



eProtocol



IRB Committee Manager & RCA Role Manual

MARCH 2018

Table of Contents

1	Overview.....	6
	1.1 Things to Remember.....	6
2	Committee Manager Role	7
	2.1 Committee Manager Role Overview	7
	2.2 Assigning a Protocol to a Panel	7
	2.3 Assigned Protocols	8
	2.4 Returning a Protocol with Return Notes	8
	2.5 Returned Protocols	9
	Delete Protocol from List.....	9
3	RCA Role	10
	3.1 RCA Role Overview.....	10
	3.2 Protocol Event Types	10
	Receipt of Protocol.....	11
	Reviewer(s) Assigned.....	11
	Panel Manager Review	11
	Comments Received (Cycle X).....	11
	Comments Sent (Cycle X).....	11
	Responses Received (Cycle X).....	11
	Responses Sent (Cycle X).....	11
	Recommended for Approval	11
	Contingent	11





Moved.....	11
Tabled	11
3.3 Polling	11
Assigning and Sending Poll Requests	11
3.4 Assigning Reviewers to a Protocol	13
How to Select and Assign	13
Action Buttons and Functionality	14
Comments Page Functionality	15
Get Protocol.....	15
Approval Notes	15
Reviewers.....	16
Protocol Decision	16
Write Comment(s).....	16
Edit all Comments	16
Show All Comments	16
Submit to PI.....	17
Comments Cycle Explanation	18
3.5 Active Protocols	19
Close Protocol	19
3.6 Non-Active Protocols	20
How to Build and Generate a Report	20
3.7 Submitted Protocols	20
Reassign Panel	21
Reassign Reviewers.....	22





- 3.8 Returned Protocols22
 - Return a Protocol23
- 3.9 Reports24
 - Setup Criteria24
 - Report Display and Types24
- 3.10 Generic Report.....25
 - How to Build and Generate a Report.....26
 - Report Output Formats26
- 3.11 Meeting Agenda26
 - Delete Agenda27
 - Accessing Agenda27
 - Pre-Meeting Set-up27
 - Planned Attendees27
 - Set-up Early Agenda28
 - Preview Early Agenda.....30
 - Agenda.....30
 - Meeting31
 - Meeting Attendees31
 - Post Meeting32
 - Minutes of Meeting32
- 3.12 Email History32





4	Search Protocol.....	33
---	----------------------	----

5	Summary	34
---	---------------	----



1 OVERVIEW

The IRB Committee Manager and RCA Role Manual is for any user whose role in eProtocol is either the Committee Manager or the Research Compliance Administrator (RCA). In this manual, users will be shown examples of dashboards, steps in managing protocols and descriptions of job functionality, duties, and role requirements.

1.1 Things to Remember

Before getting started on the IRB Committee Manager and RCA Role Manual, please review the information from the General Functionality and Dashboard Manual.

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 or higher or Apple Safari.

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

The steps in the Committee and RCA Role Manual cannot be completed if the pop-up blocker is still active. See the General Functionality & Dashboard 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.



2 COMMITTEE MANAGER ROLE

2.1 IRB Committee Manager Role Overview

The IRB Committee Manager and RCA Role Manual examines the functions, job duties and requirements of each role.

2.2 Assigning a Protocol to a Panel

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

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

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

eProtocol » Committee Manager » Home

Panel has been assigned for the protocol 14-09-105.

Assign Panel Return Protocol

IRB

Transactional Events

NEW

	Protocol ID	Principal Investigator	Title	Protocol Event	
<input checked="" type="checkbox"/>	14-09-105	Investigator, Principal	testing CFC training	PANEL ASSIGNED	Please Select IRB Test Panel Test Panel 2
<input type="checkbox"/>	14-07-049	Investigator, Principal	September 9th is going to be a good day	PANEL ASSIGNED	

Figure 2.1



2.3 Assigned Protocols

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

eProtocol » Committee Manager » [Home](#) » Assigned Protocols

IRB

Protocol ID	Principal Investigator	Title	Assigned Date	Panel Name	Form Type
14-09-092	Investigator, Principal	testing Dept Chair WF	09/09/2014	Pre-Review	NEW
14-10-133	Investigator, Principal	testing the training required	10/13/2014	IRB	NEW
14-09-105	Investigator, Principal	testing CFC training	10/13/2014	Pre-Review	NEW
14-08-076	Investigator, Principal	testing on August 5th	10/13/2014	Test Panel	NEW

Figure 2.2

2.4 Returning a Protocol with Return Notes

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

1. On the home dashboard, open the protocol you wish to return by clicking on the Protocol ID number.
2. The protocol will open in a new window. Click on the **Return Notes** menu option as seen highlighted below, 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 protocol and return to the Committee Manager dashboard.
5. Check the box next to the protocol you are returning followed by clicking on the **Return Protocol** action button to complete the process.



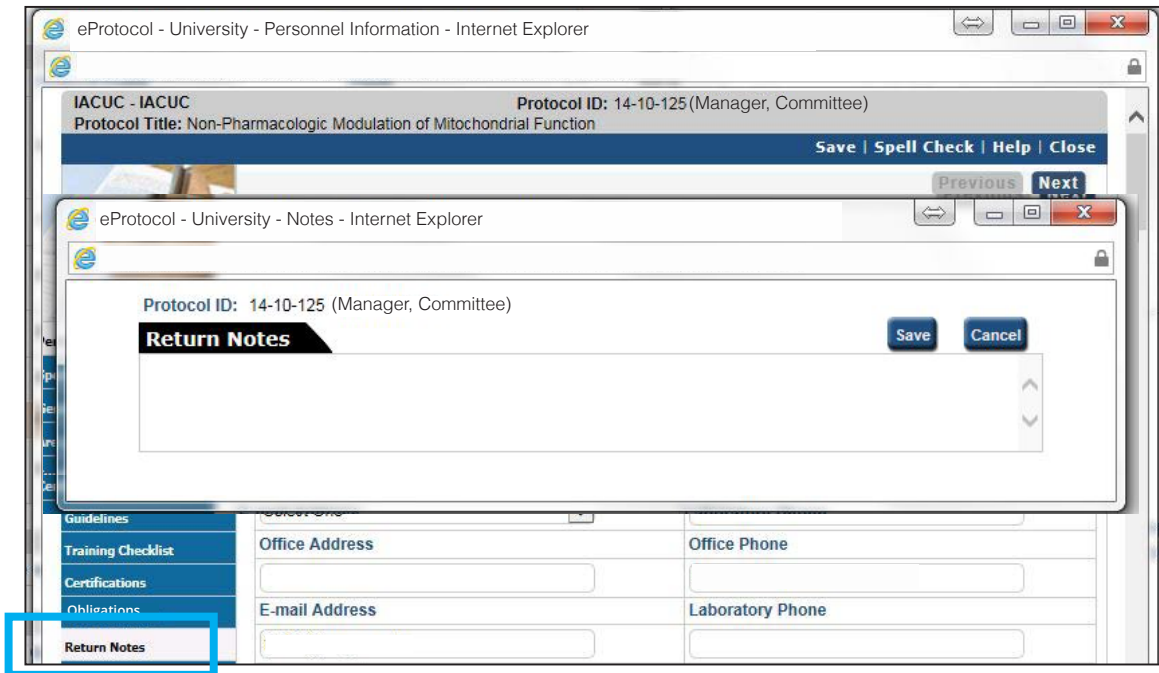


Figure 2.3

2.5 Returned Protocols

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

Delete Protocol from List

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

Protocol » Committee Manager » [Home](#) » Returned Protocols

IRB		Delete Protocol			
<input type="checkbox"/>	Protocol ID	Principal Investigator	Title	Submission Date	Returned Date
<input type="checkbox"/>	14-10-125	Investigator, Principal	Sample Study 1	10/13/2014	10/13/2014

Figure 2.4

3 RCA ROLE

3.1 RCA Role Overview

The Committee Manager and RCA Role Manual examines the functions, job duties and requirements of an eProtocol user logged in as a Committee Manager or Research Compliance Administrator (RCA). This portion of the manual is dedicated to users logging in as a RCA.

From the eProtocol menu on the main page, select RCA, then RCA Home. The window will display all the protocols submitted to the IRB. In order to sort by the different IRB boards, select the dropdown menu beside the word “panel”, to sort by date, select the menu beside “Meeting Date”.

3.2 Protocol Event Types

The **Protocol Event** column is the 3rd column on the RCA Homepage. The Protocol Events are further explained on page 11.



- 1 **Receipt of Protocol** - The RCA assigns reviewers to a protocol.
- 2 **Reviewer(s) Assigned** - The protocol has been assigned to Reviewers for revision.
- 3 **Panel Manager Review** - The protocol 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 protocol.
- 5 **Comments Sent (Cycle X)** - Comments on the protocol 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 protocol.
- 7 **Responses Sent (Cycle X)** - Responses of the Investigator to the comments are sent to Reviewers.
- 8 **Recommended for Approval** - Reviewers have recommended the protocol for approval.
- 9 **Contingent** - The protocol is approved on contingent criteria. Contingent Approval is also known as modification required to secure approval.
- 10 **Moved** - The protocol is moved to another meeting date from the assigned meeting date.
- 11 **Tabled** - The protocol will require another full committee review. It is the responsibility of the PI to make the changes and resubmit the protocol.

3.3 Polling

Polling allows the RCA to send the protocol on to panel members to get their vote on the review type. To get to this page, click the blue **Review Decision** action button within the grid. This will result in a pop-up containing a list of panel members [Figure 3.2, page 12].

Assigning and Sending Poll Requests

1. Select the members you would like to send a poll request to by checking the box next to their name [Figure 3.2].
2. Click the **Send** action button to send the members an email regarding the review decision.

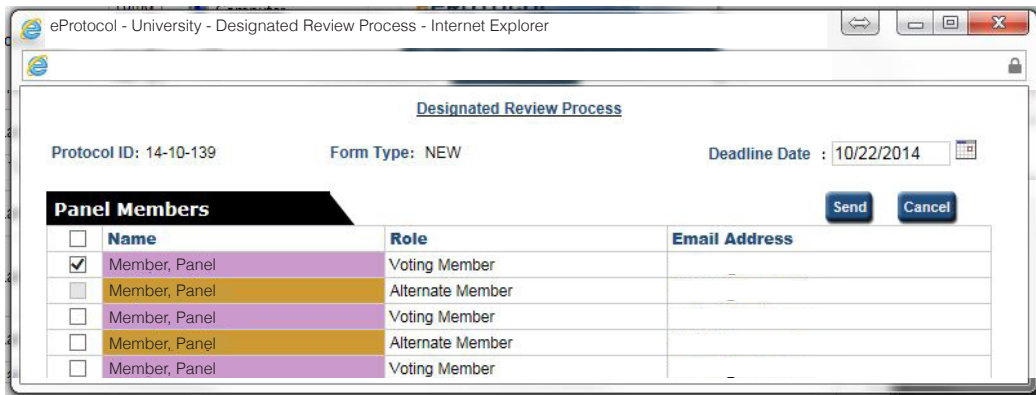


Figure 3.2

After the poll requests have been sent, the RCA see how reviewers voted by clicking the **Review Decision** action button located in the home dashboard. Clicking the button will result in a pop-up shown in Figure 3.3. It is in this pop-up the RCA is able to view the vote and notes of reviewers.

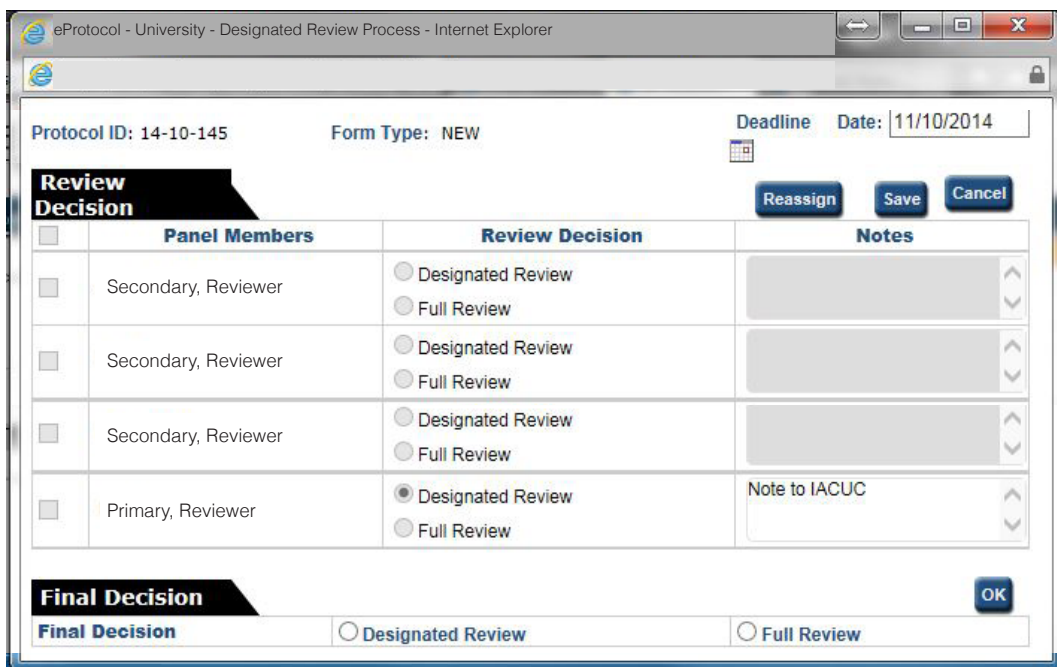


Figure 3.3



3.4 Assigning Reviewers to a Protocol

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

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

Protocol ID: [14-09-105](#) (Investigator, Principal) Write Comment(s)

Panel: Pre-Review Meeting Date: 10/13/2014 Review Type: Please Select

Panel Members Assign Cancel

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

Figure 3.4

How to Select and Assign

1. Click on the **Receipt of Protocol** link under the “Protocol Events” column on the dashboard. Clicking on the link directs the user to the page shown in Figure 3.4.
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 protocol.
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

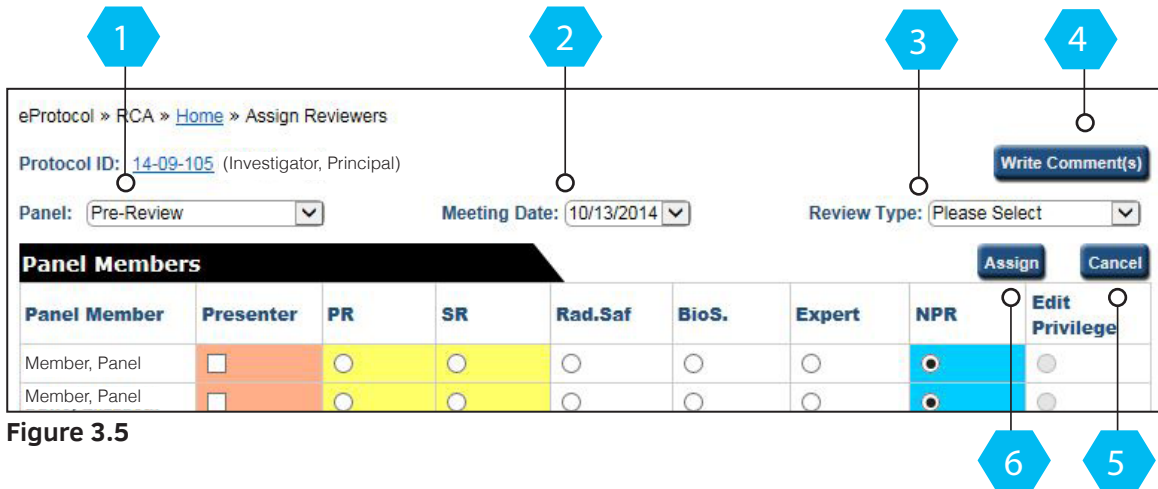


Figure 3.5

- 1 The **Panel** drop-down allows the RCA to filter members by the panel they are on.
- 2 The **Meeting Date** drop-down allows the RCA to filter protocols 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 By clicking on the **Write Comment(s)** action button, the RCA can add and view comments within the protocol. Clicking on the action button will direct the user to another page where they may add comments and view other aspects of the protocol.
- 5 Clicking on the **Cancel** action button will back out to the home dashboard without saving any selections.
- 6 Clicking the **Assign** action button will assign the selected reviewers to a protocol.



Comments Page Functionality



Figure 3.6

- 1 **Get Protocol** - The **Get Protocol** button activates a pop-up window allowing the user to Edit or View the protocol.
- 2 **Approval Notes** - Clicking on the **Approval Notes** button will result in a pop-up window [Figure 3.7] allowing the user to view Notes to the IRB. Click the **Close** button in the top right corner to close the pop-up window.

Approval Notes				Close
Reviewer	Recommended	Notes to IRB	Date Submitted	
Cycle: 1				
Last Name, First Name	NO	Sample text	02/06/2018	

Figure 3.7

- 3 **Reviewers** - The **Reviewers** button allows the RCA to see the reviewers that are assigned to the protocol.
- 4 **Protocol Decision** -The protocol decision button allows the RCA to select the decision recommended by the committee or single reviewer. The drop down menu under the “Action” column allows the user to choose the appropriate protocol event type. Choose the appropriate expiration date and include comments if needed (see pages16-18 for more information).

Select the “notes” tab to add “Meeting Notes,” “Form Findings” and “Voting” comments.

Meeting Notes Tab – Select the correct motion using the drop down menu and save changes. You can also type in comments from the meeting.

Form Findings Tab – Click on the Add button to add findings such as risk categories, HIPAA waivers, consent waivers and waiver to screen for eligibility. After saving your selection(s), select each check box and type in the justification for the selection in the rationale box.

Voting Tab – Select the relevant option for each member. The voting options available are: For, opposed and abstain. Other options are: COI, arrived late, out of room and left meeting.

Note: You have access to the motion drop down menu by clicking on any of the three tabs: meeting notes, form findings or voting tabs.

To submit to the PI – on the protocol decision page – click on Submit, an approval date window will pop-up for you to select an approval date. The row will turn light blue indicating that an approval letter has been generated and an email has been sent to the study team notifying them about the approval.

- 5 **Write Comment(s)** - The **Write Comment(s)** button allows the user to navigate to a page like the one shown in Figure 3.8.

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.

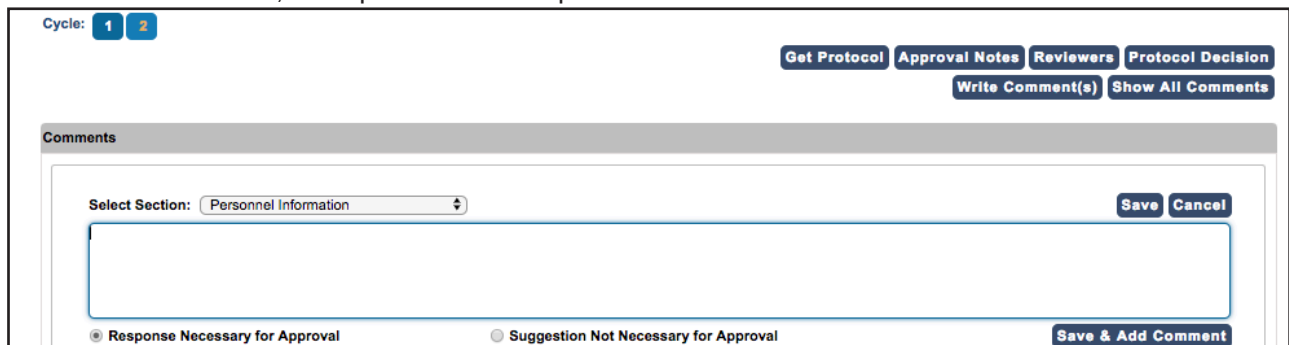


Figure 3.8



- 6 **Edit All Comments** - The **Edit All Comments** button enables editing on all comments in the protocol.
- 7 **Show All Comments** - The **Show All Comments** button allows the user to view a list of all the comments and notes within the protocol [Figure 3.9].

Protocol ID: [IRB-17-10-0369](#) (Last Name, First Name) OK

Comment Title	Section Name	Comment/Response	Date	Reviewer	Response Necessary	Panel Name	PI Comment Title
Cycle: 1							
BIELAWSKID1	Consent Information	Consent medical terms are not in lay language. ok	12/12/2017 12/12/2017	Bielawski, Dawn (Secondary)	Yes	PH1	1
LIJ1	Personnel Information	please revise the consent section 1 ok	12/12/2017 12/12/2017	Li, Jing (Secondary)	Yes	PH1	2
SHIELDSA1	Consent Information	I would like to add a change to the consent. Tony Shields ok	12/12/2017 12/12/2017	Shields, Anthony (Secondary)	Yes	PH1	3
GEISLERA1	Consent Information	p. 6 2nd Para., Not lay language ok	12/12/2017 12/12/2017	Geisler, Allan (Secondary)	No	PH1	4
BIELAWSKID2	Risks	Some obvious risks are not stated and they need to be. ok	12/12/2017 12/12/2017	Bielawski, Dawn (Secondary)	Yes	PH1	5
TANCERM1	Personnel Information	How do I attach a document? ok	12/12/2017 12/12/2017	Tancer, Manuel (Presenter / Primary)	Yes	PH1	6

Figure 3.9

- 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 3.10.
 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.

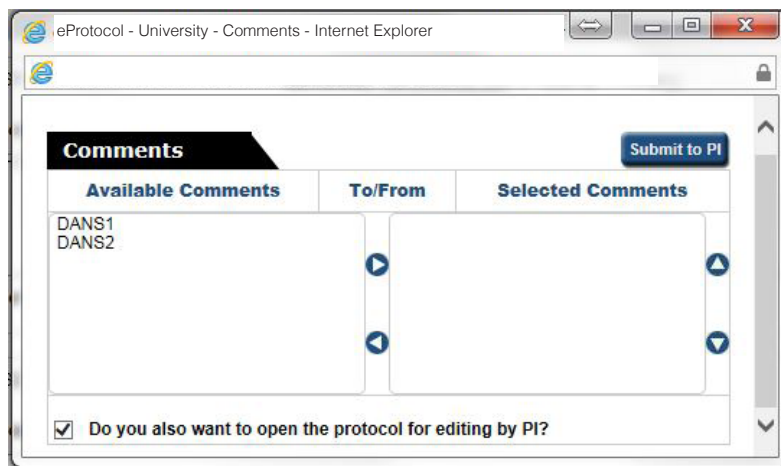


Figure 3.10

Comments Cycle Explanation

Comments Received (Cycle 1) means at least one Primary Reviewer assigned for review sent comments on the protocol. The RCA 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 RCA(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 3.11 for a visual representation of the comments cycle.

Protocol ID: [14-09-103](#) (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 PI did not respond to this comment.	10/13/2014	Reviewer, Primary	Yes	Test Panel	1
Cycle: 2							
WL1	Personnel Information	PI plsnote the changes in the personnel seccion modification made in protocol	09/15/2014 09/15/2014	Reviewer, Primary	Yes	Test Panel	1
Cycle: 1							
BG1	Non-Surgical Procedure Details	added anesthetic agent modified protocol	09/15/2014 09/15/2014	Reviewer, Primary (Presenter / Primary)	No	Test Panel	1
BG2	Procedure Relationships	this needs detail modified protocol 2	09/15/2014 09/15/2014	Reviewer, Primary (Presenter / Primary)	Yes	Test Panel	2

Figure 3.11



3.5 Active Protocols

The RCA can access the list of active protocols by clicking on the **Active Protocols** tab under the eProtocol drop-down. The RCA will then be directed to the page shown in Figure 3.12.

CS	IACUC	IBC	IRB	RSC		
Protocol ID	Principal Investigator	Approval Date	Last Approval Date	Expiration Date	Form Type	Decision
17-09-0330	Last Name, First Name	09/29/2016	09/29/2016	09/30/2017	NEW	
IRB-17-10-0360	Last Name, First Name	12/21/2013	12/21/2013	12/20/2014	NEW	
IRB-17-10-0349	Last Name, First Name	11/14/2017	11/14/2017	N/A	NEW	<input type="radio"/> Close
IRB-17-11-0385	Last Name, First Name	11/14/2017	11/14/2017	11/13/2018	NEW	<input type="radio"/> Close
IRB-17-10-0353	Last Name, First Name	11/19/2017	11/27/2017	12/29/2017	CONTINUING REVIEW	<input type="radio"/> Close
IRB-17-10-0370	Last Name, First Name	11/05/2017	11/14/2017	11/04/2018	AMENDMENT	<input type="radio"/> Close

Figure 3.12

Close Protocol

To close a protocol, select “close” under the “Decision” column on the grid [Figure 3.12]. A pop-up will appear like the one in Figure 3.13. Fill out a note giving the reason for closing the protocol and complete the action by clicking the **Confirm** action button.

Figure 3.13

3.6 Non-Active Protocols

A user can access the **Non Active Protocols** page [Figure 3.14] by clicking on the appropriate tab in the top menu bar drop-down. This page displays a list of all the non-active protocols. The RCA can filter through the protocols by using the status drop-down bar.

Selecting “Reactivate” for a non active protocol under the “Reactivate Protocol” column, will generate a pop-up window where the RCA can reactivate the protocol making the protocol active again.

eProtocol » RCA » [Home](#) » Non Active Protocols

IRB Status: All

Protocol ID	Principal Investigator	Title	Status/Comments	Approval Date	Last Approval Date	Expiration Date	Closed/ Not Approved/ Withdrawn/ Expired Date	Reactivate Protocol
14-07-011	Investigator, Principal	Title	CLOSED	07/07/2014	08/13/2014	07/06/2016	10/15/2014	<input type="radio"/> Reactivate
14-07-012	Investigator, Principal	Title	NOT APPROVED				07/14/2014	
14-07-025	Investigator, Principal	Title	CLOSED	07/10/2014	09/15/2014	07/09/2017	10/15/2014	<input type="radio"/> Reactivate
14-08-074	Investigator, Principal	testing on August 5th	NOT PREAPPROVED					
14-07-068	Investigator, Principal	testing again on July 25th	CLOSED	10/10/2014	10/10/2014	10/09/2017	10/15/2014	<input type="radio"/> Reactivate

Figure 3.14

3.7 Submitted Protocols

To access the Submitted Protocols page, go to the top menu bar drop-down and click on the **Submitted Protocols** tab which will direct the user to a page like the one shown in Figure 3.15. The functionality within the Submitted Protocols page can be found on pages 21 and 22.



eProtocol » RCA » [Home](#) » Submitted protocols list

IRB

Panel:

	Protocol ID	Investigator	Title	CMNTS/RSPNS	Submitted Date	Meeting Date	Form Type
<input type="checkbox"/>	14-07-065	Investigator, Principal	testing	Comment	07/31/2014	11/21/2014	NEW
<input type="checkbox"/>	14-09-109	Investigator, Principal	this is an example of a test title	Comment	09/22/2014		AMENDMENT
<input type="checkbox"/>	14-09-103	Investigator, Principal	testing the reviewer to PI cycle additional cycle	Comment	09/15/2014		NEW

Figure 3.15

Reassign Panel

To reassign a panel follow the directions below:

1. Check the box next to the protocol you would like to reassign reviewers.
2. Click on the blue **Reassign Panel** action button which will direct you to the page like the one shown in Figure 3.16.
3. Select a panel from the 'Panel' drop-down followed by clicking the blue **Reassign Panel** action button.

eProtocol » Submitted protocols list

Protocol:

Panel:

B3
M1
MP2
MP4
✓ PH1

Meeting Date:

Review Type:

Panel Members

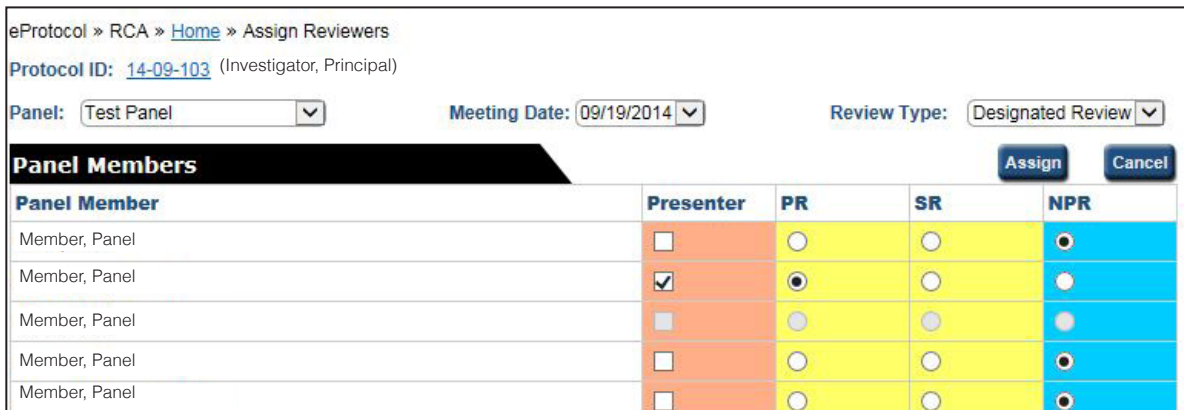
Panel Member	Presenter	PR	SR	Rad.Saf	BioS.	Expert	NPR
Member, Panel	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Member, Panel	<input type="checkbox"/>	<input type="radio"/>	<input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

Figure 3.16

Reassign Reviewers

To reassign reviewers, please follow the directions below:

1. Select the box next to the protocol where you would like to reassign reviewers [Figure 3.15].
2. Click on the blue **Reassign Reviewers** action button which will direct you to the page like the one shown in Figure 3.17.
3. Select the reviewers you would like to assign to the protocol followed by clicking on the **Assign** action button to complete this process.



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

Protocol ID: [14-09-103](#) (Investigator, Principal)

Panel: Meeting Date: Review Type:

Panel Members

Panel Member	Presenter	PR	SR	NPR
Member, Panel	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Member, Panel	<input checked="" type="checkbox"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Member, Panel	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Member, Panel	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Member, Panel	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Figure 3.17

3.8 Returned Protocols

To access the Returned Protocols page, go to the top menu bar drop-down and click on the **Returned Protocols** tab. Clicking on this tab will direct the user to a page listing returned protocols. If there are any protocols to eliminate, check the box of the protocol and click on the **Delete** action button complete the process [Figure 3.18].



eProtocol » RCA » [Home](#) » Returned Protocols

IACUC

<input type="checkbox"/>	Protocol ID	Principal Investigator	Title	Submission Date	Returned Date
<input type="checkbox"/>	14-10-151	Investigator, Principal	test using 2.4.30	10/21/2014	10/21/2014

Figure 3.18



Return a Protocol

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

1. Open the protocol you wish to return by clicking on the protocol ID number. A pop-up will appear asking if you want to edit or view the protocol. Click the 'edit' button to proceed.
2. The protocol will open in a new window. Click on the blue **Return Notes** tab on the left side of the screen, to generate another pop-up window [Figure 3.19].
3. Enter the reason for return in the Return Notes pop-up, followed by clicking the **Save** action button and closing the protocol.
4. Proceed to the **Submitted Protocols** page.
5. Select the box next to the protocol you are returning followed by clicking on the **Return Protocol** action button to complete the process.

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

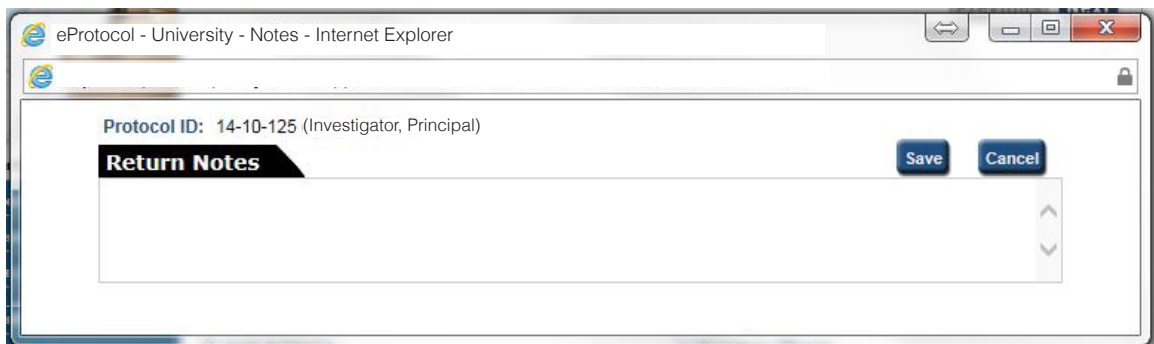


Figure 3.19

Once the protocol has been returned, a blue message appears in the content area notifying the user of the return [Figure 3.20].

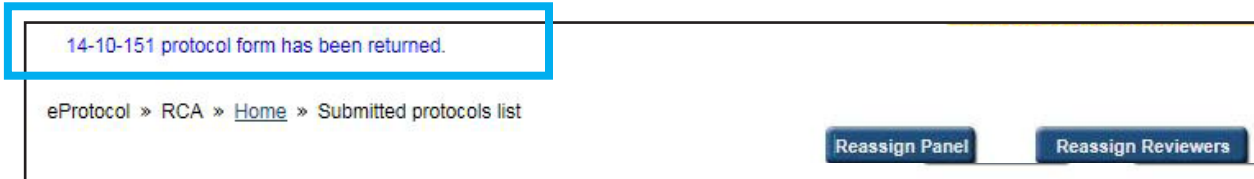


Figure 3.20

3.9 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 3.21.

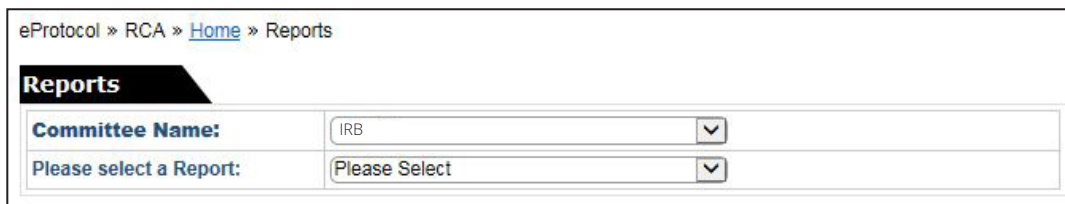


Figure 3.21

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 3.22 where the user will only have to fill out the Panel Name and dates.

Report Display and Types

Once the report is complete, the RCA can choose how the report will be displayed by selecting any of the format options [Figure 3.22].



Figure 3.22

3.10 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 3.23.

Figure 3.23

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 in the upper right-hand corner.
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 3.24].



Figure 3.24

3.11 Meeting Agenda and Minutes

In order to access the Meeting Agenda and Minutes page, go to the top menu bar drop-down and click on the **Meeting Agenda and Minutes** tab, navigating the user to the page seen in Figure 3.25. The RCA can filter the agendas displayed by the “Panel” and “Meeting Date” drop-down bars. Select the appropriate Agenda ID to open up the agenda.



eProtocol » RCA » [Home](#) » Meeting Agenda & Minutes

Panel: Meeting Date:

CS	IACUC	IBC	IRB	RSC	Delete
Agenda ID	Meeting Date	Reminder Sent Date	Agenda and Previous Minutes Sent Date		
<input type="checkbox"/> 103	02/14/2018				

Figure 3.25

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. Review the agenda details on pages 27-32.

Pre-Meeting Set-up



Figure 3.26

1 The **Planned Attendees** tab displays a list of attendees who are expected to join the meeting [Figure 3.27]. The RCA 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 RCA 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	4	0	0
Member, Panel	<input checked="" type="checkbox"/>	0	0	4	0	0
Member, Panel	<input checked="" type="checkbox"/>	0	0	4	0	0
Member, Panel	<input type="checkbox"/>	0	0	4	0	0

Figure 3.27

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.

Meeting Location:

Next Meeting Location:

Planned Meeting Start Time: 08 : 00 AM/PM

Planned Next Meeting Start Time: 08 : 00 AM/PM

Planned Meeting End Time: 10 : 00 AM/PM

Planned Next Meeting End Time: 10 : 00 AM/PM

Buttons: Add Item, Add End Item, Create Item Sequence, Add Protocol, Create Protocol Sequence, Delete

Item Name	Notes	Documents
Confidentiality of Panel Proceedings	The members of the panel and the persons employed by the panel shall maintain the confidentiality of the panel's proceedings unless such information is already made available to the public. The Parties shall maintain the confidentiality of the panel's proceedings, deliberations and initial report.	

Figure 3.28



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 3.29] in the Item Name column of Figure 3.28. Use the drop-down bar to choose and Item Name and click on the pencil icon to add any necessary notes.



Figure 3.29

D - Clicking on the **Add End Item** action button will create a new drop-down bar [Figure 3.29] in the Item Name column of Figure 3.28. Use the drop-down bar to choose and Item Name and click on the pencil icon to add any necessary notes..

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 3.30. 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.

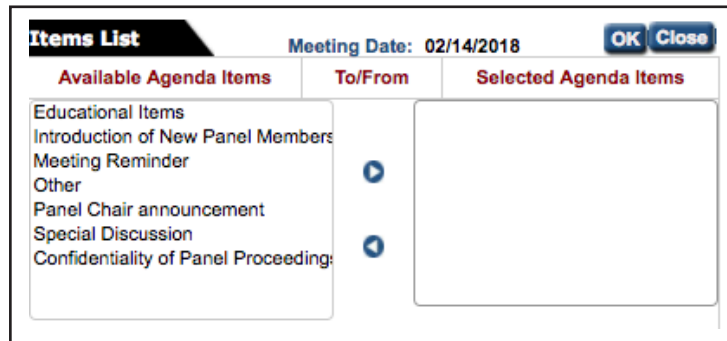


Figure 3.30

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

G - Clicking on the **Create Protocol Sequence** action button will result in a pop-up shown in Figure 3.31. Follow the same steps used in creating an item sequence to create a protocol sequence.

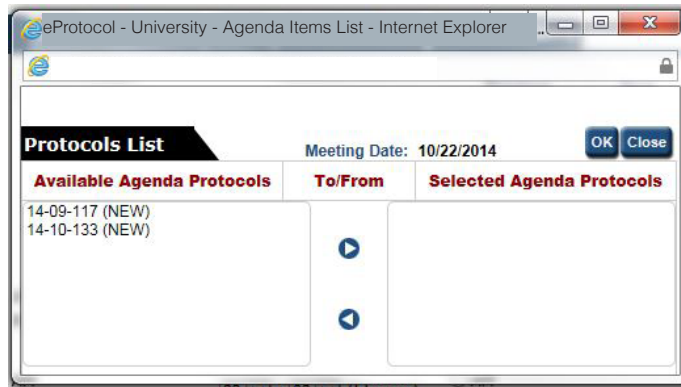


Figure 3.31

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 protocols involved in the meeting [Figure 3.32].



Figure 3.32

- 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 RCA to look at the agenda in different formats. Including: .doc(x) (Microsoft Word), PDF (Adobe/Print View), and digitally (see figure 3.33).



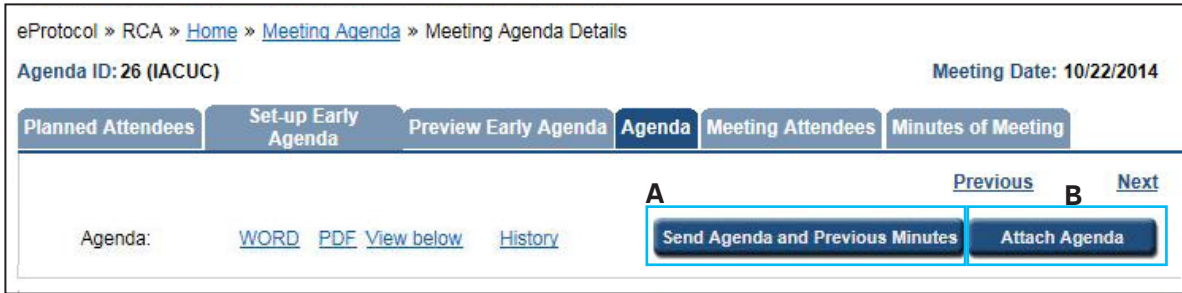


Figure 3.33

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

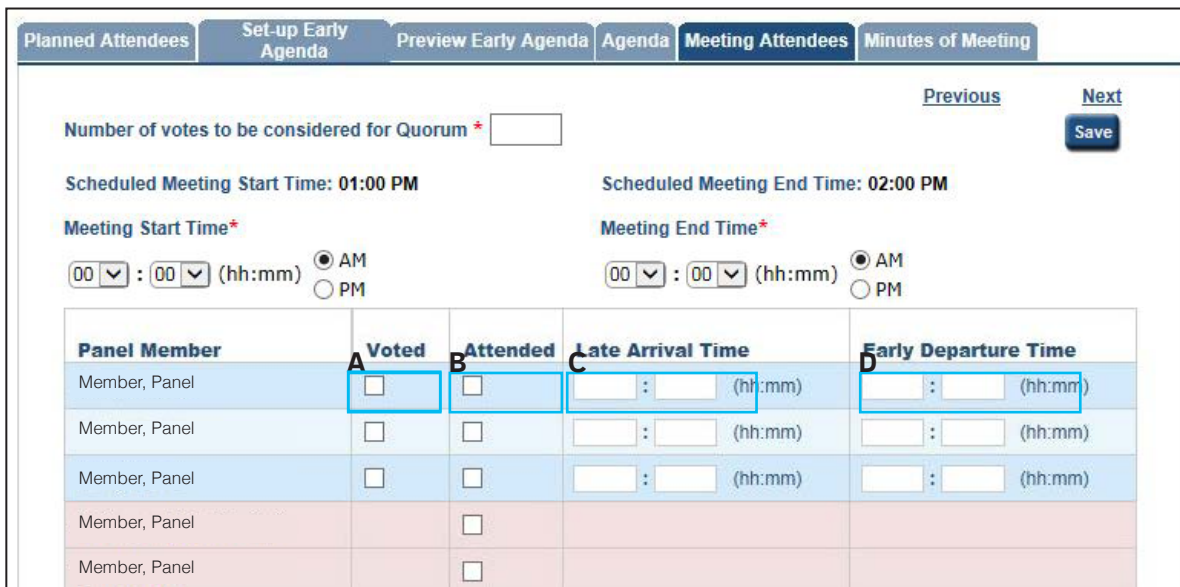


Figure 3.34

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 3.35.

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 3.35

3.12 Email History

To review the emails that are sent to the PI, study team, reviewers, office staff etc.

From the RCA Home page / protocol decision page, select a specific protocol by clicking on the protocol ID. A pop-up window will appear, asking if you want to open the protocol, when you click on “view”, the protocol will open up. Select “Event History” (on the lower left corner). A table with 2 tabs will pop-up: Event History and Email History. The list is organized by dates. Identify the email/letter/attachment, then view/print.



4 SEARCH PROTOCOL

Overview

No matter your role, all members have the ability to search a protocol. A user can access the Search Protocol page by first selecting the eProtocol menu on the top menu bar. Hover your mouse over your role and click on the menu tab titled **Search Protocol**.

You will be directed to a search page like the one shown in Figure 4.1. On this screen, you may search for all protocols that you have access rights to. Protocols can be searched by Study Title, Principal Investigator and Protocol ID. Searches can be saved for future use. Saved searches maintain the search criteria for faster subsequent searches.

eProtocol » RCA » [Home](#) » Search Protocol

Search **Clear** **Save** **Cancel**

CS	IACUC	IBC	IRB	RSC
Protocol ID	<input type="text"/>	Study Title	<input type="text"/>	
Principal Investigator	<input type="text"/>	Applicant	<input type="text"/>	
Form Type	---Please Select---	Panel	---Please Select---	
Department	---Please Select---	Meeting Date	<input type="text"/>	
Form Name	---Please Select---			
Sponsor	---Please Select---	SPO #	<input type="text"/>	
Protocol Status	---Please Select---			

Figure 4.1

5 SUMMARY

You have successfully completed the Committee Manager and RCA Role Manual. We hope you have a better understanding of the overall functionality of your role. To review the overall functionality of eProtocol, please see the General Functionality and Dashboard Manual.

For more information on the functionality of other operating roles in eProtocol, please see The Investigator Role Manual or the Reviewer Role Manual.

