National Institutes of Health Office of Extramural Research

Financial Conflict of Interest (FCOI)

User Guide

Commons System Version 2.19.1.4
Document Version 1.0.0.0
December 3, 2008

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Document History

Date	System Version	Document Version	Description of Change	Author
12-03-2008	2.19.1.4	1.0.0.0	Initial Release of Document	NIH eRA USB Documentation Team

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

Purpose

The purpose of this *Financial Conflict of Interest* (FCOI) *User Guide* is to provide basic and useful information to Institutional (external) users of the NIH Grants system within *Commons* as it relates to the FCOI process.

Scope

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

Overview

The Electronic Research Administration (eRA) *Commons* is a Web-based system for applicants and institutions to participate in the electronic grant administration process. Using the Java 2 Enterprise Edition (J2EE) specification, *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. This *Financial Conflict of Interest* (FCOI) *User Guide* will provide the step-by-step process to allow Institutions to report the existence of any identified FCOI to the NIH as required by Federal regulation on FCOI, specifically Title 42 Code of Federal Regulations Part 50 Subpart F for grants and cooperative agreements. Additional information on the reporting requirements can be found in the regulation, *Frequently Asked Questions* and NIH's Web-based *Tutorial* found on the Office of Extramural Research's Conflict of Interest website at http://grants.nih.gov/grants/policy/coi/index.htm.

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 NIH staff after a FCOI submission is received. Although *Commons* is not the system of record, the FCOI information will be stored within another internal system of record (IMPAC II) database. The FCOI system will also allow Institutions to submit additional information that may subsequently be requested by the NIH after the initial FCOI report, and the system will allow the Institution's authorized FCOI users to view reports and associated data online. *(See Table 1.)*

Process Objectives
Allow Institutions to submit FCOI reports via the *Commons* (IMPAC II) database
Notify institutions and NIH staff after the FCOI submission is received
Integrate the data with the internal system of record
Allow organizations to submit additional information when requested by NIH
Allow FCOI users to view reports and associated data

Table 1: FCOI Objectives

User Roles

NIH extramural grantee Institutions, OPDIVs, grantees and the public are the primary users of *Commons*. Access to *Commons* is granted only by authorized *Commons* users who are assigned to a specific role(s) that allows for user account creation. The following diagram displays an example of how different user roles function within the *Commons* system. *(See Figure 1.)*
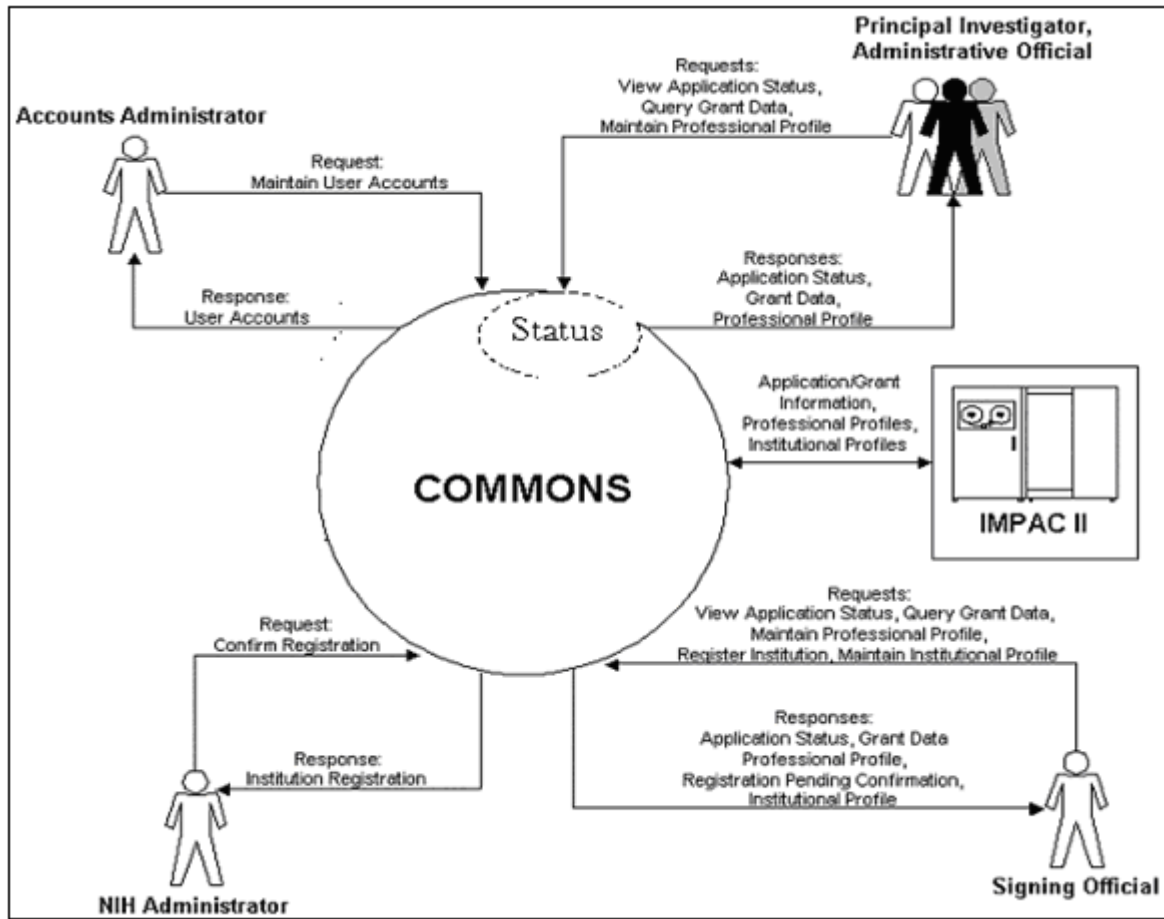
Figure 1: Commons User Roles Diagram

Signing Official Role (SO)

A Signing Official or SO is a Business Official (BO) within an institutional organization that is authorized to assign FCOI roles. 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.

Financial Conflict of Interest Role (FCOI)

The FCOI role would be assigned to the user(s) in the Institution that would manage the FCOI process. This person or persons would be able to initiate, edit, submit, view and delete records and documents. This FCOI role can only be assigned by the SO.

Financial Conflict of Interest Assistant Role (FCOI ASST)

The FCOI Assistant (ASST) is delegated access by the FCOI role to assist with data entry and completion of FCOI reports.

Financial Conflict of Interest View Only Role (FCOI View Only)

The designated person or persons within the Institution that have been granted the View-Only role is delegated access by a user with the FCOI role. A person with this View-Only authority can view FCOI information entered by the Institution in the FCOI module.

NOTE: A table of the FCOI Roles, capabilities and assignments is provided in *Table 2* of the *Financial Conflict of Interest Process* section.

The FCOI Application

What is FCOI?

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

- Initiate and prepare a FCOI report within *Commons.*
  - o Multiple FCOI officials and delegates can access and edit a report while in *Work In Progress* (WIP) status.

- Submit the FCOI report and supporting documents, if applicable, electronically to the Agency.
  - o This can include comments at the time of submission that are included in email notifications to the Agency.

- Search and view FCOI reports that were previously submitted through *Commons.*
  - o Does not provide visibility to any reports previously submitted on paper.

- Edit or rescind submitted reports (rescinding a report requires Agency involvement).

- Access the history of actions.

The Basic Conflict of Interest (FCOI) Process

Managing FCOI Roles

Signing Official (SO) Assigns FCOI Roles to Institutional Users

The Signing Official (SO) is the authorized official at the Institution that has authority to sign for the Institution. He or she is the overall responsible person for any and all grants related activities whether 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.

Delegating FCOI Authority to FCOI ASST and FCOI View Only Users

The Signing Official (SO) may delegate FCOI authority to other individuals within the Institution. The SO can delegate or assign individuals to serve as an FCOI ASST and have FCOI View-Only authority. This is accomplished by logging into the FCOI *Commons* system, clicking on the **Admin** tab at the top of the screen, selecting the **Accounts** tab and then clicking on the **Delegate FCOI Authority** tab. Here the SO can select from the *Current Institution Users* listed on the left side of the screen and move or **Assign** their names to the right side of the screen. Reversely, the SO can revoke or remove FCOI ASST authority or FCOI View-Only authority by selecting a name on the right side of the screen and clicking on the **Revoke** key in the center of the screen. *(See Figure 2.)*
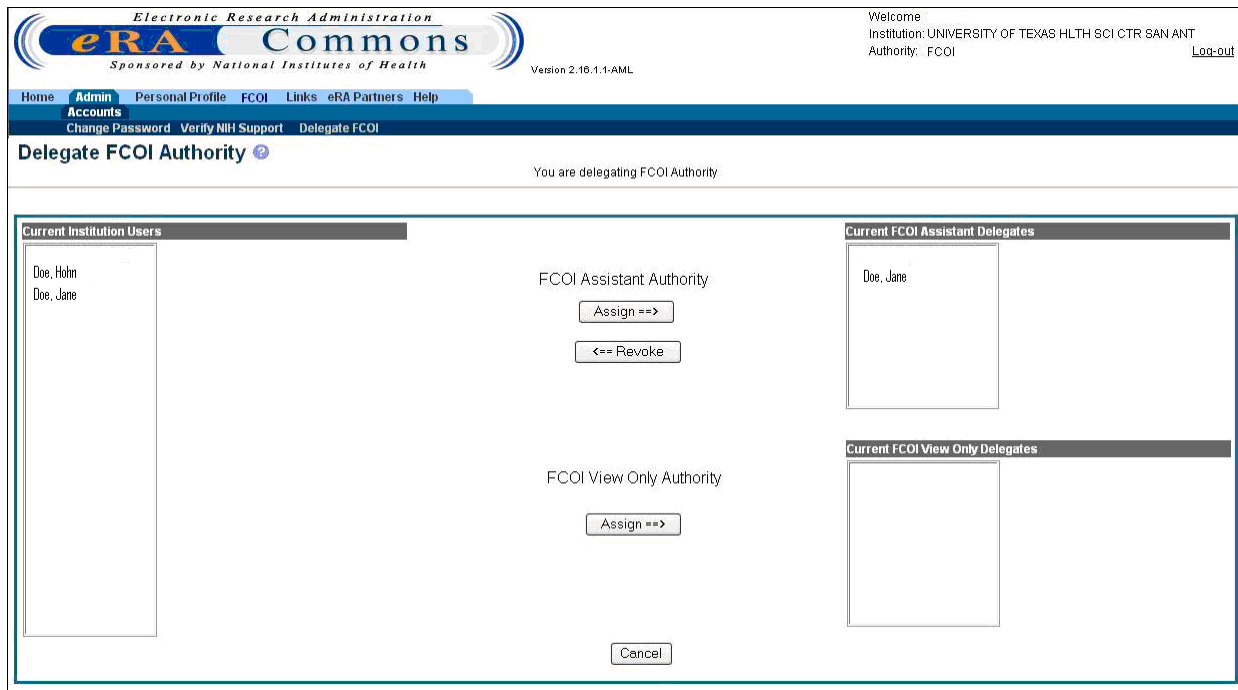

Figure 2: Sample Delegate FCOI Authority Screen

The role of the designated ASST has the following privileges:

- Enter FCOI information for an awarded project

Flow Diagram

The following Electronic Research Administration (eRA) FCOI *Process Flow Diagram* provides an overview for submitting and processing a FCOI Report. *(See Figure 3.)*
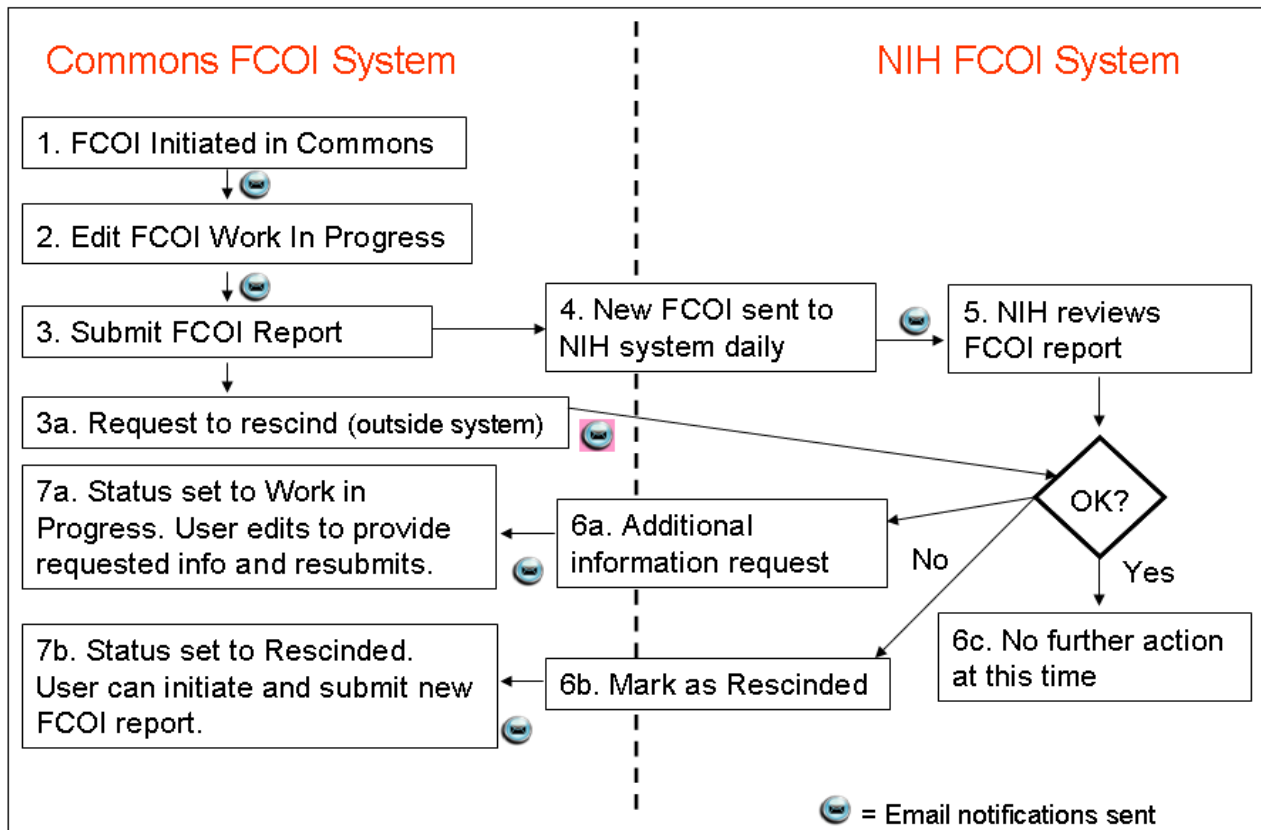

Figure 3: FCOI Process Flow Diagram

Creating FCOI Report

Once a FCOI role is created, creating or initiating a FCOI record can be accomplished by logging into the eRA *Commons* application, clicking on the **FCOI** tab at the top of the screen, clicking on the **Initiate** sub-tab and entering the required information. Here a FCOI report can be initiated and filed within the system. Note the required fields marked with an asterisk (*) must be completed before saving the information. The following fields are required when initiating a FCOI:

- IC Code
- Serial Number
- Support Year
- Name of Investigator with Conflict

- Sub-Recipient Report (No or Yes)

- FCOI Action

Also note the options available under **FCOI Action** field (Managed, Reduced or Eliminated) within the dropdown box. One of these options must be selected before clicking on the **Upload** button. The following image represents the screen from which a FCOI record can be initiated. *(See Figure 4.)*

Figure 4: Sample FCOI – Initiate Screen

Comments or attachments can be provided with the submission of an initial report at the discretion of the Institution. *(See Figure 6.)*

Note: There is a maximum 2000 character limit including spaces and punctuation

Once the information is entered, the FCOI ASST may choose **Save** or the FCOI role may choose to **Save and Submit** the report to the Agency.

FCOI History

An event record is generated in the FCOI history log each time a user takes an action on the record. The following screen depicts an example of the history log. *(See Figure 5.)*

Figure 5: Sample FCOI History Screen

Comments may be added at the discretion of the Institution to the FCOI record (maximum 2000 characters including spaces and punctuation) that become part of the FCOI record history. *(See Figure 6.)*

Figure 6: Sample FCOI History Comments Screen

Searching Existing FCOI

Searching for a FCOI record can be accomplished by logging into the eRA *Commons* application, clicking on the **FCOI** tab at the top of the screen and entering the required or available information. The following fields are available for entering search data:

- FCOI #

- Grant #

- Name of Investigator with Conflict

Note the options available under **FCOI Action** and **Status** within the dropdown boxes. The following image represents the **Search** screen. *(See Figure 7.)*
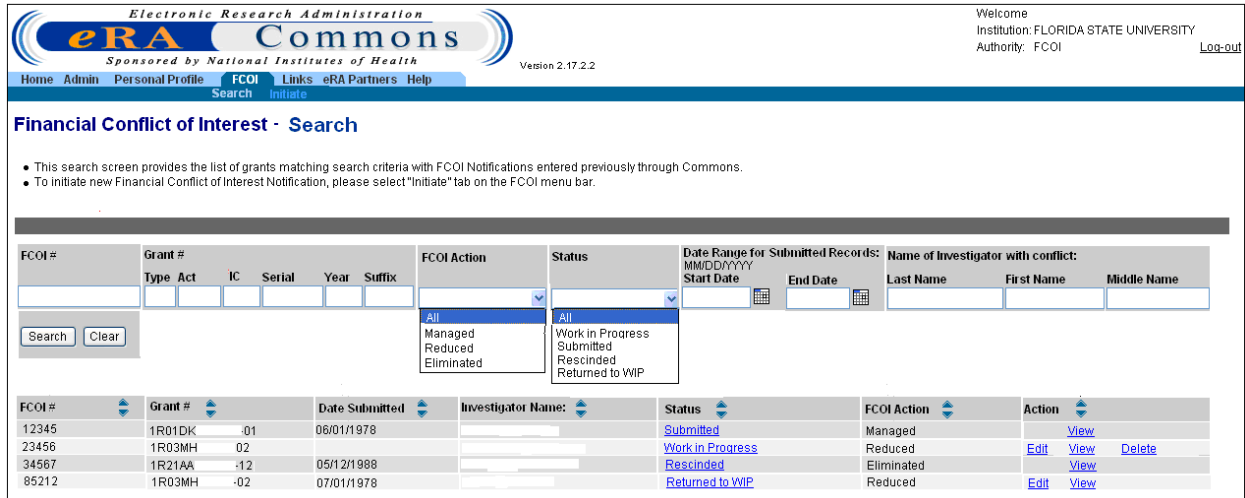
Figure 7: Sample FCOI Search Screen

Editing/Reviewing FCOI

The edit and review authorization is issued or assigned to institutional members by the SO. Review and edit functions for a FCOI record can be accomplished by the authorized person logging into the eRA *Commons* application, clicking on the **FCOI** tab at the top of the screen and entering the required and available information. The following fields are available for reviewing and/or editing data:

- IC Code

- Serial Number

- Support Year

- Name of Investigator with Conflict

- Sub-Recipient Report (No or Yes)

- FCOI Action

Note the options available within the **FCOI Action** dropdown box (Managed, Reduced or Eliminated). The following image represents the screen from which a review or edit function can be performed. *(See Figure 8.)*

Figure 8: Sample FCOI Edit Screen

A sample FCOI **View** screen has been provided below. *(See Figure 9.)*

Figure 9: Sample CFCOI View Screen

NOTE: As with most *Commons* screens, required fields are indicated by an asterisk (*).

Submitting FCOI Reports

The FCOI Submit function is part of the *Commons* system that allows the SO, or the delegated FCOI Authority to submit an identified FCOI report to the Agency. These FCOI reports should be submitted electronically prior to the expenditure of funds under a new award or when a FCOI is identified during the award, the FCOI report should be submitted within 60 days of identification.

Submitting Reports via Commons

FCOI reports are submitted through *Commons*. The submitter will be able to submit one report for each identified FCOI.

For each report, the following data will be collected:

- The grant number

- The PD/PI name and *Commons* account for the identified grant number

- The name of the Investigator with the conflict.

- Whether the conflict has been (1) *managed*, (2) *reduced*, or (3) *eliminated*

- Whether this report is for a sub-recipient

- Name of sub-recipient if the report is for a sub-recipient

The submitter may provide comments or attach a PDF file with additional information if applicable. This function is optional at the time of submission.

Note: There is a maximum 2000 character limit including spaces and punctuation

These reports will be submitted by a delegated FCOI official at the Institution—which could be a Signing Official (SO) or another official. The submission will be limited to *Commons* users with the FCOI role; submitters will need to be authenticated upon submission.

At any time before the FCOI report is submitted, the submitter will have the option to cancel the submission.

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

Sending Electronic Notifications

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

1. When the FCOI ASST role is assigned.

2. When the FCOI report is initiated.

3. Any time a FCOI report is edited.

4. Any time a FCOI report is submitted to NIH, to those with the FCOI role and FCOI ASST role, and to Chief Grants Management Officer (CGMO) for the Institute and/or Center (IC) in the eRA Notifications mailbox.

5. When the NIH CGMO requests additional documentation from the Institution, to those with the FCOI role and FCOI ASST role, and to the Grants Management System (GMS) centralized mailbox.

6. When the FCOI View-Only role is assigned.

7. Any time FCOI or FCOI View-Only authority is revoked by a person with the FCOI role, to those with FCOI and FCOI ASST, or FCOI View-Only roles, respectively.

Viewing Information about the Submission

Any FCOI official at an Institution is able to view in *Commons* all FCOI reports submitted to date for that Institution. The Program Director/Principal Investigator (PD/PI) cannot view the FCOI report.

Requesting Additional Information to be Submitted

The NIH CGMO will be able to request additional information from the submitting Institution. This action will generate notification of the request to the Institution and change the status of the FCOI record to a Return to WIP status in IMPAC II.

The Institution will then use *Commons* to submit the additional documentation.

The Financial Conflict of Interest (FCOI) Process

This section of the *Financial Conflict of Interest (FCOI) User Guide* shows the step-by-step process associated with the FCOI system:

- Creating a new account for a FCOI role

- Establishing FCOI Authority

- Delegating FCOI Authority

- Initiating a First-Time FCOI Report

- Submitting a FCOI Report

- Searching for a previously filed FCOI Record

- Editing a FCOI Report

Additionally, each institutional Signing Official (SO) needs to be aware of the following FCOI process flow and the various steps needed to perform the system functions:

- Under Create, the SO needs to know how to:

    1. Create a new FCOI role

    2. Add a FCOI role to an existing account

    3. Revoke a FCOI role

- The SO and the FCOI roles include the following processes:

    1. Assign ASST (assistant) authority

    2. Assign View-Only authority

    3. Revoke authority

The following *Commons* roles and delegation of FCOI authority will be used to accommodate the FCOI process. *(See Table 2.)*

Role/Authority	Description	Capabilities	Assigned By
FCOI - role	This role would be assigned to the user(s) in the institution that would manage the FCOI process	Initiate, Edit, Submit, View and Delete (Record & Document)	Role must be assigned by SO
FCOIASST - authority	User with this delegated authority can assist in working on FCOI process	Initiate, Edit, View, Search and Delete (Record & Document)	Authority can be delegated by the user with FCOI
FCOI View - authority	User with this delegated authority can search and view existing notifications	Search and View	Authority can be delegated by the user with FCOI

Table 2: Roles and Delegation of Authority

Flow of Events

The following is a list of basic FCOI flow of events associated with the FCOI process:

Initiate New FCOI Reports

This action is available to users with the FCOI or FCOI ASST role. Grants accessible through the FCOI system have been awarded.

1. To initiate a new *FCOI Report*, navigate to the **FCOI** tab on the main *Commons* screen and select the **Initiate** tab.

2. The system provides the *Initiate FCOI Report* screen.

3. Enter information in the fields and select one of two possible buttons (**Save** or **Cancel**).

Note: Upload document section will be grayed out until you fill out all required fields on the screen and click the **Save** button for the first time. After the grant number entered is validated and is correct, the Upload section will be available for use.

4. If you choose to upload relevant information or not, you will have a choice of 3 possible actions (**Save** – to put the record in WIP status, **Save and Submit** – to submit to Agency and **Cancel** – to go back to the blank Initiate FCOI screen).

5. The system sends an email notification only in case of **Save and Submit** and during the initial **Save**.

Submit New FCOI Report

This action is only available to users with the FCOI role.

1. After you have completed the *Initiate FCOI Report* flow (see above) for the new FCOI report or finished editing a *WIP FCOI Report*, select the **Save and Submit** button.

2. The system changes the status from *WIP* or *Initiated* to *Submitted*.

3. The system sends a "*FCOI was submitted to Agency*" Email notification to the appropriate (CGMO, FCOI ASST) parties.

Search for FCOI Reports

This action is available to users with the FCOI, FCOI ASST or FCOI View-Only role.

1. You can request to search for existing FCOI reports by navigating to the **Search** tab in the FCOI menu.

2. When you press the **Search** button, the system queries *Commons* and provides you with a hit list of retrieved records.

Note: Records returned will include only Grant numbers for Funded/Awarded grant applications that contain FCOI reports created earlier in Commons from the Institution of the person that is logged in. Also, the results will only be for reports submitted to *Commons* from the user's Institution.

Edit Existing FCOI Reports

This action is available to users with the FCOI or FCOI ASST role. This flow is executed when FCOI is in the *WIP* or *Returned to WIP* status.

1. You can request to edit a FCOI report by selecting the **Edit** link from the *FCOI Search* screen next to *FCOI Record* in the *Action* column.

2. The system provides the *Edit FCOI* screen featuring all pre-populated information from the time the FCOI report was initiated. All the fields on this screen will be editable, including attachments.

3. You can edit the fields and select one of 5 possible buttons (**Save**, **Save and Submit**, **FCOI History**, **Cancel** or **Delete**).

Pull Institution FCOI History

This action is available to users with the FCOI, FCOI ASST or FCOI View-Only role. The user can get to the *View FCOI History* screen from the following places:

o Status link on the *FCOI Search Results* screen for each record.

o *Edit FCOI* screen (**View FCOI History** button).

1. You can request to *View FCOI History* for a particular record by selecting the **Edit** link on the *Search FCOI* screen.

2. The system provides you with the *Edit FCOI* screen.

3. Select the **View FCOI History** button on the bottom of the screen.

Appendix A: Acronym List

A

ASST   Assistant

B

BO   Business Official

C

CGMO   Chief Grants Management Officer

CO   Contract Official

D

DCO   Division of Communications Outreach

DGCO   Division of Grants Compliance and Oversight

DOB   Date of Birth

E

eRA   Electronic Research Administration

F

FCOI   Financial Conflict of Interest

FOA   Funding Opportunity Announcement

G

GM   Grants Management

GMO   Grants Management Officer

GMS   Grants Management System

H

HHS   Health and Human Services

J

JIT   Just-in-Time

N

NIH   National Institute of Health

NRSA   National Research Service Award

O

OER   Office of Extramural Research

OPDIV   Operating Divisions

OPERA   Office of Policy for Extramural Research Administration

P

PD   Program Director

PD/PI   Program Director/Principal Investigator

PHS   Public Health Service

PI   Principal Investigator

S

SDLC   Software Development Life Cycle

SO   Signing Official

SSN   Social Security Number

T

TA   Training Activities

U

USCIS   US Customs and Immigration Services

W

WIP   Work In Progress