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Office of Extramural Research

Financial Conflict of Interest (FCOI) External User Guide

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Please contact the eRA Help Desk:

Toll-free: 1-866-504-9552

Phone: 301-402-7469

TTY: 301-451-5939

Web: <http://grants.nih.gov/support> (Preferred method of contact)

Email: commons@od.nih.gov (for Commons Support)

Email: helpdesk@od.nih.gov (for IMPAC II Support)

Hours: Mon-Fri, 7 a.m. to 8 p.m. Eastern Time

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The most current version of this document will be available on the eRA website: <http://era.nih.gov>.

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1 Overview

The Electronic Research Administration (eRA) *Commons* is a Web-based system for applicants and institutions to participate in the electronic grant administration process. *Commons* provides a modular framework and infrastructure that allows National Institutes of Health (NIH) extramural grantee organizations, Operating Divisions (OPDIVs), grantees, and the public to conduct grant-related business with NIH.

The *Financial Conflict of Interest User Guide* will instruct a user on how to allow specific users to manage the Financial Conflict of Interest (FCOI) reporting process for their particular Institution. This FCOI reporting process allows Institutions to report the existence of any identified FCOI to the Agency as required by the Federal regulation, specifically Title 42 Code of Federal Regulation Part 50 Subpart F for grants and cooperative agreements. The institution's Signing Official (SO) completes this reporting process unless an FCOI role is delegated to another user (the SO can also assign the FCOI_ASST and FCOI_View roles to other users). To do this, the SO must log into the eRA Commons and navigate to the FCOI sub-system.

Additional information on the reporting requirements can be found in the *Frequently Asked Questions* found on the Office of Extramural Research's Financial Conflict of Interest website at <http://grants.nih.gov/grants/policy/coi/index.htm>.

The information in this user guide is also available as online help. Select the '?' icon on most FCOI screens to open content specific help for that screen, or access the Commons Online Help System *Financial Conflict of Interest (FCOI) Module* topic directly at: http://era.nih.gov/erahelp/commons/#Commons/FCOI/fcoi_module.htm

2 Objectives

The objective of the FCOI system is to allow institutions to submit FCOI reports using the eRA *Commons* system. The system will notify the institution and Agency staff after an FCOI report submission is received. Although *Commons* is not the system of record, the FCOI information will be stored within another internal system of record (IMPAC II) database. The FCOI system will also allow institutions to submit additional information that subsequently may be requested by the Agency after the submission of an FCOI report. The system also will allow the institution’s authorized FCOI users to view reports and associated data online.

Process Objectives
Allow institutions to submit FCOI reports via the <i>Commons</i> (IMPAC II) database
Notify institutions and Agency staff after the FCOI submission is received
Allow Grantee to revise an existing FCOI report following a Retrospective Review, if necessary.
Allow Grantee to submit an annual FCOI report
Integrate the data with the internal system of record
Allow organizations to submit additional information when requested by the Agency
Allow FCOI users to view reports and associated data
Allow Grantee to revise an existing FCOI report to submit a Mitigation Report when bias is found following a Retrospective Review

Table 1: FCOI Objectives

3 User Roles

NIH extramural grantee institutions, OPDIVs, grantees and the public are the primary users of *Commons*. Access to *Commons* is granted only by authorized *Commons* users who are assigned to a specific role(s) that allows for user account creation. The following diagram displays an example of how different user roles function within the *Commons* system.

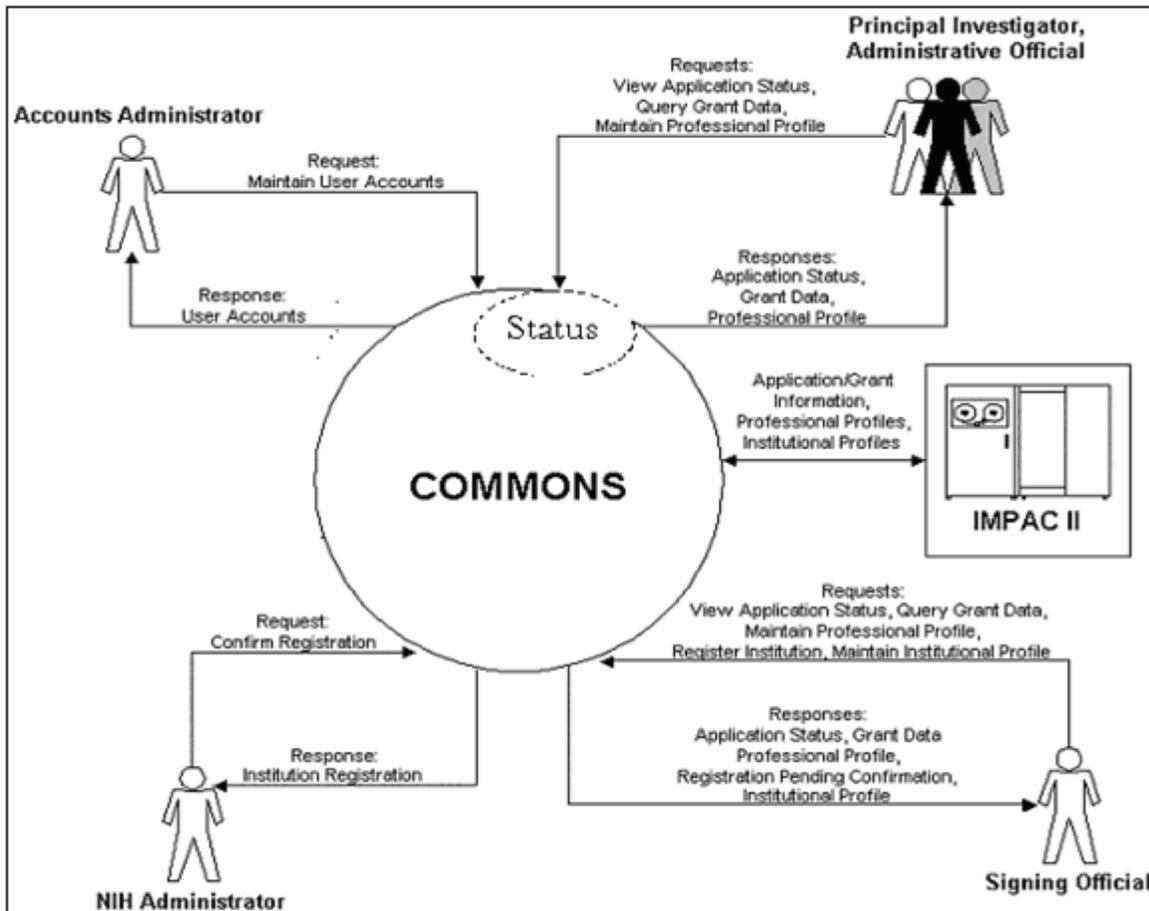


Figure 1: Commons User Roles Diagram

3.1 Signing Official (SO) Role

A Signing Official (SO) within an institutional organization is authorized to assign FCOI roles to others within their organization. The SO has institutional authority to legally bind the institution in grants administration matters by providing signature approval on submissions. The SO monitors grant related activities with the grantee institution and may have a number of titles.

3.2 Financial Conflict of Interest (FCOI) Role

Assign the FCOI role to the user(s) in the institution who would manage the FCOI reporting process. This person or persons would be able to initiate, edit, submit, revise, view, and delete records and documents.

Only the SO can assign the FCOI role.

3.3 Financial Conflict of Interest Assistant (FCOI_ASST) Role

Assign the FCOI_ASST role to those users in the institution who will assist in working on the FCOI reporting process. FCOI_ASST users can initiate, edit, view, search, and delete forms.

Only the SO can assign the FCOI role.

3.4 Financial Conflict of Interest View Only (FCOI_View) Role

Assign the FCOI_View role to those users who need authority to search for and view FCOI information entered by the institution in the FCOI module, but who will not perform any data entry or make changes to the information. These users have read-only access to FCOI report data.

Only the SO can assign the FCOI role.

4 The FCOI Application

4.1 What is FCOI?

The FCOI Module in *Commons* allows grantee institutions to:

- Initiate and prepare an FCOI report within *Commons*
 - Multiple FCOI officials and delegates can access and edit a report while in *Work In Progress* (WIP) status
- Submit the FCOI report and supporting documents, if applicable, electronically to the Agency
 - This can include comments at the time of submission that are included in email notifications to the Agency
- Submit the Annual FCOI report and supporting documents, if applicable, electronically to the Agency
- Revise an Initial 2011 FCOI Report to update FCOI data following completion of the Retrospective Review or to submit a Mitigation Report when bias is found following the completion of a Retrospective Review. Do not notify the Agency that the Retrospective Review has been completed and no bias is found.
- Search and view FCOI reports that were previously submitted through *Commons*
 - Does not provide visibility to any reports previously submitted on paper
- Edit or rescind submitted reports (rescinding a report requires Agency involvement)
- Access the history of actions

5 The Basic Financial Conflict of Interest (FCOI) Reporting Process

5.1 *Managing FCOI Roles*

5.1.1 **Signing Official (SO) Assigns FCOI Roles to Institutional Users**

The Signing Official (SO) is the authorized official at the institution that has the authority to sign for the institution. The SO is the overall responsible person for any and all grant related activities whether the tasks are delegated to other institutional users or not. With this authority, the SO can assign or delegate various tasks, duties, and other limited responsibilities to other staff within the SO's institution.

The SO is responsible for assigning the FCOI, FCOI_ASST, and FCOI_VIEW roles to the appropriate system users in the institution. SOs can assign roles using the Account Management System (AMS) accessible via the eRA Commons Account tab. Refer to the AMS Online Help System for information on adding roles

(http://era.nih.gov/erahelp/ams/#Modify_Account/Add_User_Roles.htm).

5.2 *Flow Diagram*

The following Electronic Research Administration (eRA) *FCOI Reporting Process Flow Diagram* provides an overview for submitting and processing an FCOI Report. The 2011 Revised Regulation covers the following FCOI reports: Original, Revision of the Original, and Annual.

1995/2011 Regulation Flow

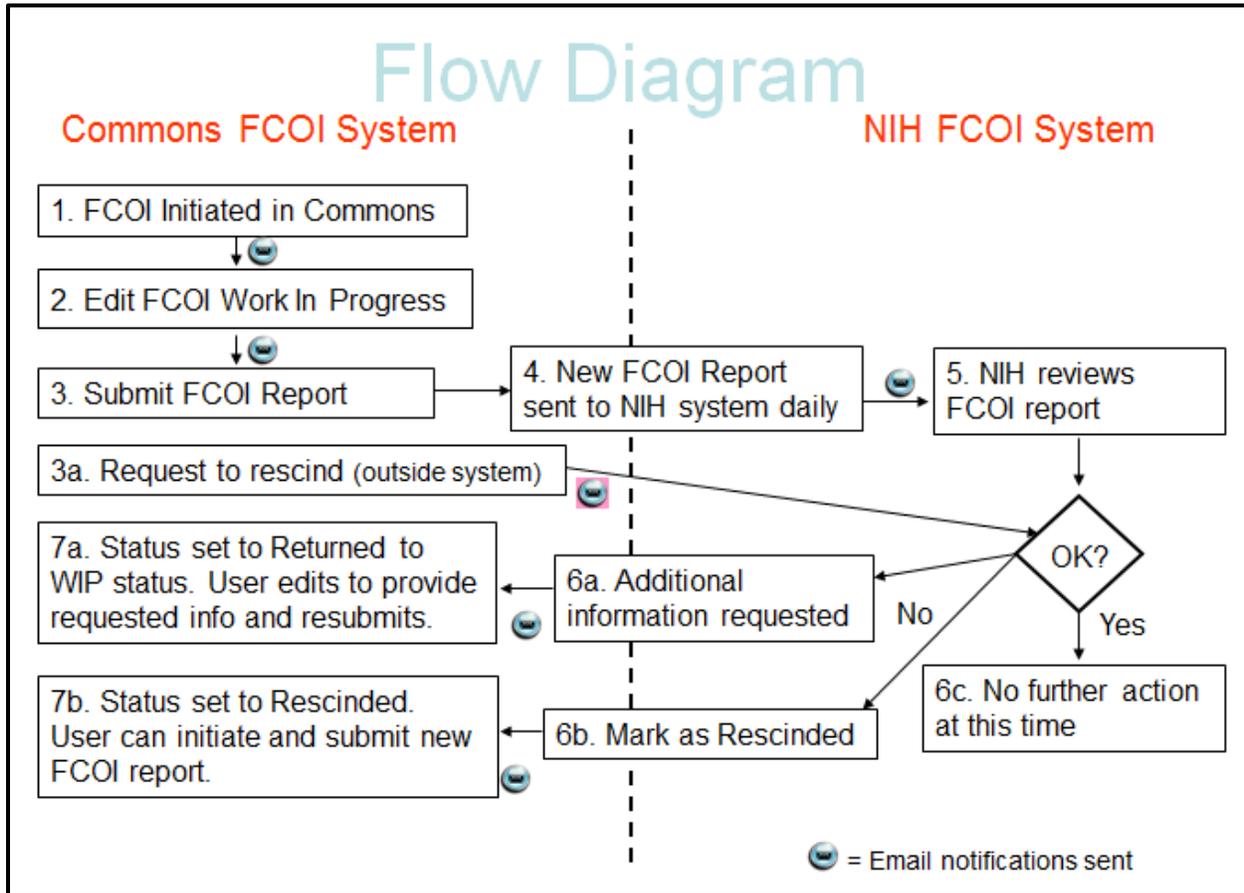


Figure 2: FCOI Process Flow Diagram

5.3 Initiate FCOI Report

Commons users with the FCOI role and/or the FCOI_ASST role are able to initiate new FCOI Reports. If the FCOI user has multiple affiliations, the user is only able to access grants associated with the institution for which the user has the FCOI role. FCOI Reports are permissible for Active awards. FCOI reports should be submitted during an ongoing project and not after the project period end date. When initiating a new FCOI report, the report should be submitted under the current, active grant year.

To initiate a new FCOI Report:

1. From the Commons main menu tabs, select the **FCOI** tab.



Figure 3: FCOI Menu Tab

The *FCOI Search* screen displays. Along with the search option, the FCOI menu includes the tab to **Initiate 2011 FCOI Report**.

2. Select the **Initiate 2011 FCOI Report**.

The *Financial Conflict of Interest – Initiate New Report* screen displays.

The screenshot shows a web application interface. At the top, there is a navigation bar with tabs: Home, Admin, Institution Profile, Personal Profile, Status, RPPR, xTrain, FCOI, Admin Supp, and eRA Partners. Below this is a secondary navigation bar with 'Search' and 'Initiate 2011 FCOI Report' (the latter is circled in red). The main content area is titled 'FCOI Search' with a help icon. Below the title is a search form with several input fields: 'FCOI #' (with a dropdown arrow), 'Grant #' (with sub-fields for 'Type', 'Act', 'IC', 'Serial #', 'Year', and 'Suffix'), 'Status' (with a dropdown menu showing 'All'), and 'Date Range of Subm' (with sub-fields for 'MM/DD/YYYY', 'Start Date', and 'End Date'). There are also 'Search' and 'Clear' buttons at the bottom of the form.

Figure 4: Initiate FCOI Options

The initial fields on this screen are as follows:

- **Grant Number** (**IC Code**, **Serial Number**, and **Support Year** are required)
- **Name of Investigator with Conflict** (**Last Name** and **First Name** are required)
- **Subrecipient Report** (**No** or **Yes** – with the **Subrecipient Institution Name** for **Yes** – is required)
- **PD/PI or Contact PD/PI** (populated upon initiation and disabled for entry)
- **Project Title** (populated upon initiation and disabled for entry)
- **Project Period Start & End Dates** (populated upon initiation and disabled for entry)
- **Budget Period Start & End Dates** (populated upon initiation and disabled for entry)

Before the FCOI report can be completed, the information in the required fields must be validated.

3. Enter the required fields. Required fields are marked with an asterisk (*).
4. Select the **Validate** button.

Home Admin Institution Profile Personal Profile Status eSNAP xTrain FCOI Admin Supp eRA Partners
 Search Initiate 1995 FCOI Report Initiate 2011 FCOI Report

Financial Conflict of Interest - Initiate New Report

* indicates required field

	Type	Activity	IC Code*	Serial Number*	Support Year*	Suffix Code	PD/PI or Contact PD/PI:
Grant Number:	<input type="text"/>	<input type="text"/>	CA	123456	1	<input type="text"/>	<input type="text"/>
Name of Investigator with Conflict:	Last Name *		First Name *		Middle Name		Project Title:
	Austen		Jane		<input type="text"/>		<input type="text"/>
Subrecipient Report: *	Subrecipient Institution Name						Project Period Start & End Dates:
	<input checked="" type="radio"/> No <input type="radio"/> Yes		<input type="text"/>				<input type="text"/>
							Budget Period Start & End Dates:
							<input type="text"/>

Validate

Save Save and Submit Cancel

Figure 5: 2011 Regulation FCOI Report – Validate Button

Commons validates the entered information. If Commons finds that the entered grant number is invalid for initiating the FCOI Report, an error message displays as follows:

Grant was not found. Grant year is not active or was not awarded.

If the validations pass with no errors, the *Financial Conflict of Interest – Initiate New Report* screen expands for entering additional information. The fields in the upper portion of the screen automatically populate based on the entered grant data. These fields are disabled for editing.

The lower portions of the screen – **FCOI Information**, **Noncompliance with Regulation**, and **Upload PDF Documents** – display and are enabled for editing.

Financial Conflict of Interest - Initiate New Report

* indicates required field

	Type	Activity	IC Code*	Serial Number*	Support Year*	Suffix Code	PD/PI or Contact PD/PI:
Grant Number:	1	R01	CA	123456	1	<input type="text"/>	CHARLES DICKENS
Name of Investigator with Conflict	Last Name *		First Name *		Middle Name		Project Title
	Austen		Jane		<input type="text"/>		Very Important Scientific Resear
Subrecipient Report: *	Subrecipient Institution Name						Project Period Start & End Dates
	<input checked="" type="radio"/> No <input type="radio"/> Yes		<input type="text"/>				07/01/2011 - 06/30/2014
							Budget Period Start & End Dates
							07/01/2011 - 06/30/2012

Validate

Figure 6: 2011 FCOI New Report Displaying Grant Information

Financial Conflict of Interest - Initiate New Report ?

* indicates required field

Grant Number:	Type	Activity	IC Code *	Serial Number *	Support Year *	Suffix Code	PD/PI or Contact PD/PI
	1	R01	CA	123456	1		CHARLES DICKENS
Name of Investigator with Conflict	Last Name *		First Name *		Middle Name		Project Title
	Austen		Jane				Very Important Scientific Resear
Subrecipient Report *	Subrecipient Institution Name						Project Period Start & End Dates
	<input checked="" type="radio"/> No <input type="radio"/> Yes						07/01/2011 - 06/30/2014
							Budget Period Start & End Dates
							07/01/2011 - 06/30/2012

FCOI Information

1. Entity * Please use the full name of the Entity as it appears on the Entity's publicly accessible Web site or type in the full name as it is known.

Nature of SFI(s)	Annual
Significant Financial Interest (SFI) <input type="text" value="Please select the nature of SFI"/>	Value <input type="text" value="Please select the value of the SFI within these dollar rang"/>
Other <input type="text"/>	\$ <input type="text"/>

Click the "Add New SFI" button to document each SFI that is applicable to this FCOI report. This button is used to add multiple SFIs within one FCOI report for the same entity.

Nature of SFI(s)	Value	Action
Nothing found to display.		

2. For each Significant Financial Interest include a description of how the financial interests relates to the funded research identified above and the basis for the Institution's determination that the financial interest conflicts with such research. *

Enter required information below or upload an attachment.

Files	File Name	Date Created	Status	Action
FCOI Information:			NOT UPLOADED	<input type="button" value="Import"/> <input type="button" value="Delete"/> <input type="button" value="View"/>

3. Include a description of the key elements of the Institutions management plan, including: *

A) Role and principal duties of the conflicted Investigator in the research project;
 B) Conditions of the management plan;
 C) How the management plan is designed to safeguard objectivity in the research project;
 D) Confirmation of the Investigator's agreement to the management plan;
 E) How the management plan will be monitored to ensure Investigator compliance; and
 F) Other information as needed.

Enter required information below or upload an attachment.

Files	File Name	Date Created	Status	Action
FCOI Information:			NOT UPLOADED	<input type="button" value="Import"/> <input type="button" value="Delete"/> <input type="button" value="View"/>

4. Does this FCOI report include a failure to comply with the regulation? * No Yes

The section below is used for submitting additional information if requested by the PHS Awarding Component or to upload additional attachments which are optional.

Upload PDF documents

Description:

Figure 7: 2011 Regulations FCOI Report

5. Update the fields in the **FCOI Information** block (Questions #1–4).
 - a. Enter the **Entity** name (required). Use the full name of the Entity as it appears on the Entity's publicly accessible Web site or type in the full name as it is known.

- b. Select the nature of the financial interest from the **Significant Financial Interest (SFI)** drop-down list. The options are as follows:
- Equity Interest – Non-publicly traded entity (e.g., stock, stock option, or other ownership interest)
 - Equity Interest – Publicly traded entity (e.g., stock, stock option, or other ownership interest)
 - Intellectual property rights (e.g., royalties, patents, copyrights) not from the awardee institution
 - Investment vehicles, such as mutual funds and retirement accounts, controlled by the investigator
 - Other (Provide an explanation that describes the SFI)*
 - Payment for services (e.g., consulting fees, honoraria, paid authorship)
 - Reimbursed or sponsored travel
 - Salary not from the awardee Institution
- *When selecting **Other**, enter specifics on the enabled and required **Other** text field.
- c. Select an option from the **Value** drop-down list:
- The choices in value ranges from \$0 to \$599,999
 - >\$600,000*
 - The interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.
- *Requires that a specific value be placed in the enabled line located under the **Value** field.
- d. Select the **Add New SFI** button to save the information to the table. Repeat the steps if multiple SFIs for the same entity are held by an Investigator.

The selected information displays in the table at the bottom of the **FCOI Information** block. Additional information may be added in the same manner, for up to 8 SFIs. To remove any SFI information, select the **Delete** link in the **Action** column of the table.

FCOI Information

1. Entity * Please use the full name of the Entity as it appears on the Entity's publicly accessible Web site or type in the full name as it is known.

	Nature of SFI(s)	Annual Value
Significant Financial Interest (SFI)	<input type="text" value="Please select the nature of SFI"/>	<input type="text" value="\$10,000 - \$19,999"/>
Other	<input type="text"/>	\$ <input type="text"/>

Click the "Add New SFI" button to document each SFI that is applicable to this FCOI report. This button is used to add multiple SFIs within one FCOI report for the same entity.

Nature of SFI(s)	Value	Action
Intellectual property rights (e.g., royalties, patents, copyrights) not from the awardee Institution	700000	Delete
Equity Interest - Non-publicly traded entity (e.g., stock, stock option, or other ownership interest)	\$10,000 - \$19,999	Delete

Figure 8: Significant Financial Interest Entries on 2011 Regulation FCOI Report

- e. Enter text or upload an attachment to describe how each financial interest relates to the funded research (Question #2).
- f. Enter text or upload an attachment to describe the key elements of the institution’s management plan (Question #3).

2. For each Significant Financial Interest include a description of how the financial interests relates to the funded research identified above and the basis for the Institution's determination that the financial interest conflicts with such research. *

Enter required information below or upload an attachment.

Sample description of how the financial interest relates to the funded research...

Files	File Name	Date Created	Status	Action
FCOI Information:	Sample Document.pdf	06/12/2012	UPLOADED	Import Delete View

3. Include a description of the key elements of the Institutions management plan, including: *

A) Role and principal duties of the conflicted Investigator in the research project;
 B) Conditions of the management plan;
 C) How the management plan is designed to safeguard objectivity in the research project;
 D) Confirmation of the Investigator's agreement to the management plan;
 E) How the management plan will be monitored to ensure Investigator compliance; and
 F) Other information as needed.

Enter required information below or upload an attachment.

Sample description of key elements of management plan...

Files	File Name	Date Created	Status	Action
FCOI Information:	Sample Document.pdf	06/12/2012	UPLOADED	Import Delete View

Figure 9: Descriptions and Uploads Supporting the FCOI Report

- 6. Select the **No** or **Yes** radio button for question #4: **Does this FCOI report include a failure to comply with the regulation?**

If the **Yes** radio button is selected, a pop-up displays the following message: *An FCOI report represents noncompliance when an FCOI is not identified or managed in a timely manner including failure by the Investigator to disclose a Significant Financial Interest; failure by the Institution to review or manage a financial conflict of interest; or failure by the Investigator to comply with the management plan.*

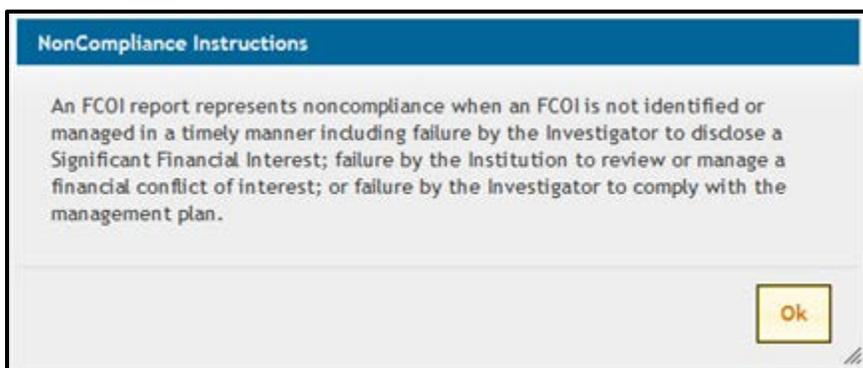


Figure 10: Non-Compliance Instructions

After selecting **OK** to close the pop-up, the **Description of Noncompliance with the FCOI Regulation** section appears containing a text box for comments and question **5. Retrospective Review Completed?** These are both required fields when *Yes* is selected for Question 4.

7. *Only if response to Question 4 is Yes:*

- a. Enter comments in the text box below the label **Describe the situation of noncompliance in the text box below.**
- b. Select the **No** or **Yes** radio button for question **5. Retrospective Review Completed?** to indicate whether a retrospective review was completed. If **Yes** is selected, the response for question #6 is enabled and required.

4. Does this FCOI report include a failure to comply with the regulation? * No Yes

Description of Noncompliance with the FCOI regulation

An FCOI report represents noncompliance when an FCOI is not identified or managed in a timely manner, including: failure by the Investigator to disclose a Significant Financial Interest; failure by the Institution to review or manage a financial conflict of interest; or failure by the Investigator to comply with the management plan.

Describe the situation of noncompliance in the text box below.

5. Retrospective Review Completed? * No Yes

If there is noncompliance associated with this FCOI report, a retrospective review must be completed within 120 days of the Institution's determination of noncompliance. In addition, a mitigation report must be submitted if bias is found.

Figure 11: Comments Required when Response to Question 4 is Yes

c. *Only if response to Question 5 is Yes:*

Select the **No** or **Yes** bias found radio button for question **6. Mitigation Report Required?** to indicate whether a mitigation report is required when bias is found. If the **Yes bias found** button is selected, provide the Mitigation Report information in the enabled text box or upload a file in the table below it.

4. Does this FCOI report include a failure to comply with the regulation? * No Yes

Description of Noncompliance with the FCOI regulation

An FCOI report represents noncompliance when an FCOI is not identified or managed in a timely manner, including: failure by the Investigator to disclose a Significant Financial Interest; failure by the Institution to review or manage a financial conflict of interest; or failure by the Investigator to comply with the management plan.

Describe the situation of noncompliance in the text box below.

5. Retrospective Review Completed? * No Yes

If there is noncompliance associated with this FCOI report, a retrospective review must be completed within 120 days of the Institution's determination of noncompliance. In addition, a mitigation report must be submitted if bias is found.

6. Mitigation Report Required? * No Yes bias found

If bias is found, the regulation requires the Institution to notify the NIH Awarding Component promptly; update previously submitted FCOI report if applicable; and submit a mitigation report to the PHS Awarding Component that shall address the following: Impact of the bias on the research project and the Institution's plan of action or actions taken to eliminate or mitigate the effects of the bias.

If appropriate, a revised FCOI report is required to update a previously submitted FCOI report to the specific action that will be taken to manage the FCOI going forward. Thereafter, the Institution shall submitted FCOI reports annually, in accordance with the regulation. Depending on the nature of the financial conflict of interest, an institution may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date that the Financial Conflict of Interest is identified or the Investigator's noncompliance is determined and the completion of the Institution's independent retrospective review, in accordance with 42 CFR 50.60(a)(3) and 42 CFR 50.605(b)(3).

Provide mitigation report per 42 CFR 50.605(a)(3)(iii)

Files	File Name	Date Created	Status	Action
Mitigation Report Information:	Sample Document.pdf	02/04/2015	UPLOADED	Import Delete View

Figure 12: Noncompliance Reporting for FCOI Report

8. *Optional:* Add attachments in the **Upload PDF Documents** block.
 - a. Enter a description in the **Description** field and select the **Upload** button.
 - b. Select the **Browse** button to search for and select a file from your computer.
 - c. Select the **Upload** button once the file is selected.
 - d. *Optional:* Use the **Delete** and **View** links in the table as needed.

Upload PDF documents

Description:

Document Name	Description	Upload Date	Action
Sample Document.pdf		06/12/2012	Delete View

Figure 13: Upload PDF Documents Feature of 2011 Regulation FCOI Report

9. Perform one of the following actions:
 - Select the **Save** button to put the record in WIP status

- Select the **Save and Submit** button to submit to agency
- Select the **Cancel** button to return to the *FCOI Search* screen

When the **Save and Submit** button is selected, a comments screen displays for entering optional comments before submission. The comments entered on this screen are recorded within the *FCOI History*. In addition, the comments are added to the email notification sent to Agency.

10. *Optional after selecting Save and Submit:* Enter any appropriate comments in the **Comments** text box (up to 2000 characters) and select the **Continue** button.

Figure 14: Entering Comments when Submitting a 2011 Regulation FCOI Form

Upon saving and submitting, the system sends out an e-mail notification informing the FCOI user (and potentially the FCOI_ASST user) that the FCOI Report was submitted.

5.4 Submit FCOI Report to Agency

The FCOI Submit function is part of the *Commons* system that allows an SO with an FCOI role to submit an identified FCOI Report to the Agency.

Only those with FCOI roles may submit the report. To submit an FCOI Report:

1. Access the FCOI feature from Commons.
2. After completing the Initiate FCOI Report process for the FCOI Report or editing a WIP notification, select the **Save and Submit** button.
3. *Optional:* On the next screen, enter comments in the **Comments** text box and select the **Continue** button.

Commons updates the status of the report from *WIP* to *Submitted*. Email notifications are sent to the SO who submitted the report and to the Agency to indicate that the FCOI Report is submitted.

Once the FCOI is submitted, the record is searchable with the status *Submitted*.

NOTE: If an FCOI Report has been submitted incorrectly (i.e., an incorrect **Grant Number**, **Name of Investigator with a Conflict**, or **Subrecipient Name**), contact the Grant Manager identified on the Notice of Award to ask the Agency to rescind the FCOI report. Other corrections to an FCOI Report can be made by contacting the Agency and asking the Agency to send the grantee a Request for Additional Information. This will change the status of the report to a Return

to WIP status to allow the grantee to make corrections to other FCOI report data that is below the validation line.

5.5 Searching Existing FCOI Reports (Notifications)

Commons users with the FCOI, FCOI_ASST, or FCOI_VIEW roles have the ability to search for grants in their institution with existing FCOI Reports.

To search for an FCOI record:

1. Select the **FCOI** tab from the Commons menu structure.
2. Enter the appropriate search information for returning the desired records. The following fields are available for entering search data:
 - **FCOI #**
 - **Grant Number**
 - **Status** (All, Work in Progress, Submitted, Rescinded, Returned to WIP, Annual Report Due)
 - **Annual Report Due** option returns Annual Reports in WIP status as well as Original Reports with an Annual Report due.
 - **Date Range of Submitted Records**
 - **Name of Investigator with Conflict**
3. Select the **Submit** button.

NOTE: Selecting the **Clear** button clears the information in the search fields.

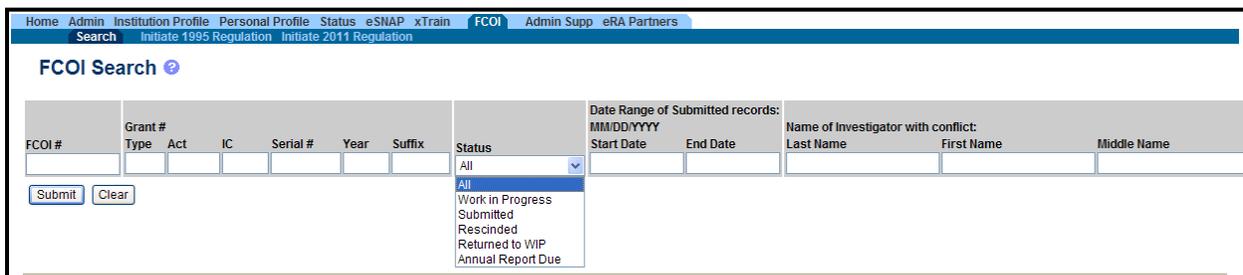


Figure 15: FCOI Search Screen Parameters

The matching records based on the search appear in a table at the bottom of the screen. The columns in the table are sortable by selecting the up/down arrows in the column headings (for all columns except **Action**).

If more than one record of an FCOI family are in the search results, the FCOI # and Grant # will only display for the first record.

The data in the search results is as follows:

- **FCOI #**

- **Grant #**
- **Date Submitted**
- **Investigator Name**
- **Status**
- **FCOI Type** (Original, Revision, or Annual Report)
- **Action** links

FCOI Search

FCOI #	Grant #						Status	Date Range of Submitted records:		Name of Investigator with conflict:		
	Type	Act	IC	Serial #	Year	Suffix		Start Date	End Date	Last Name	First Name	Middle Name
							All					

Submit Clear

25 items found, displaying 1 to 20. 1, 2 →

FCOI#	Grant#	Date Submitted	Investigator Name	Status	FCOI Type	Action
292	5R01HL123456-02	2009-07-01	Camus, Albert	Rescinded	Original *	View
1073	1R21HL456789-01	2010-03-03	JOYCE, JAMES	Returned to WIP	Original *	Edit View
448	1U01HL654321-01		CHEKHOV, ANTON	Work in Progress	Original *	Edit View Delete
3152	2R01MH123456-04A1	2012-05-16	POE, EDGAR ALLAN	Submitted	Original	View Revise
3141	5K08EB123456-04	2012-05-15	LAWRENCE, DH	Submitted	Original	View Revise Annual Report
3150	3U01CA111111-04S1	2012-05-16	Melville, Herman	Submitted	Original	View Revise
3142	1R01CA123456-01	2012-05-17	Austen, Jane	Submitted	Revision	View Revise
3143	1R21CA012345-01A1		Lee, Harper	Work in Progress	Original	Edit View Delete

Figure 16: FCOI Search Results

NOTE: The **FCOI Type** column displays an asterisk (*) next to the type for all 1995 Regulation FCOI Reports (e.g., **Original***).

The **Action** column displays each available action as a hyperlink (options vary depending on the user’s authority and/or the status of the FCOI Report). Selecting the hyperlink performs the associated action as follows:

- **View:** Opens the FCOI Report or Annual Report for as read-only
- **Edit:** Opens the *Financial Conflict of Interest – Edit* screen. Changes to the FCOI Report can be made using this screen. Displayed only for *Work In Progress* or *Returned to WIP (by Agency)* FCOIs and is available only to users with the FCOI or FCOI_ASST roles.
- **Delete:** Opens the *FCOI Deletion Confirmation*. Selecting the **Yes** button from this confirmation screen deletes the FCOI Report. Displayed only for FCOI Reports in a status of *Work in Progress* and is available only to users with the FCOI or FCOI_ASST roles.
- **Annual Report:** Opens the *Annual FCOI Report* screen. Displayed 75 days prior to the next budget period start date.
- **Revise:** Opens the editable FCOI Report. Displayed if **Yes** is selected as the answer to question 4 **Does this FCOI report include a failure to comply with the regulation?** – and– **No** is selected as the answer to question 5 **Retrospective Review Completed?** This link only appears within 150 days after original submission.

The **Status** column displays the status of the FCOI Report in a hyperlink. Selecting this hyperlink opens the *Financial Conflict of Interest History* screen for the grant.

FCOI History				
Grant Number:	1R01CA123456-01			
FCOI Current Status:	Rescinded			
Sub-Recipient Institution:				
Investigator with Conflict:	Austen, Jane			
Event	Action Taken By	Action Date	Action Comments	
Initiated	SHAKESPEARE, WILLIAM	2012-05-15	Started working on this FCOI	
Edited	SHAKESPEARE, WILLIAM	2012-05-15	Working on this situation	
Submitted	SHAKESPEARE, WILLIAM	2012-05-15	Completed work on this FCOI	
Returned to WIP	AGENCY	2012-05-30	Additional action required	
Submitted	SHAKESPEARE, WILLIAM	2012-06-05	Re-submitting the FCOI	
Rescinded	AGENCY	2012-06-15	FCOI rescinded	
Back				

Figure 17: FCOI History Viewable from Search Screen

5.6 Editing FCOI Before Submission

Commons users with FCOI or FCOI_ASST roles can perform edits on the FCOI Report. To edit the FCOI Report:

1. Log into the eRA *Commons* application and select the **FCOI** tab at the top of the screen.
2. Perform a search for the appropriate FCOI Report.
3. Select the **Edit** link in the **Action** column for the specific FCOI Report.

The *Financial Conflict of Interest – Initiate New Report* screen displays for editing. The fields are enabled for editing, with information pulled from the previously submitted FCOI form.

4. Update the fields as appropriate and select the **Save and Submit** button to submit the FCOI Report to Agency or select the **Save** button to save the information without submitting the FCOI Report.

NOTE: Only Commons users with an FCOI role can perform a **Save and Submit**.

5.7 Revising a Submitted FCOI Report (Following a Retrospective Review only)

The feature to revise a previously submitted FCOI report is used only in those situations following a Retrospective Review. For example, a revised FCOI report is submitted following the Retrospective Review when the Institution discovers new information that results in a change to a previously submitted FCOI report (e.g., an increase in value of a previously reported SFI) or a change to the management of the FCOI from what was previously reported under the initial report. In addition, if bias is found following the completion of the Retrospective Review, the grantee must submit a Mitigation Report. A Mitigation report is submitted through the submission of a Revised FCOI report if the Retrospective Review is pending at the time of initial report submission.

NOTE: If an FCOI Report is submitted with errors, the institution should contact the Agency to determine whether to rescind the FCOI report or to allow the grantee to make corrections through a response to an Agency's Request for Additional Information.

As discussed above, following the Retrospective Review it is possible to make changes to the FCOI Report. The FCOI Report can be revised to add, update and/or delete significant financial interest data and any other information that was previously submitted in the initial FCOI report. A revision can be made on an existing FCOI report by selecting the **Revise** link on *FCOI Search* up to 150 days following the initial FCOI report submission date.

To revise and submit an FCOI report:

1. Log into the eRA *Commons* application.
2. Select the **FCOI** tab at the top of the screen.
3. From the *FCOI Search* screen, perform a search for the appropriate FCOI report.
4. Select the **Revise** link in the **Action** column for the specific FCOI report.

FCOI Search										
FCOI #	Grant #			Status	Date Range of Submitted records:		Name of Investigator with conflict:			Middle Name
	Type	Act	IC		Serial #	Year	Suffix	MM/DD/YYYY	Start Date	
<input type="button" value="Submit"/> <input type="button" value="Clear"/>										
25 items found, displaying 1 to 20. 1, 2 →										
FCOI#	Grant#	Date Submitted	Investigator Name	Status	FCOI Type	Action				
292	5R01HL123456-02	2009-07-01	Camus, Albert	Rescinded	Original *	View				
1073	1R21HL456789-01	2010-03-03	JOYCE, JAMES	Returned to WIP	Original *	Edit View				
448	1U01HL654321-01		CHEKOV, ANTON	Work in Progress	Original *	Edit View Delete				
3152	2R01MH123456-04A1	2012-05-16	POE, EDGAR ALLAN	Submitted	Original	View Revise				
3141	5K08EB123456-04	2012-05-15	LAWRENCE, DH	Submitted	Original	View Revise Annual Report				
3150	3U01CA111111-04S1	2012-05-16	Melville, Herman	Submitted	Original	View Revise				
3142	1R01CA123456-01	2012-05-17	Austen, Jane	Submitted	Original	View Revise				
3143	1R21CA012345-01A1		Lee, Harper	Work in Progress	Original	Edit View Delete				

Figure 18: FCOI Search – Revise Link

The *FCOI – Revision* screen displays the information from the current FCOI report as read-only. The summary of reported significant financial interests (SFI(s)) is displayed in the table at the bottom of the screen.

5. Select the **Edit** link in the table to edit the SFI.

Submitted FCOI Information			
Grant Number:	1R01CA123456-01	PI/PI or Contact PI/PI:	DICKENS, CHARLES
Name of Investigator with Conflict:	Austen, Jane	Project Title:	Very Important Scientific Research
Subrecipient Institution Name:		Project Start & End Dates:	07/01/2011 - 06/30/2014
Existing FCOI ID:	3142	Budget Period Start & End Dates:	07/01/2011 - 06/30/2012

Entity	Significant Financial Interests	Values	Action
XYZ Corporation	Intellectual property rights (e.g., royalties, patents, copyrights) not from the awardee Institution	700000	Edit
	Equity Interest - Non-publicly traded entity (e.g., stock, stock option, or other ownership interest)	\$10,000 - \$19,999	

Figure 19: FCOI – Revision Screen

The *FCOI – Revision* screen expands to enable the report fields to be edited. The fields for revision are identical to those available when first initiating the FCOI form. The information displayed on the *FCOI – Revision* is pulled from the latest submitted FCOI form. An additional text field is added for summarizing the changes. This field is required.

6. Use the text box under the title **Please summarize any revisions to previously submitted FCOI Report using the text below** to summarize the submitted changes.

Figure 20: Summary of Changes on the FCOI – Revision Screen

7. Complete the revisions as appropriate under the **FCOI Information** section. Refer to the section of this document titled [Initiate FCOI Report](#) for more information about the questions and fields on this form.

During a revision, existing SFI information may be changed or deleted and new SFI information may be added only following a Retrospective Review. Text may be edited or added to the supporting information text boxes on the form. Additionally, new PDFs may be uploaded and existing ones deleted.

NOTE: The **Entity** field is read-only for a revision and may not be edited.

A revised FCOI form retains the FCOI ID number of the original form being revised.

8. Update the fields in the **Description of Noncompliance with the FCOI regulation** block (Questions #5–6).
 - a. Update the response for question #5 (**Retrospective Review Completed?**) to **Yes**. When **Yes** is selected, the response for question #6 is enabled and required.
 - b. Select the **Yes bias found** radio button for question #6 (**Mitigation Report Required?**) to indicate that a mitigation report is required. When the **Yes bias found** button is selected, provide the Mitigation Report information in the enabled text box or upload a file in the table below it.
9. Perform one of the following actions:
 - Select the **Save** button to put the record in WIP status.

- Select the **Save and Submit** button to submit to agency.
- Select the **Cancel** button to return to the *FCOI Search* screen.

When the **Save and Submit** button is selected, a comments screen displays for entering optional comments before submission. The comments entered on this screen are recorded within the *FCOI History*. In addition, the comments are added to the email notification sent to Agency.

10. *Optional after selecting Save and Submit:* Enter any appropriate comments in the **Comments** text box (up to 2000 characters) and select the **Continue** button.

Figure 21: Entering Comments when Submitting a 2011 Regulation FCOI Form Revision

Upon saving and submitting, the system sends out an e-mail notification informing the FCOI user (and potentially the FCOI_ASST user) that the FCOI Report was submitted. The **FCOI Type** is updated to **Revision** in the *FCOI Search* results.

FCOI #	Grant # Type Act IC	Serial #	Year	Suffix	Status	Date Range of Submitted records: MM/DD/YYYY Start Date End Date	Name of Investigator with conflict: Last Name First Name Middle Name
292	5R01HL123456-02		2009-07-01		Camus, Albert	Rescinded	Original * View
1073	1R21HL456789-01		2010-03-03		JOYCE, JAMES	Returned to WIP	Original * Edit View
448	1U01HL654321-01				CHEKOV, ANTON	Work in Progress	Original * Edit View Delete
3152	2R01MH123456-04A1		2012-05-16		POE, EDGAR ALLAN	Submitted	Original View Revise
3141	5K08EB123456-04		2012-05-15		LAWRENCE, DH	Submitted	Original View Revise Annual Report
3150	3U01CA111111-04S1		2012-05-16		McVillie, Herman	Submitted	Original View Revise
3142	1R01CA123456-01		2012-05-17		Austen, Jane	Submitted	Revision View Revise
3143	1R21CA012345-01A1				Lee, Harper	Work in Progress	Original Edit View Delete

Figure 22: FCOI Type of Revision

5.8 Agency Requests for More Information

The NIH Chief Grants Management Officer or designee is able to request additional information from the submitting institution when necessary. This action generates a notification of the request to the institution and changes the status of the FCOI record to *Returned to WIP* in IMPAC II.

FCOI users at the institution use *Commons* to submit the additional documentation.

To edit the FCOI Report in response to a Request for More Information:

1. Access *FCOI Search* by selecting the FCOI tab from the Commons menu.
2. From the *FCOI Search* screen, perform a search for the appropriate FCOI report.
3. Select the **Edit** link in the **Action** column for the specific FCOI report.

The *Financial Conflict of Interest – Initiate New Report* screen displays. When editing an FCOI to provide requested additional information keep in mind the following:

- Additional documentation may be added as attachments, but existing attachments cannot be deleted
 - Any enabled fields may be updated
 - The **Delete** button for deleting the FCOI is disabled; the FCOI Report cannot be deleted
4. Select the **Save** button to save the information and keep the FCOI Report as a WIP
–OR–
Select the **Save and Submit** button to submit the FCOI Report to the Agency.

NOTE: Only Commons users with an FCOI role may use the **Save and Submit** feature.

When the **Save and Submit** button is selected, a comments screen displays for entering comments before submission. These comments are required when an FCOI Report is submitted after being returned for more information.

The comments entered on this screen are recorded within the *FCOI History*. In addition, the comments are added to the email notification sent to Agency.

5. Enter the appropriate comments in the **Comments** text box (up to 2000 characters) and select the **Continue** button.

Upon saving and submitting, the system sends out an e-mail notification informing the FCOI user that the FCOI Report was submitted.

5.9 FCOI History

Commons users with the FCOI, FCOI_ASST, or FCOI_VIEW roles can view the history of an FCOI Report from initiation to submission. Event records are generated in the *Financial Conflict of Interest History* log each time a user takes an action on the record.

The *FCOI History* screen is accessible by selecting the hyperlink in the **Status** column of the *FCOI Search* results or by selecting the **View FCOI History** button on the *Financial Conflict of Interest – Initiate New Report* and *FCOI – Revision* screens.

FCOI Search

FCOI #	Grant #						Status	Date Range of Submitted records:		Name of Investigator with conflict:		
	Type	Act	IC	Serial #	Year	Suffix		Start Date	End Date	Last Name	First Name	Middle Name
							All					

Submit Clear

25 items found, displaying 1 to 20. 1, 2 →

FCOI#	Grant#	Date Submitted	Investigator Name	Status	FCOI Type	Action
292	5R01HL123456-02	2009-07-01	Carnus, Albert	Rescinded	Original *	View
1073	1R21HL456789-01	2010-03-03	JOYCE, JAMES	Returned to WIP	Original *	Edit View
448	1U01HL654321-01		CHEKOV, ANTON	Work in Progress	Original *	Edit View Delete
1468	2R01MH123456-04A1	2010-07-20	POE, EDGAR ALLAN	Submitted	Original *	View

Figure 23: Status Hyperlink for Viewing Financial Conflict of Interest History

Financial Conflict of Interest - Edit

*Indicates required field

FCOI Form

Grant Number: Type: 1 Activity: R01 IC Code: CA Serial Number: 123456 Support Year: 1 Suffix Code: A1 PD/PI or Contact PD/PI: DICKENS, CHARLES

Name of Investigator with Conflict: Last Name: Austen First Name: Jane Middle Name:

Sub-Recipient Report?: No Yes Sub-Recipient Institution Name:

FCOI Action: Managed

Upload PDF documents

File Name: Description: Upload

Document Name	Description	Upload Date	Action
---------------	-------------	-------------	--------

Save Save and Submit Delete History Cancel

Figure 24: History Button on the 1995 Regulation FCOI–Edit Screen

The *Financial Conflict of Interest History* screen displays read-only information for the FCOI Report. The displayed information is as follows:

Grant Number

FCOI Current Status

Sub-Recipient Institution (if applicable)

Investigator with Conflict

Event (Initiated, Edited, Submitted, Returned to WIP, Rescinded)

Action Taken By

Action Date

Action Comments (if applicable)

To close the screen, select the **Back** button.

FCOI History				
Grant Number:	1R01CA123456-01			
FCOI Current Status:	Rescinded			
Sub-Recipient Institution:				
Investigator with Conflict:	Austen, Jane			
Event	Action Taken By	Action Date	Action Comments	
Initiated	SHAKESPEARE, WILLIAM	2012-05-15	Started working on this FCOI	
Edited	SHAKESPEARE, WILLIAM	2012-05-15	Working on this situation	
Submitted	SHAKESPEARE, WILLIAM	2012-05-15	Completed work on this FCOI	
Returned to WIP	AGENCY	2012-05-30	Additional action required	
Submitted	SHAKESPEARE, WILLIAM	2012-06-05	Re-submitting the FCOI	
Rescinded	AGENCY	2012-06-15	FCOI rescinded	
Back				

Figure 25: Sample FCOI History Screen

5.10 Submitting FCOI Annual Reports

FCOI Annual Reports are submitted through *Commons* by institution users with the FCOI role. An Annual FCOI report follows the submission of an initial 2011 FCOI Report when future years exist within a competitive segment. The annual report provides a means for the institution to report on the status of the reported FCOI and any changes to the management plan that was submitted under the original or initial FCOI report.

The **Annual Report** link only appears 75 days prior to the next budget period start date or after the Institution extends the grant via *Commons*. An email notification is sent to the Institution’s FCOI SO (i.e., the *Commons* user who submitted the original report) when the link is available. The Annual report link will not appear for the last year of a competitive segment unless the grant is extended via the *Commons*. Under this situation, the Annual Report link will appear the day after the grant is extended. For subsequent extensions, contact the Agency’s Awarding Component for Annual Reporting requirements.

Submissions can be saved (they will be placed in a *Work in Progress*—WIP—status), edited at a later date, and then submitted (or they may be deleted if necessary).

To initiate an Annual FCOI Report:

1. Access the *FCOI Search* screen by selecting the **FCOI** tab from the *Commons* menu.
2. From *FCOI Search*, perform a search for the appropriate FCOI Report.
3. Select the **Annual Report** link in the **Action** column for the specific FCOI Report.

FCOI Search												
FCOI #	Grant #			Serial #	Year	Suffix	Status	Date Range of Submitted records:		Name of Investigator with conflict:		
	Type	Act	IC					Start Date	End Date	Last Name	First Name	Middle Name
							All					
<input type="button" value="Submit"/> <input type="button" value="Clear"/>												
25 items found, displaying 1 to 20. 1, 2 →												
FCOI#	Grant#	Date Submitted	Investigator Name	Status	FCOI Type	Action						
292	5R01HL123456-02	2009-07-01	Camus, Albert	Rescinded	Original *	View						
1073	1R21HL456789-01	2010-03-03	JOYCE, JAMES	Returned to WIP	Original *	Edit View						
448	1U01HL654321-01		CHEKHOV, ANTON	Work in Progress	Original *	Edit View Delete						
3152	2R01MH123456-04A1	2012-05-16	POE, EDGAR ALLAN	Submitted	Original	View Revise						
3141	5K08EB123456-04	2012-05-15	LAWRENCE, DH	Submitted	Original	View Revise Annual Report						
3150	3U01CA111111-04S1	2012-05-16	Melville, Herman	Submitted	Original	View Revise						

Figure 26: FCOI Search – Annual Report Link

Commons checks to determine if there are any annual reports which were not submitted to Agency for previous years. If found, a warning message displays as follows:

*Our records indicate that an annual FCOI report from the prior grant year was not submitted and is overdue. This report must be submitted before the current annual FCOI report may be submitted. **There are [#] Reports missing.***

These overdue reports must be submitted first before the current year’s report can be completed.

4. *If overdue Annual Report exist:* Acknowledge the message by selecting the **Create Report** button.

The Commons system automatically opens the overdue annual report (starting with the report for the earliest year when more than one annual report is overdue) for completion. The *Annual Report* form displays information based on the latest submitted information. This includes grant information as well as the entity, significant financial interests (SFI), and SFI values for the identified FCOI. Each previously reported SFI is listed on the Annual Report and must be addressed separately.

Annual Reports are submitted under the currently funded grant year (e.g., year 04) without regard to the grant year when the Initial or Original FCOI report was submitted (e.g., year 01).

5. *Optional:* Select the **View** link in the **Action** column to view read-only specifics as reported on the original FCOI report.

Financial Conflict of Interest - Annual Report ⓘ

Submitted FCOI Information

Grant Number:	5K08EB123456-04	PD/PI or Contact PD/PI:	CRANE, STEPHEN
Name of Investigator with Conflict:	Lawrence, DH	Project Title:	Control of Brain Development
Subrecipient Institution Name:		Project Start & End Dates:	08/01/1997 - 03/31/2014
Existing FCOI ID:	3222	Budget Period Start & End Dates:	04/01/2011 - 03/31/2012

Entity	Significant Financial Interests	Values	Action
Entity 1	Equity Interest - Publicly traded entity (e.g., stock, stock option, or other ownership interest)	\$0 - \$4,999	View
	Intellectual property rights (e.g., royalties, patents, copyrights) not from the awardee Institution	\$10,000 - \$19,999	
	Investment vehicles, such as mutual funds and retirement accounts, controlled by the Investigator	\$100,000 - \$149,999	
	Payment for services (e.g., consulting fees, honoraria, paid authorship)	\$20,000 - \$39,999	
	Equity Interest - Non-publicly traded entity (e.g., stock, stock option, or other ownership interest)	\$10,000 - \$19,999	
	Reimbursed or sponsored travel	\$10,000 - \$19,999	
	This is an example of 'Other'	\$10,000 - \$19,999	

Any changes to a previously reported SFI, other than its value or management plan, requires the submission of new FCOI report.

Figure 27: Annual Report – View Link

6. Answer the questions for each SFI listed.
 - a. For question **1. Indicate the status of the FCOI since the FCOI was previously reported**, select the radio button for one of the options: **Managed** or **No longer exists**. When **No longer exists** is chosen, this FCOI is removed from future annual reporting.
 - b. For question **2. Are there any changes to the Management Plan**, select the radio button for one of the options: **Yes** or **No**. Use the textbox or document upload feature to

provide an explanation of the changes to the management plan as necessary. This question is only displayed when the response to Question 1 is **Managed**.

Figure 28: FCOI Annual Report – Questions 1 & 2

- c. For question 3. **Explain why FCOI no longer exists**, enter an explanation in the text box or use the upload feature to attach documentation explaining why the FCOI no longer exists. This question is only displayed when the response to Question 1 is **No longer exists**.

Figure 29: FCOI Annual Report – Questions 1 & 3

7. Perform one of the following actions:
 - Select the **Save** button to put the record in WIP status.
 - Select the **Save and Submit** button to submit to agency.
 - Select the **Cancel** button to return to the *FCOI Search* screen.

Once created, the Annual Report displays as its own record in the *FCOI Search* screen results as an FCOI Type of *Annual*, whether submitted to Agency or still a Work in Progress.

FCOI Search

FCOI #	Grant #						Status	Date Range of Submitted records:		Name of Investigator with conflict:		
	Type	Act	IC	Serial #	Year	Suffix		MM/DD/YYYY	End Date	Last Name	First Name	Middle Name
							All					
<input type="button" value="Submit"/>		<input type="button" value="Clear"/>										
25 items found, displaying 1 to 20.											1, 2 →	
FCOI#	Grant#	Date Submitted	Investigator Name	Status	FCOI Type	Action						
292	5R01HL123456-02	2009-07-01	Carnus, Albert	Rescinded	Original *	View						
1073	1R21HL456789-01	2010-03-03	JOYCE, JAMES	Returned to WIP	Original *	Edit View						
448	1U01HL654321-01		CHEKOV, ANTON	Work in Progress	Original *	Edit View Delete						
3152	2R01MH123456-04A1	2012-05-16	POE, EDGAR ALLAN	Submitted	Original	View Revise						
3141	5K08EB123456-04	2012-05-15	LAWRENCE, DH	Submitted	Annual	View Revise						

Figure 30: FCOI Search Results for Annual Report

5.11 Sending Electronic Notifications

The system sends a notification electronically under any of the following conditions:

1. When a New, Revision, or Annual, report is submitted, an email is sent to the SO who submitted the report.
2. When a Mitigation Report is uploaded and submitted to the Agency in the Revision report, an email is sent to the SO who submitted the report.
3. When a request for additional information is made, an email is sent to all Commons users who submitted a report for the FCOI ID.
4. When an Annual report is due, an email is sent to the SO who submitted the FCOI report.