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Office of Extramural Research

Financial Conflict of Interest (FCOI) External User Guide

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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 Financial Conflict of Interest (FCOI) Module

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.The Financial Conflict of Interest (FCOI) reporting process allows institutions to report the existence of any identified financial conflicts of interest 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.

The FCOI module is an online interface within Commons that allows grantees and Federal staff to share information. The module is mandatory for all institutions. An institution's Signing Official completes this reporting process unless another Commons user is delegated with the proper authority to access the module.

The FCOI module in Commons allows institutional users to:

- Initiate and prepare FCOI reports
- Electronically submit reports and supporting documents as well as annual FCOI reports
- Receive notification via email upon the submission and receipt of an FCOI
- Search and view FCOI reports previously submitted through the Commons
- 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.
- Access history of actions
- Assign FCOI access to other Commons users

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

For more information on the FCOI module, refer to the FCOI topic of the Commons Online Help System (https://era.nih.gov/erahelp/commons/) or the *Financial Conflict of Interest (FCOI) External User Guide* (https://era.nih.gov/files/fcoi_user_guide.pdf).

1.1 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 reportsubmission is received. Although Commons is not the system of record, the FCOI informationwill be stored within another internal system of record (IMPAC II) database. The FCOI systemwill also allow institutions to submit additional information that subsequently may be requestedby the Agency after the submission of an FCOI report. The system also will allow theinstitution's authorized FCOI users to view reports and associated data online.

Table 1: FCOI Objectives

Process Objectives
Allow institutions to submit FCOI reports via the Commons (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

1.2 Who Can Access the FCOI Module?

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.

1.2.1 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.

1.2.2 Financial Conflict of Interest (FCOI role)

This role should be assigned to the Commons 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 concerning FCOI.

Only the SO can assign the FCOI role.

1.2.3 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_Asst role.

1.2.4 Financial Conflict of Interest Assistant (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.

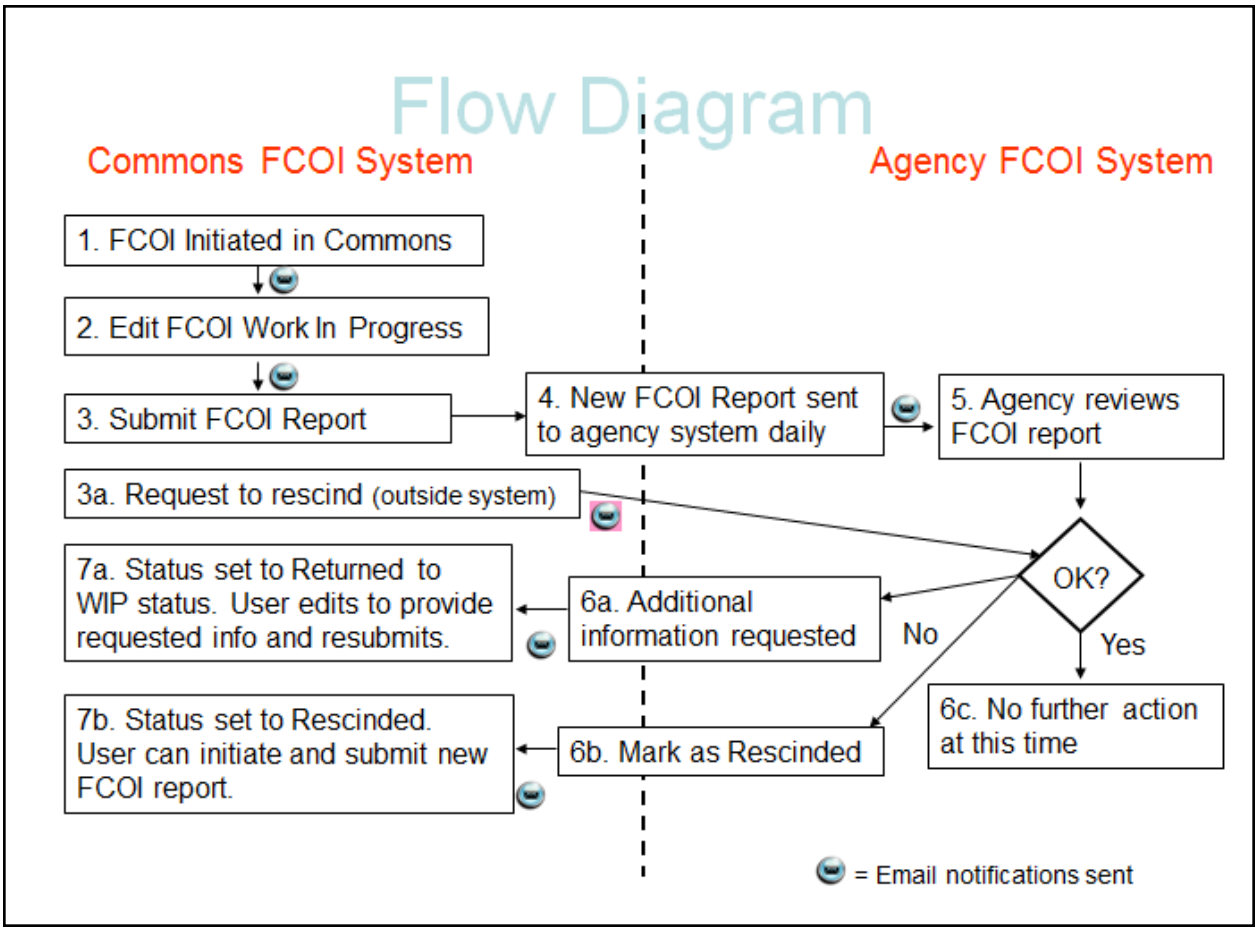
Only the SO can assign the FCOI_View role.

1.3 Basic Financial Conflict of Interest (FCOI) Report Process

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 (https://era.nih.gov/erahelp/AMS_NEW/#Create_Accounts/Create_User_Accts/Add_Roles.htm).

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.


Flow Diagram
Commons FCOI System
Agency FCOI System
1. FCOI Initiated in Commons
2. Edit FCOI Work In Progress
3. Submit FCOI Report
4. New FCOI Report sent to agency system daily
5. Agency reviews FCOI report
3a. Request to rescind (outside system)
OK?
7a. Status set to Returned to WIP status. User edits to provide requested info and resubmits.
6a. Additional information requested
No
Yes
6c. No further action at this time
7b. Status set to Rescinded. User can initiate and submit new FCOI report.
6b. Mark as Rescinded
= Email notifications sent

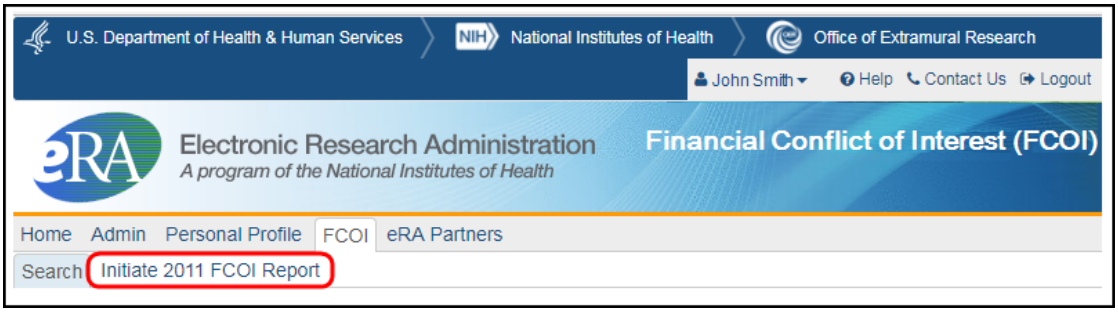
2 Initiating an FCOI Report

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.

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** tab.

   The *Financial Conflict of Interest – Initiate New Report* screen displays (see below)

   The initial fields on this screen are as follows:

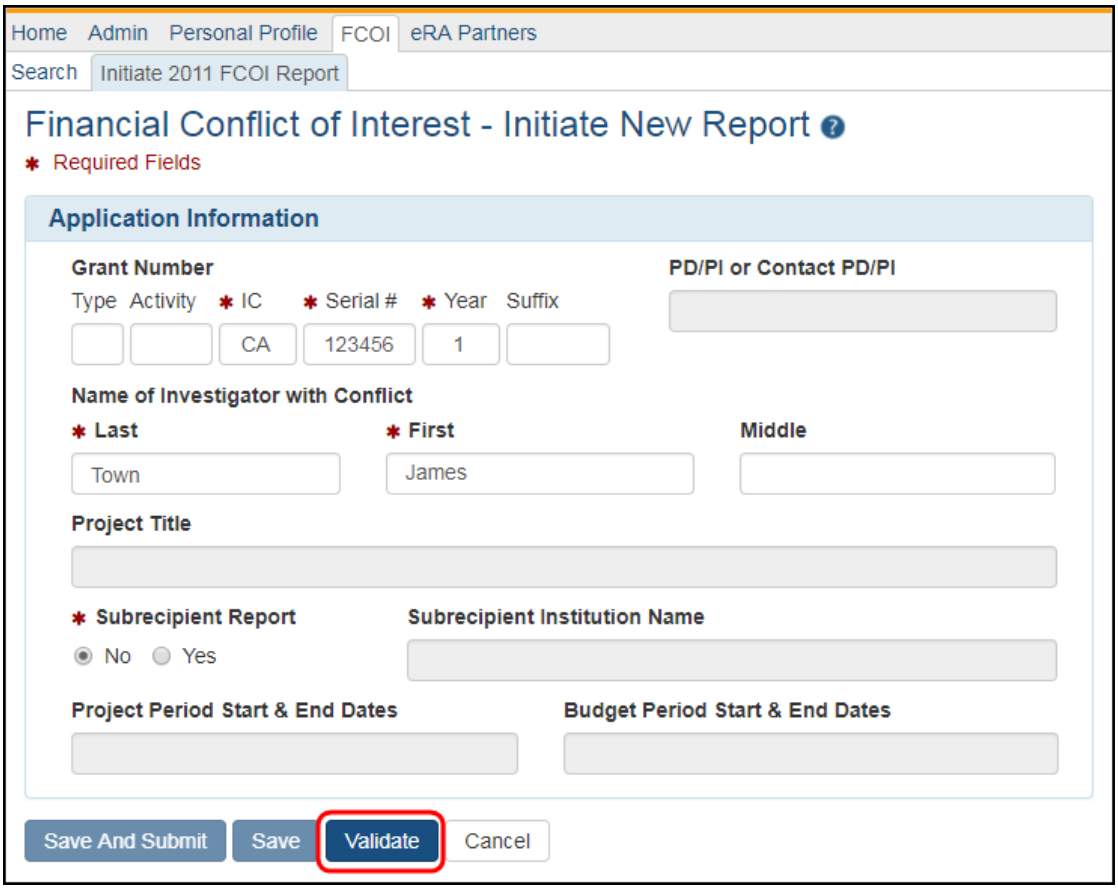
   - **Grant Number** (**IC Code**, **Serial Number**, and **Support Year** are required)
   - **Name of Investigator with Conflict** (**Last Name** and **First Name** are required)

- **Subrecipient Report** (**No** or **Yes** – along 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 (*).

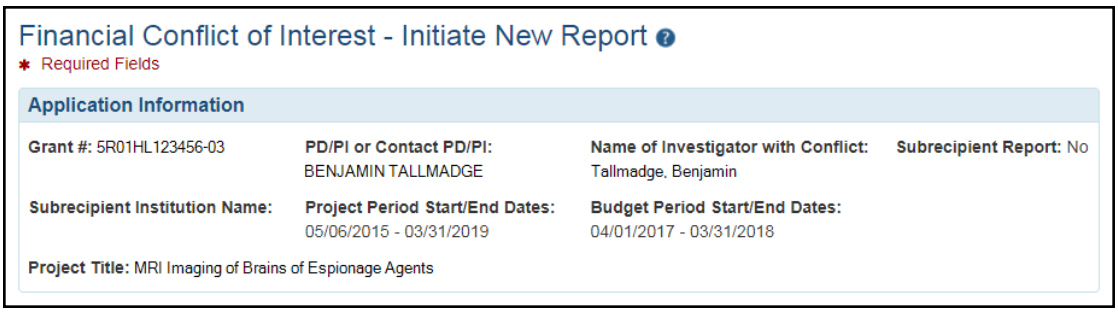
4. Select the **Validate** button.



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:

ERROR! 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** (sections 1-3), **Noncompliance with Regulation** section 4 (sections 5 and 6 if "Yes" answers), and **Upload PDF Documents** – display and are enabled for editing.

FCOI Information

Section 1.

* **Entity**

MRIs R Us

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. Enter the name of the entity that the Investigator has a financial interest.

Nature of SFI(s)

Equity Interest - Non-publicly traded entity (e.g., stock, stock option, or other ownership

Annual Value

$250,000 - $299,999

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

Section 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.** (2000 character maximum)

2000 remaining.

Upload To upload a report, you may either click the Upload button or drag the desired file here.

File Name	Date Created	Status	Action
No documents provided			

Section 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.** (2000 character maximum)

2000 remaining.

Upload To upload a report, you may either click the Upload button or drag the desired file here.

File Name	Date Created	Status	Action
No documents provided			

Section 4.

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

Upload PDF Documents

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

Description:

Upload To upload a report, you may either click the Upload button or drag the desired file here.

File Name	Description	Date Created	Action
No documents provided			

Save And Submit | Save | View FCOI History | Cancel

5. Update the fields in the **FCOI Information** block.

   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*

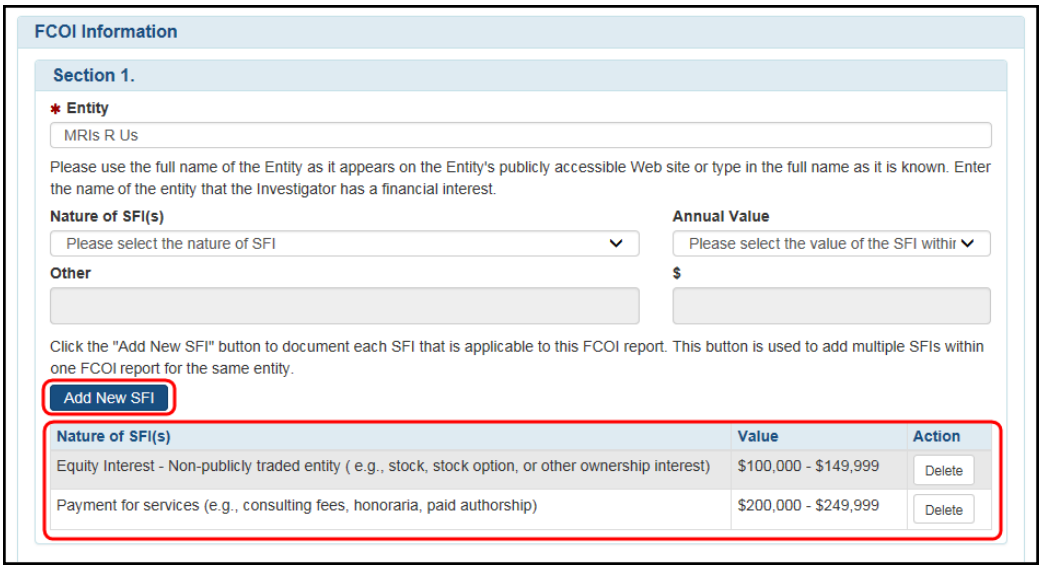
NOTE: Do not use punctuation or symbols (i.e. commas or "$") when entering values greater than $600,000. Use numbers only.

- The interest is one who value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

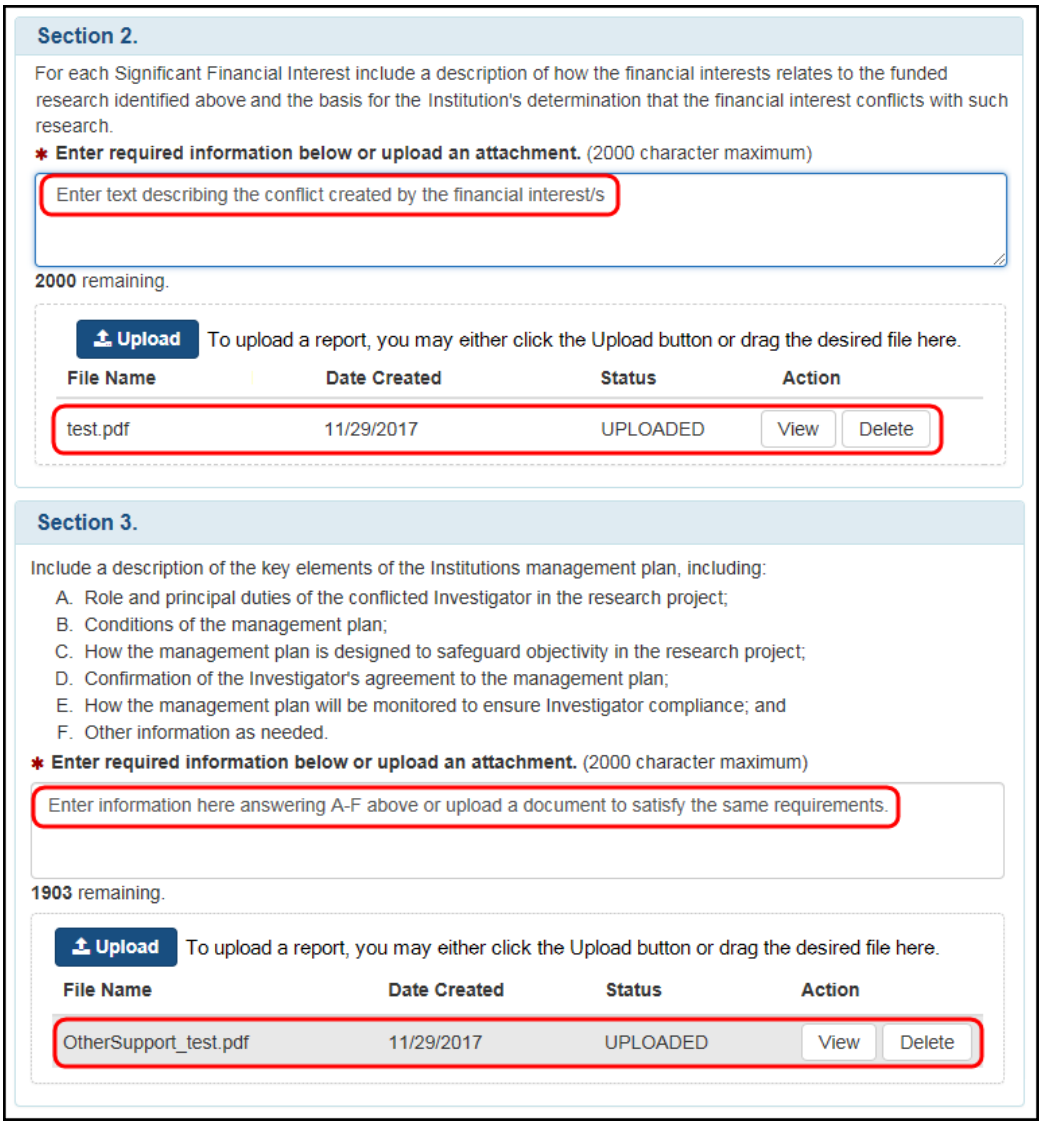
*Requires that a specific value be placed in the enabled line located under the Value field.

d. Select the **Add New SFI** button 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.

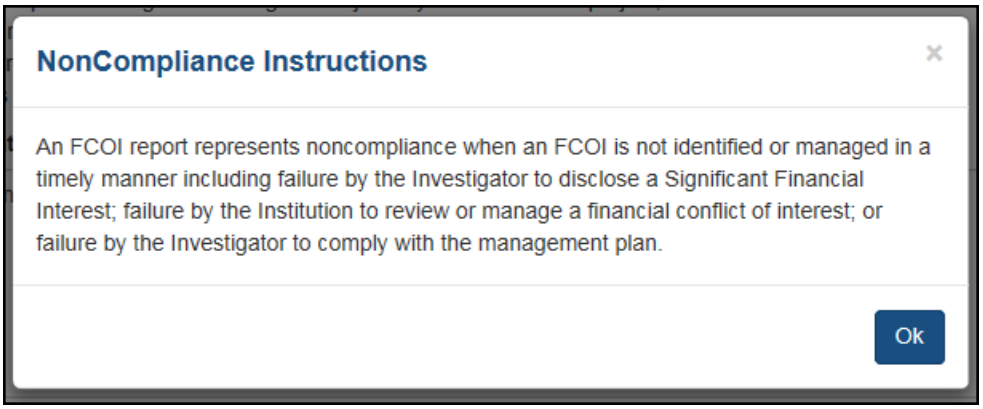


e. Enter text or upload an attachment to describe how each financial interest relates to the funded research (Question #2).
f. Enter text or upload an attachment to describe the key elements of the institution's management plan (Question #3).



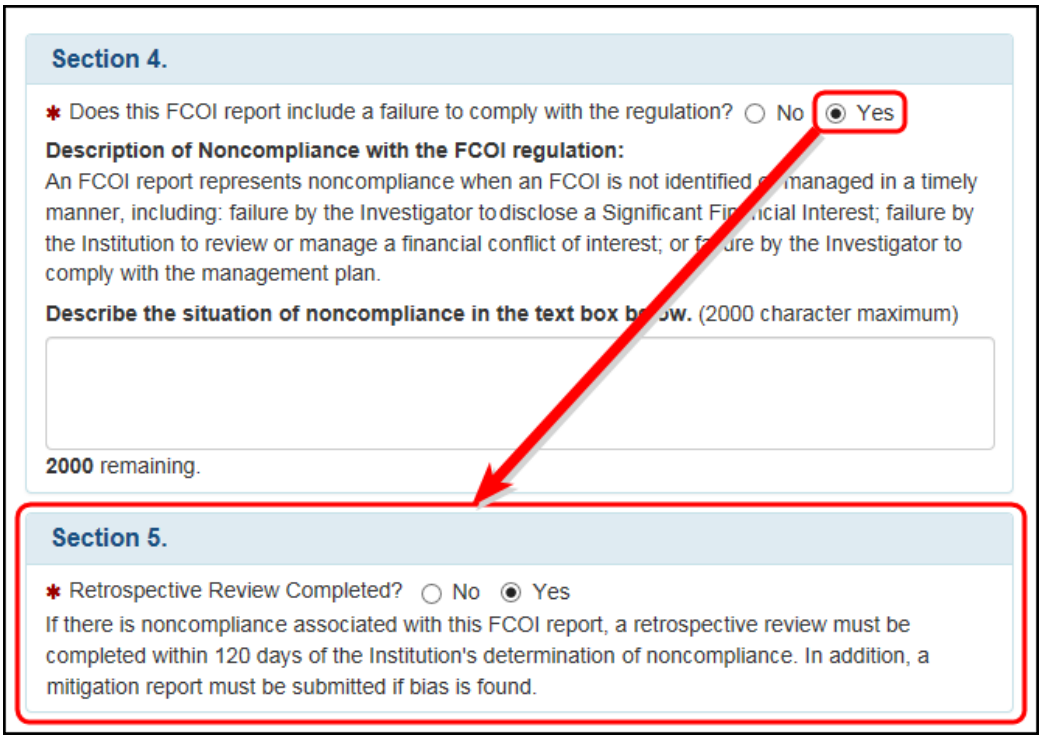
6. Select the **No** or **Yes** radio button for question #4 **Does this FCOI report include a failure to comply with the regulation?**

   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.*



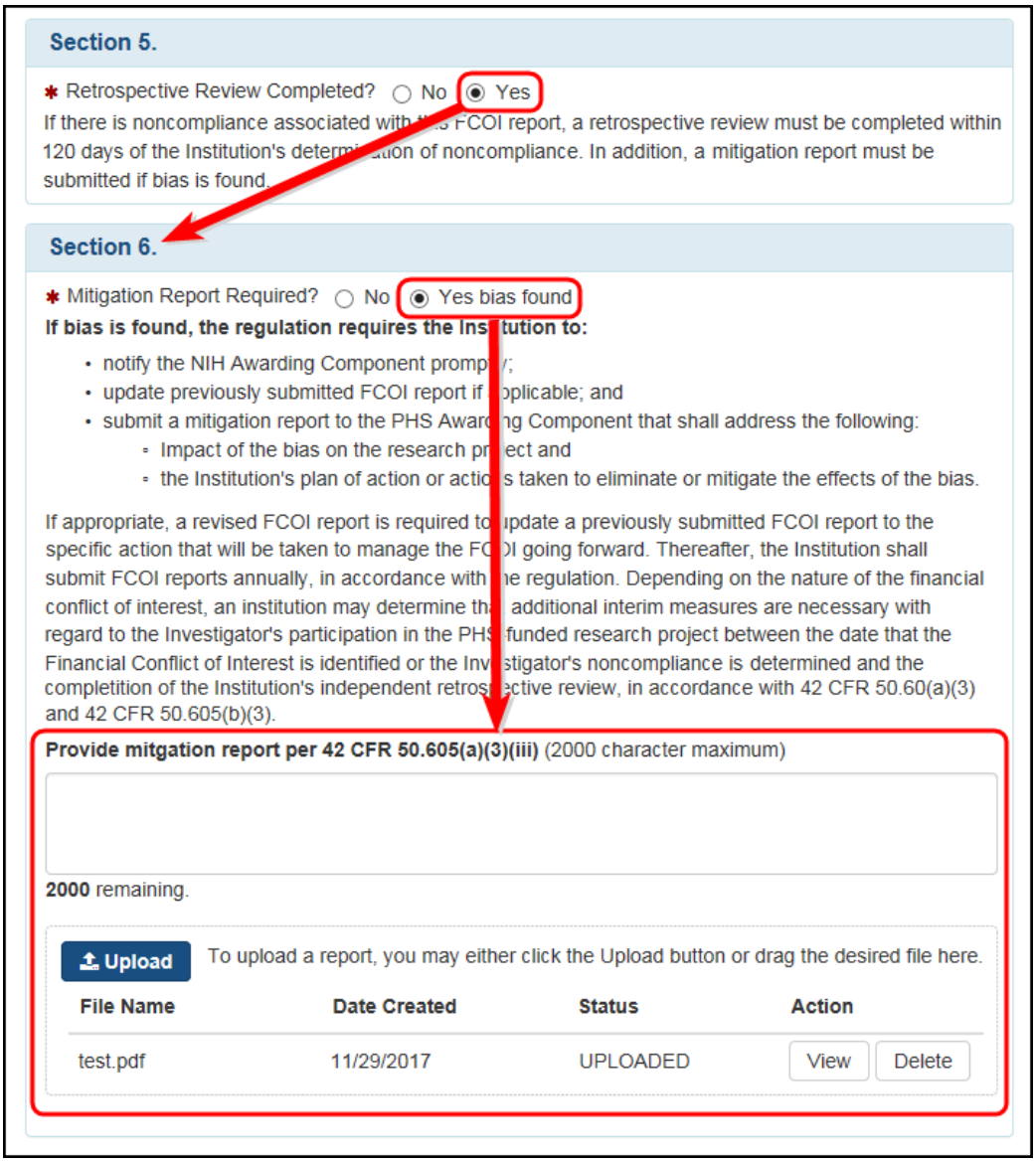
After selecting **OK** to close the pop-up, the **Description of Noncompliance with the FCOI Regulation** section appears containing a text box for comments and question **5. Retrospective Review Completed?** These are both required fields when *Yes* is selected for Question 4.

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.

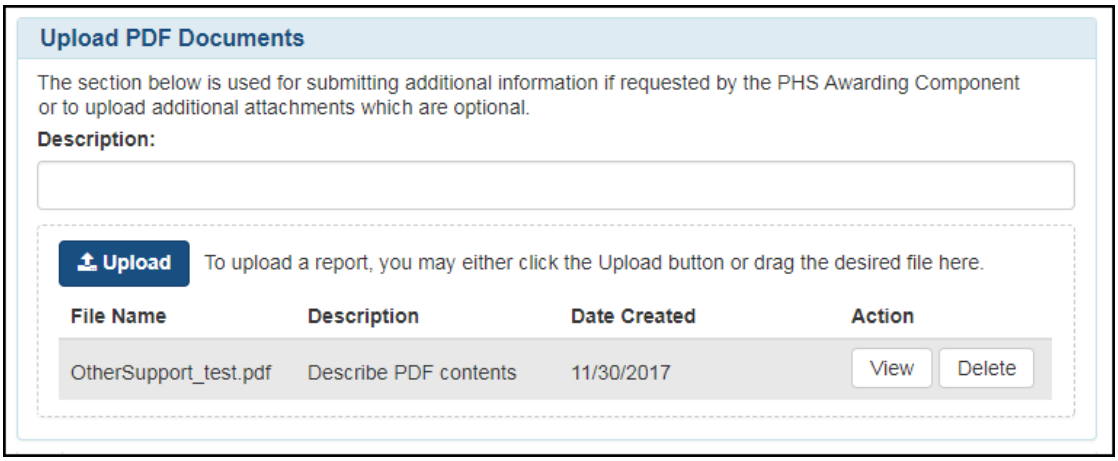


c. *Only if response to Question 5 is Yes:*

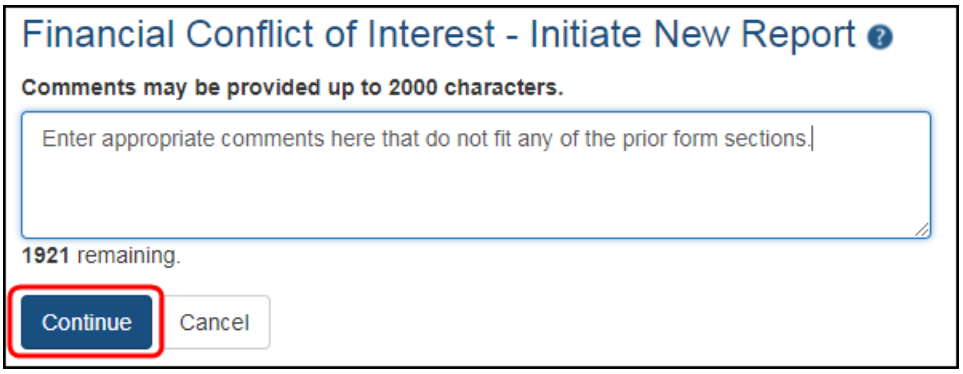
Select the **No** or **Yes bias found** radio button for question **6. Mitigation Report Required?** to indicate whether a mitigation report is required when bias is found. If the **Yes bias found** button is selected, provide the Mitigation Report information in the enabled text box or upload a file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



8. *Additional and Optional Information*: Add any additional or optional information in the **Upload PDF Documents** section. Enter a brief description (up to 30 characters) and then use the **Upload** or drag and drop feature to add the PDF file.



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 **View FCOI History** button to see the actions taken so far.
   - Select the **Cancel** button to return to the FCOI Search screen.
10. **Save and Submit** and related comments:
   - 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. After entering the appropriate comments, select the **Continue** button to complete the submission. (Selecting **Cancel** will return you to the form page)



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.

3 Submitting 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.

The report can be submitted at the time it was initiated or a later time if the report was saved and is in a status of *Work in Progress*.

3.1 Submitting the Report While Initiating

To submit an FCOI report while initiating it:

1. Access the FCOI module by selecting **FCOI** tab from the Commons main menu.
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 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 (e.g., 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.

Refer to the section of this document titled *Initiating an FCOI Report* on Page 6 for more information and steps for initiating the report.

3.2 Editing the FCOI Before Submission

Commons users with FCOI or FCOI_ASST roles can perform edits on saved FCOI reports in *Work in Progress* status. During editing, the report can also be submitted if the user holds the FCOI role.

To edit the FCOI Report and submit it:

1. Select select the **FCOI** tab at the Commons main menu.
2. From the *FCOI Search* screen, perform a search for the FCOI Report. Refer to the section of this document titled *Searching Existing FCOI Reports (Notifications)* on Page 20
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 the **Save and Submit**.

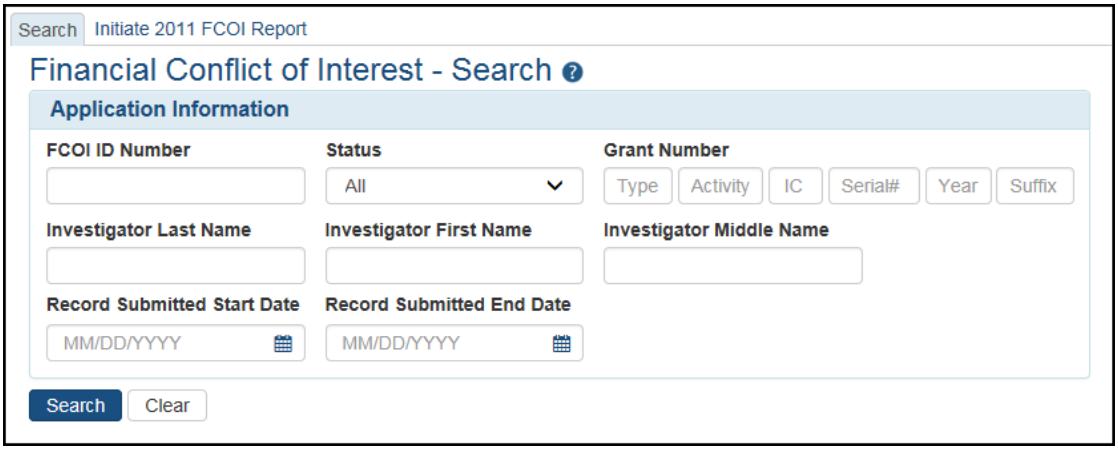
4 Searching Existing FCOI Reports (Notifications)

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 **Search** button.

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

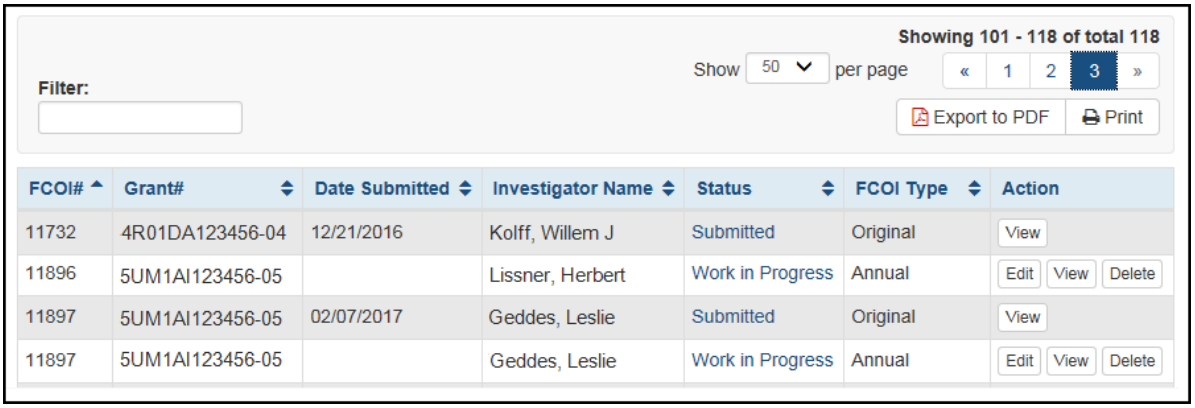


The matching records based on the search appear in a table at the bottom of the screen. The columns in the table are sortable by selecting the up/down arrows in the column headings (for all columns except **Action**).

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**



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.

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*.

Annual Report: Opens the *Annual FCOI Report* screen. This link is 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 the 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.

5 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.

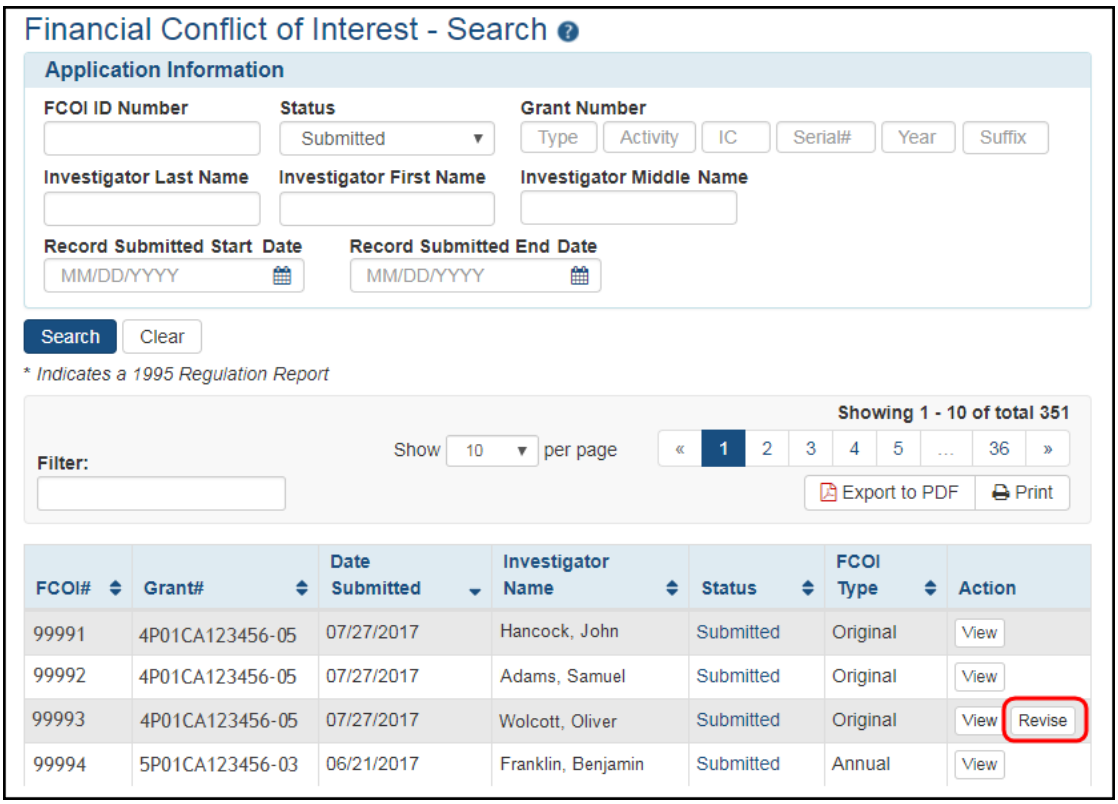
NOTE: If an FCOI Report is submitted with errors, the institution should contact the Agency to determine whether to rescind the FCOI record or to allow the grantee to make corrections through a response to a Request for Additional Information.

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 submission date to submit a Revised FCOI report.

To revise and submit an FCOI report:

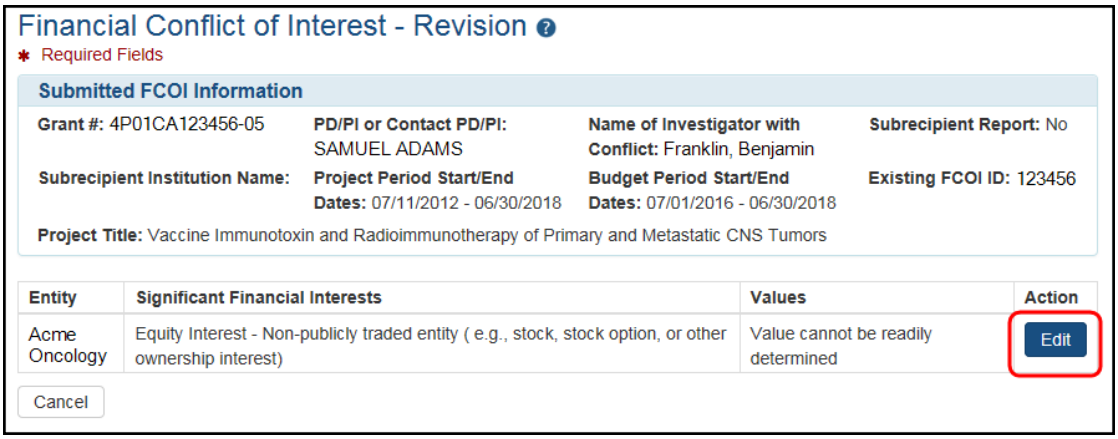
1. Access *FCOI Search* by selecting the **FCOI** tab from the Commons menu.
2. From the *FCOI Search* screen, perform a search for the appropriate FCOI report.

3. Select the **Revise** button in the **Action** column for the specific FCOI report.



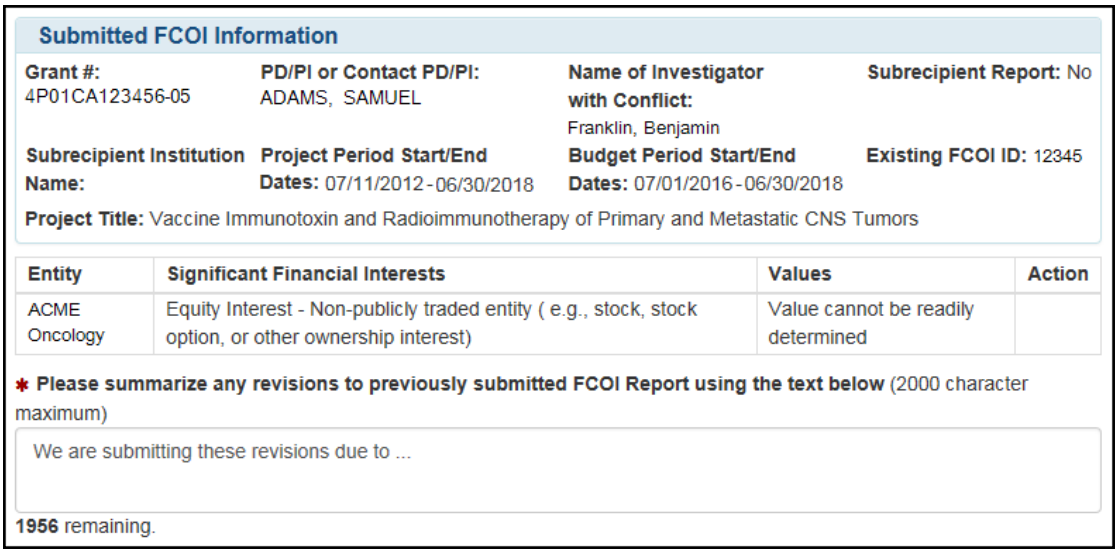
The *FCOI – Revision* screen displays the information from the current FCOI report as read-only. The summary of reported significant financial interests (SFI(s)) is displayed in the table at the bottom of the screen.

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



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.

5. 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.



Submitted FCOI Information

Grant #: 4P01CA123456-05
PD/PI or Contact PD/PI: ADAMS, SAMUEL
Name of Investigator with Conflict: Franklin, Benjamin
Subrecipient Report: No
Subrecipient Institution Name:
Project Period Start/End Dates: 07/11/2012 - 06/30/2018
Budget Period Start/End Dates: 07/01/2016 - 06/30/2018
Existing FCOI ID: 12345
Project Title: Vaccine Immunotoxin and Radioimmunotherapy of Primary and Metastatic CNS Tumors

Entity	Significant Financial Interests	Values	Action
ACME Oncology	Equity Interest - Non-publicly traded entity (e.g., stock, stock option, or other ownership interest)	Value cannot be readily determined	

* **Please summarize any revisions to previously submitted FCOI Report using the text below** (2000 character maximum)

We are submitting these revisions due to ...

1956 remaining.

6. Complete the revisions as appropriate under the **FCOI Information** section. Refer to the section of this document titled *Initiating an FCOI Report* on Page 6 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.

FCOI Information

Section 1.

*** Entity**

ACME Oncology

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. Enter the name of the entity that the Investigator has a financial interest.

Nature of SFI(s)

Please select the nature of SFI

Annual Value

Please select the value of

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
Equity Interest - Non-publicly traded entity (e.g., stock, stock option, or other ownership interest)	Value cannot be readily determined	Delete

Section 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.** (2000 character maximum)

Dr. Franklin has IP being used in clinical trials which will be supported by grant carryover funds with NCI approval. The IP has been licensed to Adams, a company in which he has equity.

1810 remaining.

Upload To upload a report, you may either click the Upload button or drag the desired file here.

File Name	Date Created	Status	Action
No documents provided			

Section 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.** (2000 character maximum)

Sample of key elements of the management plan...

1952 remaining.

Upload To upload a report, you may either click the Upload button or drag the desired file here.

File Name	Date Created	Status	Action
CA154_July 2017.pdf	12/04/2017	UPLOADED	View Delete

Section 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. (2000 character maximum)

Describe the noncompliance issue here...

1998 remaining.

Section 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.

Section 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 completition of the Institution's independent retrospective review, in accordance with 42 CFR 50.60(a)(3) and 42 CFR 50.605(b)(3).

Provide mitgation report per 42 CFR 50.605(a)(3)(iii) (2000 character maximum)

2000 remaining.

Upload To upload a report, you may either click the Upload button or drag the desired file here.

File Name	Date Created	Status	Action
No documents provided			

Upload PDF Documents

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

Description:

Upload To upload a report, you may either click the Upload button or drag the desired file here.

File Name	Description	Date Created	Action
OtherSupport_test.pdf		12/04/2017	View Delete

Save And Submit | Save | View FCOI History | Cancel

7. Update the fields in the **Description of Noncompliance with the FCOI regulations** 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.

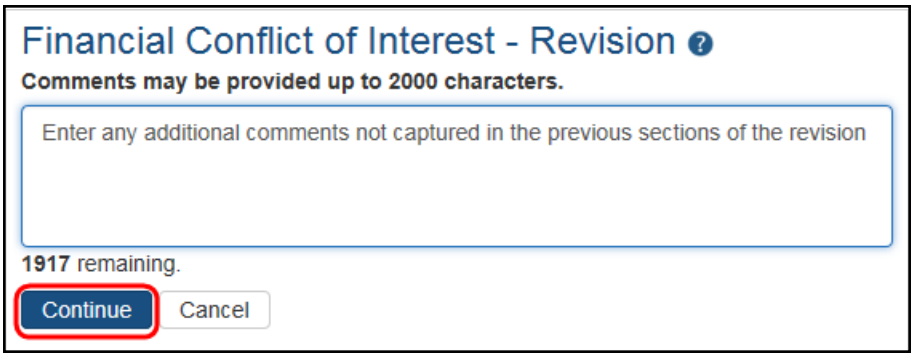
   b. Select the **Yes bias found** radio button for question #6 (**Mitigation Report Required?**) to indicate that a mitigation report is required. When the **Yes bias found** button is selected, provide the Mitigation Report information in the enabled text box or upload a file in the table below it.

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.

NOTE: Only Commons users with an FCOI role may use the **Save and Submit** feature. ASST users with FCOI authority cannot submit the report.

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.



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.

** Indicates a 1995 Regulation Report*

Showing 1 - 50 of total 352

Filter:

Show 50 per page « 1 2 3 4 5 … 8 »

Export to PDF | Print

FCOI#	Grant#	Date Submitted	Investigator Name	Status	FCOI Type	Action
99991	4P01CA123456-05	12/04/2017	Franklin, Benjamin	Submitted	Original	View
99991	4P01CA123456-05	12/04/2017	Franklin, Benjamin	Submitted	Revision	View
99992	4P01CA123456-05	12/04/2017	Adams, Samuel	Submitted	Original	View Revise

6 Agency Requests for Additional Information

The Agency 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*.

Commons users with access to FCOI can open the report 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 report to provide requested additional information or to make a correction to previously submitted data, 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

   Refer to the section of this document titled *Initiating an FCOI Report* on Page 6 for more information about the fields on the report and sample figures.

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. ASST users with FCOI authority cannot submit the report.

   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.

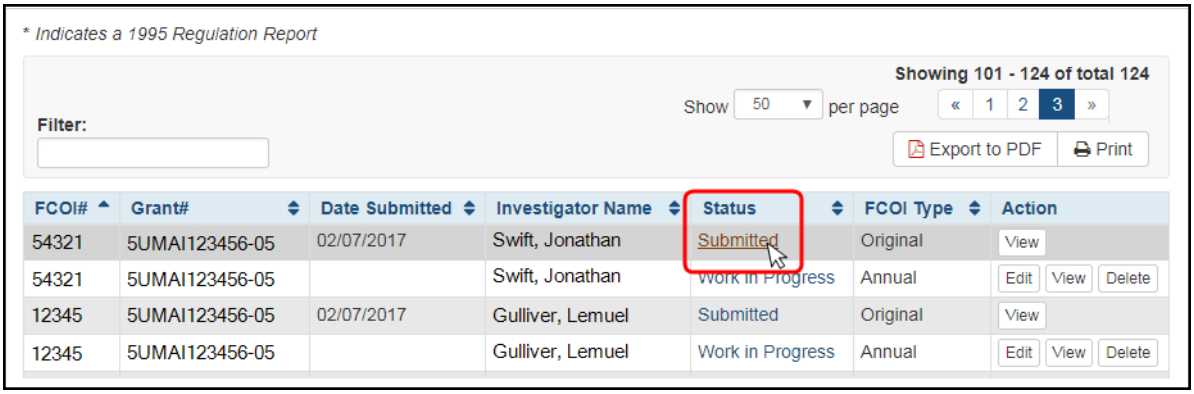
5. Enter the appropriate comments in the **Comments** text box (up to 2000 characters) and select the **Continue** button.

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

7 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 found on the *Financial Conflict of Interest – Initiate New Report* and *FCOI – Revision* screens.



The *FCOI 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)

Financial Conflict of Interest - History

FCOI Information

Grant Number:	FCOI Current Status:	Sub-Recipient Institution:	Investigator with Conflict:
4R01DA123456-04			Wren, Christoper

Events Information

Showing 1 - 3 of total 3

Event	Action Taken by	Action Date	Action Comments
Initiated	Pravaz, Charles	04/03/2017	
Submitted	Pravaz, Charles	04/03/2017	No changes to report. Thank you, Pravaz, Charles
		04/13/2017	Email reminder sent to PO

Close

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

8 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.

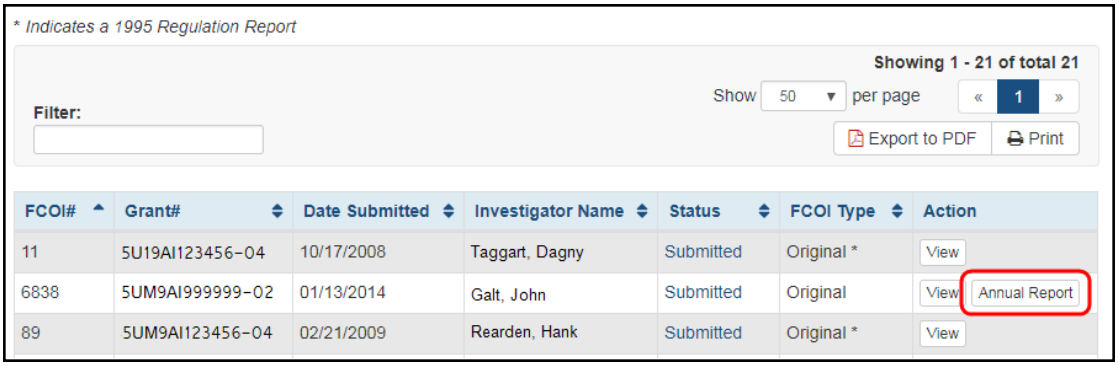
The **Annual Report** link only appears 75 days prior to the next budget period start date or after the Institution extends the grant via Commons for NIH funded grants. For AHRQ funded grants, the link appears 120 days before the budget period end date.

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 appears 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* 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** button in the **Action** column for the specific FCOI Report.



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.***

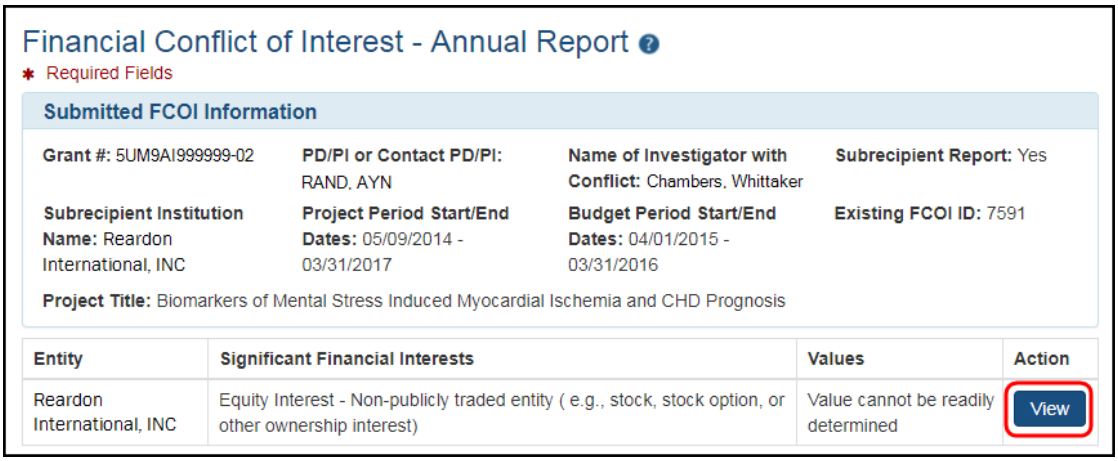
These overdue reports must be submitted first before the current year's report can be completed.

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.



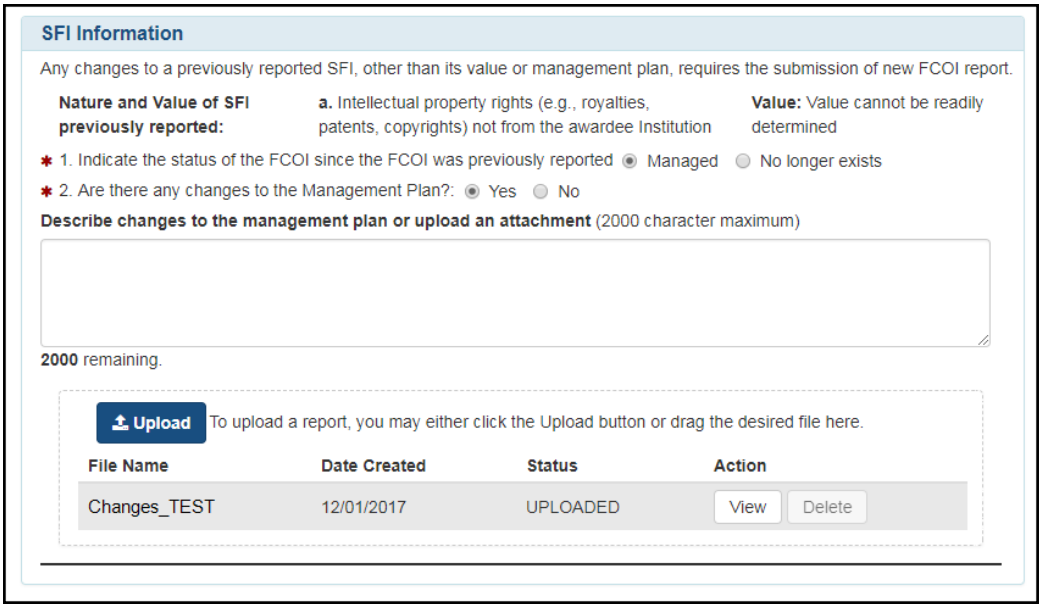
6. Answer the questions for each SFI listed.
   a. For question **1. Indicate the status of the FCOI since the FCOI was previously reported**, select the radio button for one of the options: **Managed** or **No longer exists**. When **No longer exists** is chosen, this FCOI is removed from future annual

reporting.

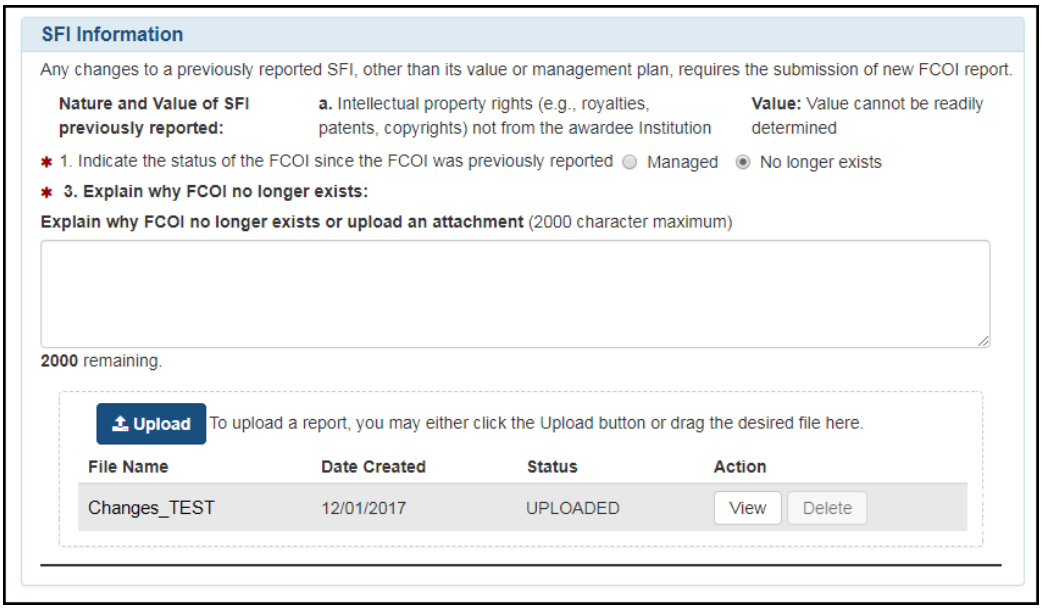
NOTE: If you had previously entered an answer for Question 1 (i.e., this is not the first time entering the Annual Report information or it is a Revision), you will receive a warning message as follows: *You are about to change the status of the FCOI from what was previously selected. Any entered data associated with that previous selection will be deleted from the report, if applicable.*

Select **Yes** to continue or **No** to cancel.

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**.

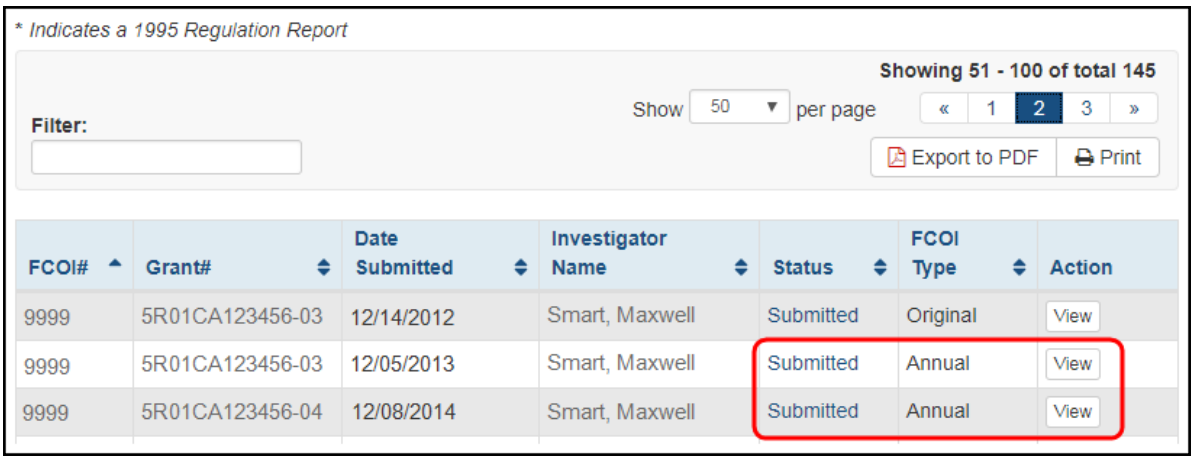


c. For question **3. Explain why FCOI no longer exists**, enter an explanation in the text box or use the upload feature to attach documentation explaining why the FCOI no longer exists. This question is only displayed when the response to Question 1 is **No longer exists**.



7. Perform one of the following actions:
   - Select the **Save** button to put the record in *Work in Progress* 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.



9 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.