ePROTOCOL
enabling paperless research compliance

eProtocol - Protocol Management System (PMS) Investigator User Guide

Version 2.0

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Product Version: 2.0.16

Table of Contents

1. Introduction

1.1. Purpose of the Document

This document explains the steps to perform various functions of Investigator 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 Investigators to learn working with the Investigator 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 can take desired action on the protocol like – approve, disapprove, move or table to another meeting date, conditionally approve the protocol, etc. Before taking any of the actions, the committee may ask Investigators to provide certain clarifications or update protocol document to meet the committee's criteria for review and approval. After the approval, the Investigator needs to submit various other forms specific to the committee till the completion of research. This document explains how Investigators 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.
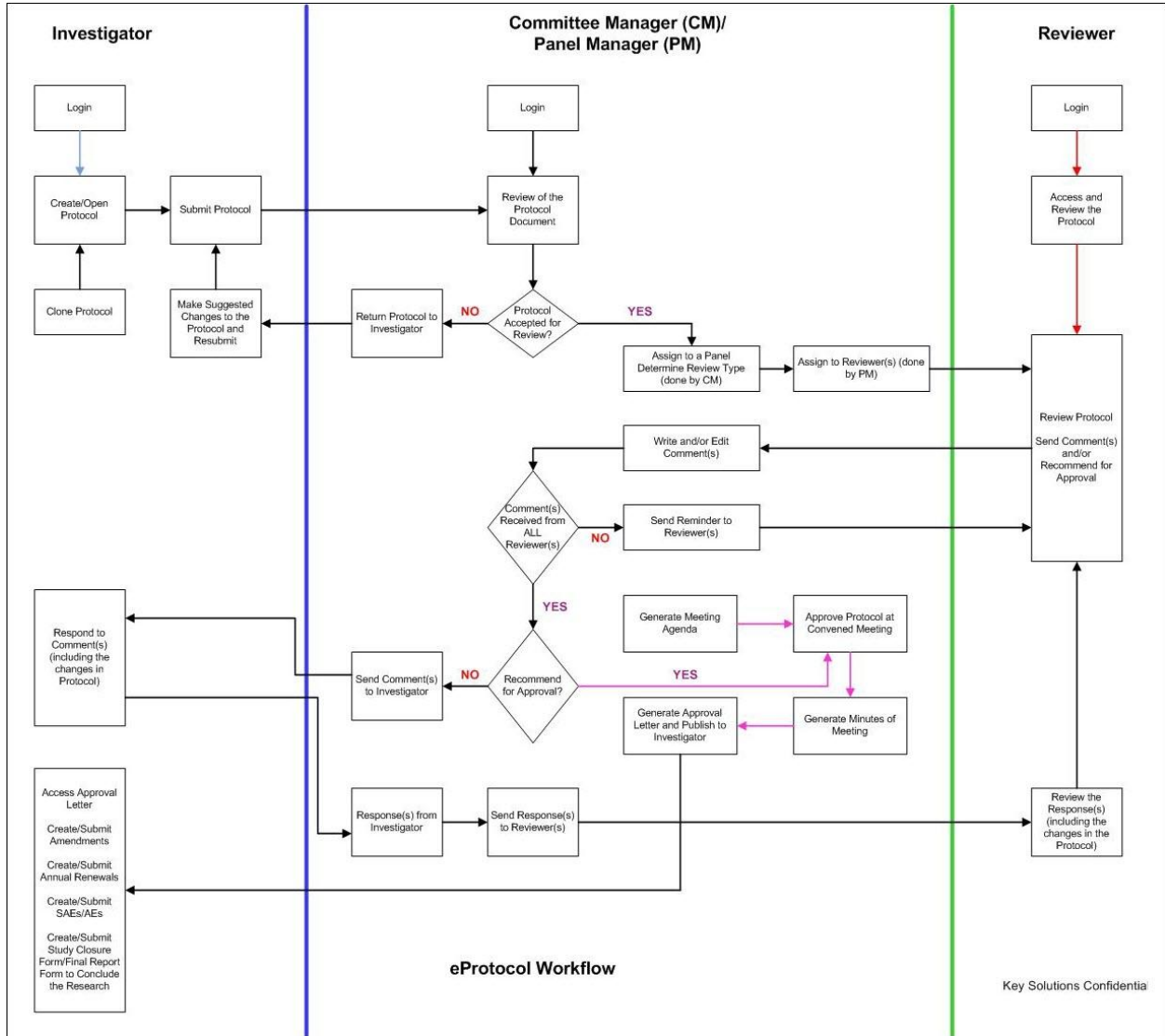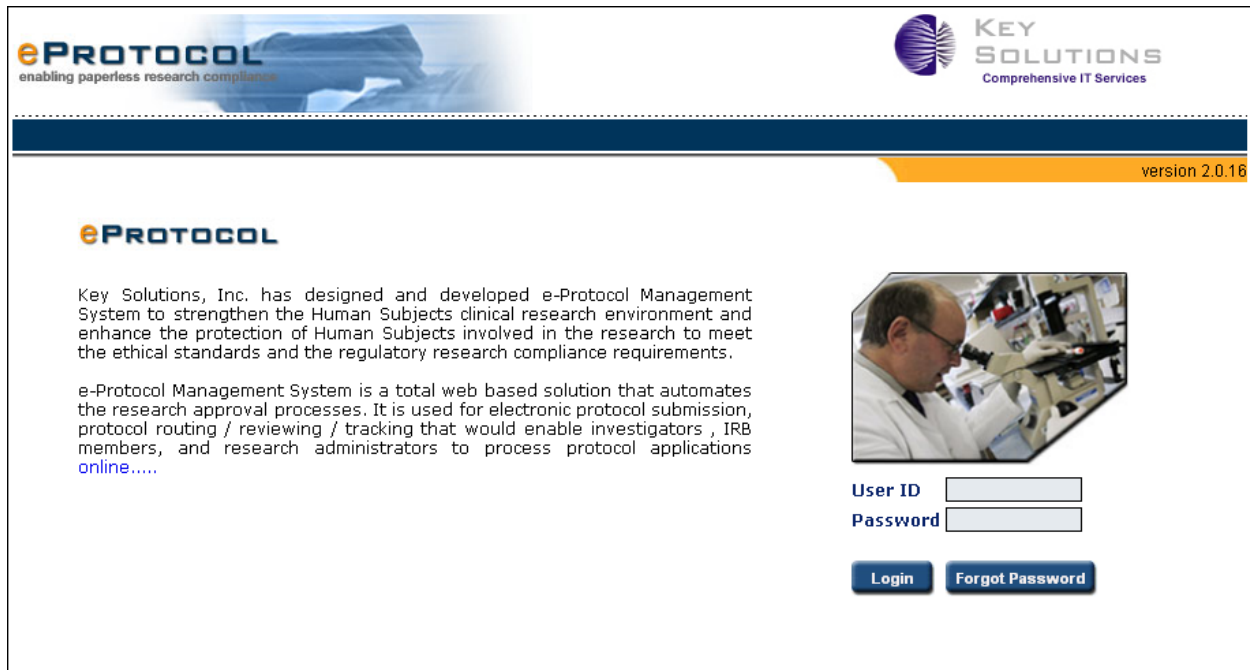
2. Product Workflow Diagram

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.

Fig 2: eProtocol Login Page

1. Enter the User ID and Password for the Investigator.
2. Click **Login**, or press **Enter**. Investigator **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. Investigator Home Page

The functions of an Investigator are to create, fill in and submit protocols to respective committees for review. After the approval of the protocols, Investigators can create Amendment, Continuing Review and other forms depending on requirement. If Panel Manager asks for any clarifications for the protocol form, Investigator need to send responses to them.

Home page is the starting point for Investigators to perform various key functions. On Home page, details of all ongoing protocols within your purview are displayed. The protocols created by you and the protocols in which you are a member are automatically displayed on the **Home** page after their creation.

You are automatically directed to the **Home** page after login. You can go to the **Home** page at any stage by clicking on **Investigator** on top menu or by clicking on **Investigator Home** displayed after pointing the cursor to **Investigator**.
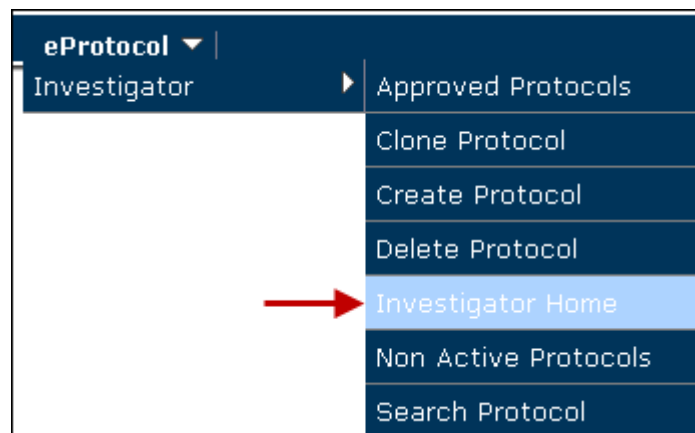

Fig 3: Menu

Home

Create Protocol **Clone Protocol** **Delete Protocol**

IRB

Protocols (In Preparation / Submitted) ⌄

NEW ⌄

Protocol ID	Principal Investigator	Department Name	Protocol Event	Panel	Meeting Date
10-01-310	Atherton, Michael	Pharmacy	Responses Sent (Cycle 1)	Test Panel	01/05/2010
10-01-311	Atherton, Michael	Pharmacy	SUBMITTED TO IRB	Test Panel	01/05/2010
09-05-0010	Atherton, Michael	Pharmacy	Yet to Submit to IRB		

AMENDMENT Test Panel ⌄

Protocol ID	Principal Investigator	Department Name	Protocol Event	Panel	Meeting Date
09-11-184	Atherton, Michael	Pharmacy	SUBMITTED TO IRB	Test Panel	
09-05-0008	Atherton, Michael	Pharmacy	Comments Received (Cycle 2)	Test Panel	10/04/2009

CONTINUING REVIEW ⌄

Protocol ID	Principal Investigator	Department Name	Protocol Event	Panel	Meeting Date	Expiration Date
09-11-141	Atherton, Michael	Pharmacy	Yet to Submit to IRB	Test Panel		10/31/2010
09-11-145	Atherton, Michael	Pharmacy	Yet to Submit to IRB	Test Panel		10/31/2010

REPORT ⌄

Protocol ID	Principal Investigator	Department Name	Protocol Event	Panel	Meeting Date
09-12-295	Atherton, Michael	Provost's Office	SUBMITTED TO IRB	Test Panel	07/07/2013
09-12-231	Herke, Marsha	Imaging	SUBMITTED TO IRB	Test Panel	
09-10-0041	Atherton, Michael	Pharmacy	Yet to Submit to IRB	Test Panel	
09-09-0001	Atherton, Michael	Pharmacy	SUBMITTED TO IRB	Test Panel	09/06/2009
09-05-0004	Atherton, Michael	Pharmacy	SUBMITTED TO IRB	Test Panel	09/06/2009

DEVIATION ⌄

Protocol ID	Principal Investigator	Department Name	Protocol Event	Panel	Meeting Date
09-12-296	Atherton, Michael	Pharmacy	SUBMITTED TO IRB	Test Panel	07/07/2013
09-09-0001	Atherton, Michael	Pharmacy	SUBMITTED TO IRB	Test Panel	09/06/2009

FINAL REPORT ⌄

Protocol ID	Principal Investigator	Department Name	Protocol Event	Panel	Meeting Date
09-09-0001	Atherton, Michael	Pharmacy	SUBMITTED TO IRB	Test Panel	09/06/2009
09-09-0001	Atherton, Michael	Pharmacy	SUBMITTED TO IRB	Test Panel	09/06/2009
09-09-0001	Atherton, Michael	Pharmacy	SUBMITTED TO IRB	Test Panel	09/06/2009
09-05-0004	Atherton, Michael	Pharmacy	SUBMITTED TO IRB	Test Panel	09/06/2009

Approved Protocols ⌄

Protocol ID	Principal Investigator	Department Name	Initial Approval Date	Last Approval Date	Expiration Date	Status/Comments	Protocol Type
09-10-0038	Jones, Simon	Pharmacy	11/07/2009	11/07/2009	11/06/2010	APPROVED	NEW
09-12-231	Herke, Marsha	Imaging	12/09/2009	12/09/2009	12/08/2010	APPROVED	NEW

Non Active Protocols ⌄

Protocol ID	Principal Investigator	Department Name	Initial Approval Date	Last Approval Date	Status/Comments	Protocol Type
09-12-267	Herke, Marsha	Imaging			NOT APPROVED	NEW

Fig 4: Home page

All the committees in your site are displayed in the **Committee** tab. Select the committee to view the protocol forms of the committee.

Under each committee, protocol forms are categorized and displayed in the following sections

Protocols (In Preparation/Submitted)

In this list, protocol forms which are in preparation state, submitted to the committee for review and/or undergoing review by the committee are displayed. The protocol forms are categorized based on their Form Type – New, Amendment, Continuing Review, Report, Deviation, Final report, etc. The Form Types vary for different committees.

Pre-Approvals

In this list, New protocols which are submitted for pre-approval by pre-reviewers and which are received for your pre-approval decision are displayed.

Approved Protocols

In this list, the protocols approved by the review committee are displayed.

Non-Active Protocols

In this list, the protocols not approved/ closed/ withdrawn/ expired are displayed

Note:
Click **Show/Hide** button to view/hide the protocols list of the form type.

Definition of Form Types

Different Protocol Form Types in '(In Preparation/Submitted)' list of protocols are explained below.

1. **New**: This is the first document prepared for a protocol. When a protocol is created for the first time, it is considered as New form.
2. **Amendment**: After a protocol form is approved, if there are any major revisions to the protocol, an Amendment form should be submitted.
3. **Continuing Review**: For an approved protocol, a renewal form should be submitted before its expiration.
4. **Protocol Deviation**: In case of an incident of deviation, violation or participant non-compliance during research, a deviation form should be submitted for committee's notice and approval.
5. **Report**: In case of any adverse events or new information that may pose risks to subjects or others and alter the risks, benefits, or alternatives to subjects, a report form should be submitted for committee's notice and approval.
6. **Final Report**: At the conclusion of research, a final report form mentioning various details specific to the protocol closure should be submitted for committee's notice and approval. This is final document submitted for a protocol.

Important Note:

New, Amendment and Continuing Review are considered as the main protocol documents. Only one of these forms can exist for a protocol at any point of time. The protocol information present in New form is carried forward to the other two types of forms. The other forms except Final Report are considered as child forms/sub-forms as multiple forms can be created for a protocol based on need. Only one Final

Report can be created for a protocol, as this is the document submitted for protocol closure. The child forms and Final Report form will have a single page only for entering the information specific to that form.

Explanation of Columns in the Tables

Different columns in the protocol tables are explained in detail below.

Protocol ID

Protocol ID, a unique ID assigned to a protocol when it is created, is displayed in this column. It is the default method of identifying protocols, though each protocol is given a title by Investigator. This Protocol ID stays with the protocol throughout its life cycle - all the way to the archival.

Principal Investigator

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

Protocol Event

The event happening for the protocol form is displayed in the column. Different Protocol Events are explained below.

    a. **Pre-Approval Required**: Protocol requires pre-approval, but it is still not submitted to pre-approvers for their decision.
    b. **Submitted for Pre-Approval**: Protocol requires pre-approval and is submitted to pre-approvers for their decision.
    c. **Yet to Submit to Committee**: Protocol form is still being filled out, and it can be seen in view/edit mode. You can submit it any time later.
    d. **Submitted to Committee**: Protocol form is submitted to committee for review.
    e. **Moved**: Protocol form is moved to some other meeting date from the assigned meeting date.
    f. **Tabled**: Protocol form not completely discussed due to some unresolved issues during the meeting is tabled for discussion on some other meeting date. When the protocol is tabled, the review process should be re-initiated by the committee for further processing.
    g. **Contingent**: Protocol form 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 waiting for Reviewers' comments.
    h. **Comments Received (Cycle 1*)**: The protocol form submitted for review has received the first cycle (cycle 1) of comments from the Panel Manager.
    i. **Responses Sent (Cycle 1*)**: The Investigator has responded to the comments received from the Panel Manager - informing them of how s/he has acted on the comments made on the protocol form or in fulfilling the changes they wanted to see.
    j. **Resubmit the Protocol**: Protocol form is returned for resubmission asking for changes to be made.
    k. **Resubmitted to Committee**: Protocol form returned by the committee is resubmitted after making required changes.

Note: * If there are any further comments/responses cycles after the first cycle, those will be numbered with higher cycle numbering and the event will be updated accordingly.

Status/Comments

The current status of the protocol form submission is displayed in the column. Different protocol statuses are explained below.

a. **New:** The protocol is newly created and yet to be submitted to the review committee.
b. **Submitted:** The protocol is submitted to the committee for review.
c. **In Progress:** The protocol is undergoing review.
d. **Returned:** The protocol is returned for resubmission asking changes to be made.
e. **Resubmitted**: The protocol returned is resubmitted after making required changes.
f. **Moved:** The protocol is moved to some other meeting date from the assigned meeting date.
g. **Tabled:** The protocol is not completely discussed due to some unresolved issues during the meeting have the Tabled status. When a protocol is tabled, the review process should be re-initiated by the committee for further processing.
h. **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 Investigators without Reviewers' comments.

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 form.
▪ Click **Column Heads** to sort the protocol form in ascending/descending order.
▪ Click **Comments Received/Responses Sent** in **Protocol Event** column to view the comments/responses.
▪ Click **Create Protocol** to start creating a new protocol. **Create Protocol** page is displayed.
▪ Click **Clone Protocol** to start cloning an existing protocol. **Clone Protocol** page is displayed.
▪ Click **Delete Protocol** to start deleting a protocol form. **Delete Protocol** page is displayed.

5. Investigator Functions

5.1. Create Protocol

To conduct research on your study, you need to create a protocol and submit it for review to the respective committee. Creation of protocol is an easy process and can be completed in few simple steps, as explained below.

Point to **Investigator** on top menu and click **Create Protocol**. **Create Protocol** page is displayed. You can also click on **Create Protocol** button (if enabled) on the **Home** page and navigate to **Create Protocol** page.
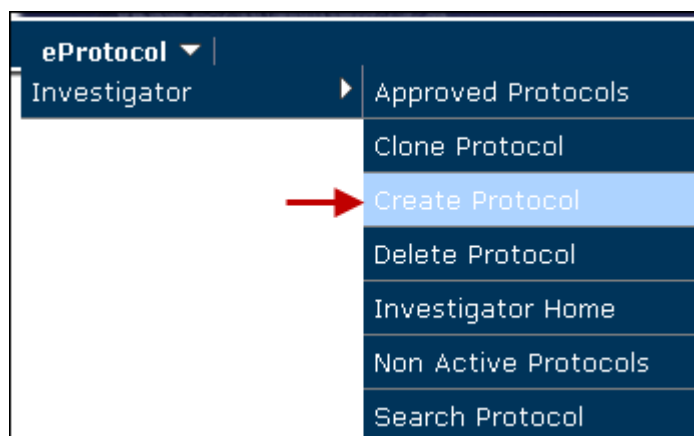
Fig 5: Menu
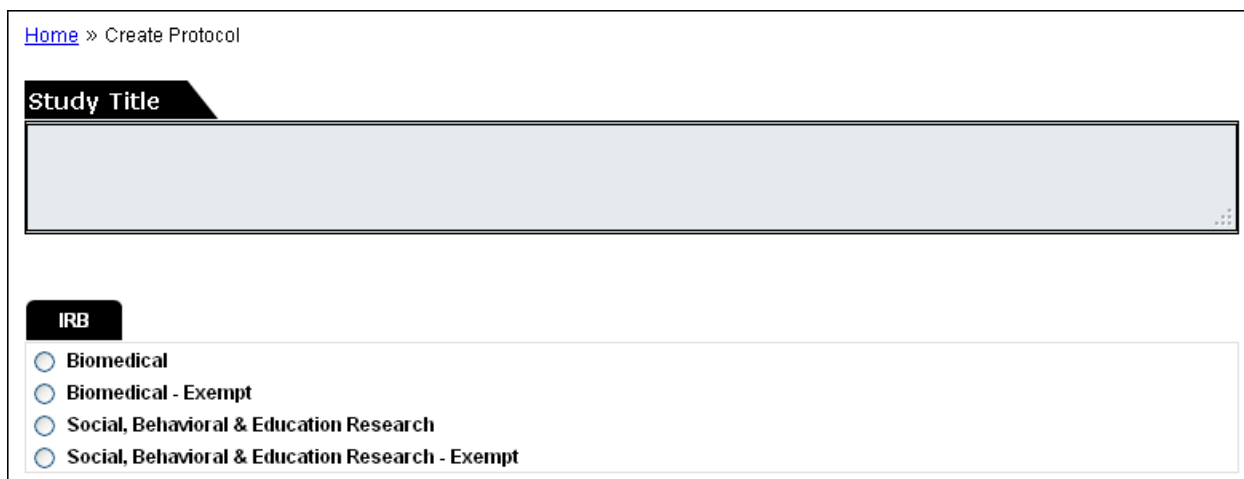
Fig 6: Create Protocol

Enter the title of your research study in **Study Title** textbox. Select the committee under which you are planning to conduct your research study. Various forms available under the selected committee are displayed below. If there is only single committee, then the committee is not displayed in this page and the form names are displayed by default. Select the form. The personnel information related to the selected form is displayed below.

Fig 7: Create Protocol

You may be auto-selected as the Principal Investigator/Protocol Director, depending on the configuration set by Administrator. In such case, if you want to play other role in the research study, you can assign another user as the Principal Investigator/Protocol Director and add yourself to the desired role. But, be sure to add you to a role which has create privileges (given by Administrator). Otherwise, you will not be able to create the protocol.

To add any other user as Principal Investigator for the protocol, click the binocular icon near the **Name** field. **Find User** popup is displayed.

Fig 8: Find User popup

Search the user, select and add. Selected user's name and other details are displayed in the role section. Enter any missing details for the user.

Add other users to the protocol following the steps above, and click **Create**. Protocol Form opens in a new window.

Protocol ID is assigned to the newly created protocol for identification. You can find the protocol added to the respective committee on **Home** page with event **Yet to Submit to Committee**.

Fig 9: Home page

Note:

- In **Create Protocol** page, if you unselect a committee, the related entries will be cleared.
- If there is dependency for different forms or multiple committee forms are selected, then the personnel information of the parent form is displayed. Also, all dependent committee forms are created with a single **Protocol ID**. And, you can submit all dependent forms at a time after providing all the required information. Note that, though the protocol numbering format is different for different committees, the numbering format of the parent form will be used for other committee forms.
- Click **Clear** to clear the details of a user.
- Click the links, if any, to view the related information and guidelines.

5.2. Clone Protocol

Instead of creating a new protocol, you can clone an existing protocol if there are little or no modifications. Follow the steps given below to clone a protocol.

Point to **Investigator** on top menu and click **Clone Protocol**. **Clone Protocol** page is displayed. You can also click on **Clone Protocol** button (if enabled) on the **Home** page and navigate to **Clone Protocol** page.
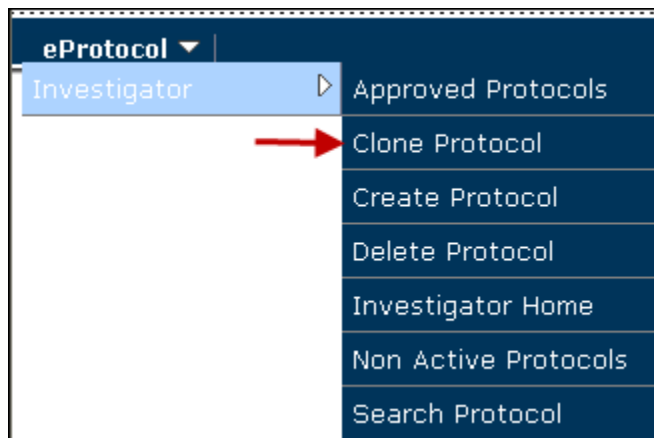

Fig 10: Menu

Fig 11: Clone Protocol

Select a committee from **Committee** tab. List of protocols is displayed. Select a protocol and click **Clone Protocol**. Confirmation popup is displayed. Click **Yes**. New protocol is created and added to the **Home** page. New protocol created is opened in a new window.

Note:
- Click the **Protocol ID** to view/edit the protocol.
- Click **Column Heads** to sort the protocols in ascending/descending order.

5.3. Guidelines for Filling Protocol Forms

The protocol contains the content as defined by the committee divided into several sections. In each section, you need to provide the relevant information.

Various key sections common in most of the protocols forms are explained below. There are several other important sections which vary based on committee requirements.

Personnel Information

In this section, you can add users to various research roles. The Edit/View privileges and Submit privileges for these roles will be configured by the Administrator. For some roles, you can add multiple users, and for some, only one user can be added. If there is Other Personnel category, you can add users not present in the system i.e. not having the User ID. But, the user cannot access the protocol.

General Checklist/Are You Using

This is an important section in the protocol. Based on selection of items in this section, corresponding sections/sub-sections/questions are enabled in the Protocol Information section of the form.

Attachments

In this section, you can add various attachments related to the protocol.

Certifications/Assurance/Obligations

In this section, you can find various obligations you have to abide as an Investigator conducting the research. This section will contain a checkbox, which you have to select to be able to submit the form.

Event History

In this section, you can find the complete history of the protocol form submissions and their review.

Email History

In this section, you can find the complete history of emails related to the protocol. This section can be a part of the Event History or be in the left navigation of the form, based on the configurations set by the Administrator.

The following functions are present in the form.

Check for Completeness

This function allows you to ensure that all the required information is provided in the protocol form. The sections that are incomplete are displayed in the 'Check for Completeness' window displayed upon clicking 'Check for Completeness' or 'Submit Form' in left navigation of the form. Click on the section links to navigate to the corresponding section and provide the complete details required.

Print View

This function allows you to print the protocol and comments/responses written for the protocol in PDF format. Click on **Print View** button in left navigation of the form. **Print View** popup opens. Select one of the print options. If you have selected the protocol to print, you can select the sections you want to print.

By default, all the sections except Event History are selected for printing. Select/unselect the sections and click **OK**. PDF is generated.

Submit Form

To submit the form, after filling in all the required details, click **Submit Form** button in the left navigation. Confirmation popup is displayed. Click **Yes**. The form is submitted to the committee and the status of the form changes as **Submitted to Committee** in your dashboard.

5.4. Creation and Submission of Child forms for an Approved Protocol

For an approved protocol you can create different associated forms like – Amendment, Continuing Review, Report, Deviation and Final Report - based on requirement. To create a form, you should be assigned to a personnel category in the form with create privileges.

Follow the steps given below to create different associated forms for a protocol.

Point to **Investigator** on top menu and click **Approved Protocols**. **Approved Protocols** page is displayed.

Fig 12: Menu

Fig 13: Approved Protocols

Note:
You can also find the list of approved protocols on your dashboard in **Approved Protocols** section.

Click Protocol ID. **Approved Protocol Decision** popup is displayed with various options - *Open in View Mode, Protocol Details, Start Amendment, Start Continuing Review, Start Protocol Deviation Form, Start Report Form* and *Start Final Report Form.* The options vary based on the forms associated for the protocol form in the committee.

Fig 14: Approved Protocol Decision

Select required form creation option and click **OK**. The selected form is created and displayed in a new window.

To view the details of different forms created for the protocol, select **Protocol Details** and click **OK**. You are directed to **Details** page where you can view the complete form history of the protocol.

Fig 15: Details

If you select **Start Final Report Form**, you are directed to **Final Report** page.

Fig 16: Final Report

Read the obligations. You should be able to answer **Yes** to all these questions to create Final Report form. Select **Yes** for all the obligations and click **Continue**. Final Report Form is created and displayed in a new window.

Instead of submitting the Final Report form, you can also submit a close request to the Panel Manager. However, the option to submit a close request will be available only when Administrator allows it. When this is enabled by Administrator, **Close Protocol** option is displayed in the **Approved Protocol Decision** popup. Select this option and click **OK**. In Approved Protocols list, the status of the protocol changes as **Close Requested**. When the close request is approved, all other forms existing for the protocol are deleted and the closed form moves to Non-Active Protocols list.

Important Notes:
1. The options in **Approved Protocol Decision** popup depend on the committee and configuration settings by the Administrator.
2. When Amendment or Continuing Review form is created for a New protocol you cannot create these forms again till they are available. However, you can create these forms once the already created form is deleted.
3. In case of Protocol Deviation and Report forms for a protocol, you can create multiple forms at a time.
4. When a protocol form is approved, it will replace the already existing approved form of the protocol in **Approved Protocols** section.
5. When a Final Report form is created or close request is sent, options to create all other forms are removed in **Approved Protocol Decision** popup.
6. When the Final Report form is approved, the protocol will be made inactive and moves to **Non-Active Protocols** list.

7. To view the protocol details, select Protocol Details option and click **OK** in the **Approved Protocol Decision** popup. **Details** page is displayed, where you can view the complete form history of the protocol.

In case of Amendment and Continuing Review forms, in addition to the information present in New form, Amendment and Continuing Review pages are added to the protocol respectively. You have to provide the required information and submit the form by clicking the **Submit Form** button.

In case of Protocol Deviation, Report and Final Report forms, the protocol contains only a single page/section to enter the required information. You have to provide the required information and submit the form by clicking the **Submit Form** button. In these forms, **Get Protocol** link is displayed in the left navigation. Click on the link to view the last approved New/Amendment/Continuing Review form of the protocol.
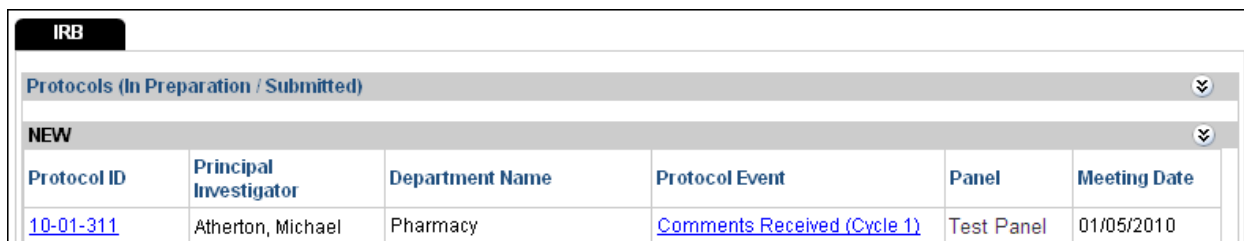
5.5. Respond to Comments

When Panel Manager and Reviewers review the protocol submitted, they may need few clarifications or may want you to provide detailed information in regards to certain aspects of the form. In such cases, Panel Manager submits his/her comments and also the comments written by the Reviewers for your feedback. You need to provide responses to the comments and also update the protocol form, if needed, and submit your responses to the Panel Manager.

Follow these steps to write and send responses to comments submitted by Panel Manager.

Navigate to **Home** page.

When you receive comments from Panel Manager, the event of the protocol form changes as 'Comments Received (Cycle 1)'.

Protocol ID	Principal Investigator	Department Name	Protocol Event	Panel	Meeting Date
10-01-311	Atherton, Michael	Pharmacy	Comments Received (Cycle 1)	Test Panel	01/05/2010

Fig 17: Home page

When you receive comments from Panel Manager, the event of the protocol changes as 'Comments Received (Cycle 1)'. To view and respond to comments, click the event. You are directed to **Comments** page, where you can view the comments sent by Panel Manager and the sections they commented on.

Fig 18: Comments

In the **Response** textbox below a comment, enter your response and click **Save**. Your response is saved.

Enter responses for the comments; especially the ones mentioned 'Response Necessary for Approval' which are mandatory. Click **Submit to Committee**. Confirmation popup is displayed.

Fig 19: Confirmation popup

Click **OK**. Your responses are sent to the Panel Manager. Panel Manager will also receive a mail with all the details.

Note:
- Protocol members with view-only privileges can also send responses.
- If the Panel Manager has allowed you to edit the protocol form, you can edit it as per the comments sent by him/her.
- You can edit the responses saved by the other protocol members before sending them to the Panel Manager. Similarly, other protocol members can also edit your responses.
- Click **Show All Comments** to view the comments/responses.

- Click **Get Protocol** button to view/edit the protocol. You can edit the protocol details only if Manager gives edit permissions to the protocol. Protocol details can be modified by other Protocol Personnel also as per the edit privileges configured by the Administrator.
- If you receive comments from Panel Manager after you send the first cycle of responses, they are displayed as new cycles like cycle 2, cycle 3, etc. on **Home** page.
- Click **Cycle Number** to view the respective Comments/Responses. Present cycle number is shown in red color.

5.6. Delete Protocol

You can delete a protocol form before it is submitted to the respective committee.

Follow the steps given below to delete a protocol.

Point to **Investigator** on top menu and click **Delete Protocol**. **Delete Protocol** page is displayed. You can also click on **Delete Protocol** button (if enabled) on the **Home** page and navigate to **Delete Protocol** page.

Fig 20: Menu

Fig 21: Delete Protocol

Select a committee from **Committee** tab. List of protocols that are not submitted to the committee are displayed. Select protocols you want to delete and click **Delete Protocol**. Confirmation popup is displayed. Click **Yes**. The selected protocols are deleted.

Note:
- Administrator can restore the deleted protocols. After restoring, the protocols reappear on **Home** and **Delete Protocol** pages of the protocol personnel.
- Click **Protocol ID** to view/edit the protocol.
- Click **Column Heads** to sort the protocols in ascending/descending order.

5.7. Search Protocol

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

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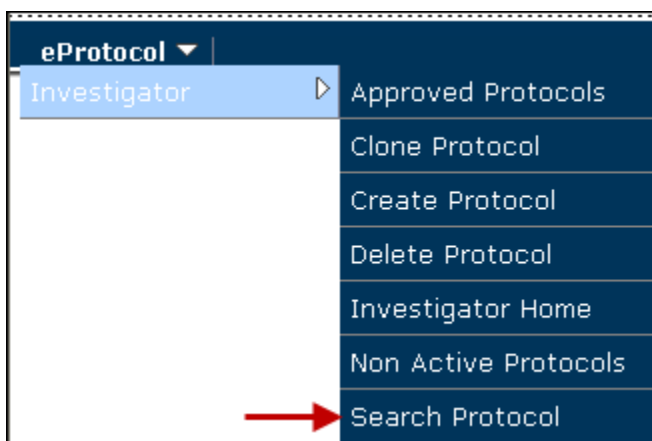

Fig 22: Menu

Fig 23: 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.
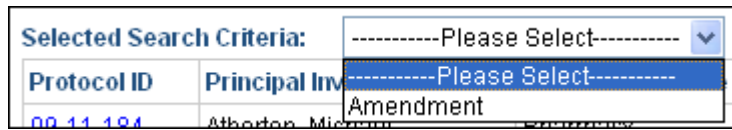
Fig 24: Search Protocol

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.

5.8. Non Active Protocols

The protocols that have become inactive and on which the research cannot be conducted any longer are displayed in **Non Active Protocols** list.

Point to **Investigator** on top menu and click **Non Active Protocols**. **Non Active Protocols** page is displayed.
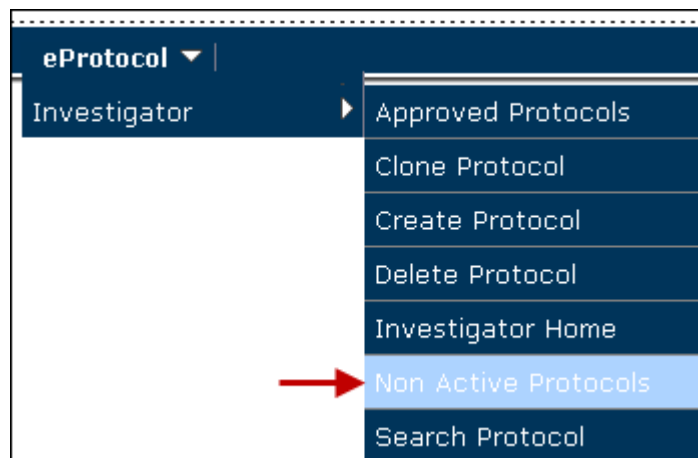

Fig 25: Menu

Fig 26: Approved Protocols

Note:
You can also find the list of inactive protocols on your dashboard in **Non Active Protocols** section.

The list of protocol statuses which are considered as non-active and their meanings are given below.

Not Pre Approved – The protocol is disapproved by at least one of the pre-approvers assigned to review the protocol.
Withdrawn – The protocol is withdrawn by the Panel Manager.
Closed – The protocol is closed by the Panel Manager.
Not Approved – The protocol is not approved by the Panel Manager.
Expired– The protocol is expired after the expiration date.

In general, the non-active protocols are read-only and no edits can be done. However, attachments can be added in Attachments section of the form if configured and allowed by the Administrator.

Based on configurations set by the Administrator, you can create Continuing Review form and/or report forms for an expired protocol.

To create Continuing Review form and/or report forms for an expired protocol, click on the Protocol ID link. **Non Active Protocol Decision** popup is displayed a shown below.
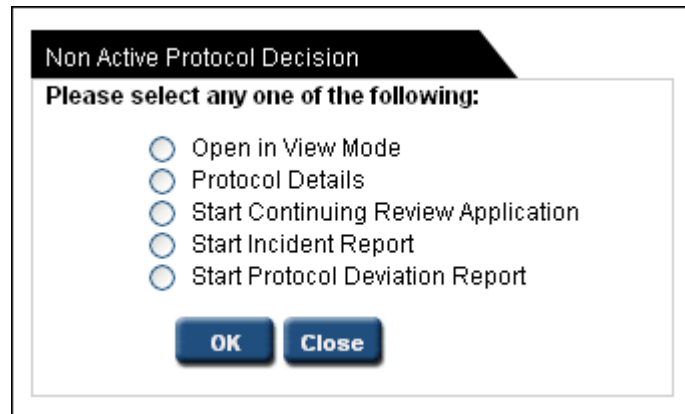

Fig 27: Non Active Protocol Decision popup

Select the form option and click Create. The form is created and displayed on your dashboard. The protocol will remain in non active state i.e. expired state till the child form created is approved by the review panel. Once the child form is approved, the protocol becomes active and the approved child form appears in Approved Protocols list. The expired protocol disappears from the Non Active Protocols section.