



CONFLICT OF INTEREST ASSISTANT

For Covered Persons: Completing and Submitting the Annual COI

Version 10.03.02

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Conflict of Interest – Annual COI Submission

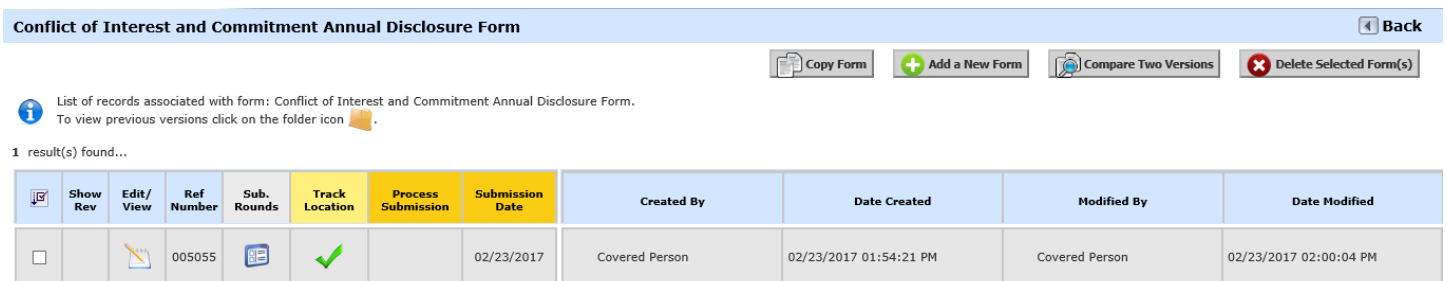
Completing and Submitting the Annual COI and Commitment Reporting Form of Individuals

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 or completed Annual forms you have filled out. 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.

Ref Number – For every form that is submitted in iRIS, a unique number is assigned to that form, called the Reference Number. Each Annual COI form that is submitted will get assigned a unique reference number.

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.

Workflow – Submission Tracking

Workflow - Submission Tracking				
Status	View Details	Date Received / Date Completed		Event Description
✓		10/18/2012 08:35 AM PDT 10/18/2012 08:36 AM PDT	⊕	All of the signoffs for the Management Strategy outcome letter have been completed.
✓		10/17/2012 04:15 PM PDT 10/17/2012 04:15 PM PDT	⊕	COI received the submission
✓		10/17/2012 04:11 PM PDT 10/17/2012 04:15 PM PDT	⊕	COI User, MD as Submitter review and apply signoff
✓		10/17/2012 04:06 PM PDT 10/17/2012 04:11 PM PDT	⊕	Annual COI and Commitment Reporting Form is waiting to be submitted

Any steps that are still in process will be displayed at the top of the list with the status of **In Process**. 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 be cancelled and the red X Cancel icon will be displayed.

The date the process was received is displayed in the **Date Received/Date Completed** column. The **Event Description** will display the description of the process. 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:

✓		02/23/2017 02:38 PM PST 02/23/2017 02:38 PM PST	⊕	COI received the submission
---	--	--	---	-----------------------------

This will cause the item to appear as so:

✓		02/23/2017 02:38 PM PST 02/23/2017 02:38 PM PST	⊖	<table border="1"> <tr> <td>COI received the submission</td> <td></td> </tr> <tr> <td>Submission Type:</td> <td>Conflict of Interest and Commitment Annual Disclosure Form</td> </tr> <tr> <td>Reference Number:</td> <td>005057</td> </tr> </table>	COI received the submission		Submission Type:	Conflict of Interest and Commitment Annual Disclosure Form	Reference Number:	005057
COI received the submission										
Submission Type:	Conflict of Interest and Commitment Annual Disclosure Form									
Reference Number:	005057									

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

If the details of a step can be viewed, an icon will be displayed under the **View Details** column. Select the icon to view the event details. Select the **Back** button to return to the Workflow Tracking.

Annual Disclosure Form Back										
Copy Form Add a New Form Compare Two Versions Delete Selected Form(s)										
<p>List of records associated with form: Annual Disclosure Form. To view previous versions click on the folder icon </p>										
1 result(s) found...										
	Show Rev	Edit/View	Ref Number	Sub. Rounds	Track Location	Process Submission	Submission Date	Created By	Date Created	Modified By
<input type="checkbox"/>			000025				07/14/2015	Susan Investigator	07/14/2015 10:18:03 AM	Susan Investigator

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

Created By – Will display the name of the user who created the form record.

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

Modified By – Will display the name of the user who last modified the form record.

Date Modified - Will display the date and 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.

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.

System Form Designer - Conflict of Interest and Commitment Annual Disclosure Form Back

Save Form Setup Details

<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 View Form View Branching Form Database Details 	<p>Define Form Usage Properties & Details</p> <p>Form Type: Conflict of Interest Annual Form</p> <p>Form Name: My Conflict of Interest Manager x</p> <p>Form Abbreviation: RB#- null</p> <p>Form Order Number: 1</p> <p>Navigation Name: coi form</p> <p>Use Routing Signoff Sheet: <input type="radio"/> Yes <input checked="" type="radio"/> No</p> <p>Control Locking of Form: <input type="radio"/> Yes <input checked="" type="radio"/> No</p>	<p>Paging Increment: 50</p> <p>Use Section Numbering: <input type="radio"/> Yes <input checked="" 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> <p>Use Name Modified: <input checked="" type="radio"/> Yes <input type="radio"/> No</p> <p>Use Date Modified: <input checked="" type="radio"/> Yes <input type="radio"/> No</p> <p>Use Reference: <input checked="" type="radio"/> Yes <input type="radio"/> No</p>	<p>Use Wizard: <input type="radio"/> Yes <input checked="" type="radio"/> No</p> <p>Display Form Option for New Study: <input type="radio"/> No <input checked="" type="radio"/> Yes</p> <p>Validate by Section: <input checked="" type="radio"/> Yes <input type="radio"/> No</p> <p>Use Numbering: <input type="radio"/> No <input checked="" type="radio"/> Yes</p> <p>Does Receipt Satisfy Continuing Review Notification: <input type="radio"/> No <input checked="" type="radio"/> Yes</p>
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- Conflict of Interest Forms
- Project Assistant
- Study Assistant

My Conflict of Interest Manager

Pin Conflict of Interest to Content Dashboard

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.


Ref. Number – For every form that is submitted in iRIS, a unique number is assigned to that form, called the Reference Number. Each Annual COI form that is submitted will get assigned a unique reference number.


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.

 **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	Ref Number	View Details	Track Location	Process Submission	Submission Date	Preliminary Request	Date Created	Date Modified	Create Revision
<input type="checkbox"/>			1.1	005059			 In Process	02/23/2017		02/23/2017 03:54:27 PM	02/23/2017 03:55:44 PM	 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
Equity Interests in Biomedical or Healthcare Entities		Sponsor		> \$100,001				N/A			No	

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.

Covered Person: Investigator, Susan
Reference Number:

Annual Disclosure Form

Print Friendly Refresh Constant Fields Save Section Continue

Section view of the Form Entire view of the Form

Instructions

Instructions

1. This Form must be completed by you as required by the [General Hospital \(GH\) Conflicts of Interest/Commitment policies](#). This Form has been developed to help GH identify situations that could create a [Conflict of Interest](#) and/or [Conflict of Commitment](#).
2. Before you complete this Form, you should take reasonably diligent steps to determine the existence, nature, and scope of your actual and potential [Interests](#). To the extent this Form asks you questions about the actual and potential [Interests](#) and [Commitments of Related Persons](#), you are not required to undertake any additional fact-gathering and only need to report what you already know.
3. In general, if you are unsure about whether information is responsive to a question, you should err on the side of reporting it.
4. If you have any questions regarding how to complete this Form, please contact Greg Thompson at gthompson@gh.org

Depending on what you have to report, this Form takes approximately 20 minutes to complete. At any time you may save your work and return to finish and submit it.

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 form. 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.

on view of the Form Entire view of the Form

Instructions

Instructions

A situation where a Commitment inappropriately interferes with your professional obligations to GH.

This Form must be completed by you as required by the [General Hospital \(GH\) Conflicts of Interest/Commitment policies](#). This Form has been developed to help GH identify situations that could create a [Conflict of Interest](#) and/or [Conflict of Commitment](#).

Before you complete this Form, you should take reasonably diligent steps to determine the existence, nature, and scope of your actual and potential [Interests](#). To the extent this Form asks you questions about the actual and potential [Interests](#) and [Commitments of Related Persons](#), you are not required to undertake any additional fact-gathering and only need to report what you already know.

3. In general, if you are unsure about whether information is responsive to a question, you should err on the side of reporting it.

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.

Covered Person: Investigator, Susan
Reference Number:

Annual Disclosure Form

-
-

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

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.

Covered Person: Investigator, Susan
Reference Number:

Annual Disclosure Form

-
-
-

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

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.

Covered Person: Investigator, Susan
Reference Number: **Annual Disclosure Form**

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

Section view of the Form | **Entire view of the Form**

- Instructions
- Background Information
- Investments with Biomedical Third Parties**

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](#)

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

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](#)

Begin filling in the values. You will 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.

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: [We are not finding a company name match. Please click here to enter.](#)

Click on the message that appears below the Biomedical third party field.

The page will refresh. Other will be identified as the third party, and a new field will populate below, allowing you to type in 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 at the bottom of the Entry 1 information.

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 red X icon on the top right of the 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.

Covered Person: Investigator, Susan
Reference Number: **Annual Disclosure Form**

Print Friendly Refresh Constant Fields Save Section Continue

Section view of the Form **Entire view of the Form**

- Instructions
- Background Information
- Investments with Biomedical Third Parties
- Investments with Non-Biomedical Third Parties**

Investments with Non-Biomedical Third Parties

Do you or a [Related Person](#) have an investment interest in any [non-Biomedical](#) third parties?
You do not need to report investments that are in:
a: publicly held mutual funds or
b: publicly traded securities that represent less than 5% of the total ownership in the company.

Yes No

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.

My Conflict of Interest Manager - (Version 2.0)

Print Friendly Signoff and Submit

Entire view of the Form

Electronic Signature Required

Signoff and Submit

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, you will be brought to the Electronic Signature Required screen. Click the **Signoff and Submit** button to start the signoff process.

Submission Routing Signoff [Back](#)

Submission Reference Number: 005060

Electronic Signature: This form requires your electronic signature. Enter the User ID and Password that you used to access the Ethics Management System.

By entering my User ID and Password, I certify that the statements I have made on this form and all attached statements are true, complete, and correct to the best of my knowledge.

UTN:

Password:

[Submit](#)

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.

User ID and Password – For iRIS to successfully apply the electronic signature, you must provide your ID and password. No other user can apply the signature.

Submission Complete [Back](#)

Thank You!
Your submission is now completed.
Please download a copy of your submission below and keep it for your records.

[Download](#)

[Logout](#)

After you complete your signoff, you will be brought to a screen where you can download a copy of the form for your records and/or log out of the system. This will show that the Conflict of Interest board received your submission. If you click the **Back** button, you will then be brought back to the **My Conflict of Interest Manager** page. If you wish to view the workflow routing for the form you just submitted, click the green checkmark icon in the Track Location column.

Workflow - Submission Tracking ◀ Back				
Print Friendly				
Status	View Details	Date Received / Date Completed		Event Description
✓		02/24/2017 10:01 AM PST 02/24/2017 10:01 AM PST		COI received the submission
✓		02/24/2017 10:01 AM PST 02/24/2017 10:01 AM PST		Send Predefined Email
✓		02/24/2017 10:01 AM PST 02/24/2017 10:01 AM PST		Send Email with Submission Forms
✓		02/24/2017 09:57 AM PST 02/24/2017 10:01 AM PST		Covered Person as Submitter review and apply signoff

Responding to a Management Plan

◀ Welcome Covered Person (*Last Login: 02/23/2017 03:13 PM PST*)

Below are your incomplete Conflict of Interest tasks:

Respond to Conflict Management Plan				1
1 task(s) found...			1 - 1	
Open	Covered Person	Task Name	Annual COI Due	Received
	Covered Person	COI returned the submission with the outcome of Management Plan	02/28/2017	02/24/2017

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.

Conflict of Interest Management Plan Response


[Back](#)

[Return Management Plan Response](#)


Response to Conflict of Interest Management Plan: Susan Investigator

Matched Object Number/Group Name: 000022

Management Plan Document

Click to open the Management Plan	Management Plan Title
	Management Plan Letter

Outcome Letter

Click to open the letter	Letter Title
	Approval with Management Plan

Management Strategies

1. Adhere to xyz

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

--none--

2. Report findings every 3 months.

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

--none--

By providing your electronic signature, you indicate you will follow the Management Plan

User ID:
 Password:

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.

Management Strategies

1. Adhere to xyz

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

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.

By providing your electronic signature, you indicate you will follow the Management Plan.	User ID: <input type="text"/>
	Password: <input type="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.