



CONFLICT OF INTEREST ASSISTANT

Administrative Manual for Form Design and Workflow

Version 10.03.02

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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.

System Form Designer - Create electronic data capture forms within iRIS ◀ Back

View forms by type: **All**

View forms by category: ----- Study Review Forms -----
Project & Study Top Level Application Forms
Study Submission Forms
Study Attachment Forms
Project Submission Forms
Project Attachment Forms
Workflow Routing Forms
Non Project Submission Forms
Non Project Attachment Forms
Conflict of Interest Annual Form
Conflict of Interest Study Disclosure Form
Conflict of Interest Project Disclosure Form
Conflict of Interest Non-User Specific Disclosure Form
Conflict of Interest Miscellaneous Disclosure Form

29 result(s)

Form Name:

Table Name:

Find

Operations ▼

Setup Form Tools ▼

				Version	Form Type	Category	Group	Form Status
<input type="checkbox"/>				1	Study Application Form			Active
<input type="checkbox"/>				1	Study Application Form			Update

1 - 10 ▶

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.

System Form Designer - Create electronic data capture forms within iRIS ◀ Back

View forms by type: **Conflict of Interest Annual Form**

View forms by category: **All**

Form Name:

Table Name:

Find

Operations ▼

Setup Form Tools ▼

1 result(s) found...

					Form Name / Table Name	Version	Form Type	Category	Group	Form Status
<input type="checkbox"/>					Annual Disclosure Form GEN_N_SUB_COH_COI	2	Conflict of Interest Annual Form			Update

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.

System Form Designer - Annual Disclosure Form ← Back

Publish Form
Goto Workflow Template
Download Form to Excel
Export Form to XML
Save Section Order
Add Section

Section List	
Edit/Save Form details	
Form Tool Tips	
Branching into Form Logic	
COI Match Rule Setup	
Fillable PDF Print Options	
View Form	
View Branching	
Form Database Details	

Form Section List				
Expand Details	Remove Section	Edit	Section Order	Section Caption
			100	Introduction
			150	Background Information
			200	Investments with Biomedical Third Parties
			300	Investments with Non-Biomedical Third Parties
			400	Compensation from Biomedical Third Parties

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.

Covered Person: Investigator, Susan
Reference Number: **Annual Disclosure Form - (Version 1.0)**

Print Friendly
Save Section
Continue

Section view of the Form
Entire view of the Form

- 1.0 Introduction
- 2.0 Background Information
- 3.0 Investments to Report with BioMedical Companies

3.0 Investments with Biomedical Third Parties

3.1 Do you or a **Related Person** have an investment interest in any **Biomedical** third party?
 You do not need to report investments in publicly held mutual funds.

Yes No

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.

Entry 1

Who engaged in the activity?	<input type="radio"/> You <input type="radio"/> Related Person
Provide the name of the Biomedical third party:	<input type="text"/>
Select the estimated current value of the investment:	--none--
Select the current estimated ownership percentage:	--none--

[+ Click here to add another investment](#)

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

Background Information

Our records reflect your position(s) at GH as listed below. If you are listed as holding a position you do not believe you hold, please contact Greg Thompson at gthompson@gh.org

Role Name
No role(s) have been assigned

Please indicate whether you hold any additional positions that are listed below. (Check all that apply)

Role Name

- IRB Board Member
- Vice President
- Researcher
- Officer
- Practitioner
- Dean
- Principal Investigator
- Other

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.

COI - Review Board Administration

System Setup | List Maintenance Setup

Review Board Lists

- Internal Document Category
- Internal Routing User Roles
- Predefined Strategies
- Review Outcome/Outcome Configuration List
- Reviewer Rank Configuration List
- Office of General Counsel Outcome List
- Setup Review Board Strategy Actions
- [Setup Institutional Role Name List](#)

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

Institutional Role Name Setup Back						
Download Role List Template Upload Role List Code Add a New Role						
List of Institutional Roles						
8 result(s) found...						
Delete	Edit	Order Number	Role	is KDM?	is 990?	Display in COI Form
		1	IRB Board Member	Yes	No	Yes
		1	Vice President	Yes	No	Yes
		2	Researcher	No	No	Yes
		3	Officer	Yes	No	Yes
		4	Practitioner	No	No	Yes

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 user to notify using this data value that they have a role that is flagged **Is 990**.

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. 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. This explanation is how all the COI Annual sections are setup and can be applied to any of the data values listed above.

Investments with Biomedical Third Parties

Do you or a **Related Person** have an investment interest in any **Biomedical** third party?
You do not need to report investments in publicly held mutual funds.

Yes No

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.

Entry 1

Who engaged in the activity? You Related Person

Provide the name of the Biomedical third party:

Select the estimated current value of the investment:

Select the current estimated ownership percentage:

[+ Click here to add another investment](#)

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.

System Form Designer - Annual Disclosure Form Back

Cancel - Return to List Save Data Value

Question Text: Do you or a Related Person have an investment interest in any Biomedical third party?
You do not need to report investments in publicly held mutual funds.

***Data Type:** COI Annual Disclosure Form Investment BioMedical

***Database Column Name:** INTEREST_IN_BIOMED

***Value Required:** Yes No

***Order in Question:** 2

Is the value Read Only? Yes No

Element info:

Rich text editor toolbar: ABC, Bold, Italic, Underline, Text color, Background color, Bulleted list, Numbered list, Indent, Outdent, Undo, Redo, Link, Unlink, Table, Insert image, Insert video, Insert audio, Insert link, Insert unlink.

To set up the value in the form within your question, you can add a new data value. From the **Data Type** dropdown, select the COI Annual Disclosure Form Investment BioMedical value. The page will refresh, allowing you to indicate whether the value is required or not, if it is Read Only, the Order in Question, and, you can provide Element Info, if needed.

You must provide a unique Database Column Name.

Save Data Value to add this value to the form.

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

Investments with Biomedical Third Parties

Do you or a **Related Person** have an investment interest in any **Biomedical** third party?
You do not need to report investments in publicly held mutual funds.

Yes No

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.

Entry 1

Who engaged in the activity? You Related Person

Provide the name of the Biomedical third party:

Select the estimated current value of the investment:

Select the current estimated ownership percentage:

[+ Click here to add another investment](#)

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.






Conflict of Interest - Review Board Administration

System Setup
List Maintenance Setup
Clean-up

















Review Board System Setup

- Board Definition
- Board Configuration Options
- Broadcast Notice
- Setup Committee List
- Setup Review Board Roles
- Setup Role Access
- Setup Agenda Categories
- Setup Finalized Agenda Document Template
- Setup Agenda Revision Document Template
- Setup Meeting Minutes Template
- Setup Management Plan
- Setup Outcome Letter Templates
- Setup Template Language
- Setup Correspondence Template
- Setup COI Annual Due
- Annual COI Form Label Configuration list**

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.

Annual COI Label Setup 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:	

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.

Review Board	
	Configure Dollar Amount Selection list
	Configure Percent Ownership Selection list
	Configure Compensated Biomedical Service list
	Configure Compensated Non-Biomedical Service list
	Configure UnCompensated Biomedical Service list
	Configure UnCompensated Non-Biomedical Service list
	Configure Intellectual Property list
	Configure Gift Type list
	Configure Gift Amount list
	Configure Related Person list
	Configure Family Member list
	Configure Study Financial Interest list
	Configure Study Associational Interest list
	Configure Study Intellectual Property Interest list
	Configure Study Associational Activity list
	Issue Reporting Types

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, as the Annual is not associated to a Research Study.

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.

Order	What to Validate	Data Value	Join by, if any
1	User Roles	IS_990	--none--
	EQUAL		
	Value	<input type="radio"/> Yes <input checked="" type="radio"/> No	

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 from 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 Is 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 Is 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

Associate Access for Form:	Study Management and Review Boards	Create Form Access	Allow View Access
Study/Protocol Management	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ARC	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
COI	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Finance Assistant	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IACUC	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

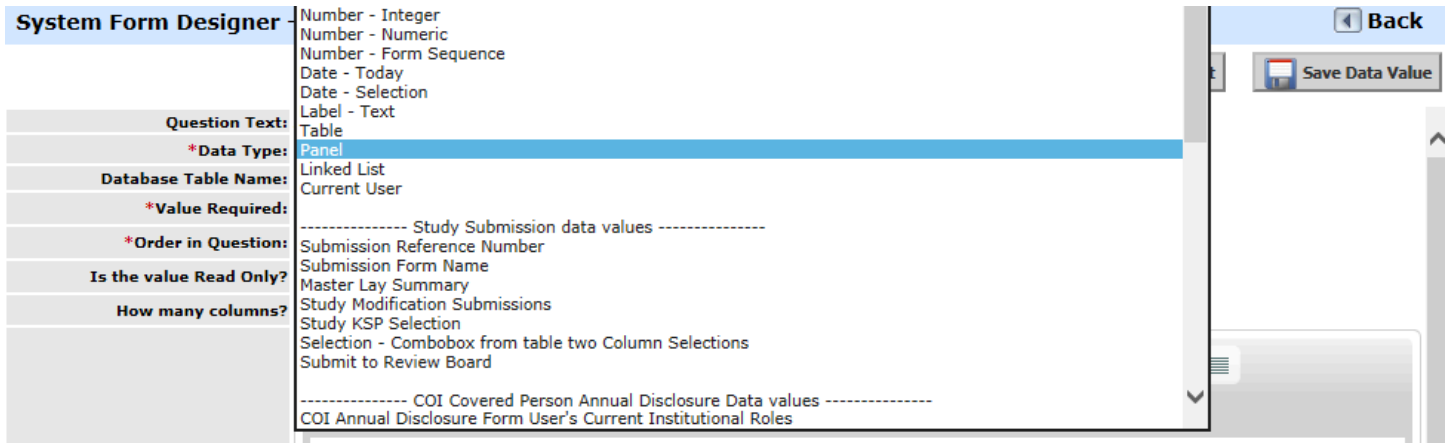
Within Edit/Save Form Details, you will need to ensure that the Conflict of Interest Board has Allow View Access checked off in the **Associate Access for Form** table. You must also have Create Form Access turned on for Study Management.

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.

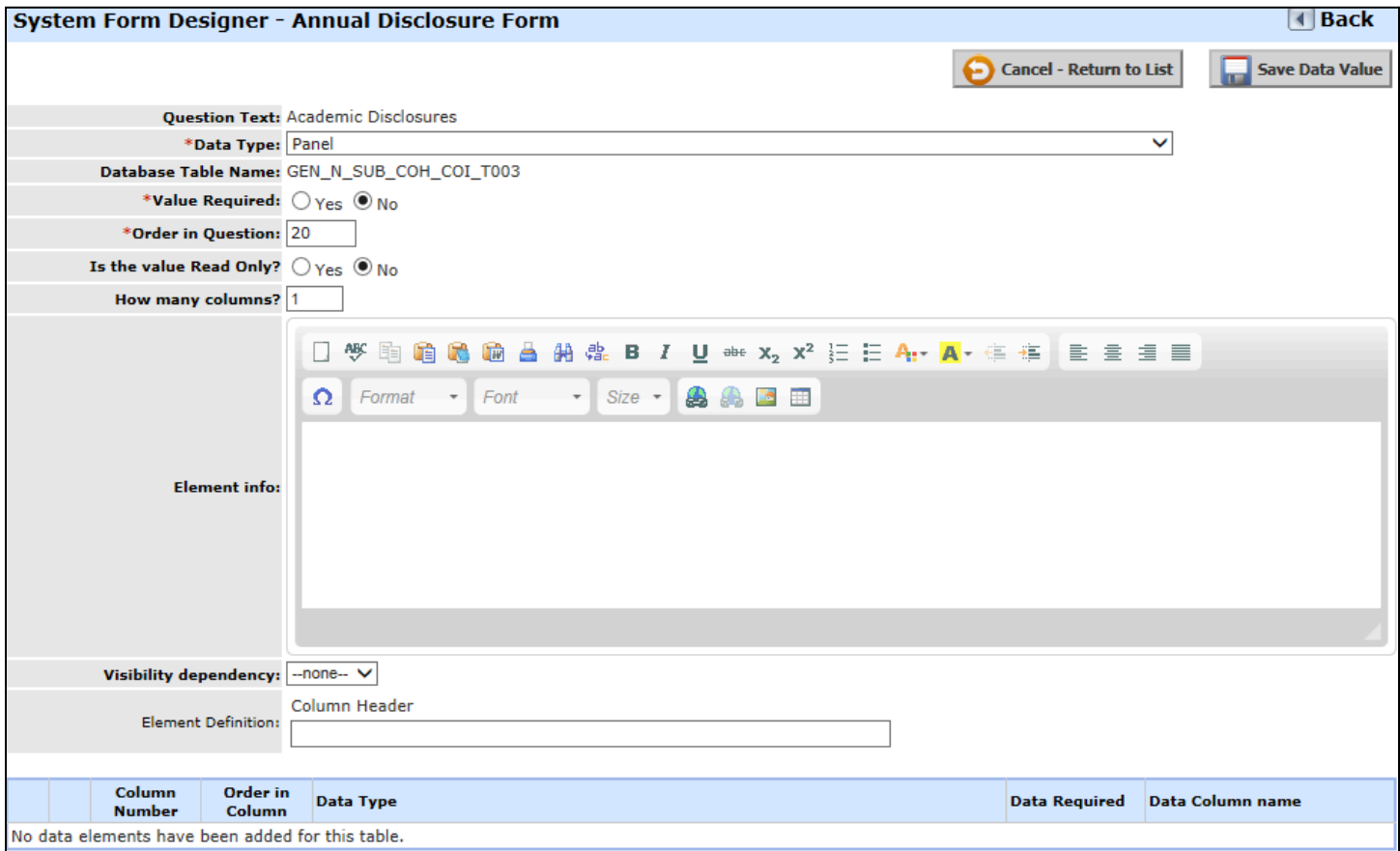
Panels

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.

Question Text:	Do you or a Related Person have an investment interest in any Non-Biomedical third party? You do not need to report investments in publicly held mutual funds.
*Data Type:	Panel
Database Table Name:	GEN_N_SUB_DANNUALCOI_T002
*Value Required:	<input type="radio"/> Yes <input checked="" type="radio"/> No
*Order in Question:	10
Is the value Read Only?	<input type="radio"/> Yes <input checked="" type="radio"/> No
How many columns?	4

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

The screenshot shows a panel titled 'Entry 1'. At the top, there is a button with a green plus icon and the text 'Click here to add another entry'. Below this, there are several sections: 'Entity' with a 'Provide t...' label; 'Relationship' with an 'Add' button (green plus icon) and a dropdown menu showing 'Person with in'; 'Monetary Amount' with the instruction 'Indicate the mone...' and an input field; and 'Comments' with a text area. A grey area on the left side of the panel contains labels for 'Entity', 'Relationship', 'Monetary Amount', and 'Comments'.

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

Visibility dependency:	--none--			
Element Definition:	Column Header Entity Relationship Monetary Amount Comments			
Column Number	Order in Column	Data Type	Data Required	Data Column name
No data elements have been added for this table.				

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.

Covered Person: Administrator
Reference Number:

Annual Disclosure Form

Section view of the Form

Entire view of the Form

Instructions

Background Information

Academic Interest

Academic Interest

Academic Disclosures

Do you have an Academic Disclosure to report?

Yes No

Entry 1

+ Click here to add another entry

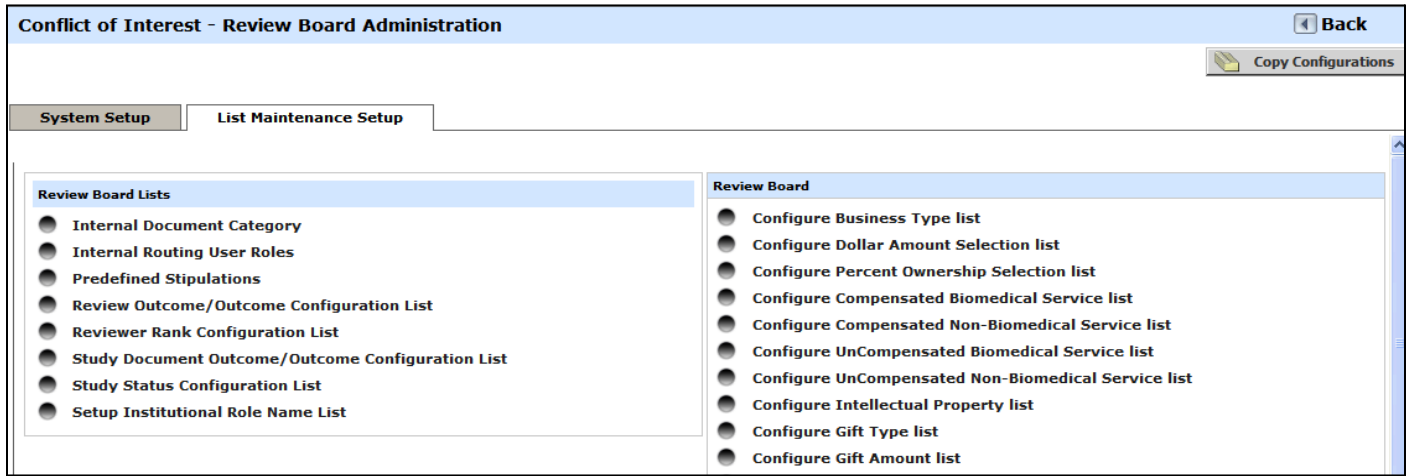
Entity	Provide the name of the Agency: <input type="text" value="nih/cen"/>
Relationship	<input type="button" value="Add a new row"/> <ul style="list-style-type: none"> NIH/Center for Information Technology (CIT) NIH/Center for Scientific Review (CSR)

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.

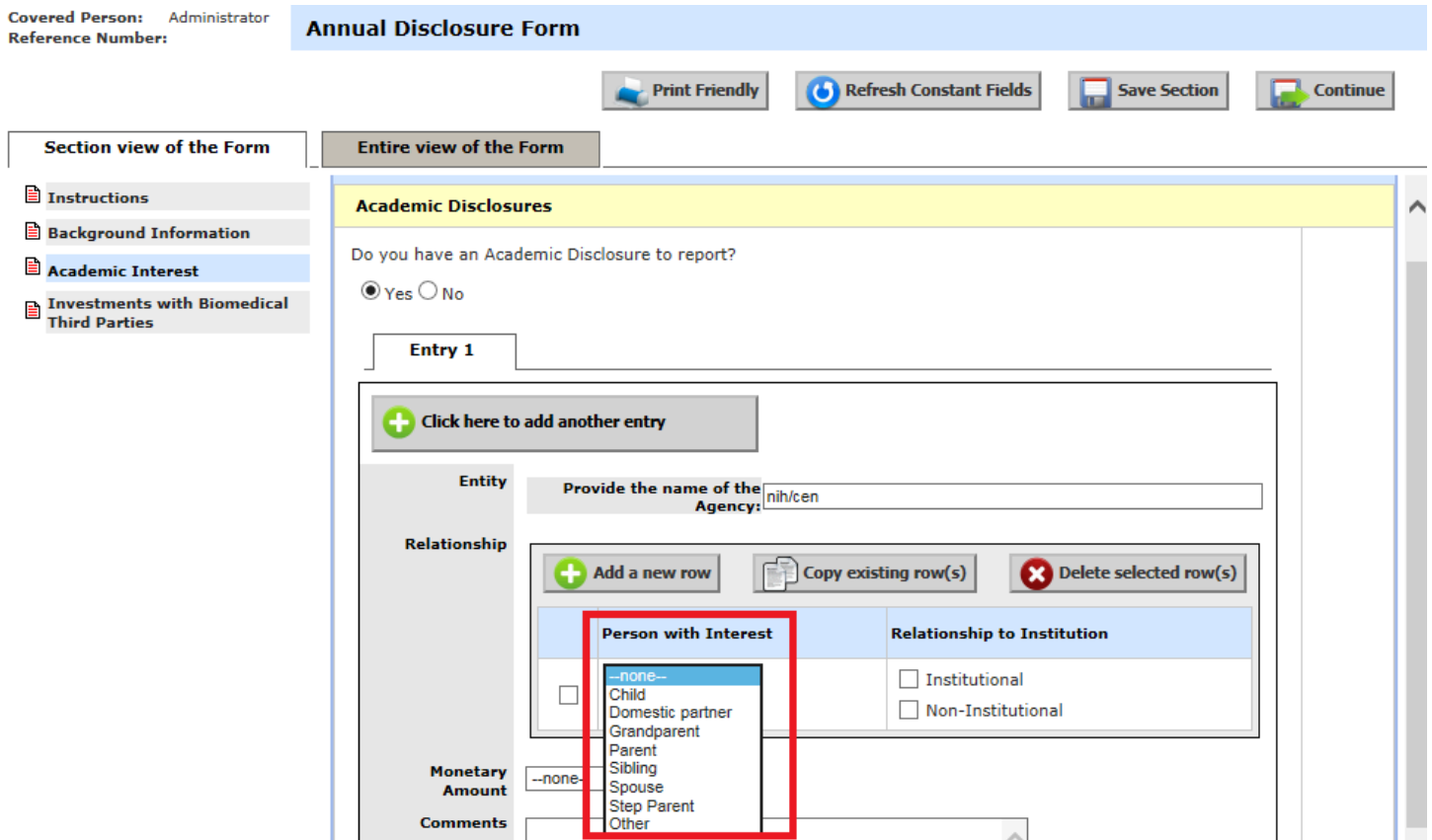
Conflict of Interest Configuration List Data Type

*Data Type:	Selection - Configuration List
*Database Column Name:	<input type="text"/>
*Value Required:	<input type="radio"/> Yes <input checked="" type="radio"/> No
*Column Number:	<input type="text" value="2"/>
User defined Error Message override for required fields	<input type="text"/>
*Order in Column:	<input type="text" value="1"/>
Data Dictionary Definition:	<input type="text"/>
Unique Code used for data merge:	<div style="border: 1px solid black; padding: 5px;"> <ul style="list-style-type: none"> Study Adverse Event Attribution Study Adverse Event Grade Country Race Job Title Ethnicity Specialty Study Phase Highest Degree Study Financial Role Study Peds Category Language Research Type Blinding Method Stage Radiation Use Diagnosis Therapeutic Area Dollar Amount List Ownership Percentage List Compensated Biomedical Service List Compensated Non-Biomedical Service List Uncompensated Biomedical Service List Uncompensated Non-Biomedical Service List Intellectual Property Type List </div>
Element info:	
Element Definition:	

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

System Form Designer - Annual Disclosure Form Back

Cancel - Return to List
Save Data Value

*Data Type:

Database Table Name: GEN_N_SUB_COH_COI_T004

*Value Required: Yes No

*Order in Question:

Dynamic Table:
Allow user to add rows? Yes No

How many columns?

Element info:

ABC [Rich Text Editor Icons]

Format Font Size [Rich Text Editor Icons]

Element Definition:

Column Header:

+ Add a New Data Value

#	Column Number	Order in Column	Data Type	Data Required	Data Column name
No data elements have been added for this table.					

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.

Entry 1

+ Click here to add another entry

Entity: Provide the name of the Agency:

Relationship:

+ Add a new row		Copy existing row(s)	Delete selected row(s)
#	Person with Interest	Relationship to Institution	
<input type="checkbox"/>	<input type="text" value="Parent"/>	<input checked="" type="checkbox"/> Institutional	<input type="checkbox"/> Non-Institutional

Monetary Amount:

Comments:

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

Panel Functionality

Covered Person: Investigator, Susan
Reference Number:

Annual Disclosure Form - (Version 1.0)

Section view of the Form

- 1.0 Introduction
- 2.0 Background Information
- 3.0 Academic Interest
- 4.0 Investments to Report with BioMedical Companies

Entire view of the Form

3.0 Academic Interest

3.1 Academic Disclosures

Do you have an Academic Disclosure to report?
 Yes No

Entry 1

+ Click here to add another entry

Entity	<input type="text"/>				
Relationship	<div style="display: flex; justify-content: space-between; align-items: center;"> + Add a new row </div> <table style="width: 100%; border-collapse: collapse; border: 1px solid #ccc;"> <thead> <tr style="background-color: #e0f0ff;"> <th style="width: 50%; padding: 2px;">Person with Interest</th> <th style="width: 50%; padding: 2px;">Relationship to Institution</th> </tr> </thead> <tbody> <tr> <td colspan="2" style="text-align: center; padding: 2px;">No records have been added</td> </tr> </tbody> </table>	Person with Interest	Relationship to Institution	No records have been added	
Person with Interest	Relationship to Institution				
No records have been added					
Monetary Amount	--none--				
Comments	<input style="width: 100%;" type="text"/>				

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.

Do you have an Academic Disclosure to report?
 Yes No

Entry 1

Entry 2

+ Click here to add another entry
✖ Click Here to Delete this entry

Entity	Provide the name of the Agency: <input type="text"/>				
Relationship	<div style="display: flex; justify-content: space-between; align-items: center;"> + Add a new row 📄 Copy existing row(s) ✖ Delete selected row(s) </div> <table style="width: 100%; border-collapse: collapse; border: 1px solid #ccc;"> <thead> <tr style="background-color: #e0f0ff;"> <th style="width: 50%; padding: 2px;">Person with Interest</th> <th style="width: 50%; padding: 2px;">Relationship to Institution</th> </tr> </thead> <tbody> <tr> <td colspan="2" style="text-align: center; padding: 2px;">No records have been added</td> </tr> </tbody> </table>	Person with Interest	Relationship to Institution	No records have been added	
Person with Interest	Relationship to Institution				
No records have been added					
Monetary Amount	--none--				
Comments	<input style="width: 100%;" type="text"/>				

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.

Conflict of Interest - Conflict Matched Objects Back

Not Assigned | Assigned | Completed | Agendas Create Group | Add to Group | Remove from Group

2 result(s) found... 1 - 2

				Interest 1				
Open	Ref Number	Group Name	Show Form	Covered Person's Name	Reported Interest Type	Reported Interest Third Party	Reported Role	
<input type="checkbox"/>	000009			COI User	Academics - Entity Relationship	Abbott Vascular	Not KDM - Other Institutional Role	
<input type="checkbox"/>	000010			COI User	Academics - Entity Relationship	Pfizer	Not KDM - Other Institutional Role	

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

System Form Designer - Annual Disclosure Form Back

+ Add COI Match Rule

<ul style="list-style-type: none"> Section List Edit/Save Form details Form Tool Tips Branching into Form Logic COI Match Rule Setup Fillable PDF Print Options View Form 	<p>Form COI Match rules used to determine the COI matched objects for COI review</p> <table border="1"> <thead> <tr> <th>Remove COI Match</th> <th>Edit</th> <th>Order</th> <th>Name of Match Definition</th> <th>Match Type</th> <th>Type of Interest</th> <th>Business Type</th> </tr> </thead> <tbody> <tr> <td></td> <td></td> <td>10</td> <td>Academic</td> <td>Conflict of Interest</td> <td>Individual</td> <td>Academic</td> </tr> <tr> <td></td> <td></td> <td>20</td> <td>Business</td> <td>Conflict of Interest</td> <td>Individual</td> <td>Business</td> </tr> </tbody> </table>	Remove COI Match	Edit	Order	Name of Match Definition	Match Type	Type of Interest	Business Type			10	Academic	Conflict of Interest	Individual	Academic			20	Business	Conflict of Interest	Individual	Business
Remove COI Match	Edit	Order	Name of Match Definition	Match Type	Type of Interest	Business Type																
		10	Academic	Conflict of Interest	Individual	Academic																
		20	Business	Conflict of Interest	Individual	Business																

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.

Conflict of Interest - Conflict Matched Objects Back

Not Assigned | Assigned | Completed | Agendas Create Group | Add to Group | Remove from Group

2 result(s) found... 1 - 2

				Interest 1				
Open	Ref Number	Group Name	Show Form	Covered Person's Name	Reported Interest Type	Reported Interest Third Party	Reported Role	
<input type="checkbox"/>	000009			COI User	Academics - Entity Relationship	Abbott Vascular	Not KDM - Other Institutional Role	
<input type="checkbox"/>	000010			COI User	Academics - Entity Relationship	Pfizer	Not KDM - Other Institutional Role	

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

Conflict of Interest - Review Board Administration Back

Copy Configurations

System Setup | List Maintenance Setup

<p>Review Board Lists</p> <ul style="list-style-type: none"> Internal Document Category Internal Routing User Roles Predefined Stipulations Review Outcome/Outcome Configuration List 	<p>Review Board</p> <ul style="list-style-type: none"> Configure Business Type list Configure Dollar Amount Selection list Configure Percent Ownership Selection list Configure Compensated Biomedical Service list
--	--

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

Add Form COI Match Rule

*Enter a Name Tag for this Match: Academic

*Order: 30

*Match General Description: Academic

*Match Type: Conflict of Interest Conflict of Commitment

*Business Type: Academic

*Type of Interest: Individual Imputed

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.

Edit Form COI Match Rule

*Enter a Name Tag for this Match: Academic

*Order: 30

*Match General Description: Academic

*Match Type: Conflict of Interest Conflict of Commitment

*Business Type: Academic

*Type of Interest: Individual Imputed

[+ Add a new Rule](#)

Order	What to Validate	Data Value	Join by, if any
1	Current Form all columns EQUAL Value	ACADEMIC_DISCLOSURE_YN Yes No Not Set	AND
2	Current Form all columns NOT EQUAL Value	GEN_N_SUB_COH_COI_T003 Which Column? ACADEMIC_ENTITY NULL	--none--

Cancel Save

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 an Academic Disclosure. 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.

Covered Person: Investigator, Susan
Reference Number:

Annual Disclosure Form - (Version 1.0)

Print Friendly Refresh Constant Fields Save Section Continue

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.

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.

Edit Form COI Match Rule

***Enter a Name Tag for this Match:**

***Order:**

***Match General Description:**

***Match Type:** Conflict of Interest Conflict of Commitment

***Business Type:**

***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](#)

Order	What to Validate	Data Value	Join by, if any
1	Current Form all columns EQUAL Value	ACADEMIC_DISCLOSURE_YN <input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Not Set	AND
2	Current Form all columns NOT EQUAL Value	GEN_N_SUB_COH_COI_T003 Which Column? ACADEMIC_ENTITY NULL	--none--

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

Covered Person: Aaron User
Match Object Number: 000005
Review Round Number: 1

COI - Match Review for Covered Person Aaron User

[Back](#)

Match Summary	List of Match Object(s) for Review	
<ul style="list-style-type: none"> Internal Documents Review Assignment 	Interest 1	Interest 2
	<p>Show Form: </p> <p>Covered Person's Name: Aaron User</p> <p>Reported Interest Type: Financial Interest</p> <p>Reported Interest Third Party: New River Pharmaceuticals</p> <p>Reported Role: KDM - Not a Board Member</p> <p>Reporting Action: Individual Annual Reporting Form</p> <p>Date Submitted: 07/06/2015 1:49:39 PM PDT</p> <p>Interest Ref Number: 000023</p>	<p>Show Form: </p> <p>Covered Person's Name: General Hospital</p> <p>Reported Interest Type: Financial Interest</p> <p>Reported Interest Third Party: New River Pharmaceuticals</p> <p>Reported Role: Co-Investigator</p> <p>Reporting Action: Study Application</p> <p>Date Submitted: 06/30/2015 3:28:37 PM PDT</p> <p>Interest Ref Number: 000014</p> <p>Protocol Number: GH-2015-25</p> <p>Study Status: Active</p>

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.

Covered Person: Investigator, Susan
Reference Number:

Annual Disclosure Form - (Version 1.0)

[Print Friendly](#)
[Refresh Constant Fields](#)
[Save Section](#)
[Continue](#)

Section view of the Form | Entire view of the Form

- 1.0 Introduction
- 2.0 Background Information
- 3.0 Academic Interest
- 4.0 Investments to Report with BioMedical Companies

3.0 Academic Interest

3.1 Academic Disclosures

Do you have an Academic Disclosure to report?

Yes No

Entry 1

[Click here to add another entry](#)

Entity	Pfizer
Relationship	Add a new row

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 Academic Disclosure question is “Yes.”

Covered Person: Investigator, Susan
Reference Number:

Annual Disclosure Form - (Version 1.0)

[Print Friendly](#)
[Refresh Constant Fields](#)
[Save Section](#)
[Continue](#)

Section view of the Form | Entire view of the Form

- 1.0 Introduction
- 2.0 Background Information
- 3.0 Academic Interest
- 4.0 Investments to Report with BioMedical Companies

3.0 Academic Interest

3.1 Academic Disclosures

Do you have an Academic Disclosure to report?

Yes No

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

System Form Designer - Annual Disclosure Form [Back](#)

[Cancel - Return to List](#)
[Save Show Visibility Order](#)
[Add Show Visibility](#)

Section Definition Section Questions Section Branching Section Show Visibility Section Validation Section Exclude from Review Board	<p>Define the Show Visibility Rules for the Section</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr style="background-color: #e1eef6;"> <th style="width: 10%;">Remove Visibility</th> <th style="width: 10%;">Edit</th> <th style="width: 10%;">Order</th> <th style="width: 40%;">Name of Show Rule</th> <th style="width: 30%;">Comments</th> </tr> </thead> <tbody> <tr> <td colspan="5" style="text-align: center; padding: 5px;">No show visibility rules defined for this section.</td> </tr> </tbody> </table>	Remove Visibility	Edit	Order	Name of Show Rule	Comments	No show visibility rules defined for this section.				
Remove Visibility	Edit	Order	Name of Show Rule	Comments							
No show visibility rules defined for this section.											

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. The rule in the example above is setup to look at the “Yes/No” value for the Academic Disclosure question. iRIS will take note if the value is answered “Yes.”

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.

System Form Designer - Annual Disclosure Form

Question Text: Academic Disclosures

*Data Type: Panel

Database Table Name: GEN_N_SUB_COH_COI_T003

*Value Required: Yes No

*Order in Question: 3

Is the value Read Only? Yes No

How many columns? 4

Element info:

Visibility dependency: --none--
Academics

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.

System Form Designer - Form Definition Back

Save Selection

What type of form do you want to add?	Description of Form Type
<input type="radio"/> Non Study Submission Form	Financial Disclosures and other user specific rather than study specific information. They are available to users in the My Submission Forms menu item in the software found under My Assistant.
<input type="radio"/> Non Study Attachment/Sub Form	These forms are used to store information like compliance issues unrelated to a study. This form is NOT submitted to a review board, but is simply kept as a record. They are available to users in the My Submission Forms menu item in the software found under My Assistant.
<input type="radio"/> Annual Conflict of Interest Submission Form	This form is similar to a Non-Study Submission form and is designated for the purpose of conflict of interest disclosures.
<input type="radio"/> Conflict of Interest Study Disclosure Form	Conflict of Interest Study disclosure forms that are submitted to the review board.
<input type="radio"/> Conflict of Interest Project Disclosure Form	Conflict of Interest Project disclosure forms that are submitted to the review board.
<input type="radio"/> Conflict of Interest Non-User Specific Disclosure Form	This form is similar to a Non-Study Submission form and is designated for the purpose of non-user specific conflict of interest disclosures.
<input type="radio"/> Conflict of Interest Miscellaneous Disclosure Form	This form is similar to a Non-Study Submission form and is designated for the purpose of miscellaneous conflict of interest disclosures.

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.

System Form Designer - Non-User Disclosure Form ◀ Back

New Form Version
Goto Workflow Template
Export Form to XML
Save Section Order

Section List	Form Section List				
<ul style="list-style-type: none"> Edit/Save Form details Form Tool Tips Branching into Form Logic COI Match Rule Setup Fillable PDF Print Options View Form View Branching Form Database Details 	Expand Details	Remove Section	Edit	Section Order	Section Caption
	+	✖	✎	50	Business Transactions
	+	✖	✎	100	Inventory Disclosure Form
	+	✖	✎	200	Other Inventory Information

Define the form content using the tools available in the forms designer.

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

System Form Designer - Non-User Disclosure Form ◀ Back

+ Add COI Match Rule

Section List	Form COI Match rules used to determine the COI matched objects for COI review						
<ul style="list-style-type: none"> Edit/Save Form details Form Tool Tips Branching into Form Logic COI Match Rule Setup Fillable PDF Print Options 	Remove COI Match	Edit	Order	Name of Match Definition	Match Type	Type of Interest	Business Type
	✖	✎	5	Business Transaction	Conflict of Interest	Individual	Business Transaction
	✖	✎	10	Institutional Inventory	Conflict of Interest	Individual	Inventory

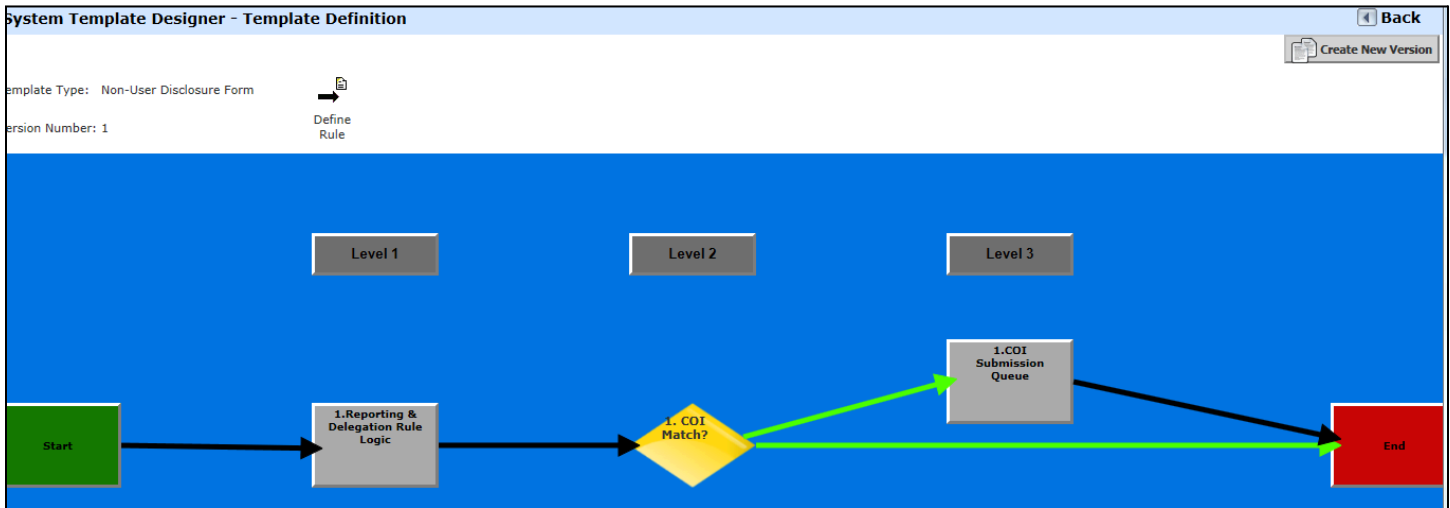
You will also need to define rules within COI Match Rule Setup.

System Form Designer - Non-User Disclosure Form ◀ Back

Save Form Setup Details

Section List	Define Form Usage Properties & Details		
<ul style="list-style-type: none"> Edit/Save Form details Form Tool Tips Branching into Form Logic COI Match Rule Setup Fillable PDF Print Options View Form View Branching Form Database Details 	Associate Access for Form:		
	Study Management and Review Boards	Create Form Access	Allow View Access
	Study/Protocol Management	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	ARC	<input type="checkbox"/>	<input type="checkbox"/>
	COI	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	IACUC	<input type="checkbox"/>	<input type="checkbox"/>
	IBC	<input type="checkbox"/>	<input type="checkbox"/>
	IRB	<input type="checkbox"/>	<input type="checkbox"/>
	Radiation Safety Committee (RSC)	<input type="checkbox"/>	<input type="checkbox"/>

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.

System Form Designer - Miscellaneous Disclosure

<p>Section List</p> <ul style="list-style-type: none"> Edit/Save Form details Form Tool Tips Branching into Form Logic COI Match Rule Setup Fillable PDF Print Options 	<p>Define Form Usage Properties & Details</p> <p>Form Type: Conflict of Interest Miscellaneous Disclosure Form</p> <p>Form Name: Miscellaneous Disclosure</p> <p>Form Abbreviation: RB#- null -<Version#>.<Revision#></p> <p>Form Order Number: 1</p> <p>Paging Increment: 50</p> <p>Use Section Numbering: <input checked="" type="radio"/> Yes <input type="radio"/> No</p> <p>Use Name Created: <input checked="" type="radio"/> Yes <input type="radio"/> No</p> <p>Use Date Created: <input checked="" type="radio"/> Yes <input type="radio"/> No</p>
--	--

System Form Designer - Form Definition

What type of form do you want to add?	Description of Form Type
<input type="radio"/> Submission Signoff Routing Form	Forms are used to customize a unique signoff page and designate its use towards a particular role and form.
<input type="radio"/> Non Study Submission Form	Forms of this type are designated for submitting information/issues to the review board that are not pertinent to any particular study. Generally they can be used for Financial Disclosures and other user specific rather than study specific information. They are available to users in the My Submission Forms menu item in the software found under My Assistant.
<input type="radio"/> Non Study Attachment/Sub Form	These forms are used to store information like compliance issues unrelated to a study. This form is NOT submitted to a review board, but is simply kept as a record. They are available to users in the My Submission Forms menu item in the software found under My Assistant.
<input type="radio"/> Conflict of Interest Study Disclosure Form	Conflict of Interest Study disclosure forms that are submitted to the review board.
<input type="radio"/> Conflict of Interest Project Disclosure Form	Conflict of Interest Project disclosure forms that are submitted to the review board.
<input type="radio"/> Conflict of Interest Miscellaneous Disclosure Form	This form is similar to a Non-Study Submission form and is designated for the purpose of miscellaneous conflict of interest disclosures.
<input type="radio"/> ARC Submission Form	This form is to submit any form for review by the Animal Resource Center(ARC).

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

System Form Designer - Miscellaneous Disclosure Back

New Form Version
Goto Workflow Template
Export Form to XML
Save Section Order

Section List	Form Section List				
<ul style="list-style-type: none"> Edit/Save Form details Form Tool Tips Branching into Form Logic COI Match Rule Setup Fillable PDF Print Options View Form View Branching Form Database Details 	Expand Details	Remove Section	Edit	Section Order	Section Caption
	+	-	✎	100	Travel Disclosure Information

Define the form content using the tools available in the forms designer.

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

System Form Designer - Miscellaneous Disclosure Back

+ Add COI Match Rule

Form COI Match rules used to determine the COI matched objects for COI review							
Remove COI Match	Edit	Order	Name of Match Definition	Match Type	Type of Interest	Business Type	
✖	✎	10	Misc Item	Conflict of Interest	Individual	Outside Activities Employed by Colleagues	

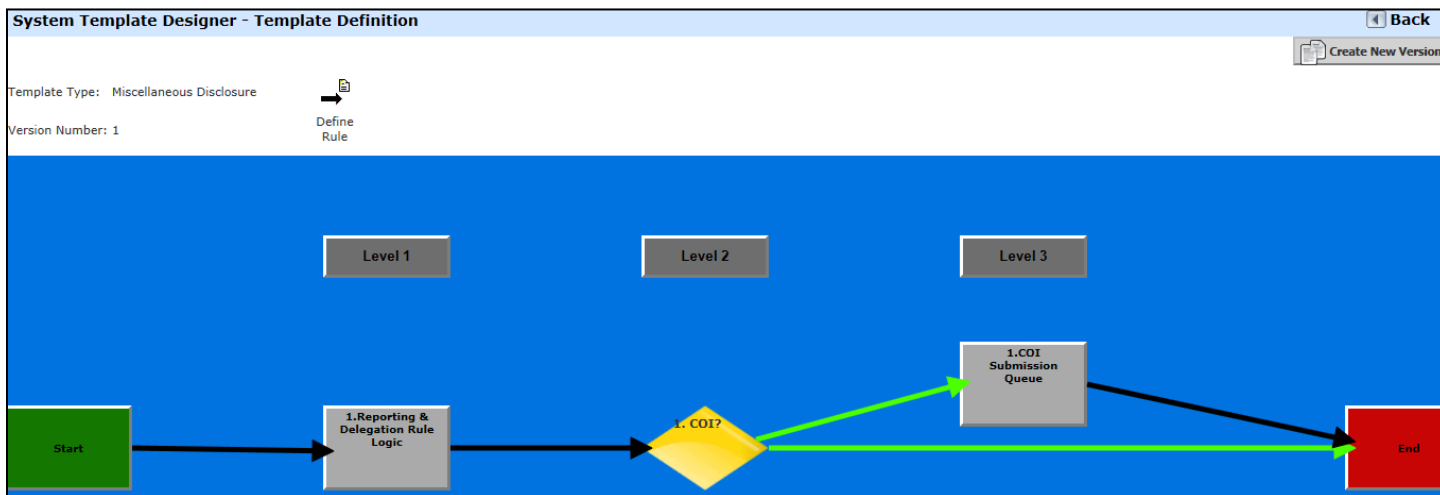
You will also need to define rules within COI Match Rule Setup.

System Form Designer - Miscellaneous Disclosure Back

Save Form Setup Details

Section List	Define Form Usage Properties & Details		
<ul style="list-style-type: none"> Edit/Save Form details Form Tool Tips Branching into Form Logic COI Match Rule Setup Fillable PDF Print Options View Form View Branching Form Database Details 	Associate Access for Form:		
	Study Management and Review Boards	Create Form Access	Allow View Access
	Study/Protocol Management	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	ARC	<input type="checkbox"/>	<input type="checkbox"/>
	COI	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	IACUC	<input type="checkbox"/>	<input type="checkbox"/>
	IBC	<input type="checkbox"/>	<input type="checkbox"/>
	IRB	<input type="checkbox"/>	<input type="checkbox"/>
	Radiation Safety Committee (RSC)	<input type="checkbox"/>	<input type="checkbox"/>
	Scientific Review Board: SRS	<input type="checkbox"/>	<input type="checkbox"/>
	Sponsored Research Assistant: C&C	<input type="checkbox"/>	<input type="checkbox"/>

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 forms 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.

System Form Designer - COI Study Disclosure Back

Save Form Setup Details

Section List	Define Form Usage Properties & Details		
Edit/Save Form details			
Form Tool Tips			
Branching into Form Logic			
COI Match Rule Setup			
Fillable PDF Print Options			
View Form			
	Associate Access for Form:		
	Study Management and Review Boards	Create Form Access	Allow View Access
	Study/Protocol Management	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	ARC	<input type="checkbox"/>	<input type="checkbox"/>
	COI	<input type="checkbox"/>	<input checked="" type="checkbox"/>

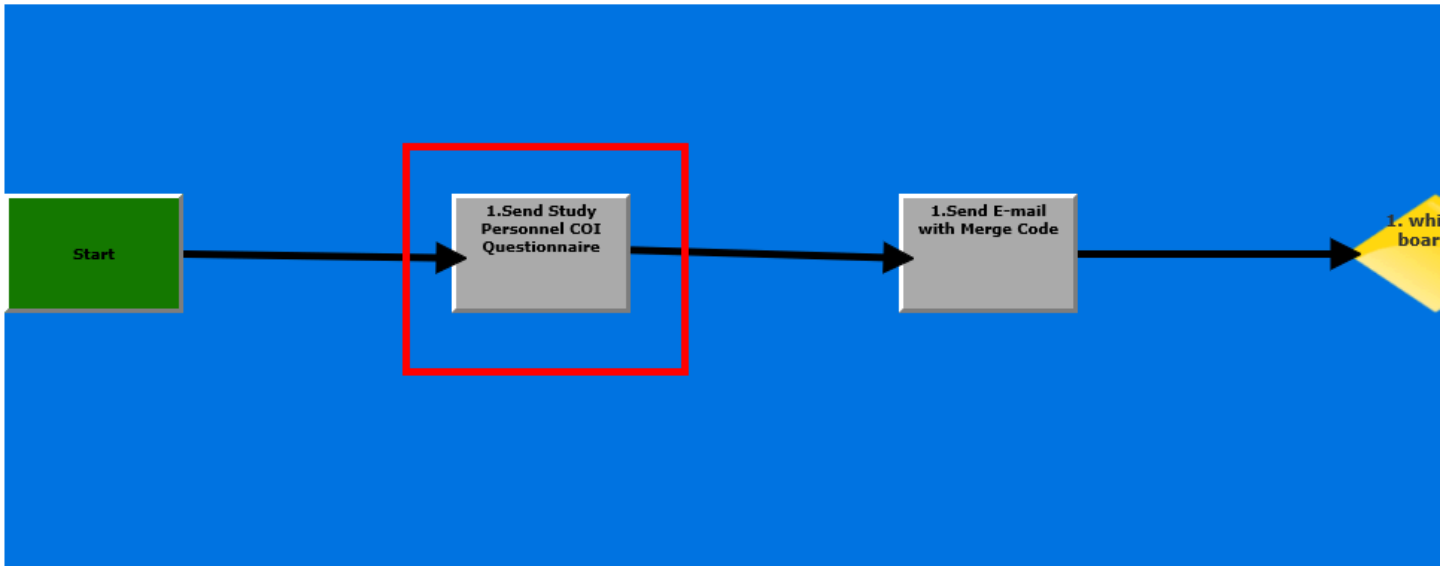
Within Edit/Save Form details, “Create Form Access” for Study/Protocol Management must be set to allow KSP to be able to create the form. “Allow View Access” must be set for COI.

If you wish for study personnel to fill out an 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.

System Template Designer - Template Definition

Template Type: iMedRIS Initial Review Submission Form

Version Number: 174



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.

Config Research Role ◀ Back

+ Add a New Role

Filter By Role Group: Find

Filter By In Use on Study: Yes No Both

Filter By In Use on Project: Yes No Both

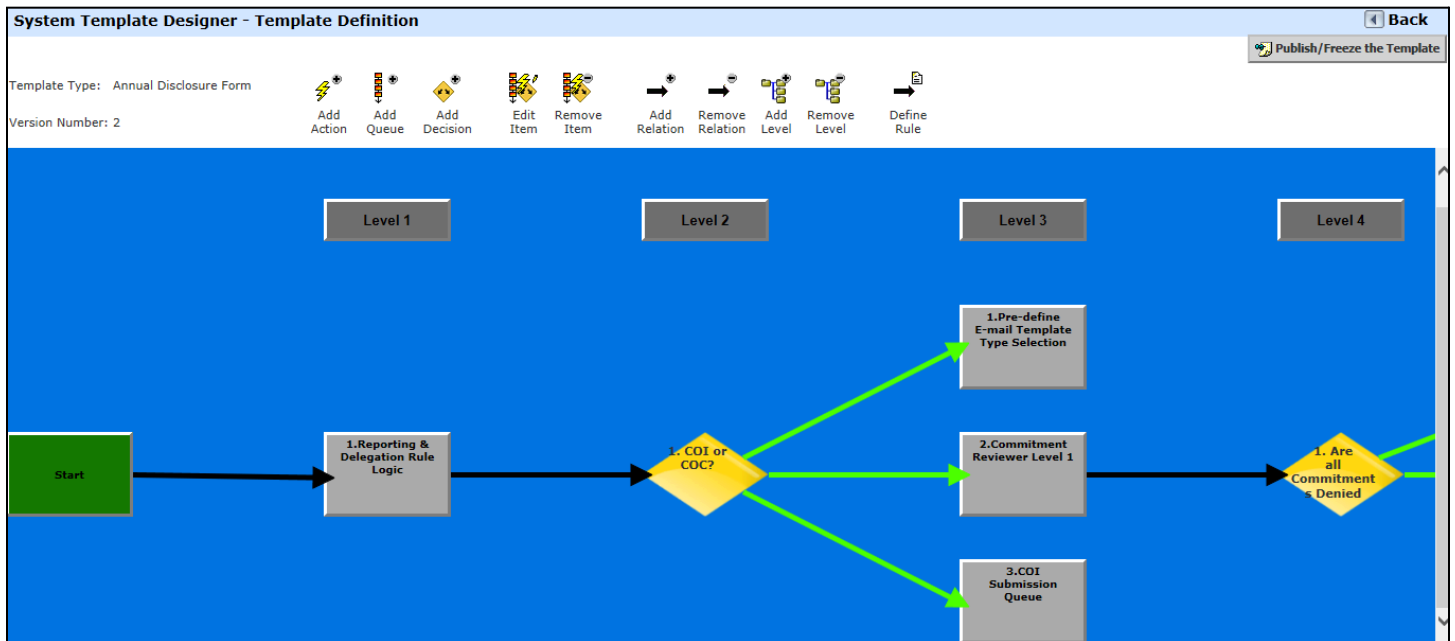
53 result(s) found... 1 - 10 ▶

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	No	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
			2	Investigator	Site Principal Investigator	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
			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	No	Yes	No
			4	Investigator	Collaborating Investigator	No	No	No	Yes	Yes	No	Yes	No	Yes	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 to indicate there is no conflict found.

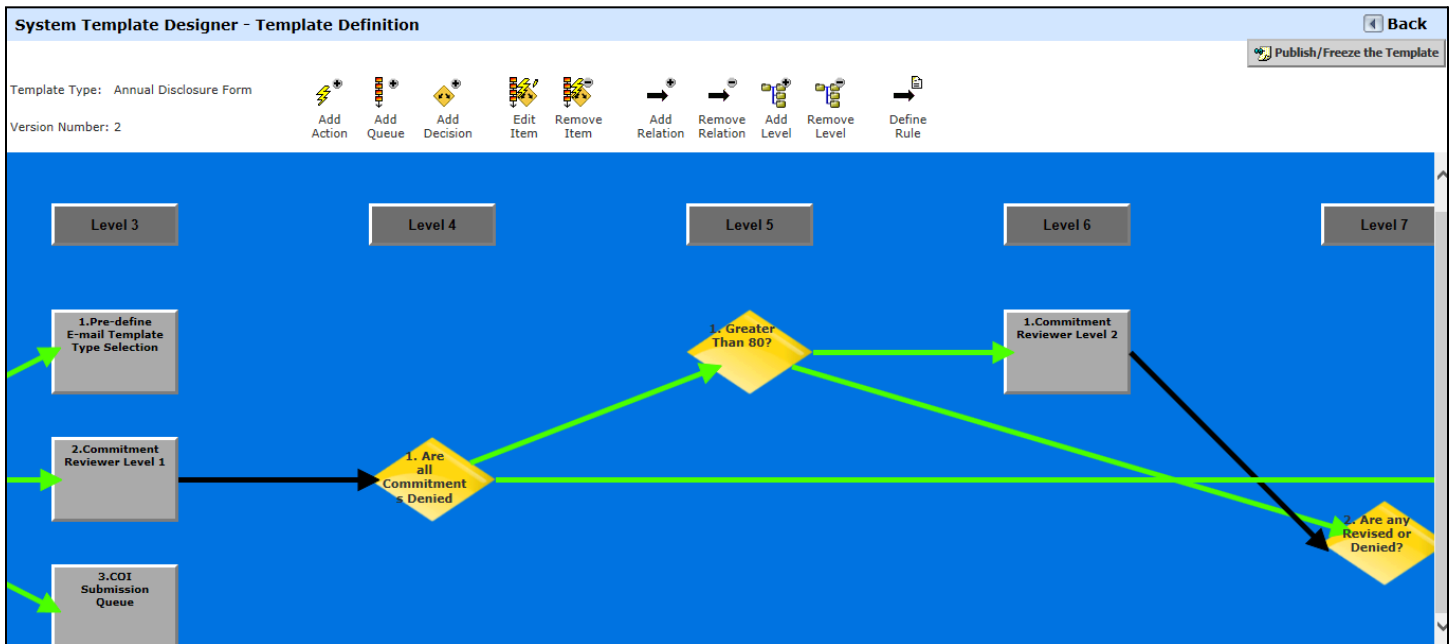
Conflict of Commitment – If the user indicated that one of their roles exceeds a certain percentage of time, the COI Annual form will branch down a path that will begin a Level of Effort review starting with Commitment Reviewer Level 1. This will allow a reviewer to look at the indication of time and 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 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:

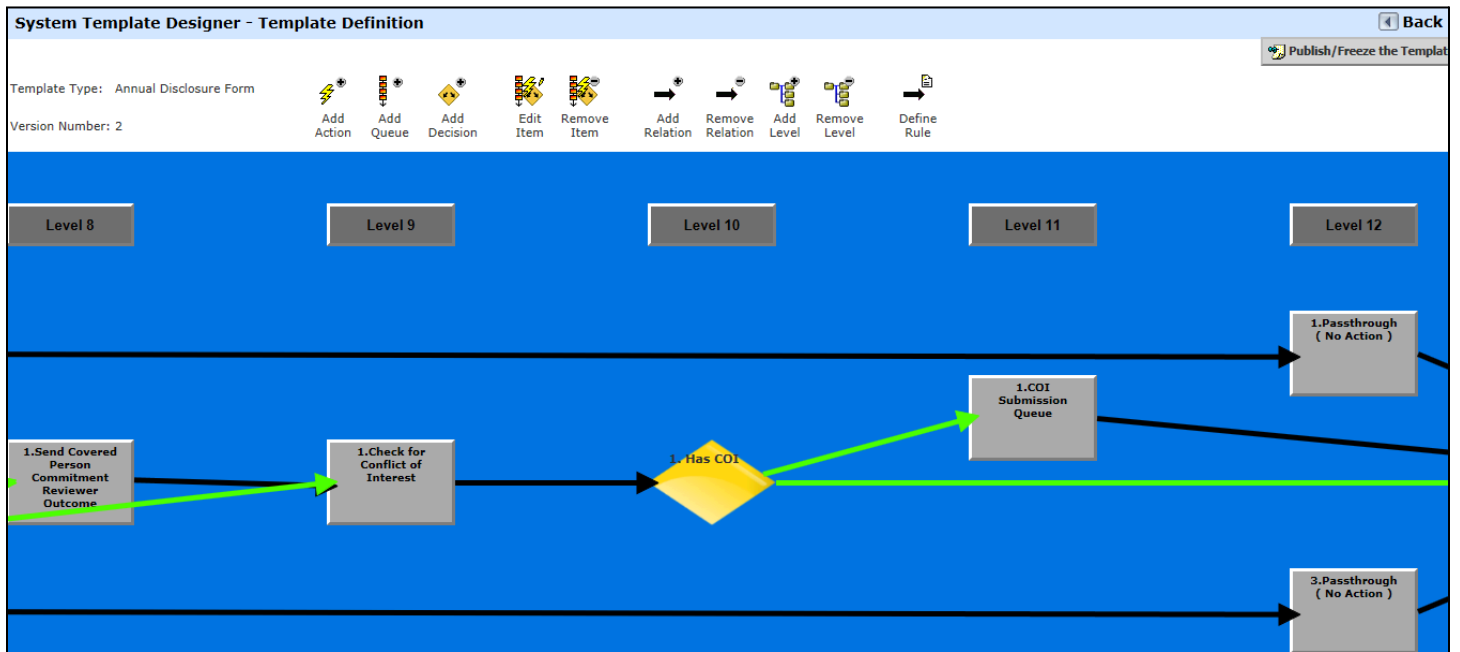


Level 4 – After the Commitment Reviewer has reviewed the match, they can either deny or approve it. If they deny the match, then the process will go to Level 8, to send the covered person the outcome (denied), which will mean they cannot conduct their project. The COI Annual will then check to see if 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.

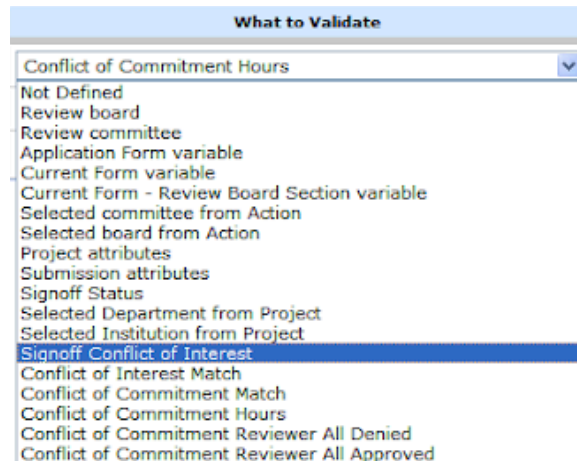
Commitment Reviewer Level 2 - This action is used with Conflict of Commitment reviews. This step in the workflow will look at the user’s defined Reviewer 2 and assign the form to that person for review.

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

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.