

eCOI



User Role & Dashboard Functionality Manual

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Chapter I

Functionality & Dashboard Overview

1 OVERVIEW

The eProtocol software is a web-based platform for creating, managing, and reviewing financial conflict of interest disclosures in an efficient and timely manner.

This User Role & Dashboard Functionality Manual outlines the overall functionality of the software and dashboards within eProtocol software. It is intended to explain the functions of the software and to provide guidance as you explore this easy-to-use application.



2 LOGIN & WINDOW MANAGEMENT

2.1 Supported browsers & turning off pop-up blocker

Supported Browsers

In order to use eProtocol to its full capabilities, a supported web browser is mandatory. The browsers compatible with eProtocol are: Firefox 12 and above and Safari 7. To begin working with the system, launch the eProtocol link in a supported web browser.

NOTE: Using an unsupported browser will limit the functionality of the application.



Turning off pop-up blockers

Before using eProtocol, it is critical to turn off the pop-up blocker on your browser. Pop-up window navigation is essential and therefore pop-up blockers on this site must be disabled.

Your browser should alert you of a working pop-up blocker upon your entry into the application. Figure 2.1 shows an example of the Internet Explorer browser alerting the user that content is currently being blocked.

In order to allow pop-up access, click the “Options for this site” drop-down button and select “always allow from this site”. This way, the next time you login to eProtocol, the computer will allow all pop-up content specifically from the site.

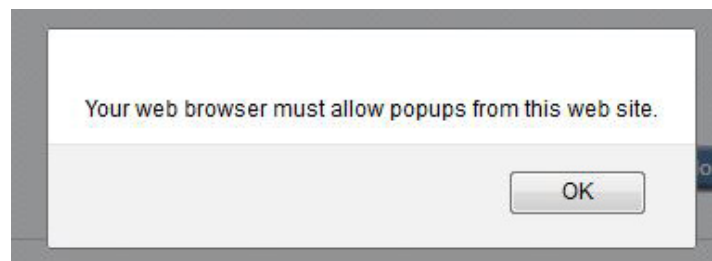


Figure 2.1

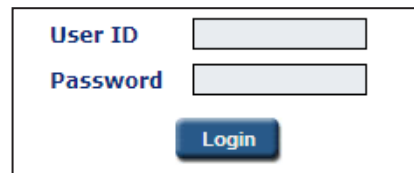


2.2 WSU Access ID

In order to login to eProtocol, you must have a Wayne State University Access ID. If you have forgotten your Access ID and password, please contact C&IT help desk for further assistance at (313)-577-4778. If you do not have an Access ID, go to the eProtocol home page for further instructions.

2.3 How to login into eProtocol

On the right side of the screen is the login box. Enter your Access ID followed by your password and click the **Login** button. You will be directed to the eProtocol homepage.



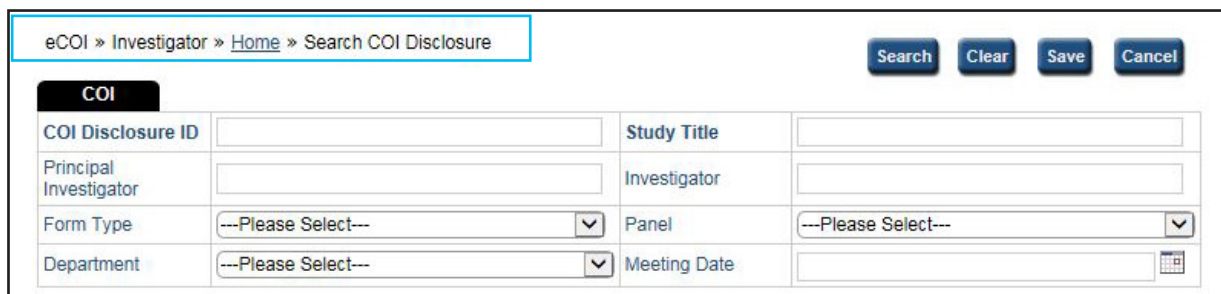
A login form with two input fields. The first field is labeled "User ID" and the second is labeled "Password". Below the fields is a blue button labeled "Login".

Figure 2.2

2.4 Navigation Aid

The **Navigation Aid** allows users to keep track of their current location within pages or documents and can be located on the upper left side of any user dashboard. Any navigation aid in eProtocol that is the color blue signifies it is an active link. Clicking the active link will direct the user back to the home dashboard.

NOTE: Do NOT use your browsers back button as it causes serious errors. In all cases, you will be logged out, losing any recently added content.



A navigation aid breadcrumb showing the path: eCOI » Investigator » Home » Search COI Disclosure. The "Home" link is highlighted in blue. To the right are buttons for Search, Clear, Save, and Cancel. Below is a search form with a "COI" header and several input fields: COI Disclosure ID, Study Title, Principal Investigator, Investigator, Form Type (dropdown), Panel (dropdown), Department (dropdown), and Meeting Date (calendar icon).

Figure 2.3



2.5 User Interface & Functionality

After successfully signing in with your Access ID and password, you will be directed to the eCOI home dashboard. The home dashboard is separated into two primary areas: the menu bar (top) and the content area. This easy-to-use navigation allows for intuitive and quick operation and is further examined in the pages to follow.

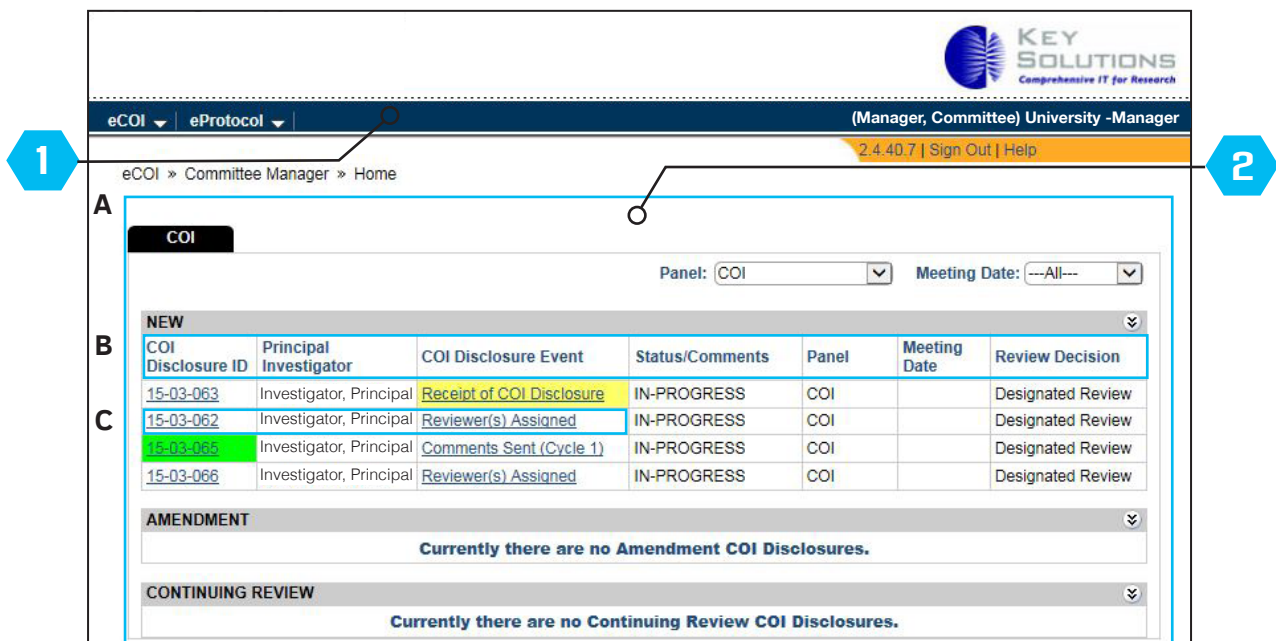


Figure 2.4

- 1 The **top menu** bar is a stationary element in eProtocol and, as such, is always visible from any screen within the eProtocol software. The menu bar holds the primary navigation for the software with its drop-down button features. See pages 18 -21 for a more detailed description on the functionality and use of the top menu bar.
- 2 The **content area** contains important features such as the navigation aid along with a grid. The majority of user interaction will be within the content area of the application.



A - The grid, highlighted in Figure 2.4, page 15, is an imperative feature of eProtocol as it organizes and displays content matter necessary for creating, viewing and managing disclosures.

B - All dashboards are organized by grids with blue column headers [Figure 2.4, page 15]. The columns have minimal functionality and sort the content. Clicking on the column header will change the listed orientation numerically or alphabetically. See page 24 for more details.

C - Any words with a blue underline in the content represents an active link, meaning, if the user clicks on the link, a pop-up window will appear. See page 24 for more details.

2.6 Sizing of Grids, Windows, & Layouts

This portion of the manual will discuss the sizing of panels and pop-up windows to better support your needs of the eProtocol application.

The arrow icons in Figure 2.5a control the amount of information displayed in the content area by opening or collapsing the content. Limiting the amount of content displayed can make for a less overwhelming experience and a cleaner dashboard.

COI Disclosure ID	Principal Investigator	COI Disclosure Event	Status/Comments	Panel	Meeting Date	Review Decision
15-03-063	Investigator, Principal	Receipt of COI Disclosure	IN-PROGRESS	COI		Designated Review
15-03-062	Investigator, Principal	Reviewer(s) Assigned	IN-PROGRESS	COI		Designated Review
15-03-065	Investigator, Principal	Comments Sent (Cycle 1)	IN-PROGRESS	COI		Designated Review

AMENDMENT

CONTINUING REVIEW

Currently there are no Continuing Review protocols.

Figure 2.5



Figure 2.5a



Many of the links in eProtocol generate pop-up windows. The windows appear in the middle of the screen and are all relatively the same size. If a window initially pops up but then goes away, it most likely is hidden behind other tabs in your browser. In most cases, your browser will alert you when a new window has opened by flashing the window or browser icon.

In order to change the size of the windows you can either click the maximize button on the upper right of the pop-up window [Figure 2.6a] or drag and pull the window to your desired size [Figure 2.6b].

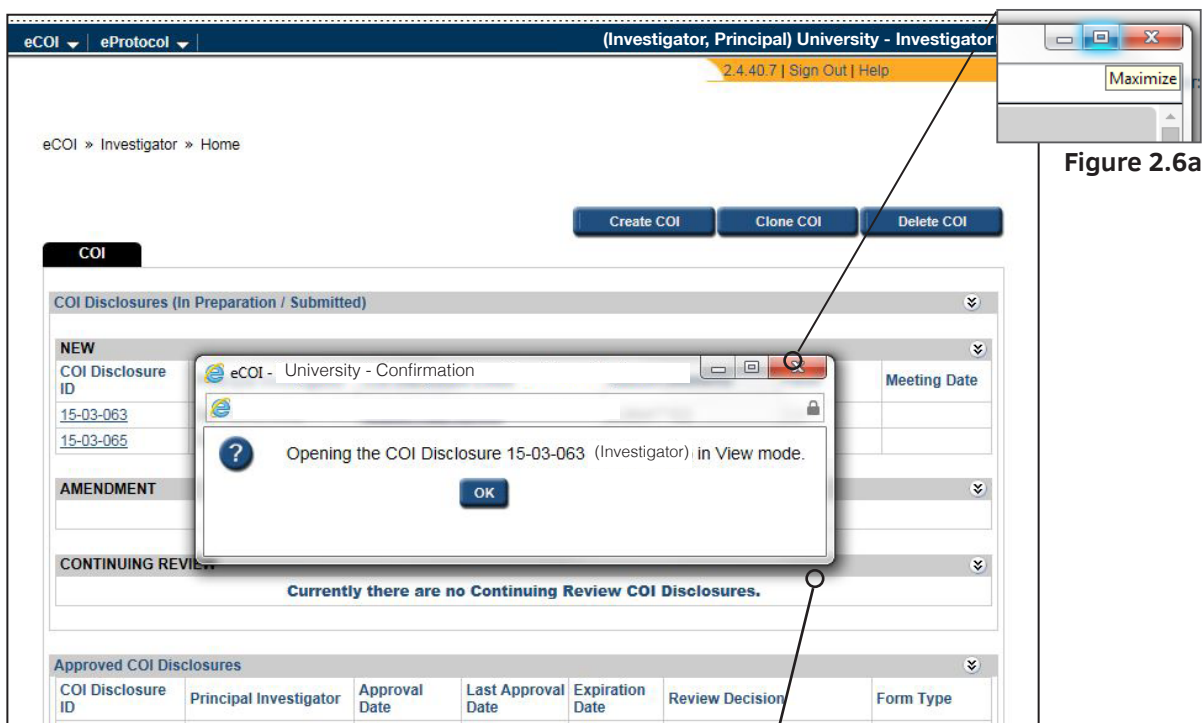


Figure 2.6a

Figure 2.6

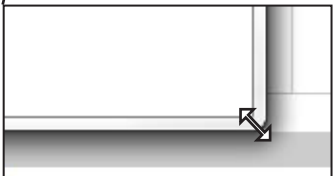


Figure 2.6b

3 TOP NAVIGATION BAR

3.1 Sign Out / Help / User name

When you have saved your work and are ready to sign out of eProtocol, click on the **Sign Out** button found in the upper right hand corner of the browser as seen in Figure 3.1a. It is important to sign out to protect your work and personal information.

When in need of assistance, click the **Help** button located to the right of the sign out button. A pop-up window will appear in the middle of the screen to assist the user. Follow the instructions in the pop-up window.

NOTE: Not signing out could cause a disclosure to be “locked for editing” when accessed by another user.

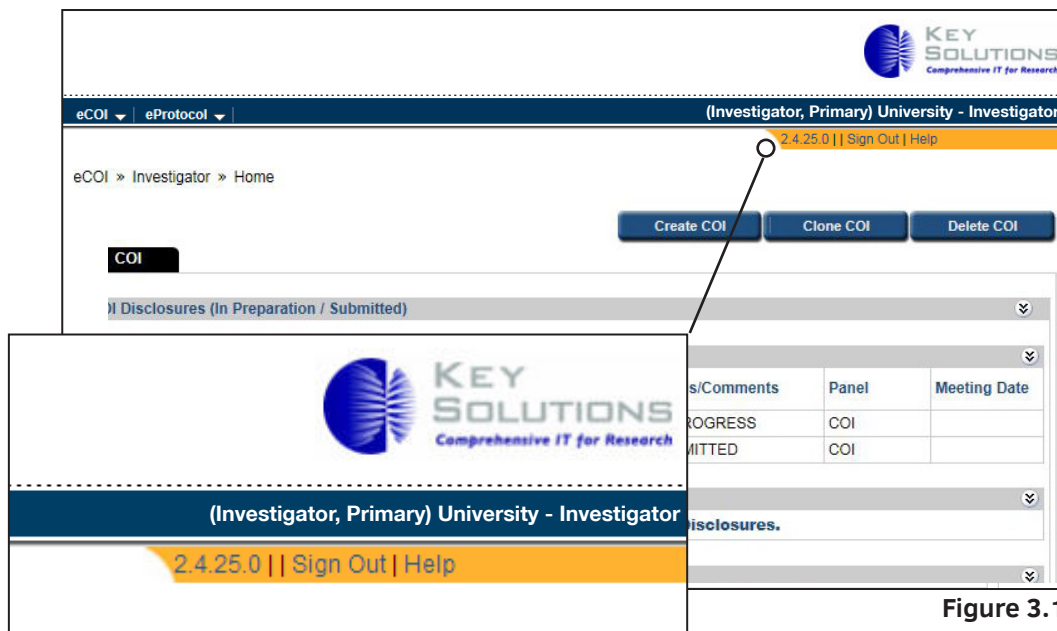


Figure 3.1a

Figure 3.1



The dashboard will display the logged-in user’s last name and their current role [Figure 3.1b]. Some users (such as committee members) will have more than one role and each role has a separate dashboard homepage.



Figure 3.1b

3.2 Module Options Drop-down

Primary navigation for all eProtocol users will be at the upper left-hand corner of the browser under the tab “eCOI”. The following pages demonstrate what each drop-down menu will look like depending on your role. Further explanation into the drop-down menus and their tabs will be explored more throughout this manual.

NOTE: All dashboards will remain the same but will display different content depending on the user's role.



Figure 3.2

Figure 3.2a



1 Committee Manager

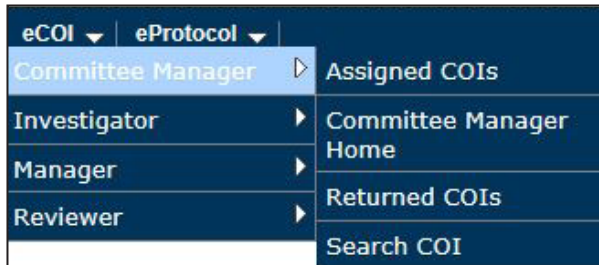


Figure 3.3

Assigned COIs - A list of disclosures that have been assigned to a panel.

Committee Manager Home - Navigates the user back to the Committee Manager home dashboard.

Returned COIs - COIs that have been returned to the Principal Investigator (PI).

Search COI - Allows the user to search disclosures by the Disclosure ID, Title, and the Principal Investigator.

2 Investigator



Figure 3.4

Approved Disclosures -A list of all disclosures that have been approved and are active.

Clone COI - Duplicates an existing disclosure and assigns a new Disclosure ID.

Create COI - Creates a new form and assigns a new Disclosure ID number.

Investigator Home - Returns the user back to the Investigator home dashboard.

Non Active COIs - Disclosures that have been closed, expired or withdrawn.

Search COI - Allows the user to search disclosures by the Disclosure ID, Title and PI.



3 Manager

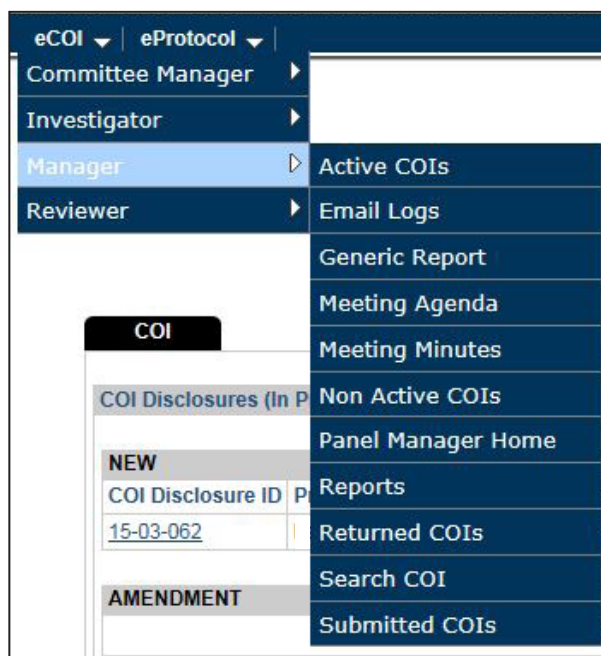


Figure 3.5

Active COIs - A list of all active disclosures.

Email Logs - All emails logged under a disclosure.

Generic Report - Ad-hoc reporting.

Meeting Agenda - Creating, setup and management of meetings.

Meeting Minutes - A list of disclosure submissions to a specific meeting with actions, comments and voting.

Non Active COIs - Disclosures that have been closed, expired, or withdrawn.

Panel Manager (PM) Home - Directs the user back to the PM home dashboard.

Reports - Standard reporting functionality.

Returned COIs - Disclosures that have been returned to the PI.

Search COI - Allows the user to search disclosures by the Disclosure ID, Title and PI.

Submitted COIs - A view of submitted and in progress disclosures.

4 Reviewer



Figure 3.6

Reviewer Home - Takes the user back to the Reviewer dashboard.

Search COI - Allows the user to search disclosures by the Disclosure ID, Title and PI.

4 ADDITIONAL NAVIGATION

4.1 Module Tabs Navigation

The module tabs are located above the content area. The tabs are used to navigate throughout the modules without navigating to another page. Clicking the module tab highlighted in Figure 4.1 will change the content area so that it pertains to the selected tab. The tab currently being viewed is identifiable by its highlighted color. Clicking the module tab will refresh the dashboard.

The screenshot shows the eCOI dashboard interface. At the top right is the KEY SOLUTIONS logo with the tagline 'Comprehensive IT for Research'. Below the logo is a navigation bar with 'eCOI' and 'eProtocol' dropdown menus, and the text '(Manager, Committee) University - Manager'. A status bar below that shows '2.4.25.0 | Sign Out | Help'. The breadcrumb trail reads 'eProtocol » Manager » Home'. A row of module tabs is displayed: 'COI' (highlighted in black), 'IACUC', 'IRB', 'CS', and 'RS'. Below the tabs is a 'Panel:' dropdown menu set to 'COI' and a 'Meeting Date:' dropdown menu set to '--All--'. The main content area is divided into sections: 'NEW' (with a dropdown arrow), 'AMENDMENT' (with a dropdown arrow), 'CONTINUING REVIEW' (with a dropdown arrow), and 'FINAL REPORT' (with a dropdown arrow). The 'NEW' section contains a table of COI disclosures.

COI Disclosure ID	Principal Investigator	COI Disclosure Event	Status/Comments	Panel	Meeting Date	Review Decision
15-03-063	Investigator, Principal	Receipt of COI Disclosure	IN-PROGRESS	COI		Designated Review
15-03-062	Investigator, Principal	Reviewer(s) Assigned	IN-PROGRESS	COI		Designated Review
15-03-065	Investigator, Principal	Comments Sent (Cycle 1)	IN-PROGRESS	COI		Designated Review

Currently there are no Amendment protocols.

Currently there are no Continuing Review protocols.

Currently there are no Final Report forms.

Figure 4.1

NOTE: For the purpose of this manual, COI is used as an example. Based on your research discipline, some options may vary.



4.2 Dashboard Action Buttons

The action buttons are located in the dashboard content area above the grid. Because each dashboard displays different content based on the user's role, the action buttons will be different per dashboard.

The primary function of the action buttons are to manage and monitor disclosures. The action buttons are a key element in the eProtocol software and will be given a more in depth explanation later in the manual. The primary action buttons are: Create, Clone, Delete and more, as you will see later.

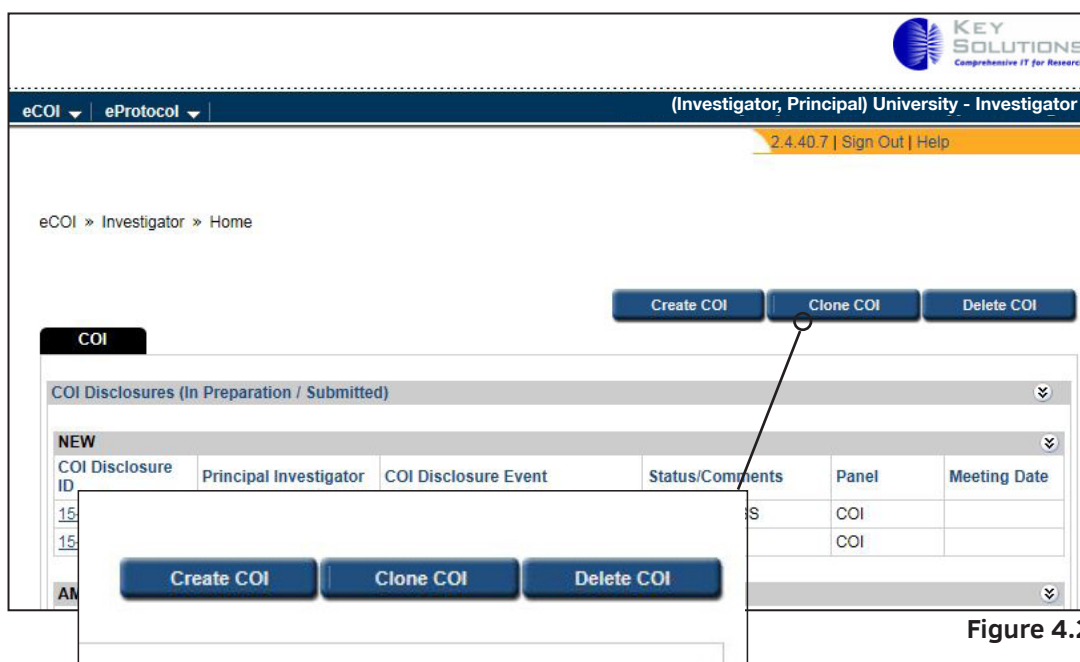


Figure 4.2

Figure 4.2a

5 DASHBOARD GRIDS OVERVIEW & LAYOUT

5.1 Grid Layout & Elements

Though all dashboards will have slight differences pertaining to the role of the user, the overall appearance of the home dashboards are primarily the same. Figure 5.1 shows the standard elements that are displayed in each of the functioning dashboards. A brief explanation of each element is located on page 25.

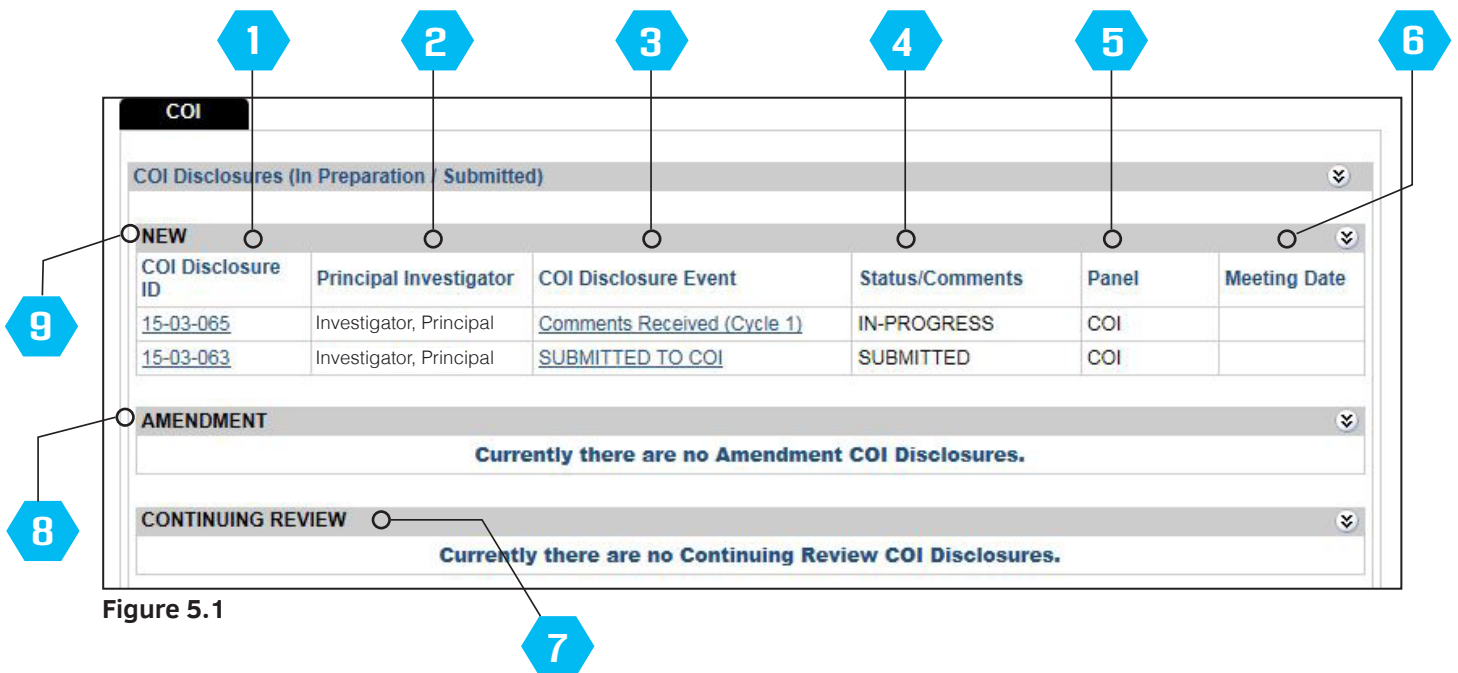


Figure 5.1

Grid Elements

- 1** **COI Disclosure ID** - Displays the seven digit identification number that is assigned when the disclosure is created. A disclosure can be accessed by clicking on the COI Disclosure ID number. Clicking on any disclosure number will generate a pop-up window that will allow the user to view and/or edit the disclosure.





- 2 Principal Investigator** - Displays the name of the Principal Investigator of a disclosure. Clicking on the Principal Investigator column header will change the listing alphabetically.
- 3 COI Disclosure Event** - Displays essential action items for the disclosure. The content in the disclosure event column differs per role and will be examined in later pages.
- 4 Status/Comments** - Displays the status of the disclosure.
- 5 Panel** - Displays which Committee the disclosure has been assigned to.
- 6 Meeting Date** - Displays the meeting date the disclosure has been assigned to.
- 7 Continuing Review** - Lists disclosures undergoing annual review.
- 8 Amendment** - Lists active disclosures that are in the process of being amended.
- 9 New** - Lists all new disclosures that are currently in progress.

Conflict Management Plan (CMP)

The Conflict Management Plan (CMP) is developed when there is any potential for conflict of interest. It is a suggested plan that must be reviewed and approved by eCOI Committee members before being sent to the PI for acceptance.

The CMP is created by the Panel Manager(PM) and sent to the Reviewer(s) to be viewed, commented on, and/or recommended for approval. The information received from the Committee Members is compiled by the PM. The PM adds any necessary comments or makes any necessary changes then sends the revised CMP back to the Committee for review/ approval.

A meeting is held where all Committee Members must agree on the CMP before beginning the next step. The PM will document the final CMP decision in the meeting minutes. Once agreed upon and documented, the CMP is sent to the PI to accept or decline.

A deeper explanation on the CMP functionality in accordance to your role will be further explained in later chapters of this manual.

NOTE: At any time during the CMP approval process the CMP is not approved, the current CMP will be dismissed and another round of collaboration will form to generate a new CMP.



5.2 Committee Manager Dashboard

Overview

This section of the software manual pertains to the role of the Committee Manager. The next several pages give an in-depth explanation of the action buttons and their functionality, as well as define the **Transactional Events** and **In Preparation** grid sections and the purpose they serve. If you are not a Committee Manager, you may skip pages 26-28 of this chapter.

NOTE: Full functionality of the Committee Manager role is further explained in the Committee Manager chapter of this manual. Please refer to that chapter on page 67 for more information.

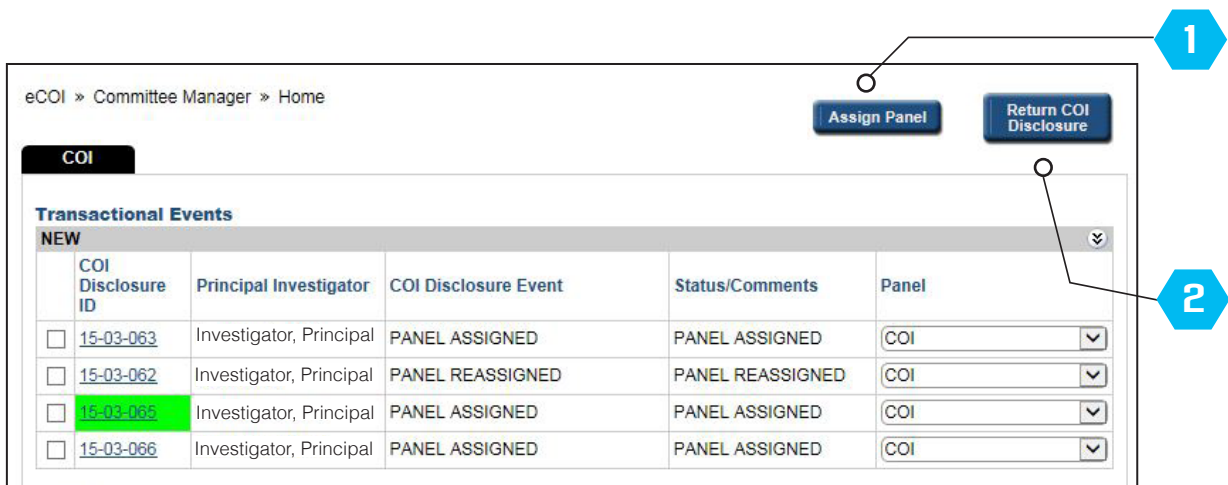


Figure 5.2

Action Buttons and Functionality

- 1 The action button **Assign Panel** is used to assign disclosures to a specific panel. In order to assign a disclosure, you must first check the box of the COI Disclosure ID number you wish to assign a panel to, as seen in Figure 5.3.

After selecting the COI Disclosure ID number, choose the Committee you would like the disclosure assigned to under Panel the drop-down. Once both the disclosure and panel have been selected, click the **Assign Panel** button to complete the process.





Figure 5.3

- The **Return COI Disclosure** action button follows similar steps to that of the Assign Panel button, however there must be Return Notes added to the disclosure before it can be returned. To return a disclosure to the PI, you must select the box of the Disclosure you wish to return, and click on the **Return COI Disclosure** button.

Interacting with Grid Content

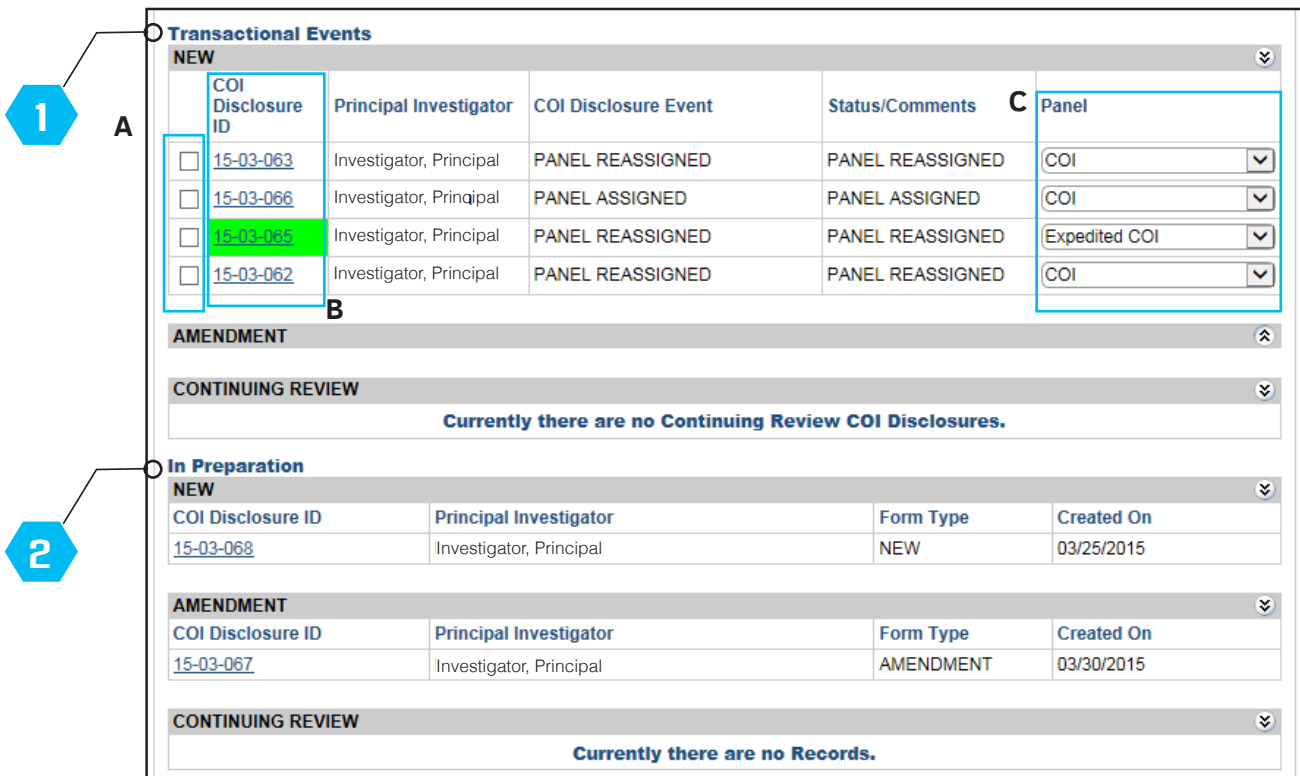


Figure 5.4



1 Transactional Events - Is a part of the content area that categorizes the different grids. One of the grids within the Transactional Events has three elements that are interactive with the user.

A - The outlined blue box on the far left is highlighting the check mark boxes that are a key functional item in eProtocol. In order to assign or return disclosures, one of the check mark boxes has to be selected.

B - The disclosure numbers highlighted are significant because of their functionality. Clicking on a COI Disclosure ID number as a Committee Manager enables a pop-up window shown in Figure 5.5.

NOTE: It is under the COI Disclosure Event column that the PI can access the Conflict Management Plan (CMP). Further detail on this functionality will be explained in the Principal Investigator Role chapter of this manual [pg 43].



Figure 5.5

C - The drop-down menu under the panel column header lists the committees that the disclosure can be assigned to.

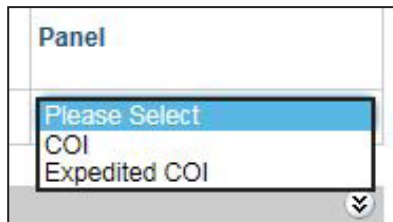


Figure 5.6

2 In Preparation - Is a part of the content area that categorizes three grids that contain in preparation disclosures of different status levels.



5.3 Investigator Dashboard

Overview

This section of the software manual pertains to the role of the Principal Investigator. The next several pages give an in-depth explanation of the action buttons and their functionality. If you are not a Principal Investigator you may skip pages 29-32 of this manual.

NOTE: Full functionality of the Principal Investigator is further explained in the Principal Investigator Role chapter of this manual. Please refer to that chapter on page 43 for more information.

The screenshot shows the Investigator Dashboard interface. At the top, there is a breadcrumb trail: "eCOI » Investigator » Home". Below this, there are three blue buttons: "Create COI", "Clone COI", and "Delete COI". Above each button is a blue hexagon with a white number (1, 2, and 3 respectively) and a line connecting it to the button. Below the buttons is a section titled "COI" with a sub-section "COI Disclosures (In Preparation / Submitted)". Underneath, there is a table with a "NEW" header and a table with the following data:

COI Disclosure ID	Principal Investigator	COI Disclosure Event	Status/Comments	Panel	Meeting Date
15-03-065	Investigator, Principal	Comments Received (Cycle 1)	IN-PROGRESS	COI	

Figure 5.7

Action Buttons and Functionality

- 1 In order to create a new disclosure, click on the **Create COI** button located above the content area. Clicking the action button will direct the user to another page where he/she can create a new disclosure [Figure 5.8]. Check the Conflict of Interest circle button to display more required data fields. Once all of the necessary fields have been completed, click the **Create** button to continue drafting a new disclosure. Further explanation in creating disclosures is found in the Investigator Role chapter.



eCOI » Investigator » [Home](#) » Create COI Disclosure

COI Report Title Create Cancel

Test

COI

Conflict of Interest

Figure 5.8

- The **Clone COI** action button is used to duplicate a disclosure. Clicking on this button will direct the user to another page shown in Figure 5.9. Check the circle next to the COI Disclosure ID number you wish to clone followed by clicking the **Clone COI** button. A duplicate disclosure will appear with a newly assigned COI Disclosure ID number; after which the new disclosure can be modified.

eCOI » Investigator » [Home](#) » Clone COI Disclosure Clone COI Disclosure

COI All

	COI Disclosure ID	Principal Investigator	COI Disclosure Event	Form Type	Panel	Meeting Date
<input checked="" type="radio"/>	15-03-063	Investigator, Principal	SUBMITTED	NEW		
<input type="radio"/>	15-03-062	Investigator, Principal	NEW	NEW		

Figure 5.9

- Clicking on the **Delete COI** action button takes the user to a page where a list of 'In Preparation' disclosures are displayed as shown in Figure 5.10. Check the box to the left of the COI Disclosure ID number you want to delete. Complete this action by clicking on the **Delete COI Disclosure** button.

eCOI » Investigator » [Home](#) » Delete COI Disclosure Delete COI Disclosure

COI

	COI Disclosure ID	Principal Investigator	COI Disclosure Event	Form Type	Panel	Meeting Date
<input checked="" type="checkbox"/>	15-03-064	Investigator, Principal	NEW	NEW		
<input type="checkbox"/>	15-03-062	Investigator, Principal	NEW	NEW		

Figure 5.10



Interacting with Grid Content

The screenshot displays the eCOI dashboard for an Investigator. At the top, there are navigation elements: 'eCOI' and 'eProtocol' dropdowns, and the user's role and institution: '(Investigator, Principal) University - Investigator'. A version and utility bar shows '2.4.40.7 | Sign Out | Help'. The breadcrumb trail is 'eCOI » Investigator » Home'. Three buttons are visible: 'Create COI', 'Clone COI', and 'Delete COI'. The main content area is titled 'COI' and contains several sections:

- COI Disclosures (In Preparation / Submitted):** This section is divided into three sub-sections:
 - NEW:** A table with columns: COI Disclosure ID, Principal Investigator, COI Disclosure Event, Status/Comments, Panel, and Meeting Date. Two rows are shown:

COI Disclosure ID	Principal Investigator	COI Disclosure Event	Status/Comments	Panel	Meeting Date
15-03-065	Investigator, Principal	Comments Received (Cycle 1)	IN-PROGRESS	COI	
15-03-063	Investigator, Principal	SUBMITTED TO COI	SUBMITTED	COI	
 - AMENDMENT:** A message stating 'Currently there are no Amendment COI Disclosures.'
 - CONTINUING REVIEW:** A message stating 'Currently there are no Continuing Review COI Disclosures.'
- Approved COI Disclosures:** A table with columns: COI Disclosure ID, Principal Investigator, Approval Date, Last Approval Date, Expiration Date, Review Decision, and Form Type. One row is shown:

COI Disclosure ID	Principal Investigator	Approval Date	Last Approval Date	Expiration Date	Review Decision	Form Type
15-03-067	Investigator, Principal	03/10/2015	03/10/2015	03/09/2016	Full Review	NEW
- Non Active COI Disclosures:** A message stating 'Currently there are no Non Active COI Disclosures.'

Figure 5.11



1 **COI Disclosures (In Preparation/Submitted)** - Lists all disclosures currently in progress.

A - Clicking any of the COI Disclosure ID numbers as an Investigator results in a pop-up window to open the disclosure, as seen in Figure 5.12.



Figure 5.12

B - A disclosure may be accessed by clicking on the active links in the Disclosure Event column. The pop-up window generated is the same as the one in Figure 5.12.

2 **Approved COI Disclosures** are a list of all disclosures that have been approved and are currently active. This is where a disclosure can be opened for viewing or to start an amendment.

3 **Non Active COI Disclosures** are disclosures that are inactive.



5.4 Manager Dashboard

Overview

This section of the software manual pertains to the role of the Manager. The next several pages give an in-depth explanation of the action buttons and their functionality. If you are not a Manager, you may skip pages 33-38 of this manual.

NOTE: Full functionality of the Manager role is further explained in the Manager Role chapter of this manual. Please refer to that chapter on page 73 for more information.

Panel: COI Meeting Date: ---All---

COI Disclosure ID	Principal Investigator	COI Disclosure Event	Status/Comments	Panel	Meeting Date	Review Decision
15-03-063	Investigator, Principal	Receipt of COI Disclosure	IN-PROGRESS	COI		Designated Review
15-03-062	Investigator, Principal	Reviewer(s) Assigned	IN-PROGRESS	COI		Designated Review
15-03-065	Investigator, Principal	Comments Sent (Cycle 1)	IN-PROGRESS	COI		Designated Review
15-03-066	Investigator, Principal	Reviewer(s) Assigned	IN-PROGRESS	COI		Designated Review

AMENDMENT
Currently there are no Amendment COI Disclosures.

CONTINUING REVIEW
Currently there are no Continuing Review COI Disclosures.

Figure 5.13

Interacting with Grid Content

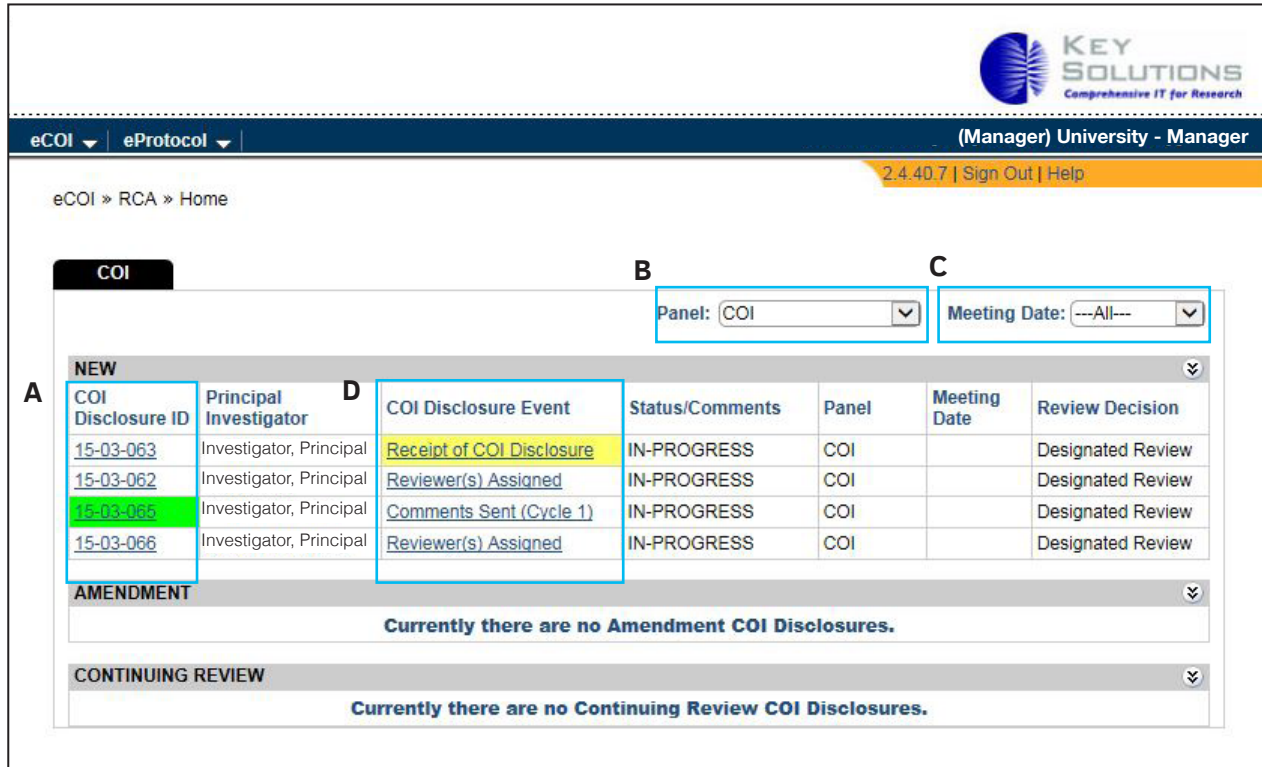


Figure 5.14

A - Clicking on a **COI Disclosure ID** number will generate a pop-up as seen in Figure 5.15. You may view the disclosure by clicking on either of the action buttons.

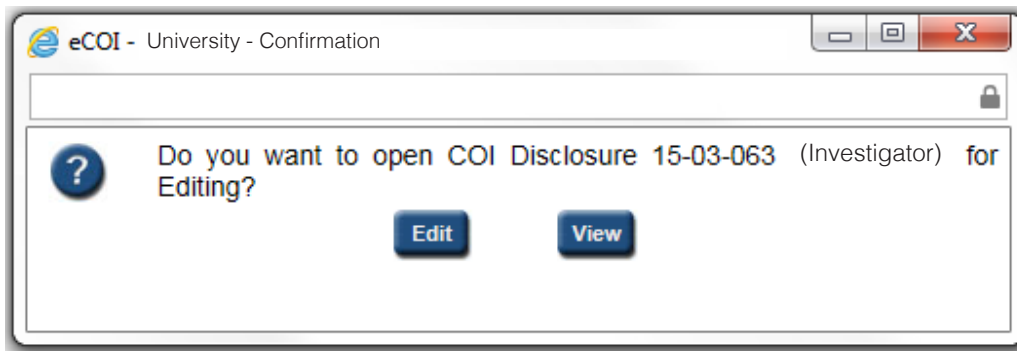


Figure 5.15



B - The **Panel** drop-down allows the Manager to filter disclosures based on the board it has been assigned to [Figure 5.16].

eCOI » RCA » Home

COI

Panel: ---All---
COI
 Expedited COI

Meeting Date: ---All---

NEW

COI Disclosure ID	Principal Investigator	COI Disclosure Event	Status/Comments	Panel	Meeting Date	Review Decision
15-03-063	Investigator, Principal	Receipt of COI Disclosure	IN-PROGRESS	COI		Designated Review
15-03-062	Investigator, Principal	Reviewer(s) Assigned	IN-PROGRESS	COI		Designated Review
15-03-065	Investigator, Principal	Comments Sent (Cycle 1)	IN-PROGRESS	COI		Designated Review

Figure 5.16

C - The **Meeting Date** drop-down allows the Manager to filter disclosures by their assigned meeting date [Figure 5.17].

eCOI » RCA » Home

COI

Panel: COI

Meeting Date: ---All---
03/27/2015

NEW

COI Disclosure ID	Principal Investigator	COI Disclosure Event	Status/Comments	Panel	Meeting Date	Review Decision
15-03-063	Investigator, Principal	Receipt of COI Disclosure	IN-PROGRESS	COI		Designated Review
15-03-062	Investigator, Principal	Reviewer(s) Assigned	IN-PROGRESS	COI		Designated Review
15-03-065	Investigator, Principal	Comments Sent (Cycle 1)	IN-PROGRESS	COI		Designated Review

Figure 5.17

D - The **COI Disclosure Event** column within the dashboard grid holds several active links [Figure 5.14]. Clicking on the **Receipt of COI Disclosure** link will direct the user to a page like Figure 5.18 on page 36. This is where the Manager assigns Reviewers to a disclosure.



eCOI » RCA » [Home](#) » Assign Reviewers

COI Disclosure ID: [15-03-063](#) (Investigator, Principal) Further Review:

Panel: Meeting Date: Review Type:

Panel Members

Panel Member	Presenter	PR	SR	Rad.Saf	BioS.	Expert	NPR
Member, Panel	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Member, Panel	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Member, Panel	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Member, Panel	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Member, Panel	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Member, Panel	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Member, Panel	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Member, Panel	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

Figure 5.18

Reviewer(s) Assigned [Figure 5.19] allows the Manager to review and comment on active disclosures.

eProtocol » RCA » [Home](#) » Comments

COI Disclosure ID: [15-03-062](#) (Investigator, Principal)
Review Type: Designated Review

Cycle:

Comments

Please click on Write Comment(s) to add Comment(s).

Figure 5.19

The **Comments Sent** [Figure 5.20] and **Responses Received** [Figure 5.21] navigates the user to a page where comments and/or direct responses can be viewed. Refer to Figure 5.14 on page 34 to view the location of these links on the dashboard.





eProtocol » RCA » [Home](#) » Comments

COI Disclosure ID: [15-03-065](#) (Investigator, Principal)
 Review Type: Designated Review

Cycle: **1**

[Get COI Disclosure](#) [Reviewers](#) [Meeting Minutes](#)
[Conflict Mgmt Plan](#) [Write Comment\(s\)](#) [Show All Comments](#)

Comments

Section: Conflict Management Plan
Title: LW1 **Reviewer:** (Reviewer) **Date:** 03/10/2015
 Please refer to the CMP
 Response Necessary for Suggestion Not Necessary for Approval

Section: Personnel Information
Title: GB1 **Reviewer:** (Presenter/Primary) **Date:** 03/10/2015
 CMP looks fine
 Response Necessary for Suggestion Not Necessary for Approval

Notes

Reviewer	Recommended	Notes to COI Disclosure	Date Submitted
Cycle: 1			
Reviewer, Primary			03/10/2015

Figure 5.20

eProtocol » Manager » [Home](#) » Comments

Protocol ID: [14-07-065](#) (Investigator, Principal)

Cycle: **1** **2** **3**

[Get Protocol](#) [Guidelines](#) [Reviewers](#) [Meeting Minutes](#)
[Write Comment\(s\)](#) [Show All Comments](#)

Comments

Section: Personnel Information
Title: WL1 **Reviewer:** Reviewer, Primary **Date:** 07/31/2014
 comments from PM after the Reviewer in cycle 1
 are more people needed than this?
 Fusce consectetur lobortis ante nec luctus. Suspendisse bibendum mollis ipsum sed vehicula. Quisque auctor vestibulum sem id mattis. Phasellus in eleifend nisi, at hendrerit turpis. Nam iaculis diam a facilisis feugiat. Duis laoreet metus et lectus dictum, non bibendum sem scelerisque. Mauris sollicitudin mollis eget. Sed vitae velit eu purus sodales mattis volutpat vel mi. Suspendisse posuere ullamcorper

Response Necessary for Approval Suggestion Not Necessary for Approval

Response **Date:** 08/01/2014
 nice use of latin text

Figure 5.21



The **Recommended for Approval** link displays Reviewers and their recommendation [Figure 5.22]. Refer to Figure 5.14 on page 34 to see how we got to this page.

eProtocol » Manager » [Home](#) » Comments

COI Disclosure ID: [15-03-065](#) (Investigator, Principal)
 Review Type: Designated Review

Cycle: **1**

[Get COI Disclosure](#) [Reviewers](#) [Meeting Minutes](#)
[Conflict Mgmt Plan](#) [Write Comment\(s\)](#) [Show All Comments](#)

Comments

Section: Conflict Management Plan

Title: LW1 **Reviewer:** Reviewer **Date:** 03/10/2015

Please refer to the CMP

Response Necessary for Approval for Suggestion Not Necessary for Approval

Section: Personnel Information

Title: GB1 **Reviewer:** Reviewer, Primary (Presenter/Primary) **Date:** 03/10/2015

CMP looks fine

Response Necessary for Approval for Suggestion Not Necessary for Approval

Notes

Reviewer	Recommended	Notes to COI Disclosure	Date Submitted
Cycle: 1			
Reviewer, Primary	YES		03/10/2015

Figure 5.22

Lastly, **Panel Manager Review** generates a pop-up allowing the user to review the panel content.





5.5 Reviewer Dashboard

Overview

This section of the software manual pertains to the role of the Reviewer. The next several pages give an in-depth explanation the main functionality of the dashboard. If you are not a Reviewer, you may skip pages 39-40 of this manual.

NOTE: Full functionality of the Reviewer role is further explained in the Reviewer Role chapter of this manual. Please refer to that chapter on page 101 for more information.

The screenshot shows the Reviewer Dashboard interface. At the top right is the KEY SOLUTIONS logo with the tagline 'Comprehensive IT for Research'. Below the logo is a navigation bar with 'eCOI' and 'eProtocol' dropdown menus, and the user's role '(Reviewer) University - Reviewer'. A status bar indicates '2.4.40.7 | Sign Out | Help'. The main content area shows the breadcrumb 'eCOI » Reviewer » Home' and a 'COI' tab. The 'COI Member (Action Items)' section is expanded to show a table of new items. The table has columns for Role, COI Disclosure ID, Principal Investigator, COI Disclosure Event, Status/Comments, Panel, and Meeting Date. Two rows are visible, both with the role 'Presenter' and status 'IN-PROGRESS'. The first row has COI Disclosure ID '15-03-062' and the event 'Assigned as Reviewer'. The second row has COI Disclosure ID '15-03-066' and the event 'Assigned as Reviewer'. Below this table are sections for 'AMENDMENT' and 'CONTINUING REVIEW'. The 'COI Member (COI Disclosures for Review)' section is also expanded, showing a table with the same columns as above, but it contains the message 'No data available in table'. Below this table are also sections for 'AMENDMENT' and 'CONTINUING REVIEW'.

Figure 5.23



Disclosures for Review

A - Clicking on a COI Disclosure ID number while logged in as a Reviewer will generate a pop-up window as shown in Figure 5.24. The Reviewer has the option to view disclosures.

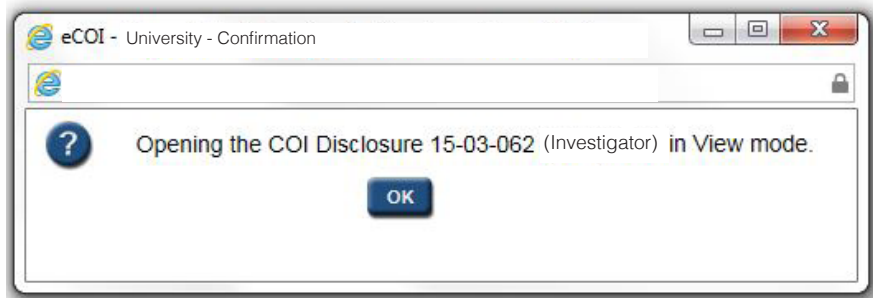


Figure 5.24

B - Clicking on the **Assigned as Reviewer** link directs the user to another page as shown in Figure 5.25. On this page the Reviewer has the ability to view, add comments and send their recommendation to the panel manager.



Figure 5.25



6 SEARCH DISCLOSURE

Overview

No matter your role, all members have the ability to search a disclosure. A user can access the search disclosure page by first selecting the eCOI drop-down top menu bar. Hover your mouse over your job title and click on the menu tab titled **Search COI Disclosures**.

You will be directed to a search page like the one shown in Figure 6.1. On this screen, you may search for all disclosures that you have access rights to. Disclosures can be searched by Title, PI Name, and COI Disclosure ID. Searches can be saved for future use. Saved searches maintain the search criteria for faster subsequent searches.

eCOI » Committee Manager » [Home](#) » Search COI Disclosure

Search Clear Save Cancel

COI

COI Disclosure ID	<input type="text"/>	Study Title	<input type="text"/>
Principal Investigator	<input type="text"/>	Investigator	<input type="text"/>
Form Type	---Please Select---	Panel	---Please Select---
Department	---Please Select---	Meeting Date	<input type="text"/>
Form Name	---Please Select---		
COI Disclosure Status	---Please Select---		

Figure 6.1





Chapter II

Principal Investigator Role



1 OVERVIEW

The Principal Investigator Role chapter examines the functions, job duties and requirements of an eCOI user logged in as a Principal Investigator (PI). The following pages show screen shots as well as examples of the Investigator dashboard and walks the user through the process of creating a disclosure.

1.1 Things to Remember

Before getting started on the Investigator Role chapter, please review the following information from the Functionality & Dashboard Overview chapter.

1. Choose a supported browser

Using an unsupported browser will cause the software to not work properly; limiting the users full functionality. The browsers compatible with eProtocol are: Firefox 12 and above and Safari 7.

2. Make sure the Pop-Up Blocker is turned OFF

The steps in the Investigator Role chapter cannot be completed if the pop-up blocker is still active. See the Functionality & Dashboard Overview chapter for more information and instructions.

3. Avoid using the Back button

Using the Back button will log the user out.

4. Resizing the screens

There are numerous pop-up windows used in the software. Don't forget you can resize the screens to better suit your view.

NOTE: For the purpose of this manual, COI is used as an example. Based on your research discipline, some options may vary.



2 CREATING A NEW DISCLOSURE: ENTRY SCREEN

2.1 Administrative & Standard Disclosure Application

In order to create a new disclosure, follow the steps below.

1. Select the eCOI drop-down in the top menu bar, find your role, and select the appropriate tab to navigate to your home dashboard.
2. Once on the home dashboard, click on the blue **Create COI** action button [Figure 2.1] or select the tab from the eCOI menu drop-down. You will then be directed to another page as seen in Figure 2.2.

The screenshot shows the eCOI system interface for an Investigator. The top navigation bar includes 'eCOI' and 'eProtocol' dropdowns, and the user's role '(Investigator, Principal) University - Investigator'. A version and utility bar shows '2.4.40.7 | Sign Out | Help'. The breadcrumb trail is 'eCOI » Investigator » Home'. In the 'COI' section, there are three buttons: 'Create COI' (highlighted with a red box), 'Clone COI', and 'Delete COI'. Below these are two expandable sections: 'NEW' and 'AMENDMENT'. The 'NEW' section contains a table with two rows of disclosures.

COI Disclosure ID	Principal Investigator	COI Disclosure Event	Status/Comments	Panel	Meeting Date
15-03-065	Investigator, Principal	Comments Received (Cycle 1)	IN-PROGRESS	COI	
15-03-063	Investigator, Principal	SUBMITTED TO COI	SUBMITTED	COI	

The 'AMENDMENT' section is currently empty, with the message: 'Currently there are no Amendment COI Disclosures.'

Figure 2.1



eCOI » Investigator » [Home](#) » Create COI Disclosure

COI Report Title Create Cancel

Test

COI

Conflict of Interest

Figure 2.2

3. Give your study a title.
4. Select the Conflict of Interest circle button. Upon your selection, more content will appear on your screen [Figure 2.3].
5. Fill out all of the required data fields
6. Click the **Create** action button.

Reporting Individual* Clear

Name *	Degree (MS/PhD)	University Title	
Investigator, Principal			
E-mail Address *	Office Phone	Ext	Fax
School	Department Name	Mailing Address	
Select One	Select One		

Administrative Contact Clear

Name	Degree (MS/PhD)	University Title	
E-mail Address *	Office Phone	Ext	Fax
School	Department Name	Mailing Address	
Select One	Select One		

Create Cancel

Figure 2.3



3 DISCLOSURE ENTRY PROCESS NAVIGATION

3.1 Top & Bottom Navigation Buttons

There are several ways to navigate through your newly created disclosure. The top and bottom of the page contain the same menu bar for easier navigation throughout the form setup. The buttons, shown in Figure 3.1 and 3.2, are: Save, Spell Check, Help, Close, Previous and Next. The next three pages will explore the functionality of the navigation buttons.

The screenshot shows a web browser window titled "eCOI - University - Personnel Information". The main content area is titled "COI - Conflict of Interest" and "COI Disclosure ID: (Investigator, Principal)". A navigation bar at the top right contains buttons for "Save | Spell Check | Help | Close" and "Previous | Next". Below this is a form titled "Reporting Individual*" with the following fields:

Name *	Degree (MS/PhD)	University Title	
Investigator, Principal			
E-mail Address *	Office Phone	Ext	Fax
School	Department Name	Mailing Address	
Select One	Select One		

At the bottom of the form, it says "No training data is available."

Figure 3.1

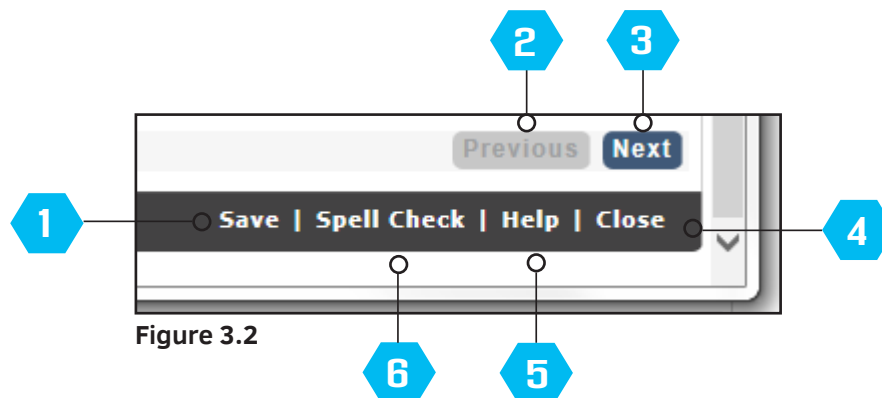


Figure 3.2



3.2 Spell Check, Help, Save, Auto-Save, Close, Previous & Next

- 1 Clicking the **Save** button will save any information entered when creating the disclosure. The information will continue to be saved regardless of being logged in or out. Navigating from one page to the next will **Auto-Save** any work documented before moving to the next page.

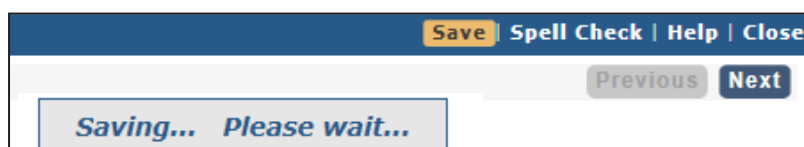


Figure 3.3

- 2 The **Previous** button allows the user to go to the previous page while saving any data before re-navigating [Figure 3.4]. The **Previous** and **Next** buttons have the same functionality as clicking up and down the left navigation menu and Auto-Save any data before navigating to another page.

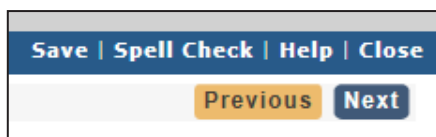


Figure 3.4

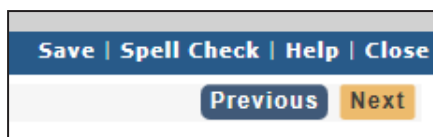


Figure 3.5

- 3 The **Next** navigates to the next consecutive page [Figure 3.5].
NOTE: The functionality of the Previous and Next buttons are dependent on all mandatory fields being completed. If there are any required fields left empty, you may not be able to proceed to the next page.
- 4 In order to close the disclosure, you may click the **Close** button at the top or bottom navigation bar. Clicking the Close button results in a pop-up window prompting the user if they wish to proceed before closing the disclosure.



- 5 The **Help** button generates a pop-up window that displays relevant help information specific to the page the user is on.
- 6 The **Spell Check** button in the top navigation bar checks for any words that have been misspelled [Figure 3.6].

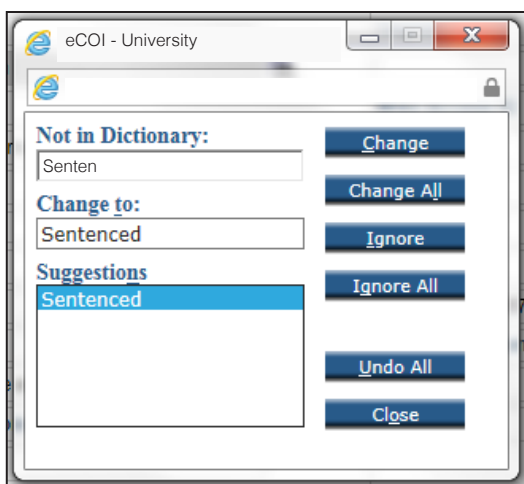


Figure 3.6

NOTE: When the spell check window initially opens, it hides behind open windows. It also gets hidden after clicking any of the action buttons within the spell check pop-up. Resizing the windows and setting them side by side when editing may be the best alternative to avoid this issue.

3.3 Error Message Location

An error message will appear on any dashboard or pop-up window when information was not entered correctly or a step was missed. The red text alerts the user of an error and notes the reason for the error.



Figure 3.7

4 LEFT NAVIGATION BAR

4.1 Overview

On the left side of the disclosure window is a blue menu bar. This menu is one of several ways to navigate through the disclosure forms. Clicking on a menu tab will direct the user to the specified page. Each page contains important forms and information required to complete and submit the disclosure. Figure 4.1 below demonstrates what the left menu bar looks like and gives a brief definition to the tabs on page 51. Next to the definitions is a page number where the user can view a more in-depth explanation of each tab and its functionality.

4.2 Disclosure Menu Bar Items

On the left side of the disclosure window is a blue menu bar. This menu is one of several ways to navigate throughout the disclosure.

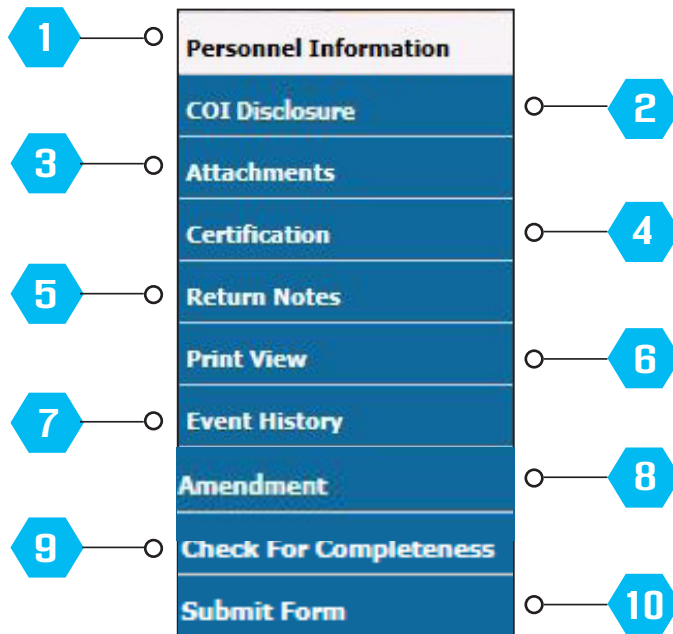


Figure 4.1





- 1 **Personnel Information** - Use this section to add an Administrative [pg 54].
- 2 **COI Disclosure** - This navigation tab contains a contact the disclosure form [pg 55].
- 3 **Attachments** - All applicable attachments can be uploaded on this page [pg 56].
- 4 **Certifications** - The **Certifications** page is to ensure that you comply and abide by the rules and guidelines pertaining to the disclosure established in the CMP [pg 57].
- 5 **Return Notes** - Allows the user to enter any notes before submitting the disclosure [pg 57].
- 6 **Print View** - PDF versions of all sections of the disclosure with or without comments can be generated with this tab [pg 59].
- 7 **Event History** - A catalog of dates in the life of the disclosure and a list of all e-mail correspondence from the system are listed here. Through this tab you can access the approved supplemental documents, approval letter and past PDF versions of the disclosure to be printed or saved [pg 60].
- 8 **Amendment** - The **Amendment** page is used to document any changes made within the disclosure [pg 59].
- 9 **Check For Completeness** - Use this feature to check for any unanswered questions before submitting the disclosure [pg 58].
- 10 **Submit Form**- When the disclosure is finalized the PI must click **Submit Form** in the left navigation menu [pg 58].

5 DISCLOSURE ENTRY PROCESS

5.1 Requirements to Begin

In order to begin the disclosure entry process, the user must know the general information regarding the disclosure. A reporting individual is mandatory in creating any disclosure and must be known before the initial set up. Any required data specific to the disclosure must be known as well.

5.2 Interacting with Data Fields

The following pages will explore the functionality and user interaction with the data fields.

The screenshot shows a web form titled "Publicly Traded Entity" with a "Save | Cancel" button in the top right. A note at the top left states: "Note: * denotes mandatory field." The form is divided into several sections:

- Section 1:** "1. Reporting for *" with a dropdown menu currently showing "Select One". A blue callout '1' points to the dropdown.
- Section 2:** "2. Type of relationship [check all that apply] *" with a list of checkboxes and labels: "Advisory Board or Committee", "Equity Holdings", "Expert Witness", "Governing Board or Officer", "Stock", "Stock Option", and "Other Ownership Interest (list below)". A blue callout '2' points to the right side of this section.
- Section 3:** "3. Name of external entity *" with a text input field containing "S". A blue callout '3' points to the input field.
- Section 4:** "4. Address of external entity" with a text input field.
- Section 5:** "5. Can you determine the value of compensation or financial interest in the reporting calendar year? *" with radio buttons for "Yes" and "No" (the "No" button is selected). Below this is a text input field for a dollar amount, starting with a "\$" symbol. A blue callout '4' points to the "No" radio button.

At the bottom left of the form is an "Explain" link. A blue callout '4' also points to the bottom right corner of the form area.

Figure 5.1





Publicly Traded Entity				Add	Delete
	Reporting for	Type	Name	Value (\$)	
<input type="checkbox"/>	Self	Equity Holdings, Expert Witness	S	50,000	

Figure 5.2

- 1 **Required Fields Designation** - Any entry field with a red asterisk, denotes it is a mandatory field. If mandatory fields have not been filled, an error message will appear at the top of the dashboard.
- 2 **Drop-down Data Fields** - Drop-down data fields allows the user to filter through specific data.
- 3 **Field Dependence and Input Display Linkage** - Upon entering information in mandatory data fields, the user may notice other data fields have become active or inactive. Certain data fields are dependent upon the information entered. The example in Figure 5.1 shows an inactive text box that is dependent on other information being entered in order to become active.
- 4 **Field Dependence and Input Display Linkage** - Single and multi-line text boxes are found throughout eProtocol. The single box [Figure 5.1] generally has an “x” in the box, indicating the box only allows for a single line of text. Clicking on the “x” will delete any information entered. Multi-line text boxes are typically larger and allow multiple lines of text.
- 5 **Add/Delete Functionality of Data Grids** - The Add/Delete Functionality allows for the Investigator to change information within the disclosure [Figure 5.2].

Add - Clicking this button will generate a pop-up with a number of data fields to be completed. Complete the required data fields and press the **Save** button at the upper right of the pop-up to complete the addition.

Delete - Check the box next to the species you wish to eliminate from the protocol followed by clicking the **Delete** button. A pop-up window confirming your decision will appear for your final approval [Figure 5.3].

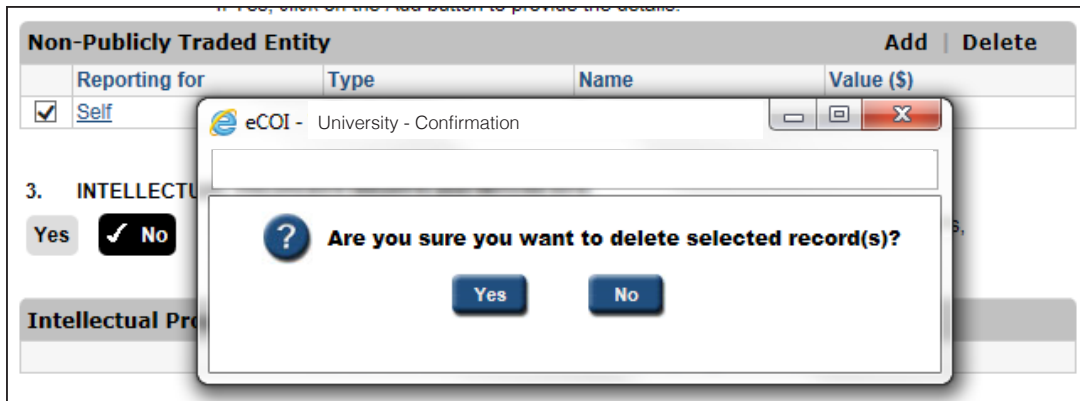


Figure 5.3

5.3 Personnel Information

The Personnel tab is the area of the disclosure where you, as the Investigator, are entered. In addition to your own information, this is where an Administrative Contact can be included, if applicable.

Find User Search Functionality

Some fields have a binocular icon next to them [Figure 5.4] which signifies the search and add functionality. Clicking on the icon generates a pop-up window like the one in Figure 5.5.

Administrative Contact

Name

University Title

Department

Select One

Office Address

Figure 5.4





Find User		Find
User ID:	<input type="text"/>	
First Name:	<input type="text"/>	
Last Name:	<input type="text"/>	

Figure 5.5

1. Find a user by filling out any one of the entry fields or a combination of the first and last name, followed by clicking the **Find** button.

NOTE: The Find User functionality will not work if all three search fields are entered as they do not work together.

2. After clicking Find, another pop-up window is displayed with a list of users matching the information entered in the Find User function.

3. Select the user you wish to add by checking the circle next to their name.

4. Click on the **OK** button and resume to the original page.

Auto-Population of Stored User Data

After you have made a selection using the search and add function, any previously saved information regarding the user will auto-populate in the data fields. After adding the designated individual, fields such as title, e-mail address, and office phone will automatically be filled out from saved user data.

5.4 COI Disclosure

The COI Disclosure page is required to be filled. Most of the content is field dependent and could expand with more mandatory information to be inputted.

5.5 Attachments

This portion of the disclosure is where any documents should be attached. Follow the steps below to add an attachment to the disclosure.

How to Add an Attachment

In order to add an attachment, go to the **Attachments** tab on the top tab bar or the side menu bar and follow the steps below.

1. Click the **Add** button highlighted in the image below. A pop-up window will appear [Figure 5.6] with mandatory data fields.
2. Use the drop-down tab to select the **Document Type** and select the **Browse** button to navigate through documents on your computer.
3. Select the document you wish to attach and press **OK**, which will result in bringing you back to the attachment pop-up window.
3. Click **Save** as your process is now complete.

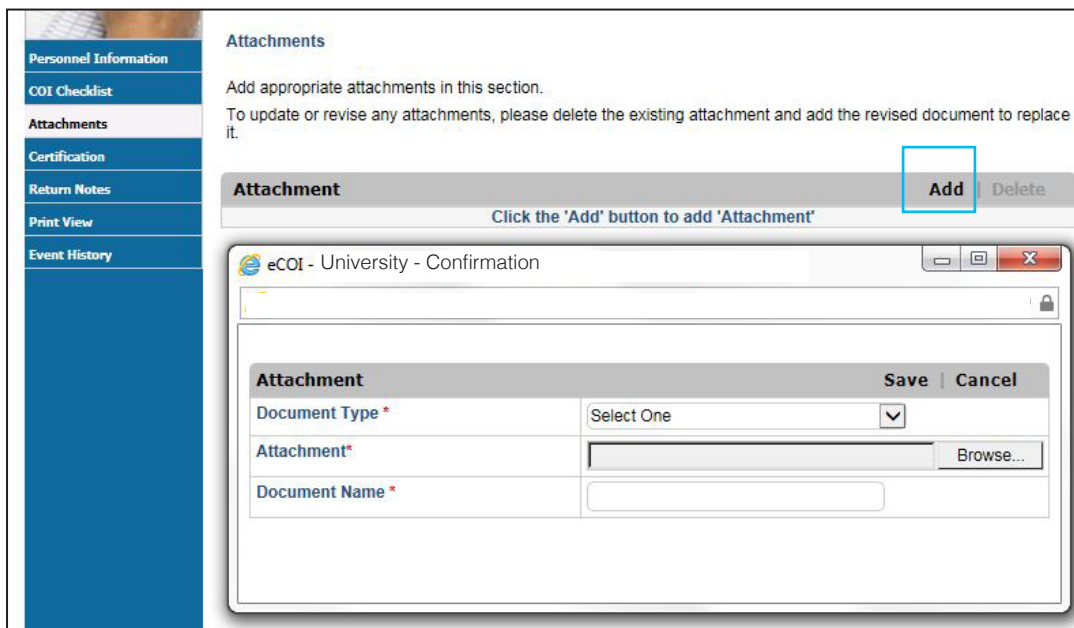


Figure 5.6

NOTE: All files can be uploaded here.



5.6 Certifications

It is mandatory that the Principal Investigator of the disclosure sign and complete the required certifications in order for a disclosure to be approved. Check all of the necessary boxes to verify you have read and understand the document.

The **Certification** is to ensure you comply and will abide by the rules and guidelines pertaining to the disclosure.




Figure 5.7

5.7 Return Notes

Click on the Return Notes tab in the blue menu bar within the disclosure. A pop-up window will appear for you to enter in any notes you would like to return the disclosure with [Figure 5.8]. After the notes have been entered, click the OK button to close the window.

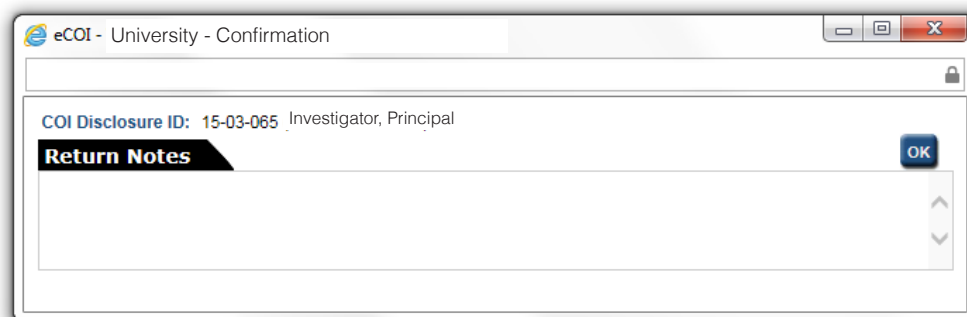


Figure 5.8



5.8 Check for Completeness

As you near the end of filling out the disclosure, click the **Check for Completeness** tab in the blue menu bar to check that all mandatory fields have been completed. Clicking this menu button will result in a pop-up window that shows the user the areas that have not yet been completed. Click on the active blue links within the pop-up to navigate to the pages still awaiting mandatory fields to be entered.

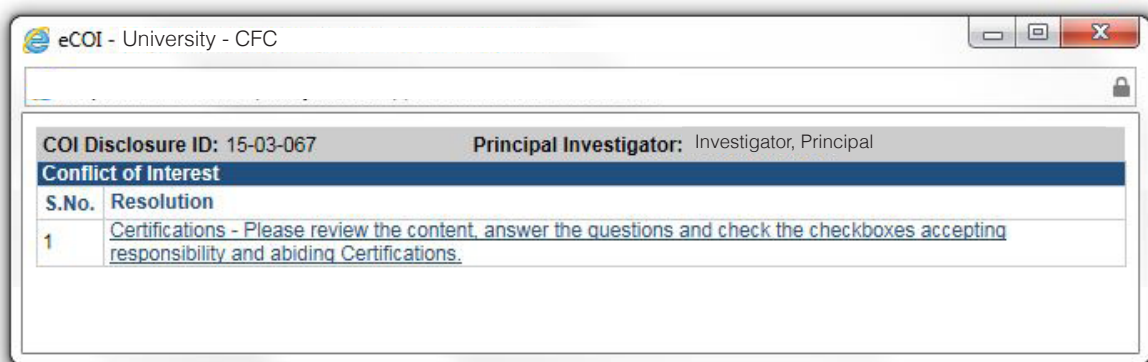


Figure 5.9

5.9 Submit Form

Before you can submit the disclosure, you as the PI, must have completed the certification section.

In order to submit the COI Disclosure, click on the **Submit Form** tab in the blue menu bar. Clicking the tab will result in a pop-up window asking the user if they would like to submit the form. Select the appropriate action button to complete this portion of the disclosure.





5.10 Print View

PDF versions of any or all sections of the form can be generated using the Print View. Upon clicking the **Print View** tab in the left menu bar, a pop-up window will appear like in Figure 5.10. You may then check which sections you would like to view and print, followed by the page orientation and whether or not you would like any comments within the protocol to be viewed. Click the **OK** action button to see the Print View PDF.

Print View OK

Please select any one of the following:

- COI Disclosure Only
- COI Disclosure with Comments
- Comments only

Sections to Print	Select Orientation	
	Portrait	Landscape
<input checked="" type="checkbox"/> All		
<input checked="" type="checkbox"/> Personnel Information	<input checked="" type="radio"/>	<input type="radio"/>
<input checked="" type="checkbox"/> COI Checklist	<input checked="" type="radio"/>	<input type="radio"/>
<input checked="" type="checkbox"/> Attachments	<input checked="" type="radio"/>	<input type="radio"/>
<input checked="" type="checkbox"/> Certification	<input checked="" type="radio"/>	<input type="radio"/>
<input checked="" type="checkbox"/> Event History	<input checked="" type="radio"/>	<input type="radio"/>

Note: File types of more than 10 MB in size and the files which cannot be converted to PDF are in disabled mode.

Attachments

Currently there are no Attachments

OK

Figure 5.10

5.11 Amendment

To amend a disclosure, click the link under the COI Disclosure Event column on the Amendment grid of the dashboard. The disclosure will open and the PI can make the necessary change then submit the amendment [Figure 5.11].



COI - Conflict of Interest COI Disclosure ID: 15-03-067 Investigator, Principal

COI Disclosure Title: Save | Spell Check | Help | Close

Previous **Next**

Amendment

Personnel Information

COI Checklist

Attachments

Certification

Amendment

Describe the changes made in amendment?

Figure 5.11

5.12 Event History

The Event History section of the disclosure [Figure 5.12] enables the user to view all transactions and submissions regarding the disclosure. Any of the blue links under the “Status” column generate a pop-up window like that of the **Print View** window [Figure 5.10], allowing the user to see a list view of the form. Approval Letters can be found in the “Letters” column.

Personnel Information	Event History			
COI Checklist	Date	Status	View Attachments	Letters
Attachments	03/10/2015	NEW FORM REVIEWER(S) ASSIGNED		
Certification	03/10/2015	NEW FORM PANEL ASSIGNED		
Return Notes	03/10/2015	NEW FORM SUBMITTED		
Print View	03/10/2015	NEW FORM CREATED		
Event History	Email History			
	Email Date	Email Type	Attachments	
	03/10/2015	COI Comments sent (Cycle 1): 15-03-065, Investigator, Principal		
	03/10/2015	COI Recommended for Approval: 15-03-065, Investigator, Principal		
	03/10/2015	COI Assigned as Presenter and Primary Reviewer: 15-03-065, Investigator, Principal		
	03/10/2015	COI Disclosure Assigned to Panel: 15-03-065, Investigator, Principal		

Figure 5.12



6 APPROVED DISCLOSURES

Whether you have an annual renewal or want to update an approved disclosure, follow the steps below.

6.1 Start an Amendment

In order to start an Amendment, go to the PI home dashboard and click on a COI Disclosure ID of an Approved Disclosure. Clicking on the ID number will generate a pop-up window providing the option to **Start Amendment** [Figure 6.1]. Upon pressing **OK**, the user is taken to the disclosure [Figure 6.2]. Fill out the required data fields on the Amendment form and submit the COI Disclosure by clicking on the **Submit Form** tab in the blue menu bar. Clicking the tab will result in a pop-up window asking the user if they would like to submit the form. Select the appropriate action button to complete this portion of the disclosure.

NOTE: If an amendment is in progress, that option will not be available.

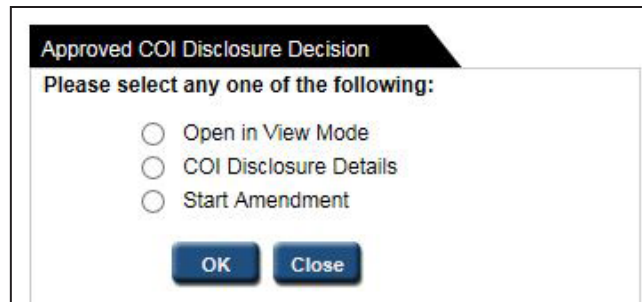


Figure 6.1

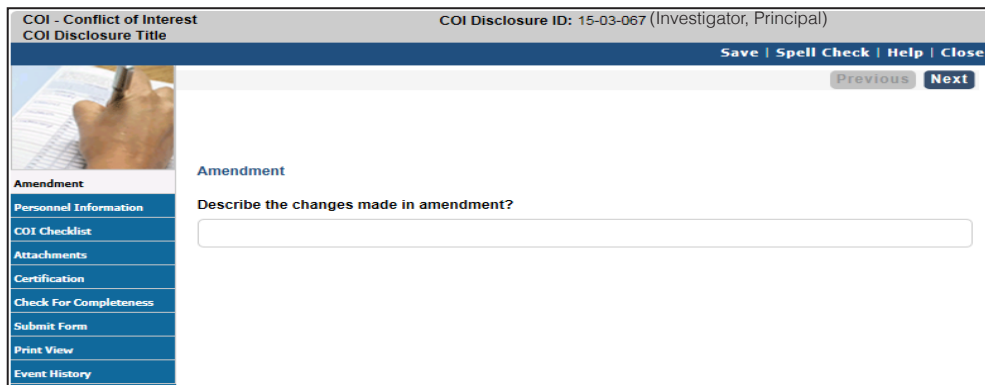


Figure 6.2

7 EDIT/CLONE/DELETE

7.1 Who can Edit a Disclosure

The PI has the ability to edit or view disclosures within the Disclosures (In Preparation/ Submitted) grid on the home dashboard, highlighted in the image below. Clicking on any of the COI Disclosure ID numbers results in a pop-up, as seen below, prompting the user to either Edit or View the selected disclosure.

The only other member that is allowed to edit a disclosure within the Investigator role is the administrative contact.

The screenshot shows the eCOI Investigator Home dashboard. At the top, there are navigation links for 'Create COI', 'Clone COI', and 'Delete COI'. Below this is a 'COI' section with a dropdown menu for 'COI Disclosures (In Preparation / Submitted)'. The main grid is divided into three sections: 'NEW', 'AMENDMENT', and 'CONTINUING REVIEW'. The 'NEW' section contains a table with columns for 'COI Disclosure ID', 'Principal Investigator', 'COI Disclosure Event', 'Status/Comments', 'Panel', and 'Meeting Date'. A row with ID '15-03-068' is highlighted, and a pop-up window is open over it. The pop-up asks 'Do you want to open COI Disclosure 15-03-068 (Investigator) for Editing?' and has 'Edit' and 'View' buttons. The 'AMENDMENT' section contains a table with columns for 'COI Disclosure ID', 'Principal Investigator', 'Approval Date', 'Last Approval Date', 'Expiration Date', 'Review Decision', and 'Form Type'. A row with ID '15-03-067' is visible. The 'CONTINUING REVIEW' section is currently empty. Below the grid is a section for 'Approved COI Disclosures' and a section for 'Non Active COI Disclosures' which states 'Currently there are no Non Active COI Disclosures.'

Figure 7.1





eCOI » Investigator » [Home](#) » Clone COI Disclosure

[Clone COI Disclosure](#)

COI						
COI Disclosure ID	Principal Investigator	COI Disclosure Event	Form Type	Panel	Meeting Date	
<input checked="" type="radio"/> 15-03-063	Investigator, Principal	SUBMITTED	NEW			
<input type="radio"/> 15-03-062	Investigator, Principal	NEW	NEW			

Figure 7.2

- 2 The **Clone COI Disclosures** action button is used to duplicate a disclosure. Clicking on the action button will direct the user to another page as seen in Figure 7.2. Check the circle next to the COI Disclosure ID number you wish to clone followed by clicking the **Clone COI Disclosures** button. A duplicate disclosure will appear with a newly assigned COI Disclosure ID number [Figure 7.3].

COI Disclosure 15-03-064 is created by cloning the COI Disclosure 15-03-063

eCOI » Investigator » [Home](#)

[Create COI](#) [Clone COI](#) [Delete COI](#)

COI						
COI Disclosures (In Preparation / Submitted)						
NEW						
COI Disclosure ID	Principal Investigator	COI Disclosure Event	Status/Comments	Panel	Meeting Date	
15-03-064	Investigator, Principal	Yet to Submit to COI	NEW			
15-03-063	Investigator, Principal	SUBMITTED TO COI	SUBMITTED			

Figure 7.3

- 3 Clicking on the **Delete COI Disclosure** button takes the user to a page where a list of In Preparation disclosures are displayed as shown in Figure 7.4. Check the box to the left of the COI Disclosure ID number you want to delete. Complete this action by clicking on the **Delete COI Disclosure** action button.

eCOI » Investigator » [Home](#) » Delete COI Disclosure

[Delete COI Disclosure](#)

COI						
COI Disclosure ID	Principal Investigator	COI Disclosure Event	Form Type	Panel	Meeting Date	
<input checked="" type="checkbox"/> 15-03-064	Investigator, Principal	NEW	NEW			
<input type="checkbox"/> 15-03-062	Investigator, Principal	NEW	NEW			

Figure 7.4

8 COMMENTS/RESPONSES



eCOI » Investigator » Home

Create COI Clone COI Delete COI

COI

COI Disclosures (In Preparation / Submitted)

NEW

COI Disclosure ID	Principal Investigator	COI Disclosure Event	Status/Comments	Panel	Meeting Date
15-03-068	Investigator, Principal	Resubmit the COI Disclosure	RETURNED		
15-03-063	Investigator, Principal	Comments Received (Cycle 1)	IN-PROGRESS	COI	
15-03-065	Investigator, Principal	Responses Sent (Cycle 2)	IN-PROGRESS	Expedited COI	

Figure 8.1

8.1 Responding to Comments

Reviewers have the ability to comment on disclosures which are then sent to the Investigator for a response or submission. Follow the steps below to send a response to the comments received.

1. Click on the **Comments Received (Cycle 1)** link under the COI Disclosure Event column on the home dashboard to be directed to the Comments page [Figure 8.2] On this page, the Investigator can view the comments sent and if his/her response is required.

NOTE: The checked circle next to Response Necessary for Approval [Figure 8.2] lets the Investigator know a response is needed. If the circle checked is next to Suggestion Not Necessary for Approval, this notifies the Investigator that a response is not needed.

2. Write your response in the text box and save your work.

3. Click on the Submit to COI action button to send off your response. The disclosure event link on the home dashboard will now read “Responses Sent (Cycle 2)”.



The screenshot shows a web interface for managing comments on a protocol. At the top, there is a breadcrumb trail: "eProtocol » Investigator » Home » Comments". Below this, the "COI Disclosure ID" is listed as "15-03-063" with "(Investigator, Principal)" in parentheses. A "Cycle:" indicator shows the number "1" inside a blue square. A row of four buttons is displayed: "Get COI Disclosure", "Conflict Mgmt Plan", "Show All Comments", and "Submit to COI". The main section is titled "Comments" and contains a form for a specific comment. The "Section" is "COI Checklist" and the "Comment" is "1". The text of the comment is "Looks fine". There are two radio button options: "Response Necessary for Approval" (which is unselected) and "Suggestion Not Necessary for Approval" (which is selected). Below these options is a "Response" text area and two buttons: "Save" and "Clear".

Figure 8.2

Comments Cycle Explanation

Comments Received (Cycle 1) means at least one Reviewer assigned for review sent comments on the protocol. The Manager is responsible for taking the comments and sending them to the Principal Investigator which is also referred to as **Comments Sent (Cycle 1)**.

Responses Received (Cycle 1) is when the Investigator has responded to the comments written by the Reviewer(s) and/or Panel Manager. The Investigator must then send his/her responses to the comments to the Reviewer(s) which is called **Responses Sent (Cycle 1)**.

Completing those four steps is considered a Cycle. Should the four steps be repeated, the comments will then be in their second cycle and so on.

Responding to Conflict Management Plan (CMP)

The process in responding to a CMP is the similar to responding to comments received. However, once on the comments page, different actions must be taken. Follow the steps below to respond to the CMP.

1. Click on the **Comments Received (Cycle 1)** link under the COI Disclosure Event column on the home dashboard to be directed to the Comments page [Figure 8.2]
2. Click on the blue **Conflict Mgmt Plan** action button on the comments page to open the CMP pop-up window as seen in Figure 8.3. Here, the Investigator can view and print the CMP and send his/her response. If the CMP is lengthy, the note will say “View Attachments”. The CMP has been created as an attachment and can be accessed by clicking the “Attachments” section.
3. Check the circle next to the appropriate response. Checking “Yes” will send the response off to the COI. Checking “No” will stop the current CMP and require another round of collaboration and a new CMP.
4. You may add a response to your decision in the provided space below followed by clicking the **Save** button and closing the pop-up window.
5. Upon returning to the comments page, submit your response by clicking on the **Submit to COI** action button.

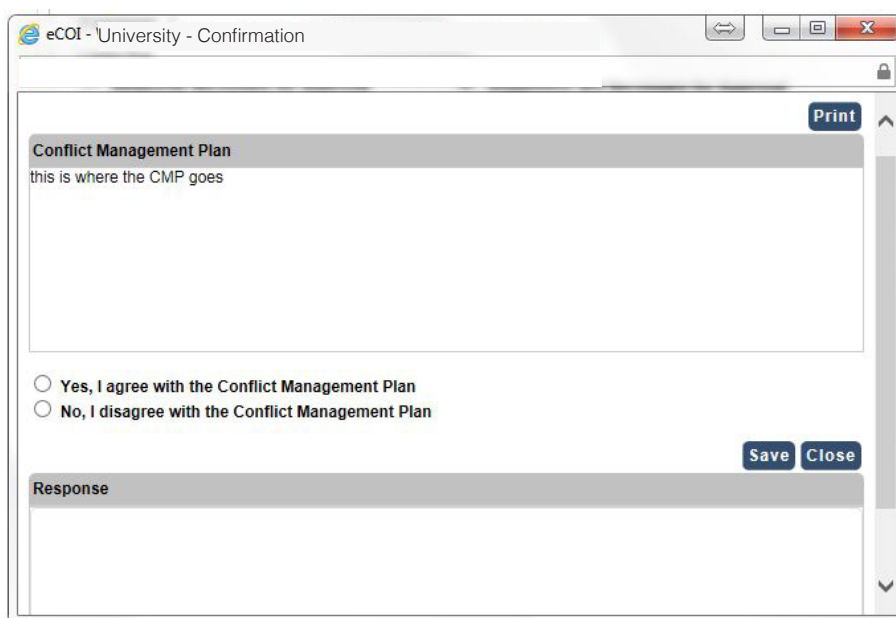


Figure 8.3



Chapter III

Committee Manager Role





1 OVERVIEW

The Committee Manager chapter of the manual is for any user whose role in eCOI is a Committee Manager. In this chapter, users will be shown examples of dashboards, steps in managing disclosures and descriptions of job functionality, duties, and role requirements.

1.1 Things to Remember

Before getting started on the Committee Manager Role chapter, please review the information from the Functionality & Dashboard Overview chapter at the beginning of the manual.

1. Choose a supported browser

Using an unsupported browser will cause the software to not work properly; limiting the users full functionality. The browsers compatible with eProtocol are: Firefox 12 and above and Safari 7.

2. Make sure the Pop-Up Blocker is turned OFF

The steps in this chapter cannot be completed if the pop-up blocker is still active. See the Functionality & Dashboard Overview chapter of this manual for more information and instructions.

3. Avoid using the Back button

Using the Back button will cause errors in the system and logout the user.

4. Resizing the screens

There are numerous pop-up windows used in the software. Don't forget to resize the screens to better suit your view.

NOTE: For the purpose of this manual, COI is used as an example. Based on your research discipline, some options may vary.



2 MANAGING DISCLOSURES

2.1 Assigning a Disclosure to a Panel

Under the eCOI drop-down, select Committee Manager to access the Committee Manager home dashboard. Once on the dashboard, you may begin assigning disclosures by following the steps below [Figure 2.1].

1. Check the box next to the COI Disclosure ID number you wish to assign a panel to.
2. After selecting the disclosure, choose the panel you want the disclosure assigned to by selecting from the panel drop-down menu.
3. Once both the disclosure and panel have been selected, click the blue **Assign Panel** action button to complete the process.

NOTE: When a disclosure has been assigned to a panel, a blue message will appear in the content area, notifying the user the disclosure has been assigned.

eCOI » Committee Manager » Home

Assign Panel **Return COI Disclosure**

COI

Transactional Events

NEW

COI Disclosure ID	Principal Investigator	COI Disclosure Event	Status/Comments	Panel
<input checked="" type="checkbox"/> 15-03-063	Investigator, Principal	Receipt of COI Disclosure	SUBMITTED	Please Select COI Expedited COI

AMENDMENT

Figure 2.1



2.2 Assigned Disclosures

A Committee Manager can access the list of assigned disclosures by clicking the **Assigned COIs** tab under the eCOI drop-down. The user will be directed to a page as shown in Figure 2.2.

	COI Disclosure ID	Principal Investigator	Form Type	Assigned Date	Status
<input type="radio"/>	15-03-065	Investigator, Principal	NEW	03/10/2015	IN-PROGRESS
<input type="radio"/>	15-03-063	Investigator, Principal	NEW	03/10/2015	IN-PROGRESS
<input type="radio"/>	15-03-062	Investigator, Principal	NEW	03/10/2015	IN-PROGRESS
<input type="radio"/>	15-03-066	Investigator, Principal	NEW	03/10/2015	IN-PROGRESS

Figure 2.2

2.3 Returning a Disclosure with Return Notes

The steps in returning a disclosure to the Principal Investigator are similar to that of assigning a disclosure, however the Committee Manager must write a note in the disclosure giving reason for the return. Follow the steps below to return a disclosure back to the Principal Investigator.

1. On the home dashboard, open the disclosure you wish to return by clicking on the COI Disclosure ID number. A pop-up will appear asking if you want to edit or view the disclosure. Click the **Edit** button to proceed.
2. The disclosure will open in a new window. In that window, click on the **Return Notes** menu option to generate another pop-up window [Figure 2.3].



3. Enter the reason for return in the Return Notes pop-up, followed by clicking **Save**.
4. Save and close the disclosure and return to the Committee Manager dashboard.
5. Check the box next to the disclosure you are returning followed by clicking on the **Return COI Disclosure** action button to complete the process.

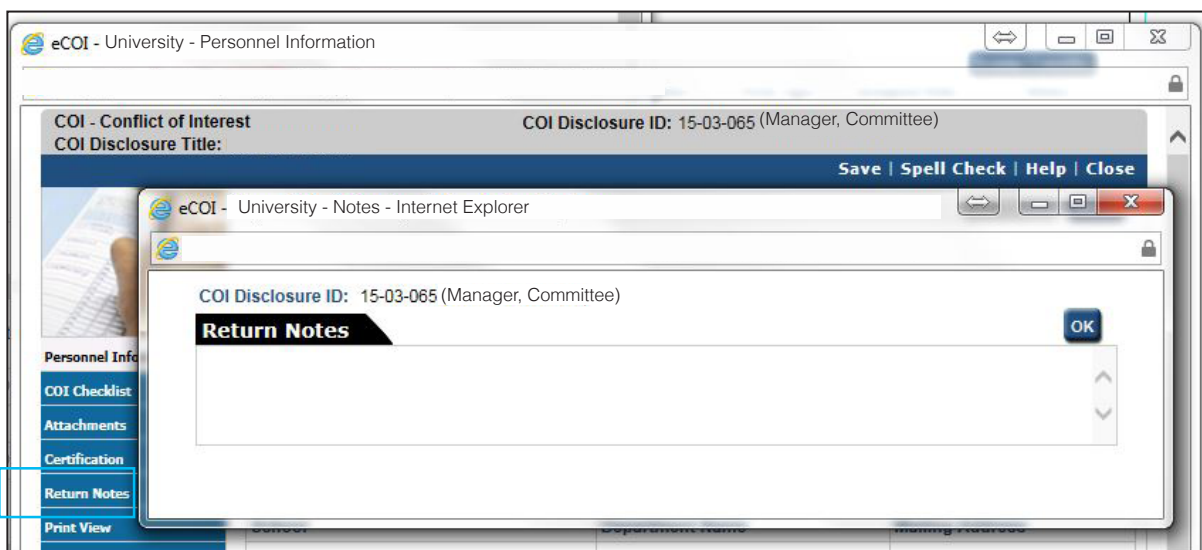


Figure 2.3

2.4 Returned Disclosures

A Committee Manager can access the list of returned disclosures by clicking the **Returned Disclosures** tab under the top menu bar drop-down. The user will then be directed to a page as seen in Figure 2.4.



Delete Disclosure from List

To delete the returned disclosure from the returned disclosure list, the Committee Manager must select the box next to the COI Disclosure ID number they wish to delete, followed by clicking on the **Delete Disclosure** button. A pop-up window will appear asking if the user wants to delete the disclosure. Click the **Yes** button and the returned disclosure will be deleted from the list.

eCOI » Committee Manager » [Home](#) » Returned COI Disclosures

COI		Delete COI Disclosure		
<input type="checkbox"/>	COI Disclosure ID	Principal Investigator	Submission Date	Returned Date
<input type="checkbox"/>	15-03-068	Investigator, Principal	03/25/2015	03/25/2015

Figure 2.4





Chapter IV

Manager Role



1 OVERVIEW

The Manager Role chapter examines the functions, job duties and requirements of an eProtocol user logged in as a Manager. This portion of the manual is dedicated to users logging in as a Manager.

1.1 Things to Remember

Before getting started on the Manager Role chapter, please review the following the following information from the Functionality & Dashboard Overview chapter.

1. Choose a supported browser

Using an unsupported browser will cause the software to not work properly; limiting the users full functionality. The browsers compatible with eProtocol are: Firefox 12 and above and Safari 7.

2. Make sure the Pop-Up Blocker is turned OFF

The steps in the Manager chapter cannot be completed if the pop-up blocker is still active. See the Functionality & Dashboard Overview chapter for more information and instructions.

3. Avoid using the Back button

Using the Back button will log the user out.

4. Resizing the screens

There are numerous pop-up windows used in the software. Don't forget you can resize the screens to better suit your view.



2 DASHBOARD ELEMENTS

2.1 Disclosure Event Types

The **COI Disclosure Event** column of the grid displays the status of the disclosure. The Disclosure Events are further explained on page 76.



Figure 2.1



- 1 Receipt of Disclosure** - The Manager must assign reviewers to a disclosure.
- 2 Reviewer(s) Assigned** - The disclosure has been assigned to Reviewers for revision.
- 3 Panel Manager Review** - The disclosure is assigned to the Panel Manager for revision.
- 4 Comments Received (Cycle X)** - At least one Primary Reviewer assigned for review, sent comments on the disclosure.
- 5 Comments Sent (Cycle X)** - Comments on the disclosure are sent to the Investigator.
- 6 Responses Received (Cycle X)** - The Investigator sent responses to the comments from the Reviewers and Panel Manager - informing them of how he/she acted on the comments made on the disclosure.
- 7 Responses Sent (Cycle X)** - Responses of the Investigator to the comments are sent to Reviewers.
- 8 No Conflict** - The disclosure has been approved.

Conflict Management Plan (CMP)

Though not shown on the disclosure event types, the Conflict Management Plan is an important feature found on some of the links within the COI Disclosure Event column. It is the responsibility of the Manager to create a plan for any conflict that may arise in a disclosure. Several steps must be taken in order for the CMP to be passed. The first step done by the Panel Manager is creating the CMP.

Follow the steps below to create a CMP

1. On the Manager home dashboard, click on the **Receipt of COI Disclosure** link under the COI Disclosure Event column.



2. Upon clicking the link, the user will then be directed to a page listing panel members as seen in Figure 2.4 on page 79.
3. On this page, click the blue Conflict Mgmt Plan action button to open the CMP pop-up window as shown in Figure 2.2.

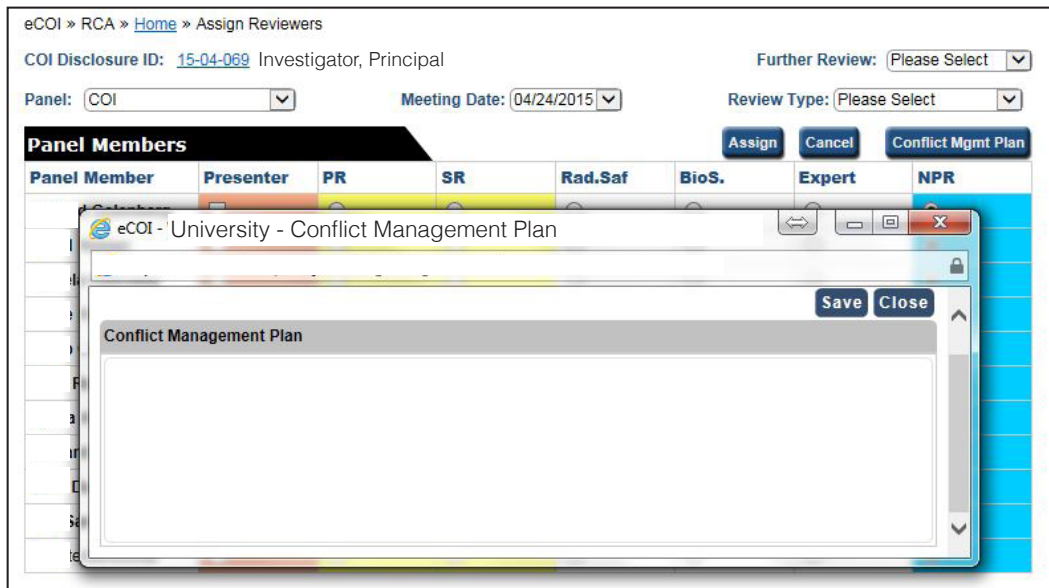


Figure 2.2

4. Enter in notes for the CMP in box shown above, followed by clicking on the **Save** button.

NOTE: The disclosure is then sent off to other members for approval. Once the disclosure has been approved or denied by other members, it will appear back to the manager in a link titled Responses Received. By clicking on the disclosure link, the manager can view the responses made to the CMP. It is the responsibility of the manager to confirm or deny the CMP. Follow the next steps to add the CMP consensus to the disclosure.

1. Click on the **Responses Received** link in the COI Disclosure event column on the dashboard to be directed to the comments page.
2. Once on the comments page, click the blue **Meeting Minutes** action button which will then direct the user to the Meeting Minutes page as seen in Figure 2.3.

The screenshot shows a web interface for managing COI disclosures. At the top, there is a 'COI' header, a 'Panel: COI' dropdown, and a 'Meeting Date: 03/27/2015' dropdown. There are 'Submit' and 'Undo' buttons on the right. Below this is a table with columns: 'All Range', 'COI Disclosure ID', 'Principal Investigator', 'Form Type', 'Action', 'Expiration Date', 'Comments', and 'Notes'. The table contains four rows of data. The third row is highlighted in light blue, and its 'Action' dropdown menu is open, showing options: 'Please Select', 'NO CONFLICT', and 'NEGOTIATION'. The 'Comments' and 'Notes' columns for this row contain 'Yes' and 'Yes' respectively.

All Range	COI Disclosure ID	Principal Investigator	Form Type	Action	Expiration Date	Comments	Notes
<input type="checkbox"/>	15-03-063	Investigator, Principal	NEW	Please Select		Yes	No
<input type="checkbox"/>	15-03-066	Investigator, Principal	NEW	Please Select		Yes	No
<input checked="" type="checkbox"/>	15-03-067	Investigator, Principal	NEW	NO CONFLICT	03/09/2016	Yes	Yes
<input type="checkbox"/>	15-03-062	Investigator, Principal	NEW	Please Select		Yes	No

Figure 2.3

3. Check the box next to the appropriate COI Disclosure ID followed by selecting one of the two options in the drop-down under the Action column.
4. Once the above steps have been completed, click the **Submit** action button to confirm the CMP has been approved or denied.





2.2 Assigning Reviewers to a Disclosure

As the manager, you are responsible to assign a reviewer to a disclosure. Follow the instructions below to learn how to assign a reviewer.

eCOI » RCA » [Home](#) » Assign Reviewers

COI Disclosure ID: [15-03-063](#) (Investigator, Principal) Further Review:

Panel: Meeting Date: Review Type:

Panel Members

Panel Member	Presenter	PR	SR	Rad.Saf	BioS.	Expert	NPR
Member, Panel	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Member, Panel	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Member, Panel	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Member, Panel	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Member, Panel	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Member, Panel	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Member, Panel	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

Figure 2.4

How to Select and Assign

1. Click on the **Receipt of Disclosure** link under the COI Disclosure Events column on the dashboard. Clicking on the link directs the user to the page shown in Figure 2.4.
2. To assign a presenter, check the box next to the designated user’s name in the Presenter column. Only one presenter can be assigned to a disclosure.
3. You may add other reviewers by checking the circles in the same row as their name. Each column represents the users review status. You may also determine the Primary Reviewer (PR) and Secondary Reviewer (SR) by selecting the correct circle of the user you wish to assign.
4. Click on the blue **Assign** action button to complete this process.

Action Buttons and Functionality

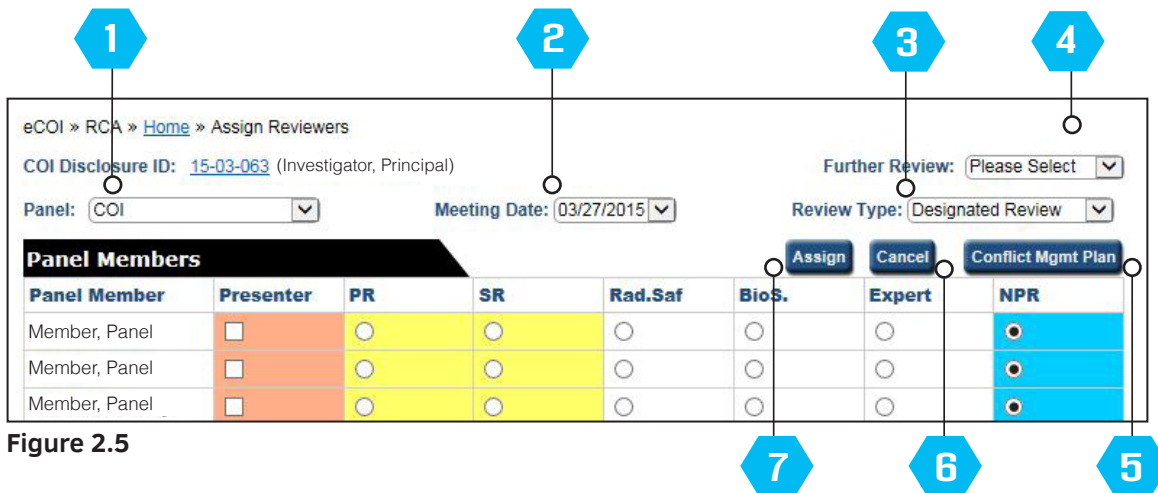


Figure 2.5

- 1 The **Panel** drop-down allows the Manager to filter members by the panel they are on.
- 2 The **Meeting Date** drop-down allows the Manager to filter disclosures by their assigned meeting date.
- 3 The **Review Types** drop-down determines the review type by Panel Manager Review, Designated Review and Full Review.
- 4 The **Further Review** drop-down allows the user to choose Yes or No on whether they would like to have a further review.
- 5 Clicking on the **Conflict Mgmt Plan** action button will result in a pop-up window, allowing the Manager to create a Conflict Management Plan.
- 6 Clicking on the **Cancel** action button will back out to the home dashboard without saving any selections.
- 7 Clicking the **Assign** action button will assign the selected reviewers to a disclosure.



Comments Page Functionality



Figure 2.6

- 1 **Get COI Disclosure** - The **Get COI Disclosure** button activates a pop-up window allowing the user to Edit or View the disclosure.
- 2 **Reviewers** - The **Reviewers** button allows the Manager to see the reviewers that are assigned to the disclosure.
- 3 **Meeting Minutes** - The **Meeting Minutes** button allows the Manager to view and sequence comments, notes, changing the action status and review the expiration date of the disclosure. For further information on the functionality of Meeting Minutes, please see page 98.
- 4 **Conflict Mgmt Plan**- Clicking on **Conflict Mgmt Plan** button activates a pop-up window where the Conflict Management Plan will be written and reviewed.
- 5 **Write Comment(s)** - The **Write Comment(s)** button allows the user to navigate to a page like the one shown in Figure 2.7.

How to Write and Save a Comment:

Write your comment in the text box followed by clicking the **Save** button. Once saved, the option to Edit is present.

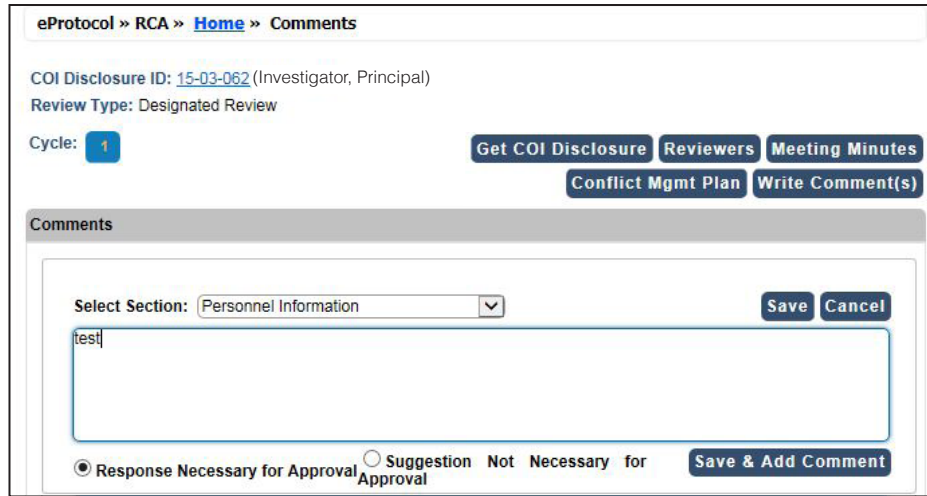


Figure 2.7

- 6 Edit All Comments** - The **Edit All Comments** button enables editing on all comments in the disclosure.
- 7 Show All Comments** - The **Show All Comments** button allows the user to view a list of all the comments and notes within the disclosure.
- 8 Submit to PI** - The **Submit to PI** button enables submission to the PI after the comments section has been filled. To do so, follow the steps below.
 1. Click the **Submit to PI** action button to generate a pop-up as seen in Figure 2.8.
 2. Select the comments you want to submit, from the “Available Comments” section.
 3. Click on the appropriate arrow to transfer the comments to the “Selected Comments” section. Click on the **Submit to PI** button to complete the process.

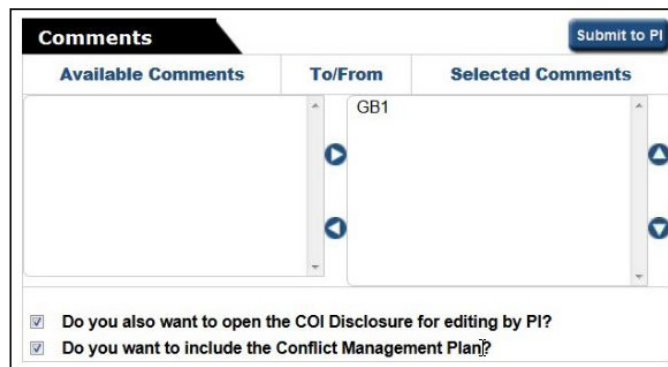


Figure 2.8





Comments Cycle Explanation

Comments Received (Cycle 1) means at least one Primary Reviewer assigned for review sent comments on the disclosure. The Manager is responsible for taking the comments and sending them to the Principal Investigator which is also referred to as **Comments Sent (Cycle 1)**.

Responses Received (Cycle 1) appears when the Principal Investigator has responded to the comments written by the Reviewer(s) and/or Panel Manager. The Principal Investigator must then send his/her responses to the comments to the Reviewer(s) which is called **Responses Sent (Cycle 1)**.

Completing those four steps is considered a Cycle. Should the four steps be repeated, the comments will then be in their second cycle and so on. Refer to Figure 2.9 for a visual representation of the comments cycle.

COI Disclosure ID: [15-03-062](#) (Investigator, Principal) OK

Comment Title	Section Name	Comment/Response	Date	Reviewer	Response Necessary	Panel Name	PI Comment Title
Cycle: 3							
WL2	Personnel Information	need to return to PI	10/13/2014	Reviewer, Primary	Yes	Test Panel	1
		PI did not respond to this comment.					
Cycle: 2							
WL1	Personnel Information	PI plsnote the changes in the personnel seccion	09/15/2014	Reviewer, Primary	Yes	Test Panel	1
		modification made in protocol	09/15/2014				
Cycle: 1							
BG1	Non-Surgical Procedure Details	added anesthetic agent	09/15/2014	Reviewer, Primary (Presenter / Primary)	No	Test Panel	1
		modified protocol	09/15/2014				
BG2	Procedure Relationships	this needs detail	09/15/2014	Reviewer, Primary (Presenter / Primary)	Yes	Test Panel	2
		modified protocol 2	09/15/2014				

Figure 2.9

2.3 Active Disclosures

The Manager can access the list of active disclosures by clicking on the **Active COIs** tab under the eCOI drop-down. The Manager will then be directed to the page shown in Figure 2.10.



Figure 2.10

Close Disclosure

To close a disclosure, check the circle under the "Decision" column on the grid [Figure 2.10]. A pop-up will appear like the one in Figure 2.11. Fill out a note giving reason for closing the disclosure and complete the action by clicking the **Confirm** action button.

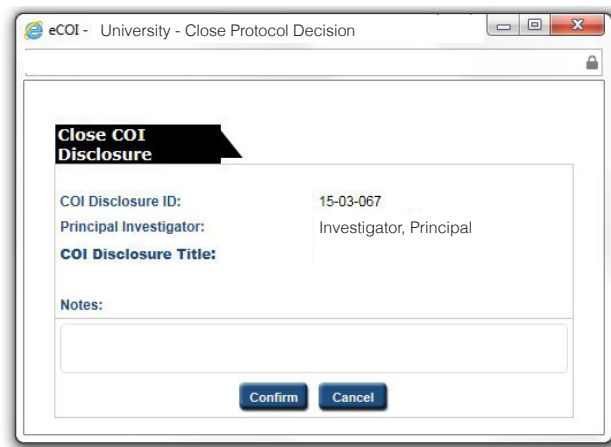


Figure 2.11



2.4 Non Active Disclosures

A user can access the **Non Active Disclosures** page by clicking on the appropriate tab in the top menu bar drop-down. This page displays a list of all the non-active disclosures. The Manager can filter through the disclosures by using the status drop-down bar.

Checking the circle of a non active disclosure under the Reactivate Disclosure column, will generate a pop-up window where the Manager can reactivate the disclosure.

2.5 Submitted Disclosures

To access the Submitted COIs page, go to the top menu bar drop-down and click on the **Submitted COIs** tab which will direct the user to a page like the one shown in Figure 2.12. The functionality within the Submitted Disclosures page can be found on pages 85 and 86.

	COI Disclosure ID	Investigator	CMNTS/RSPNS	Submitted Date	Meeting Date	COI Disclosure Status	Form Type
<input type="checkbox"/>	15-03-065	Investigator, Principal	Comment	03/10/2015		PANEL REASSIGNED	NEW
<input type="checkbox"/>	15-03-063	Investigator, Principal	Comment	03/09/2015		IN-PROGRESS	NEW
<input type="checkbox"/>	15-03-062	Investigator, Principal	Comment	03/10/2015		IN-PROGRESS	NEW

Figure 2.12

Reassign Panel

To reassign a panel follow the directions below:

1. Check the box next to the disclosure you would like to reassign reviewers [Figure 2.12].
2. Click on the blue **Reassign Panel** action button which will direct you to the page like the one shown in Figure 2.13.
3. Select a panel from the Panel drop-down followed by clicking the blue **Reassign Panel** action button.

eCOI » RCA » Home » Assign Reviewers

COI Disclosure ID: [15-03-065](#) (Investigator, Principal) Further Review: Please Select

Panel: Expedited COI Meeting Date: Review Type: Please Select

Panel Members

Panel Member	Presenter	PR	SR	Rad.Saf	BioS.	Expert	NPR
Member, Panel	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Member, Panel	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Member, Panel	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Member, Panel	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

Figure 2.13

Reassign Reviewers

To reassign reviewers, please follow the directions below:

1. Check the box next to the disclosure you would like to reassign reviewers [Figure 2.12].
2. Click on the blue **Reassign Reviewers** action button which will direct you to the page like the one shown in Figure 2.14.
3. Select the reviewers you would like to assign to the disclosure to followed by clicking on the **Assign** action button to complete this process.



eCOI » RCA » [Home](#) » Assign Reviewers

COI Disclosure ID: [15-03-063](#) (Investigator, Principal) Further Review:

Panel: Meeting Date: Review Type:

Panel Members

Panel Member	Presenter	PR	SR	Rad.Saf	BioS.	Expert	NPR
Member, Panel	<input checked="" type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Member, Panel	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Member, Panel	<input type="checkbox"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Member, Panel	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

Figure 2.14

2.6 Returned Disclosures

To access the Returned COIs page, go to the top menu bar drop-down and click on the **Returned COIs** tab. Clicking on this tab will direct the user to a page listing returned disclosures. If there are any disclosures to eliminate, check the box of the disclosure and click on the **Delete** action button complete the process [Figure 2.15].

eCOI » RCA » [Home](#) » Returned COI Disclosures

COI

<input type="checkbox"/>	COI Disclosure ID	Principal Investigator	Submission Date	Returned Date
<input type="checkbox"/>	15-03-068	Investigator, Principal	03/25/2015	03/25/2015

Figure 2.15

Return a Disclosure

The steps in returning a disclosure are similar to that of assigning a disclosure, however the Manager must write a Return Note in the disclosure giving reason for the return. Follow the steps below to return a disclosure back to the Principal Investigator.

1. Open the disclosure you wish to return by clicking on the COI Disclosure ID number. A pop-up will appear asking if you want to edit or view the disclosure. Click the Edit button to proceed.
2. The disclosure will open in a new window. Click on the **Return Notes** tab to generate another pop-up window [Figure 2.16].
3. Enter the reason for return in the Return Notes pop-up, followed by clicking the **Save** action button and closing the disclosure.
4. Proceed to the **Submitted Disclosures** page.
5. Check the box next to the disclosure you are returning followed by clicking on the **Return Disclosure** action button to complete the process.

NOTE: You cannot return a disclosure if the review is still in progress.



Figure 2.16

Once the disclosure has been returned, a blue message appears in the content area notifying the user of the return [Figure 2.17].



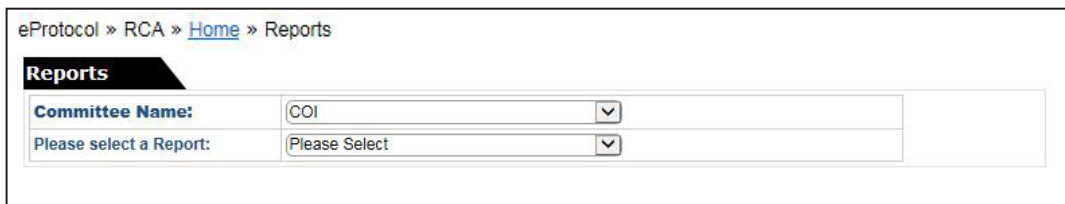
Figure 2.17



3 MEETINGS & REPORTS

3.1 Reports

To access the Reports page, go to the top menu drop-down and click on the **Reports** tab, directing the user to a page like the one shown below in Figure 3.18. Select the necessary drop-down tabs on the Reports page to continue creating a report.



eProtocol » RCA » [Home](#) » Reports

Reports

Committee Name:	COI	▼
Please select a Report:	Please Select	▼

Figure 3.1

Setup Criteria

The criteria in setting up a report will differ based on the type of report. Some reports will generate more data fields and some allow the user to make changes and add comments. The most common report looks like the one in Figure 3.2 on page 90 where the user will only have to fill out the Panel Name and dates.

Report Display and Types

Once the report is complete, the Manager can choose how the report will be displayed by selecting any of the format options [Figure 3.2].



eCOI » RCA » [Home](#) » Reports

Reports

Committee Name: COI

Please select a Report: Active COI Disclosures

Active COI Disclosures Preview Report

Panel Name: * Select Panel Name

From(mm/dd/yyyy): *

To(mm/dd/yyyy): *

Select a format to export the report

HTML PDF Excel

Figure 3.2

3.2 Generic Report

To access the Generic Report page, go to the top menu bar drop-down and click on the **Generic Report** tab which will navigate the user to the page seen in Figure 3.3.

eCOI » RCA » [Home](#) » Generic Report

Generic Report Please select format: CSV Generate Report

Available Search Criteria: --- Please Select ---

Search Criteria: **Public** Save Cancel

Input Criteria		Output Criteria	
General			
<input type="checkbox"/>	Committee *	--- Please Select ---	<input type="checkbox"/>
<input type="checkbox"/>	Panel	--- Please Select ---	<input type="checkbox"/>
<input type="checkbox"/>	COI Disclosure Status	--- Please Select ---	<input type="checkbox"/>
<input type="checkbox"/>	Form Status	--- Please Select ---	<input type="checkbox"/>
<input type="checkbox"/>	Review Type	--- Please Select ---	<input type="checkbox"/>
<input type="checkbox"/>	Review Cycle Type	--- Please Select ---	<input type="checkbox"/>
<input type="checkbox"/>	COI Disclosure ID	--- Please Select ---	<input checked="" type="checkbox"/>
<input type="checkbox"/>	Form Names	--- Please Select ---	<input type="checkbox"/>
<input type="checkbox"/>	Approval Date	From Date <input type="text"/> To Date <input type="text"/>	<input type="checkbox"/>
<input type="checkbox"/>	Expiration Date	From Date <input type="text"/> To Date <input type="text"/>	<input type="checkbox"/>
<input type="checkbox"/>	Action Date	From Date <input type="text"/> To Date <input type="text"/>	<input type="checkbox"/>
Form			

Figure 3.3



How to Build and Generate a Report

1. Check any of the boxes under the “Input Criteria” section you would like added to the report. When a box has been checked, it activates the drop-down bar in that row.
2. Select a category from each of the active drop-down bars.
3. Check the boxes under “Output Criteria” to manage what information is displayed on the report. Once all the necessary data fields have been entered and checked, click on the **Generate Report** action button.
4. A pop-up will notify the user the report has been created by asking the user to save or open the report.

NOTE: Some data fields will appear active or inactive depending on what boxes and general information have been selected.

Report Output Formats

Choosing an output format is dependent on how the user would like to view the report. Selecting a CSV or MS Excel file will open the report in a spreadsheet format. The HTML format opens the report in another browser and the PDF format is most commonly used for print [Figure 3.4].

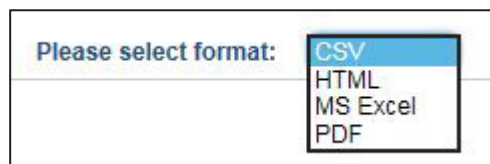


Figure 3.4

3.3 Meeting Agenda

In order to access the Meeting Agenda page, go to the top menu bar drop-down and click on the **Meeting Agenda** tab, navigating the user to the page seen in Figure 3.5. The Manager can filter the agendas displayed by the “Panel” and “Meeting Date” drop-down bars.



Figure 3.5

Delete Agenda

To delete an agenda, select the box next to the agenda you intend to delete. Click on the blue **Delete** action button to terminate the selected agenda.

Accessing Agenda

Upon selecting the active agenda link under the “Agenda ID” column, the user is navigated to a page with details pertaining to the agenda.

Pre-Meeting Set-up



Figure 3.6

1 The **Planned Attendees** tab displays a list of attendees who are expected to join the meeting [Figure 3.6]. The Manager may check the boxes under the “Specify if Attending” column to note panel members that are attending.

A - Clicking the **Save** action button will save any information the user has entered.

B - Clicking on the **RSVP Email** action button will generate a pop-up window with an email addressed to the selected attendees.

C - To add a guest to the meeting agenda, the Manager must click the blue **Add Guest** action button where they will be able to search and add a user by their User ID, First and Last name. Once the user has been found, select the box next to their name and press OK. The user will then be added to the list of attendees.



Panel Member	Specify attending	if	Presenter	PR/SR	NPR	Expert
Member, Panel	<input checked="" type="checkbox"/>	0	0	0	4	0
Member, Panel	<input checked="" type="checkbox"/>	0	0	0	4	0
Member, Panel	<input checked="" type="checkbox"/>	0	0	0	4	0
Member, Panel	<input type="checkbox"/>	0	0	0	4	0

Figure 3.7

2 **Set-up Early Agenda** displays the details of the meeting. It is on this tab that areas such as the location, start and end time are entered and modified.

Item Name	Notes	Documents
<input type="checkbox"/> General Discussion	Time to be used for general discussion	
<input type="checkbox"/> Report of Disclosures for the Quarter	Report of disclosures approved in the last quarter.	

Figure 3.8



A - To attach a document, check the box next to the item you wish to attach under the “Item Name” column followed by clicking the **Attach Document** action button. A small pop-up window will appear with the option to browse and add an agenda item attachment.

NOTE: Only one attachment may be added at a time. Please upload a file with extension .pdf, .doc or .docx.

B - Clicking the **Save** action button will save the recent information entered.

C - Clicking on the **Add Item** action button will create a new drop-down bar [Figure 3.9] in the Item Name column of Figure 3.8. Use the drop-down bar to choose and Item Name and click on the pencil icon to add any necessary notes.



Figure 3.9

D - Tee Add End Item action button has the same functionality as the Add Item button.

E - To add an item sequence, click on the **Create Item Sequence** action button which will result in a pop-up as seen in Figure 3.10. Select items from the “Available Agenda Items” section and transfer them to the “Selected Agenda Item” section using the arrow in the center of the pop-up.

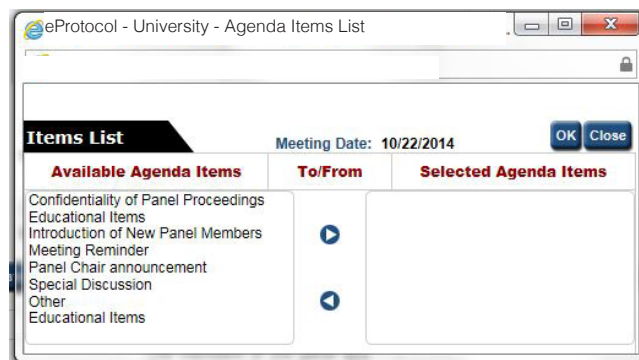


Figure 3.10

F - In order to add a disclosure to the Meeting Agenda, click the **Add COI Disclosure** action button. A window with a list of disclosures will appear allowing you to check the box next to the disclosure you wish to add, followed by clicking the **Add** action button.





G - Clicking on the **Create COI Disclosure Sequence** action button will result in a pop-up shown in Figure 3.11. Follow the same steps used in creating an item sequence to create a disclosure sequence.

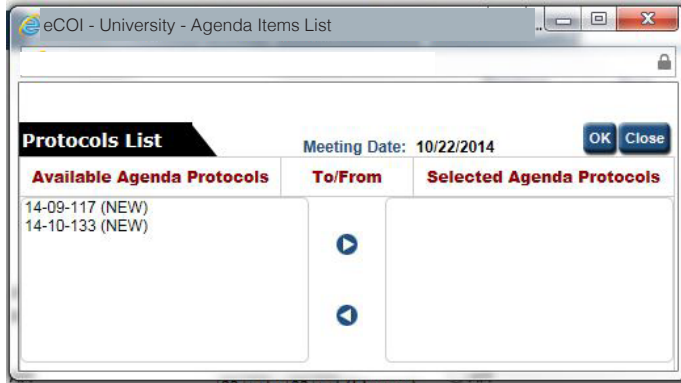


Figure 3.11

H - The **Delete** action button is used to delete an item from the Item Name column. Check the box next to the item you want to delete, followed by clicking the **Delete** action button.

3 **Preview Early Agenda** is an overview of the items, notes and disclosures involved in the meeting [Figure 3.12].



Figure 3.12

4 **Agenda** is a tab similar to the Preview Early Agenda tab in that it allows the user to review the items. Clicking on the blue active links allows the Manager to look at the agenda in different formats.

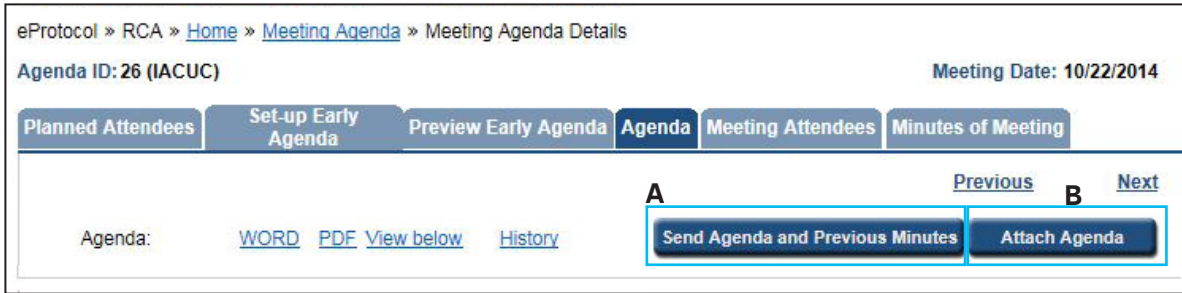


Figure 3.13

A - Clicking the **Send Agenda and Previous Minutes** action button results in a pop-up window that displays an email from the Manager to the meeting attendees.

B - The **Attach Agenda** action button permits the user to upload an attachment to the Meeting Agenda.

NOTE: Please upload a file with extension .pdf, .doc or .docx.

Meeting

5 **Meeting Attendees** is a tab used to specify quorum for the meeting.

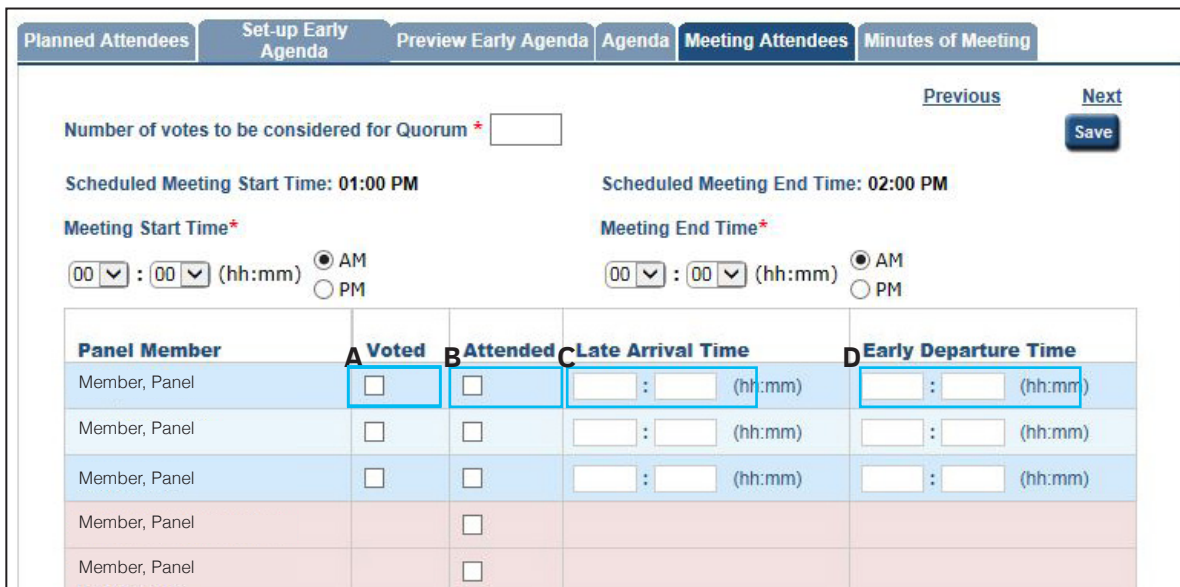


Figure 3.14





A - If a Panel Member voted, check the box in the same row as their name under the **Voted** column.

NOTE: Checking the voted box will auto-fill the Attended box.

B - If the member did not vote but attended the meeting, check the appropriate box in the **Attended** column.

C - If a member showed up after the meeting start time, enter their arrival time in the **Late Arrival Time** column.

D - If a member left the meeting early, enter their departure time under the **Early Departure Time** column next to their name.

Post Meeting

6 **Minutes of Meeting** is a tab that allows the user to view the actions taken in the meeting by clicking any of the blue active links as seen in Figure 3.15.

A - To add an attachment, click on the **Attach Minutes** action button which will generate a pop-up allowing the user to search and add an attachment.

NOTE: Please upload a file with extension .pdf, .doc or .docx.



Figure 3.15

3.4 Meeting Minutes

To access the Meeting Minutes page [Figure 3.16], go to the top menu drop-down and click on the **Meeting Minutes** tab. Once on the page, the Manager can filter the meeting minutes by both the 'Panel' and 'Meeting Date' drop-downs.

Comments

If there are comments attached to a disclosure, the active link **Yes** will be present at the end of the disclosure row and under the comments column as seen highlighted in Figure 3.16. If there are no comments, the link will read **No**.

eCOI » RCA » Home » Meeting Minutes

COI

Panel: COI Meeting Date: 03/27/2015 Submit Undo

All Range	COI Disclosure ID	Principal Investigator	Form Type	Action	Expiration Date	Comments	Notes
<input type="checkbox"/>	15-03-063	Investigator, Principal	NEW	Please Select		Yes	No
<input type="checkbox"/>	15-03-066	Investigator, Principal	NEW	NO CONFLICT		Yes	No

Figure 3.16

Clicking on the active link will result in a pop-up like the one below [Figure 3.17]. Here, the Manager is able to view all of the comments in a grid format. To order the comments, click on the **Sequence Comments** action button. The pop-up has the same overall look and functionality as Figure 3.10 and 3.11 on page 94 and 95 of the manual.

COI Disclosure ID: 15-03-062 Investigator, Principal

Comments Sequence Comments Save Close

Cycle: 1 Reviewer

Comment Title	Substantive	Comment/Response	Date	Reviewer	Response Necessary	Panel Name
DS1	<input type="checkbox"/>	test Comment not submitted to PI.		Reviewer	No	COI
DS2	<input type="checkbox"/>	Looks good Comment not submitted to PI.		Reviewer	No	COI
DS4	<input type="checkbox"/>	ok Comment not submitted to PI.		Reviewer	Yes	COI

Figure 3.17



Notes

If there are meeting notes available, the active link **Yes** will be present at the end of the disclosure row and under Notes column as seen highlighted in Figure 3.16. If there aren't any notes, the link will read **No**. Upon clicking the active link, a pop-up is generated displaying three tabs: Meeting Notes and Voting.



Figure 3.18

A - Meeting Notes is a tab that allows the Manager to view any notes on the meeting [Figure 3.19].

Figure 3.19

B - Voting is a tab that is used to record the vote, motion, and verify quorum [Figure 3.20].

Meeting Notes		Voting		Motion: Tabled		Save	Cancel	
Voting Member		Vote						
		For	Opposed	Abstain	COI	Arrived Late	Out-of-Room	Left Meeting
Member, Voting		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Member, Voting		<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Member, Voting		<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Figure 3.20

Action

The action drop-down has different functionality for submission depending on the action selected [Figure 3.21].

Meeting Date: 03/27/2015 Submit Undo				
Form Type	Action	Expiration Date	Comments	Notes
NEW	Please Select	<input type="text"/>	Yes	No
NEW	<div style="border: 1px solid black; padding: 2px;"> Please Select NO CONFLICT NEGOTIATION </div>	<input type="text"/>	Yes	No
NEW	NO CONFLICT	03/09/2016	Yes	Yes
NEW	Please Select	<input type="text"/>	Yes	No

Figure 3.21

A - The remaining **Meeting Actions** are the result of the meeting and the vote on the disclosure and will change the status as appropriate.

1. **No Conflict** - goes to the Investigator's active disclosures section of their dashboard.
2. **Negotiation** - goes to Investigator's new section of their dashboard.





Chapter V

Reviewer Role





1 OVERVIEW

The Reviewer Role chapter examines the functions, job duties and requirements of an eCOI user logging in as a Reviewer. The following pages show screen shots as well as examples of the Reviewer dashboard and walks the user through the process of reviewing a disclosure.

1.1 Things to Remember

Before getting started on the Reviewer Role chapter, please review information from the Functionality & Dashboard Overview chapter.

1. Choose a supported browser.

Using an unsupported browser may cause the software to not work properly, limiting the users full functionality. The browsers compatible with eProtocol are: Firefox 12 and above and Safari 7.

2. Make sure the Pop-Up Blocker is turned OFF.

The steps in the Reviewer Role chapter cannot be completed if the pop-up blocker is still active. See the Functionality & Dashboard Overview chapter for more information and instructions

3. Avoid using the Back button.

Using the Back button can cause errors in the system and log the user out.

4. Resizing the screens

There are numerous pop-up windows used in the software. Don't forget to resize the screens to better suit your view.

NOTE: For the purpose of this manual, COI is used as an example. Based on your research discipline, some options may vary.



2 REVIEW PROCESS

2.1 Reviewer Role Overview

Your responsibility as a Reviewer is to view the disclosures that have been assigned to you. Every disclosure you have been assigned to as a Reviewer will appear on your home dashboard. To view a disclosure, click on the COI Disclosure ID number listed under the COI Disclosure ID column on the home dashboard. To view reviewers, or guidelines within the disclosure, click on the disclosure event link listed under the Disclosure Event column. If comments or guidelines are being viewed, click on the eCOI drop down in the top menu bar, and choose Reviewer Home to return to the previous page [Figure 2.1].

The screenshot shows the eCOI Reviewer Home dashboard. At the top, there is a navigation bar with 'eCOI' and 'eProtocol' dropdown menus, and a user profile '(Reviewer) University - Reviewer'. Below the navigation bar, there is a breadcrumb trail 'eCOI » Reviewer » Home'. The main content area is divided into two sections: 'COI Member (Action Items)' and 'COI Member (COI Disclosures for Review)'. The 'COI Member (Action Items)' section contains a table with columns: Role, COI Disclosure ID, Principal Investigator, COI Disclosure Event, Status/Comments, Panel, and Meeting Date. There are two rows of data, both with the role 'Presenter' and status 'IN-PROGRESS'. The 'COI Member (COI Disclosures for Review)' section contains a similar table but is currently empty, displaying 'No data available in table'.

Role	COI Disclosure ID	Principal Investigator	COI Disclosure Event	Status/Comments	Panel	Meeting Date
Presenter	15-03-062	Investigator, Principal	Assigned as Reviewer	IN-PROGRESS	COI	
Presenter	15-03-066	Investigator, Principal	Assigned as Reviewer	IN-PROGRESS	COI	

Role	COI Disclosure ID	Principal Investigator	COI Disclosure Event	Status/Comments	Panel	Meeting Date
No data available in table						

Figure 2.1



2.2 Disclosure Event Types

The Disclosure Event column of the grid displays the status of the disclosure [Figure 2.2].

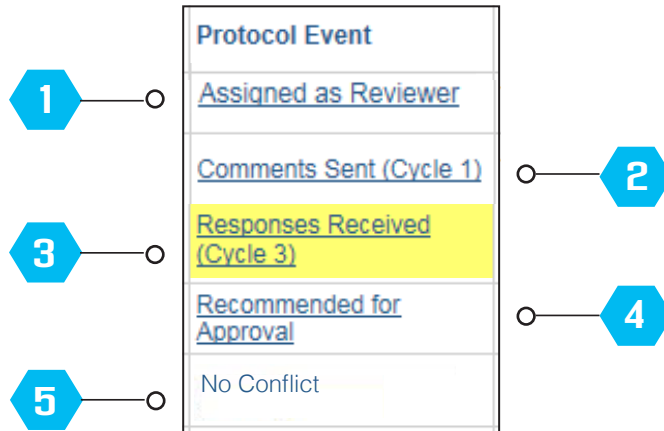


Figure 2.2

- 1 Assigned as Reviewer** - You are assigned as the reviewer for that specific disclosure.
- 2 Comments Sent (Cycle 1)** - Comments on the disclosure have been sent to the PI.
- 3 Responses Received (Cycle 1)** - The PI sent responses to the comments from the Reviewers and Panel Manager.
- 4 Recommended for Approval** - The disclosure has been recommended for approval.
- 5 No Conflict** - The disclosure has been approved.



2.3 Comments Page

The Comments Page is an important page for any reviewer and is where the majority of user interactions take place. The following pages will examine the functionality of the comments page as well as explain and show what each button is responsible for.

To access the comments page of a disclosure, click on the active link located under the Disclosure Event column and in the same row as the specified COI Disclosure ID number [Figure 2.1 page 103]. Each comments page is tied to a specified disclosure. To verify you are within the correct disclosure, check that the COI Disclosure ID number, as seen highlighted below, is accurate.



Figure 2.3

Comments Page Functionality

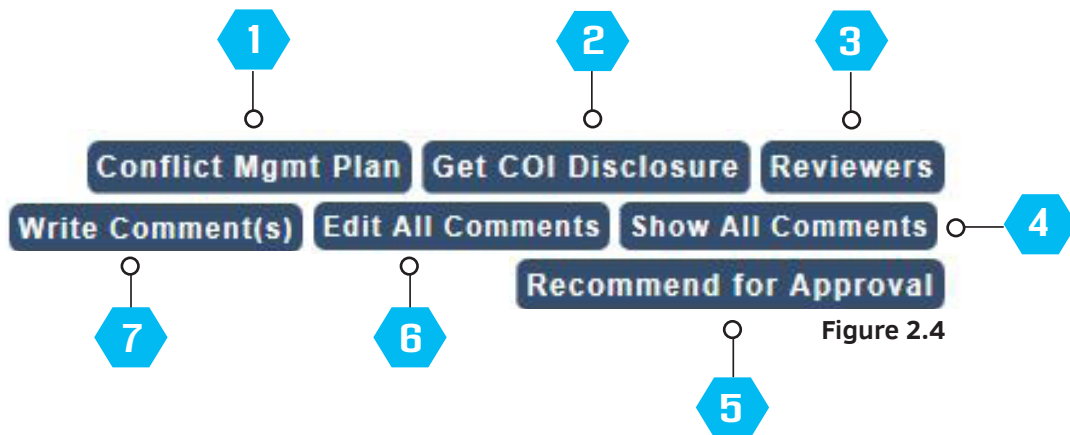


Figure 2.4



- 1 Conflict Management Plan** - Clicking on the **Conflict Mgmt Plan** button will result in a pop-up like the one in Figure 2.5. This is where the Conflict Management Plan will be written and reviewed. After viewing the CMP, the Reviewer may then recommend it by clicking the blue **Recommend for Approval** action button on the comments page. If the CMP is lengthy “View Attachment” will be displayed here. If that is the case, click on the “Attachments” section to view the CMP.

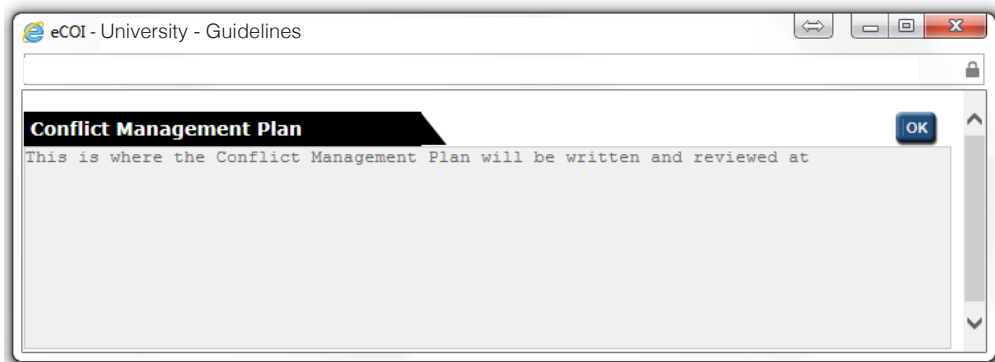


Figure 2.5

- 2 Get COI Disclosure** - Clicking on the **Get COI Disclosure** button activates a pop-up window that allows reviewers to move back and forth between the disclosure and comments window.
- 3 Reviewers** - The **Reviewers** button results in a pop-up window [Figure 2.6] displaying a list of reviewers assigned to the disclosure.

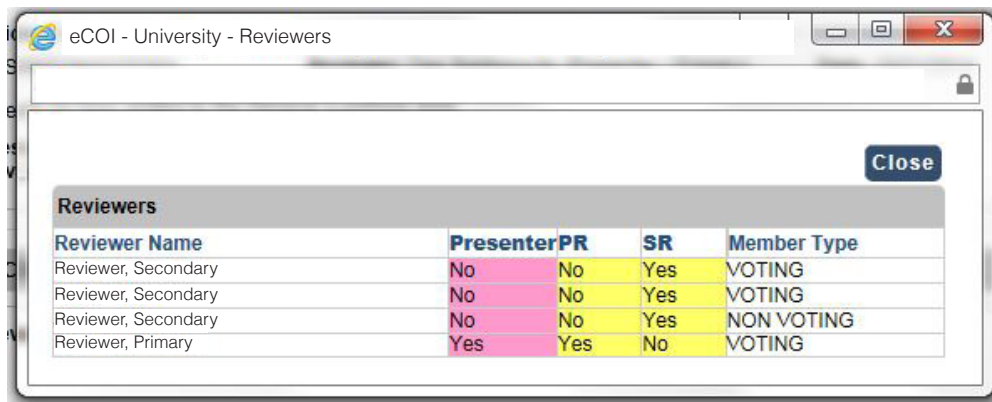


Figure 2.6





- 4 **Show All Comments** - The **Show All Comments** button allows the user to view a list of all the comments and notes within the disclosure [Figure 2.7].

eProtocol » Reviewer » [Home](#) » [Comments](#) » Show All Comments

COI Disclosure ID: [15-03-066](#) (Investigator, Principal) OK

Comments							
Comment Title	Section Name	Comment / Response	Date	Reviewer	Response Necessary	Panel Name	PI Comment Title
Cycle:2							
WL2		added an Anesthetic agent	10/14/2014	(Non Primary Reviewer)	Yes	Pre-Review	1
		ok	10/14/2014				
WL4		added ear notch for rodent ID	10/14/2014	(Non Primary Reviewer)	No	Pre-Review	2
		ok	10/14/2014				
Cycle:1							
WL1		made change in the species	10/14/2014	(Staff)	No	Pre-Review	1
		number of animals from 10 to 20 changes made	10/14/2014				
Notes to COI Disclosure							
Reviewer	Recommend for Approval					Date Submitted	
Cycle: 1							
fn9247	YES					03/25/2015	

Figure 2.7



- 5 Recommend for Approval** - If the disclosure has been reviewed and ready to submit, the Reviewer can click the **Recommend for Approval** button which results in a pop-up like the one shown in Figure 2.8.

Check the circle under the Approved Notes section to verify your approval and add any notes necessary under the Notes to COI Disclosure section. Clicking this button indicates that all of your comments or questions have been answered appropriately.

Once complete, click **Submit to COI** to send off the revised disclosure.

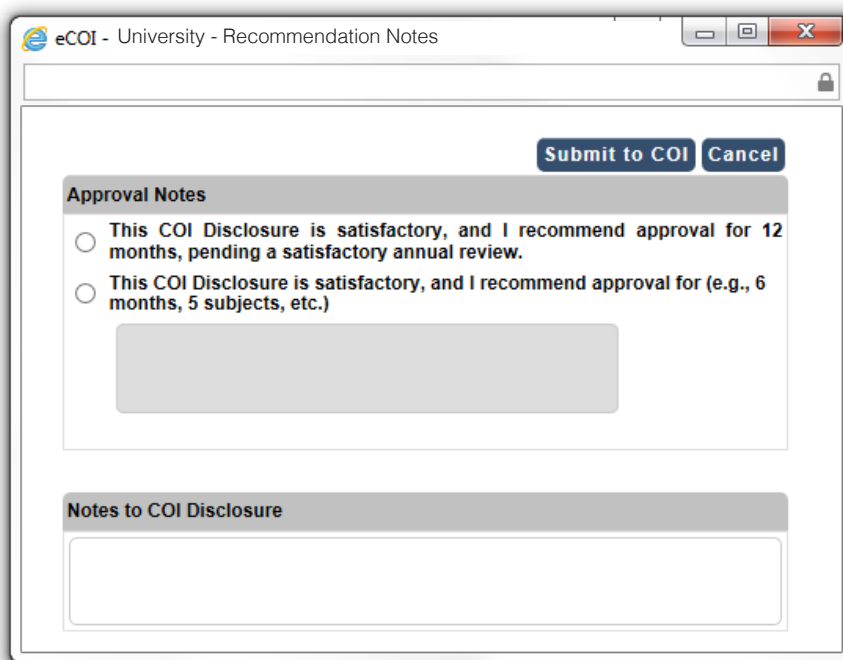


Figure 2.8

- 6 Edit All Comments** - The **Edit All Comments** button enables editing on all comments in the disclosure.
- 7 Write Comment(s)** - Clicking on the **Write Comment(s)** button will navigate to a page like the one shown in Figure 2.9. Any comments made by a Reviewer appear as anonymous to the PI. See how to write a comment below.



Figure 2.9

How to write and save a comment:

1. Click the **Write Comment(s)** button on the comments page.
2. Select a Section from the panel drop-down and check one of the two circles below the comments box determining if a response is necessary for approval.
3. Write your comment in the text box followed by clicking the **Save** button.

NOTE: Once the comment is saved, the option to Edit or Delete the comment is available as well as the ability to add additional notes.

4. If the necessary comments have been added and the disclosure is reviewed, you may now click **Submit to COI**.



Comments Cycle Explanation

Each comments cycle has 4 steps: comments received, comments sent, responses received and responses sent. Completing the four steps is considered a Cycle. Should the four steps be repeated, the comments will then be on their second cycle and so on. Refer to Figure 2.7 on page 107 for a visual representation of the comments cycle.

Comments Received (Cycle 1) means at least one Primary Reviewer assigned for review sent comments on the disclosure. The Manager is responsible for taking the comments and sending them to the Principal Investigator which is also referred to as **Comments Sent (Cycle 1)**.

Responses Received (Cycle 1) is when the Principal Investigator has responded to the comments written by the Reviewer(s) and/or Panel Manager(PM). The Principal Investigator must then send his/her responses to the comments to the PM which is called **Responses Sent (Cycle 1)**. If necessary, those comments are then sent back to the Reviewer(s).

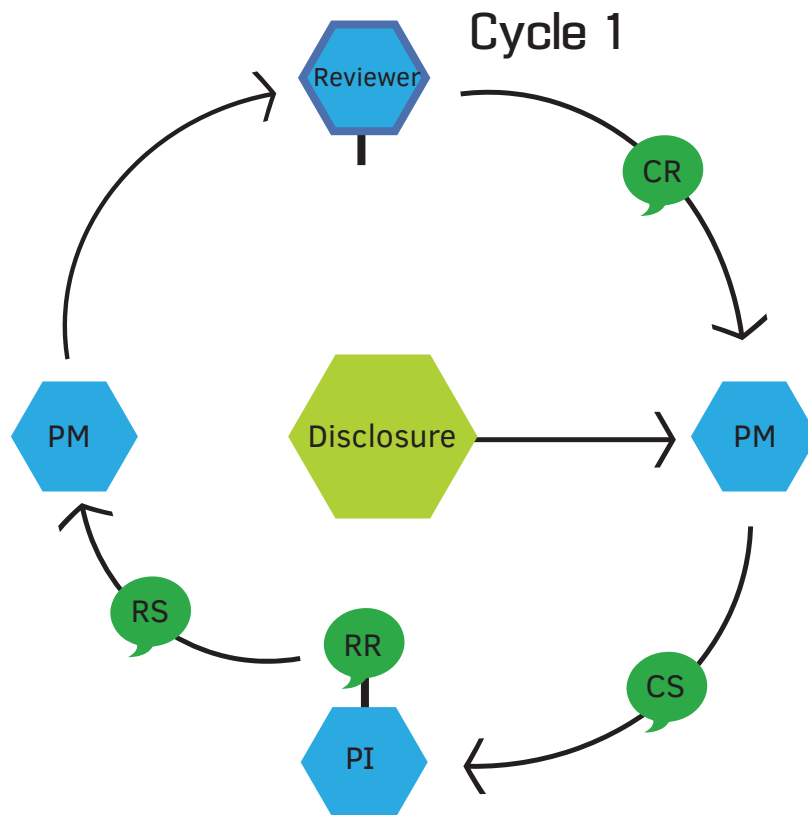


Figure 2.10



3 SUMMARY

You have successfully completed the User Role & Dashboard Functionality Manual. We hope you have a better understanding of the overall functionality, job duties and requirements of the roles that pertain to an eCOI user.

