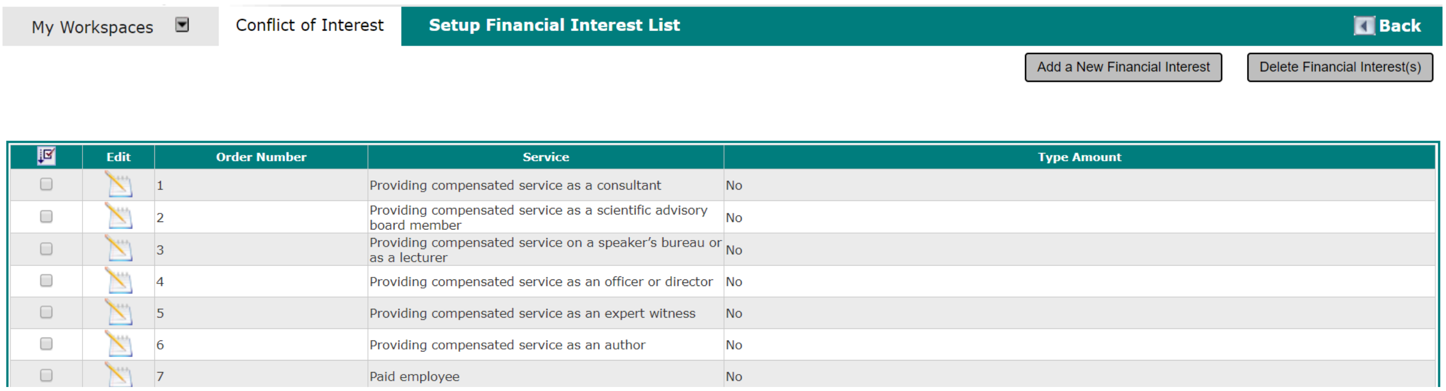


The Family Member List can also be pulled into a custom panel. The configuration list is available in the “Selection – Configuration List” data type. The configuration list to select is “Family Members List”.

If using this data value in a custom panel, and if an item with “Type Amount” set to “Yes” is selected, the user will not be prompted to specify additional information. This option will only work in the predefined panels.

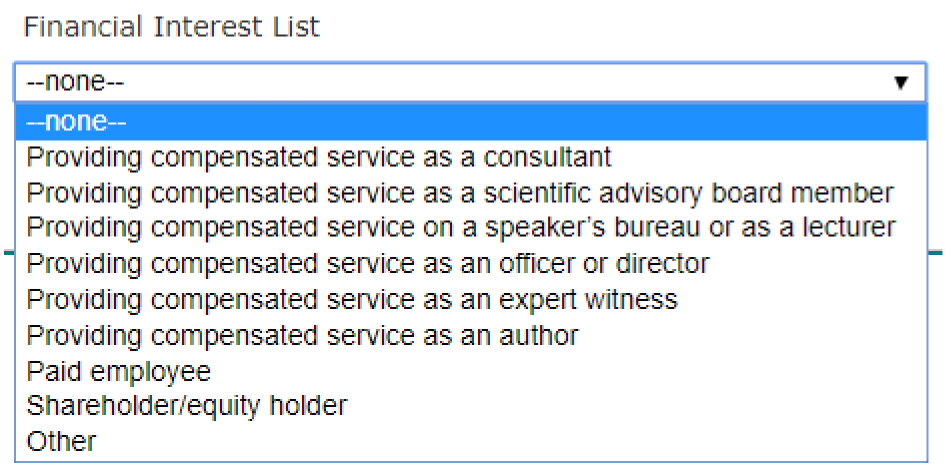
Configure Study Financial Interest list

The Study Financial Interest list allows you to setup different financial interests for users to select from within a panel of a study-related COI form.



	Edit	Order Number	Service	Type Amount
		1	Providing compensated service as a consultant	No
		2	Providing compensated service as a scientific advisory board member	No
		3	Providing compensated service on a speaker's bureau or as a lecturer	No
		4	Providing compensated service as an officer or director	No
		5	Providing compensated service as an expert witness	No
		6	Providing compensated service as an author	No
		7	Paid employee	No

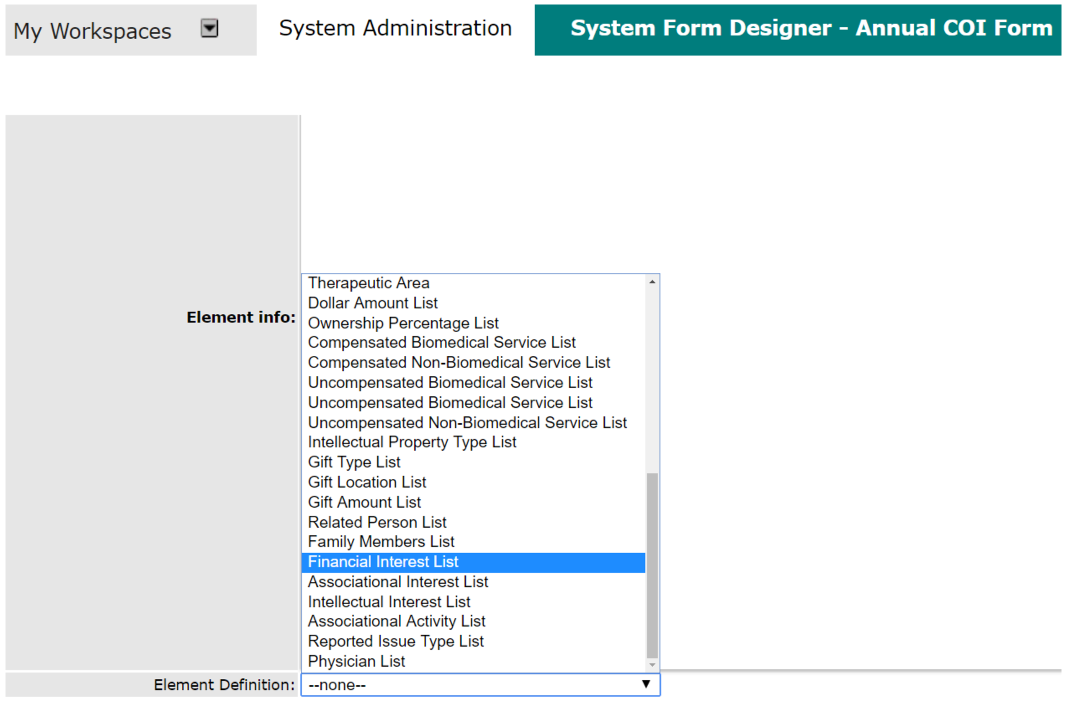
The configuration list allows you to specify the Order Number, Service, and whether "Type Amount" should be activated (for cases where you would like the user to specify additional information, e.g., "Other").



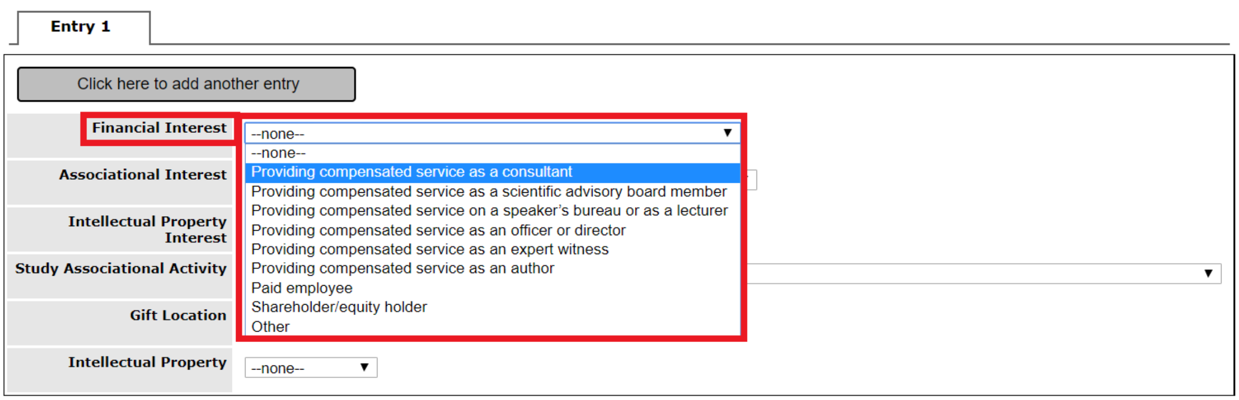
When using the "Key Personnel Form COI Study Disclosure Interest" data value within a Study COI form, upon the user selecting that the Interest is Compensated, he or she will then be given the ability to select from the Financial Interest list.

The Financial Interest List will appear in the following data values:

- Key Personnel Form COI Study Disclosure Interest (*This is available only in the Study COI form)



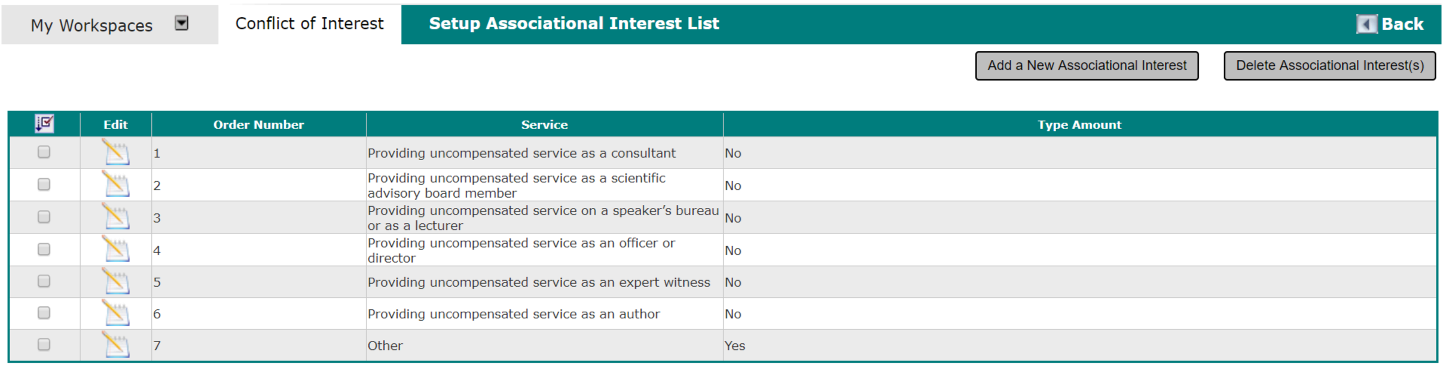
The Financial Interest List can also be pulled into a custom panel. The configuration list is available when using the “Selection – Configuration List” data type. The configuration list to select is “Financial Interest List”.



If using this data value in a custom panel, the data will display in a drop-down list. Also, if an item with “Type Amount” set to “Yes” is selected, the user will not be prompted to specify additional information. This option will only work in the predefined panels.

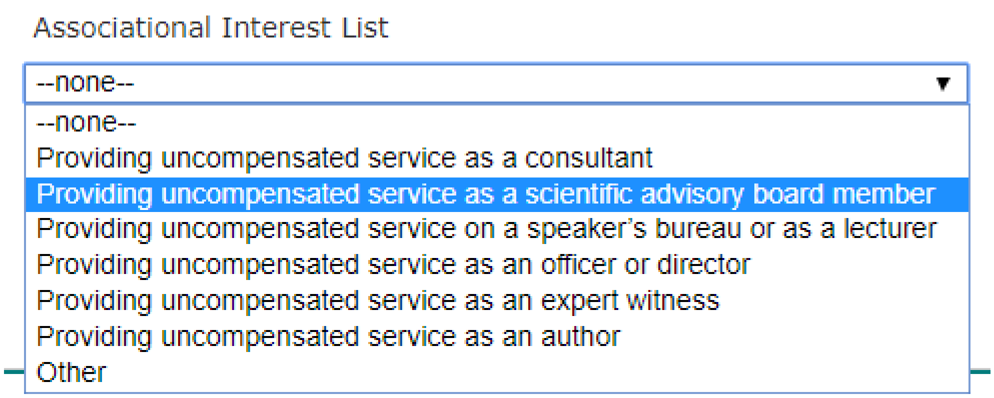
Configure Study Associational Interest List

The Study Associational Interest list allows you to set up different services for users to select within a panel in a study-related COI form.



	Edit	Order Number	Service	Type Amount
		1	Providing uncompensated service as a consultant	No
		2	Providing uncompensated service as a scientific advisory board member	No
		3	Providing uncompensated service on a speaker's bureau or as a lecturer	No
		4	Providing uncompensated service as an officer or director	No
		5	Providing uncompensated service as an expert witness	No
		6	Providing uncompensated service as an author	No
		7	Other	Yes

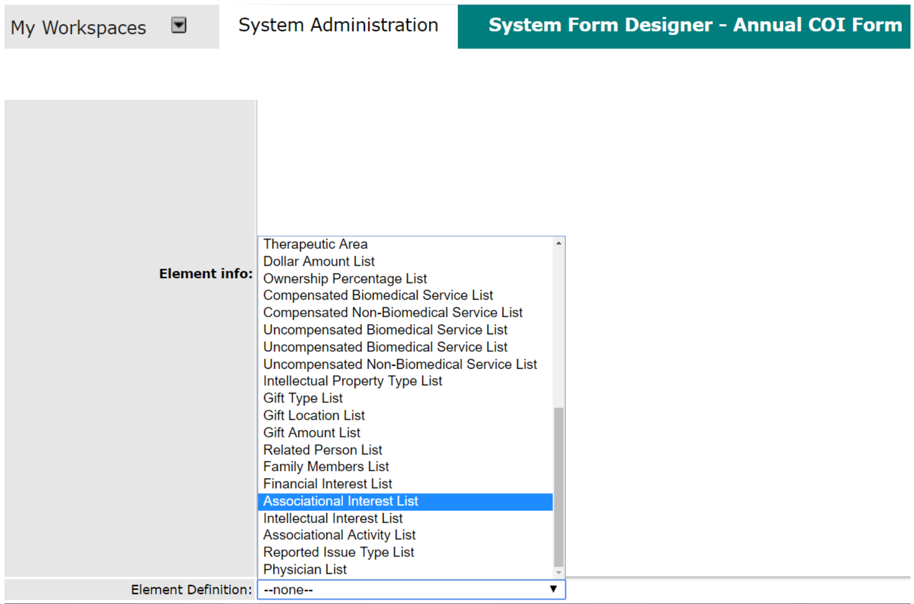
The configuration list allows you to specify the Order Number, Service, and whether “Type Amount” should be activated (for cases where you would like the user to specify additional information, e.g., “Other”).



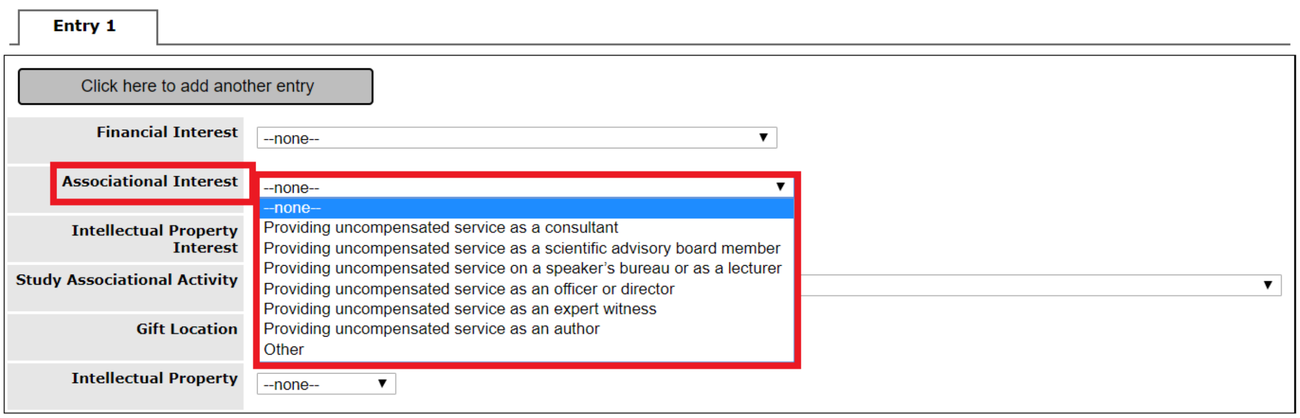
When using the Key Personnel Form COI Study Disclosure Interest data value within a Study COI form, upon the user selecting that the Interest is “Uncompensated”, he or she will then be given the ability to select from the Associational Interest list.

The Study Associational List will appear in the following data values:

- Key Personnel Form COI Study Disclosure Interest (*This is available only in the Study COI form)



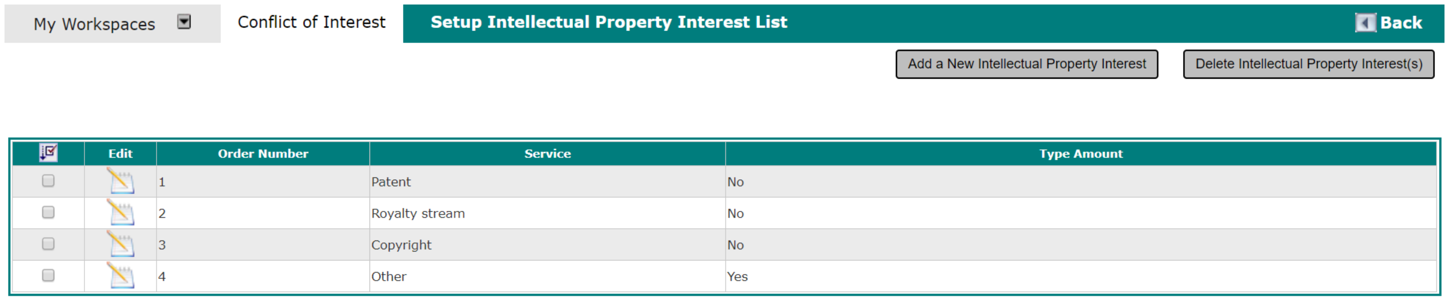
The Associational Interest List can also be pulled into a custom panel. The configuration list is available when using the “Selection – Configuration List” data type. The configuration list to select is “Associational Interest List”.



If using this data value in a custom panel, the data will display in a drop-down list. Also, if an item with “Type Amount” set to “Yes” is selected, the user will not be prompted to specify additional information. This option will only work in the predefined panels.

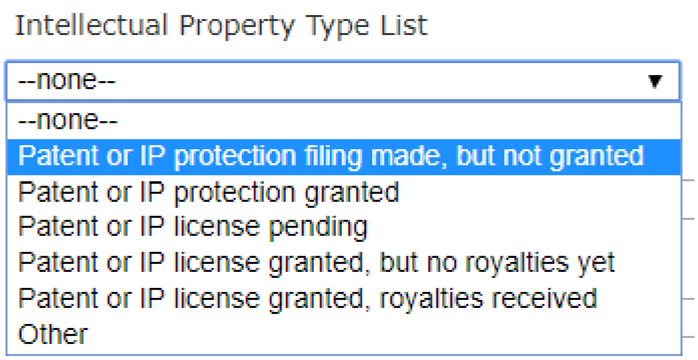
Configure Study Intellectual Property Interest List

The Study Intellectual Property Interest list allows you to set up different types of intellectual property for users to select from within a panel of a study-related COI form.



	Edit	Order Number	Service	Type Amount
		1	Patent	No
		2	Royalty stream	No
		3	Copyright	No
		4	Other	Yes

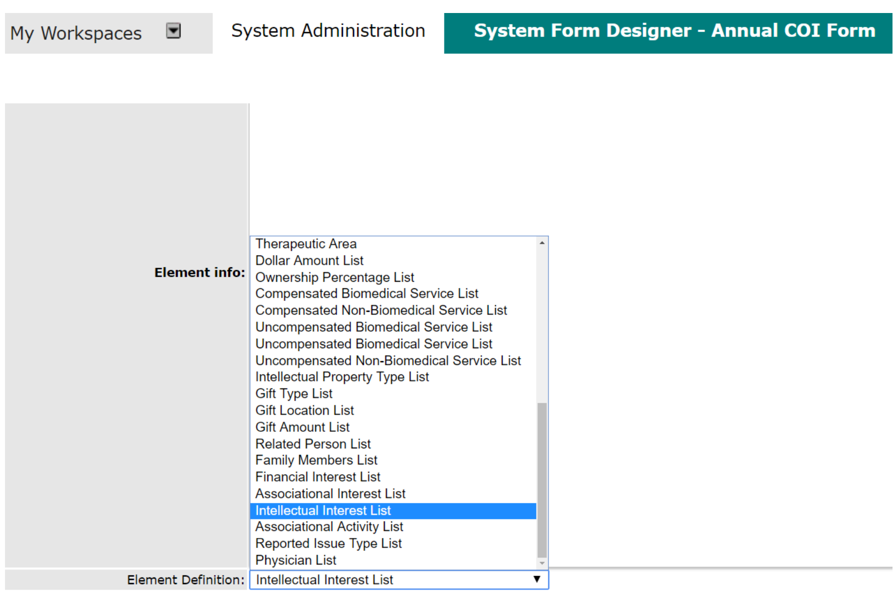
The configuration list allows you to specify the Order Number, Service, and whether "Type Amount" should be activated (for cases where you would like the user to specify additional information, e.g., "Other").



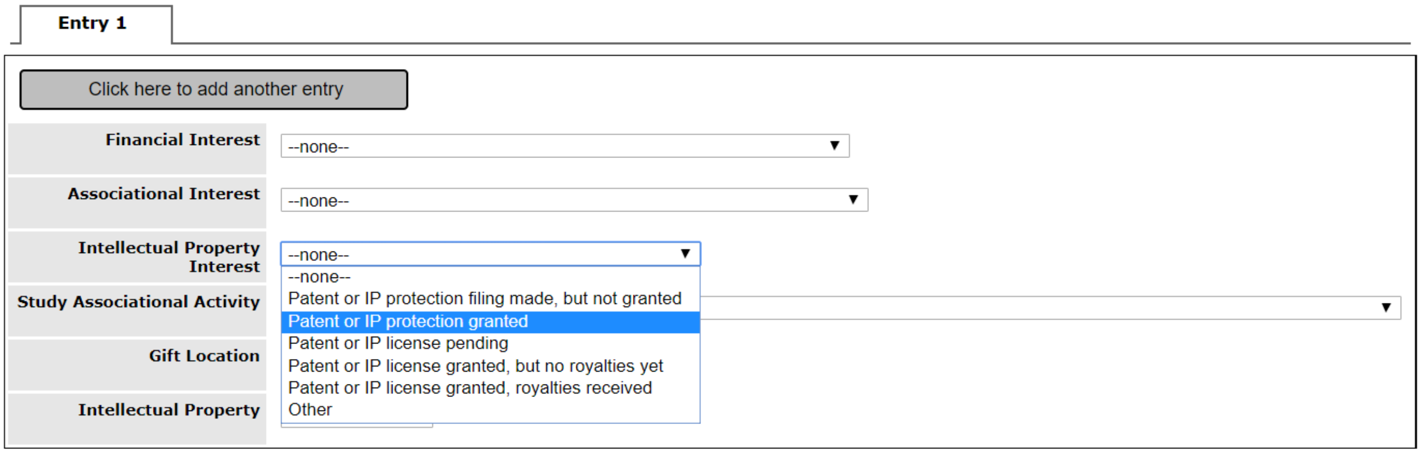
When using the Key Personnel Form COI Study Disclosure Interest data value within a Study COI form, upon the user selecting that the interest is "Intellectual Property," he or she will be given the ability to select from the Intellectual Property Interest list.

The Study Intellectual Property List will appear in the following data values:

- Key Personnel Form COI Study Disclosure Interest (*This is available only in the Study COI form)



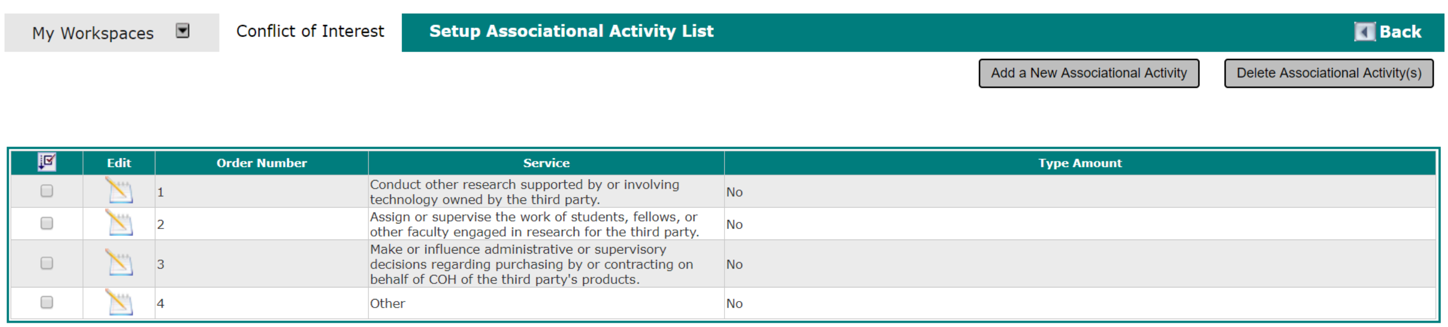
The Intellectual Property List can also be pulled into a custom panel. The configuration list is available when using the "Selection – Configuration List" data type. The configuration list to select is "Intellectual Interest List."



If using this data value in a custom panel, the data will display in a drop-down list. Also, if an item with "Type Amount" set to "Yes" is selected, the user will not be prompted to specify additional information. This option will only work in the predefined panels.

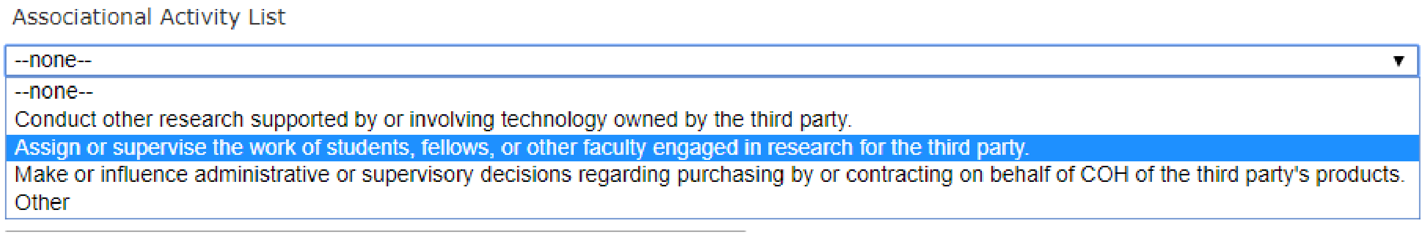
Configure Study Associational Activity List

The Study Associational Activity list allows you to set up different activities for users to select from within a panel of a study-related COI form.



	Edit	Order Number	Service	Type Amount
		1	Conduct other research supported by or involving technology owned by the third party.	No
		2	Assign or supervise the work of students, fellows, or other faculty engaged in research for the third party.	No
		3	Make or influence administrative or supervisory decisions regarding purchasing by or contracting on behalf of COH of the third party's products.	No
		4	Other	No

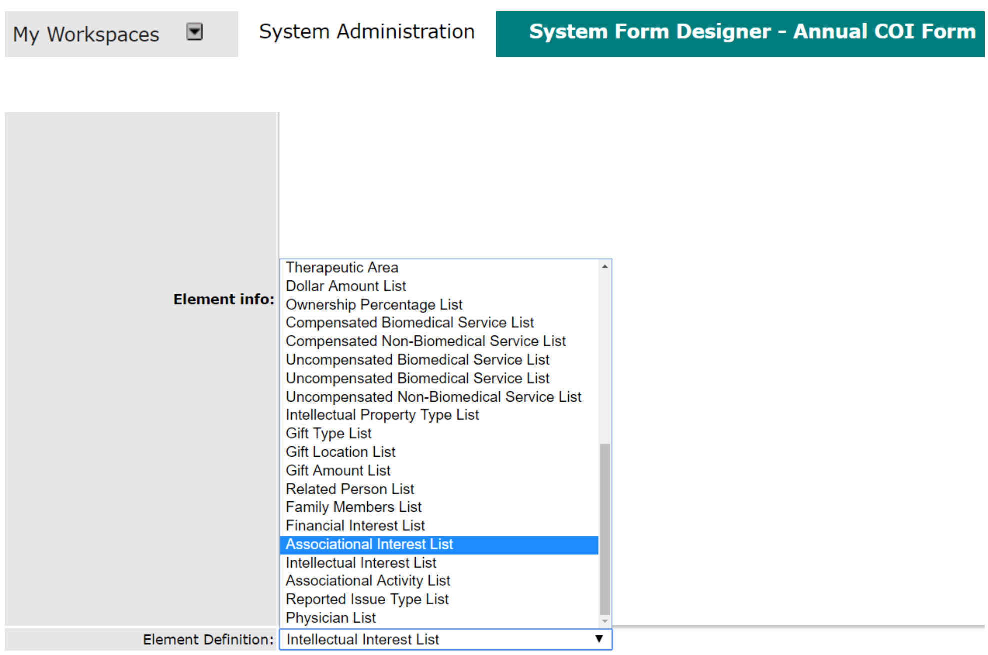
The configuration list allows you to specify the Order Number, Service, and whether "Type Amount" should be activated (for cases where you would like the user to specify additional information, e.g., "Other").



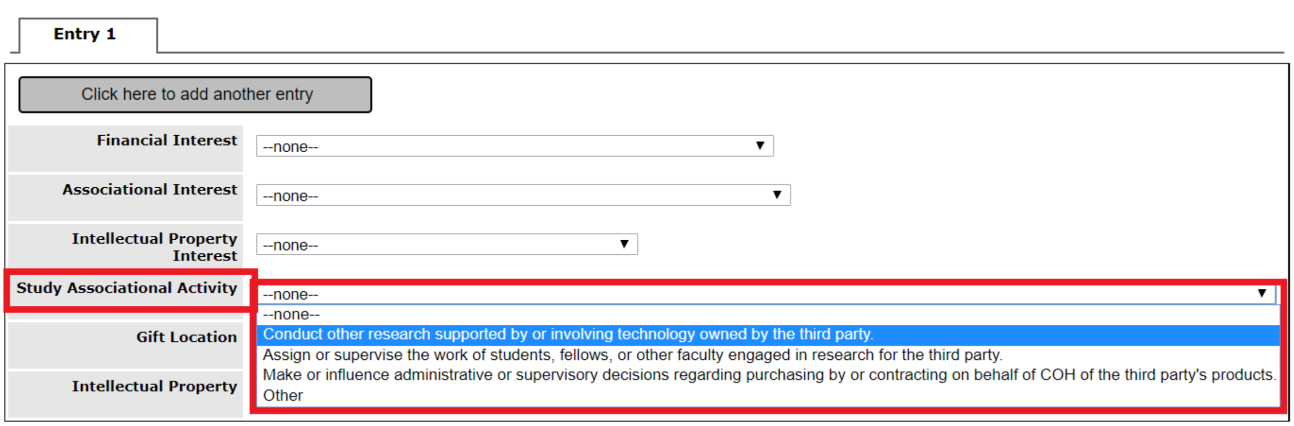
When using the "Key Personnel Form COI Study Disclosure Internal" data value within a Study COI form, the user will be given the ability to select from the Associational Activity list.

The Associational Activity List will appear in the following data values:

- Key Personnel Form COI Study Disclosure Internal (*This is available only in the Study COI form)



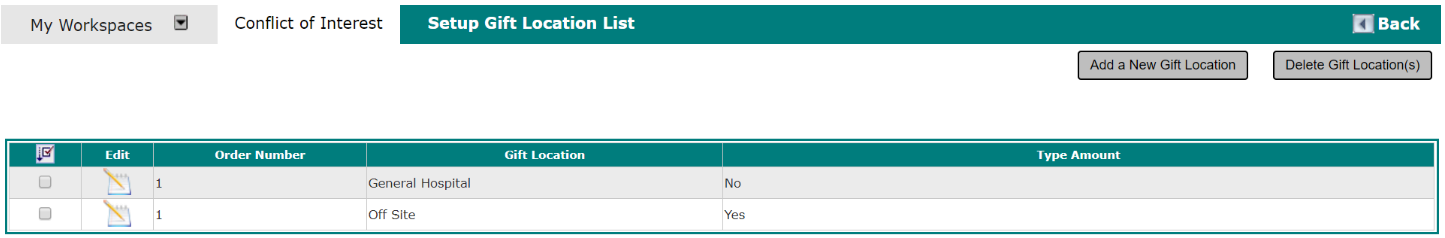
The Associational Activity list can also be pulled into a custom panel. The configuration list is available in the "Selection – Configuration List" data type. The configuration list to select is "Associational Activity List".



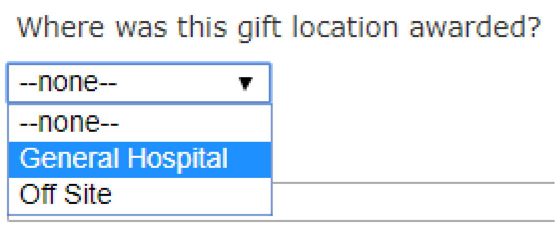
If using this data value in a custom panel, the data will display in a dropdown list. Also, if an item with “Type Amount” set to “Yes” is selected, the user will not be prompted to specify additional information. This option will only work in the predefined panels.

Configure Location List

The Gift Location list allows you to set up different gift locations for users to select from within a panel.

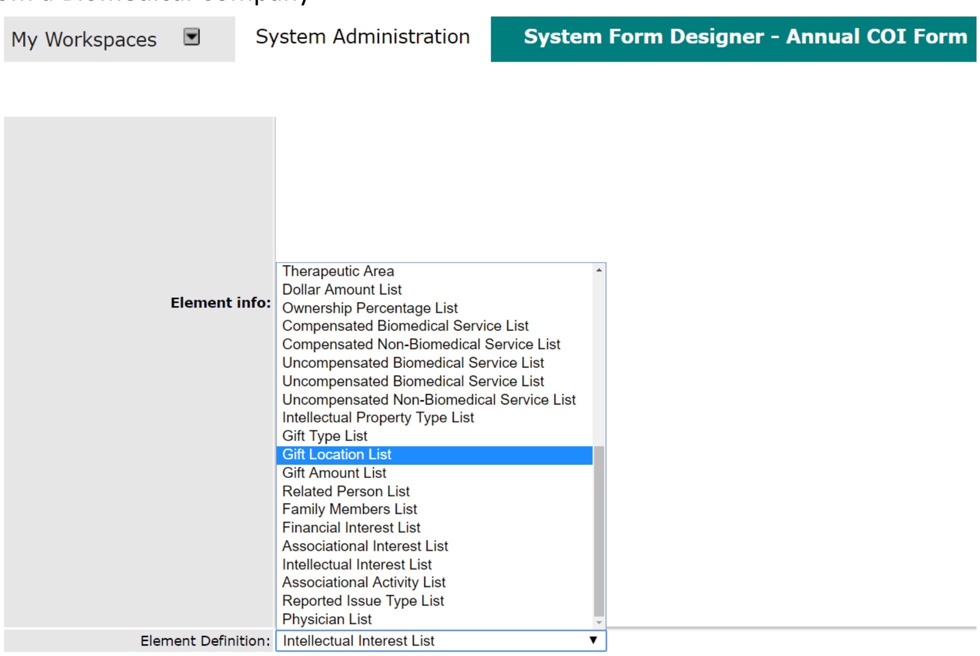


The configuration list allows you to specify the Order Number, Gift Location, and whether “Type Amount” should be activated (for cases where you would like the user to specify additional information, e.g., “Other”).

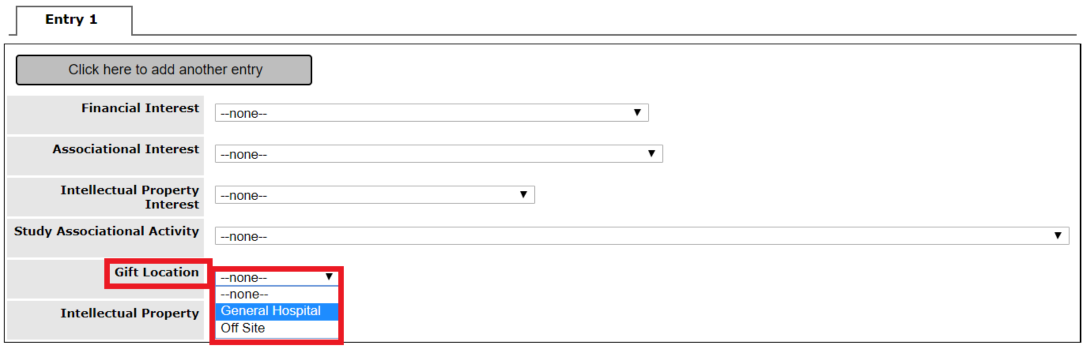


The Gift Location List will appear in the following data values:

- Gifts from a Biomedical Company



The Gift Location list can also be pulled into a custom panel. The configuration list is available in the “Selection – Configuration List” data type. The configuration item to select is “Gift Location List”.

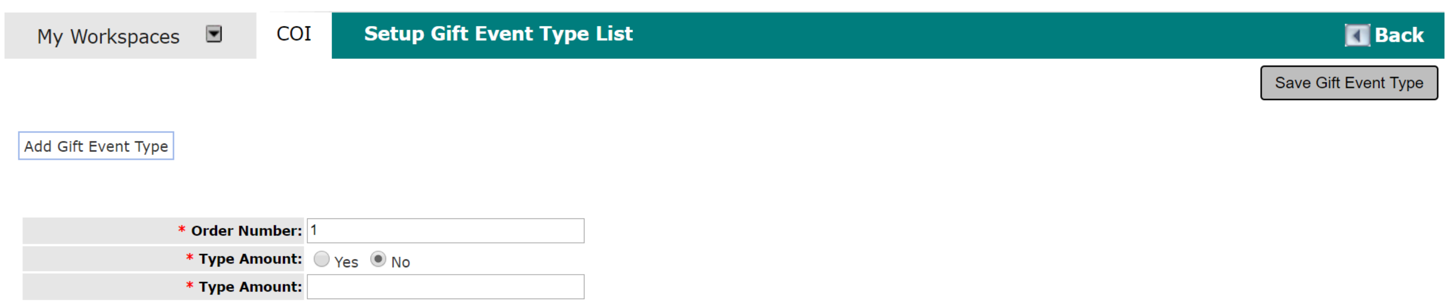


If using this data value in a custom panel, and if an item with “Type Amount” set to “Yes” is selected, the user will not be prompted to specify additional information. This option will only work in the predefined panels.

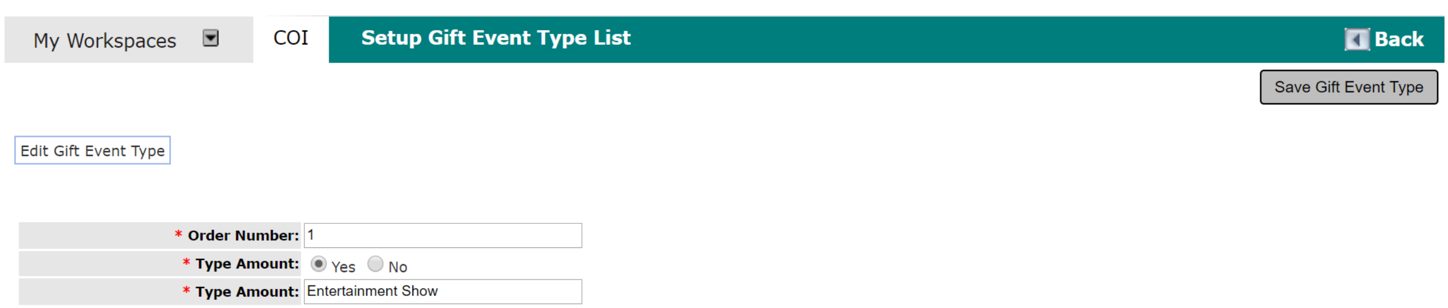
Configure Event list

The Event list allows users to set up the Gift Events.

To add a new Gift Event Type, click the button **Add a New Gift Event Type.**



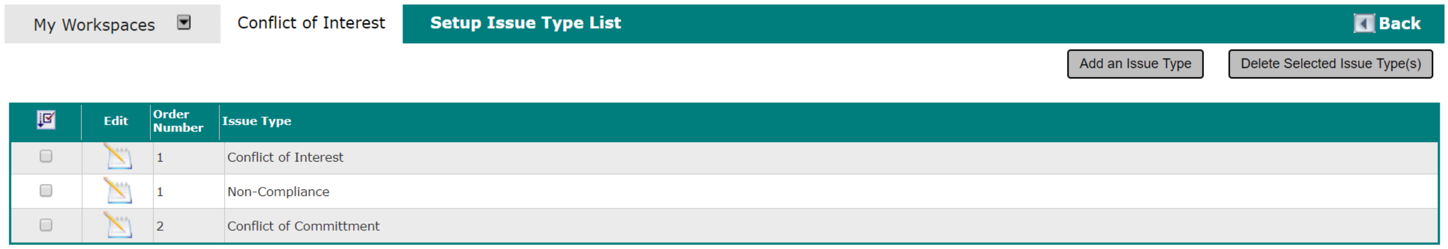
Decide the **order number,** whether the type amount should be included with the “Yes”, “No” radio buttons, and **type amount.**



You can also edit the gift event types from the previous screen. You will be able to edit all three sections.

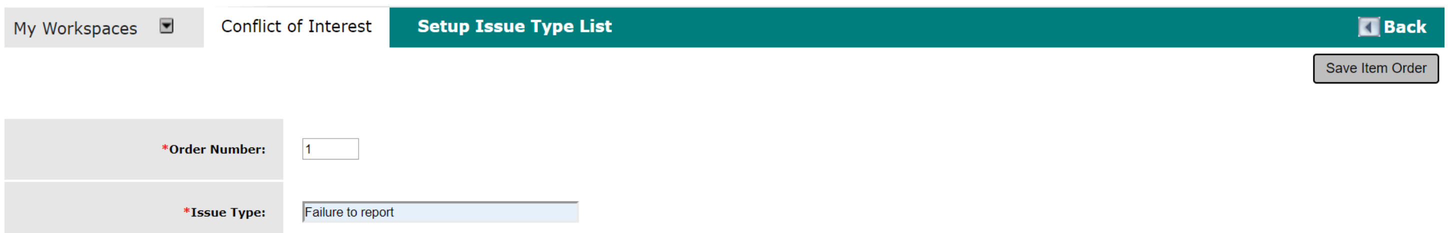
Issue Reporting Types

The Issue Type List page lists the current issue types that can be assigned to a study.



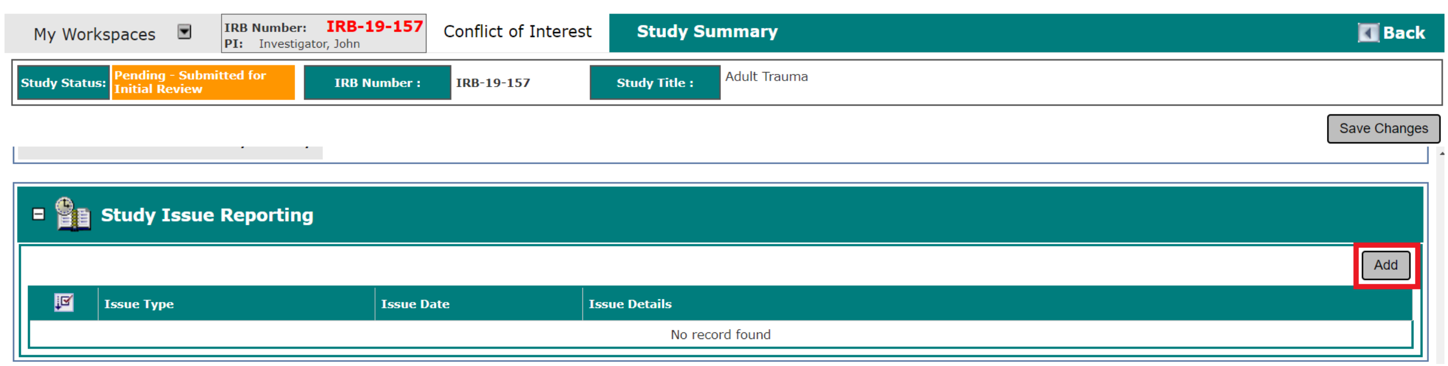
You can add a new Issue Type by clicking the **Add an Issue Type** button.

This will bring you to the Issue Type setup page. You will be required to enter the Order Number and the Issue Type. Once you have entered this information, click the **Save Item Order** button and the issue will be added to the Issue Type List.

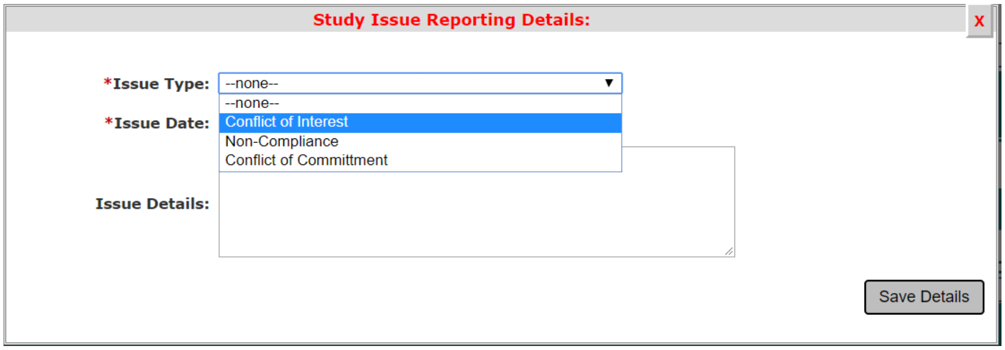


To delete Issue Type(s), check the box(es) next to the Issue Type(s) you want to delete and click the **Delete Selected Issue Type(s)** button. To edit an issue, click the  icon next to an Issue Type, and you will be brought to the screen shown above, where you can edit the Order Number and Issue Type.

You can add an issue to a study from the Study Summary/Profile page, accessed via COI Assistant > Find a Study > Study Management > Study Summary/Profile. Once you are on the Study Summary page, click the **Add** button next to the Study Issue Report section.



This will open the Study Issue Reporting Details window, where you can specify the Issue Type, Issue Date, and Issue Details. After you are done entering the issue details, click the **Save Details** button to add the issue to the study.


Study Issue Reporting Details:
x
*Issue Type:
--none--
--none--
Conflict of Interest
Non-Compliance
Conflict of Committment
*Issue Date:
Issue Details:
Save Details