

eProtocol - Protocol Management System (PMS) Reviewer User Guide

Version 2.0

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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

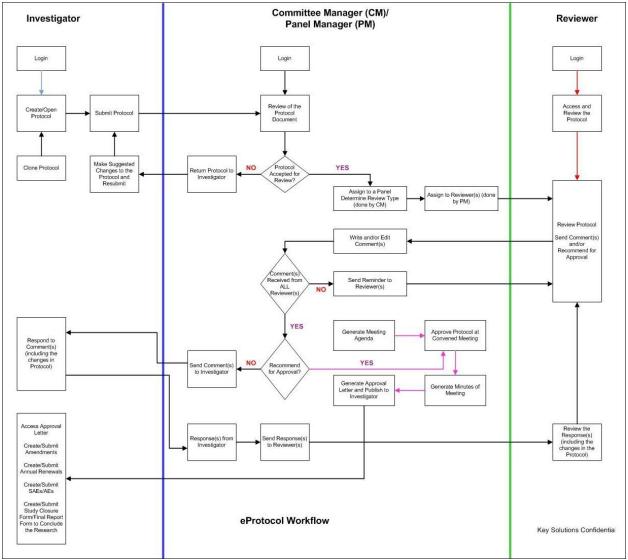
PMS - Protocol Management System PI – Principal Investigator PM – Panel Manager PR – Primary Reviewer SR – Secondary Reviewer NPR – Non Primary Reviewer

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.

enabling paperless research compliance	KEY SOLUTIONS Comprehensive IT Services
CPROTOCOL 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	version 2.0.16
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.

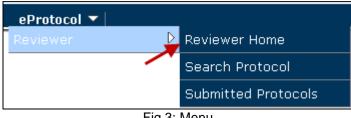


Fig 3: Menu

RB Member	(Protocols for Rev	iew)				۲
NEW						*
Role	Protocol ID	Principal Investigator	Department Name	Protocol Event	Panel	Meeting Date
Presenter	<u>11-05-1859</u>	Goodwin, Scott	Admin	Comments Sent (Cycle 1)	Test Panel	05/06/2011
AMENDMEN	т					*
Role	Protocol ID	Principal Investigator	Department Name	Protocol Event	Panel	Meeting Date
Presenter	<u>11-01-1306</u>	Goodwin, Scott	Advancement Systems	Assigned as Reviewer	Test Panel	01/02/2011
Reviewer	<u>10-06-816</u>	Atherton, Michael		Assigned as Reviewer	Test Panel	
CONTINUING	REVIEW					(*
REPORT						*
Role	Protocol ID	Principal Investigator	Department Name	Protocol Event	Panel	Meeting Date
Presenter	11-01-1297	Wrangler, Kites		Assigned as Reviewer	Test Panel	09/01/2011
Presenter	10-06-842	Atherton, Michael		Comments Sent (Cycle 1)	Test Panel	12/07/2010
SAE REPOR	T FORM					*
Role	Protocol ID	Principal Investigator	Department Name	Protocol Event	Panel	Meeting Date
Reviewer	<u>11-01-1301</u>	Wrangler, Kites		Assigned as Reviewer	Test Panel	09/01/2011
Presenter	<u>10-06-842</u>	Atherton, Michael		Comments Sent (Cycle 1)	Test Panel	12/07/2010
FINAL REPO	рт					×
Role	Protocol ID	Principal Investigator	Department Name	Protocol Event	Panel	• Meeting Date
Reviewer	11-01-1322	Wrangler, Kites		Assigned as Reviewer	Test Panel	09/01/2011
Presenter	10-06-845	Atherton, Michael		Assigned as Reviewer	Test Panel	12/07/2010
Presenter	10-06-735	Atherton, Michael		Recommended for Approval	Test Panel	14/06/2010
Presenter	10-05-674	Goodwin, Scott		Assigned as Reviewer	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.
- 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

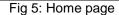
5.1. Recommend the Protocol for Approval

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.

IRB						
IRB Member (Protocols for Revi	iew)				۲
NEW						۲
AMENDMENT	ſ					۲
Role	Protocol ID	Principal Investigator	Department Name	Protocol Event	Panel	Meeting Date
Presenter	<u>11-01-1306</u>	Goodwin, Scott	Advancement Systems	Assigned as Reviewer	SLU	01/02/2011



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.



Fig 6: 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.

<u>Home</u> » <u>Comments</u> » Reviewer Checklist			
Protocol ID: <u>11-01-1306</u> (Goodwin, Scott)			Print
Study Title: Biomedical Research Form			
Reviewer Checklist	1	Save	Close
	Yes	No	N/A
Personnel Information (Research Team)			
Personnel have appropriate experience to perform selected duties			
Background and Purpose			
There are adequate past findings to justify the research			
The purpose and objectives of the research are clearly stated			

Fig 7: Reviewer 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.

Approval Notes	_	bmit to IRB	Cancel	
Proposed changes have been reviewed and a second	id approved			
				.:
lotes to IRB				

Fig 8: 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						
IRR Member (P	Protocols for Revie	(MA				*
NEW	10000013101100	, n ,				*
NEW		Principal				۴
Role	Protocol ID	Investigator	Department Name	Protocol Event	Panel	Meeting Date
Presenter	<u>10-01-312</u>	Ravuri, Tulasi	Pharmacy	Recommended for Approval	SLU	01/05/2010

Fig 9: 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.

5.2. 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: <u>11-01-1306</u> (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).	



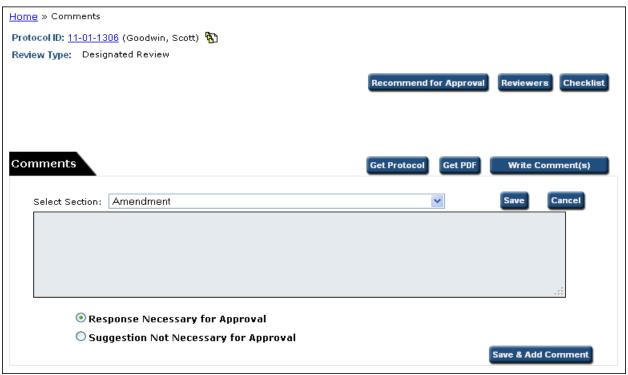


Fig 11: Comments

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.

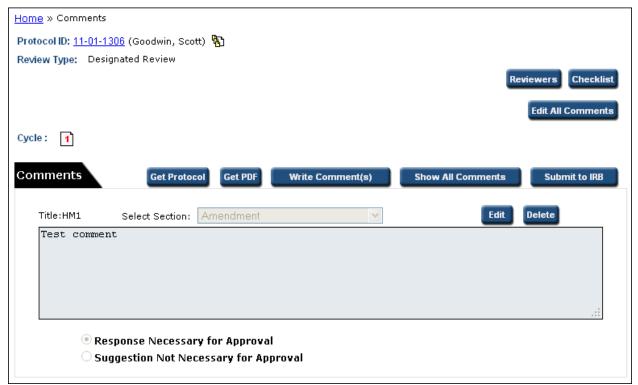


Fig 12: Comments

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.

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Fig 13: 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)**.

IRB						
RB Member ((Protocols for Rev	iew)				*
NEW						e
AMENDMEN	r					
Role	Protocol ID	Principal Investigator	Department Name	Protocol Event	Panel	Meeting Date
Presenter	11-01-1306	Goodwin, Scott	Advancement Systems	Comments Sent (Cycle 1)	SLU	01/02/2011

Fig 14: 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)**.

IRB						
RB Member ((Protocols for Rev	iew)				*
NEW						(
	r					
Role	Protocol ID	Principal Investigator	Department Name	Protocol Event	Panel	Meeting Date
Presenter	<u>11-01-1306</u>	Goodwin, Scott	Advancement Systems	Responses Received (Cycle 1)	SLU	01/02/2011

Fig 15: 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: <u>11-01-1306</u> (Goodwin, Scott)	ŧ		
Review Type: Designated Review			Reviewers Checklist
			Reviewers
Cycle: 1			
Comments	Get Protocol Get PDF	Write Comment(s)	Show All Comments
Title: BONITAK1	Reviewer: Krall, Bonita		
Select Section: Funding	~		
Test Comment			
Response Necessary for A	IDDROUAL		***
O Suggestion Not Necessary			
Response			
Test Response			

Fig 16: 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.

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 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.

5.3. 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.



<u>Home</u> » Sear	ch Protocol								
IRB							Se	arch Clear	Save
Protocol ID						Study Tit	le		
Principal Investigator					Investiga	tor			
Form Type AMENDMENT		I 🔽 I		PanelPleas		Please	e Select 🔽		
Meeting Date					SPO #				
Sponsor		Plea	se Select 🔽						
Selected Sea	rch Criteria:	Plea	ase Select 💌						
Protocol ID	Principal In	vestigator	Department Name	Panel	Meetir	ng Date	Exp	iration Date	Form Type
09-11-184	Atherton, M	ichael	Pharmacy	IRB-1			11/2	29/2010	AMENDMENT
09-05-0005	Atherton, M	ichael	Management	IRB-1	09/06/	2009	04/3	30/2010	AMENDMENT
09-05-0003	Atherton, M	ichael	Pharmacy	IRB-1	06/07/	2009	04/3	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.

Selected Search Criteria:		Please SelectPlease Select	*
Protocol ID	Principal Inv	Please SelectPlease	
00 11 194	Athorton Mic	Amendment	

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.