Conflict of Interest Assistant

Administrative Manual for Form Design and Workflow

Version 11.02

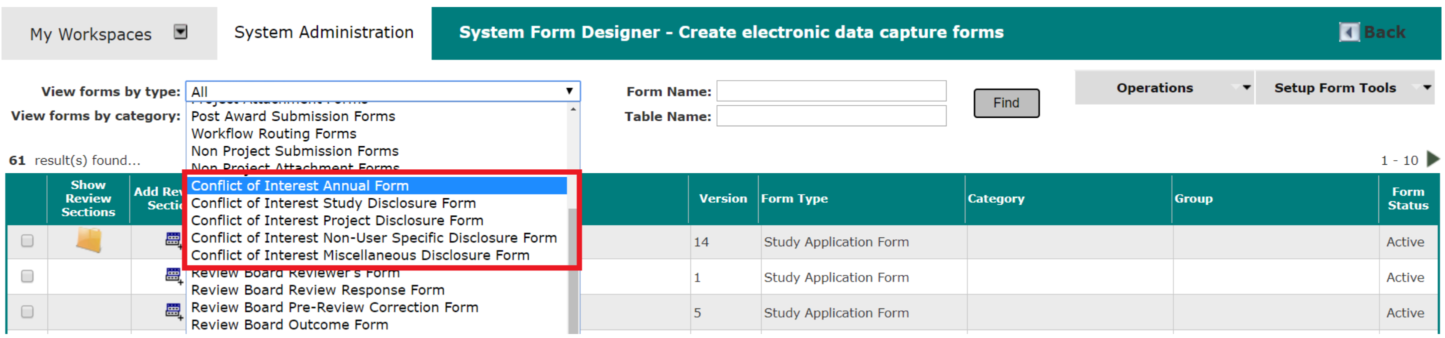
Contents

COI Administration – Forms and Workflow

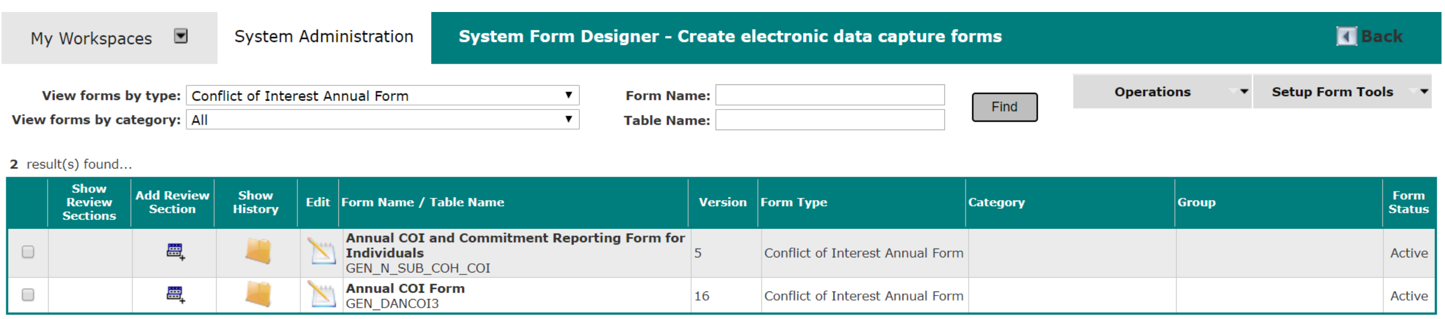
COI Forms Design

This section of the manual assumes that the reader has a general knowledge of the Form Designer. When working on COI forms, you will have the same functionality as other forms in the Form Designer. It is recommended that prior to making any changes to the Annual COI form, you have a good understanding of the Form Designer tool. You can use the System Admin - Form Designer manual for more information.

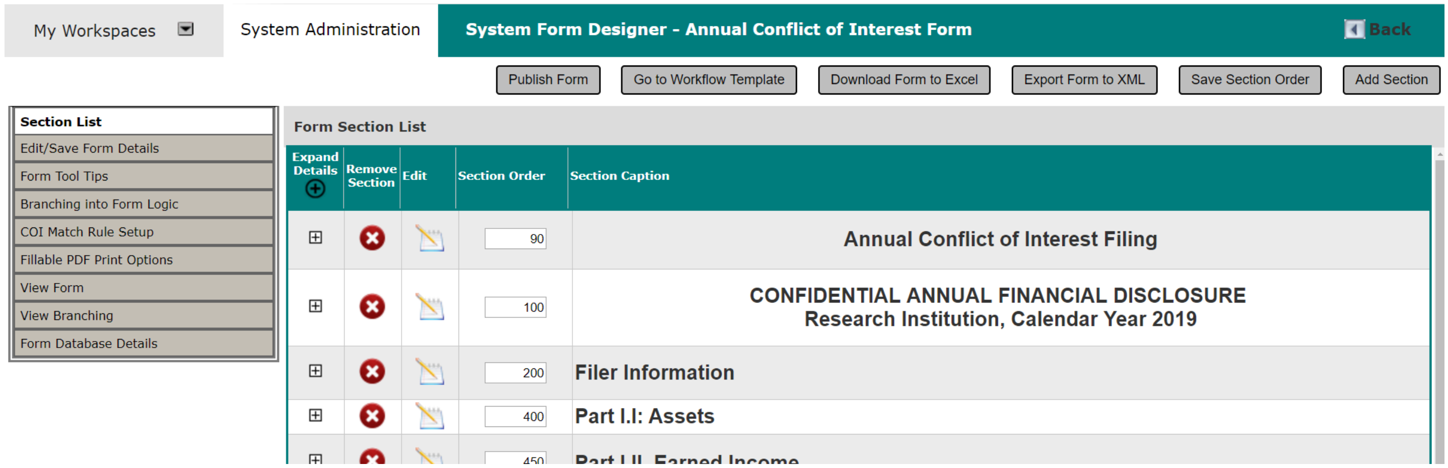
Within System Administration > System Forms Designer, you will have the ability to configure COI forms. Your iMedRIS Project Manager will initially upload our standard COI Annual and Project Disclosure form, and you will be able to remove sections/questions that are not needed, change question text and manage the Help Links.



You can locate the COI annual disclosure forms by clicking on the **View forms by type** dropdown list and selecting the **Conflict of Interest Annual Form**. You will also see other types of COI forms in the list.

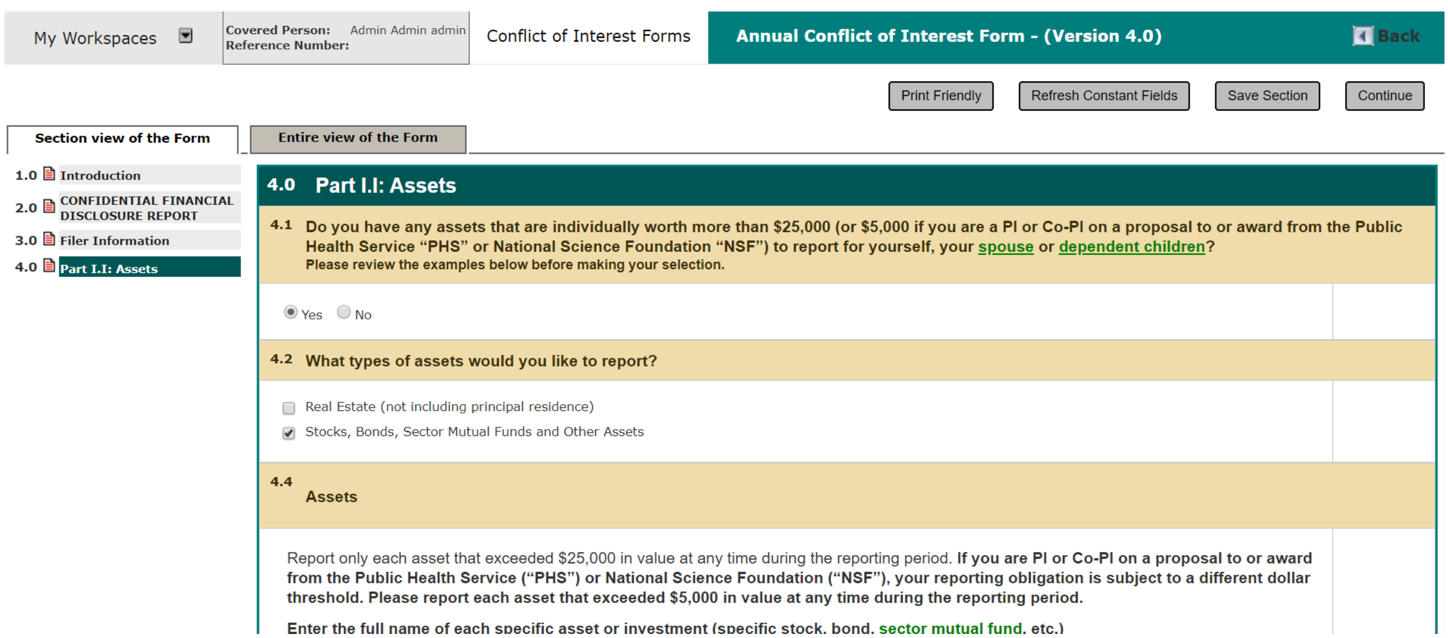


When you select a form type from the dropdown menu, it will remove all other form types from the list and display the selected COI form. Click on the **Edit** icon to open the form.



Prior to making any edits, make sure that the form is unpublished. iMedRIS also recommends that you export the form and save an .xml copy to your computer in case you need to roll back the form after making your changes.

All sections of the form are displayed in this view. Please note that the types of modifications that you can make to the Annual form are limited in nature. You can modify sections and question text, add sections and questions, edit the Help Links, and delete questions and sections.

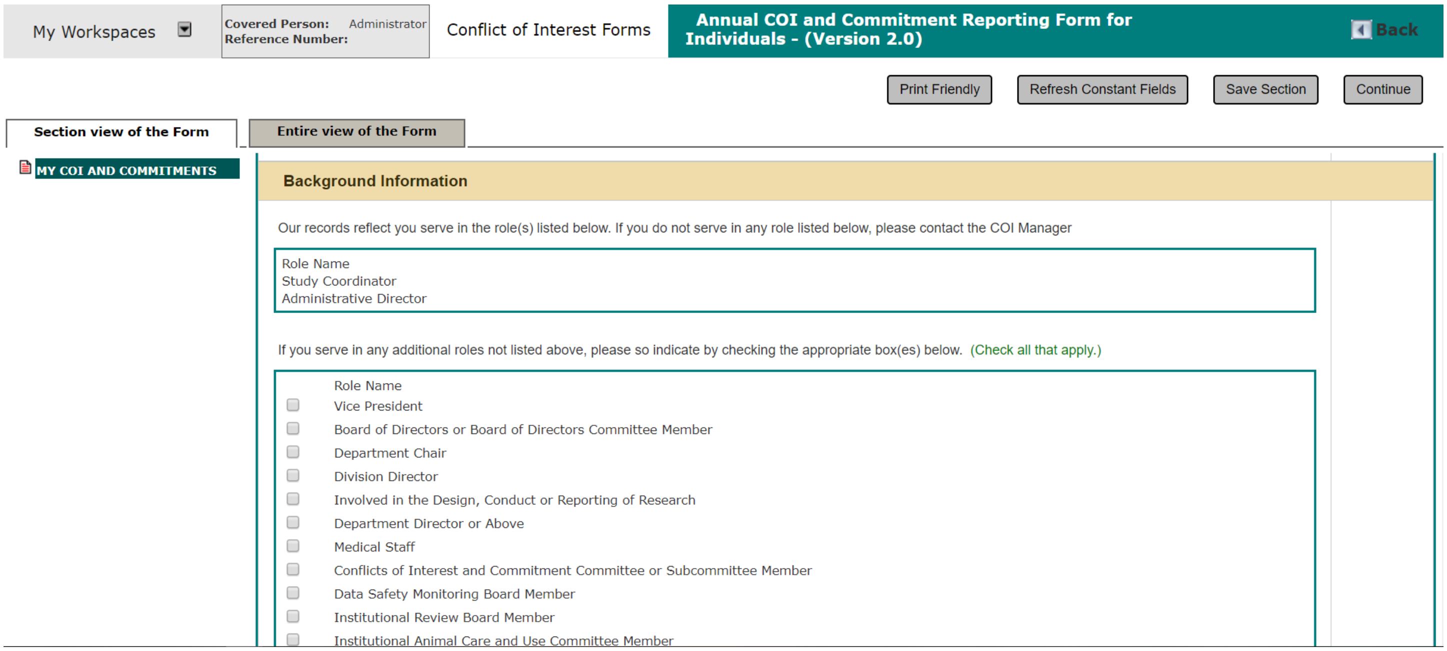


The items in the form that cannot be modified are the "Yes/No" values and entries that populate beneath the answers to questions as shown in the screenshot above. These are hard-coded, separate data values that are inserted into the form. There are labels that can be changed to control the wording. This will be done within Conflict of Interest Review Board Administration.

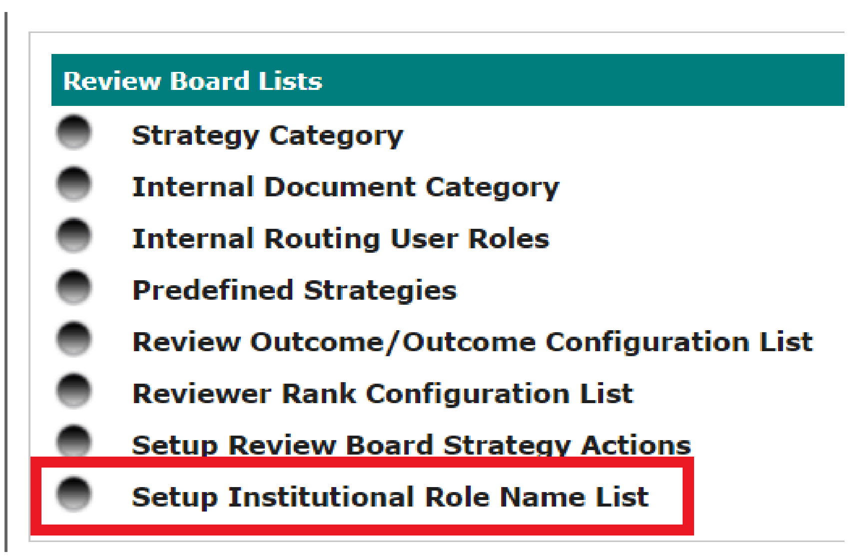
Data Values

The COI Annual form is predefined. Based on the needs of your institution's COI process, you can rearrange sections or remove sections that are not necessary. There are unique values that you can use in the COI forms which are described below.

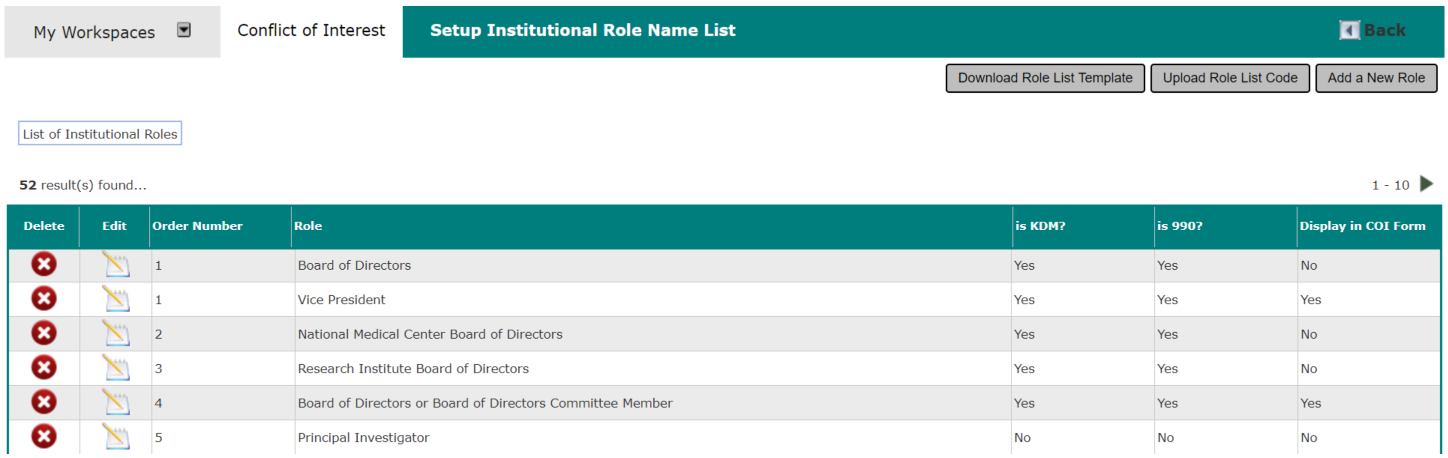
COI Annual Disclosure Form User's Current Institutional Roles and COI Annual Disclosure Form User's Selected Institutional Roles



These two values are related to roles in the system. **User's Current Institutional Roles** will display a list of roles associated to the user completing the COI form. **User's Selected Institutional Roles** provides a list of additional positions the user may hold.



This list of positions is configurable under Conflict of Interest Assistant > Review Board Administration > List Maintenance Setup.



My Workspaces | Conflict of Interest | **Setup Institutional Role Name List** | Back

Download Role List Template | Upload Role List Code | Add a New Role

List of Institutional Roles

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

Delete	Edit	Order Number	Role	is KDM?	is 990?	Display in COI Form
		1	Board of Directors	Yes	Yes	No
		1	Vice President	Yes	Yes	Yes
		2	National Medical Center Board of Directors	Yes	Yes	No
		3	Research Institute Board of Directors	Yes	Yes	No
		4	Board of Directors or Board of Directors Committee Member	Yes	Yes	Yes
		5	Principal Investigator	No	No	No

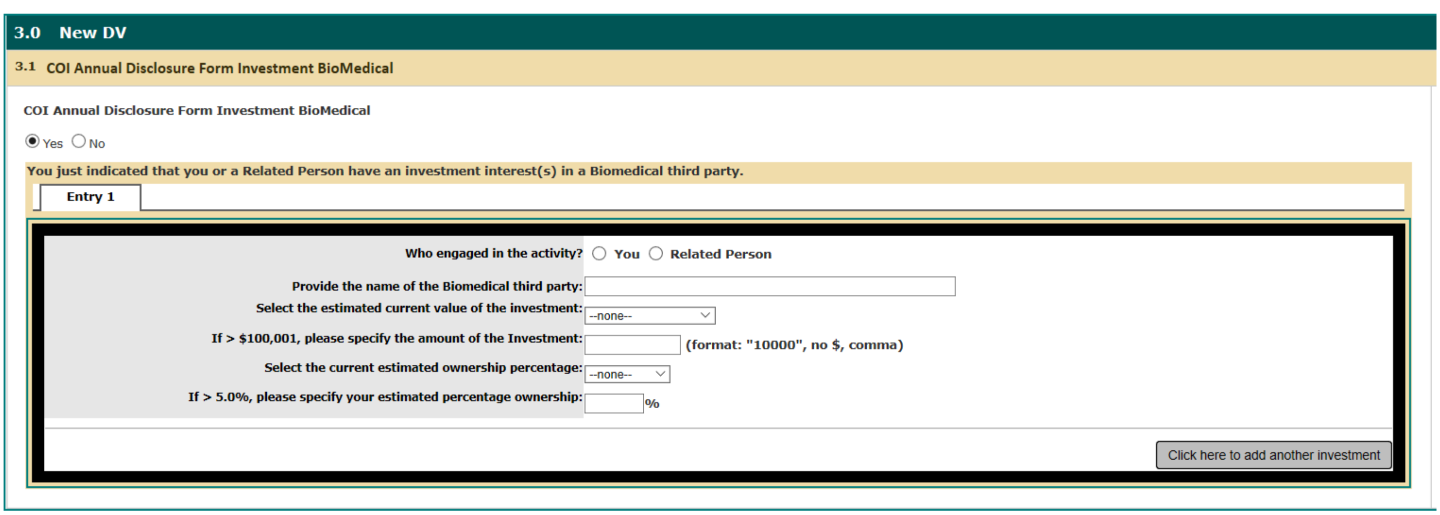
In order for a role defined to display within the COI Annual form, make sure the value **Display in COI Form** set to "Yes".

If you are using Form 990 within your COI Annual form, the only way to present users with these sections is for the role to beflagged **Is 990 as illustrated in the screenshot above**.

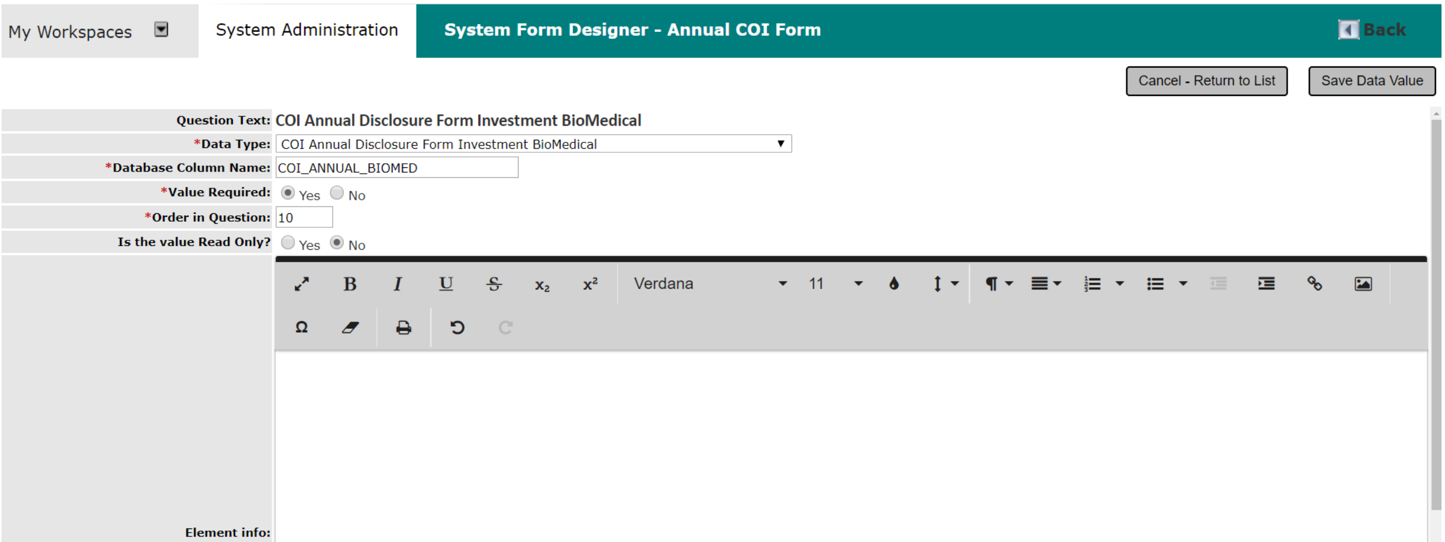
Other Data Values

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
COI Annual Disclosure Form Intellectual Property Biomedical
COI Annual Disclosure Form gifts from any Biomedical
COI Annual Disclosure Form uncompensated position Biomedical
COI Annual Disclosure Form uncompensated position non-Biomedical
COI Annual Disclosure Form employee related
COI Annual Disclosure Form have business with direct relation
COI Annual Disclosure Form have ownership with direct relation
COI Annual Disclosure Form have served with direct relation
COI Annual Disclosure Form relation of Family with Listed Persons

The rest of the COI Annual Disclosure Form data values are related to the entries presented to the user when they indicate a specific interest in a section of the form. These data values will insert a specific set of questions within the section if the user answered the question a specific way. An example below uses the **COI Annual Disclosure Form Investment BioMedical** data value and how it is used in the Investments with Biomedical Third Parties section of the COI Annual.

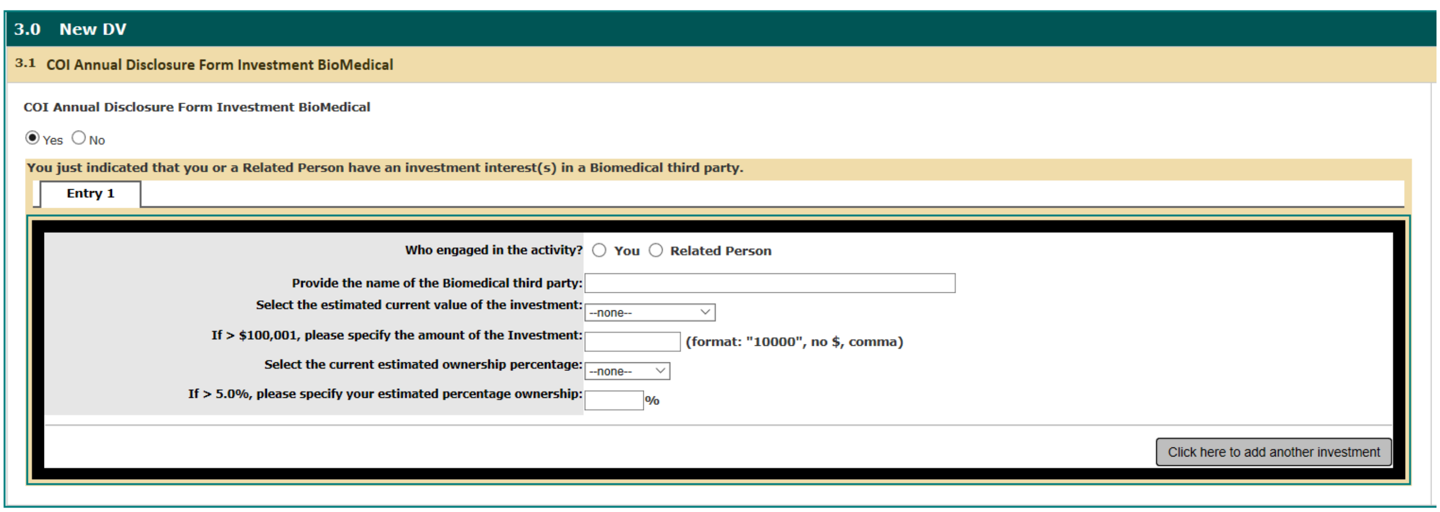


Within the Investments with Biomedical Third Parties section, if the user indicates “Yes” to the question, an Entry will populate on the screen. This is the COI Annual Disclosure Form Investment BioMedical data value. It is programmed to pull in specific questions for the user, applicable to an interest in a Biomedical Third Party.

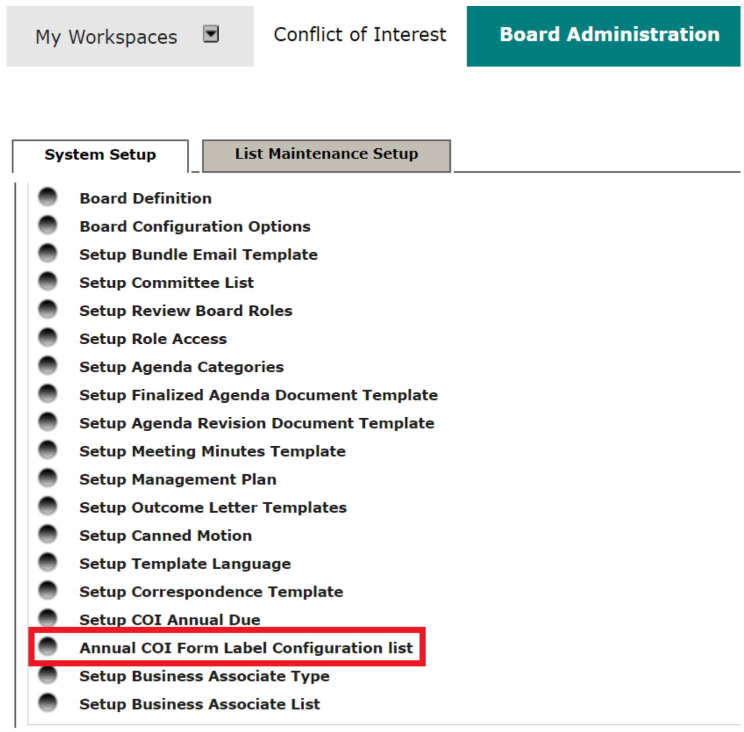


To set up the data value in the form within your question, add a new data value then select from the **Data Type** dropdown and select the **COI Annual Disclosure Form Investment BioMedical** value. The page will refresh, allowing you to indicate whether the value is required or not, the Order in Question, if it is Read Only, and Element Info can be entered, if needed. You must also provide a unique Database Column Name for this value. Then click on the **Save Data Value** to add this value to the form.

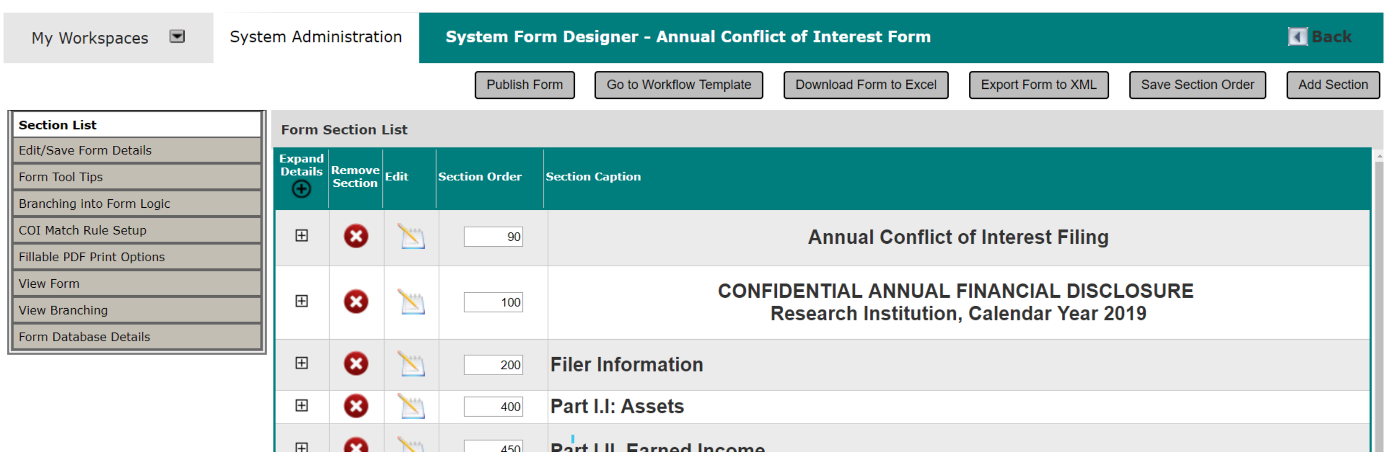
This is the only data value needed in this question, besides Question Text.



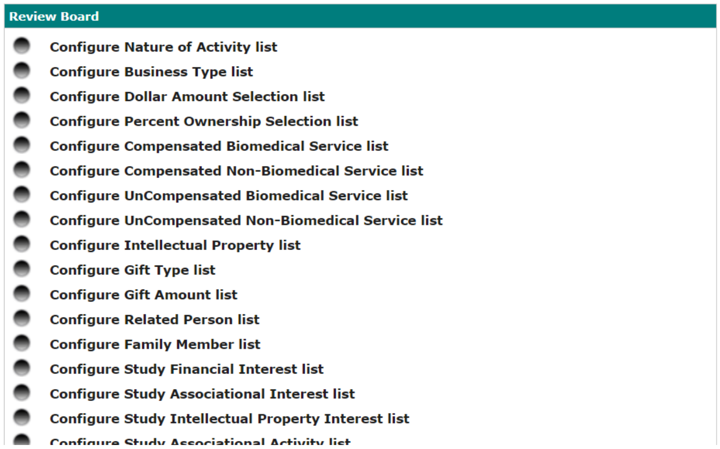
The COI Annual Disclosure Form Investment BioMedical value will add everything shown in the screenshot above from the “Yes/No” selection down, including the ability to add additional investment records.



If you would like to change the labels or dropdown lists to some of the items within these data values, you may do so within Conflict of Interest Assistant > Review Board Administration > System Setup.



Each of the data values in the Annual COI form sections 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 section. You may change any label by clicking the **Edit** icon next to the appropriate label.

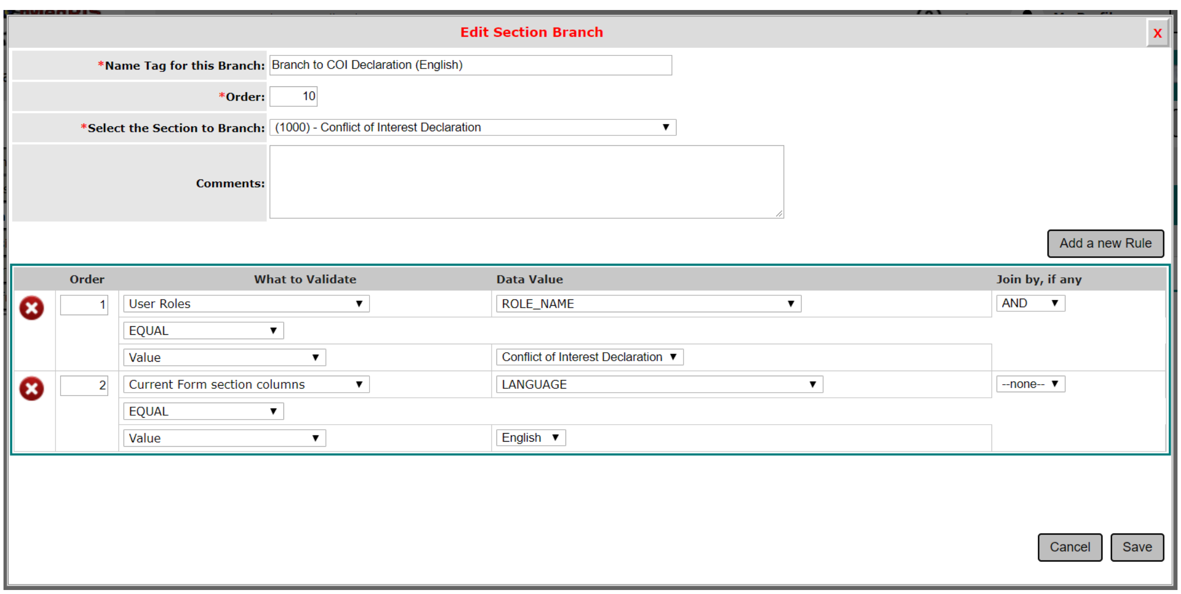


You may also configure the different drop down lists shown throughout the Annual COI form. These are modified under Conflict of Interest Assistant > Review Board Administration > List Maintenance Setup.

Branching

The Forms Designer gives you the flexibility of rearranging the predefined COI Annual Form to your institution's requirements. You may also build branching logic to branch to or around certain sections based on criteria within the Annual COI Form. You will not be able to branch based on values from any other form but the Annual COI Form.

A unique branch available in the Annual COI is the ability to branch based on User Roles selected in the **COI Annual Disclosure Form User's Selected Institutional Roles** data value.



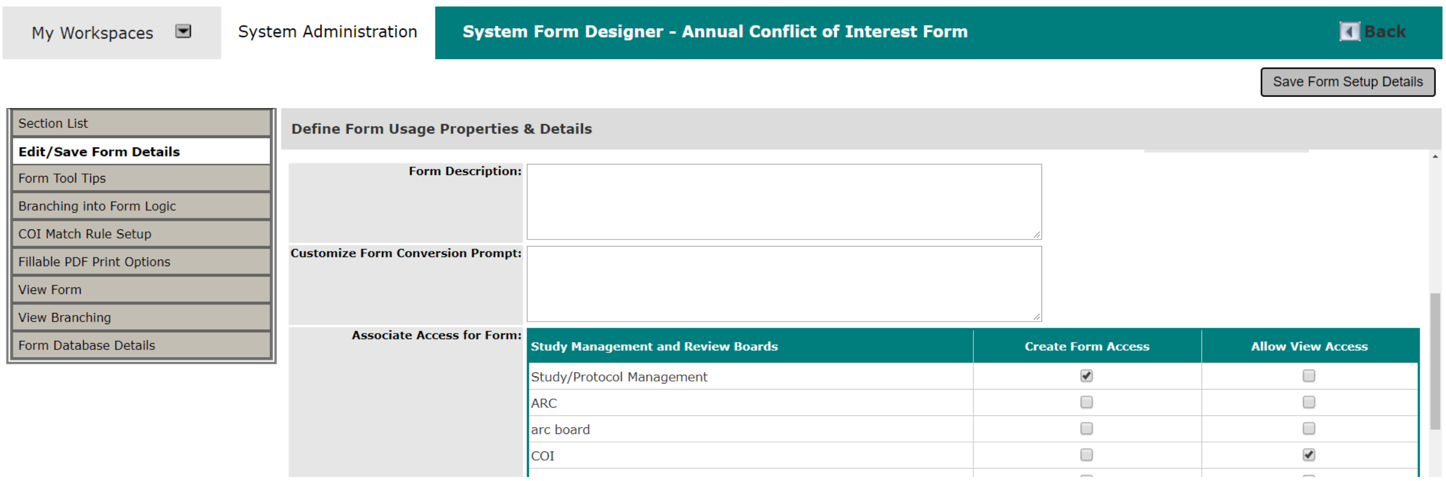
Within a branch, in the **What to Validate** dropdown list, User Roles is an option within the COI Annual Form. This will allow you to select three separate options form the **Data Value** column: IS_KDM, IS_990, and ROLE_NAME.

IS_KDM – This will look at any role selected in the **COI Annual Disclosure Form User's Selected Institutional Roles** data value, or any roles already assigned to the user, to see if the KDM flag was set in the configuration list within Conflict of Interest > Review Board Administration > List Maintenance Setup > Setup Institutional Role Name List.

IS_990 – This will look at any role selected in the **COI Annual Disclosure Form User's Selected Institutional Roles** data value, or any roles already assigned to the user, to see if the 990 flag was set in the configuration list within Conflict of Interest > Review Board Administration > List Maintenance Setup > Setup Institutional Role Name List.

ROLE_NAME – This will allow you to specify any of the Institutional Roles you have set up under Conflict of Interest > Review Board Administration > List Maintenance Setup > Setup Institutional Role Name List so you can create a branch that will go to a certain section based on a role name selected.

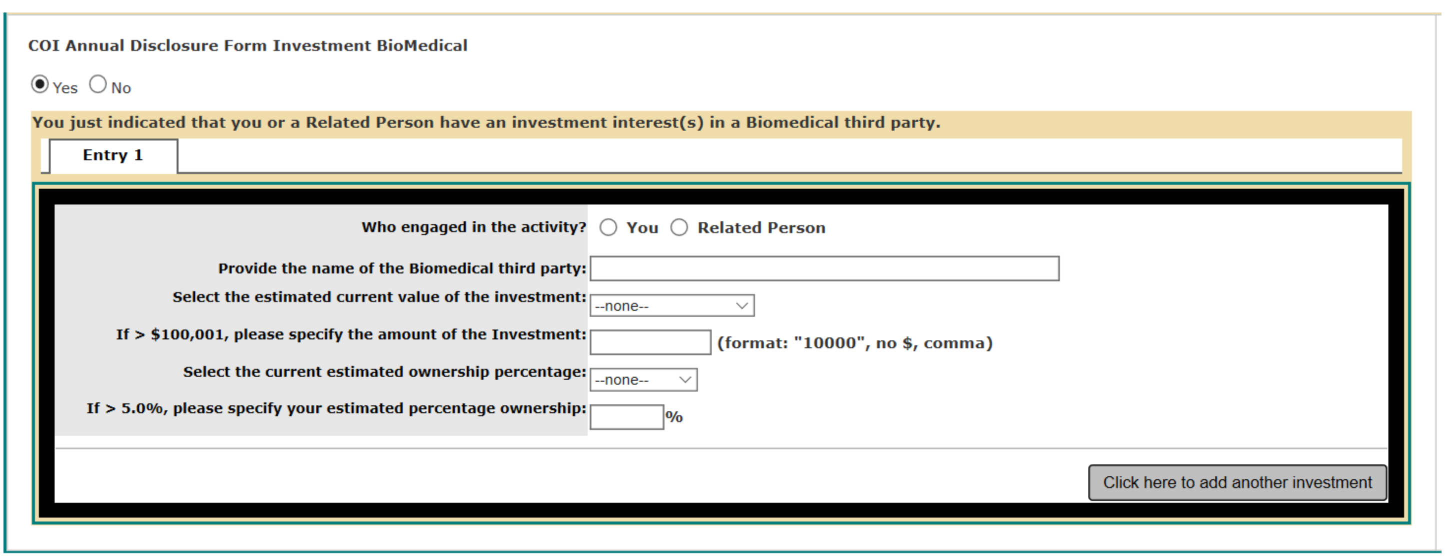
Edit/Save Form Details



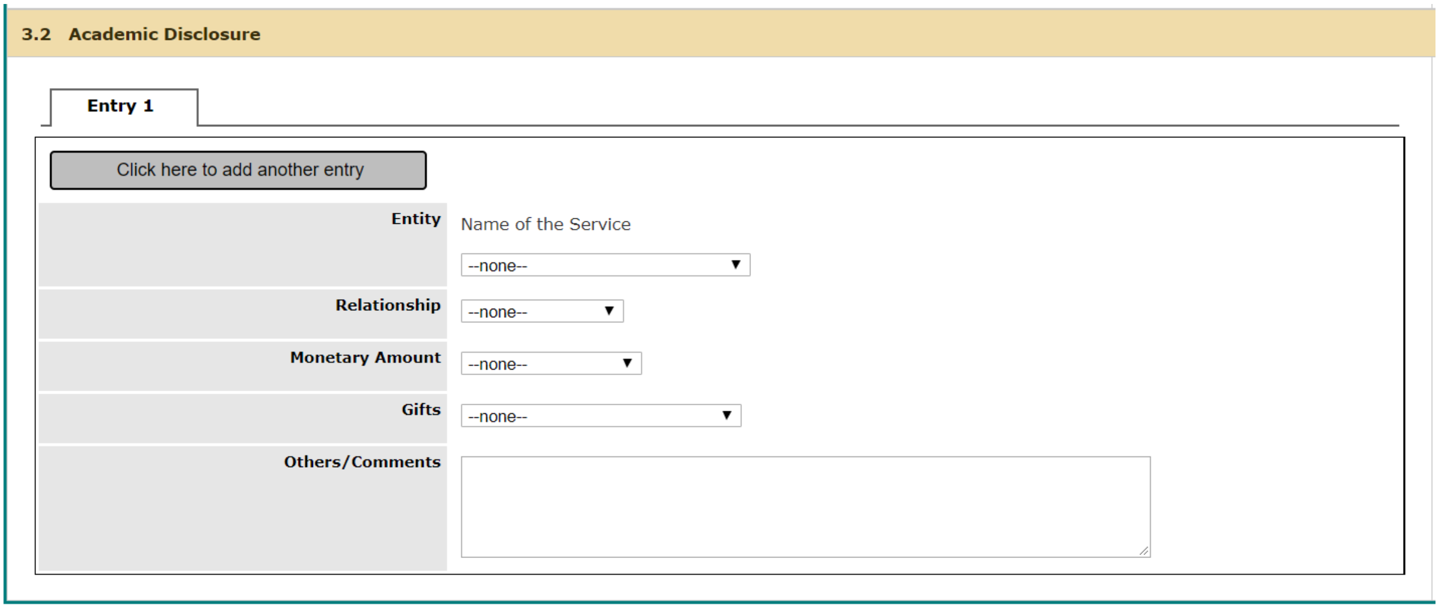
Within Edit/Save Form Details, you will need to ensure that the Conflict of Interest Board has Allow View Access checked off in the **Associate Access for Form** table. You must also have Create Form Access turned on for Study Management. This will enable the COI Annual Form from your iRIS home screen. If you do not have Create Form Access turned on for Study Management, the form will not be accessible by your users.

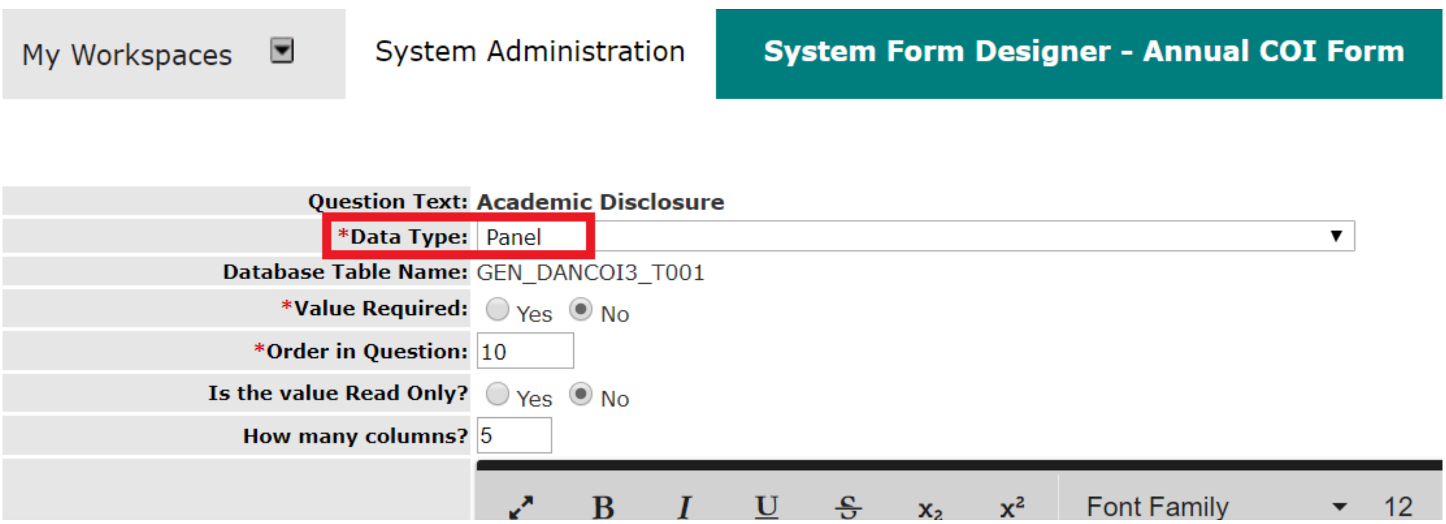
Panels

Within the Annual Conflict of Interest form, you can use the pre-defined COI panels to capture disclosure information or you can set up custom panels that function in the same way.

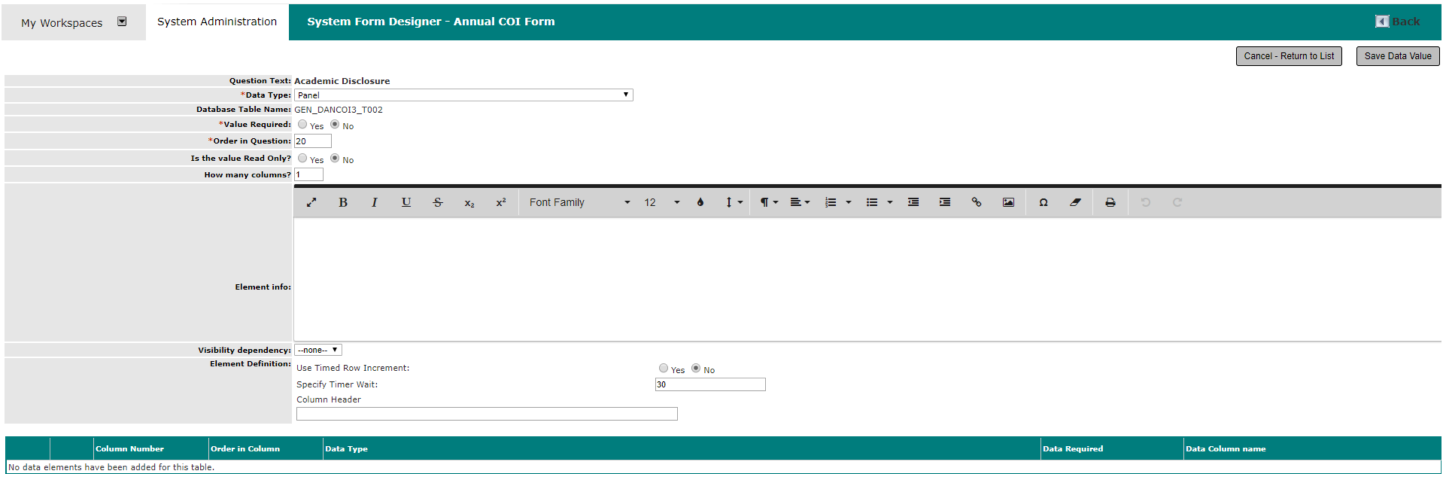


The screenshot above shows the Biomedical Third Party panel predefined by the software. Below is what a custom panel could look like, depending on how it is built in the Forms Designer.



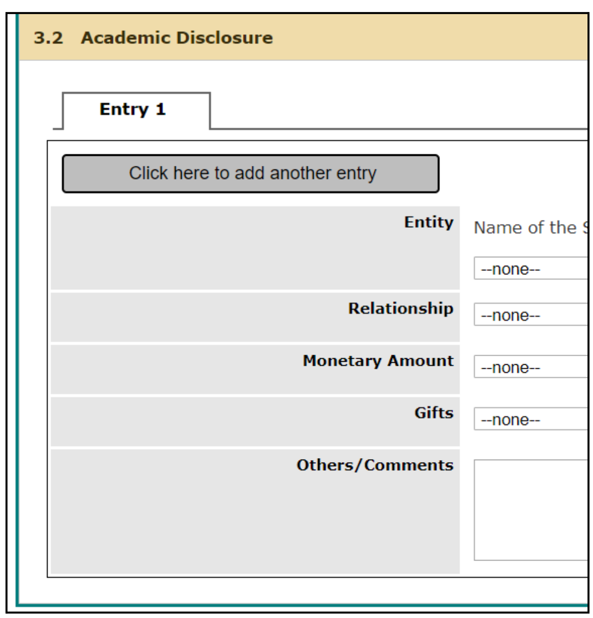


To set up a panel in a COI form, create a new data value and select the data value 'Panel' from the Data Type drop down list.

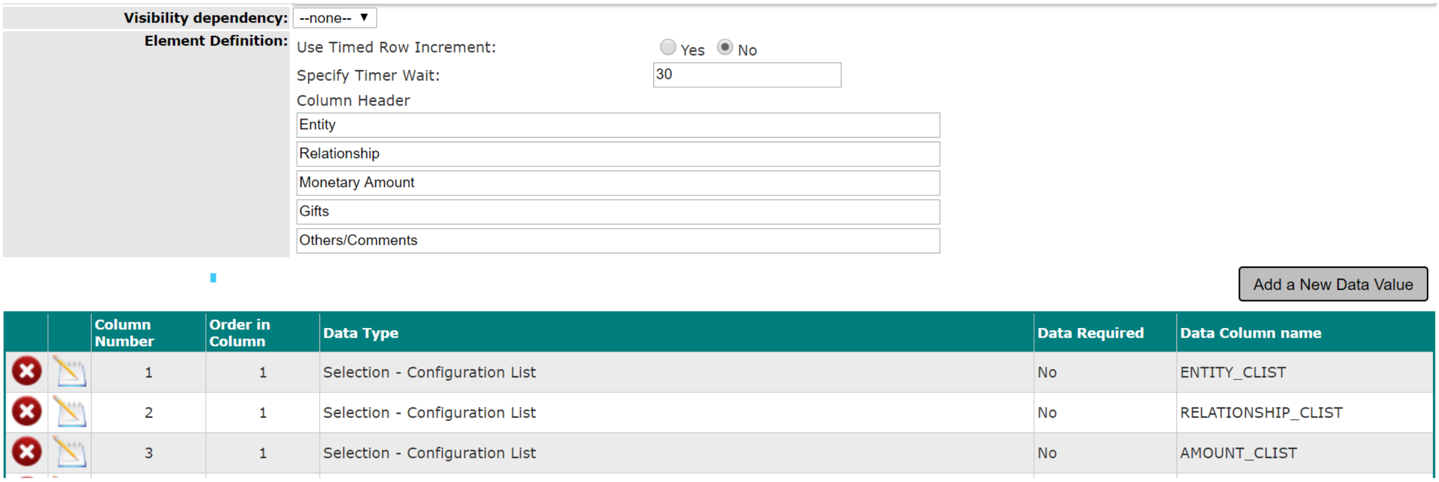


After selecting the Panel Data Type, the screen will refresh. The system will generate a Database Table Name for the panel, similar to creating a table data type. You will need to indicate the number of columns you need in your panel. Save the data value to refresh the screen.

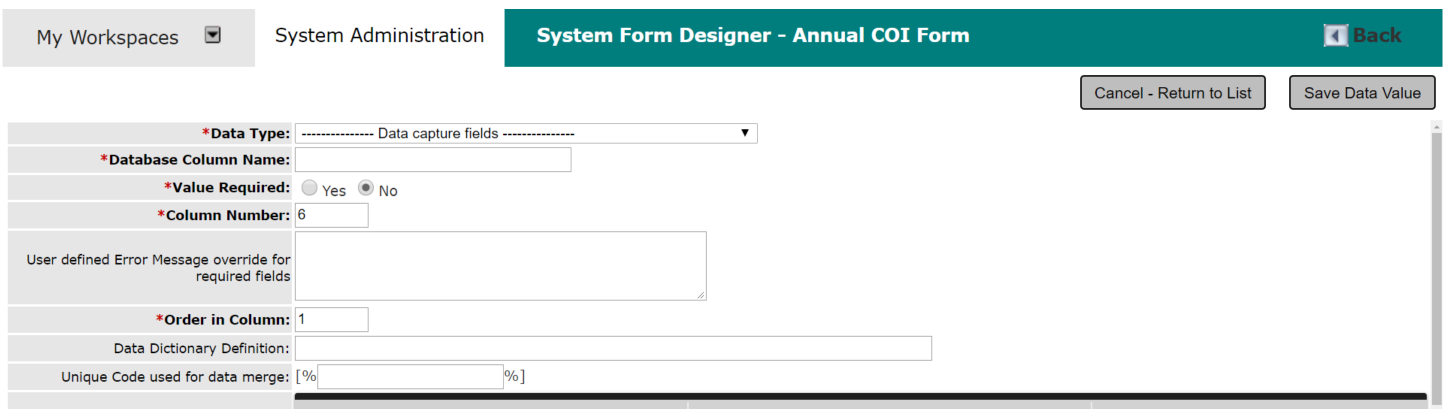
After the screen refreshes, you will be able to add labels for the number of columns specified.



Labels added in Element Definition will appear in the grey area to the left of the data values in the panel.



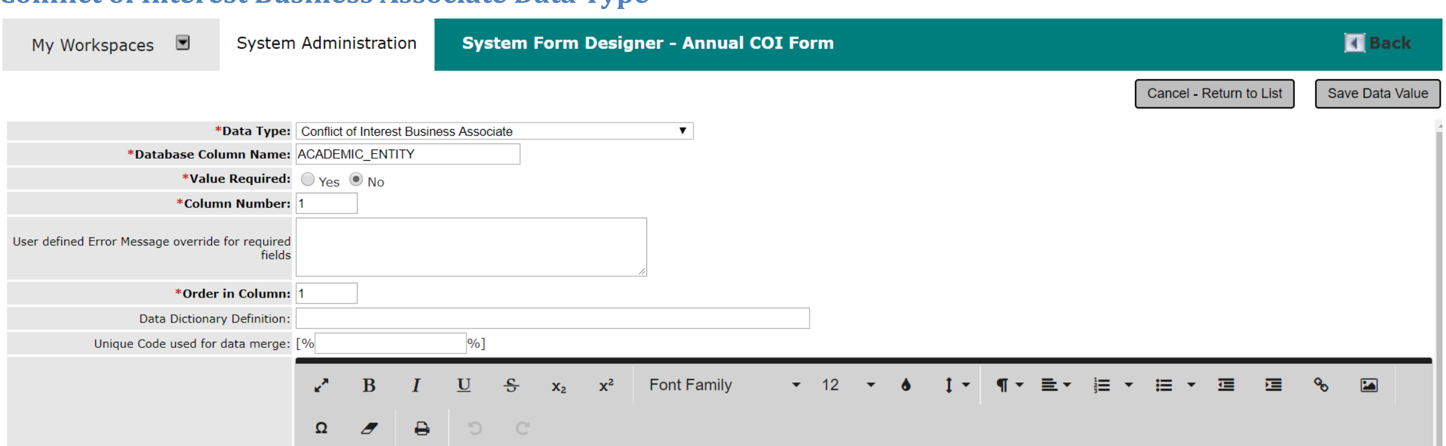
Once the labels are defined, you can add data values to the panel by clicking on the **Add a New Data Value** button at the bottom of the page.



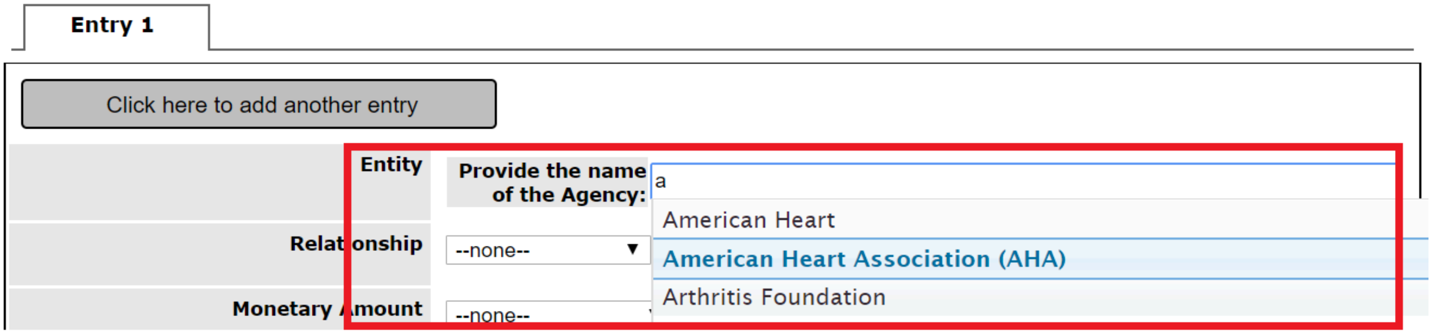
Adding data values to the panel is similar to adding data values to a table. You select the Data Type from the dropdown menu, specify the Database Column Name, indicate if the value is a required field, and specify the Column Number (this will correspond with the number of columns you indicated for the panel). Be sure to specify the Order in Column for items that are in the same column.

After you define the details for the data value, click the **Save Data Value** button, and then click the **Cancel – Return to List** button to return to the panel.

Conflict of Interest Business Associate Data Type

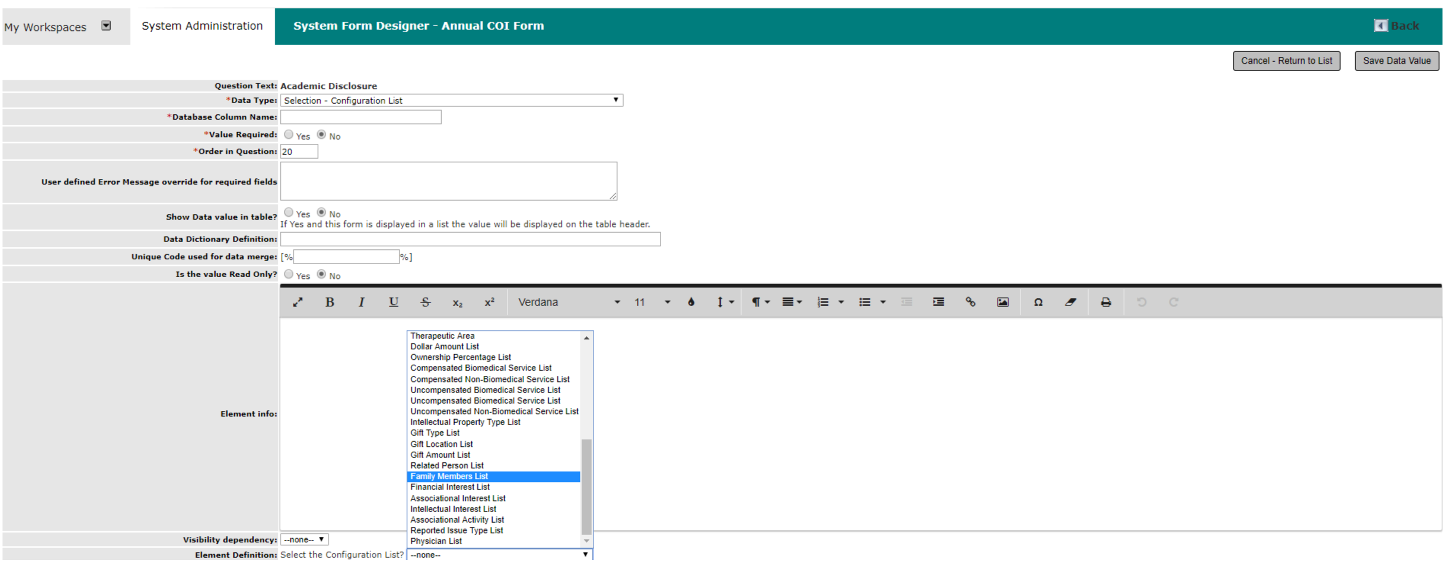


A unique data type available for the panel is the Conflict of Interest Business Associate.

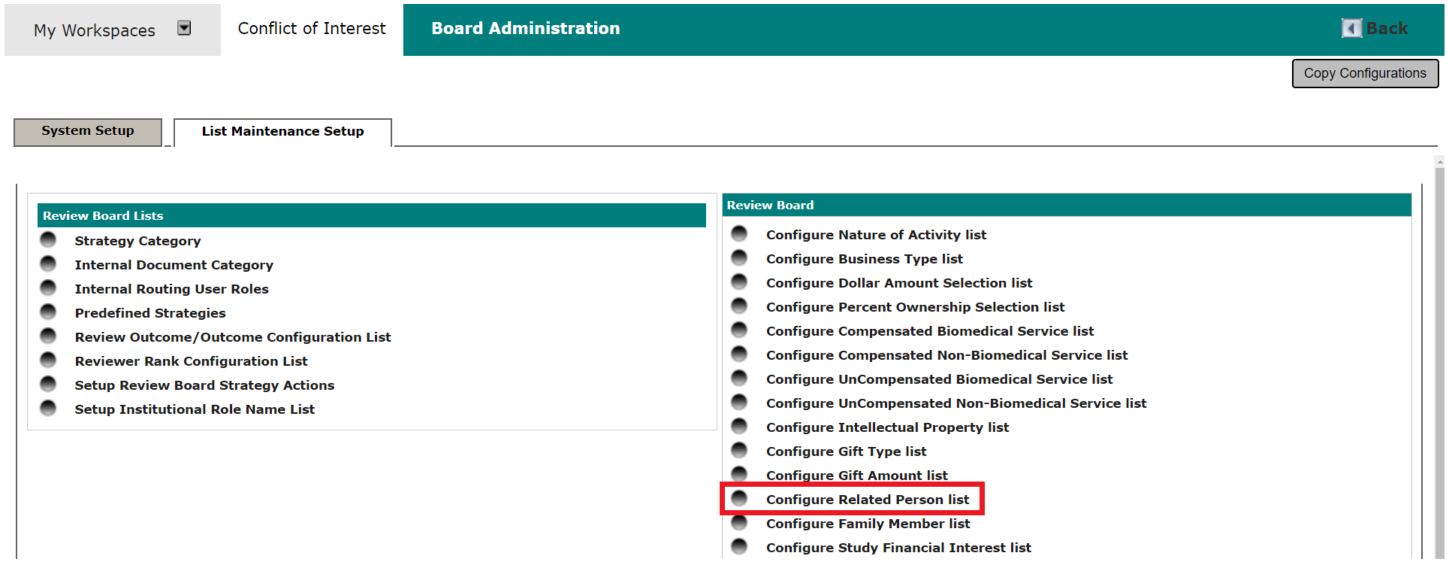


This value will link to the list of Business Associates in iRIS and allow you to specify which associate you have a conflict with, or you can enter a new entity that isn't in the system. The Business Associate that is pulled into the form can be linked to the COI Matched Object once the form is submitted to the COI board for review.

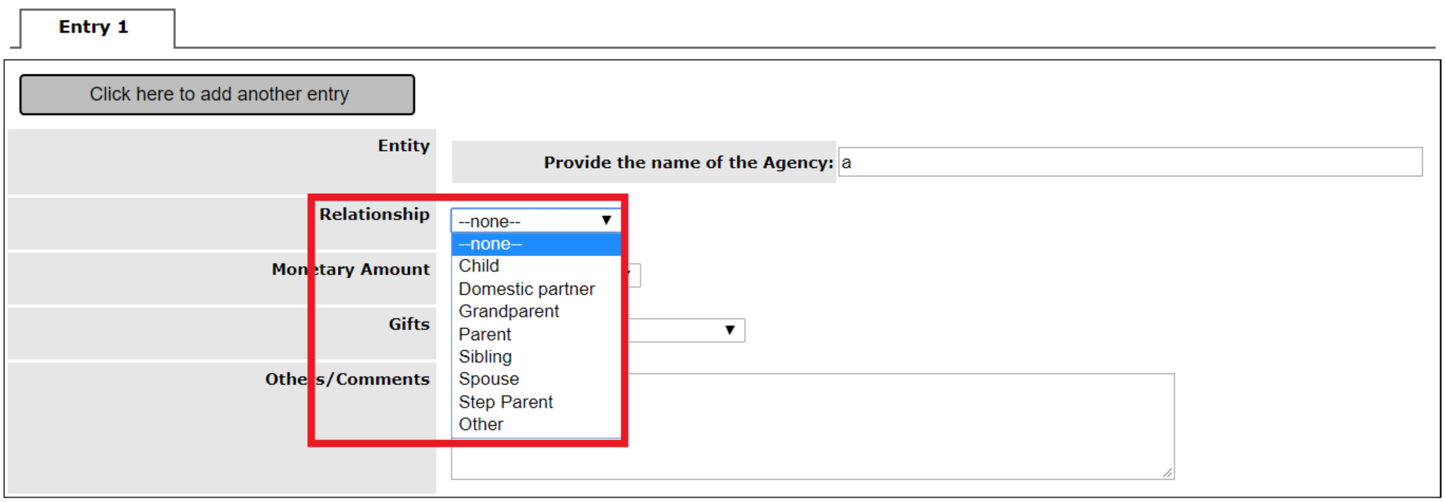
Conflict of Interest Configuration List Data Type



You can also link your panel to the configuration lists in the COI Review Board Administration. To setup this type of value, select the Selection – Configuration List from the Data Type list. This will cause the page to refresh, and in the Element Definition another drop-down list will populate. From this list you can select one of the configuration lists found in the COI Review Board Administration. The example used here is the Related Person List.

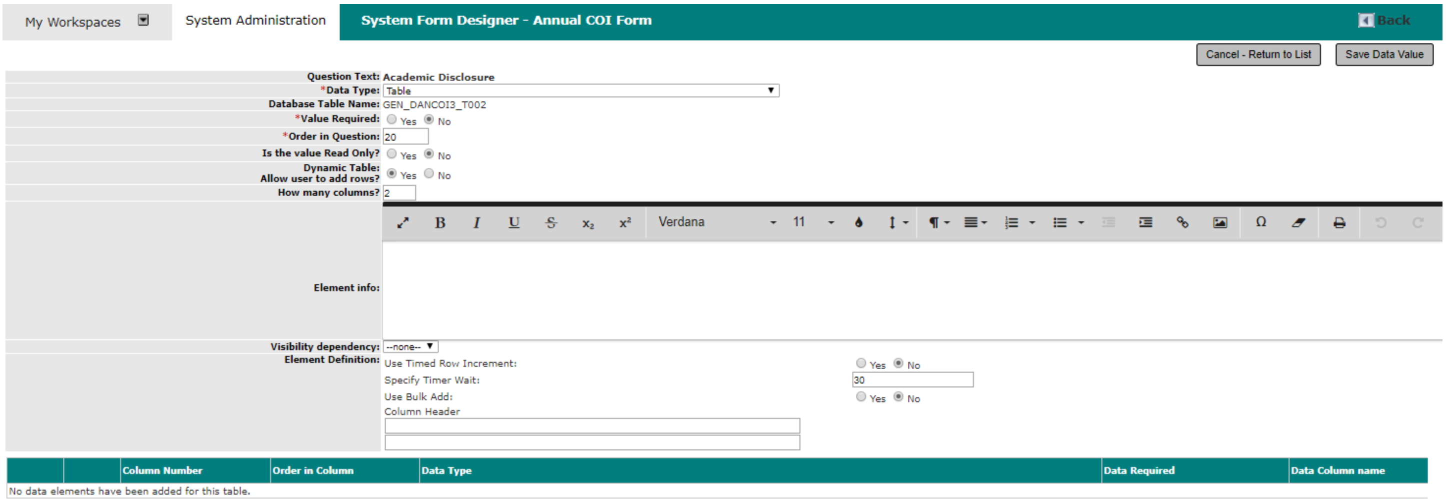


Any of the configuration lists in List Maintenance Setup – Review Board for the COI Review Board can be used in the Panel.

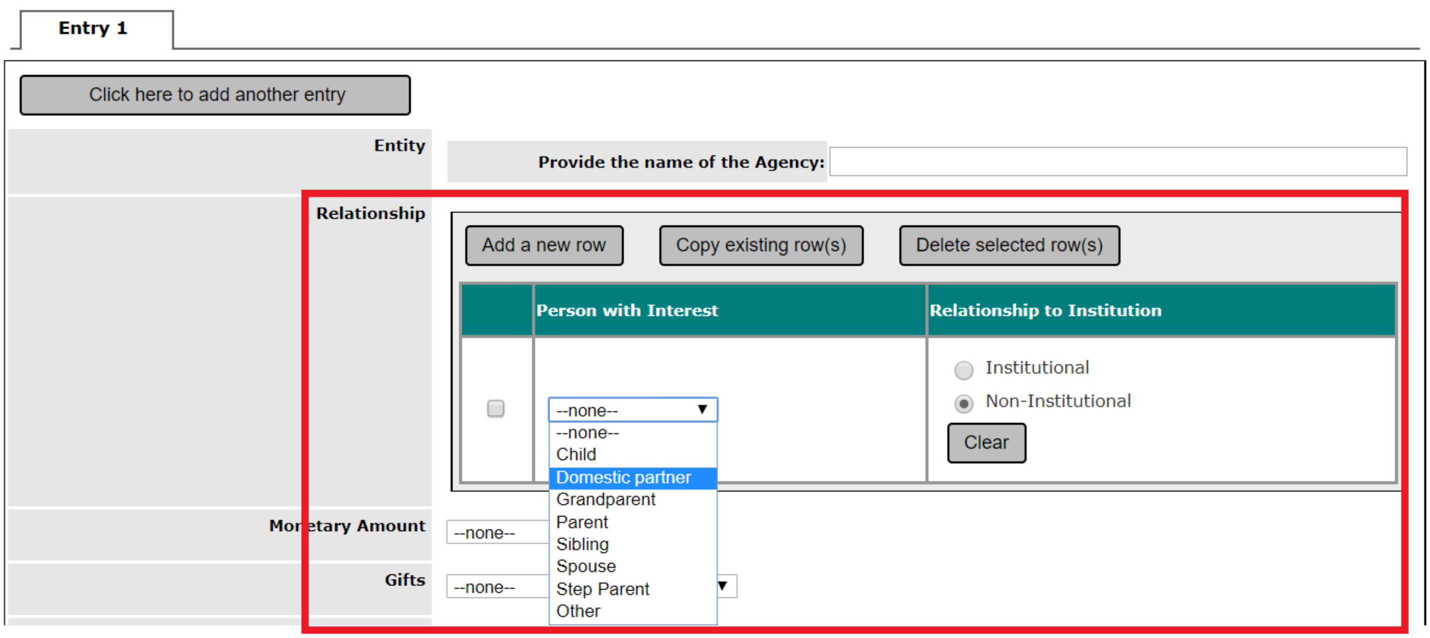


When the user is filling out the Annual COI form, they will be able to use the configuration list as defined in the panel. Any changes to this list would be made in COI Assistant – Review Board Administration; there would be no need to change the form in the Forms Designer.

Static and Dynamic Tables

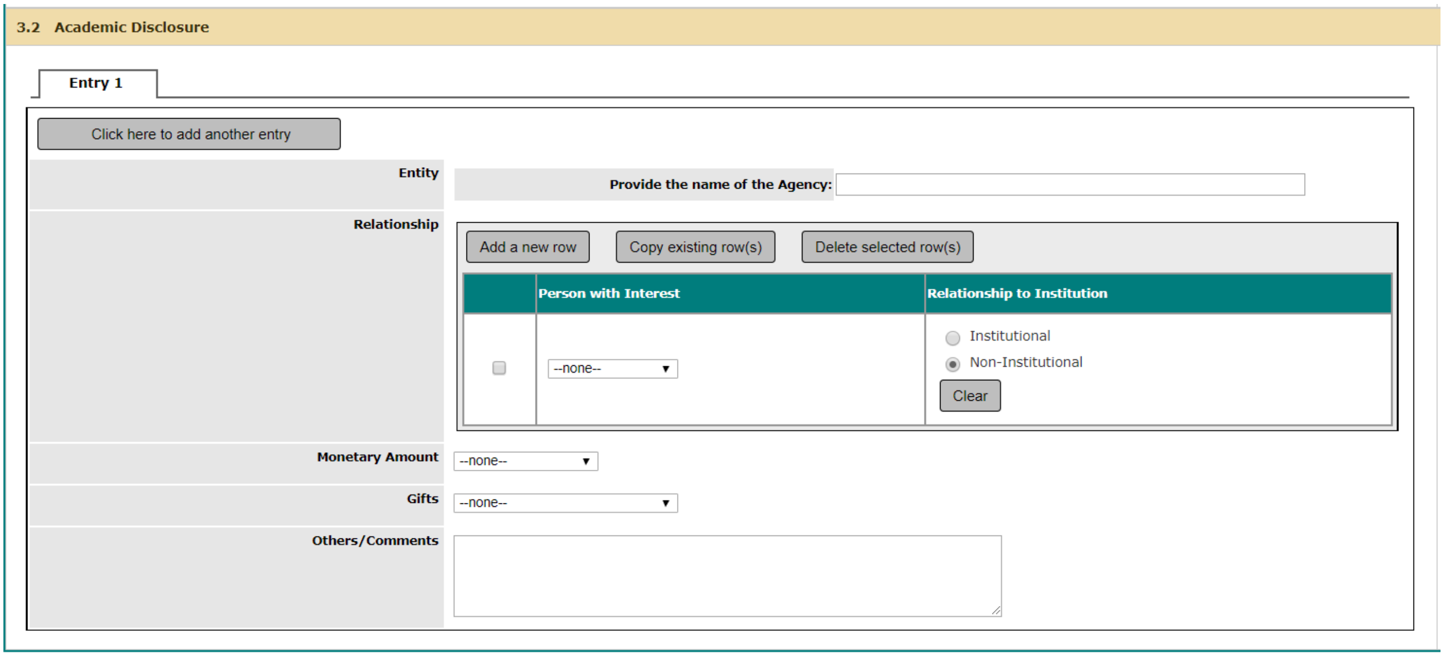


Static and dynamic tables can be built within the panels. Create the table in the same way you would if you build a table outside of the panel.

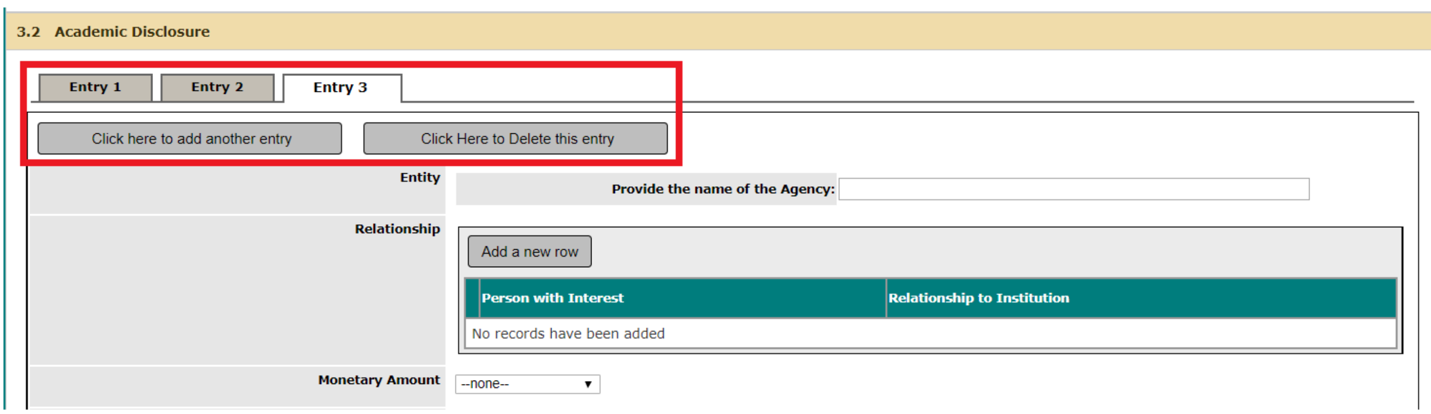


The above screenshot shows a panel that has a dynamic table built into it. Any number of rows can be added.

Panel Functionality

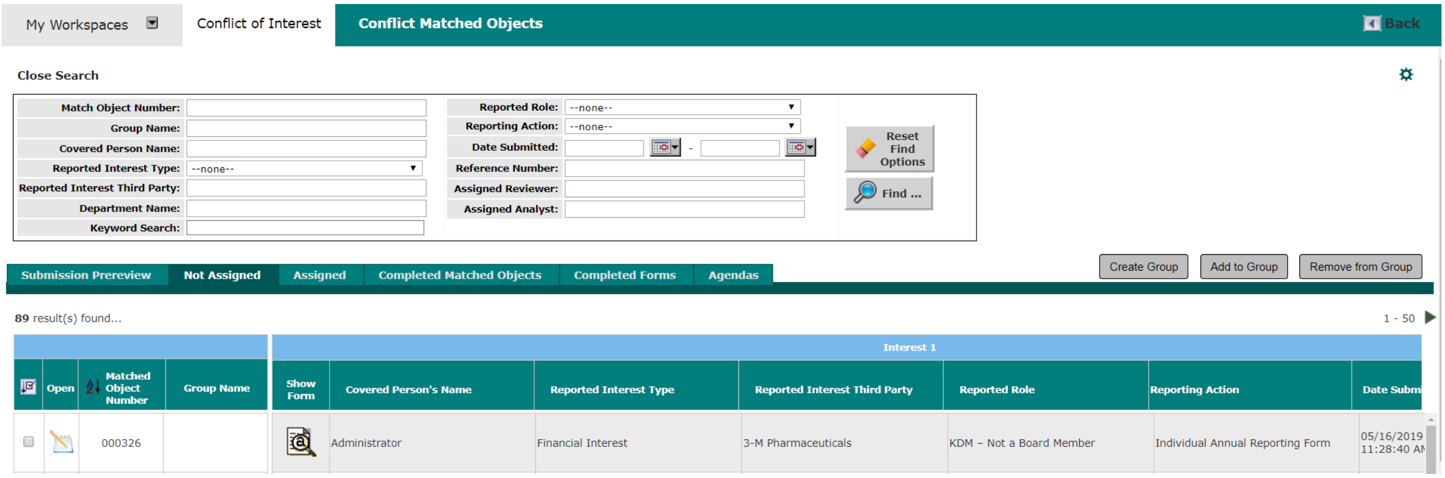


Each panel in a form will allow for multiple entries. When the panel is first displayed, it will display with only Entry 1. A user filling out the form can enter in information for Entry 1 and then add additional entries as needed. To add another entry to the panel, click on the **Click here to add another entry** button.



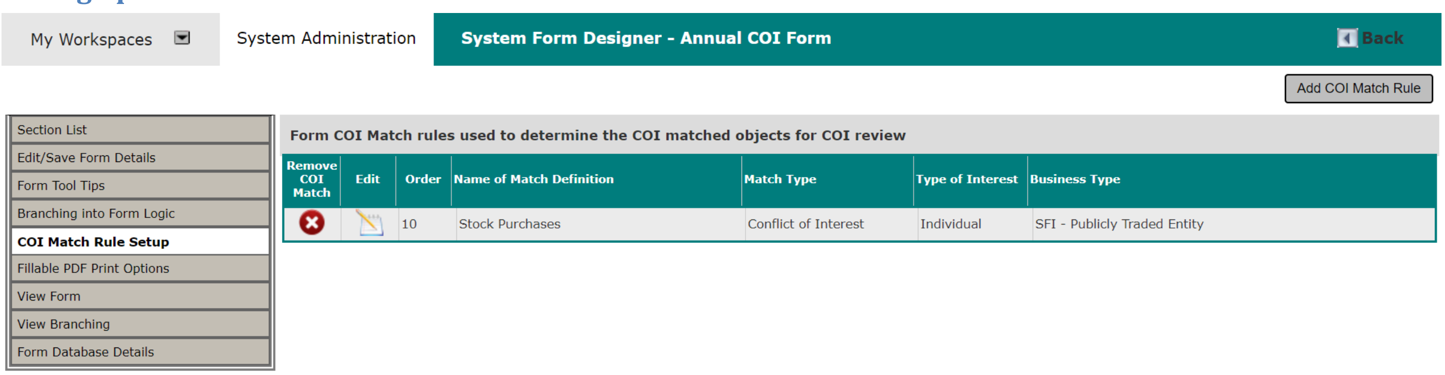
Entry 2 will be created as a separate tab in the panel, allowing the user to enter information specific to this entry. If an entry was created in error, click the **Click Here to Delete this entry** button. This will remove only the selected entry from the panel.

Allowing the use of panels in the COI form with multiple entries will allow iRIS to capture multiple COI matches per item. Rules defined in the COI form will trigger the conflict matches when the COI Annual form is submitted. Each entry in a panel can be set up to trigger a match.



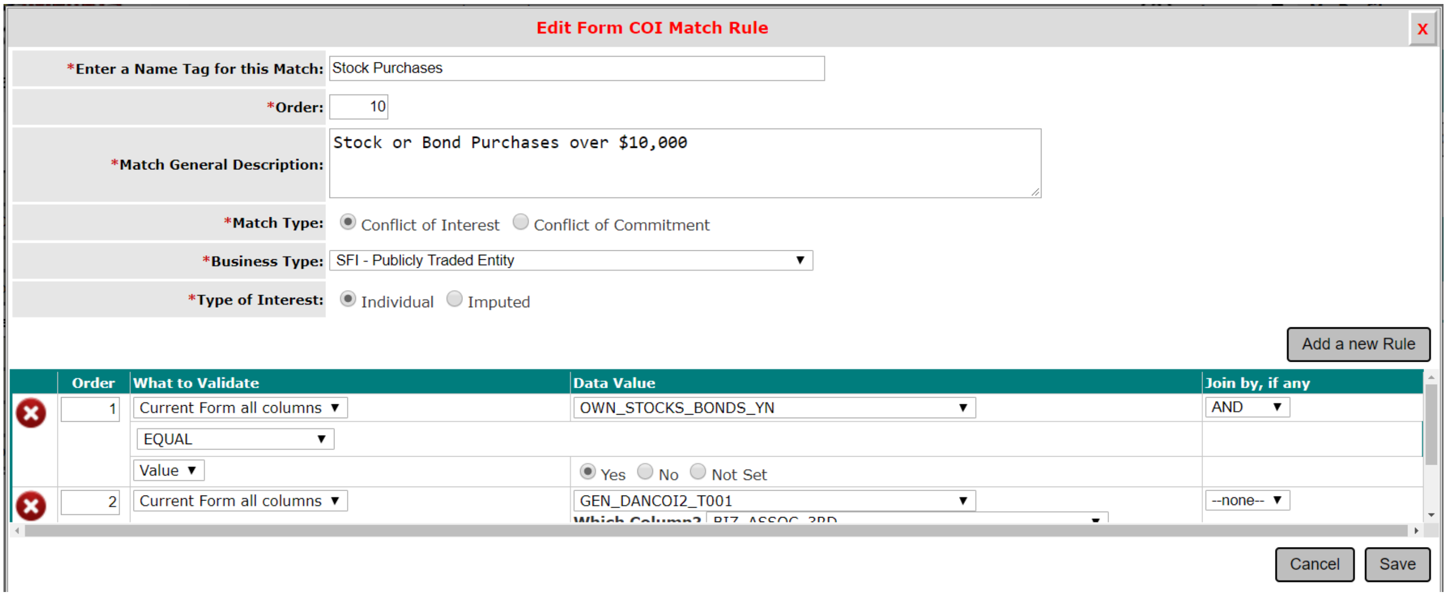
After the Annual COI form has been submitted, looking at the COI Matched Objects queue will display two separate matches for the form submitted. Each match is from one panel with two entries. The column **Reported Interest Third Party** is programmed to pull in the Business Associate defined in the panel.

Setting up COI Rules



If you are going to use the custom panels in your Annual COI form, you will need to set up rules, so the system knows when to flag an entry as a conflict match. To set up these rules, click on the **COI Match Rule Setup** button within the Annual COI form in the Forms Designer.

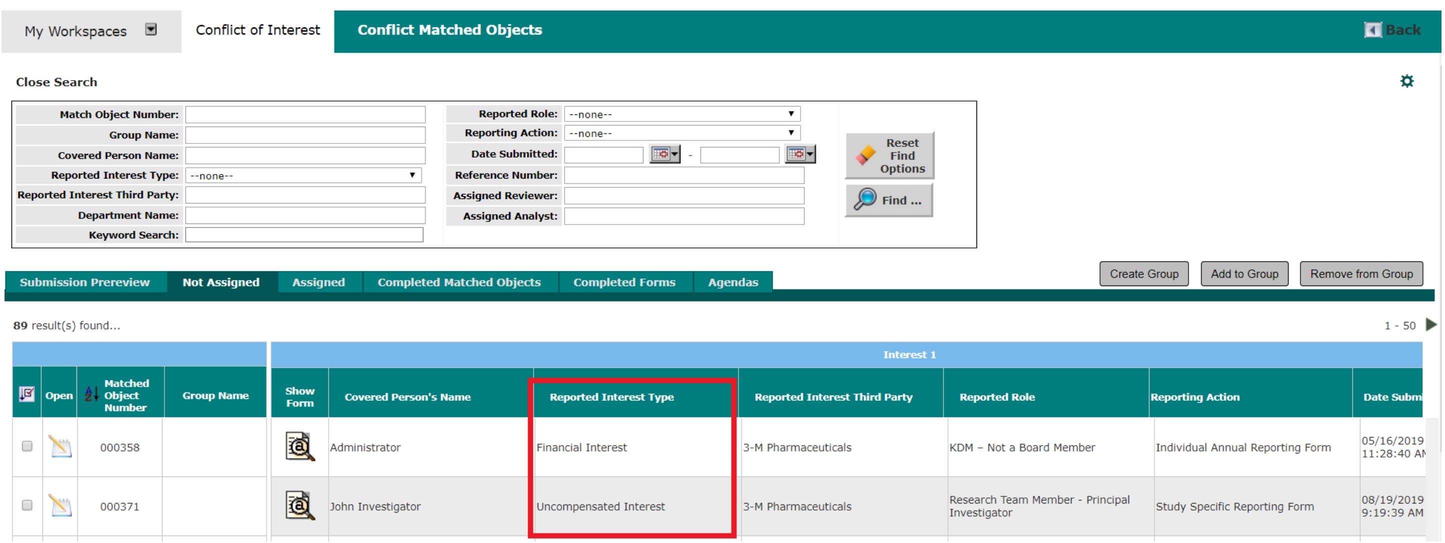
Click the **Add COI Match Rule** button to create a new rule.



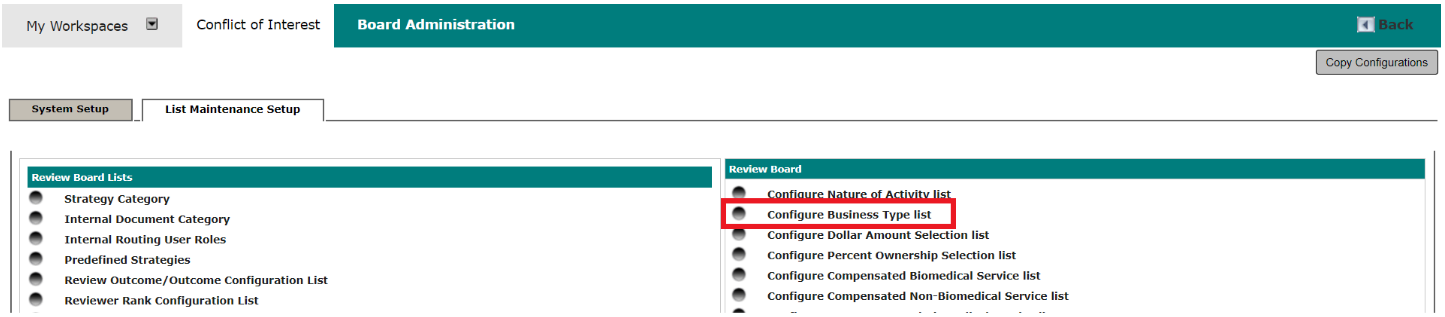
Create a rule based on how you need the match to trigger. Start by entering the name tag, order and description. These items are specific to the rule you are setting up.

Next indicate the Match Type. This can be either Conflict of Interest or Conflict of Commitment.

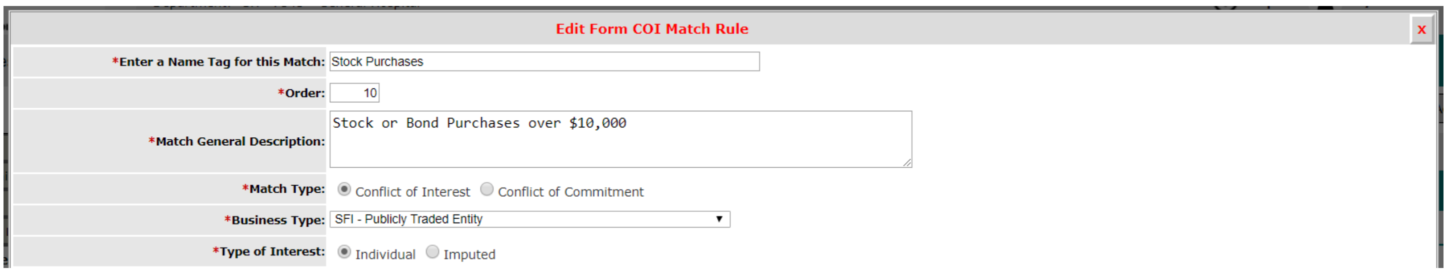
The Business Type drop down will contain all the available Reported Interest Types. You have control over how the Business Types are defined.



The Business Type associated to the COI Rule is what will display in the match queue as the Reported Interest Type.



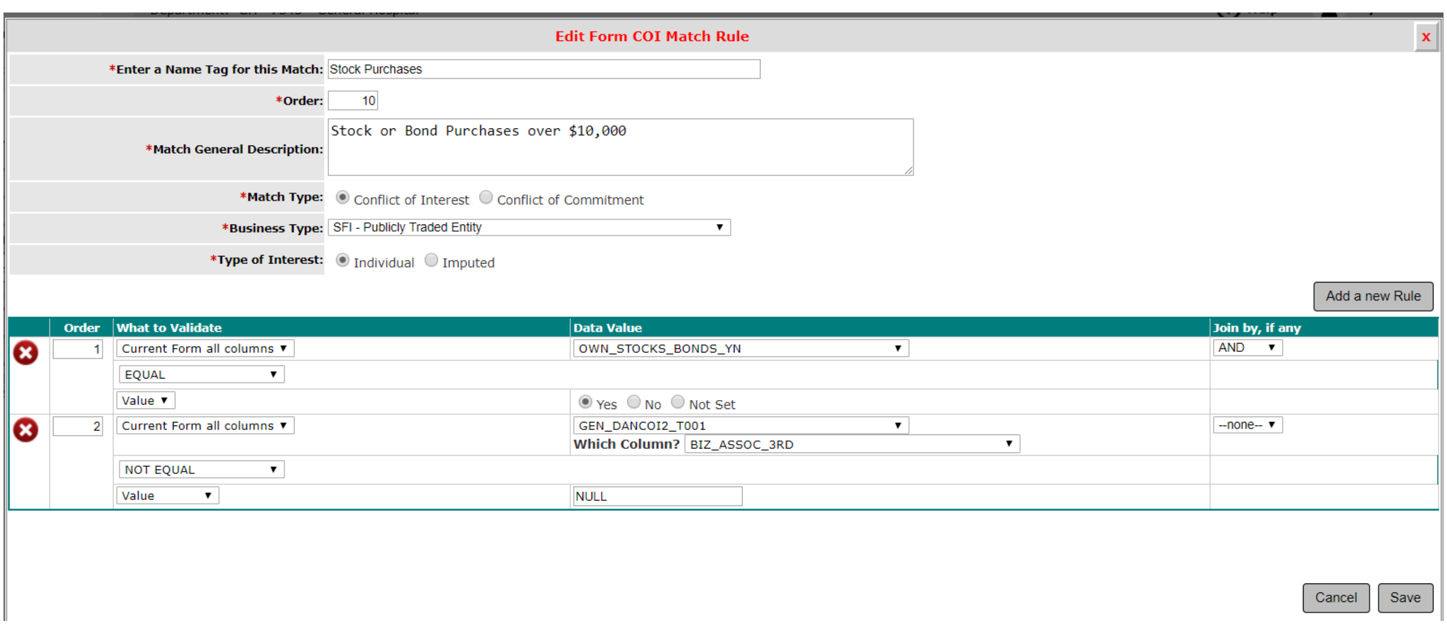
The Business Type list is set up under COI Assistant > Review Board Administration > Review Board > Configure Business Type list.



Once the name, order, description, Match Type, and Business Type have been defined, you can select the type of interest: Individual or Imputed.

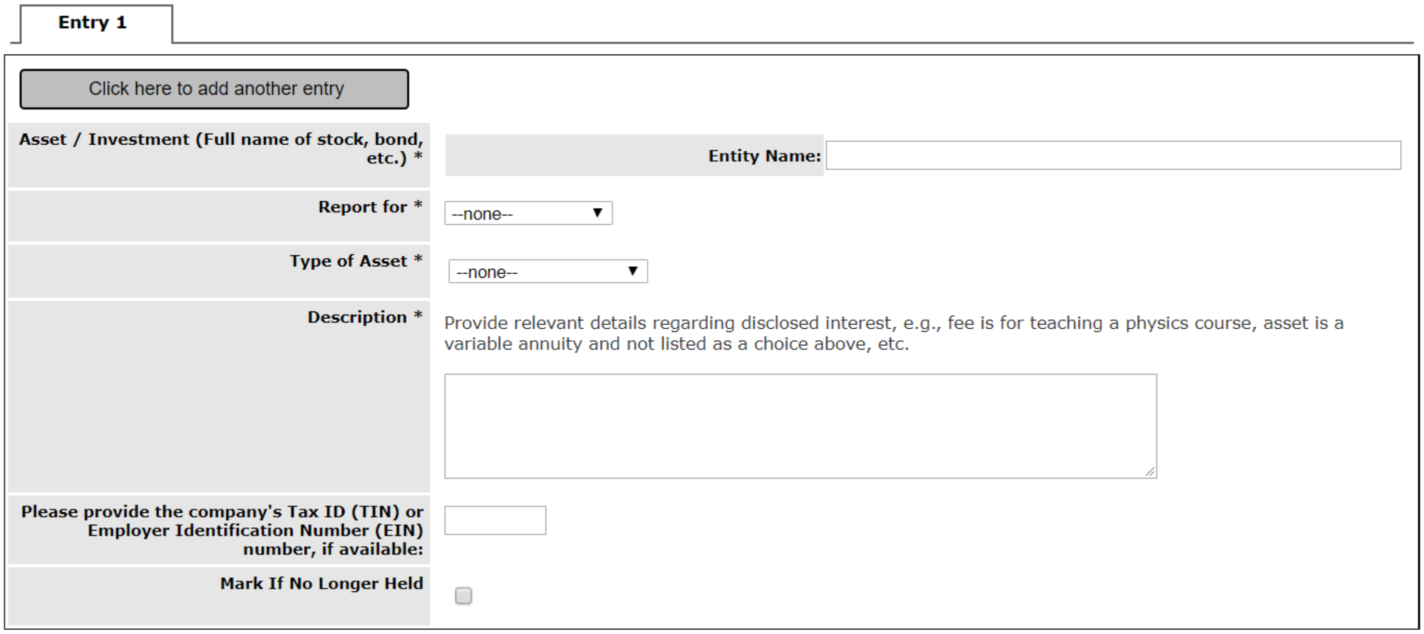
Individual

An Individual Match Type is a basic conflict match in the system. It is a simple match – meaning as long as the rules defined are met, a match should be triggered.



Rules are set up to look at the Annual COI form to see how a user answered a question. If the user's answers match the rule, a conflict match will be generated when the form is submitted.

The rule setup in the screenshot above looks at the "Yes/No" question asking the user if they have Stocks or Bonds over $10,000. The clause is joined to another clause that checks the Business Associate value in the panel. This will tell the system what Business Associate to pull into the conflict match.



Entry 1

Click here to add another entry

Asset / Investment (Full name of stock, bond, etc.) * Entity Name:

Report for * --none--

Type of Asset * --none--

Description * Provide relevant details regarding disclosed interest, e.g., fee is for teaching a physics course, asset is a variable annuity and not listed as a choice above, etc.

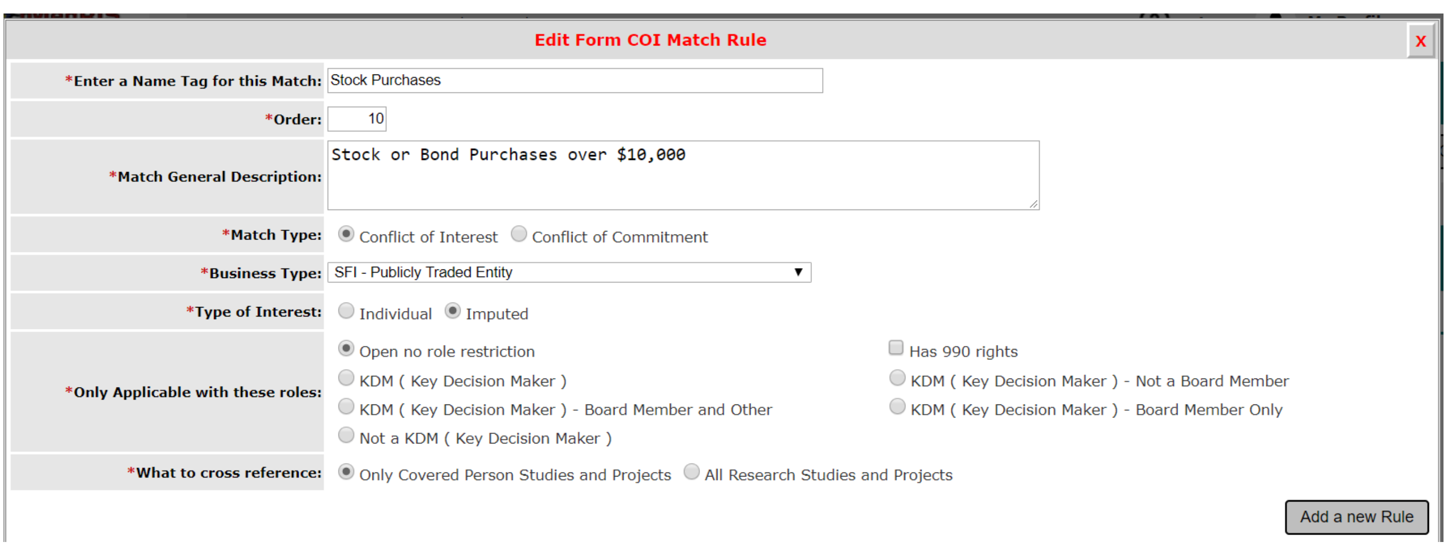
Please provide the company's Tax ID (TIN) or Employer Identification Number (EIN) number, if available:

Mark If No Longer Held

If the user answers "Yes" to the Academic Disclosure question and provides a sponsor in the Business Associate field, a COI match will be triggered when the form is submitted. Each additional panel entry will trigger a separate conflict match.

Imputed

Imputed Match Types are more complicated to set up but will allow you to build rules not only based on the answer to questions in the form, but will also check against the user's reported role and any studies in the system.



Edit Form COI Match Rule X

*Enter a Name Tag for this Match: Stock Purchases

*Order: 10

*Match General Description: Stock or Bond Purchases over $10,000

*Match Type: Conflict of Interest / Conflict of Commitment

*Business Type: SFI - Publicly Traded Entity

*Type of Interest: Individual / Imputed

*Only Applicable with these roles: Open no role restriction / Has 990 rights / KDM (Key Decision Maker) / KDM (Key Decision Maker) - Not a Board Member / KDM (Key Decision Maker) - Board Member and Other / KDM (Key Decision Maker) - Board Member Only / Not a KDM (Key Decision Maker)

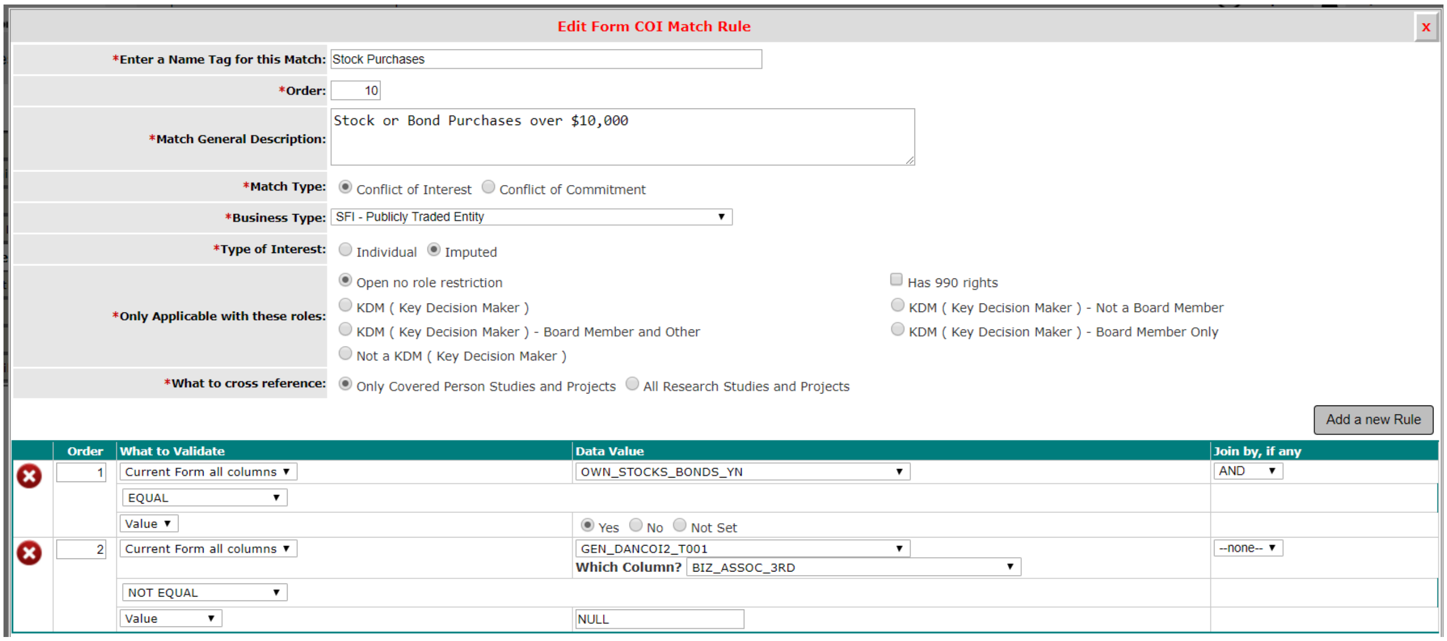
*What to cross reference: Only Covered Person Studies and Projects / All Research Studies and Projects

Add a new Rule

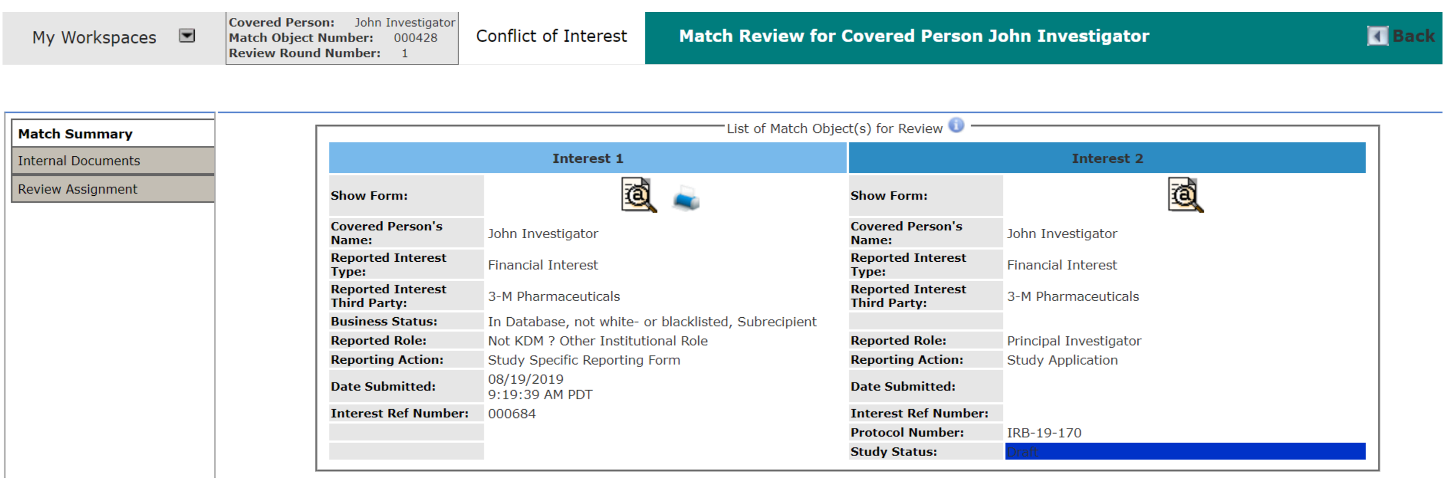
When you select Imputed, the page will refresh, giving you additional fields to setup.

Indicate if you want to trigger the match based on the user's role. The first selection, "Open no role restriction," means the match will trigger based on the rules, regardless of role. Any other option will look at the user's role – based on whether or not they are a Key Decision Maker, with or without a board member role, or if they are not a Key Decision Maker.

Next, choose a method with which to cross reference studies. You can set the rule to look at only studies associated to the Covered Person or all studies in the system. If a user indicates they have a disclosure with a sponsor not on a study, then the system will not trigger a match.



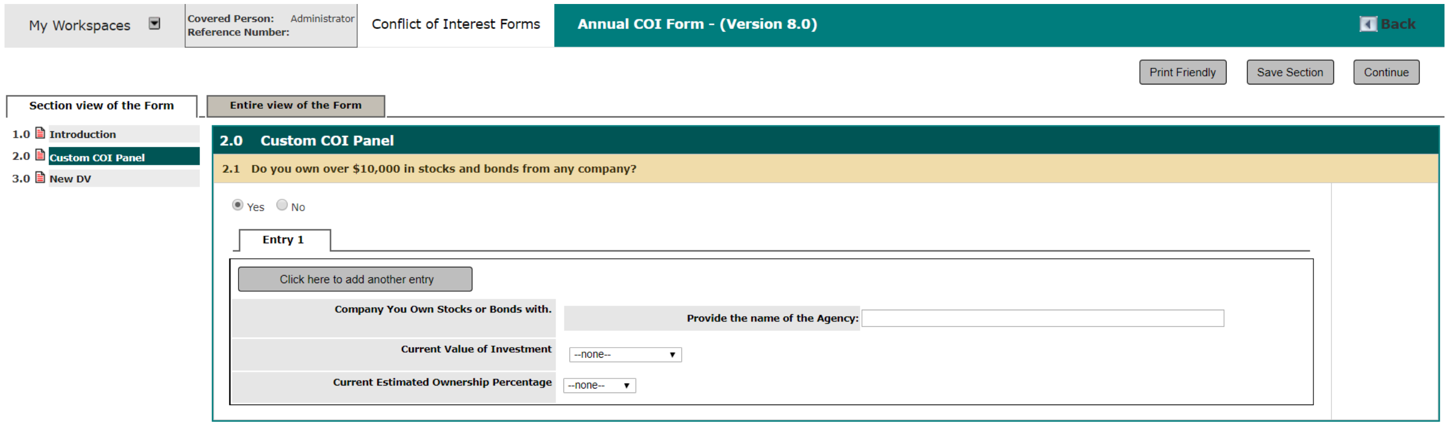
Once the additional fields are set up, rules can be set up to look at the answers to questions in the Annual COI form.



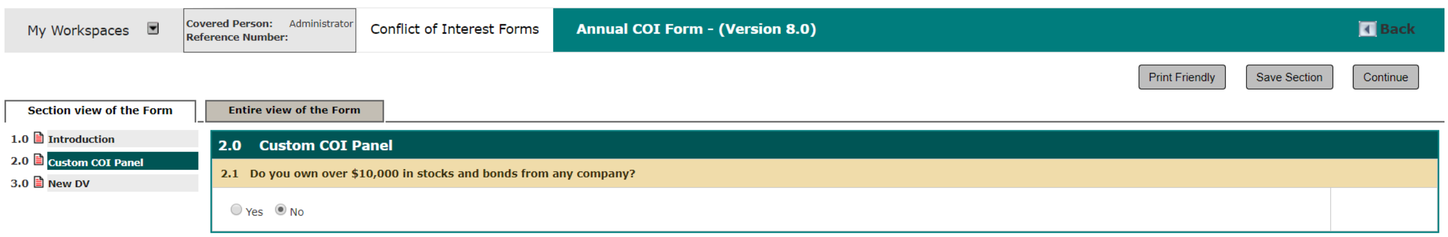
When a form is submitted that matches the rules defined, as well as the role requirements and study requirements, it will populate in the COI match queue and will list any matching studies in the Interest 2 section of the match, as shown in the screenshot above.

Show Visibility

Show Visibility allows you to setup rules to display panels only if a question is answered a certain way in the Annual COI Form. The Show Visibility rules are setup in a similar way to Branching and Validation.



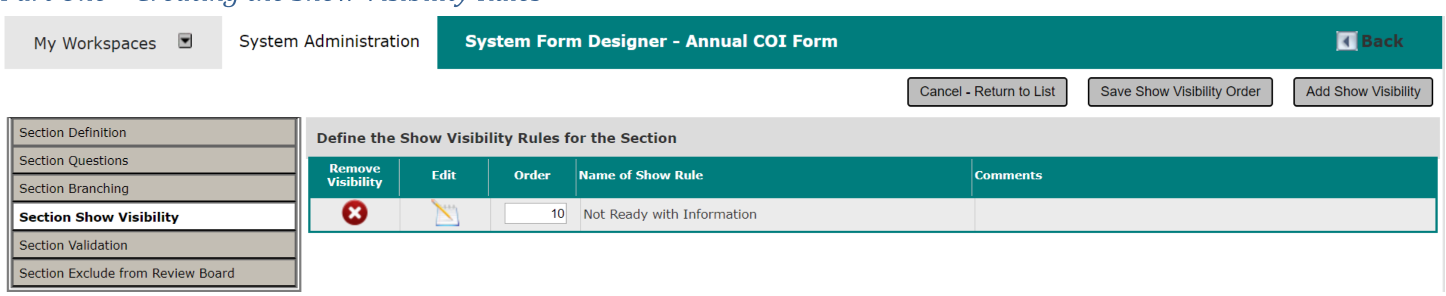
Show Visibility rules are created and associated to questions or data values so that a panel will only display if the answer to a certain question is “Yes.” The screenshot above has a rule set up and applied to the panel data value. This rule tells the system to only display the panel if the answer to the question is “Yes.”



If the value is not selected or “No,” the panel will not display in the form.

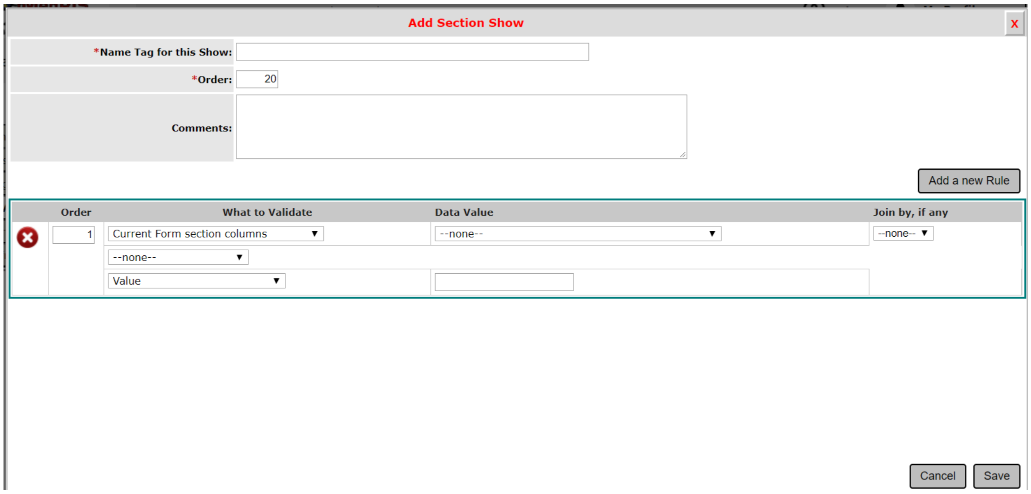
There are two parts to properly setting up the Show Visibility rules.

Part One – Creating the Show Visibility Rules



Within the Annual COI Form in the Forms Designer, click on the **Edit** icon associated with the section you would like to add the Show Visibility to. From the Section Definition, you can then click the **Section Show Visibility** link; this will open the list of current Show Visibility rules defined within this section. Since no rules have yet been defined, the list will display no results.

To create a new Show Rule, click the **Add Show Visibility** button.

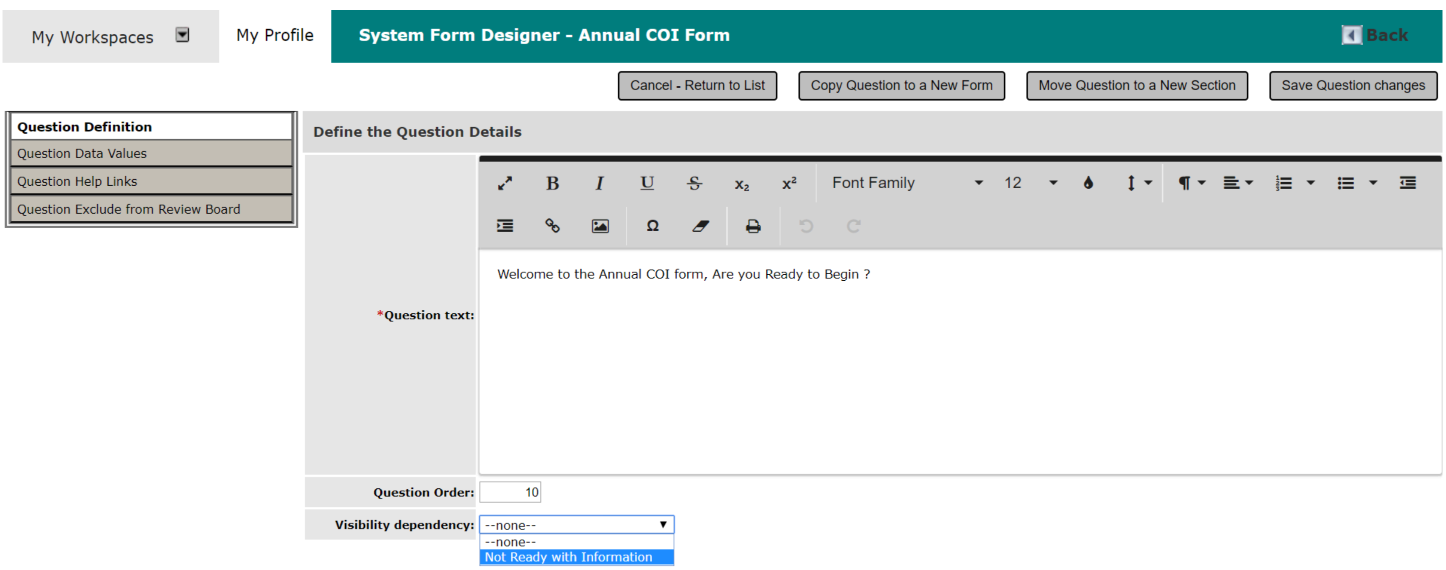


A new page will open allowing you to create the Show Visibility rule. Enter the Name Tag, Order number and Comments.

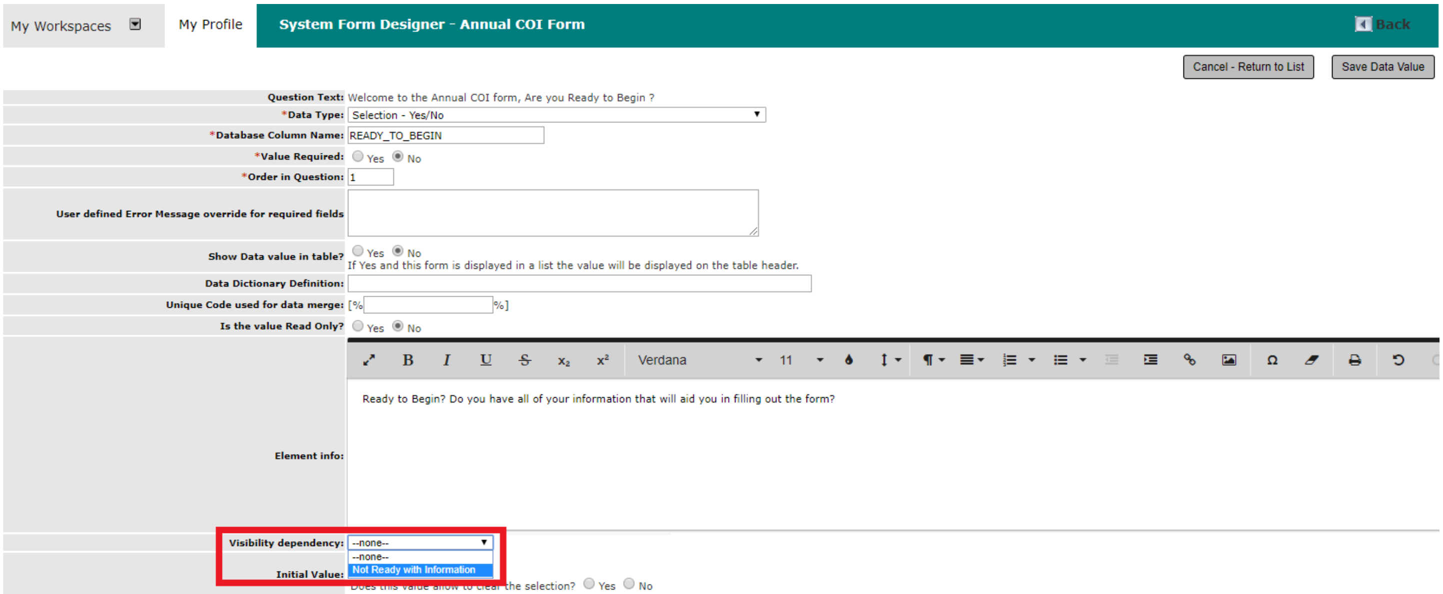
A clause is available at the bottom of the page where you can setup a rule that will look at a value in the Annual COI Form.

Part Two – Associating the Show Visibility Rule to a Question or Data Value

Once the rule is defined, you can associate that rule to a question or a data value within the question. The Show Visibility rule will only be selectable within the section you created the rule for; it cannot carry over to other sections within your form.



In the Question Details, you will be able to select a Show Visibility rule created in Step One.



You can also select a Show Visibility rule created in Step One within the setup for a data value.

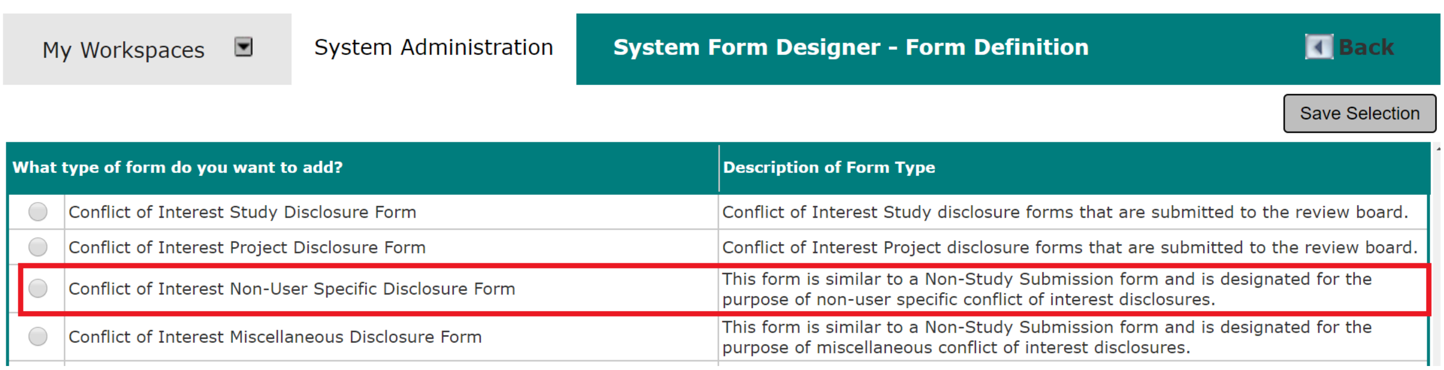
You would associate the Show Visibility to the question or data value within a question that has the panel you want to hide until the question is answered appropriately. You can associate the Show Visibility rule to multiple questions and data values, which is helpful if you have several items that need to remain hidden until the question is answered. Simply associate the Show Visibility rule to the appropriate questions or data values.

Other Forms

There are other Conflict of Interest form types that can be used to collect Conflict of Interest and Conflict of Commitment information other than the Annual COI form. These are described here.

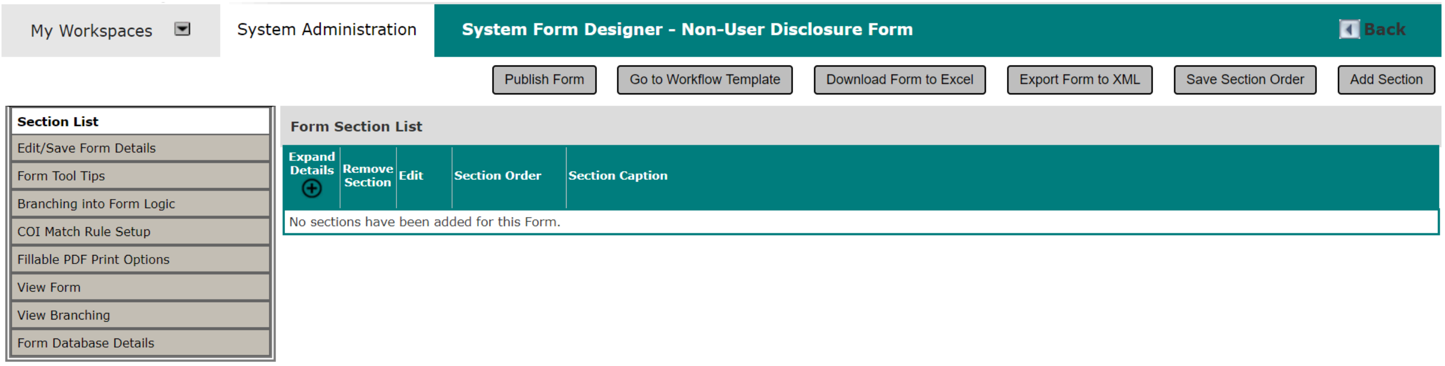
Non-User Disclosure Form

A Non-User Disclosure Form can be used to collect and process business and institutional disclosures for COI review that are not associated to a Covered Person.



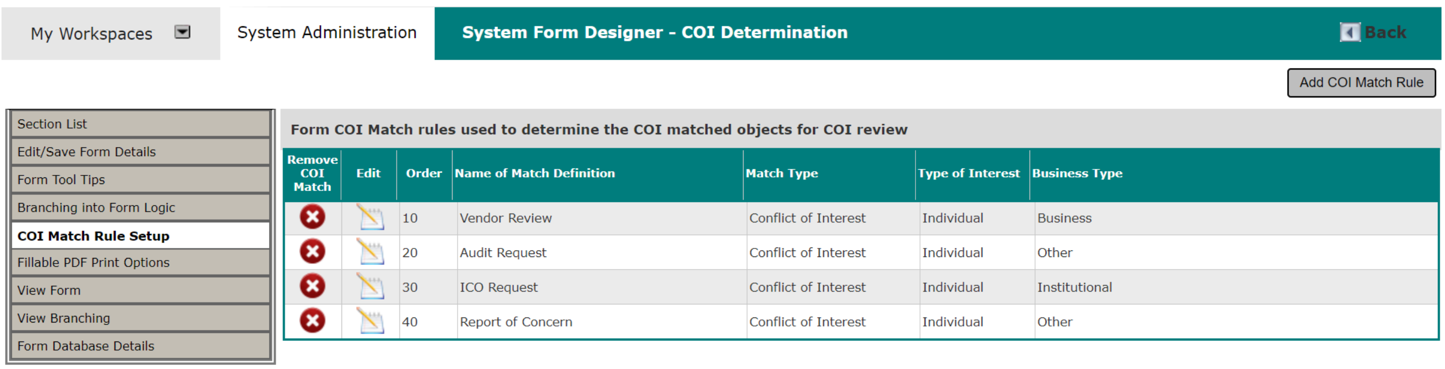
Within System Administration > System Forms Designer > Add a New Form, select the form type “Conflict of Interest Non-User Specific Disclosure Form”.

Note: You can only have one form of this type defined in the system, so if it does not appear in the page above, the form has already been created.

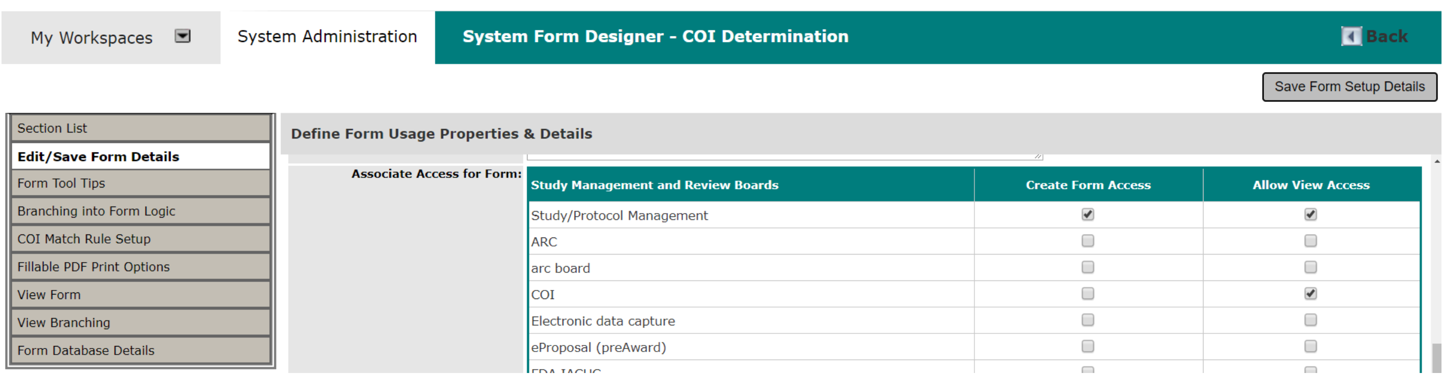


Define the form content using the tools available in the Form Designer.

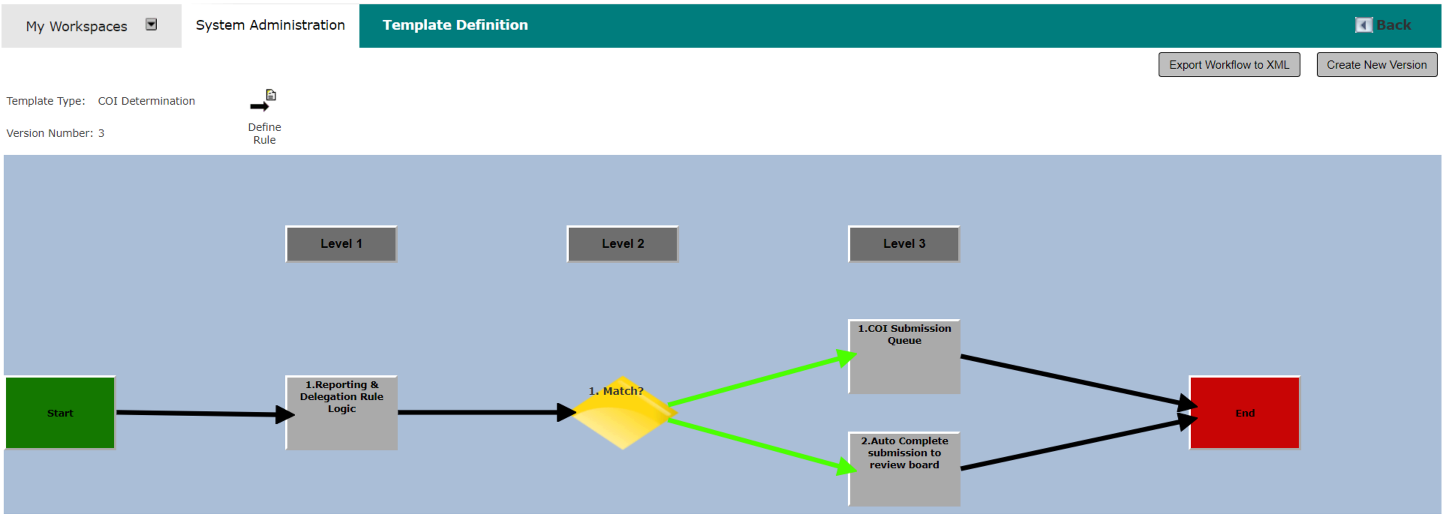
Note: In order to properly create a conflict match from data within the form, you must create panel data values.



You will also need to define rules within COI Match Rule Setup.



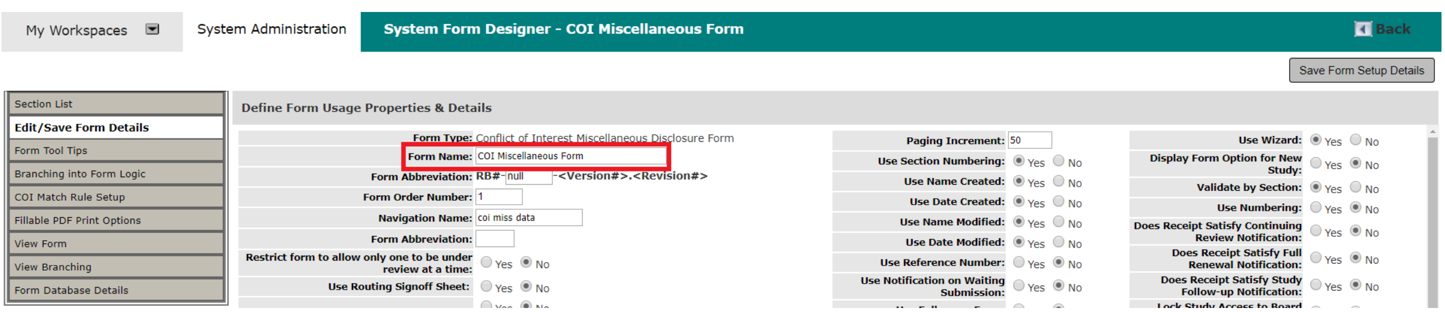
Within Edit/Save Form details, “Create Form Access” for Study/Protocol Management must be set to allow the form to populate within the list of COI forms on your home screen. “Allow View Access” must be set for COI.

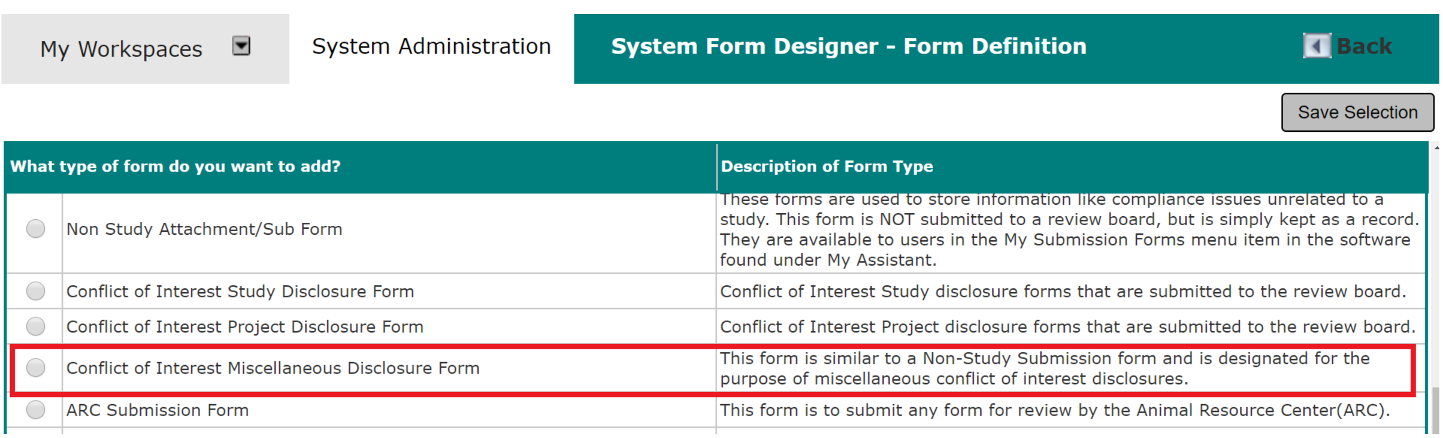


A workflow must be defined and published within System Administration > Workflow Designer. The Workflow will use the same concepts as described in the [Workflow](#) portion of this manual.

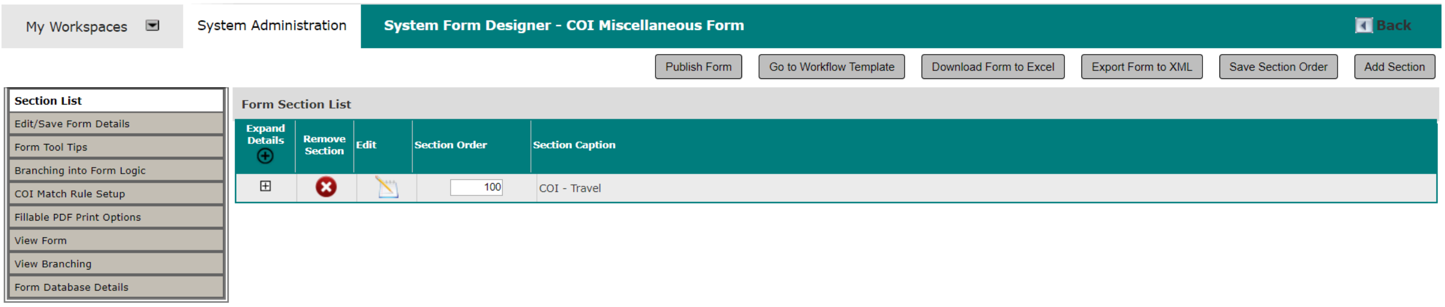
Miscellaneous Disclosure Form

Miscellaneous Disclosure Forms can be used to collect and process disclosures for COI review that are not related to the Annual Review, like Travel Disclosures. There can be any number of Miscellaneous Disclosure Forms defined in the system, and each will display within Conflict of Interest Forms on your home screen under the name provided within Edit/Save Form Details, as shown below.



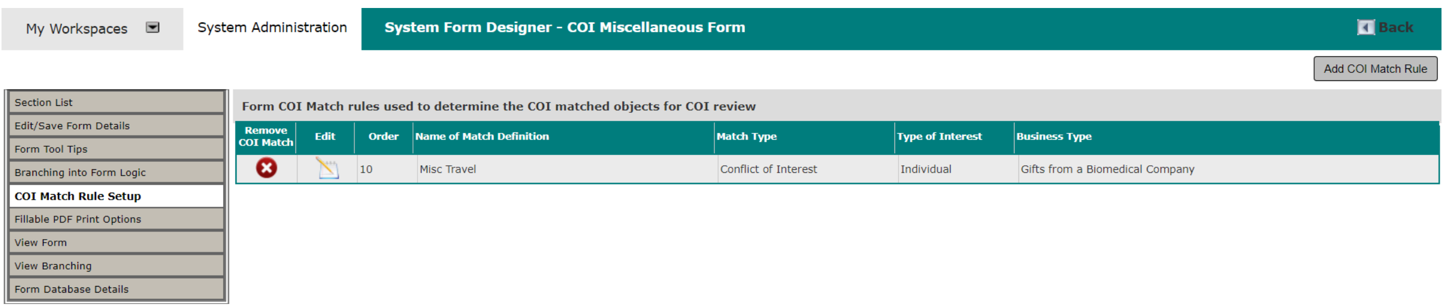


Within System Administration > System Form Designer > Add a New Form, select the form type “Conflict of Interest Miscellaneous Disclosure Form.”

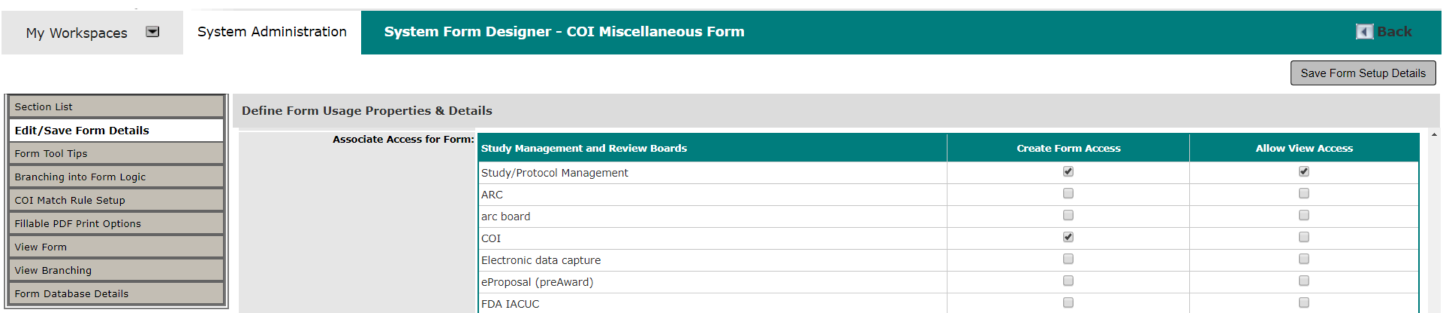


Define the form content using the tools available in the Form Designer.

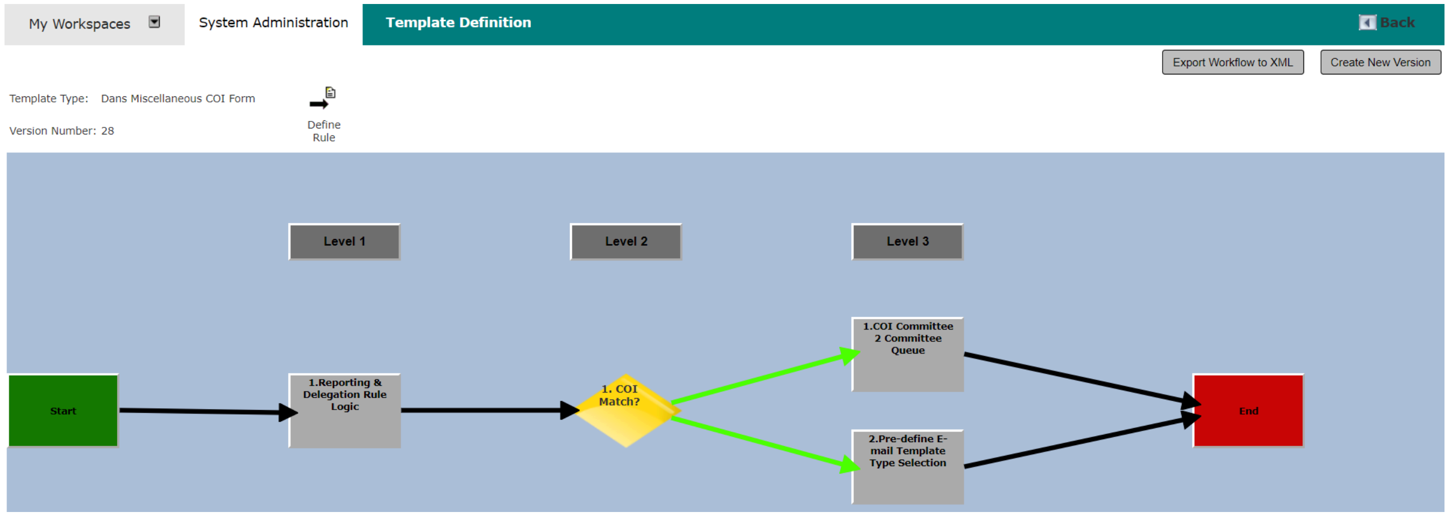
Note: In order to properly create a conflict match from data within the form, you must create panel data values.



You will also need to define rules within COI Match Rule Setup.



Within Edit/Save Form details, “Create Form Access” for Study/Protocol Management must be set to allow the form to populate on your home screen. “Allow View Access” must be set for COI.



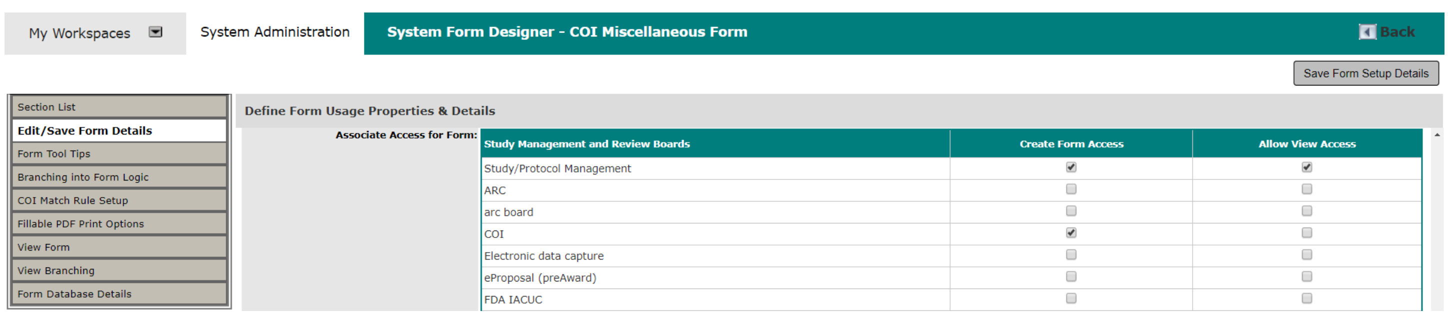
A workflow must be defined and published within System Administration > Workflow Designer. The Workflow will use the same concepts as described in the [Workflow](#) portion of this manual.

Study COI Form

The Study COI Form is a form that is sent to Key Study Personnel when a study is submitted to the review board. Within System Administration > System Forms Designer > Add a New Form, select the form type, “Conflict of Interest Study Disclosure Form”.

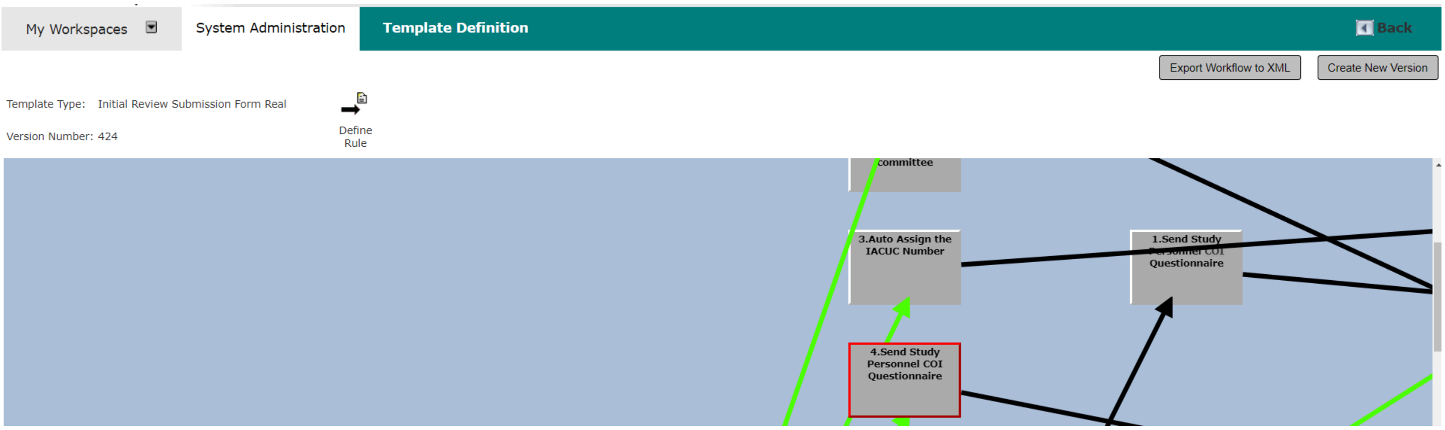
Define the form content using the tools available in the Form Designer.

Note: In order to properly create a conflict match from data within the form, you must create panel data values. You will also need to define rules within COI Match Rule Setup.

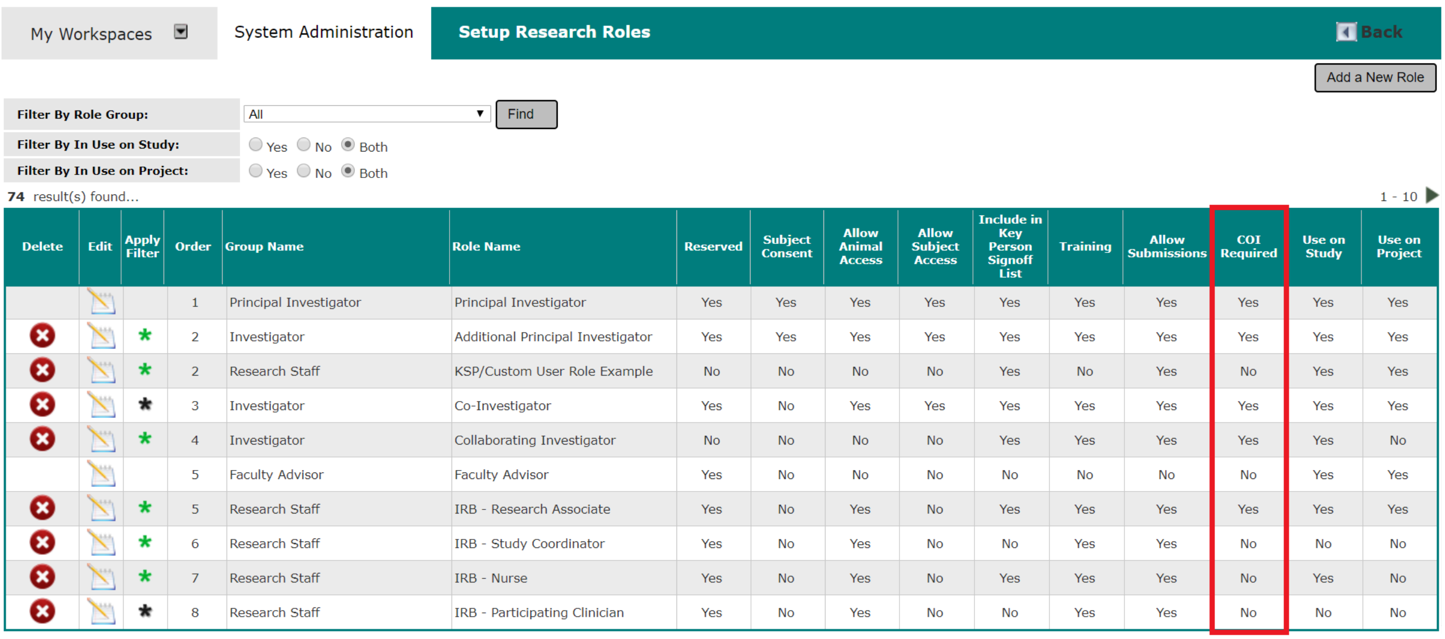


Within Edit/Save Form details, “Create Form Access” for Study/Protocol Management must be set to allow KSP to be able to create the form. “Allow View Access” must be set for COI.

If you wish for study personnel to fill out a Study COI Form, a step must be added to the workflow of the Initial Review Submission Form (or another submission form). The Send Study Personnel COI Questionnaire action is added to the workflow before the submission reaches the review board.



When this action is added to the workflow, all Key Study Personnel with a study role set with COI required under System Administration > List Configuration and Maintenance > Define Study and Project Role(s) will receive a task to complete the Study COI Form when the submission goes through the workflow.


My Workspaces | System Administration | **Setup Research Roles** | Back

Add a New Role

Filter By Role Group: All [Find]
Filter By In Use on Study: Yes No Both
Filter By In Use on Project: Yes No Both

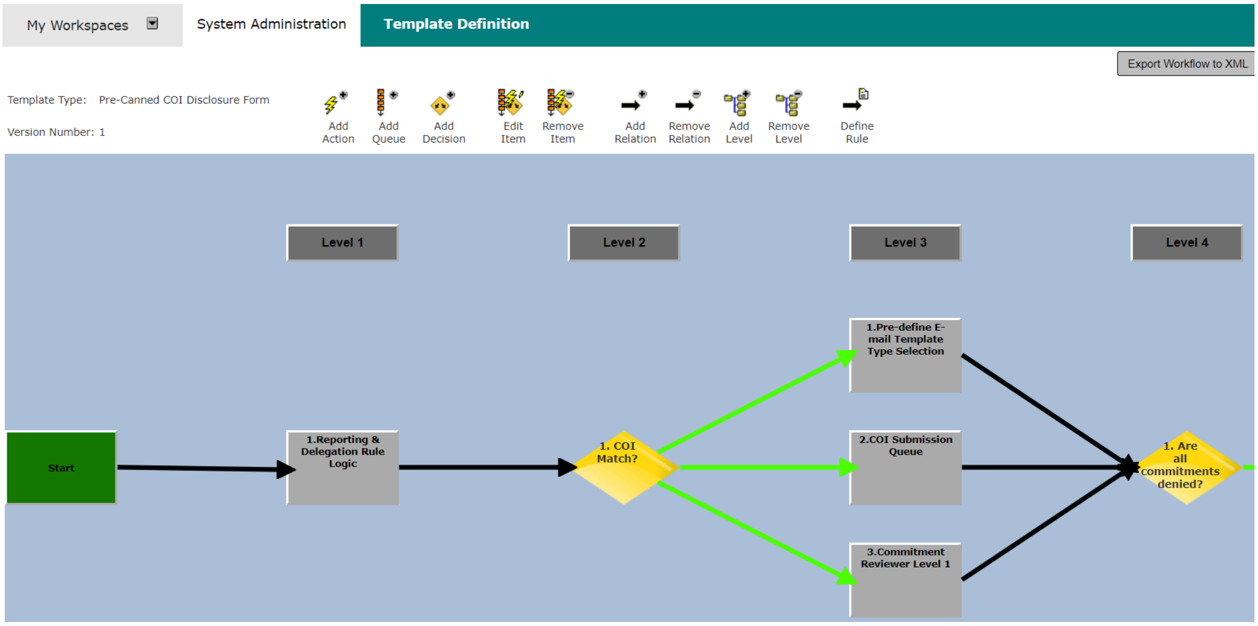
74 result(s) found... 1 - 10

Delete	Edit	Apply Filter	Order	Group Name	Role Name	Reserved	Subject Consent	Allow Animal Access	Allow Subject Access	Include in Key Person Signoff List	Training	Allow Submissions	COI Required	Use on Study	Use on Project
			1	Principal Investigator	Principal Investigator	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		*	2	Investigator	Additional Principal Investigator	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		*	2	Research Staff	KSP/Custom User Role Example	No	No	No	No	Yes	No	Yes	No	Yes	Yes
		*	3	Investigator	Co-Investigator	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		*	4	Investigator	Collaborating Investigator	No	No	No	No	Yes	Yes	Yes	Yes	Yes	No
			5	Faculty Advisor	Faculty Advisor	Yes	No	No	No	No	No	No	No	Yes	Yes
		*	5	Research Staff	IRB - Research Associate	Yes	No	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
		*	6	Research Staff	IRB - Study Coordinator	Yes	No	Yes	No	No	Yes	Yes	No	No	No
		*	7	Research Staff	IRB - Nurse	Yes	No	Yes	No	Yes	Yes	Yes	No	Yes	No
		*	8	Research Staff	IRB - Participating Clinician	Yes	No	Yes	No	No	Yes	Yes	No	No	No

Workflow

This section of the manual assumes a general knowledge of the Workflow Designer is known by the reader. You will have the same functionality as other templates in the Workflow Designer. It is recommended that prior to making any changes to the COI Annual form workflow template, you have a good understanding of the Workflow Designer tool. You can use the Workflow Designer manual for more information.

The COI Annual Form is a submission form and must have a workflow associated to it within Workflow Designer. Your iMedRIS Project Manager will create a pre-defined workflow initially within your system, but this workflow can be modified to your specific needs.



The workflow for the COI Annual form will be set up to check for any indications of a conflict of interest, and also for any interests noted for level of effort.

Level 1 – The COI Annual form workflow will first check against the rules to see if there is any kind of conflict related to the submitted form. This step is called the Reporting & Delegation Rule Logic. This is an internal check. If there are any Level of Effort (Conflict of Commitment) conflicts (if any question in the Annual form is noted about working over a certain percentage of time) the system will flag this as a conflict. If there are any Conflict of Interest matches (any type of indication in the Annual form) the system will flag this as a conflict.

Level 2 – A decision step is used to guide the COI Annual form to one or more of three paths.

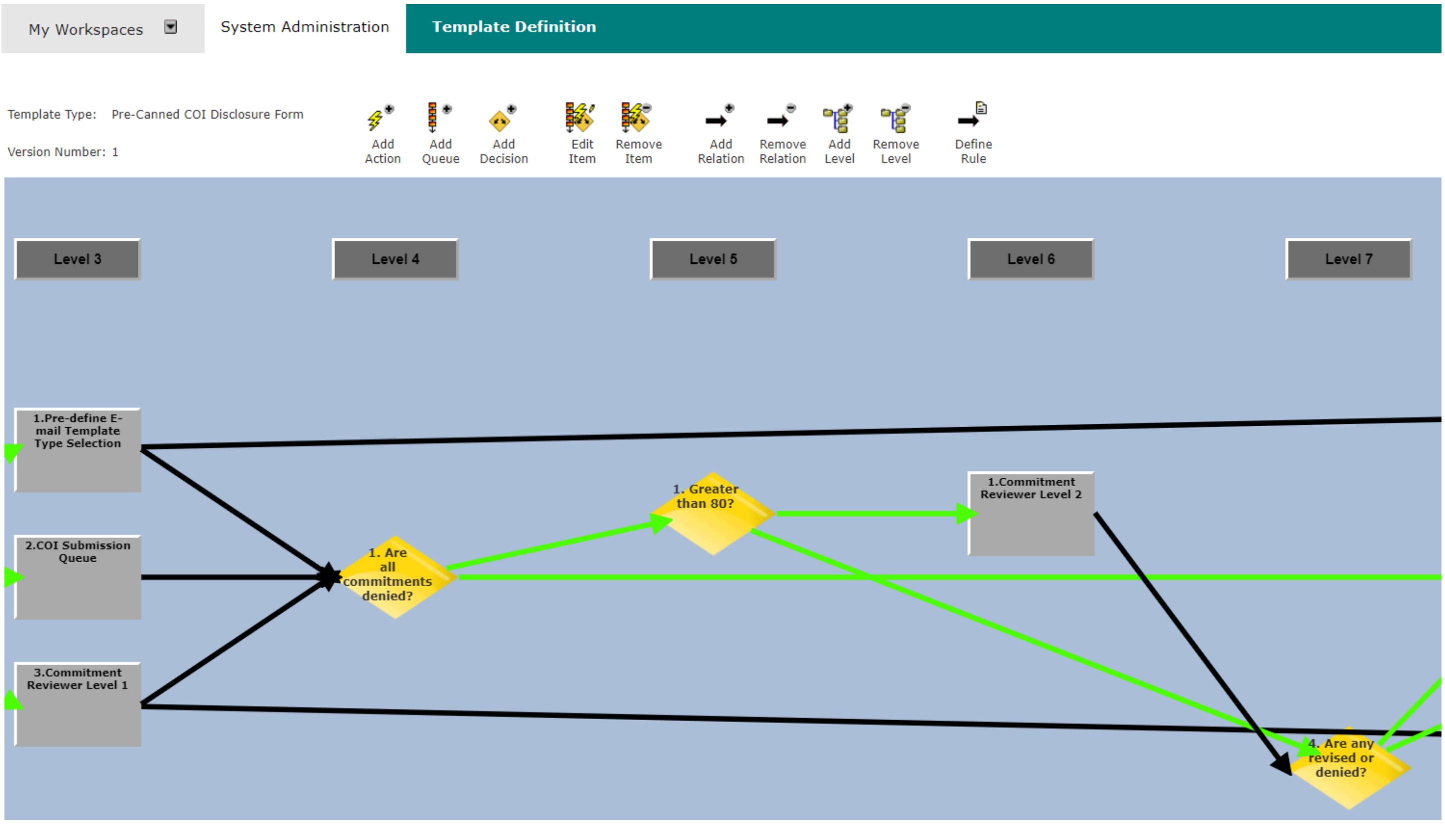
Level 3 –

> **No Conflict** – If a Level of Effort or Conflict of Interest is not found in the COI Annual form, the path branches to an email template that will send an email to indicate there is no conflict found.
>
> **Conflict of Commitment** – If the user indicated that one of their roles exceeds a certain percentage of time, the COI Annual form will branch down a path that will begin a Level of Effort review starting with Commitment Reviewer Level 1. This will allow a reviewer to look at the indication of time and decide whether the user needs to revise their level of effort or if they can proceed with their research.
>
> **Conflict of Interest** – Any indication that there is a conflict will cause the COI Annual form to branch to the Conflict of Interest submission queue. From here, any conflict matches can be reviewed separately or grouped together. Conflicts can be processed, returned for management plans, or denied altogether.

The levels after level 3 vary depending on what path the COI Annual Form branched down. If there is no conflict, the COI Annual form will end after sending the email.

If there is a Conflict of Interest, the Conflict of Interest submission queue will process the matches and when that process is complete, the process will end.

If there is a Conflict of Commitment, however, the COI Annual form will take the following steps:

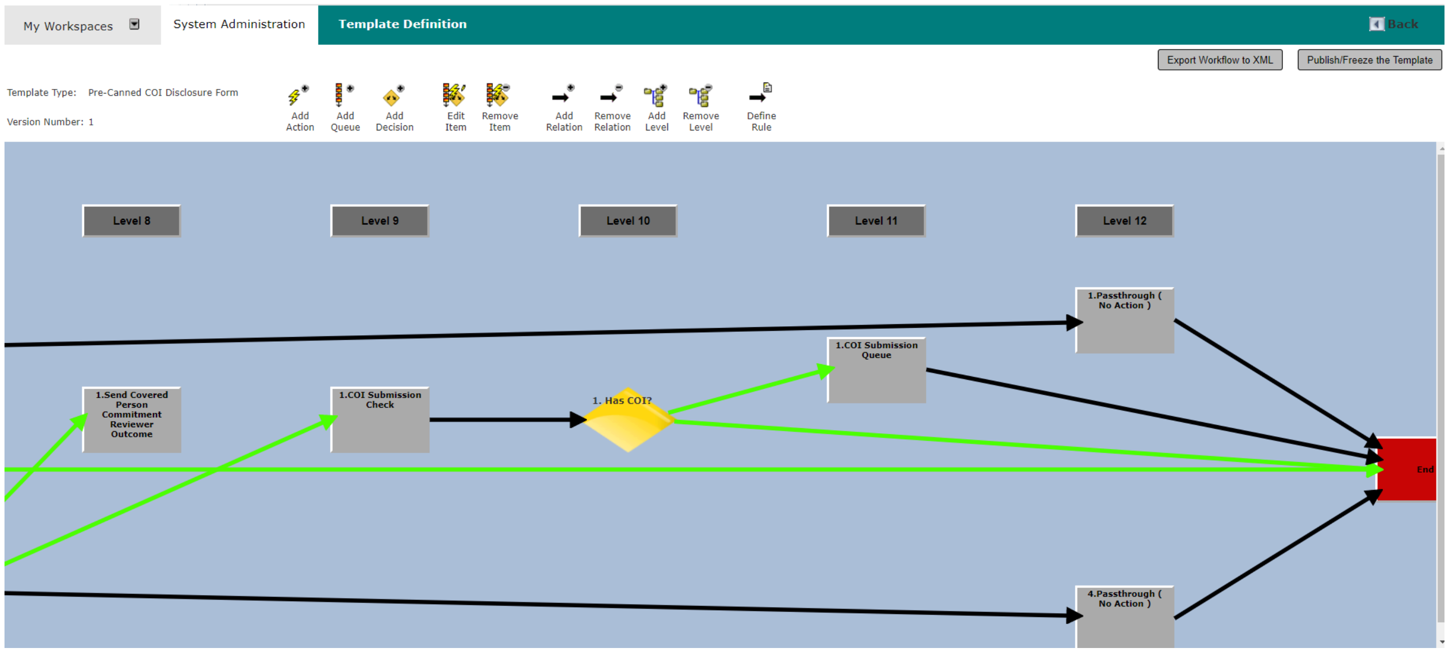


Level 4 – After the Commitment Reviewer has reviewed the match, they can either deny or approve it. If they deny the match, then the process will go to Level 8, to send the covered person the outcome (denied), which will mean they cannot conduct their project. The COI Annual will then check to see if there are any Conflict of Interest matches that need to be accounted for and will either send the COI Annual to the Conflict of Interest submission queue or the process will end.

Level 5 – If the Commitment Reviewer approves the match, the process will go on to another decision to check if the level of effort is greater than 80 hours of commitment. If so, the process will go to the next level of commitment review. If not, then the process will go on to check for a Conflict of Interest match.

Level 6 – If the level of effort is greater than 80 hours, the second level Commitment Reviewer is assigned.

Level 7 – Checks the outcome of the Commitment Reviewer.



Level 8 –This step sends the Commitment Reviewer's outcome to the covered person.

Level 9 – Checks for any Conflict of Interest in case the Conflict of Interest board needs to review the COI Annual form.

Level 10 – This step is the decision to send to the Conflict of Interest Submission queue.

Level 11 – If there is a Conflict of Interest noted along with the Level of Effort commitment, this step sends the COI Annual form to the Conflict of interest submission queue.

Unique Elements for COI in the Workflow designer

Any workflow used for a COI form can make use of certain actions and decision rules designed specifically to accommodate the COI process in iRIS. These items should not be used in other workflows unless otherwise noted.

Actions

The actions described below are used specifically for the Conflict of Interest module and cannot be used if you are not using Conflict of Interest in your instance of the software.

Reporting & Delegation Rule Logic - This action initiates the check against the COI Annual form to see if the user had indicated any type of interest. A Conflict of Interest is flagged whenever the user indicated a specific interest in the Annual COI form – whether for themselves or a related person.

Predefine Email Type by Selection - This action will cause an email to send to specified users. This step is typically used to alert a certain user that there have not been any conflicts with the Annual COI.

Commitment Reviewer Level 1 - This action is used with Conflict of Commitment reviews. This step in the workflow will look at the user's defined Reviewer 1 and assign the form to that person for review.

Commitment Reviewer Level 2 - This action is used with Conflict of Commitment reviews. This step in the workflow will look at the user's defined Reviewer 2 and assign the form to that person for review.

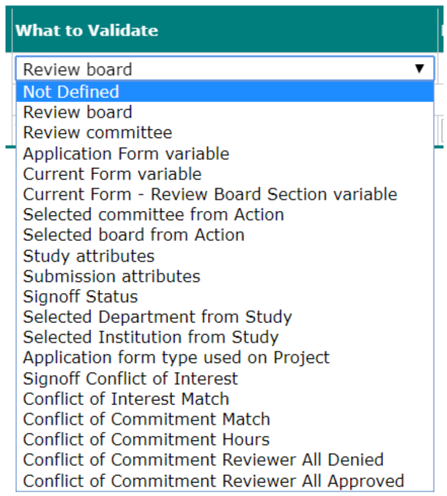
Send Covered Person Commitment Reviewer Outcome - This step will send out a commitment outcome letter to the covered person.

Update COI Annual Due Date for Covered Person Workflow – This step will change the Covered Persons Annual COI Due Date to 365 days in the future.

Send Study Personnel COI Questionnaire – This action is used for research project submission forms. If a certain submission form triggers the need for Key Personnel to complete a supplemental COI form, this action can be used to send that particular COI form to Key Personnel on the study.

Workflow Decision Rules

As shown in the Annual COI workflow in screenshots above, the form will go in a certain direction based on rules. These rules are specific to the Conflict of Interest process and look at answers in the Annual COI form.



Signoff Conflict of Interest - This option allows you to look specifically at the Commitment Reviewer outcome, and whether they approved or denied the Annual COI form.

Conflict of Interest Match - This will allow you to create a decision based on whether a Conflict of Interest match has been found within the Annual COI form. You can send the Annual COI form down a certain path based on whether there was a conflict match found or not.

Conflict of Commitment Match - This will allow you to create a decision based on whether a Conflict of Commitment match has been found within the Annual COI form. You can send the Annual COI form down a certain path based on whether there was a conflict match found or not.

Conflict of Commitment Hours - Send the submission down a certain path based on the number of commitment hours the user indicates within the Annual COI. This check will allow you to send the submission down a certain path if the user entered a specific number of hours. Example, if the user has more than 80 hours a period committed for research, you can send the form to a Commitment Reviewer for further clarification. If the user has less than 80 hours committed, the form does not need to be reviewed.

Conflict of Commitment Reviewer All Denied - If the Annual COI goes out to multiple Commitment Reviewers at once, this decision can send the submission in a certain direction based on their signoff outcome, if all reviewers denied the submission.

Conflict of Commitment All Approved - If the Annual COI goes out to multiple Commitment Reviewers at once, this decision can send the submission in a certain direction based on their signoff outcome, if all reviewers approved the submission.