eProtocol

WAYNE STATE

Reviewer Role Manual

Table of Contents

1 Overview 4

1.1 Things to Remember 4

2 Review Process 5

2.1 Reviewer Role Overview 5

2.2 Protocol Event Types 6

Assigned as Reviewer 6

Comments Sent (Cycle X) 6

Responses Received (Cycle X) 6

Recommended for Approval 6

Moved 6

Tabled 6

Contingent 7

2.3 Comments Page 7

Comments Page Functionality 7

Guidelines 8

Get Protocol 8

Reviewers 8

Show All Comments 9

Recommend for Approval 10

Write Comment(s) 10
How to Write a Comment and Save 11
Edit all Comments 11
Comments Cycle Explanation 12

3 Search Protocol 13

4 Summary 14

1 OVERVIEW

The Reviewer Role Manual examines the functions, job duties and requirements of an eProtocol 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 protocol.

1.1 Things to Remember

Before getting started on the Reviewer Role Manual, please review 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: Internet Explorer 10 and above, Firefox 12 and above, and Safari 7.

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

The steps in the Reviewer 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 can cause errors in the system and log the user out.

4. Resizing the screens

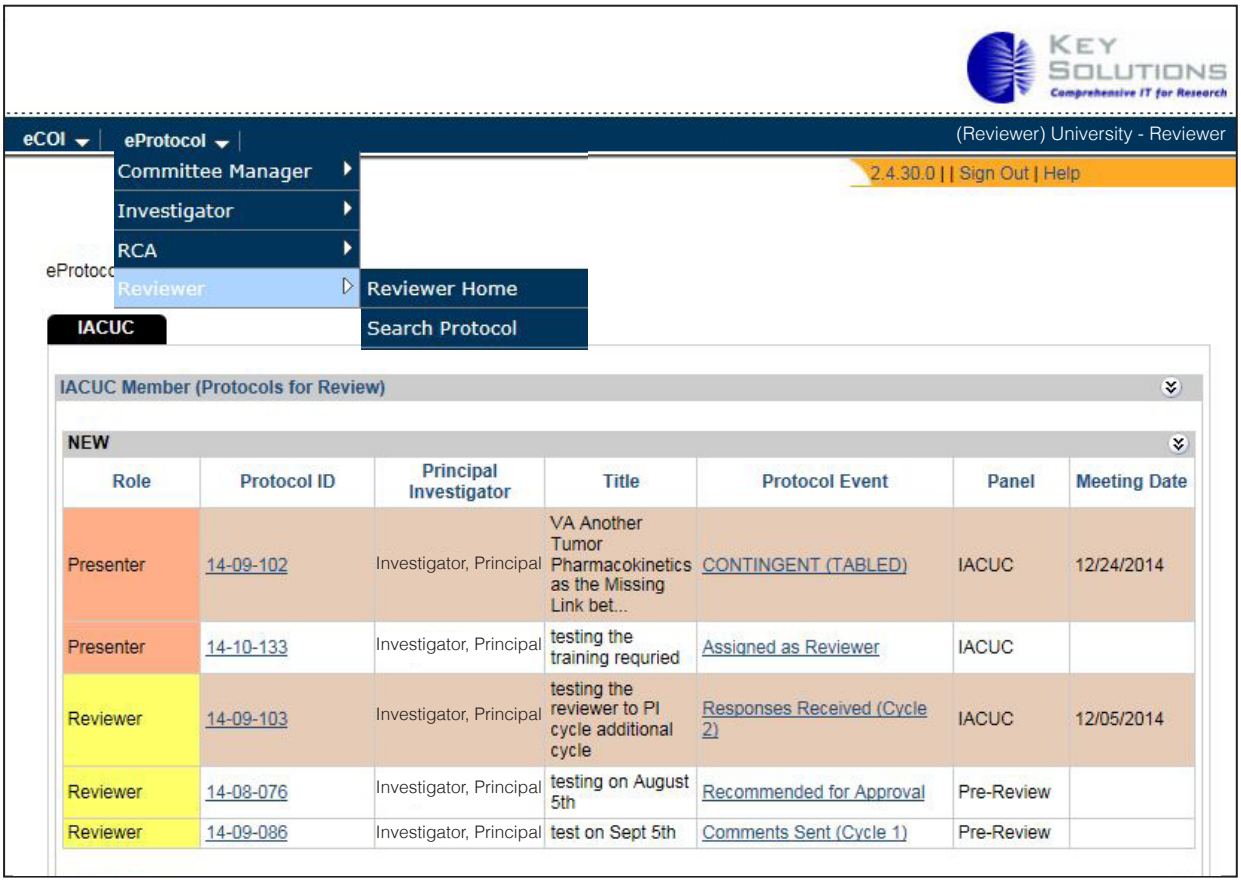
There are numerous pop-up windows used in the software. Don't forget to resize the screens to better suit your view.

NOTE: For the purpose of this manual, IACUC 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 protocols that have been assigned to you. Every protocol you have been assigned to as a Reviewer will appear on your home dashboard. To view a protocol, click on the protocol ID number listed under the Protocol ID column on the home dashboard. To view any comments, reviewers, or guidelines within the protocol, click on the protocol event link listed under the Protocol Event column. If comments or guidelines are being viewed, click on the eProtocol drop down in the top menu bar, and choose Reviewer Home to return to the previous page [Figure 2.1].



Role	Protocol ID	Principal Investigator	Title	Protocol Event	Panel	Meeting Date
Presenter	14-09-102	Investigator, Principal	VA Another Tumor Pharmacokinetics as the Missing Link bet...	CONTINGENT (TABLED)	IACUC	12/24/2014
Presenter	14-10-133	Investigator, Principal	testing the training requried	Assigned as Reviewer	IACUC	
Reviewer	14-09-103	Investigator, Principal	testing the reviewer to PI cycle additional cycle	Responses Received (Cycle 2)	IACUC	12/05/2014
Reviewer	14-08-076	Investigator, Principal	testing on August 5th	Recommended for Approval	Pre-Review	
Reviewer	14-09-086	Investigator, Principal	test on Sept 5th	Comments Sent (Cycle 1)	Pre-Review	

Figure 2.1

2.2 Protocol Event Types

The Protocol Event column of the grid displays the status of the protocol [Figure 2.2].

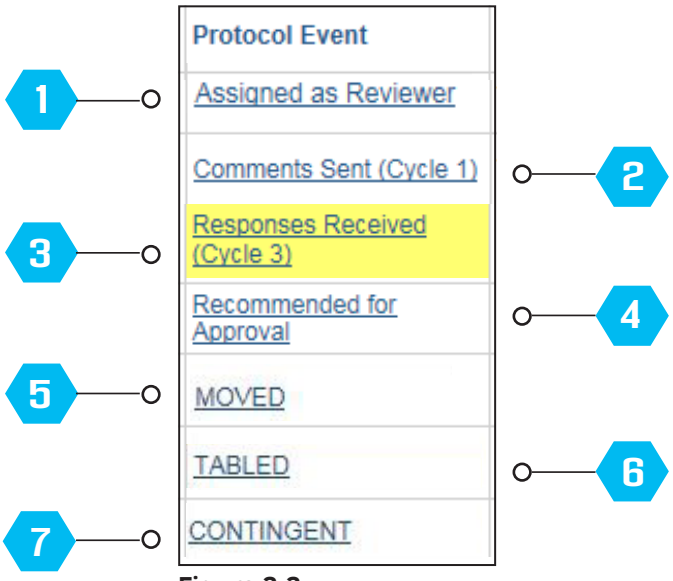


Figure 2.2

1 **Assigned as Reviewer** - You are assigned as the reviewer for that specific protocol.

2 **Comments Sent (Cycle 1)** - Comments on the protocol are sent to the PI.

3 **Responses Received (Cycle 1)** - The PI 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.

4 **Recommended for Approval** - Reviewers recommend the protocol for approval.

5 **Moved** - The protocol is moved to another meeting date from the assigned meeting date.

6 **Tabled** - The protocol which is not completely discussed due to some unresolved issues during the meeting, has the Tabled status. When the protocol is tabled, the review process should be re-initiated by the committee for further processing.

7 **Contingent** - The protocol is approved on contingent criteria. Contingent Approval is also known as modification required to secure approval.

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 protocol, click on the active link located under the Protocol Event column and in the same row as the specified Protocol ID number [Figure 2.1 page 5]. Each comments page is tied to a specified protocol. To verify you are within the correct protocol, check that the Protocol ID number, as seen highlighted below, is accurate.

Figure 2.3

Comments Page Functionality

Figure 2.4

1 **Guidelines** - The **Guidelines** button results in a pop-up window [Figure 2.5] allowing the user to view the guidelines. Clicking on any of the links within the pop-up further explains the guideline.

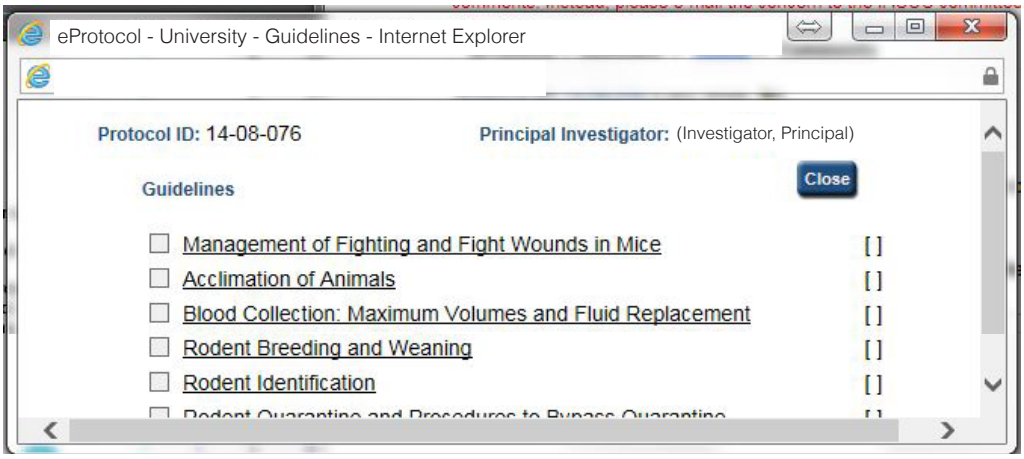


Figure 2.5

2 **Get Protocol** - Clicking on the **Get Protocol** button activates a pop-up window that allows reviewers to move back and forth between the protocol and comment windows.

3 **Reviewers** - The **Reviewers** button results in a pop-up window [Figure 2.6] displaying a list of reviewers assigned to the protocol.

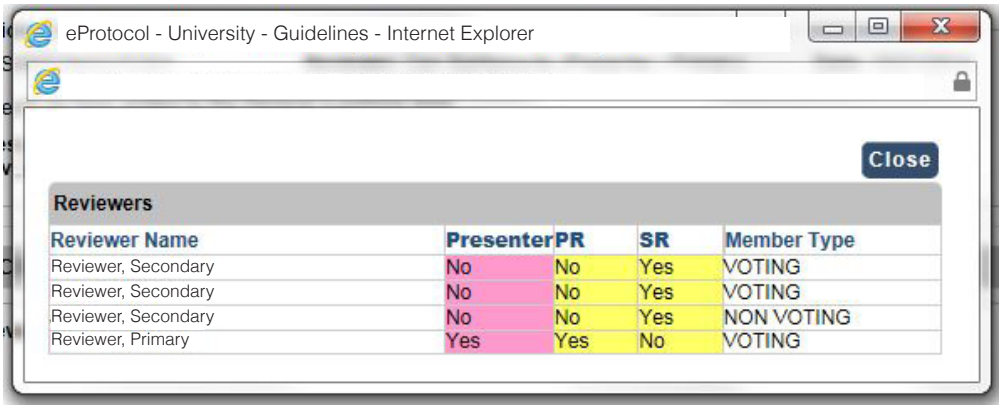


Figure 2.6

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

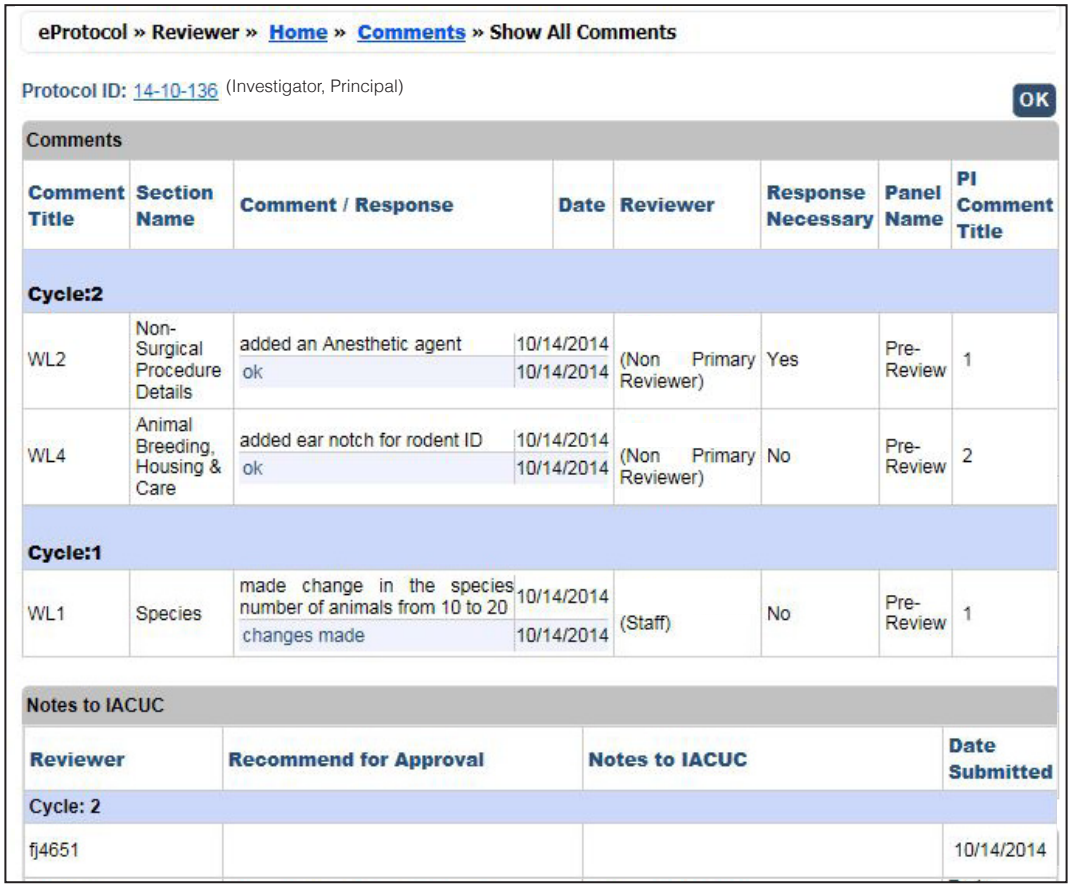


Figure 2.7

5 **Recommend for Approval** - If the protocol 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 IACUC section.

Once complete, click **Submit to IACUC** to send off the revised protocol.

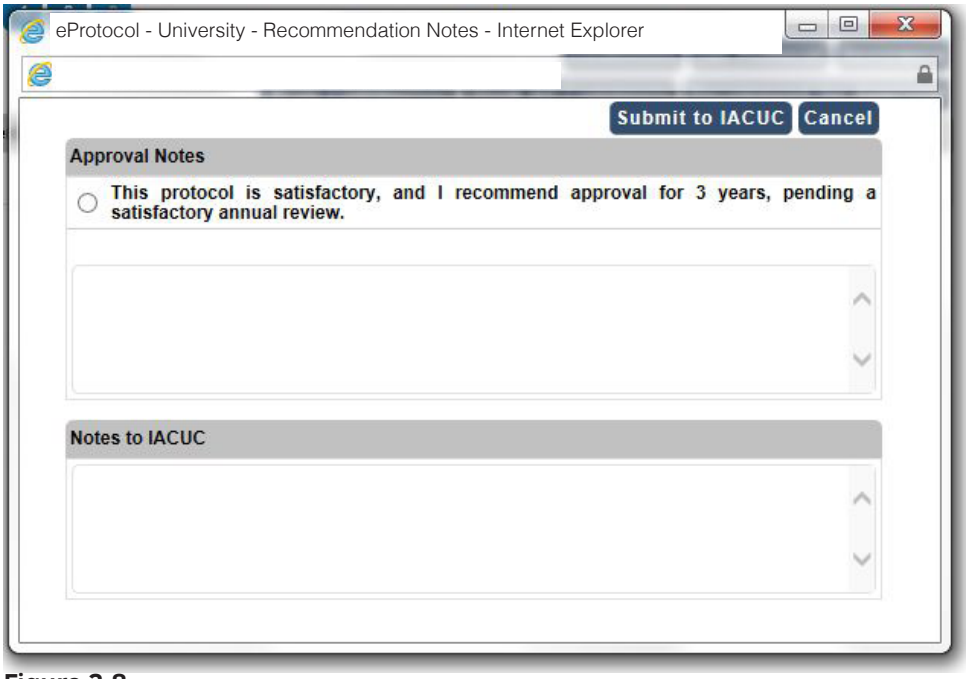


Figure 2.8

6 **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. See how to write a comment below.

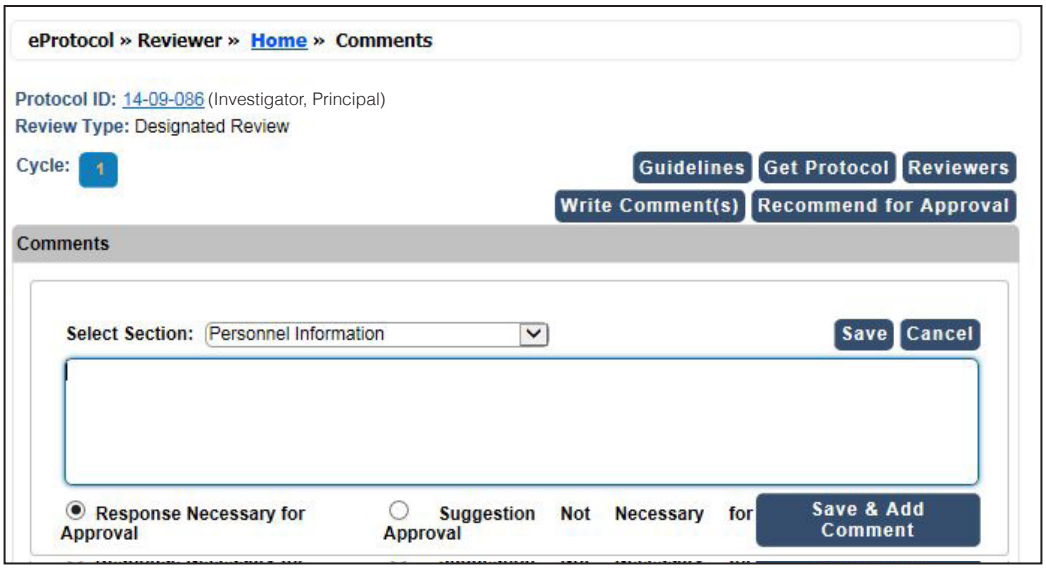


Figure 2.9

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. The button **Recommend for Approval,** has also been replaced by **Submit to IACUC.**

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

7 **Edit All Comments** - The **Edit All Comments** button enables editing on all comments in the protocol.

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 9 and Figure 2.10 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 protocol. The RCA (Research Compliance Administrator) 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. The Principal Investigator must then send his/her responses to the comments to the Reviewer(s) which is called **Responses Sent (Cycle 1)**.

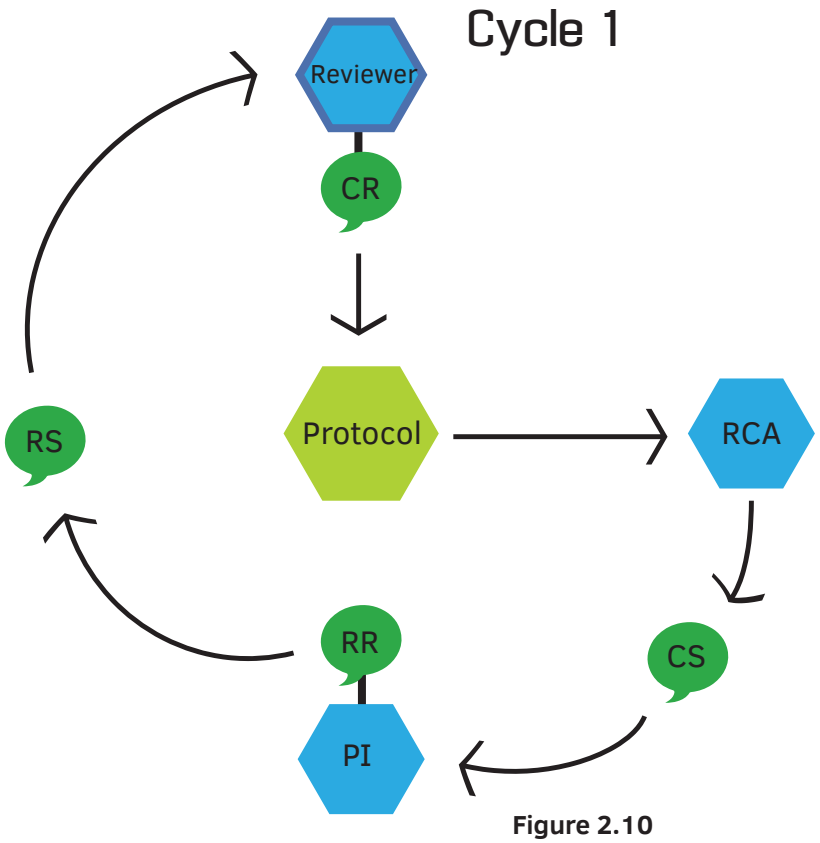


Figure 2.10

3 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 job title and click on the menu tab titled **Search Protocol.**

You will be directed to a search page like the one shown in Figure 3.1. 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.

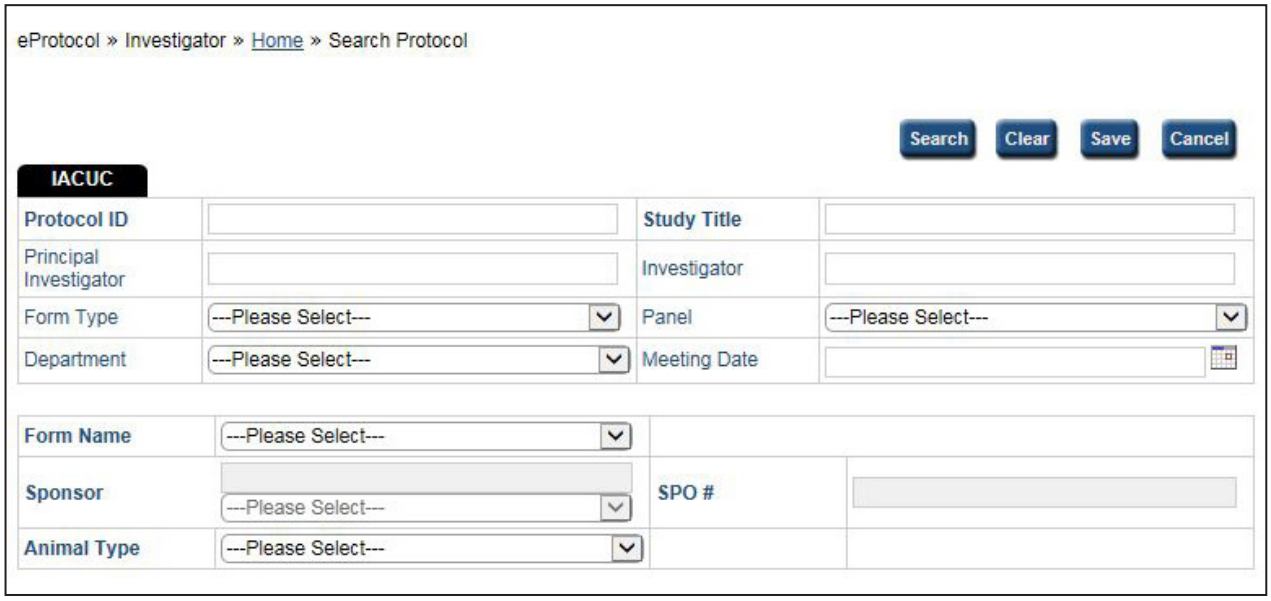


Figure 3.1

4 SUMMARY

You have successfully completed the Reviewer Role Manual. We hope you have a better understanding of the overall functionality, job duties and requirements of the Reviewer. To review the general 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 and/or the Committee Manager and RCA Role Manual.