



**eProtocol - Protocol Management System (PMS)  
Reviewer User Guide**

*Version 2.0*

Last Updated: 05/18/2011  
Product Version: 2.0.16

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## 1. Introduction

### 1.1. Purpose of the Document

This document explains the steps to perform various functions of Reviewer in Protocol Management System (PMS), a web-based protocol management system developed by Key Solutions Inc.

### 1.2. Intended Audience

This document is meant for Reviewer to learn working with the Reviewer role of Protocol Management System (PMS).

### 1.3. Scope of the Document

To proceed with the conduction of research, Investigator has to prepare the protocol document presenting various key elements of the research planned in the format proposed by the committee and submit it to the corresponding committee. The committee assigns it to the expert review panel for review and approval. The reviewers in the panel upon the request from Panel Manager have to perform various functions like - review the protocol, recommend for approval or write comments, submit the reviewer checklist, etc. This document explains how Reviewer can perform all these functions online in Protocol Management System (PMS).

### 1.4. Definitions

Protocol ID – A unique ID assigned to a protocol when it is created for identification purpose, and it stays with the protocol throughout its lifecycle - all the way to the archival.

Form Name – This denotes the name of the protocol form. The names vary for different forms e.g., 'Social, Behavioral & Education Research', 'Biomedical Exempt', 'IACUC form', 'Biosafety form', etc.

Form Type - This denotes the type of the protocol form whether it's New, Amendment, Continuing Review, Incident Report/ Protocol Deviation Report, or Study Closure Form, etc. The values vary for different committees.

Review Type – This denotes the type of review of the protocol form. e.g., Fullboard, Expedited, Exempt.

Review Cycle Type – This denotes the type of review for which the protocol is assigned, e.g., Designated Review, Full Review, Administrative Review, etc. The values vary for different committees.

Panel – This denotes the name of the panel reviewing the protocol.

Meeting Date – This denotes the date of meeting on which the protocol form is proposed for review.

### 1.5. Acronyms

PMS - Protocol Management System

PI – Principal Investigator

PM – Panel Manager

PR – Primary Reviewer

SR – Secondary Reviewer

NPR – Non Primary Reviewer

## **1.6. References**

eProtocol PMS application is referred in preparation of this document.

## **1.7. Assumptions**

It is assumed that the readers of the document have knowledge of the research protocol document preparation, submission, review and approval, so that they can understand how PMS can help in the process and successfully use this application.

## 2. Product Workflow Diagram

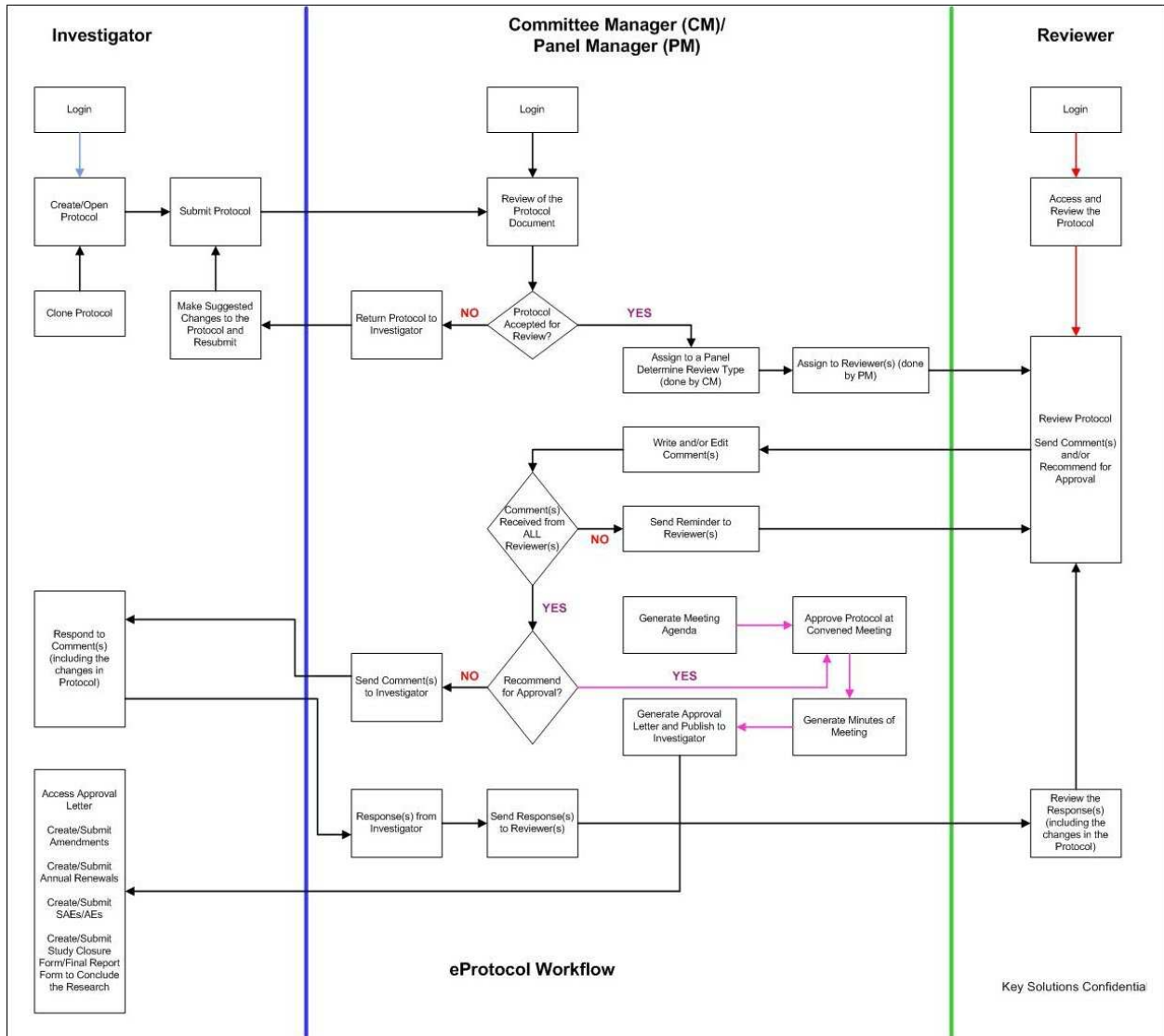


Fig 1: PMS Basic Workflow

### 3. Starting eProtocol

eProtocol application can be accessed from any computer system with a relatively current version of a web browser -- including Internet Explorer, Firefox and Safari. It can be accessed via the Internet, or an organizational Intranet, depending on the access policies of the organization.

The first page displayed upon activating the URL link is the login window of the eProtocol Application.



**ePROTOCOL**  
enabling paperless research compliance

**KEY SOLUTIONS**  
Comprehensive IT Services

version 2.0.18

**ePROTOCOL**

Key Solutions, Inc. has designed and developed e-Protocol Management System to strengthen the Human Subjects clinical research environment and enhance the protection of Human Subjects involved in the research to meet the ethical standards and the regulatory research compliance requirements.

e-Protocol Management System is a total web based solution that automates the research approval processes. It is used for electronic protocol submission, protocol routing / reviewing / tracking that would enable investigators , IRB members, and research administrators to process protocol applications online.....

**User ID**

**Password**

**Login** **Forgot Password**

Fig 2: eProtocol Login page

1. Enter the User ID and Password for Reviewer.
2. Click **Login**, or press **Enter**. Reviewer Home page is displayed.

**Note:** If the User ID and/or Password are incorrect, a message stating "Login Failed. Invalid User ID or Password" will be displayed.

## 4. Reviewer Home Page

The functions of a Reviewer are to review the protocols assigned for review by Panel Manager, give recommendations on the protocol review – Full Review or Designated Review -, recommend a protocol for approval when it meets the approval criteria, give comments on the protocol, and attend the review meetings and give voting decision. When Panel Manager assigns a protocol for review, it is automatically displayed on the **Home** page of Reviewer.

Reviewer is directed to the **Home** page after login. Reviewer can go to the **Home** page at any stage by clicking on **Reviewer** on top menu or by clicking on **Reviewer Home** displayed after pointing to **Reviewer**.

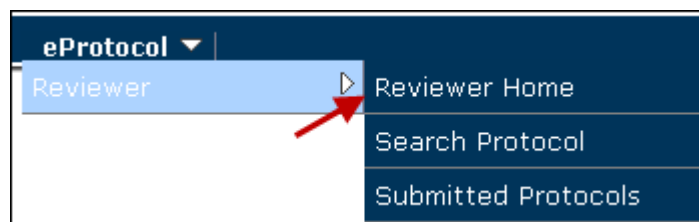


Fig 3: Menu

IRB						
<b>IRB Member (Protocols for Review)</b>						
<b>NEW</b>						
Role	Protocol ID	Principal Investigator	Department Name	Protocol Event	Panel	Meeting Date
Presenter	<a href="#">11-05-1859</a>	Goodwin, Scott	Admin	<a href="#">Comments Sent (Cycle 1)</a>	Test Panel	05/06/2011
<b>AMENDMENT</b>						
Role	Protocol ID	Principal Investigator	Department Name	Protocol Event	Panel	Meeting Date
Presenter	<a href="#">11-01-1306</a>	Goodwin, Scott	Advancement Systems	<a href="#">Assigned as Reviewer</a>	Test Panel	01/02/2011
Reviewer	<a href="#">10-06-816</a>	Atherton, Michael		<a href="#">Assigned as Reviewer</a>	Test Panel	
<b>CONTINUING REVIEW</b>						
<b>REPORT</b>						
Role	Protocol ID	Principal Investigator	Department Name	Protocol Event	Panel	Meeting Date
Presenter	<a href="#">11-01-1297</a>	Wrangler, Kites		<a href="#">Assigned as Reviewer</a>	Test Panel	09/01/2011
Presenter	<a href="#">10-06-842</a>	Atherton, Michael		<a href="#">Comments Sent (Cycle 1)</a>	Test Panel	12/07/2010
<b>SAE REPORT FORM</b>						
Role	Protocol ID	Principal Investigator	Department Name	Protocol Event	Panel	Meeting Date
Reviewer	<a href="#">11-01-1301</a>	Wrangler, Kites		<a href="#">Assigned as Reviewer</a>	Test Panel	09/01/2011
Presenter	<a href="#">10-06-842</a>	Atherton, Michael		<a href="#">Comments Sent (Cycle 1)</a>	Test Panel	12/07/2010
<b>FINAL REPORT</b>						
Role	Protocol ID	Principal Investigator	Department Name	Protocol Event	Panel	Meeting Date
Reviewer	<a href="#">11-01-1322</a>	Wrangler, Kites		<a href="#">Assigned as Reviewer</a>	Test Panel	09/01/2011
Presenter	<a href="#">10-06-845</a>	Atherton, Michael		<a href="#">Assigned as Reviewer</a>	Test Panel	12/07/2010
Presenter	<a href="#">10-06-735</a>	Atherton, Michael		<a href="#">Recommended for Approval</a>	Test Panel	14/06/2010
Presenter	<a href="#">10-05-674</a>	Goodwin, Scott		<a href="#">Assigned as Reviewer</a>	Test Panel	14/06/2010

Fig 4: Home page

All the committees in your site are displayed in the committee tab. Under each committee, protocols are categorized and displayed in the **Committee Member (Protocols for Review)** section. Select the committee to view the protocols of the committee.

Note:

- The types of protocols/forms vary for each committee.
- Click **Show/Hide** button to view/hide the protocols list in the selected section.

### Form Types

Different Protocol Form Types are explained below.

1. **New:** The protocols that are newly created by Investigators are displayed.
2. **Amendment:** The revision forms for approved protocols containing the revisions made after protocol approval are displayed.



3. **Continuing Review:** The renewal forms for approved protocols that are submitted before their expiration are displayed.
4. **Protocol Deviation:** The deviation forms created for approved protocols reporting an incident of deviation or violation or participant non-compliance are displayed.
5. **Report:** The report forms created for approved protocols reporting the events or new information that may pose risks to subjects or others and alter the risks, benefits, or alternatives to subjects are displayed.
6. **Final Report:** The final report forms created to close the approved protocols for which the research is concluded are displayed.

On **Home** page, the details of a protocol are categorized and displayed in the following columns.

### Role

The role assigned by the Panel Manager to review the protocol is displayed in the column. The roles are – Presenter, Reviewer (when assigned as Primary Reviewer or Secondary Reviewer), and NPR (when assigned as Non Primary Reviewer).

### Protocol ID

Protocol ID, a unique ID assigned to a protocol when it is created, is displayed in the column. It is the default method to identify and differentiate protocols, though each protocol is given a title by Principal Investigator. This Protocol ID stays with the protocol throughout its life cycle.

### Principal Investigator

The name of the Principal Investigator of the protocol is displayed in this column.

### Department Name

The name of the Department the Principal Investigator belongs to is displayed in this column.

### Protocol Event

The event happening for the protocol is displayed in the column. Different protocol events are explained below.

- a. **Assigned as Reviewer:** You have been assigned as a reviewer for the protocol, and you have not yet started the review or started the review but did not send approval decision or comments to the Panel Manager.
- b. **Recommended for Approval:** You have recommended the protocol for approval.
- c. **Comments Sent (Cycle 1):** You have submitted comments for the protocol.
- d. **Responses Received (Cycle 1):** The Panel Manager has forwarded the responses of Investigators to the comments submitted.
- e. **Moved:** The protocol is moved to some other meeting date from the assigned meeting date. In this state, you can continue the review process.
- f. **Tabled:** The protocol is not completely discussed due to some unresolved issues during the meeting and tabled for discussion in another meeting. When a protocol is tabled, the review process should be re-initiated by the committee for further processing. In this state, you can continue the review process.
- g. **Contingent:** Protocol is approved on contingent criteria. Contingent Approval is also known as Conditional Approval. In contingent status, the Panel Manager can directly communicate with Investigator without your comments. However, you can continue the review process.

**Note:**

If there are further comments/responses cycles, those will be numbered with higher cycle numbering: from 1 to 2, to 3, and so on.

**Panel**

The name of the panel that is reviewing the protocol is displayed in the column.

**Meeting Date**

The meeting date assigned to the protocol by the Panel Manager is displayed in the column.

**Note:**

- Click the **Protocol ID** to view/edit the protocol.
- Click **Column Heads** to sort the protocols in ascending/descending order.
- Click **Responses Received/Comments Sent** in Comments column to view Comments/Response Cycles and send your review comments to the Panel Manager. **Comments** page is displayed.
- If you are Non Primary Reviewer of a protocol, the protocol is not displayed on your dashboard in general. Based on the configuration by the administrator, the protocol is displayed on your dashboard after the Panel Manager publishes the agenda to you.

## 5. Reviewer Functions

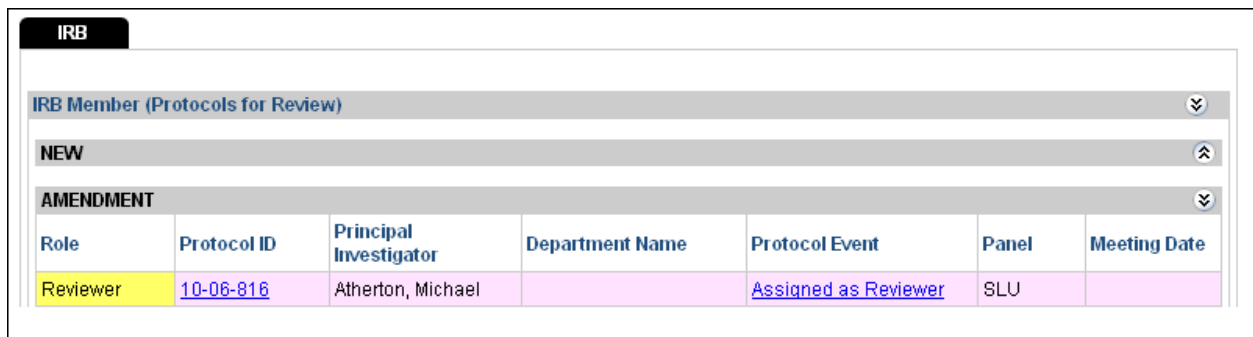
### 5.1. Give Review Decision for a Protocol

The Panel Manager may request you to give your decision whether a protocol should undergo Full or Designated Review. In such case, you have to give your preference to further the review process.

Follow the steps given below to give your review preference for a protocol.

Step 1

Go to **Home** page.



The screenshot shows the IRB Home page. At the top, there is a navigation bar with 'IRB' and a dropdown menu for 'IRB Member (Protocols for Review)'. Below this, there are sections for 'NEW' and 'AMENDMENT'. A table displays the following data:

Role	Protocol ID	Principal Investigator	Department Name	Protocol Event	Panel	Meeting Date
Reviewer	<a href="#">10-06-816</a>	Atherton, Michael		<a href="#">Assigned as Reviewer</a>	SLU	

Fig 5: Home page

Step 2

The protocol for which the Panel Manager has requested review preference will have light pink background with the protocol event - **Assigned as Reviewer**. Click the event. You are directed to **Comments** page.



The screenshot shows the Comments page for protocol ID 10-06-816 (Atherton, Michael). The page includes a breadcrumb trail 'Home » Comments', a protocol ID link, and a copy icon. There are two buttons: 'Reviewers' and 'Checklist'. A 'Comments' section is visible with three buttons: 'Get Protocol', 'Get PDF', and 'Review Decision'. A red arrow points to the 'Review Decision' button. Below the buttons, a message reads: 'Please click on Review Decision to recommend either Designated or Full Review.'

Fig 6: Comments

Note:

Click **Get Protocol** button or **Protocol ID** to view the protocol.

Step 4

Click **Review Decision** button. **Review Decision** popup is displayed.

The screenshot shows a web form titled "Review Decision" for Protocol ID 10-06-816, Form Type: AMENDMENT, and Deadline Date: 20/12/2010. The form has a header with the title and two buttons: "Submit" and "Cancel". Below the header, there are two radio button options: "Designated Review" and "Full Review". Below the options is a large text area labeled "Notes to IRB".

Protocol ID: 10-06-816      Form Type: AMENDMENT      Deadline Date: 20/12/2010

**Review Decision**      **Submit**      **Cancel**

Designated Review       Full Review

**Notes to IRB**

[Large empty text area for notes]

Fig 7: Review Decision popup

**Step 5**

Select **Designated Review** or **Full Review**, enter notes, and click **Submit**. You are directed to **Home** page and the protocol disappears from dashboard. However, the protocol reappears on the **Home** page when you are assigned as reviewer.

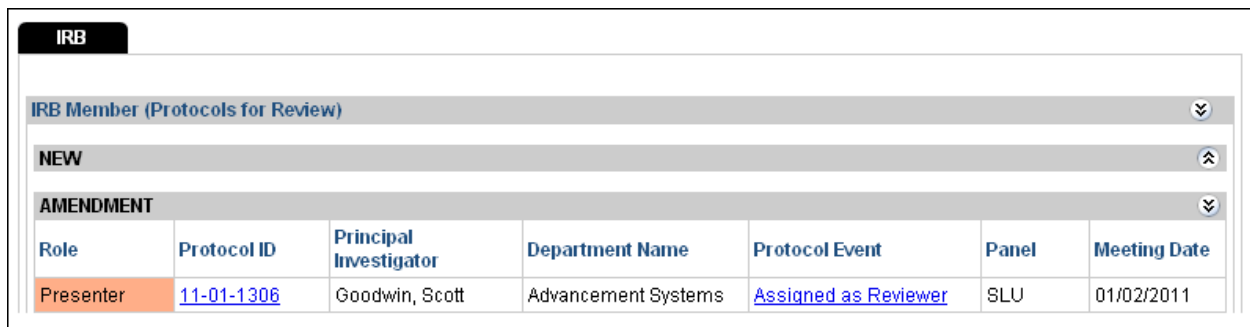
## 5.2. Recommend the Protocol for Approval

After reviewing the protocol, you can recommend the protocol for approval if you are satisfied that the protocol meets the required guidelines and contains required information. If you are not satisfied with any section information/aspect of the protocol, you can write comments and submit them to Panel Manager.

Follow the steps given below to recommend a protocol for approval.

### Step 1

Go to **Home** page.



The screenshot shows the IRB Home page. At the top, there is a navigation bar with 'IRB' and a dropdown menu for 'IRB Member (Protocols for Review)'. Below this, there are sections for 'NEW' and 'AMENDMENT'. The 'AMENDMENT' section contains a table with the following data:

Role	Protocol ID	Principal Investigator	Department Name	Protocol Event	Panel	Meeting Date
Presenter	<a href="#">11-01-1306</a>	Goodwin, Scott	Advancement Systems	<a href="#">Assigned as Reviewer</a>	SLU	01/02/2011

Fig 8: Home page

### Step 2

The protocol which you are supposed to review and give your approval decision will have white background with the protocol event - **Assigned as Reviewer**. Click the event. You are directed to **Comments** page.



The screenshot shows the Comments page for protocol 11-01-1306. The page has a breadcrumb trail 'Home » Comments'. The protocol details are: Protocol ID: [11-01-1306](#) (Goodwin, Scott) and Review Type: Designated Review. There are three buttons: 'Recommend for Approval', 'Reviewers', and 'Checklist'. Below these, there is a 'Comments' section with three buttons: 'Get Protocol', 'Get PDF', and 'Write Comment(s)'. A message at the bottom says 'Please click on Write Comment(s) to add Comment(s)'.

Fig 9: Comments

### Step 3

You have to review and respond to checklist items before submitting your recommendation for approval. Click **Checklist** button in **Comments** page. **Reviewers Checklist** page is displayed.

[Home](#) » [Comments](#) » Reviewer Checklist

Protocol ID: [11-01-1306](#) (Goodwin, Scott ) [Print](#)

Study Title: Biomedical Research Form

**Reviewer Checklist** [Save](#) [Close](#)

	Yes	No	N/A
<b>Personnel Information (Research Team)</b>			
Personnel have appropriate experience to perform selected duties	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Background and Purpose</b>			
There are adequate past findings to justify the research	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The purpose and objectives of the research are clearly stated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

[Save](#) [Close](#)

**NOTE: To open the Protocol click on the Protocol ID link**

Fig 10: Reviewers Checklist

**Step 4**

Select Yes/No/Not Applicable options for various checklist items. You can go to previous and next list of items by clicking on **Previous** and **Next** buttons (if present due to more number of checklist items).

**Step 5**

When you are done, click **Save** and click **Close**. You are directed to **Comments** page. The checklist is sent to Panel Manager when you submit recommendation, and you are not allowed to edit the checklist items after that.

**Step 6**

Click **Recommend for Approval** button. **Recommendation Notes** popup is displayed.

Fig 11: Recommendation Notes

**Step 7**

Select the option – “The proposed changes...” - and enter approval notes below.

**Note:**

The options in Approval Notes area vary based on the application design.

**Step 8**

Write notes to Panel Manager, if any, in **Notes to Committee**.

**Step 9**

Click **Submit to Committee**. You are directed to **Home** page with the event changed as **Recommended for Approval** in Protocol Event column.

IRB						
IRB Member (Protocols for Review)						
NEW						
Role	Protocol ID	Principal Investigator	Department Name	Protocol Event	Panel	Meeting Date
Presenter	<a href="#">10-01-312</a>	Ravuri, Tulasi	Pharmacy	<a href="#">Recommended for Approval</a>	SLU	01/05/2010

Fig 12: Home page

**Note:**

- In **Comments** page, click the **Protocol ID** or **Get Protocol** button to view the protocol.
- When you recommend a protocol for approval, a mail is sent to Panel Manager with the details.

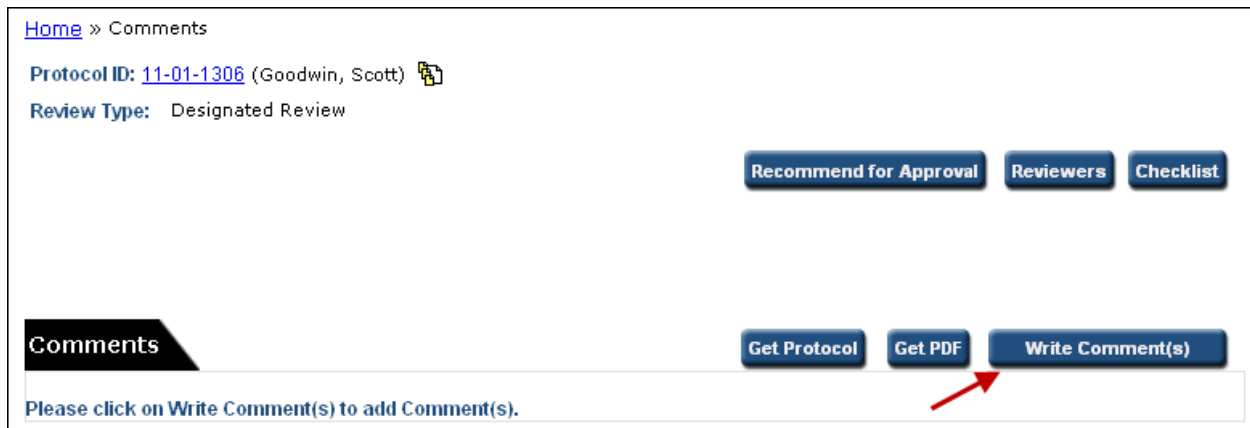
### 5.3. Comment on Protocol

After reviewing the protocol, if you are not satisfied with any section information/aspect of the protocol, you can write comments and submit them to Panel Manager.


Follow the steps given below to write and send your comments.

Step 1

On **Comments** page, click **Write Comment(s)** button. Comment text box is displayed below.



Home » Comments

Protocol ID: [11-01-1306](#) (Goodwin, Scott) 

Review Type: Designated Review

[Recommend for Approval](#) [Reviewers](#) [Checklist](#)

**Comments** [Get Protocol](#) [Get PDF](#) [Write Comment\(s\)](#)

Please click on [Write Comment\(s\)](#) to add Comment(s).

Fig 13: Comments



Home » Comments

Protocol ID: [11-01-1306](#) (Goodwin, Scott) 

Review Type: Designated Review

[Recommend for Approval](#) [Reviewers](#) [Checklist](#)

**Comments** [Get Protocol](#) [Get PDF](#) [Write Comment\(s\)](#)

Select Section:  [Save](#) [Cancel](#)

**Response Necessary for Approval**

**Suggestion Not Necessary for Approval**

[Save & Add Comment](#)

Fig 14: Comments



**Step 2**

From **Select Section** dropdown, select the section of the Protocol Application Form on which you wish to comment and write the comment below.

**Note:**

If you want to make a general comment, select **General** from **Select Section** dropdown.

**Step 3**

Select **Response Necessary for Approval**, if the Investigator's response to the comment is mandatory. Select **Suggestion Not Necessary for Approval**, if the Investigator's response to the comment is optional.

**Step 4**

Click **Save**. Your comment is saved. **Submit to Committee** button is enabled.

Home » Comments

Protocol ID: [11-01-1306](#) (Goodwin, Scott)

Review Type: Designated Review

Reviewers Checklist

Edit All Comments

Cycle: 1

**Comments** Get Protocol Get PDF Write Comment(s) Show All Comments Submit to IRB

Title:HM1 Select Section: Amendment Edit Delete

Test comment

Response Necessary for Approval  
 Suggestion Not Necessary for Approval

Fig 15: Comments

**Note:**

- To add another comment, click **Save & Add Comment** or click **Write Comment(s)** button. A new comment area is added below the existing comment(s).
- To edit more than one comment, click **Edit All Comments** button. **Edit All Comments** page is displayed. Make required changes and click **Save**. You are directed to **Comments** page with change saved.

**Step 5**

Click **Submit to Committee**. **Notes to Committee** popup is displayed.

Fig 16: Notes to Manager

**Step 6**

Write notes, if any, and click **Submit to Committee**. The comments are submitted to Panel Manager, along with the notes entered. You are directed to **Home** page with the event changed as **Comments Sent (Cycle 1)**.

Role	Protocol ID	Principal Investigator	Department Name	Protocol Event	Panel	Meeting Date
Presenter	<a href="#">11-01-1306</a>	Goodwin, Scott	Advancement Systems	<a href="#">Comments Sent (Cycle 1)</a>	SLU	01/02/2011

Fig 17: Home page

**Note:**

You need to fill in Reviewer Checklist before you send your comments. Refer to Steps 3, 4 and 5 in [Chapter 5.2](#).

**Step 7**

When you receive responses to your comments from Investigators (forwarded by Panel Manager), the event for the protocol is changed as **Responses Received (Cycle 1)**.

Role	Protocol ID	Principal Investigator	Department Name	Protocol Event	Panel	Meeting Date
Presenter	<a href="#">11-01-1306</a>	Goodwin, Scott	Advancement Systems	<a href="#">Responses Received (Cycle 1)</a>	SLU	01/02/2011

Fig 18: Home page

**Step 8**

Click protocol event. You are directed to **Comments** page, where you can view responses to your comments.

[Home](#) » Comments

Protocol ID: [11-01-1306](#) (Goodwin, Scott)

Review Type: Designated Review

[Reviewers](#) [Checklist](#)

Cycle: [1](#)

**Comments** [Get Protocol](#) [Get PDF](#) [Write Comment\(s\)](#) [Show All Comments](#)

Title: BONITAK1      Reviewer: Krall, Bonita

Select Section:

Test Comment

**Response Necessary for Approval**

**Suggestion Not Necessary for Approval**

Response

Test Response

Fig 19: Comments

**Step 9**

You can further comment on the protocol by following the steps above. New comment review cycle starts.

**Note:**

- In **Comments** page, click the **Protocol ID** or **Get Protocol** button to view the protocol.
- Click **Show All Comments** to view all comments/responses. **Show All Comments** page is displayed.
- Click **Cycle Number** to view the respective Comments/Responses. Present Comment/Response Cycle is shown in red color.
- Click **Guidelines** to view Guidelines.
- To edit a comment in the **Comments** page, click **Edit**. Make required edits and click **Save**.
- To delete a comment in the **Comments** page, click **Delete**.
- When you send comments, a mail is sent to Panel Manager with the details.
- When you get responses from Investigator forwarded by Panel Manager, you will receive a mail with all the details.

- If you select **Suggestion Not Necessary for Approval** for all the comments, **Submit to Committee** button is not enabled. You can recommend the protocol for approval by clicking on **Recommend for Approval** button.

### 5.4. Search Protocol

You can search for any protocol under your purview using the search protocol feature. Follow the steps given below to search for a protocol.

Point to **Reviewer** and click **Search Protocol**. **Search Protocol** page is displayed.

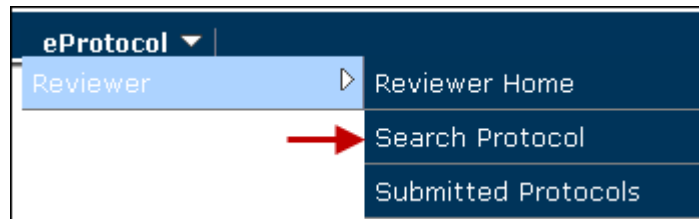


Fig 20: Menu

Home » Search Protocol

**IRB** Search Clear Save Cancel

Protocol ID	<input type="text"/>	Study Title	<input type="text"/>
Principal Investigator	<input type="text"/>	Investigator	<input type="text"/>
Form Type	AMENDMENT	Panel	-----Please Select-----
Meeting Date	<input type="text"/>	SPO #	<input type="text"/>
Sponsor	-----Please Select-----		

Selected Search Criteria: -----Please Select-----

Protocol ID	Principal Investigator	Department Name	Panel	Meeting Date	Expiration Date	Form Type
<a href="#">09-11-184</a>	Atherton, Michael	Pharmacy	IRB-1		11/29/2010	AMENDMENT
<a href="#">09-05-0005</a>	Atherton, Michael	Management	IRB-1	09/06/2009	04/30/2010	AMENDMENT
<a href="#">09-05-0003</a>	Atherton, Michael	Pharmacy	IRB-1	06/07/2009	04/30/2010	AMENDMENT

Fig 21: Search Protocol

Enter your search criteria in one or more fields and click **Search**. Search results are displayed below with all the related documents of the specified search criteria.

You can also save the search results. To save the search results, click **Save**. **Search Criteria** textbox is displayed. Enter a name for your search result and click **Save**. Search results are saved with the given name. You can refer to these search results any time later by selecting the name given (to the search result) from **Selected Search Criteria** dropdown.

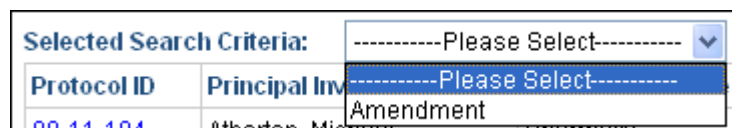


Fig 22: Search Protocol

**Note:**

- Click the **Protocol ID** to view the protocol.
- Click **Column Heads** to sort the protocols in ascending/descending order.
- Click **Clear** to clear the search criteria entered and start new search.
- You can save any number of search results using 'Save' feature and can view them at anytime using **Search Criteria** dropdown.