



Electronic Research Administration  
National Institutes of Health, Office of Extramural Research



*Powering the Advancement of Science*

# Financial Conflict of Interest (FCOI)

## User Guide

**Commons System Version 3.4.3.3**

**Document Version 3.2.0**

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## DOCUMENT HISTORY

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9-19-2012	3.4.3.3	3.2.0	Updated information regarding roles and authority.	NIH eRA Documentation Team

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[http://inside.era.nih.gov/era\\_feedback/feedback.cfm?userguide=fcoi](http://inside.era.nih.gov/era_feedback/feedback.cfm?userguide=fcoi)

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## 1 Purpose

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The purpose of this *Financial Conflict of Interest (FCOI) User Guide* is to provide basic and useful information to institutional (external) users of the NIH Grants system within *Commons* as it relates to the FCOI reporting process to the Public Health Service (PHS) Awarding Component (e.g., NIH).

## 2 Scope

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This *FCOI User Guide* provides information relating to User Roles and the basic FCOI reporting process and provides Flow of Events information relating to the FCOI reporting process.

## 3 Overview

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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 they delegate an FCOI role to another user. An SO with the FCOI role can delegate FCOI ASST authority and FCOI View Only authority 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 Conflict of Interest website at <http://grants.nih.gov/grants/policy/coi/index.htm>.

## 4 Objectives

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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 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 initial 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 submit a Mitigation Report when bias is found following a Retrospective Review

Table 1: FCOI Objectives



## 5 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.

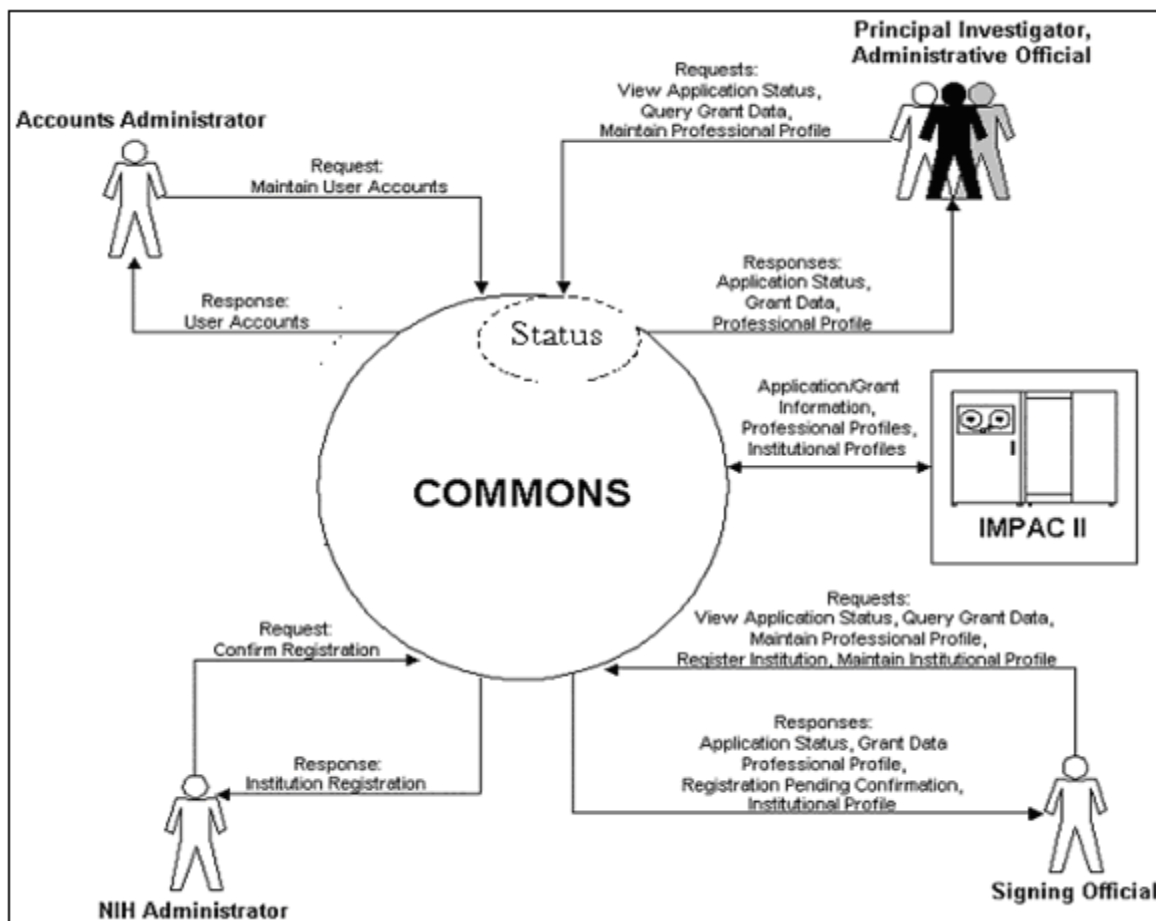


Figure 1: Commons User Roles Diagram

### 5.1 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.

## **5.2 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. Users with the FCOI role may also delegate authority to an assistant (Commons ASST role) for accessing the FCOI module in read-only or edit mode.

Only the SO can assign the FCOI role.

## **5.3 Assistant (ASST) Role**

Commons users with the Assistant (ASST) role can work with and/or view FCOI reports when given authority to do so by another user with the FCOI role. Two types of authority exist for ASST users working with FCOI: *FCOI Asst* and *FCOI View*.

FCOI users delegate this authority in the Commons under **Admin >> Delegations**. Please refer to the eRA Commons User Guide ([http://era.nih.gov/docs/COM\\_UGV2630.pdf](http://era.nih.gov/docs/COM_UGV2630.pdf)) for specific instructions on how to delegate authority.

### **5.3.1 FCOI Asst Authority**

A Commons ASST user delegated with *FCOI Asst* authority can access the FCOI module to assist with data entry and the completion of FCOI reports.

### **5.3.2 FCOI View Authority**

A Commons user delegated with *FCOI View* authority can view FCOI information entered by the institution in the FCOI module, but cannot perform any data entry or make changes to the information.

## 6 The FCOI Application

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### 6.1 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 or Annual FCOI report
- Submit a Mitigation Report when bias is found following a Retrospective Review
- 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

## 7 The Basic Financial Conflict of Interest (FCOI) Reporting Process

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### 7.1 Managing FCOI Roles

#### 7.1.1 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.

#### 7.1.2 Delegating FCOI Asst or FCOI View Authority to ASST Users

Signing Officials (SO) with the FCOI role may delegate FCOI authority to other individuals within the institution. They can delegate or assign individuals to serve as an FCOI assistant (*FCOI Asst* authority) or have FCOI view-only authority (*FCOI View* authority).

This is accomplished by logging into the FCOI *Commons* system, clicking on the **Admin** tab at the top of the screen, followed by the **Delegations** tab. Please refer to the eRA Commons User Guide ([http://era.nih.gov/docs/COM\\_UGV2630.pdf](http://era.nih.gov/docs/COM_UGV2630.pdf)) for specific instructions on how to delegate authority.

The SO can search for and select specific persons to whom to assign the authority. The SO can revoke or remove *FCOI Asst* or *FCOI View* authority from the same screen.

### 7.2 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, Annual, and Revision of the Annual)

### 1995/2011 Regulation Flow

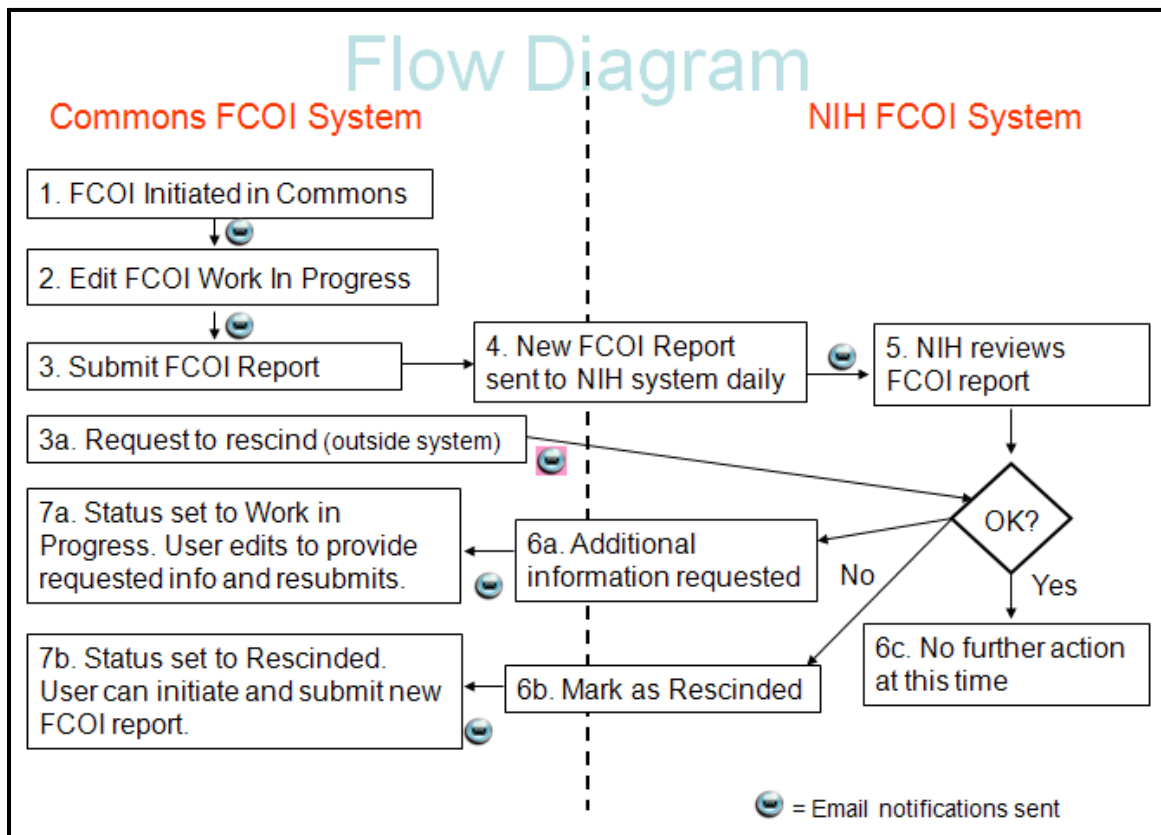


Figure 2: FCOI Process Flow Diagram

### 7.3 Initiate FCOI Report

Commons users with the FCOI role and/or FCOI ASST authority 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 Pending, Active, and Closed awards.

To initiate a new FCOI Report:

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

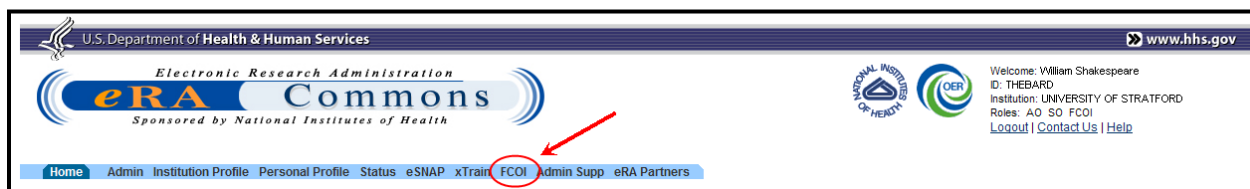


Figure 3: FCOI Menu Tab

During the transition period between the 1995 and 2011 Revised Regulation, the user has the ability to initiate either a 1995 Regulation or 2011 Revised Regulation FCOI report. Since the

1995 regulation applies to Notices of Award that are issued before August 24, 2012, the user will have the ability to submit a 1995 FCOI report until the next Notice of Award is issued on or after August 24, 2012, as applicable.

The *FCOI Search* screen displays. Along with the search option, the FCOI menu includes tabs for **Initiate 1995 FCOI Report** and **Initiate 2011 FCOI Report**. These tabs open the specific FCOI form for initiation of the applicable FCOI Report.

2. Select either **Initiate 1995 FCOI Report** or **Initiate 2011 FCOI Report**.

The *Financial Conflict of Interest – Initiate* screen displays for 1995 Regulation. For 2011 Regulation, the *Financial Conflict of Interest – Initiate New Report* screen displays. Refer to the following sections of this guide for specific information on these screens.

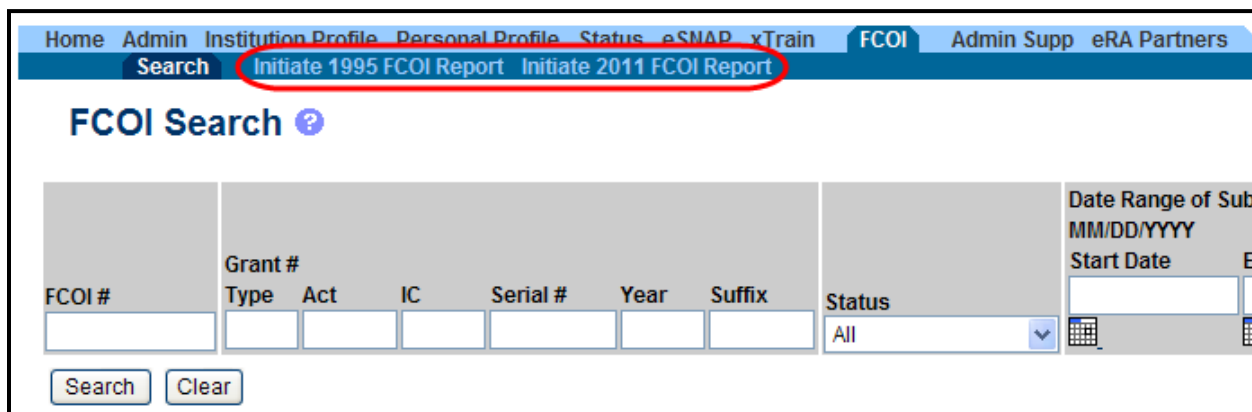


Figure 4: Initiate FCOI Options

### 7.3.1 FCOI 1995 Report

After choosing to initiate the 1995 FCOI Report, the *Financial Conflict of Interest – Initiate* screen displays. The fields on this screen are as follows:

- **Grant Number (IC Code, Serial Number, and Support Year** of the grant number are required)
- **PD/PI or Contact PD/PI**
- **Name of Investigator with Conflict (Last Name and First Name** are required)
- **Sub-Recipient Report (No or Yes – with name of Institution – is required)**
- **FCOI Action (Managed, Reduced, or Eliminated** is required)

To complete the FCOI Report:

1. Enter the required fields. Required fields are marked with an asterisk (\*).
2. Select the **Save** button.

**Financial Conflict of Interest - Initiate**  
\* 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 * Austin	First Name * Jane	Middle Name				
Sub-Recipient Report?*	<input checked="" type="radio"/> No <input type="radio"/> Yes		Sub-Recipient Institution Name				
FCOI Action:*	Managed						
This section is optional and will be available for PDF document upload after the initial save. Attachments are optional.							
Upload PDF documents							
Browse...		Description:					
Upload							
Document Name	Description			Upload Date		Action	
<input type="button" value="Save"/> <input type="button" value="Save and Submit"/> <input type="button" value="Cancel"/>							

Figure 5: FCOI Initiate Screen – Save Option

**NOTE:** The **Upload PDF document** section and the **Save and Submit** button are disabled until the user fills out all required fields on the screen and clicks the **Save** button for the first time. After the grant number is validated as correct, the upload section and submit feature will be available for use.

Once the data is entered and the **Save** button has been clicked, the system saves the data and submits the FCOI Report to the Agency. The upload document section becomes available for use and the **Save and Submit** button is enabled for submitting the FCOI Report to Agency. The following message displays above the upload section: *FCOI was successfully initiated.*

3. *Optional:* Use the upload feature to upload relevant supporting documents. Uploaded documents must be in a PDF file format.
  - a. Select the **Browse** button to search for the file on your computer.
  - b. Select the appropriate file for uploading.
  - c. Select the **Upload** button.
4. 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 go back to the blank *Initiate FCOI* screen

Figure 6: Save and Submit Options for 1995 FCOI Report

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

5. *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 7: Submission Comments for 1995 Regulation FCOI Form

Upon saving or 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.

**NOTE:** If the user chooses to cancel the Initiate FCOI reporting process, the following message displays:

*You are about to cancel the initiation of this FCOI . The latest unsaved data will be lost! Do you want to proceed?*

Selecting the **Yes** button discards all entered data and takes the user to the main menu screen, while selecting the **No** button presents the same FCOI initiation screen with all the data retained.

### 7.3.2 FCOI 2011 Report

After choosing to initiate the 2011 FCOI Report, the *Financial Conflict of Interest – Initiate New Report* screen displays. 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.

1. Enter the required fields. Required fields are marked with an asterisk (\*).
2. Select the **Validate** button.

The screenshot shows a web form titled "Financial Conflict of Interest - Initiate New Report". At the top, there is a navigation bar with links like "Home", "Admin", "Institution Profile", etc. The form itself has a header with the title and a help icon. Below the header, there is a legend: "\* indicates required field". The form is divided into several sections:

- Grant Information:** Fields for "Type", "Activity", "IC Code\*" (containing "CA"), "Serial Number\*" (containing "123456"), "Support Year\*" (containing "1"), and "Suffix Code".
- Investigator Information:** Fields for "Last Name\*" (containing "Austen"), "First Name\*" (containing "Jane"), and "Middle Name".
- Subrecipient Information:** A "Subrecipient Report:" section with radio buttons for "No" (selected) and "Yes", and a "Subrecipient Institution Name" field.
- Project Information:** Fields for "PD/PI or Contact PD/PI:", "Project Title:", "Project Period Start & End Dates:", and "Budget Period Start & End Dates:", all of which are currently disabled (greyed out).

At the bottom of the form area, there is a blue bar containing a "Validate" button, which is circled in red. Below this bar are three buttons: "Save", "Save and Submit", and "Cancel".

Figure 8: 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 or 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

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 *	<input checked="" type="radio"/> No <input type="radio"/> Yes		Subrecipient Institution Name				Project Period Start & End Dates
							07/01/2011 - 06/30/2014
							Budget Period Start & End Dates
							07/01/2011 - 06/30/2012

Validate

Figure 9: 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 style="width: 150px;" type="text"/>	Value <input style="width: 150px;" type="text"/>
Other <input style="width: 150px;" type="text"/>	\$ <input style="width: 150px;" 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 10: 2011 Regulations FCOI Report

3. 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 who 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 when 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

Significant Financial Interest (SFI)  Value

Other  \$

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. Add New SFI

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 11: 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 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 12: Descriptions and Uploads Supporting the FCOI Report

- 4. 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, the response for question #5 is enabled and required. An FCOI report represents noncompliance when an FCOI is not identified or managed in a timely manner for any of the following reasons: 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 to comply with the management plan.
- 5. *If necessary*: Update the fields in the **Noncompliance with Regulations** block (Questions #5–6).
  - a. 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.
  - b. *If necessary*: Select the **No** or **Yes** radio button for question #6 (**Mitigation Report Required?**) to indicate whether a mitigation report is required when bias is found. If the **Yes** button is selected, provide 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

**Noncompliance with Regulations**

If there was non-compliance 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.

5. Retrospective Review Completed? \*  No  Yes

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	06/12/2012	UPLOADED	Import Delete View

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

Figure 13: Noncompliance Reporting for 2011 Revised Regulation FCOI Report

6. *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 14: Upload PDF Documents Feature of 2011 Regulation FCOI Report

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

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.

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

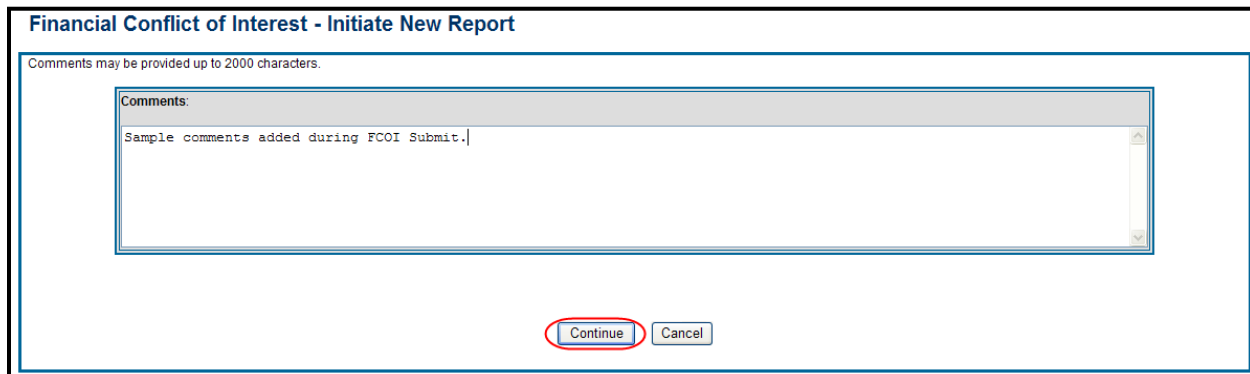


Figure 15: Entering Comments when Submitting a 2011 Regulation FCOI Form

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.

## 7.4 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 grant from *WIP* to *Submitted*. Email notifications are sent to the Signing Official (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 (e.g., an incorrect **Name of Investigator with a Conflict, incorrect value of SFI, etc.**), contact the Grant Manager identified on the Notice of Award to rescind the FCOI report.

---

## 7.5 Searching Existing FCOI Reports (Notifications)

Commons FCOI users, or those authorized as FCOI ASST or FCOI View Only, have the ability to search for applications 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)
  - **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.

---

The screenshot shows the 'FCOI Search' interface. At the top, there is a navigation bar with links: Home, Admin, Institution Profile, Personal Profile, Status, eSNAP, xTrain, FCOI, Admin Supp, eRA Partners. Below this is a search bar with 'Search' and 'Initiate 1995 Regulation' and 'Initiate 2011 Regulation' buttons. The main search area is titled 'FCOI Search' and contains several input fields: 'FCOI #' (empty), 'Grant #' (empty), 'Type' (empty), 'Act' (empty), 'IC' (empty), 'Serial #' (empty), 'Year' (empty), 'Suffix' (empty), 'Status' (dropdown menu showing 'All', 'Work in Progress', 'Submitted', 'Rescinded', 'Returned to WIP', 'Annual Report Due'), 'Date Range of Submitted records:' (with 'MM/DD/YYYY' format), 'Start Date' (empty), 'End Date' (empty), and 'Name of Investigator with conflict:' (with 'Last Name', 'First Name', and 'Middle Name' sub-fields). There are 'Submit' and 'Clear' buttons at the bottom left of the search area.

Figure 16: 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**).

The data in the search results is as follows:

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



**FCOI Search**

FCOI #	Grant #		IC	Serial #	Year	Suffix	Status	Date Range of Submitted records:		Name of Investigator with conflict:		
	Type	Act						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	<a href="#">Rescinded</a>	Original *	<a href="#">View</a>						
1073	1R21HL456789-01	2010-03-03	JOYCE, JAMES	<a href="#">Returned to WIP</a>	Original *	<a href="#">Edit View</a>						
448	1U01HL654321-01		CHEKHOV, ANTON	<a href="#">Work in Progress</a>	Original *	<a href="#">Edit View Delete</a>						
3152	2R01MH123456-04A1	2012-05-16	POE, EDGAR ALLAN	<a href="#">Submitted</a>	Original	<a href="#">View Revise</a>						
3141	5K08EB123456-04	2012-05-15	LAWRENCE, DH	<a href="#">Submitted</a>	Original	<a href="#">View Revise Annual Report</a>						
3150	3U01CA111111-04S1	2012-05-16	Melville, Herman	<a href="#">Submitted</a>	Original	<a href="#">View Revise</a>						
3142	1R01CA123456-01	2012-05-17	Austen, Jane	<a href="#">Submitted</a>	Revision	<a href="#">View Revise</a>						
3143	1R21CA012345-01A1		Lee, Harper	<a href="#">Work in Progress</a>	Original	<a href="#">Edit View Delete</a>						

Figure 17: 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 by Agency* FCOIs.
- **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*.
- **Annual Report:** Opens the *Annual FCOI Report* screen. Displayed 45 days before budget period end date or 60 days if the grant is not eSNAP eligible.
- **Revise:** Opens FCOI Report. Fields are editable, but changes are saved as a separate FCOI #. Displayed only after an FCOI Report has been submitted. Annual FCOI Reports also display the **Revise** link for updating and resubmitting an Annual FCOI Report. Revised FCOI Reports are only used following a Retrospective Review, if required.

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	
<a href="#">Back</a>				

Figure 18: FCOI History Viewable from Search Screen

## 7.6 Editing FCOI Before Submission

Commons users with FCOI roles or FCOI ASST authority 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 – Edit* screen displays for editing 1995 Regulation FCOI reports. For 2011 Regulation FCOI reports, 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**.

---

## 7.7 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. Based on the results of the retrospective review, if appropriate, the Institution is required to update the previously submitted FCOI Report, specifying the actions that will be taken to manage the FCOI going forward.

---

**NOTE:** If an FCOI Report is submitted with errors, the institution should contact the Agency to rescind the FCOI record and resubmit a new FCOI report with accurate information.

---

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*.

**NOTE:** The **Revise** link is available only for 2011 Regulation FCOI reports.

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:		
	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		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 <b>Revise</b>
3143	1R21CA012345-01A1		Lee, Harper	Work in Progress	Original	Edit View Delete

Figure 19: 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.

**FCOI - Revision**

Submitted FCOI Information

Grant Number:	1R01CA123456-01	PD/PI or Contact PD/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	

Cancel

Figure 20: FCOI – Revision Screen

The *FCOI – Revision* screen expands to enable the reports 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.

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

Submitted FCOI Information			
Grant Number:	1R01CA123456-01	PD/PI or Contact PD/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	
	Equity Interest - Non-publicly traded entity (e.g., stock, stock option, or other ownership interest)	\$10,000 - \$19,999	

Please summarize any revisions to previously submitted FCOI Report using the text below: \*

We are submitting the following changes...etc. etc. etc.

Figure 21: Summary of Changes on the FCOI – Revision Screen

- Complete the revisions as appropriate under the **FCOI Information** section. Refer to the section of this document titled [FCOI 2011 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 textboxes 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.

---

**FCOI Information**

1. Entity \*

Nature of SFI(s) Annual

Significant Financial Interest (SFI)  Value

Other  \$

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	<a href="#">Delete</a>
Equity Interest - Non-publicly traded entity (e.g., stock, stock option, or other ownership interest)	\$10,000 - \$19,999	<a href="#">Delete</a>

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	<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.

Sample description of key elements of management plan...

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

**Noncompliance with Regulations**

If there was non-compliance 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.

5. Retrospective Review Completed? \*  No  Yes

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	06/12/2012	UPLOADED	<input type="button" value="Import"/>	<input type="button" value="Delete"/> <input type="button" value="View"/>

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:

Document Name	Description	Upload Date	Action
Sample Document.pdf		06/12/2012	<a href="#">Delete</a> <a href="#">View</a>

Figure 22: FCOI Revision – FCOI Information Section

8. 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.

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

The screenshot shows a web form titled "FCOI - Revision". At the top, it says "Comments may be provided up to 2000 characters." Below this is a large text area labeled "Comments:" containing the text "These are sample comments about the revisions made to the report...". At the bottom of the form, there are two buttons: "Continue" (which is circled in red) and "Cancel".

Figure 23: 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.

The screenshot shows the "FCOI Search" interface. It includes a search filter section with fields for FCOI #, Grant # (Type, Act, IC, Serial #, Year, Suffix), Status (set to "All"), Date Range of Submitted records (MM/DD/YYYY Start Date, End Date), and Name of Investigator with conflict (Last Name, First Name, Middle Name). Below the filters are "Submit" and "Clear" buttons. A status bar indicates "25 items found, displaying 1 to 20." The main table has columns for FCOI#, Grant#, Date Submitted, Investigator Name, Status, FCOI Type, and Action. The row for FCOI# 3142 shows a status of "Submitted" and an FCOI Type of "Revision", which is circled in red.

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

Figure 24: FCOI Type of Revision

## 7.8 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 as a Request for More Information:

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 **Edit** link in the **Action** column for the specific FCOI report.

The *Financial Conflict of Interest – Edit* screen display for 1995 Regulation FCOIs or for 2011 Regulation FCOIs, 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
5. 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.

6. 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.

## 7.9 FCOI History

Commons users with FCOI, FCOI ASST, and FCOI View Only authority may 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 *Financial Conflict of Interest History* screen is accessible by selecting the hyperlink in the **Status** column of the *FCOI Search* results or by selecting the **History** button from the *Financial Conflict of Interest – Edit* screen for 1995 Regulation FCOI reports or the **View FCOI History** button on the *Financial Conflict of Interest – Initiate New Report* and *FCOI – Revision* screens.

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

Figure 25: 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: [ ] Browse..., Description: [ ] Upload

Document Name	Description	Upload Date	Action

Save Save and Submit Delete **History** Cancel

Figure 26: 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 27: Sample FCOI History Screen

## 7.10 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.

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

Figure 28: 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 maybe 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 pulled from the original FCOI report. 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.

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	<a href="#">View</a>
	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 29: 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 reports.
  - 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**.

Nature and Value of SFI previously reported

a.  Value:

1.\*Indicate the status of the FCOI since the FCOI was previously reported  Managed  No longer exists

2.\*Are there any changes to the Management Plan?:  Yes  No

Describe changes to the management plan 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"/>

Figure 30: FCOI Annual Report – Questions 1 & 2

- c. For question 3. **Explain why FCOI no longer exists**, enter an explanation in the textbox 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**.

Nature and Value of SFI previously reported

a.  Value:

1.\*Indicate the status of the FCOI since the FCOI was previously reported  Managed  No longer exists

3.\*Explain why FCOI no longer exists:

Explain why FCOI no longer exists 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"/>

Figure 31: 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. The **Annual** link, which had been displayed in the **Action** column for the original FCOI report before the Annual Report was submitted, is removed.

---

**NOTE:** Annual Reports display in the *FCOI Search* with a **Revise** link. Select this link to submit a revision of the submitted Annual Report.

---

**FCOI Search**

FCOI #	Grant #			Serial #	Year	Suffix	Status	Date Range of Submitted records:		Name of Investigator with conflict:		
	Type	Act	IC					MM/DD/YYYY	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 *	<a href="#">View</a>
1073	1R21HL456789-01	2010-03-03	JOYCE, JAMES	Returned to WIP	Original *	<a href="#">Edit View</a>
448	1U01HL654321-01		CHEKOV, ANTON	Work in Progress	Original *	<a href="#">Edit View Delete</a>
3152	2R01MH123456-04A1	2012-05-16	POE, EDGAR ALLAN	Submitted	Original	<a href="#">View Revise</a>
3141	5K08EB123456-04	2012-05-15	LAWRENCE, DH	Submitted	Annual	<a href="#">View Revise</a>

Figure 32: FCOI Search Results for Annual Report

## 7.11 Sending Electronic Notifications

### 7.11.1 1995 Regulation FCOI Reports

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

1. When FCOI ASST or FCOI View Only authority is assigned or revoked.
2. When the FCOI report is initiated (1995 regulations only)
3. Any time an FCOI report is edited (1995 regulations only)
4. Any time an FCOI report is submitted to Agency

### 7.11.2 2011 Regulation FCOI Reports

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

1. When a New, Revision, Annual, or Annual Revision 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 Annual or Annual Revision report. An email is sent to the SO who submitted the report.