eProtocol

IRB Reviewer Role Manual

MARCH 2018

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1 OVERVIEW

The IRB Reviewer Role Manual examines the functions, job duties and requirements of an eProtocol user logging in as an IRB 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 IRB 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 Firefox 12 or higher or Apple Safari.

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

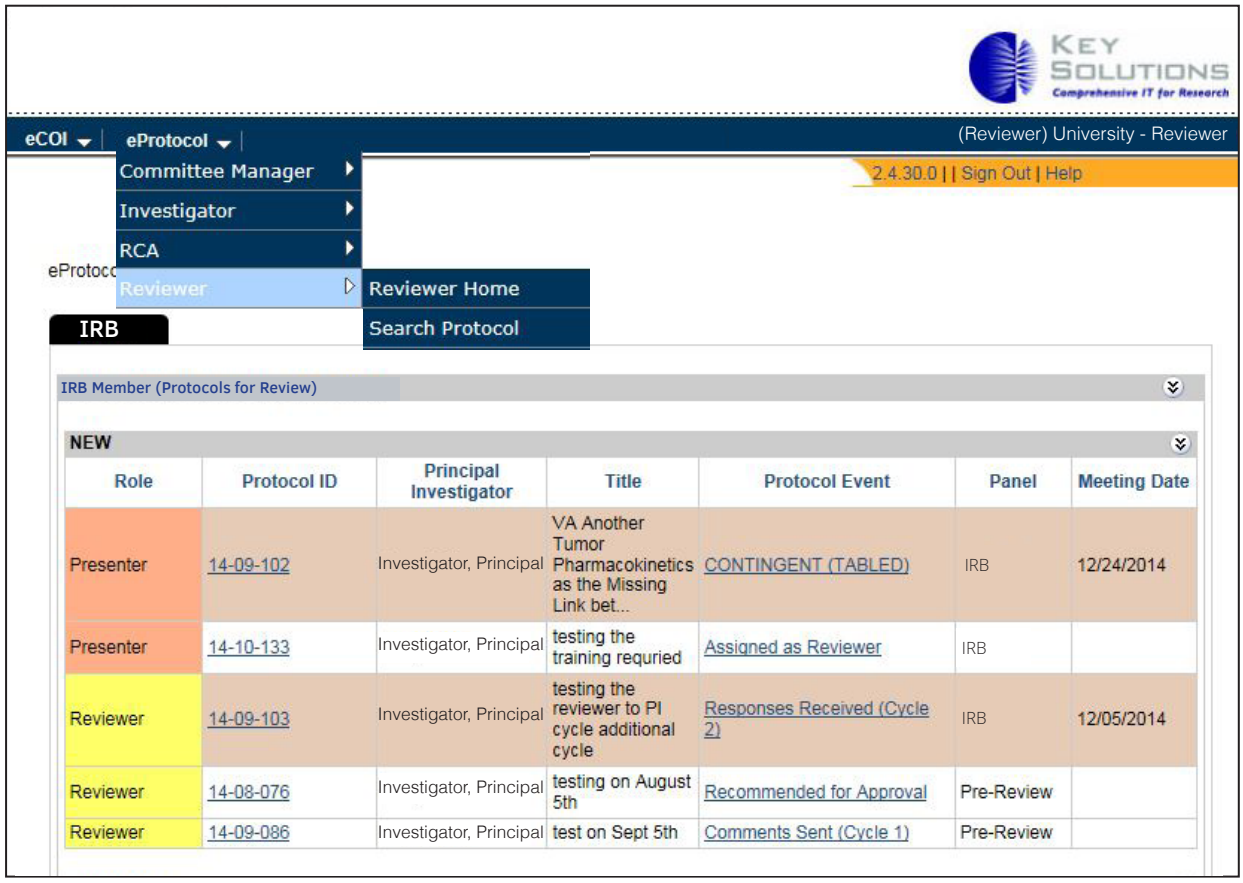
There are numerous pop-up windows used in the software. Don't forget to resize the screens to better suit your view.

NOTE: Sometimes pop-up windows will hide behind other applications when open.

2 REVIEW PROCESS

2.1 IRB Reviewer Role Overview

Your responsibility as an IRB 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 write comments, see reviewers, or obtain the Protocol checklists, 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)	IRB	12/24/2014
Presenter	14-10-133	Investigator, Principal	testing the training requried	Assigned as Reviewer	IRB	
Reviewer	14-09-103	Investigator, Principal	testing the reviewer to PI cycle additional cycle	Responses Received (Cycle 2)	IRB	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]. Status types will include the following [Figure 2.2]:

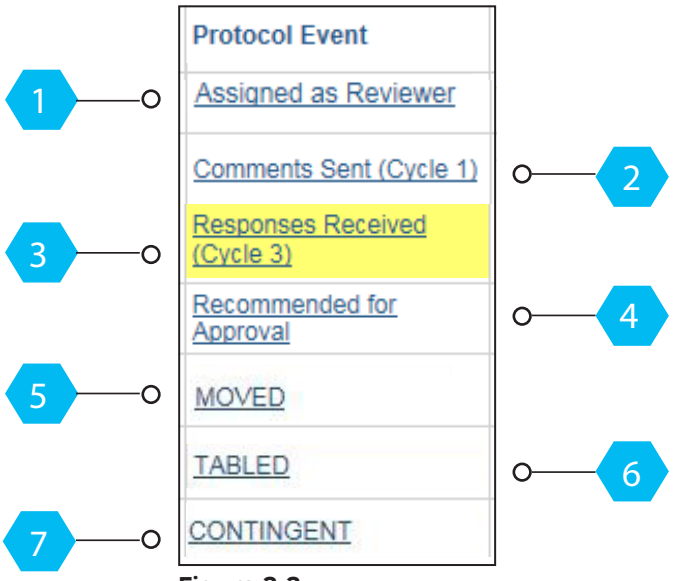


Figure 2.2

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 will require another full committee review. It is the responsibility of the PI to make the changes and resubmit the protocol.

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

2.3 Comments Page

The Comments Page is an important page for all reviewers 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 **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.

2 **Reviewers** - The **Reviewers** button results in a pop-up window [Figure 2.5] displaying a list of reviewers assigned to the protocol. Reviewer types are: Primary Reviewer (PR) and Secondary Reviewer (SR). The Primary Reviewer will also be the Presenter. All other IRB members will also be listed as a Secondary Reviewer in this section.

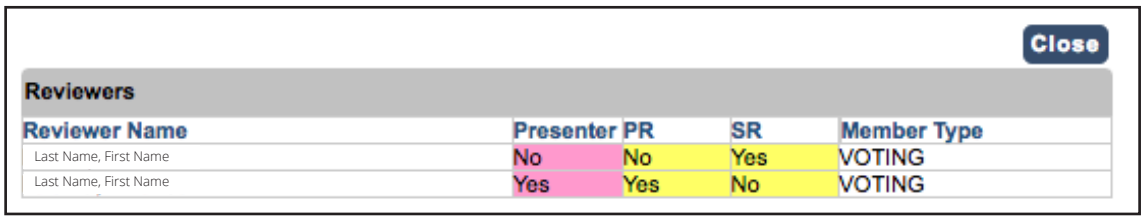


Figure 2.5

3 **Checklists** - The **Checklist** button results in a pop-up window [Figure 2.6]. The reviewer sheet must be completed, confirming that the PI has submitted the proper information regarding the protocol.

Children Reviewer Checklist - This tab [Figure 2.7] needs to be filled out by the reviewer if children are participants of the protocol.

Print - The **Print** tab results in a pop-up window [Figure 2.8] that the reviewer can use to print the protocol and checklist(s).

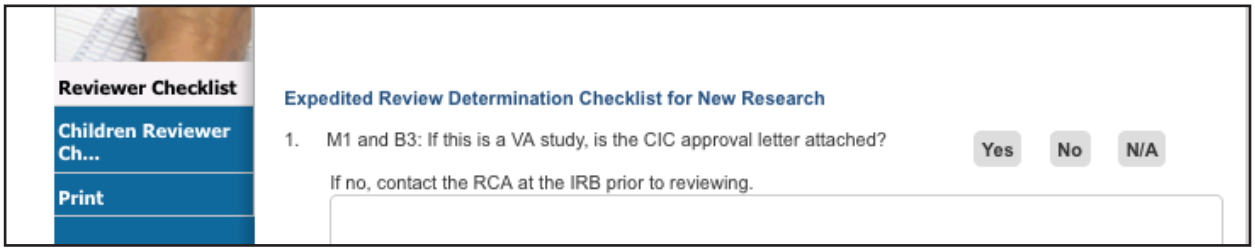


Figure 2.6

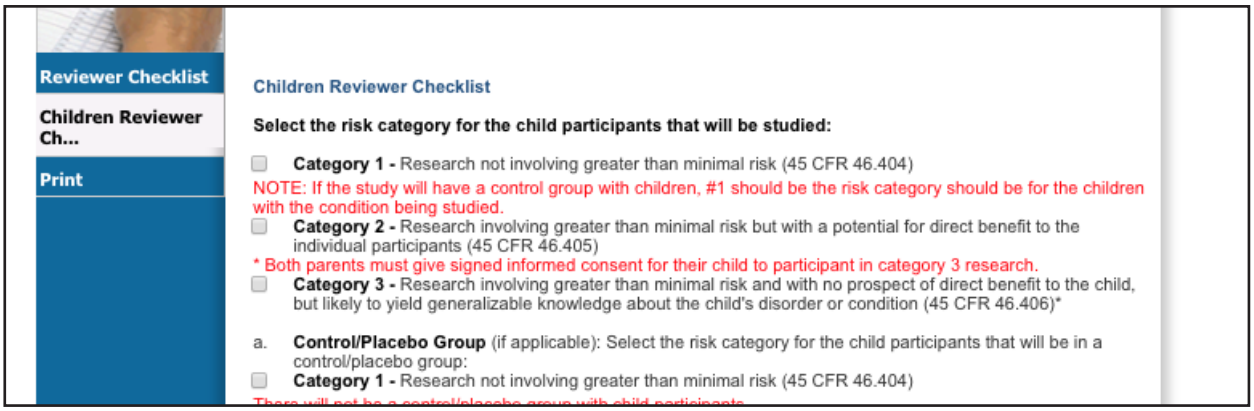


Figure 2.7

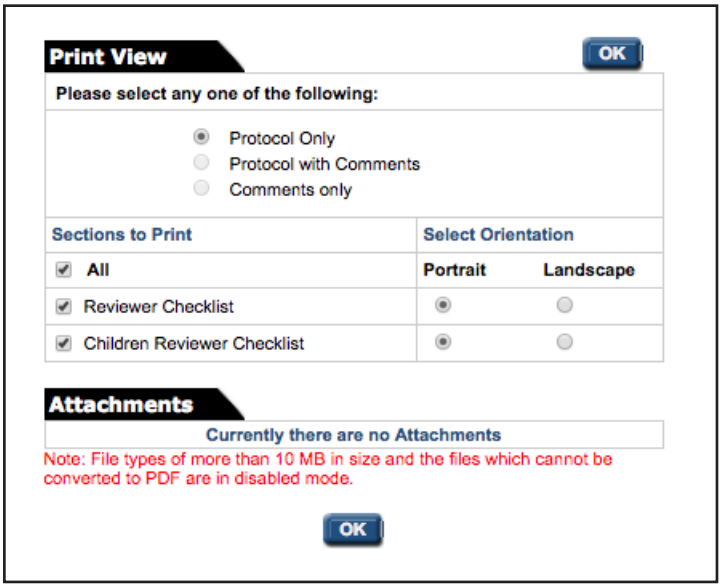


Figure 2.8

4 **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.

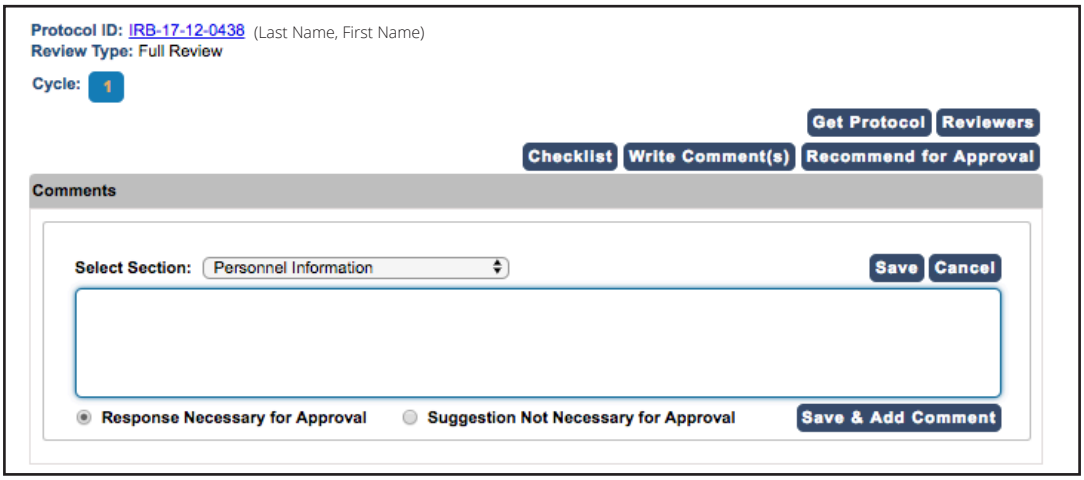


Figure 2.9

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

4. If the necessary comments have been added and the protocol is reviewed, you may now click **Submit to IRB.** Comments must be submitted to the IRB, for the Research Compliance Administrator (RCA) to forward on to the investigator.

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

6 The **Show All Comments** button allows the user to view a list of all the comments and notes within the protocol [Figure 2.10].

eProtocol » Reviewer » Home » Comments » Show All Comments

Protocol ID: IRB-17-12-0438 (Last Name, First Name)

OK

Comments

Comment Title	Section Name	Comment / Response	Date	Reviewer	Response Necessary	Panel Name	PI Comment Title
Cycle:1							
LALAMAA1	Personnel Information	Hello! Comment is not submitted to Manager.	02/06/2018	(Last Name, First Name) (Presenter / Primary)	Yes	PH1	

Notes to IRB

Reviewer	Recommend for Approval	Notes to IRB	Date Submitted
Cycle: 1			
gq0701			

Figure 2.10

7 **Recommend for Approval** - If the protocol has been reviewed and is ready to submit, the Reviewer can click the **Recommend for Approval** button which results in a pop-up like the one shown in Figure 2.11.

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

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

NOTE: For full board reviews, final determinations/votes are conducted at the convened IRB meeting.

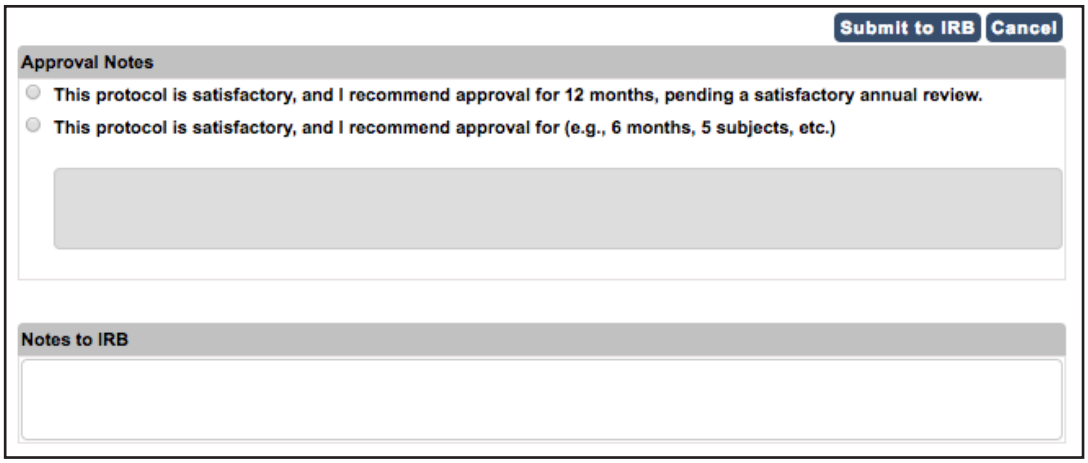


Figure 2.11

8 **Submit to IRB** - If a comment has been added, the **Recommend for Approval** button will be replaced with the **Submit to IRB** button. If the protocol is ready to submit, the Reviewer can click the **Submit to IRB** button which results in a pop-up like the one shown in Figure 2.12.

If you're ready, click **OK** to send off the revised protocol.

Figure 2.12

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 2.13 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 RCA(s) which is called **Responses Sent (Cycle 1)**.

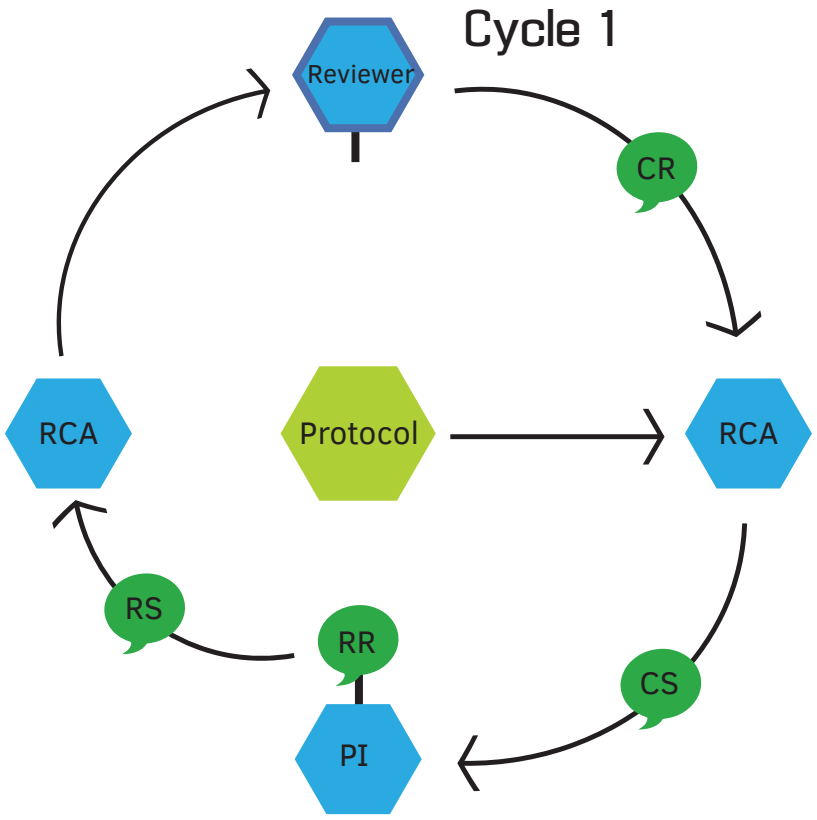


Figure 2.13

3 SEARCH PROTOCOL

Overview

No matter your role, all users have the ability to search a protocol. A user can access the Search Protocol page by first selecting the eProtocol menu on the top left menu bar [Figure 3.1]. 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 3.2. 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.

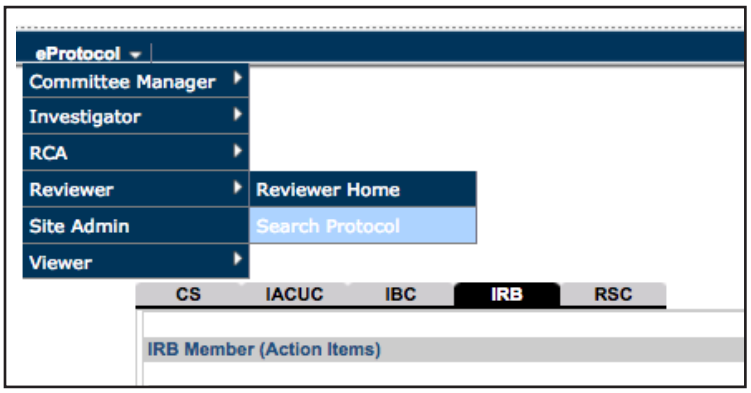


Figure 3.1

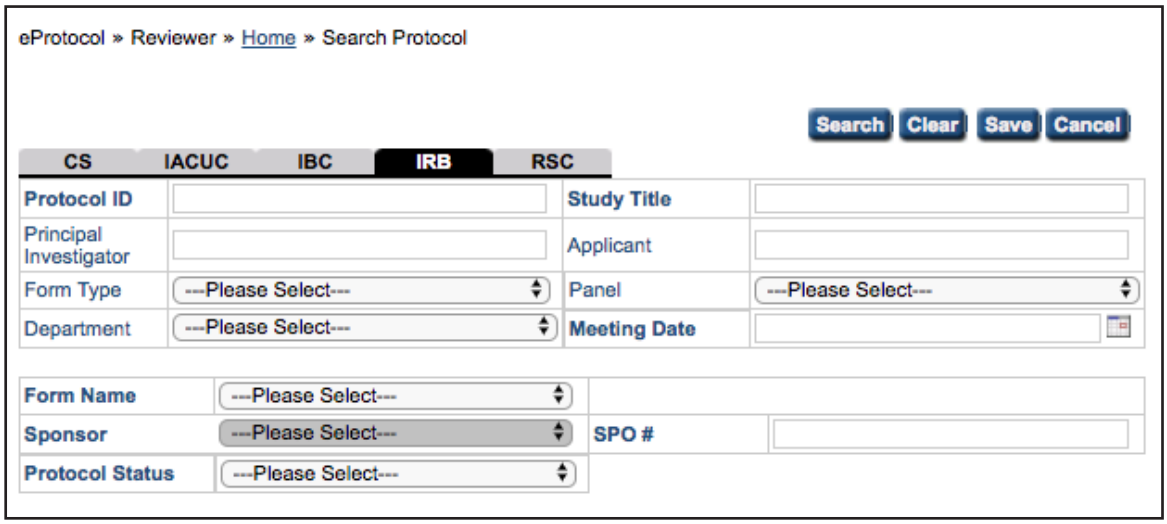


Figure 3.2

4 SUMMARY

You have successfully completed the IRB Reviewer Role Manual. We hope you have a better understanding of the overall functionality, job duties and requirements of the IRB 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.