CONFLICT OF INTEREST ASSISTANT

For Covered Persons: Completing and Submitting the Annual COI

Version 11.02

Contents

Conflict of Interest – Annual COI Submission

Completing and Submitting the Annual COI and Commitment Reporting Form of Individuals

This manual will guide you through the process of filling out the **Annual COI Disclosure Form**. Note: The name of your Institution's Annual COI Form may be different than what is used in this manual. The Annual COI and Commitment Reporting Form for Individuals, or the Annual COI for short, is the form you will fill out on a yearly basis to report any financial or effort interests you may have.

Covered persons will see the Conflict of Interest Forms menu on their iRIS home screen and will be able to access the Annual COI form from this menu.
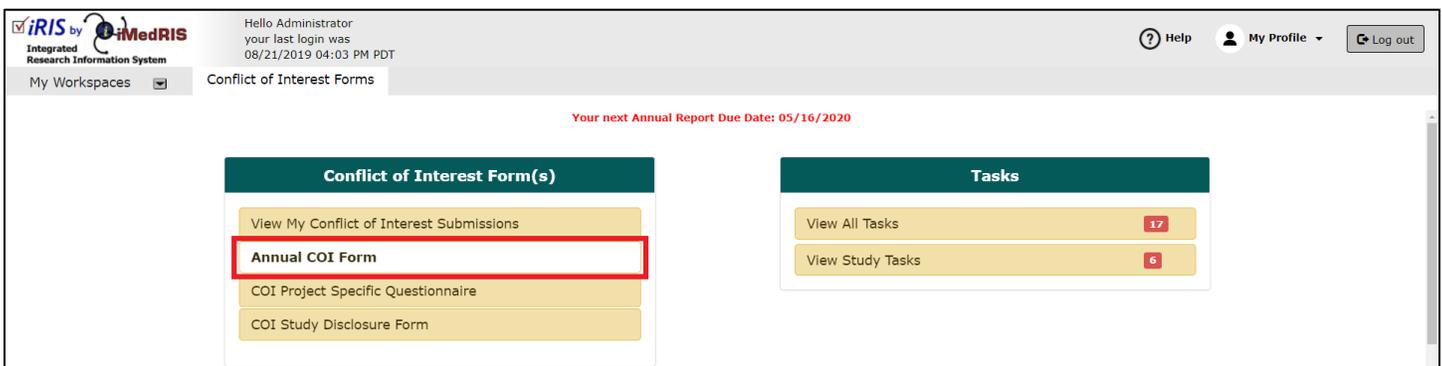
Clicking on the Annual COI and Commitment Reporting Form menu item will bring you to the following screen:
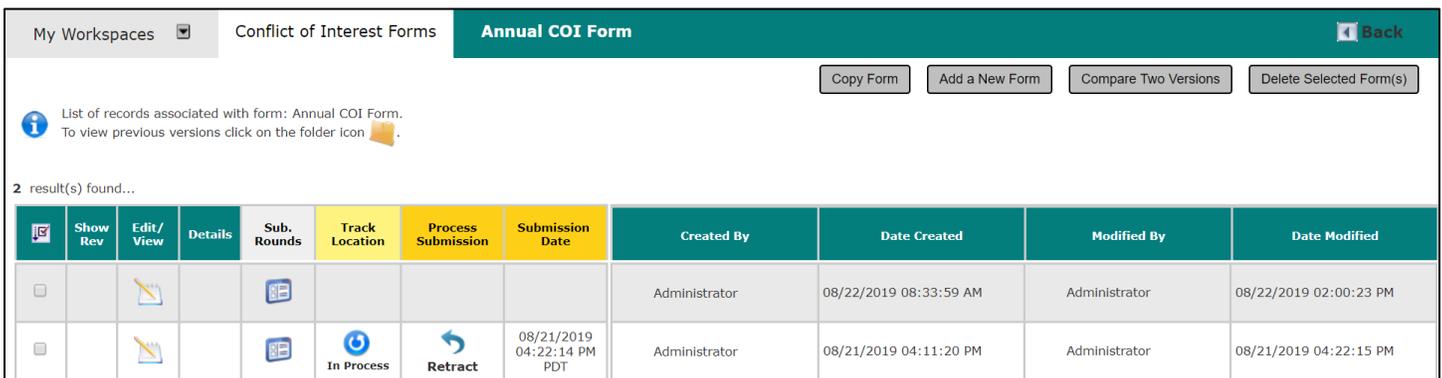
This screen will list any previously started, submitted or completed Annual forms you have filled out if you have any. The header of the page contains buttons to allow you to copy a previous Annual COI form, Add a New Form, Compare Two Versions, or Delete a form (provided it has not been submitted for review).

The table below the buttons lists any form that has already been started.

The Checkbox column is used to copy, compare and delete a form. Click the checkbox next to the form(s) to delete, and then click the **Delete Selected Form(s)** button.

Show Rev – If a form has been revised for corrections coming from a management plan, a folder will appear in this column. You can click on it to see the previous versions of the Annual COI. You will be able to open the previous

submission, but it will be read only as that version has been submitted previously. You can also compare the differences between two versions of the same form by clicking the checkboxes and then clicking the **Compare Two Versions** button.

Edit/View – Click on this icon to continue to work on a form you have already started but have not completed yet, or to view a form that has been submitted previously.

Sub. Rounds – Click this button to see the number of times this particular form has been sent back and forth for corrections.

Track Location - If a form has been submitted, this column will populate with the current status of the form. You can click on the text to view detailed information about the steps the form has taken since it was submitted.

Process Submission – This column will populate with the submission process.

Submission Date – Will display the date and the time that the submission was submitted.

Created By – Will display the User ID of the person who created the form.

Date Created – Will display the date and the time the form record was created.

Modified By – Will display the User ID of the person who last modified the form.

Date Modified - Will display the date and the time the form record was last modified.

Note: Created By, Date Created, Modified By, and Date Modified can all be turned off in the System Form Designer. Other columns from the Annual COI form can be turned on in their place. See the System Admin - Form Designer Manual for more details on displaying columns in the form table.

Workflow – Submission Tracking

Any steps that are still in process will be displayed at the top of the list with the status in the left most column. The steps that are completed will be displayed with the status of *Completed*. Once a step has moved from *In Process* to *Completed* the step will order by the date/time stamp. If any step was cancelled, the status will revert back to the last status, if applicable.

The date the process was created and completed are displayed in the **Date Created** and **Date Completed** columns. The **Task Name** will display the description of the process. You can also respond to the task by clicking on buttons that may appear under **Task Action/Details.** Each item in this table can be expanded to show more details about the Event Description. This can be done by clicking the expand button:

Task Status	Task Action/Details	Task Name		Date Created	Date Completed	Total Time
⊞ Pre-Submission			Retract Submission	08/21/2019 04:22 PM PDT	08/21/2019 04:22 PM PDT	**0** Day(s) **0** Hour(s) **0** Minute(s)
⊟ **Conflict of Interest**				08/21/2019 04:22 PM PDT		**0** Day(s) **0** Hour(s) **0** Minute(s)
Received		Conflict of Interest received the submission		08/21/2019 04:22 PM PDT		Day Hour Minute 0 0 0

This will cause the item to appear as so:

Task Status	Task Action/Details	Task Name		Date Created	Date Completed	Total Time
⊞ Pre-Submission			Retract Submission	08/21/2019 04:22 PM PDT	08/21/2019 04:22 PM PDT	**0** Day(s) **0** Hour(s) **0** Minute(s)
⊟ **Conflict of Interest**				08/21/2019 04:22 PM PDT		**0** Day(s) **0** Hour(s) **0** Minute(s)
Received		Conflict of Interest received the submission		08/21/2019 04:22 PM PDT		Day Hour Minute 0 0 0

To minimize this view, simply click on the small collapse ⊟ button.

My Conflict of Interest Manager

The My Conflict of Interest Manager is a variant of the form library described above that can be turned on under System Administration > System Configuration > Reserved Settings > system.use_coi_my_disclosure_link. The name of the My Conflict of Interest Manager is determined by the name of the Annual COI form itself. If you change the name of the form under System Form Designer > Edit/Save Form Details to My Conflict of Interest Manager, this is what will display from your home screen menu.

The My Conflict of Interest Manager contains the following columns:

Selection – This column is used to select form versions for deletion, copying, and comparisons between versions.

View History – If a form has more than one version, a folder will appear in this column. When the folder is expanded, previous versions of the form will display.

Edit/View – Click the icon in this column to open the disclosure form. If the form has not yet been submitted, it will still be editable.

Version – Every new form or revision of a form in iRIS, will create another version. For a created revision of a form the number will increase after the decimal. For a new form, the number before the decimal will increase. For example, if you have two forms, 1.0 and 2.0, in the system, then by clicking **Add Revision** on form 2.0 that was processed and

completed, a new form 2.1 will be created. If the button **Add a New Disclosure** is selected, then the new form 3.0, will be created.

View Details – Clicking the expand icon will allow you to view the details of any conflict matches that were generated when the disclosure form was completed (to be discussed further).

Track Location – If a form has been submitted, this column will populate with the current status of the form. You can click on the text to view detailed information about the steps the form has taken since it was submitted.

Process Submission – Allows you to see the current status of the submitted form:

> **Send** – When a form is filled out and can be submitted, this icon will display. When clicked, you will be brought to the signoff page for the form.

> **In Process** – Once the form has been submitted, this icon will populate.

> **Retract** – When a form has been submitted for review, but has not been processed yet, you can choose to "retract" the submission and revise it.

> **Complete** – When the matches associated to the form have been processed by the COI office and completed, the column will update to this icon.

Submission Date – Indicates the date that the form was submitted.

Preliminary Request – This form will populate with a value from the disclosure form if you have indicated that you are requesting a preliminary review of a potential interest, activity, or contract.

Date Created – Indicates the date the form was created.

Date Modified – Indicates the last time the form was modified.

Create Revision – Click the icon in this column to create a revision of the Annual Disclosure form.

A primary feature of the My Conflict of Interest Manager is the ability to view details of any conflict matches generated when the form was submitted. Click the Expand icon in the View Details column.

	View History	Edit/ View	Version	View Details	Track Location	Process Submission	Submission Date	Preliminary Request	Date Created	Date Modified	Create Revision
☐		✎	6.0	⊟	✔	✔ Complete	08/22/2019 09:14:05 AM PDT		08/22/2019 08:35:09 AM	08/22/2019 09:14:05 AM	Add Revision

Nature of Outside Activity/ Interest	Status	Outside Entity	Type of Activity	Current Value or Income Received in Last 365 Days	Date Last Compensation Received	Annual Outside Time Commitment	Related Research	Approved by Supervisor(s)?	Written Agreement with Outside Entity	Agreement Approved by OGC?	Approved By COI?	Management Plan
No Conflict Matches have been created.												

A description of the columns is as follows:

Nature of Outside Activity/Interest – This pulls in the business type, as defined by the Conflict of Interest & Commitment Match Rules that generated the conflict match.

Status – This pulls in the value of the Disclosure Status for the match, as defined on the Outcome tab of the Conflict Match processing screens.

Outside Entity – This displays the business associate associated with the match (Conflict of Interest Business Associate data value).

Type of Activity – Displays the nature of activity associated with the match, if applicable (Nature of Activity List data value).

Current Value or Income Received in Last 365 Days – Displays the value/income entered for the match, if applicable (Dollar Amount Configuration List data value).

Date Last Compensation Received – Displays the date selected from the Compensation Date data value, or "Don't Know," if applicable.

Annual Outside Time Commitment – Displays the value selected from the Time Commitment data value, if applicable.

Related Research – If there is matching study information, the associated IRB number, Study Title, and Covered Person's role on the study will be displayed.

Approved by Supervisors – This column is related to Conflicts of Commitment generated by the form. This column will display "Yes," "No," or "N/A". "Yes" displays if all assigned Commitment Reviewers have approved the commitment match. "No" displays if the match has indicated a Conflict of Commitment and has been routed for review, but the review is not complete or has been denied. "N/A" displays if the match is not a Conflict of Commitment.

Written Agreement with Outside Entity – This column will link to the document uploaded in the Written Agreement data value, if applicable.

Agreement Approved by OGC? – This column displays the Office of General Counsel outcome from the Outcome tab of the Conflict Match processing screens.

Approved by COI - This column will display "Yes" or "No". "Yes" displays if the Conflict Match has been submitted to the COI board and has been completed. "No" displays if the Conflict Match has been submitted to the COI board and has not been completed.

Management Plan – If a Management Plan has been generated for the Conflict Match, a link to the PDF will appear here.

Filling out your Disclosure Form

To start a new Annual COI form, click the **Add a New Disclosure** button. This will initiate the Annual COI form. Depending on the form's configuration in your system, the Annual COI form you see may not be configured exactly like the one in this manual.

At the top left of the form, the name of the Covered Person will populate. Later, when this form is submitted, the Reference Number will also populate in this area.

As you navigate through the Annual COI form, additional sections will populate in the Section view of the Form when you click the **Continue** button on the top right of the screen. Typically, the first section will display the instructions for the Annual COI from. At any point in the process, you can click the **Print Friendly** button to open a new page that will list out the form in a printable format.

Some of the text is bold, underlined, and green. You can hover your mouse over these links for additional information. These links are configurable in the System Form Designer. After reading the instructions, click the **Continue** button to proceed to the next section.

Notice that as you move through the form, the navigation builds to the left of the form. At any time during the completion of the form, you can navigate back to previously completed sections by clicking on the particular section in the navigation pane.

The Background Information section of the Annual COI form will list any current positions you are associated to within iRIS and will allow you to check off any additional positions that are not listed. The roles listed on this page can be configured in the COI Assistant's Review Board Administration.

Make any additional role selections and click the **Continue** button.

Note: As you work in each section of the form, you may click the **Save Section** button to save your work within the section and either exit the form to return later or continue working within the section.

Depending on the role configurations, selecting certain roles on this page will trigger a series of Form 990 questions later in the form.

After the Background Information section, you will be presented with a series of sections that ask for specific interests you or a related person may have with certain biomedical or non-biomedical third parties, compensation, intellectual property interests, etc. Each section will ask a different question regarding a specific interest, with detail provided and hover help available for certain key words.

When you answer "Yes" to a question within a section, additional questions will populate within the section related to the specific interest.

Begin filling in the values. You might be asked to identify the Biomedical third party. Type in part of the third party name, and a list of matching Sponsors will populate in a list below the field so you can select the Sponsor. If the name of your third party is not in the list, the system will allow you to click in the field and enter the name of your third party.

Other fields will prompt you for additional information.

The example above shows that if > $100,001 is selected, the amount must be specified in the field below. You will not be presented with this field unless > $100,001 is selected.

If more than one interest is associated with a question, you can add additional entries by clicking the button **Click here to add another entry** to open another Entry tab.

This will cause a second entry to be created in the section, containing the same questions as the first entry. If you created the entry by mistake, you can click on the button **Click Here to Delete this entry** to remove it from the section. You can add as many entries as needed. When you are finished, click the **Continue** button to proceed to the next section.

You will continue to be asked a series of questions about specific interests that will help identify if you have a conflict of interest with any sponsor or project in the system. For each section that you indicate "Yes" in, the system will flag that you indicated an interest and will report that information to the Conflict of Interest board upon submission of the Annual form.

After navigating through the Annual COI form you will be able to initiate the signoff process so the form can be submitted for review. Depending on your system settings and the configuration of the form you are filling out, you will be brought to the Electronic Signature Required screen and will see this message before navigating to the signoff page. Click the **Signoff and Submit** button to start the signoff process.

When you click **Signoff and Submit** you will be presented with a Submission Routing Signoff sheet. This page will list the following information:

Submission Reference Number – Lists the reference number of this Annual form. This is a unique number in the system. No other form will have this number and it will be a means of identifying this form.

Submission Form(s) – Lists all the components of the submission, including documents the user might have uploaded. You are also able to check different components and then include them into a PDF packet and can create a printable version by clicking on the button **Printable Version.** You can also click into the submission by clicking on the name of the Submission Component Name.

Electronic Signature – For iRIS to successfully apply the electronic signature, you must provide your User ID and password. No other user can apply the signature. This is also a configured setting, your system may or may not require you to submit an electronic signature.

After you complete your signoff, you are able to check the status and location of your submission by going to the homepage and clicking on "Steps" under the Conflict of Interest Submission Status Panel to see the workflow and history of the submission. In this panel, if you click the button to expand the panel, you can respond to, view, or track the status of your submission.

Reference Number	Form Name	Date Submitted	Actions
023326	**My Conflict of Interest Manager**	08/23/2019 08:34 AM PDT	Steps

Pre-Submission

Task Status	Task Action/Details	Task Name	Date Created	Date Completed	Total Time
⊟ **Pre-Submission**	Retract Submission		08/23/2019 08:34 AM PDT		**0** Day(s) **0** Hour(s) **0** Minute(s)
Completed	View Signoff	Admin Admin admin, Ph.D. Brig. Gen. as Submitter review and apply signoff, assigned by Admin A admin, Ph.D. Brig. Gen.	08/23/2019 08:34 AM PDT	08/23/2019 08:34 AM PDT	Day Hour Minute 0 0 0
Completed		Send Predefined Email	08/23/2019 08:34 AM PDT	08/23/2019 08:34 AM PDT	Day Hour Minute 0 0 0
Completed		Send Predefined Email	08/23/2019 08:34 AM PDT	08/23/2019 08:34 AM PDT	Day Hour Minute 0 0 0
Completed		Send Email with Submission Forms	08/23/2019 08:34 AM PDT	08/23/2019 08:34 AM PDT	Day Hour Minute 0 0 0

Responding to a Management Plan

Click to open	Task Type	Received	Description
☐		Respond to Conflict Management Plan	08/21/2019 10:13 AM PDT	Conflict of Interest returned the submission with the outcome of Approved with Conditions

If the COI Office sends a response to your COI submission, you will receive a task on your home page under the Respond to Conflict Management Plan group.

My Workspaces ▼	Conflict of Interest Forms	**Management Plan Response**	◄ Back

Return Management Plan Response

Response to Conflict of Interest Management Plan:	Administrator
Matched Object Number/Group Name:	000336

┌ Management Plan Document ─────────────────────

Click to open the Management Plan	Management Plan Title
📄	COI Notification to Review Your Management Plan 2

┌ Outcome Letter ─────────────────────

Click to open the letter	Letter Title
📄	COI Notification 1

┌ Management Strategies ─────────────────────

1.   Please report weekly changes in stock owned.

* Do you accept the Management Strategy? (provide explanation)

--none-- ▼   Details ...

By providing your electronic signature, you indicate you will

Clicking on the task will open a Management Plan Response page. This page will list out any Management Plan Document and Outcome Letter generated, Management Strategies, and allow you to provide feedback.

To view any Management Plan or Outcome letter, click on the PDF icon in either the Management Plan Document or Outcome Letter table.

Any Management Strategies from the COI Office will appear in the Management Strategies table.

The COI Office will need you to respond to each strategy in the table. You can respond by selecting an option from the dropdown list, and then provide any additional details, if necessary, by clicking the **Details** button. This will open a new page with a text editor allowing you to type in or copy and paste your text.

After responding to the strategies, you will need to apply your electronic signature in the fields provided at the bottom of the page. Enter your User ID and Password.

The last step is to save this page by clicking **Return Management Plan Response**. Once you save the page, the system will notify the COI Office of your response to the Management Plan Response.