



## CONFLICT OF INTEREST ASSISTANT

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*For Covered Persons: Completing and Submitting the Annual COI*

Version 11.02

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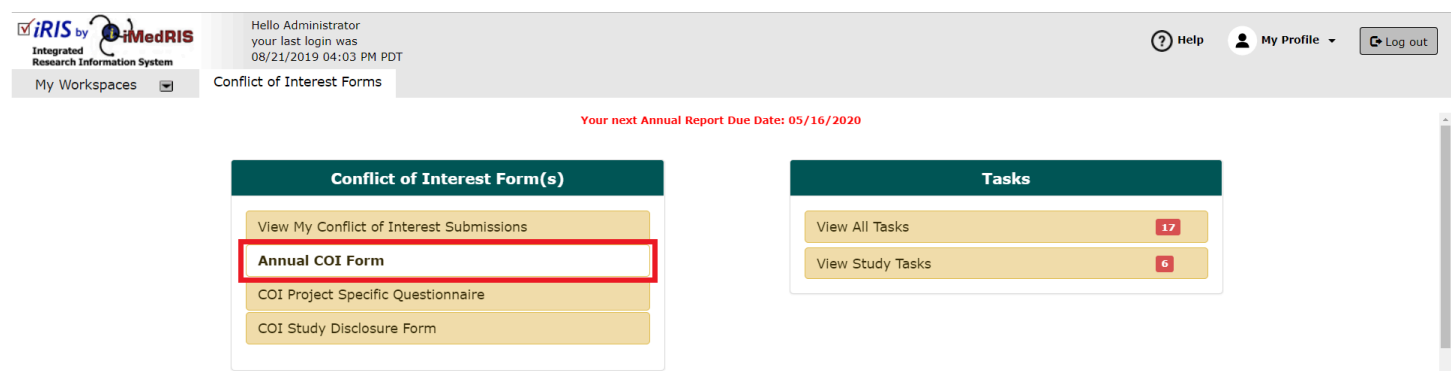
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# Conflict of Interest – Annual COI Submission

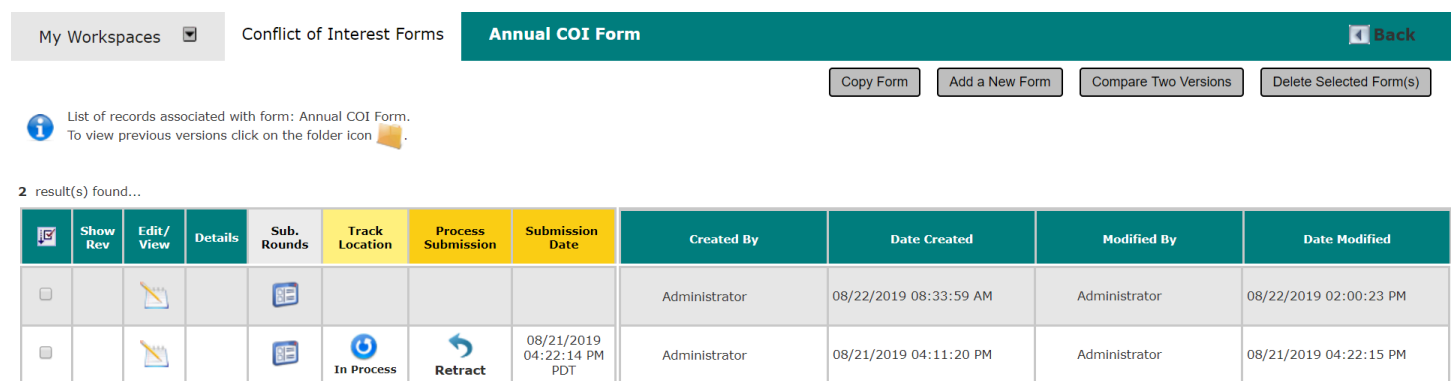
## Completing and Submitting the Annual COI and Commitment Reporting Form of Individuals

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, 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

My Workspaces ▾
Conflict of Interest Forms
Workflow - Submission Tracking
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Print Friendly

```

graph LR
    A[Pre-Submission] --> B[Pre-Review]
    B --> C[Post-Review]
    C --> B
    B --> D[Changes-Requested]
    D --> B
    C --> E[Modification-Requested]
    E --> C
    
```

Task Status	Task Action/Details	Task Name	Date Created	Date Completed	Total Time
▣	Pre-Submission	<span style="border: 1px solid #ccc; padding: 2px 5px; border-radius: 3px;">Retract Submission</span>	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) 2 Minute(s)

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
<input checked="" type="checkbox"/> Pre-Submission	<a href="#">Retract Submission</a>		08/21/2019 04:22 PM PDT	08/21/2019 04:22 PM PDT	0 Day(s) 0 Hour(s) 0 Minute(s)
<input type="checkbox"/> 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
<input checked="" type="checkbox"/> Pre-Submission	<a href="#">Retract Submission</a>		08/21/2019 04:22 PM PDT	08/21/2019 04:22 PM PDT	0 Day(s) 0 Hour(s) 0 Minute(s)
<input type="checkbox"/> 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.

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System Administration
System Form Designer - My Conflict of Interest Manager
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[Save Form Setup Details](#)

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

Define Form Usage Properties & Details

Form Type: Conflict of Interest Annual Form

Form Name: My Conflict of Interest Manager

Form Abbreviation: RB#-null -<Version#>.<Revision#>

Form Order Number:

Navigation Name:

Form Abbreviation:

Restrict form to allow only one to be under review at a time:  Yes  No

Use Routing Signoff Sheet:  Yes  No

Paging Increment:

Use Section Numbering:  Yes  No

Use Name Created:  Yes  No

Use Date Created:  Yes  No

Use Name Modified:  Yes  No

Use Date Modified:  Yes  No

Use Reference Number:  Yes  No

Use Notification on Waiting Submission:  Yes  No

Use Wizard:  Yes  No

Display Form Option for New Study:  Yes  No

Validate by Section:  Yes  No

Use Numbering:  Yes  No

Does Receipt Satisfy Continuing Review Notification:  Yes  No

Does Receipt Satisfy Full Renewal Notification:  Yes  No

Does Receipt Satisfy Study Follow-up:  Yes  No

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.

My Workspaces ▾ Conflict of Interest Forms **My Conflict of Interest Manager** [Back](#)

[Copy Disclosure](#) [Add a New Disclosure](#) [Compare Two Versions](#) [Delete Selected Disclosure\(s\)](#)

 List of records associated with form: My Conflict of Interest Manager. To view previous versions click on the folder icon .


6 result(s) found...

	View History	Edit/View	Version	View Details	Track Location	Process Submission	Submission Date	Preliminary Request	Date Created	Date Modified	Create Revision
<input type="checkbox"/>			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



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.

My Workspaces ▼ Conflict of Interest Forms **My Conflict of Interest Manager** Back

Copy Disclosure Add a New Disclosure Compare Two Versions Delete Selected Disclosure(s)

List of records associated with form: My Conflict of Interest Manager.  
To view previous versions click on the folder icon .

6 result(s) found...

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 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.

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.

**4.0 Part I.I: Assets**

**4.1** Do you have any assets that are individually worth more than \$25,000 (or \$5,000 if you are a PI or Co-PI on a proposal to or award from the Public Health Service “PHS” or National Science Foundation “NSF”) to report for yourself, your [spouse](#) or [dependent children](#)? Please review the examples below before making your selection.

Yes  No

**4.5** Examples of Assets

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.

**4.0 Part I.I: Assets**

**4.1** Do you have any assets that are individually worth more than \$25,000 (or \$5,000 if you are a PI or Co-PI on a proposal to or award from the Public Health Service “PHS” or National Science Foundation “NSF”) to report for yourself, your [spouse](#) or [dependent children](#)? Please review the examples below before making your selection.

Yes  No

**4.2** What types of assets would you like to report?

Real Estate (not including principal residence)

Stocks, Bonds, Sector Mutual Funds and Other Assets

**4.4** Assets

Report only each asset that exceeded \$25,000 in value at any time during the reporting period. If you are PI or Co-PI on a proposal to or award from the Public Health Service (“PHS”) or National Science Foundation (“NSF”), your reporting obligation is subject to a different dollar threshold. Please report each asset that exceeded \$5,000 in value at any time during the reporting period.

Enter the full name of each specific asset or investment (specific stock, bond, [sector mutual fund](#), etc.)  
 The system will try to complete the company or asset name automatically. If the name is not already in the system, click on "Please click here to

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

Entry 1

Click here to add another entry

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

Report for \* --none--

Type of Asset \* --none--

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

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

Mark If No Longer Held

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.

Entry 1

Click here to add another entry

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

Report for \* --none--

We are not finding a company name match. Please click here to enter.

Other fields will prompt you for additional information.

Biomedical third party:

Select the estimated current value of the investment:

If > \$100,001, please specify the amount of the Investment:  (format: "10000", no \$, comma)

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.

Entry 1    Entry 2

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

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

Report for \* --none--

Type of Asset \*

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.

Entry 1    Entry 2

Click here to add another entry    **Click Here to Delete this entry**

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

Report for \*    --none--

Type of Asset \*    -----

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.

My Workspaces    Covered Person: Admin Admin admin    Reference Number:    Conflict of Interest Forms    **Annual Conflict of Interest Form - (Version 6.0)**    Back

Print Friendly    Refresh Constant Fields    Save Section    Continue

Section view of the Form    Entire view of the Form

1.0 Introduction

2.0 CONFIDENTIAL ANNUAL FINANCIAL DISCLOSURE Research Instituti ...

3.0 Filer Information

4.0 Part I.I: Assets

5.0 Part I.II: Earned Income

6.0 Part II: Liabilities or Debts

7.0 Part III: Outside Positions (You ONLY)

8.0 **Part IV: Contracts, Agreements or Arrangements (You ONLY)**

8.0 Part IV. Contracts, Agreements or Arrangements (You ONLY)

8.1 Do you have any contracts, agreements or arrangements to report?  
Please review the examples below before making your selection.

Yes     No

8.3 Examples of Contracts, Agreements or Arrangements

REPORT:

- Any contract, agreement or arrangement, oral or written, that you currently have or

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 Workspaces    Covered Person: Admin Admin admin    Reference Number: 023301    Conflict of Interest Forms    **Annual Conflict of Interest Form - (Version 5.0)**    Back

Print Friendly    Signoff and Submit

Section view of the Form    Entire view of the Form

1.0 Introduction

2.0 CONFIDENTIAL ANNUAL FINANCIAL DISCLOSURE Research Instituti ...

3.0 Filer Information

4.0 Part I.I: Assets

5.0 Part I.II: Earned Income

6.0 Part II: Liabilities or Debts

7.0 Part III: Outside Positions (You ONLY)

8.0 Part IV: Contracts, Agreements or Arrangements (You ONLY)

9.0 Part V: Gifts, Hospitality and Reimbursements

10.0 Part VI: Interests Related To Your Smithsonian Position

11.0 Certification

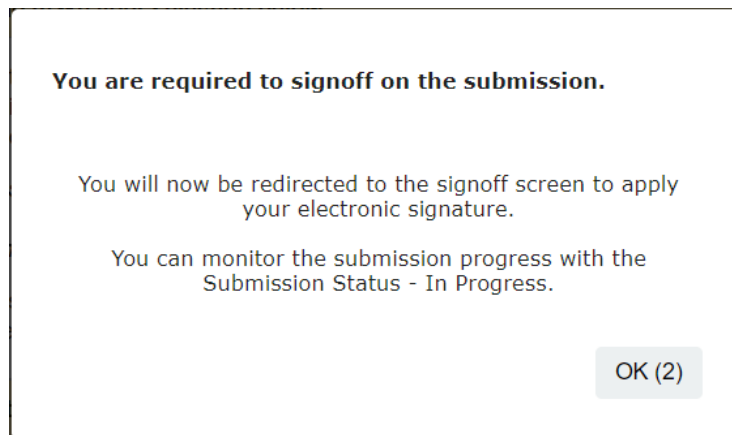
**Form has been Completed!**

Form has Been Completed Screen

**You must submit a revised form within Thirty One (31) days of becoming aware that any of your answers have changed**

Exit Form

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 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.


**Form has been Completed!**

Form has Been Completed Screen


You must submit a revised form within Thirty One (31) days of becoming aware that any of your answers have changed

Exit Form  
Signoff and Submit

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		
<span style="border: 1px solid orange; border-radius: 15px; padding: 5px 15px; background-color: #f4a460; color: white;">Pre-Submission</span>					
Task Status	Task Action/Details	Task Name	Date Created	Date Completed	Total Time
<input type="checkbox"/> Pre-Submission		<span style="border: 1px solid gray; padding: 2px 10px;">Retract Submission</span>	08/23/2019 08:34 AM PDT		0 Day(s) 0 Hour(s) 0 Minute(s)
Completed	<span style="border: 1px solid gray; padding: 2px 10px;">View Signoff</span>	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
<input type="checkbox"/>		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.

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.