Financial Conflict of Interest User Guide

August 26, 2026

NOTE: This user guide is an identical PDF version of the online help.

Contact Us

Additional Help Needed? Please contact the eRA Service Desk (https://www.era.nih.gov/need-help).

Toll-free: 1-866-504-9552; **Phone:** 301-402-7469

Hours: Mon-Fri, 7:00 a.m. to 8:00 p.m. Eastern Time

Feedback on the user guide? Please email the eRA Communications Office (era-communications@mail.nih.gov).

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Financial Conflict of Interest (FCOI) Module Overview

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* details how to manage the Financial Conflict of Interest (FCOI) reporting process for an 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 organization'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 organization'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://www.era.nih.gov/erahelp/commons/) or the *Financial Conflict of Interest (FCOI) External User Guide* (https://www.era.nih.gov/files/fcoi_user_guide.pdf).

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

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

Process Objectives
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

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.

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 organization in grants administration matters by providing signature approval on submissions. The SO monitors grant related activities with the grantee organization and may have a number of titles.

Financial Conflict of Interest (FCOI role)

This role should be assigned to the Commons user(s) in the organization 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.

Financial Conflict of Interest Assistant (FCOI_ASST) Role

Assign the FCOI_ASST role to those users in the organization 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.

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 organization 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.

Basic Financial Conflict of Interest (FCOI) Report Process

The Signing Official (SO) is the authorized official at the organization that has the authority to sign for the organization. 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 organization.

The SO is responsible for assigning the FCOI, FCOI_ASST, and FCOI_VIEW roles to the appropriate system users in the organization. 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://www.era.nih.gov/erahelp/AMS_NEW/#Create_Accounts/Create_User_Accts/Add_Roles.htm).

The following 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.

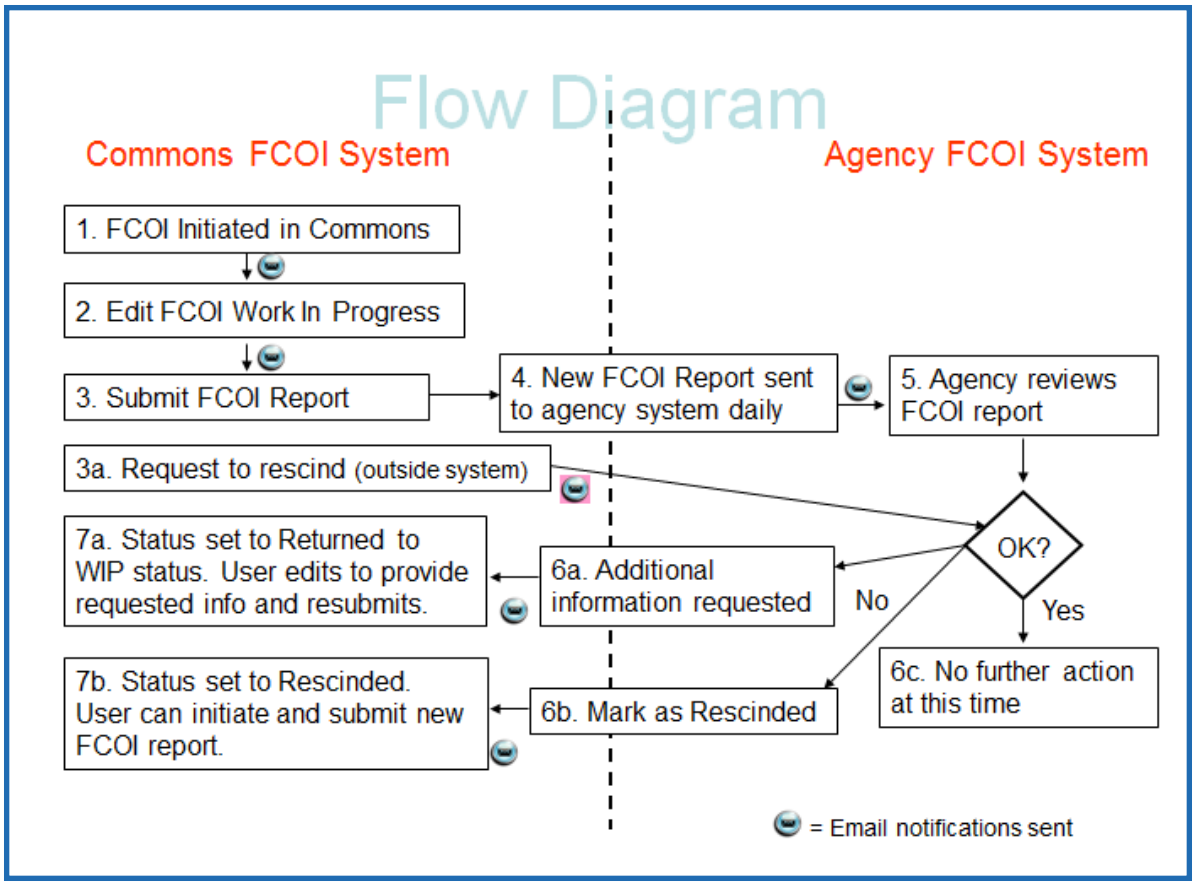


Figure 1: FCOI Process Flow

Initiating an FCOI Report

Commons users can initiate new FCOI Reports. To do so, the user must have the FCOI or FCOI_ASST role at each affiliated organization.

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. After logging into Commons, navigate to the FCOI module.

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

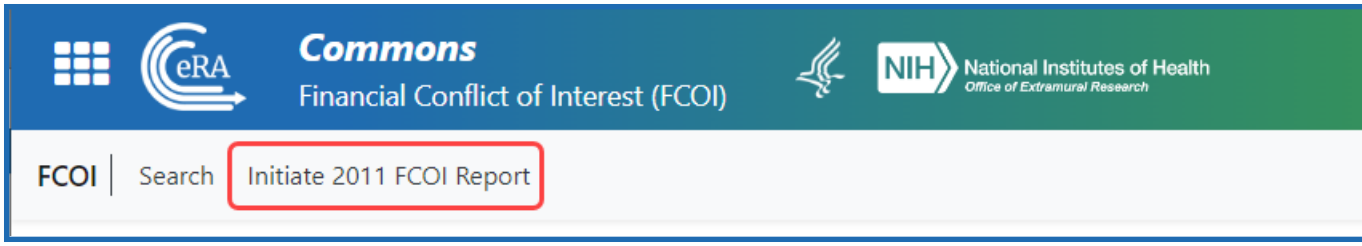


   Figure 2: Initiate 2011 FCOI Report

2. Click 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. Click the **Validate** button.

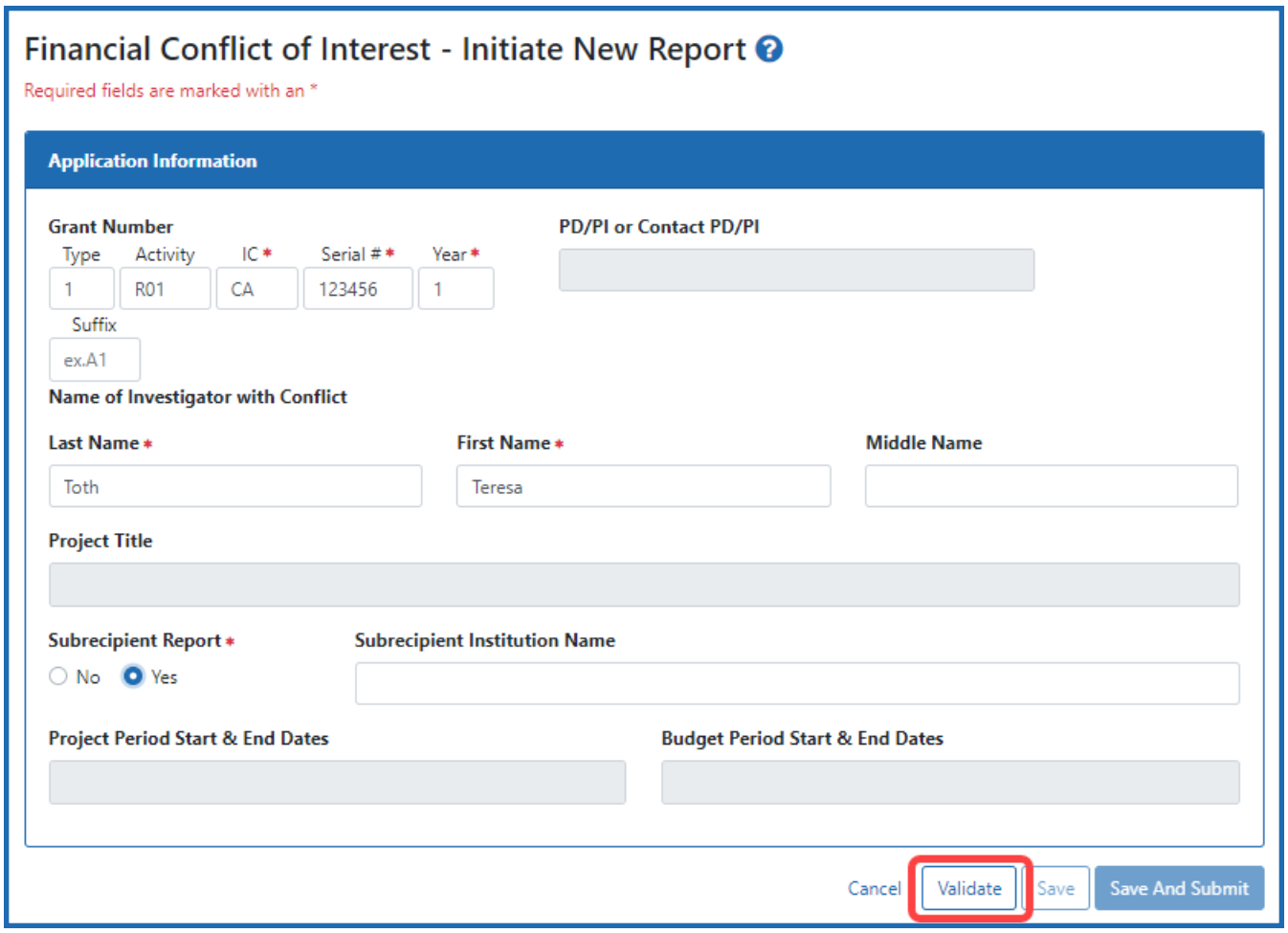


Figure 3: FCOI Report - Validate Button

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.

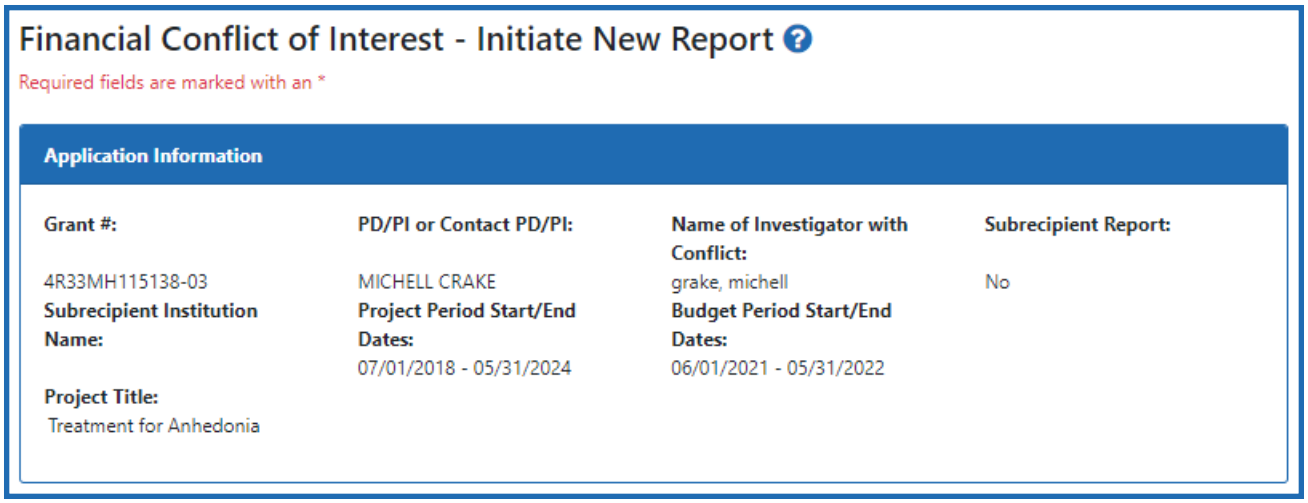


Figure 4: FCOI New Report Displaying Grant Information as Read-only

The lower portions of the screen – **FCOI Information** (sections 1-3), **Non-compliance 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 Name *

Please use the full name of the Entity as it appears on the Entity's publicly accessible website 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) | **Annual Value of the SFI Within These Dollar Ranges**

Select One | Select One

Add New SFI

Add as many SFIs (Significant Financial Interest) as needed within one FCOI report for the same entity.

Nature of SFI(s)	Value

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 remaining.

Drop file or browse to attach 1 PDF file, not exceeding 6MB.

File Name	Date Created	Status
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 remaining.

Drop file or browse to attach 1 PDF file, not exceeding 6MB.

File Name	Date Created	Status
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:

30 remaining.

Drop file or browse to attach 10 total PDF files, not exceeding 6MB.

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 organization
        - 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 details on the **Other** text field that appears.

    c. Select an option from the **Annual Value...** drop-down list:

        - The choices in value ranges from $0 to $599,999
        - >$600,000. If you select greater than 600,000, an additional **Value** field appears, where you must enter the value.

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 whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

d. Click 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, click the three-dot ellipsis menu and select **Delete**.

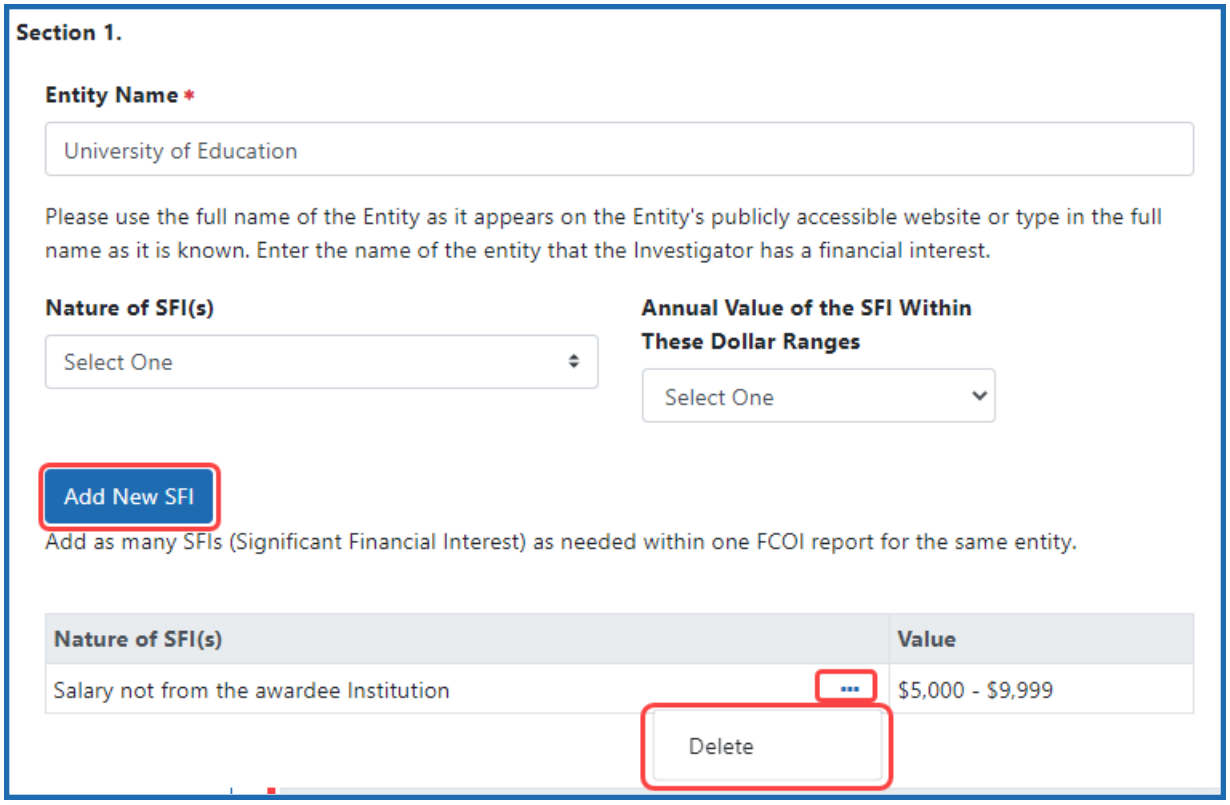


Figure 5: Significant Financial Interest Entries on FCOI Report

e. Enter text or upload an attachment to describe how each financial interest relates to the funded research (Question #2).

f. Enter text or upload an attachment to describe the key elements of the organization's management plan (Question #3).

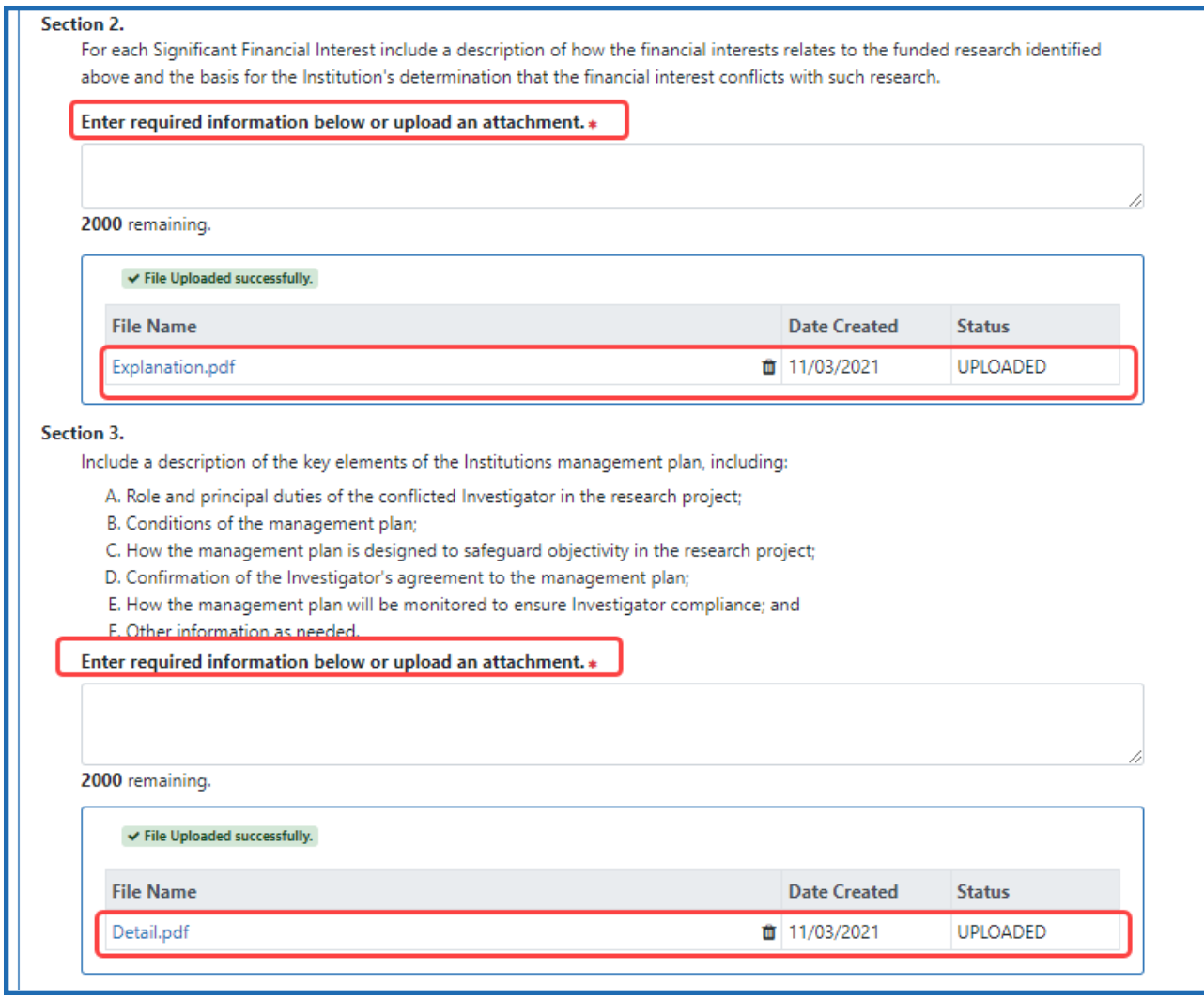


Figure 6: Descriptions and Uploads Supporting the FCOI Report (Questions 2 & 3)

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

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

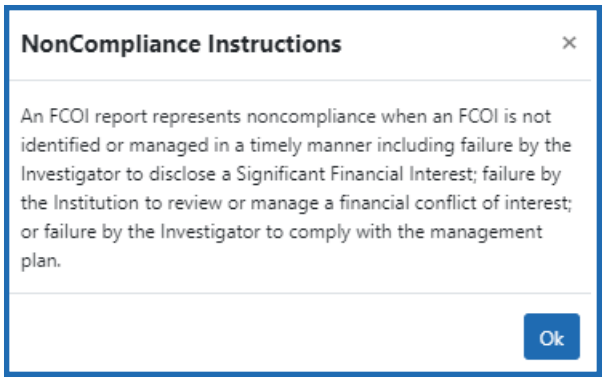


Figure 7: Noncompliance Message

After clicking **OK** to close the popup, 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. Click 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.

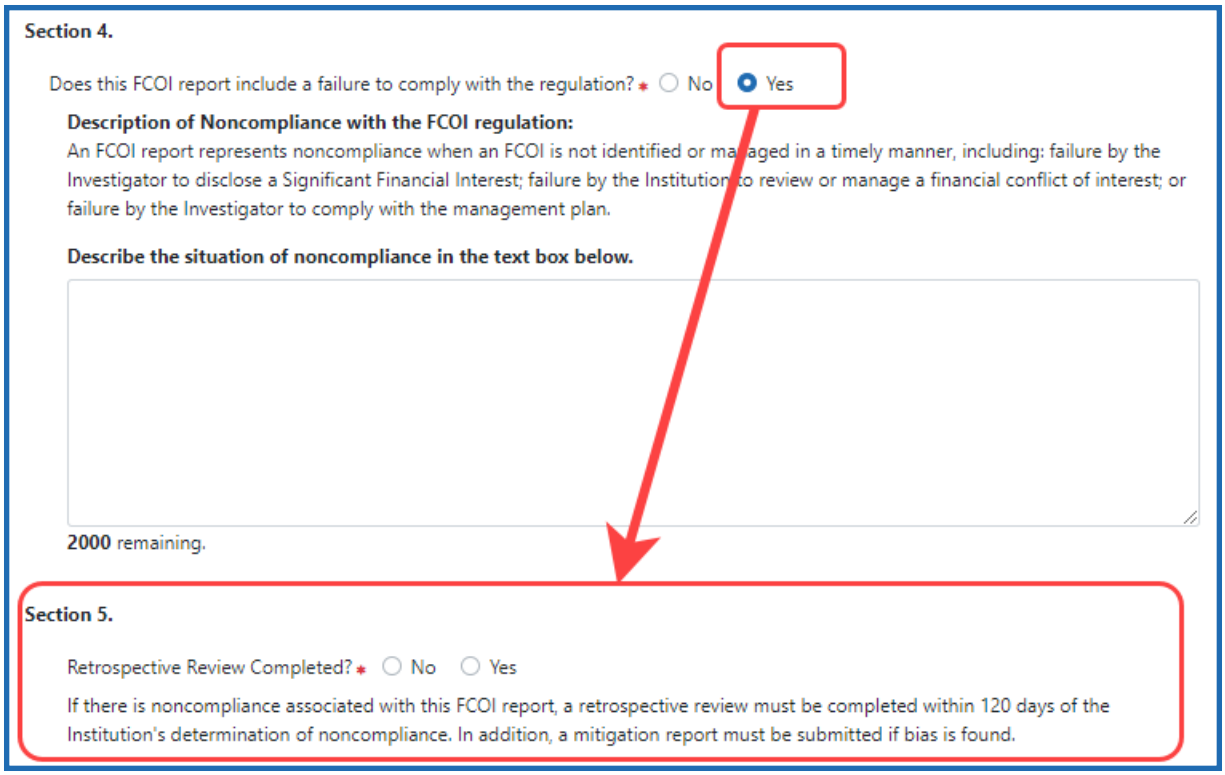


Figure 8: Comments Required when Response to Question 4 is Yes

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

Click 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.

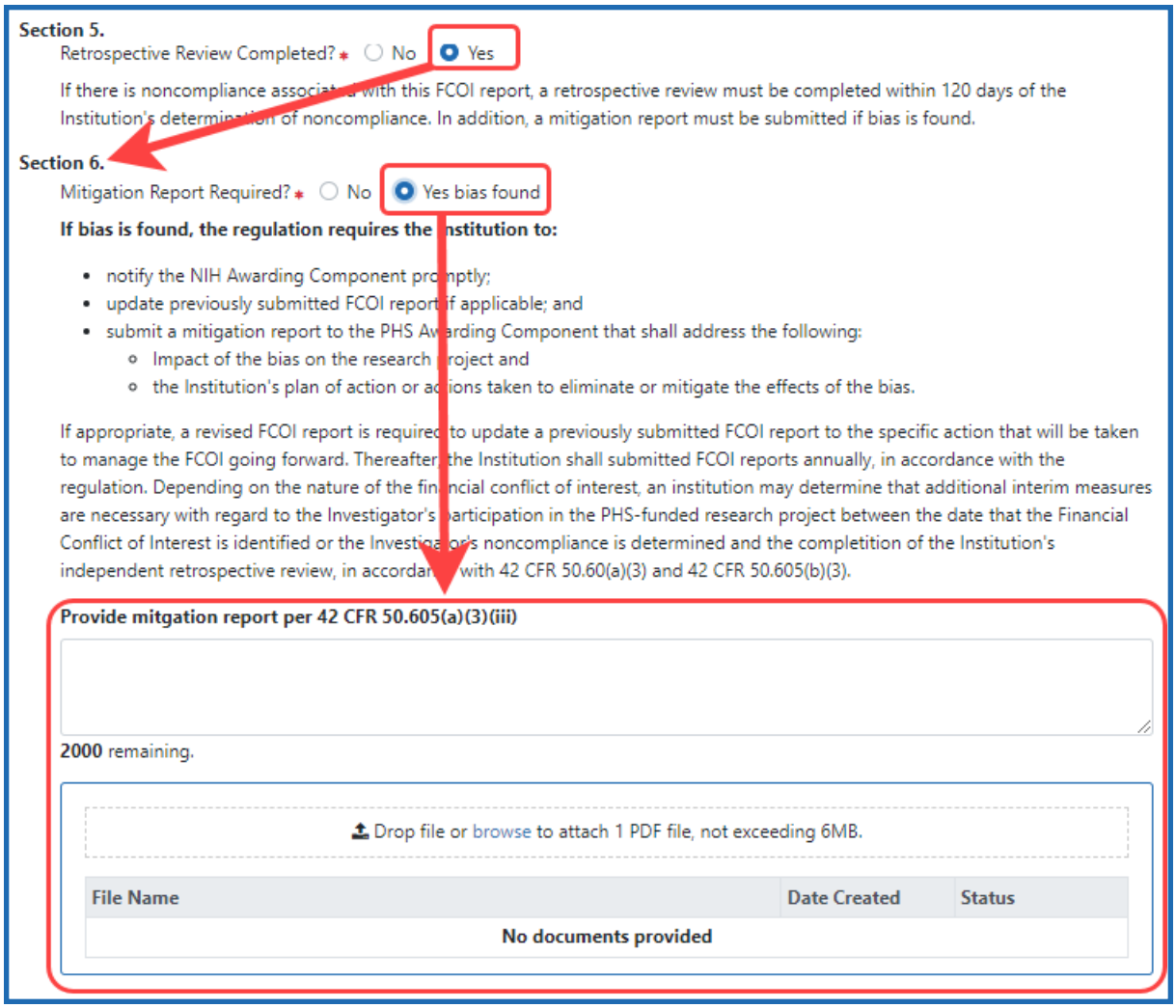


Figure 9: Noncompliance Reporting for FCOI Report

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 **browse** or drag and drop feature to add the PDF file.

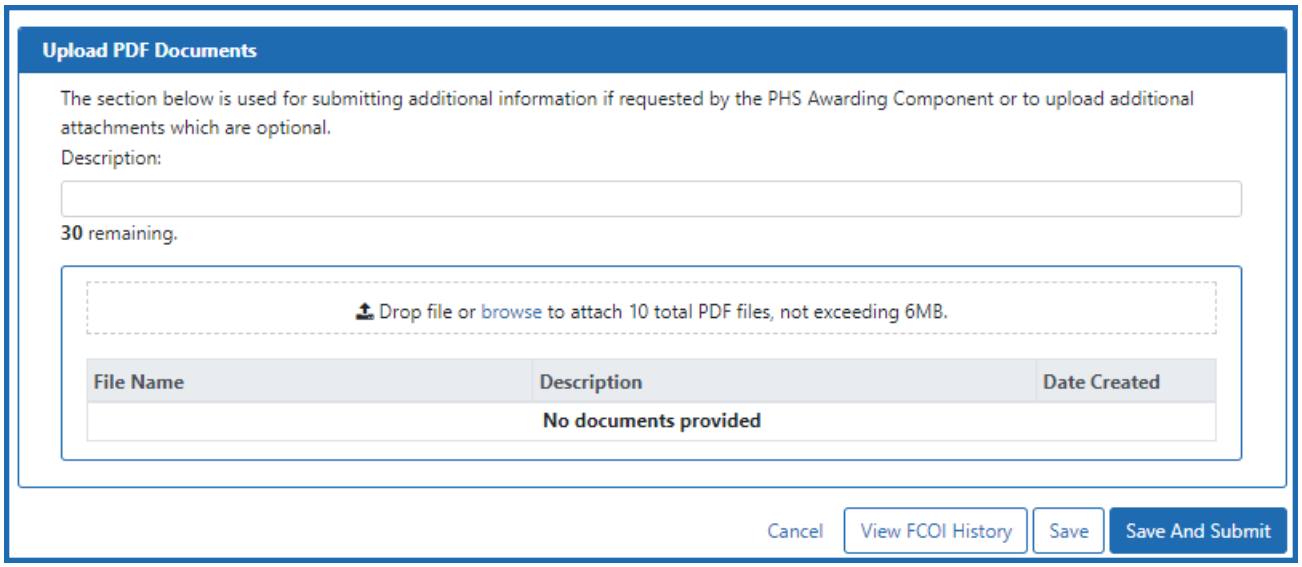
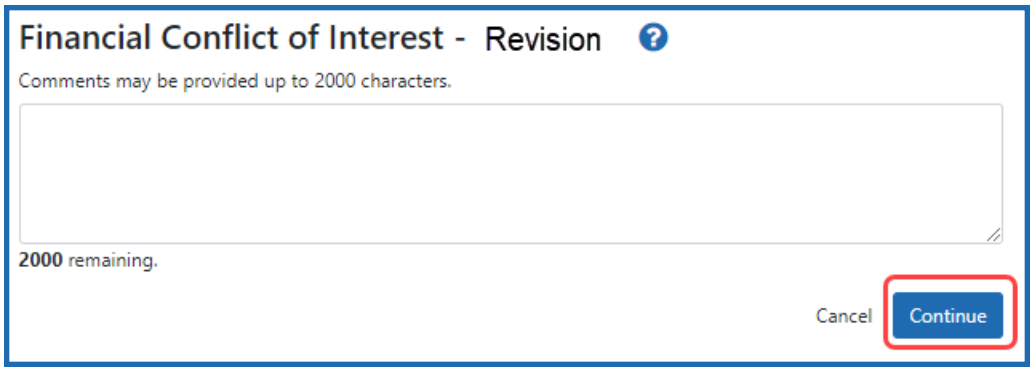


Figure 10: Additional/Optional PDF Upload for FCOI Report

9. Perform one of the following actions:
    - Click the **Save** button to put the record in WIP status.
    - Click the **Save and Submit** button to submit to agency.
    - Click the **View FCOI History** button to see the actions taken so far.
    - Click **Cancel** to return to the FCOI Search screen.
10. **Save and Submit** and related comments:
    - When the **Save and Submit** button is clicked, 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 the agency. After entering the appropriate comments, click the **Continue** button to complete the submission. (Clicking **Cancel** will return you to the form page)



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

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*.

Submitting the Report While Initiating

To submit an FCOI report while initiating it:

1. After logging into Commons, navigate to the FCOI module.
2. After completing the Initiate FCOI Report process for the FCOI Report or editing a WIP notification, click the **Save and Submit** button.
3. *Optional*: On the next screen, enter comments in the **Comments** text box and click 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 *Initiating an FCOI Report* on page 10 for more information and steps for initiating the report.

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. After logging into Commons, navigate to the FCOI module.
2. From the *FCOI Search* screen, perform a search for the FCOI Report. Refer to *Searching Existing FCOI Reports (Notifications)* on page 24
3. From the three-dot ellipsis menu for a record, select the **Edit** option for an 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 click the **Save and Submit** button to submit the FCOI Report to the awarding agency or click 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**.

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 organization with existing FCOI Reports.

To search for an FCOI record:

1. After logging into Commons, navigate to the FCOI module, which opens the *FCOI Search* screen.
2. Enter the appropriate search information for returning the desired records. The following fields are available for entering search data:
   - **FCOI ID #**
   - **Grant Number**
   - **Status** (All, Work in Progress, Submitted, Rescinded, Returned to WIP, Annual Report Due)
   - Investigator Name (Last, First, Middle). Search for those FCOIs associated with a certain investigator who has a conflict.
   - **Record Submitted Start Date** Use this along with the end date field to return records submitted within a certain date range.
   - **Record Submitted End Date**
3. Click the **Search** button.

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

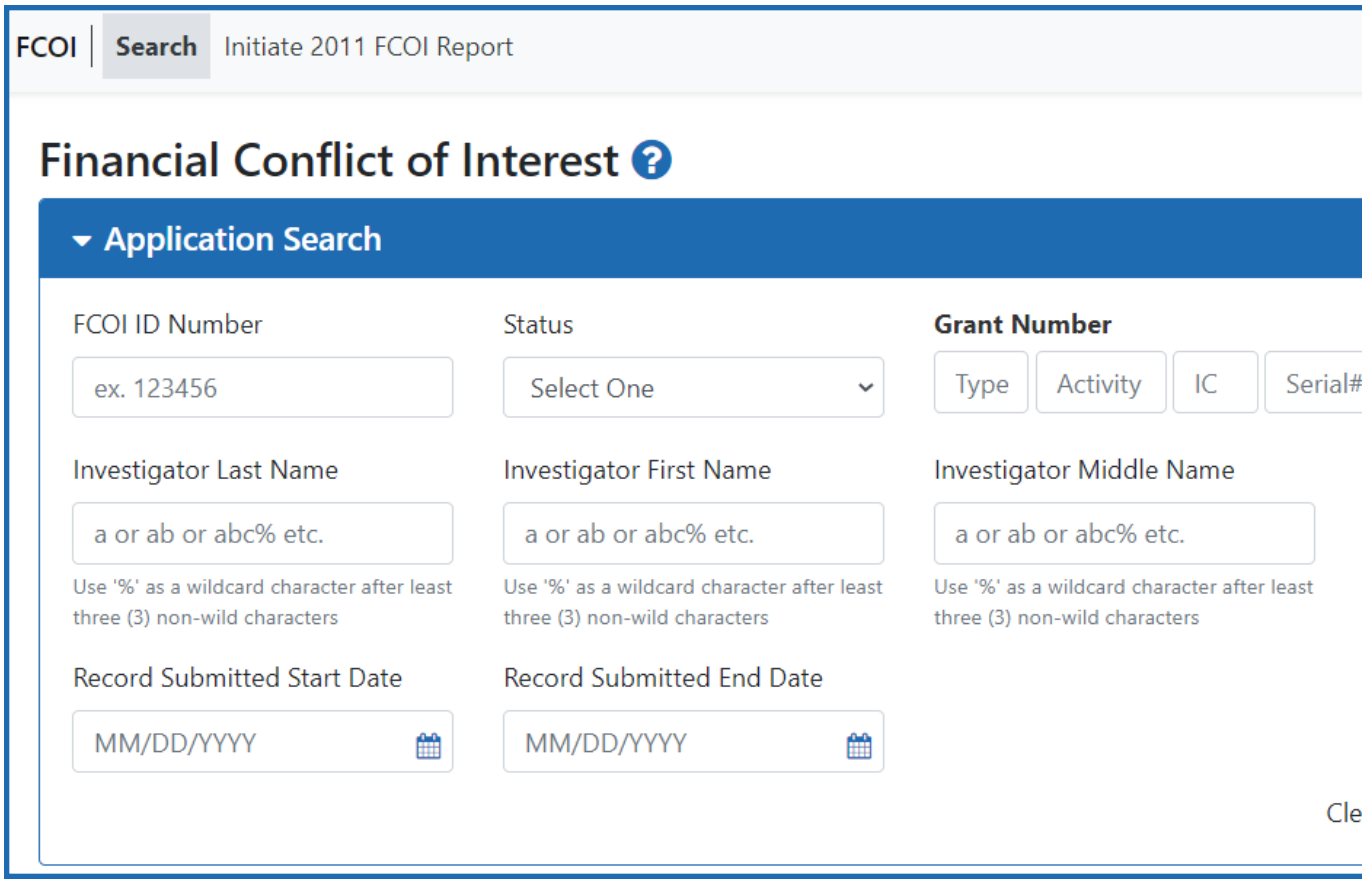


Figure 11: FCOI Search Screen

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 clicking 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)

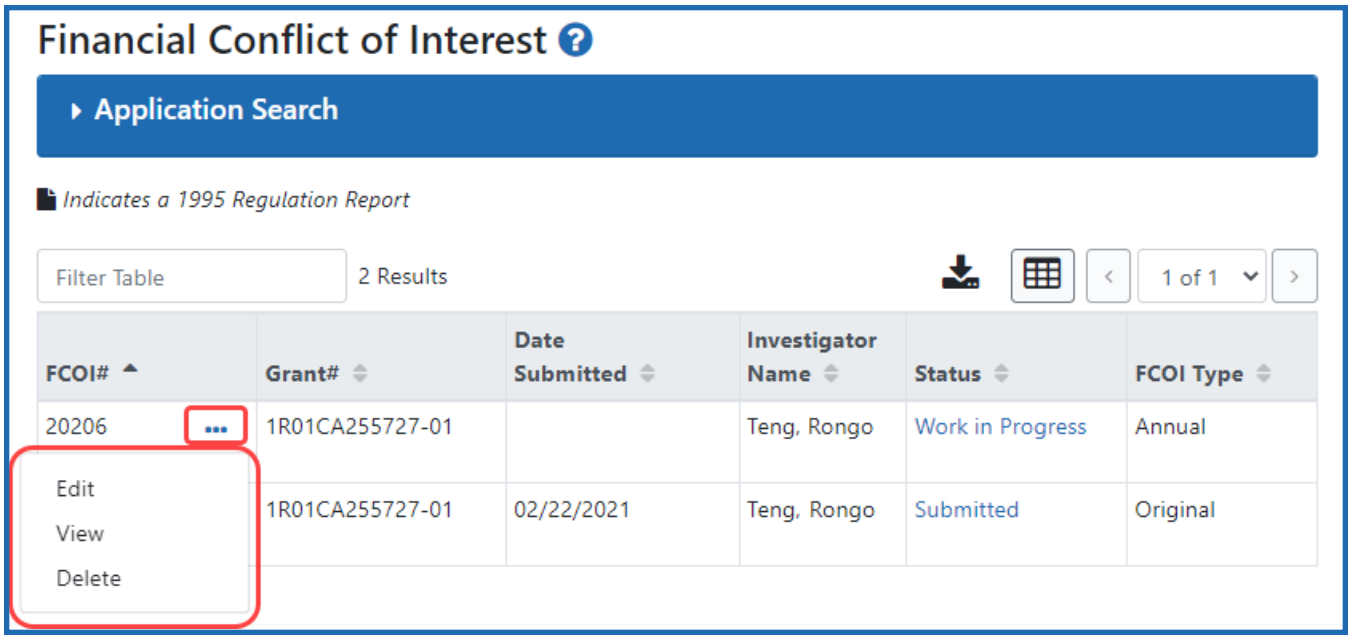


Figure 12: FCOI Search Results

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 link (options vary depending on the user's authority and/or the status of the FCOI Report).

Clicking the link 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*. Clicking 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 link. Clicking this link opens the *Financial Conflict of Interest History* screen for the grant.

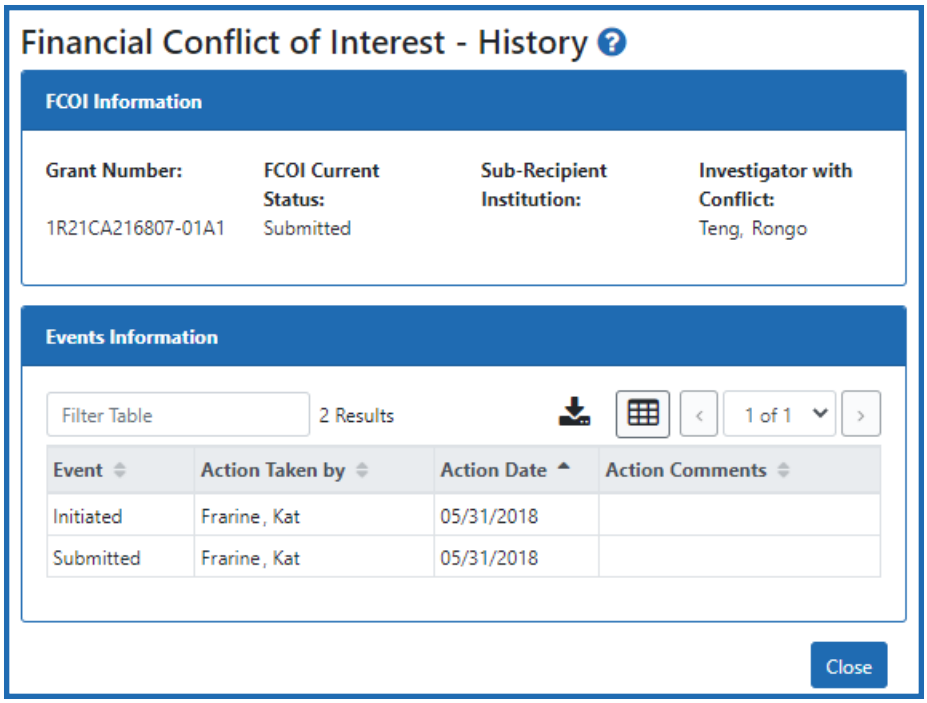


Figure 13: FCOI History

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 organization 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. After logging into Commons, navigate to the FCOI module, which opens the *FCOI Search* screen.
2. From the *FCOI Search* screen, perform a search for the appropriate FCOI report.

3. Select the **Revise** option under the three-dot ellipsis menu for a FCOI report.

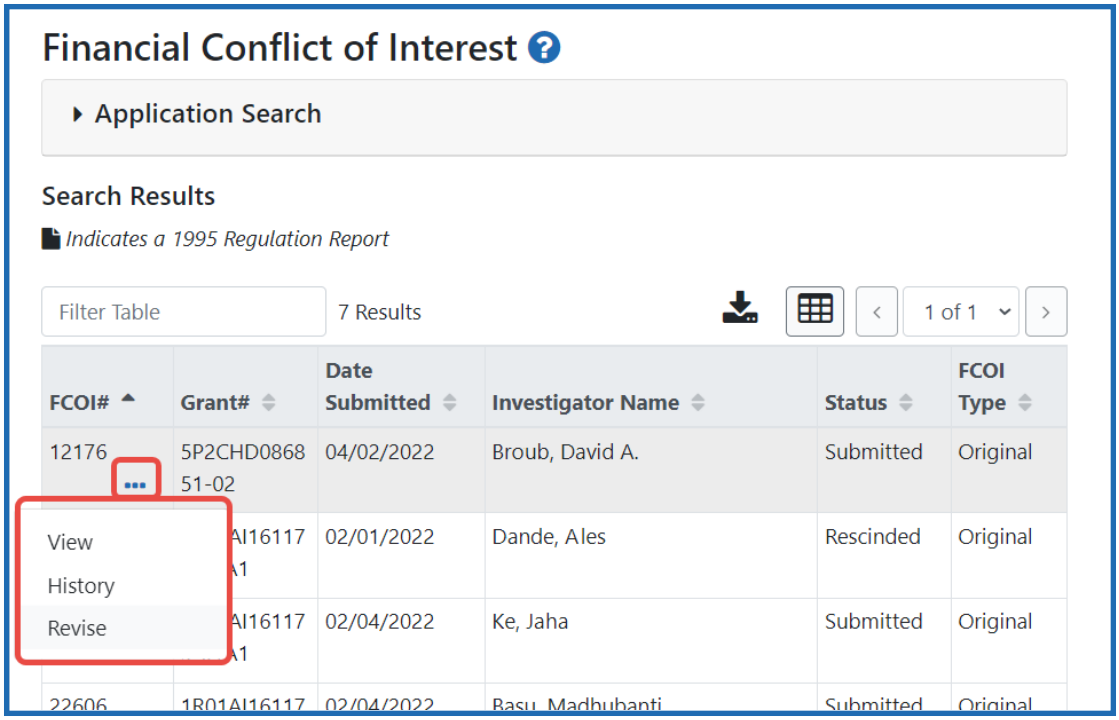


Figure 14: Revise Link on FCOI Search

4. A Create Revised Report informational message appears; click **Create**.

5. The *Financial Conflict of Interest – Revision* screen displays the information from the current FCOI report as read-only. The summary of reported significant financial interests is displayed in the table at the bottom of the screen.

6. Select the **Edit** option from the three-dot ellipsis menu to edit the Significant Financial Interest.

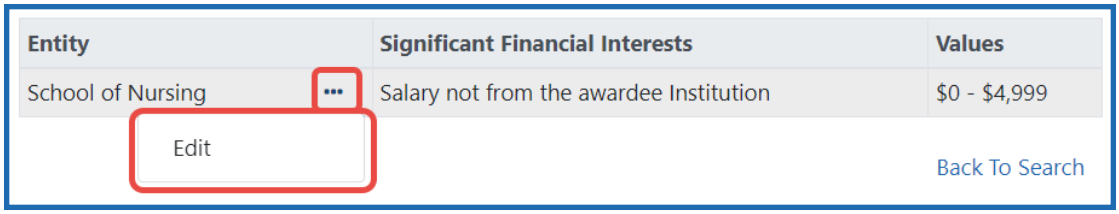


Figure 15: FCOI - Revision Screen

The Financial Conflict of Interest – 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 is pulled from the latest submitted FCOI form. An additional text field becomes available to summarize the revisions. This field is required.

Entity	Significant Financial Interests	Values
School of Nursing •••	Salary not from the awardee Institution	$0 - $4,999

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

2000 remaining.

*

FCOI Details

Section 1.

Entity Name *

School of Nursing

Please use the full name of the Entity as it appears on the Entity's publicly accessible website or type in the full name as it is known. Enter the name of the entity that the Investigator has a financial interest.

Significant Financial Interests (SFIs)

Select One

Annual Value of the SFI Within These Dollar Ranges

Select One

Add New SFI

Add as many SFIs as needed within one FCOI report for the same entity.

Nature of Significant Financial Interests (SFIs)	Value
Salary not from the awardee Institution	$0 - $4,999

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. *

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.

1752 remaining.

Drop file or browse to attach 1 PDF file, not exceeding 6MB.

File Name	Date Created	Status
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

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

Entity	Significant Financial Interests	Values
School of Nursing •••	Salary not from the awardee Institution	$0 - $4,999

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

2000 remaining.

*

Figure 16: Summary of Changes on FCOI - Revision Screen

8. Complete the revisions as appropriate under the **FCOI Details** section. Refer to *Initiating an FCOI Report* on page 10 for more information about the questions and fields on this form.

   During a revision, existing Significant Financial Interest information can be changed or deleted and new information can be added only following a Retrospective Review. You can add or edit text in the supporting information text boxes on the form. Additionally, you can upload new PDFs or delete existing ones.

   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.

9. Update the fields in FCOI Details sections 4 and 5.
   a. Update the response for section 5 (**Retrospective Review Completed?**) to **Yes**. When you click **Yes**, a section 6 appears and is required.

b. Select the **Yes bias found** radio button for section 6 (**Mitigation Report Required?**) to indicate that a mitigation report is required. If you specify that bias was found, then a new field appears titled **Provide mitigation report per 42 CFR 50.605(a)(3)(iii)**. Either provide the Mitigation Report information in the enabled text box or upload a file using the **Drop file or Browse..** section.

10. Perform one of the following actions:
    - Click **Save** button to put the record in WIP status.
    - Click **Save and Submit** button to submit to agency.

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

When you click the **Save and Submit** button, 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.

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

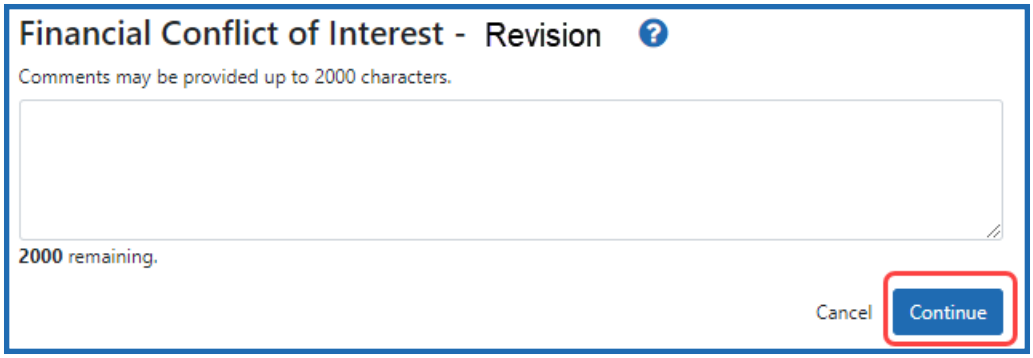


Figure 17: Entering Comments When Revising an FCOI

Upon saving and submitting, the system sends out an email 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.

Agency Requests for Additional Information

The Agency Chief Grants Management Officer or designee is able to request additional information from the submitting organization when necessary. This action generates a notification of the request to the organization 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. After logging into Commons, navigate to the FCOI module, which opens the *FCOI Search* screen.
2. From the *Application Search* screen, perform a search for the appropriate FCOI report.
3. Click the **Edit** link under the three-dot ellipsis menu 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 *Initiating an FCOI Report* on page 10 for more information about the fields on the report and sample figures.

4. Click the **Save** button to save the information and keep the FCOI Report as a WIP

   -OR-

   Click 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 you click the **Save and Submit** button, 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 email notification informing the FCOI user that the FCOI Report was submitted.

Institutional Financial Conflict of Interest Policy

The *Policy Documents* screen of the Institution Profile module lets you upload your organization's Financial Conflict of Interest (FCOI) policy. Effective November 12, 2020, each organization must upload its FCOI policy to eRA Commons for review. The institutional FCOI is required and defined by regulations, which are linked on the *Policy Documents* tab in the Institution Profile module.

The policy must be in PDF format under 6 MB in size. After uploading, NIH staff will review the policy and reject or accept it, and will notify you via one of your listed contact methods. For more information, refer to the Guide Notice NOT-OD-21-002 as well as the table of regulatory requirements on the Policy Documents tab.

IMPORTANT: Only signing official (SO) users can see the Policy Documents screen and edit Institution Profile screens.

Accessing the Financial Conflict of Interest Policy Screen

Log into eRA Commons as a signing official (SO), go to the *Institution Profile,* and then click *Policy Documents* in top navigation. The Financial Conflict of Interest Policy screen appears.

Institution Profile | Basic Information Assurances and Certifications **Policy Documents**

Financial Conflict of Interest Policy

Upload a PDF copy of the institution's financial conflict of interest (FCOI) policy in the IPF Module under the "Policy Documents" tab. The institution's FCOI policy must be compliant with the regulatory requirements provided in the FCOI regulation at 42 CFR Part 50, Subpart F, Promoting Objectivity in Research, applicable to Public Health Service (e.g., NIH) grants and cooperative agreements. The FCOI policy must be posted on a publicly accessible web site as required by the NIH Grants Policy Statement, Section 4.1.10.

NIH encourages institutions to review the Policy Development Checklist posted on the NIH Office of Extramural Research, FCOI, web page at https://grants.nih.gov/grants/policy/coi/Checklist-for-Policy-Development-For-Posting-4-23-2020.pdf to determine if the institution's policy complies with the regulatory requirements. The following table provides a summary of requirements and the regulatory citations for your reference:

REGULATORY REQUIREMENTS	REGULATORY CITATION OR NIH GPS
Training requirements	42 CFR 50.604(b)
Disclosure, Review, Manage and Monitor Requirements	42 CFR 50.603 42 CFR 50.604(e)(1)-(3) 42 CFR 50.604(f) 42 CFR 50.604 (g) 42 CFR 50.605(a)(1)-(6)
Reporting Requirements to NIH	42 CFR 50.604(h) 42 CFR 50.605(b) 42 CFR 50.605(a)(3)(iii) 42 CFR 50.606(a)
Enforcement Mechanisms and Remedies and Noncompliance	42 CFR 50.604(j)
Retrospective Review Requirements	42 CFR 50.605(a)(3)
Subrecipient Requirements	42 CFR 50.604(c) and NIH GPS 15.2.1
Public Accessibility Requirements for FCOIs identified for Senior/Key Personnel	42 CFR 50.605(a)(5)(i)-(iv)
Maintenance of Records	42 CFR 50.604(i)
Clinical Research	42 CFR 50.606(c)

FCOI Policy Submission

Drop files here to upload, or browse

Max File Count: 1 **Accepted File Types:** PDF **Max File size:** 6MB

Prior FCOI Policy Submissions

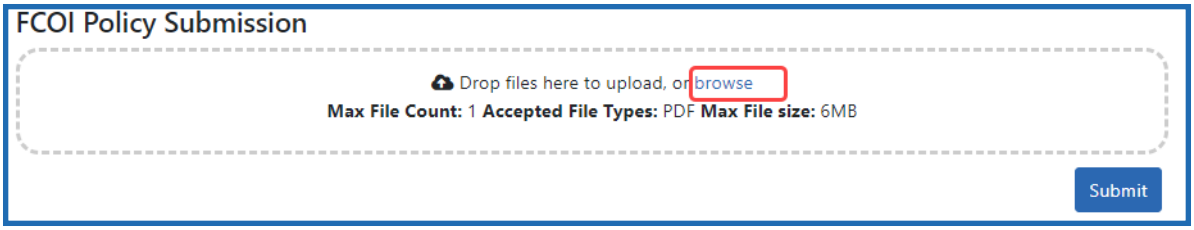
Submit

Policy ID	Submitted Date	Submitted By	Status
376	11/25/2020	Helisha, Ala	Certification Verified
1166	11/30/2020	Helisha, Ala	Certification Verified

Figure 18: Policy Documents tab of Institution Profile, where you can upload the institute's FCOI policy and view prior policies that were submitted

To upload your FCOI policy to eRA Commons for agency approval:

1. On the *Policy Documents* tab of the Institution Profile module, either drag a file to the 'Drop files here...' area or click the **browse** link (outlined below) to find a file on your drive.



FCOI Policy Submission area to upload a policy document

The file appears with a trash can icon and a download icon. At this point, you can delete the file by clicking the trash can icon or view it by clicking the download button.

Uploaded file with a trash can icon and download icon

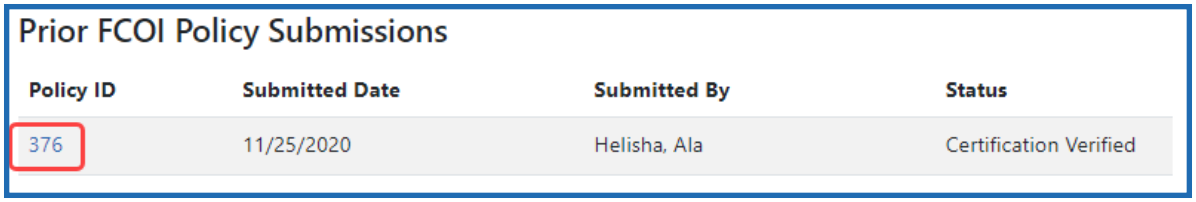
2. To submit the file that is listed, click the **Submit** button.

A new submission is then added to the *Prior FCOI Policy Submissions* section listing you as the submitter. If you make a mistake, you can simply upload another PDF file and it replaces the first. The file will be routed to agency officials for review.

TIP: If nothing appears to happen when you upload and the words **!Invalid file** appear in the upload area, the file might not meet file requirements listed in the upload area. You can upload only a single file.

To view the FCOI policy that was previously submitted:

On the *Policy Documents* tab of the Institution Profile module, click the **Policy ID** number in the *Prior FCOI Policy Submissions* area.



Prior FCOI Policy Submissions

Policy ID	Submitted Date	Submitted By	Status
376	11/25/2020	Helisha, Ala	Certification Verified

The PDF opens in your system PDF viewer.

To resubmit an FCOI policy that has been updated:

On the *Policy Documents* tab of the Institution Profile module, simply upload a new file, then click **Submit**. If someone from NIH had contacted you about the policy, notify them of the re-submission.

See:

Institution Basic Information

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 link 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.

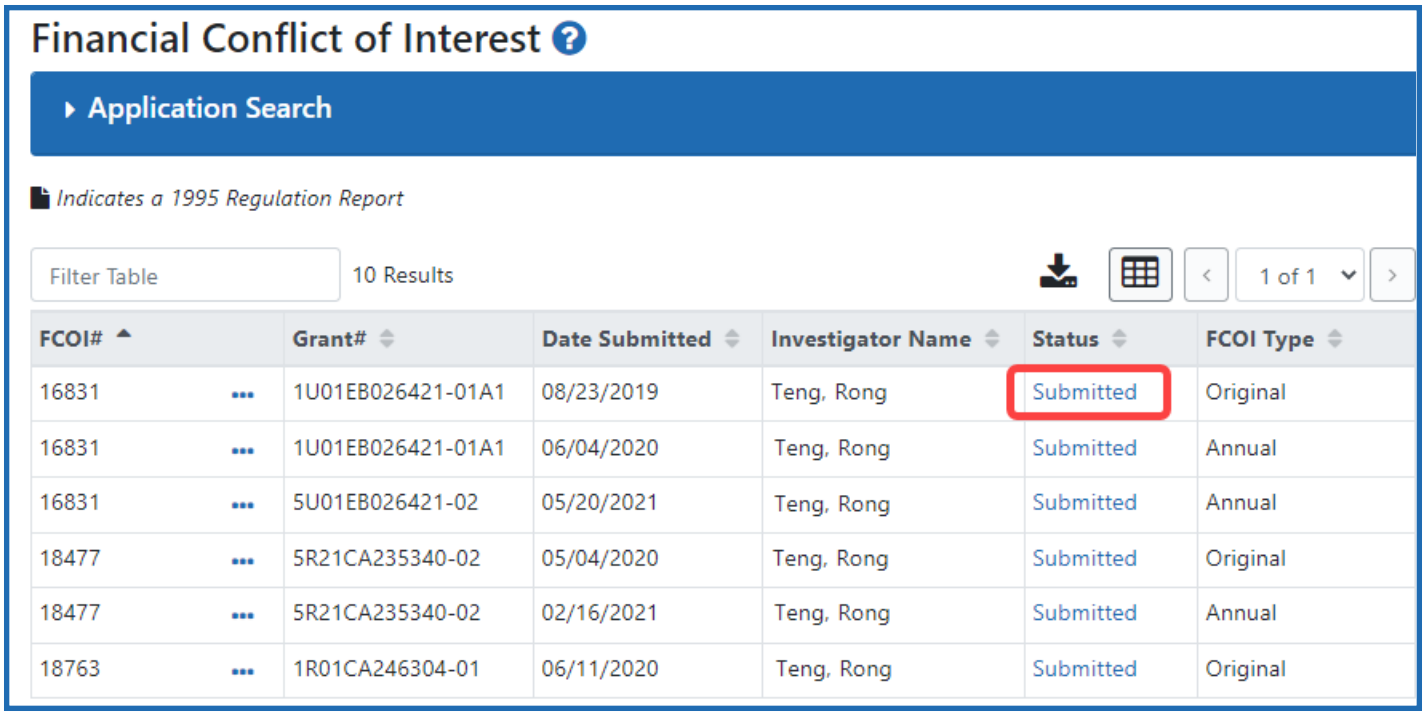


Figure 19: Status Values Display as Hyperlinks Leading to FCOI History

Figure 20: View FCOI History Button as Seen on New Report and 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)

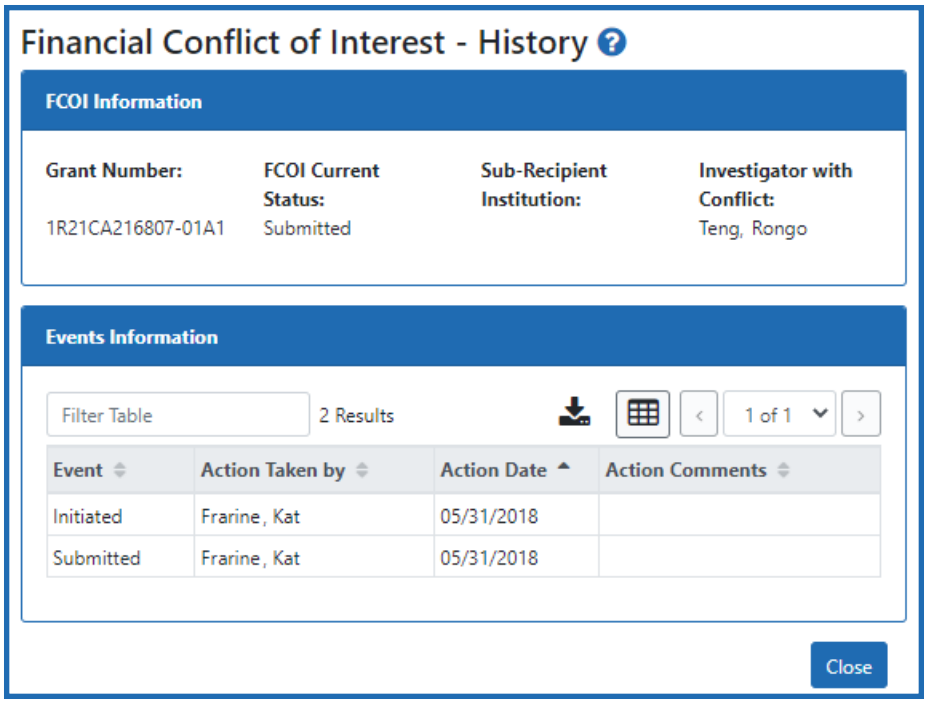


Figure 21: Sample FCOI History Screen

To close the screen, click the **Close** button.

Submitting FCOI Annual Reports

FCOI Annual Reports are submitted through Commons by organization 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 organization 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 organization'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 appears the day after the grant is extended. For subsequent extensions, contact the awarding agency.

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

To initiate an Annual FCOI Report:

1. Access the *Application Search* screen by navigating to the FCOI module.
2. From *Application Search*, perform a search for the appropriate FCOI Report.
3. Select **Annual Report** under the three-dot ellipsis menu for the specific Original FCOI Report.

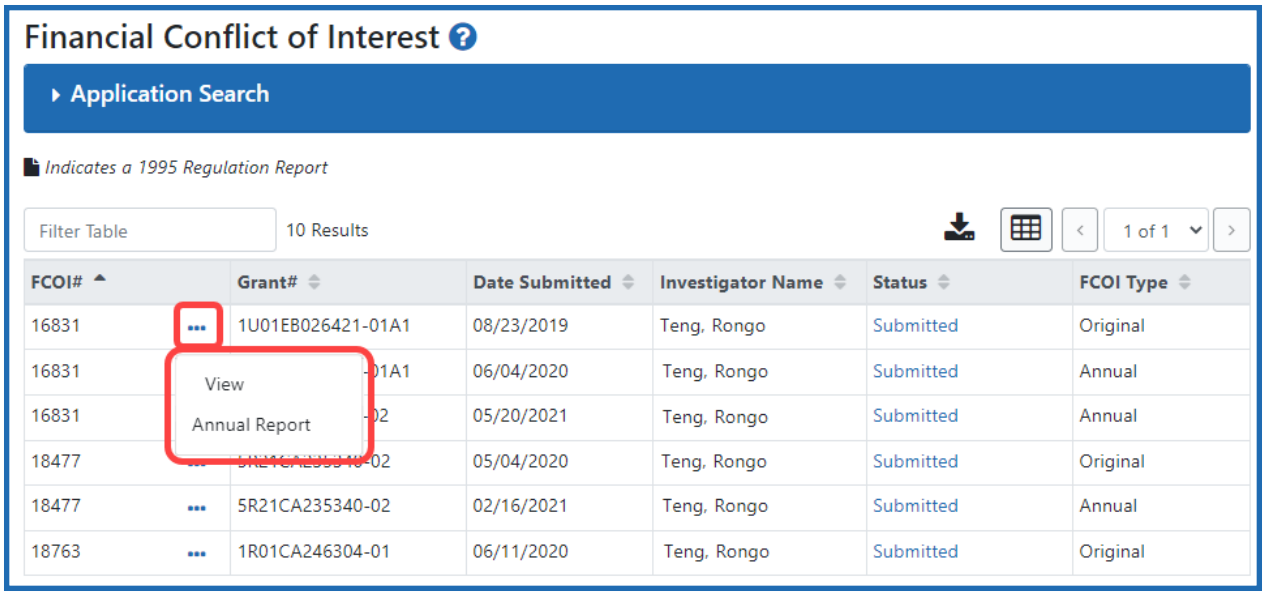


Figure 22: Annual Report Link on Application Search

In tables, you can filter, show and hide columns, download/print data, choose display options, and more. For information on table tools below, see *Standard Tools for Tables*.

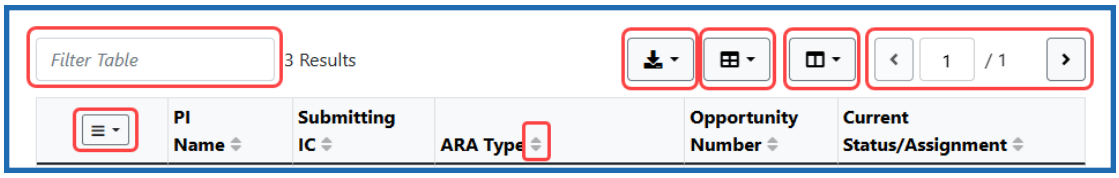


Figure 23: Table tool icons

Commons checks to determine if there are any annual reports which were not submitted to the awarding 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 clicking 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 **View** under the three-dot ellipsis menu to view read-only specifics as reported on the original FCOI report.

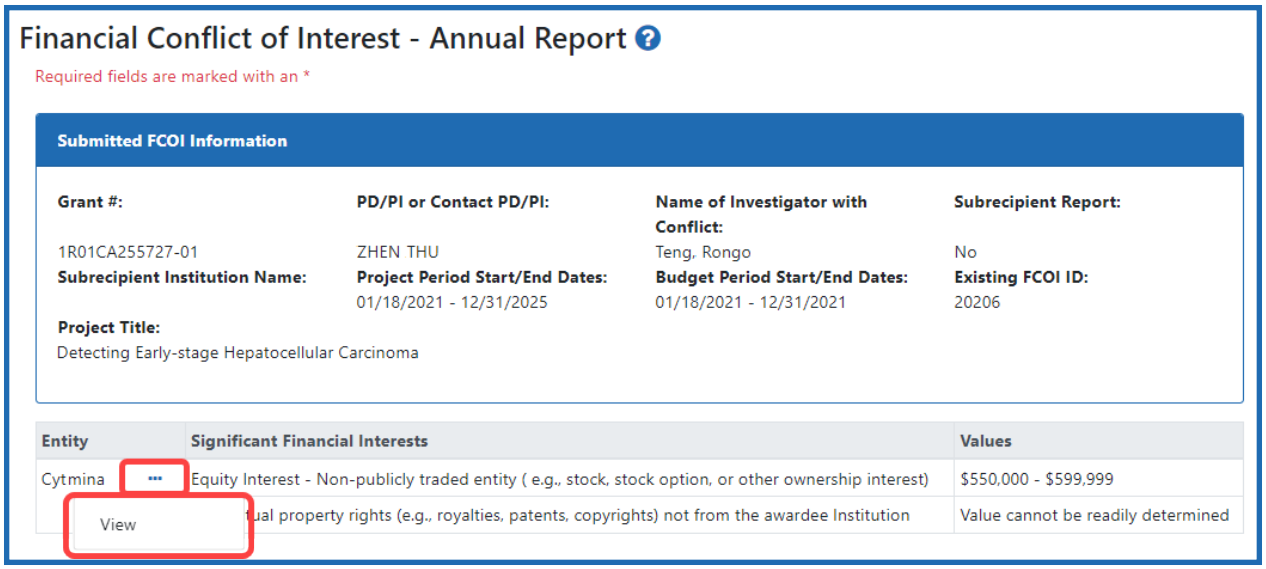


Figure 24: View Link on the Annual Report

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.

Click **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**.

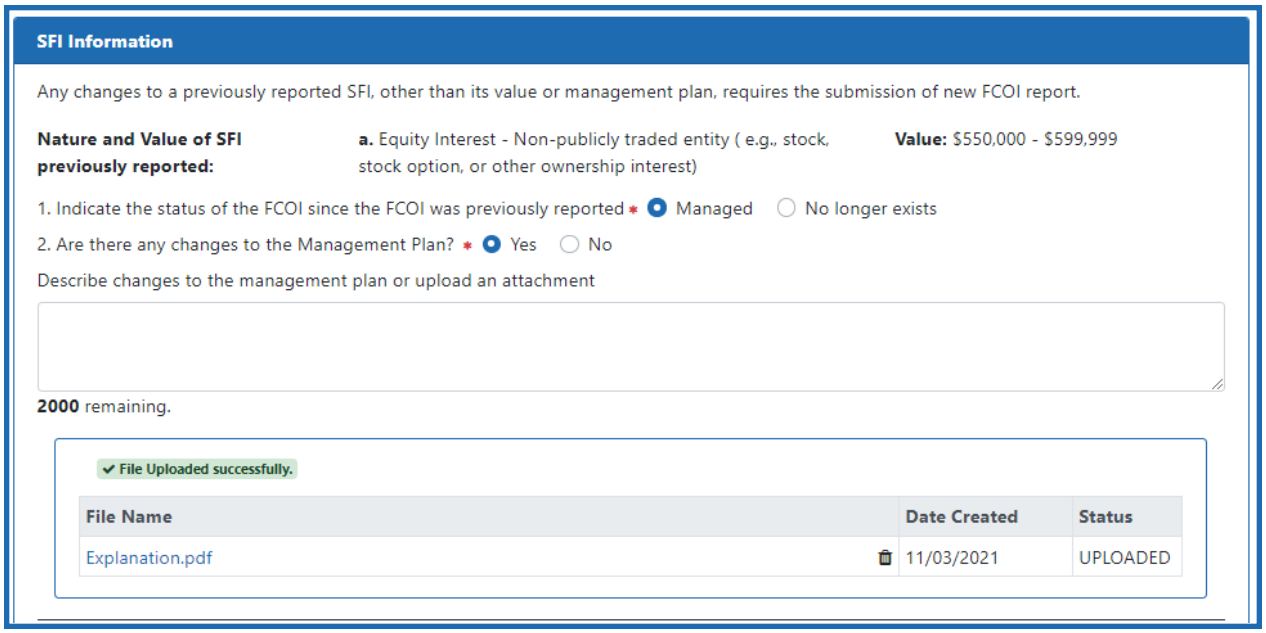


Figure 25: FCOI Annual Report - Questions 1 & 2

c. For question **3. Explain why FCOI no longer exists**, enter an explanation in the text box or use the upload feature to attach documentation explaining

why the FCOI no longer exists. This question is only displayed when the response to Question 1 is **No longer exists**.

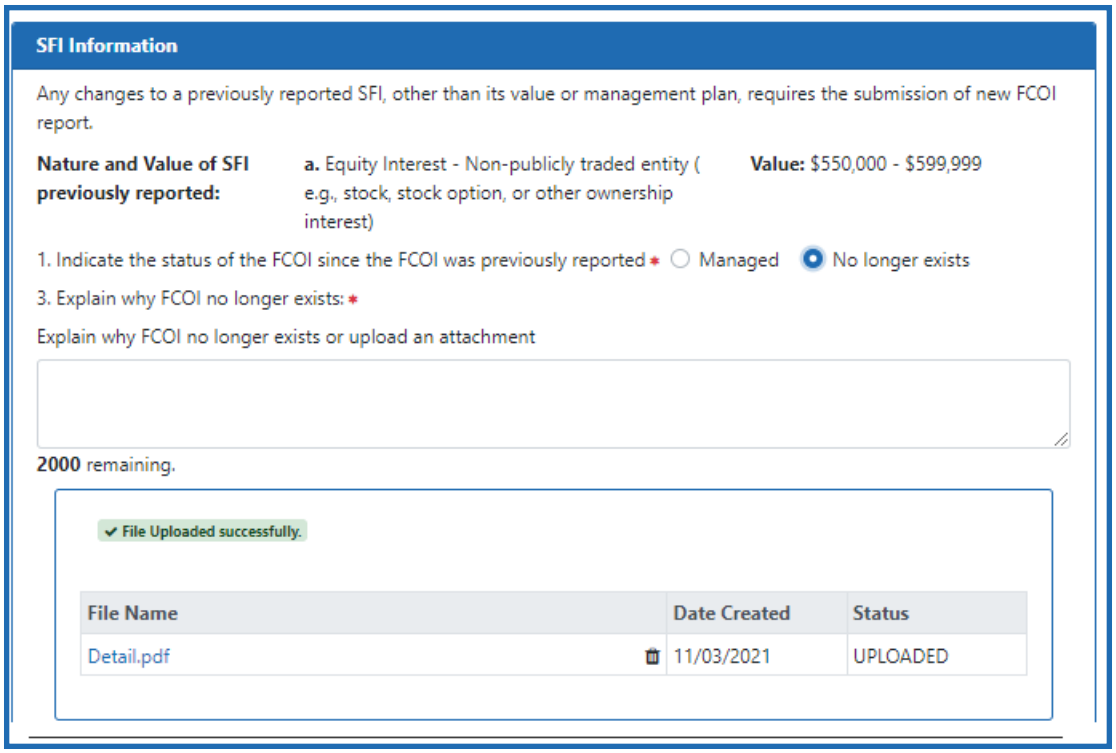


Figure 26: FCOI Annual Report - Questions 1 & 3

7. Perform one of the following actions:
   - Click the **Save** button to put the record in *Work in Progress* status.
   - Click the **Save and Submit** button to submit to agency.
   - Click 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 the agency or still a Work in Progress.

When Will I Receive a Notification?

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.