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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

![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.

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.
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. 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.

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.

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.
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.
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.

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.

![Fig 10: Comments](image1)

![Fig 11: Comments](image2)
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.

Step 5
Click Submit to Committee. Notes to Committee popup is displayed.
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)**.

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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)**.

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Step 8
Click protocol event. You are directed to **Comments** page, where you can view responses to your 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.
5.3. 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.

![Search Protocol](image)

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.