



eProtocol IBC Principal Investigator User Guide

Key Solutions, Inc.
2803 Lakeview Ct.
Fremont, CA 94538
www.keyusa.com

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1 Introduction

This guide explains how eProtocol, a Key Solutions Protocol Management System (PMS) tool, can assist a

Table 1: Common Acronyms and Definitions Encountered in this Guide

Acronym	Stands For	Definition
PI	Principal Investigator	The person responsible for creating, and completing a protocol submission.
Protocol ID	Protocol Identification Number	A unique ID assigned to a protocol when it is created. This is used mainly for identification purpose, and it stays with the protocol throughout its lifecycle.
IBC	Institutional Biosafety Committee	Committee of persons responsible for the ethical review of protocols submitted by a principal investigator (PI) within a research organization.
PR	Primary Reviewer	The primary person requested to review a protocol submitted to IBC.
PDF	Portable Document Format.	An Adobe Acrobat file type utilized for attachments.

2.2 Logging Into eProtocol

Before you begin, contact the Company Administrator to obtain the proper login credentials and the URL for eProtocol. Once you have your login credentials, go to your computer and open your browser (e.g., Firefox). It is important to deactivate the pop-up blocker for the smooth operation of eProtocol. Once you have finished those tasks, do the following:

1. Open the eProtocol web page using the URL you were provided.
2. Enter your login and password in the spaces provided on the far right of the page, as shown in Figure 1: eProtocol Login. This is your regular login.

Figure 1: eProtocol Login

3. Click Login.

screen and clicking **Investigator** or **Investigator Home** as shown in Figure 3: New Protocol Applications.

Figure 2: Investigator submenu

3.1.1 New Protocol Applications

At the top of the Investigator home page, under the heading In Preparation/ Submitted, you will find a table of New protocol applications as shown in Figure 3: New Protocol Applications.

Figure 3: New Protocol Applications

Table 2: Investigator Homepage Column Headings for New Applications

Protocol ID	A unique, linked alpha-numeric ID that is automatically assigned to a protocol when it is created and opens the protocol when it is clicked. This ID stays with the protocol throughout its life cycle.
Principal Investigator	The Investigator with privileges to directly submit and correspond with the IBC. Generally, the person who created the protocol is automatically selected as Principal Investigator (PI). You can also designate an alternate PI, or co-PI.
Protocol Event	<p>The protocol stage in the review process. Events are displayed as:</p> <ol style="list-style-type: none"> Yet to Submit: protocols which are in progress and have been assigned a Protocol ID. Submitted: submitted for review to the IBC. Moved: meeting date has been changed. Tabled: IBC discussion about the protocol is not complete. Contingent: approved contingent specified changes being made. Comments Received: response received from IBC. Responses Sent: PI has responded to IBC comments. Resubmit: protocol returned to PI for resubmission specifying changes to be made.
Status/ Comments	<p>The current status of the protocol in the review process. Statuses include:</p> <ol style="list-style-type: none"> New: has not yet been submitted for review. Submitted: submitted to the IBC. In-Progress:

If the IBC Coordinator asks for clarifications of the protocol, the eProtocol is returned to you for editing. Once you have completed your changes, you can submit your protocol again. eProtocol sends notification emails to you as your protocol moves through the process. At any time, you can view the progress from your Investigator Home page. eProtocol tracks emails sent at each stage of the review process. To see this history for a particular protocol, open the protocol and click on the Event History tab on the left side navigation.

In some cases, different colors are associated with protocols on the Homepage; Their meaning is described in Table 4: Color Coding Definitions

Table 4: Color Coding Definitions

Color	Definition
Light Brown	The protocol has been assigned a Committee Review.
Yellow	The panel has been reassigned.

3.1.3

Figure 5: Dual Reviewer and Investigator Roles

1. Provide the title of the research in the **Study Title** text area. The IBC committee is selected by default.

Figure 7: Title Field in IBC Create Protocol Page

2. Select the appropriate principal investigator's name from the **Principal Investigator** field as shown in Figure 8: Principal Investigator Fields. eProtocol auto-populates your information as Principle Iv ~~M~~Creea.73



3. Click **Create**. The protocol is created and a Protocol ID is assigned to it. You are now able to view the protocol on the **Investigator Homepage** with Protocol Event **Yet to**
Su, F3 12 Tf1 0 0 1 396.7 38.64 Tm0 g0 G()JT&TQq.00000912 0 2IBTto

Figure 11: Clone Protocol Confirmation

When you select **Yes** to cloning a new protocol, the new protocol is added to the **Homepage** with **Protocol Event** as **Yet to Submit to IBC**. A message appears on your home page stating the new Protocol ID and which Protocol ID it was cloned from. You can then select the newly cloned Protocol and prepare your protocol application as normal.

The fact

Figure 13: Toolbar Visible When Creating or Editing a Protocol

1. If you click **Save**, the protocol is saved. This option is available while creating and editing a Protocol.
2. Clicking **Spell Check** checks the spelling throughout your protocol.
3. Clicking **Help** opens the Help content for the current page.
4. Clicking **Close** will close the protocol application form. This selection does not save your protocol or any edits to the application. Therefore, you will receive a prompt asking for confirmation to proceed as shown in

4.2 Project Registration section

In this section, select the checkboxes from the options provided. You need to select the options that are relevant to the protocol. You have to select at least one option to proceed to the next section. Based on the option selected, the relevant sub-sections in the **Protocol Information** section are enabled.

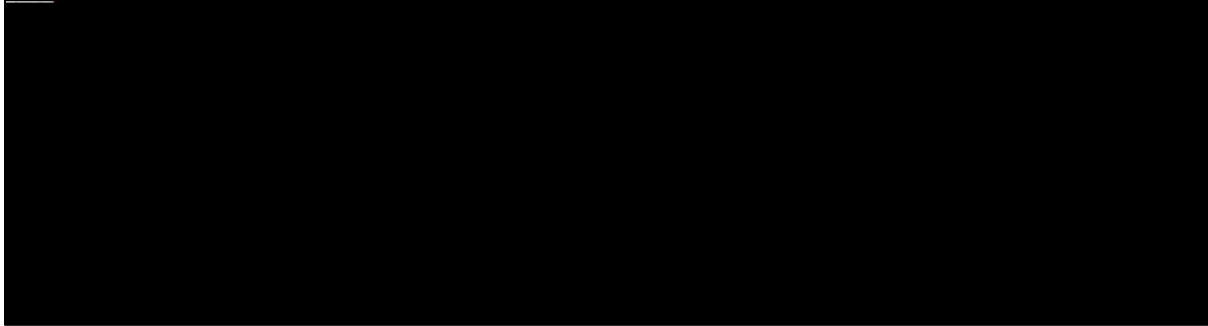


Figure 15: Project Registration section

4.3.1 Research Location

Floor	Room Number	Building Name
FLOOR 2	1202	<input type="checkbox"/> Building 1

Figure 17 Research Location

4.3.2 Biological Agents

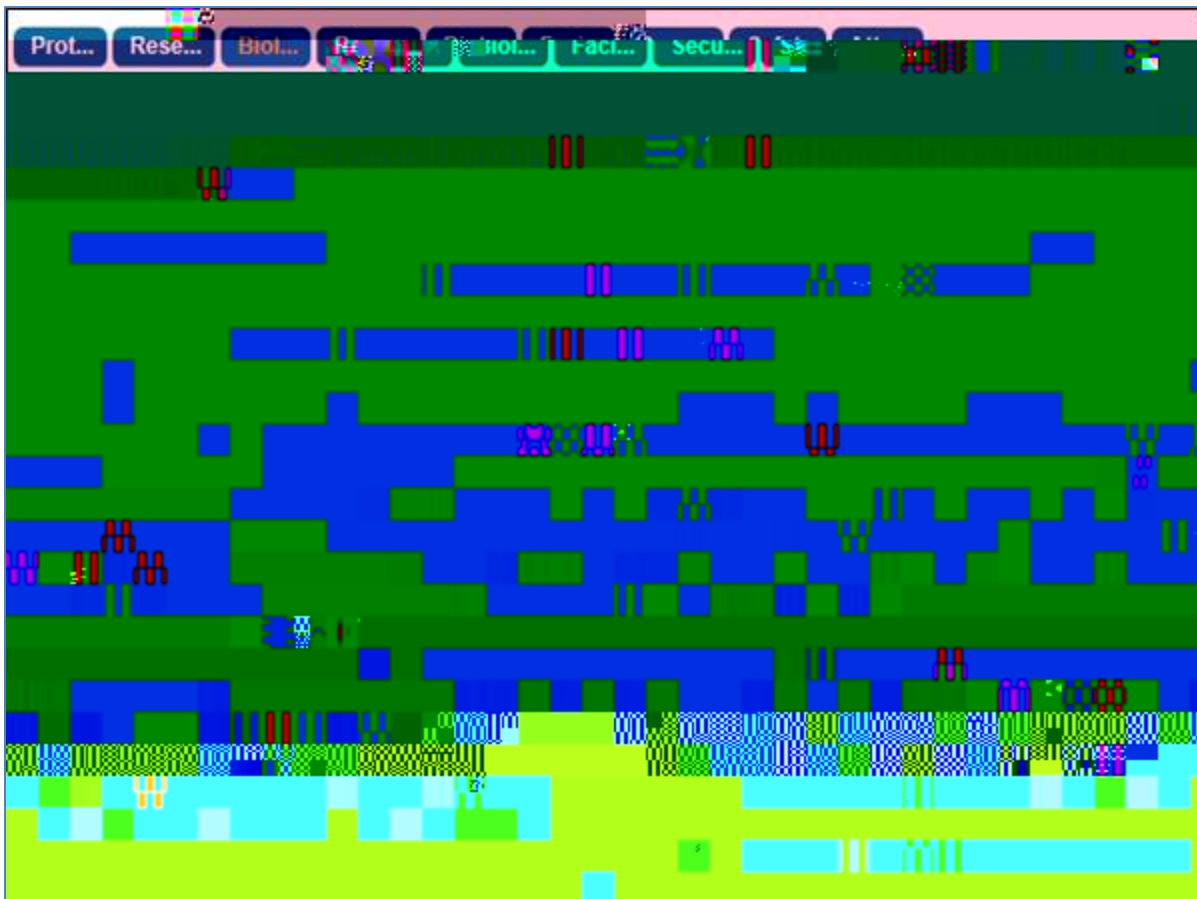


Figure 18 Biological Agents

4.3.3 Recombinant or Synthetic Nucleic Acid molecules (rsNA)

Prot...
Rese...
Biol...
Reco...
Biol...
Faci...
Secu...
Safety
Atta...

1. Biological sources of DNA/RNA whose product will be expressed (i.e., human, animal, plant, microorganism). If biological source is a viable intact microorganism, also complete Section II - Microorganism Usage

2. If Recombinant or Synthetic Nucleic Acid molecules (rsNA) is a plasmid Yes No

3. If Recombinant or Synthetic Nucleic Acid molecules (rsNA) is

a. Vector(s) Used:

b. Vector(s) Used:

Figure 19 4.3.3 Recombinant or Synthetic Nucleic Acid molecules

4.3.4 Biological Toxin Usage

Figure 20

4.3.6 Security, Shipping, Transport, and Training

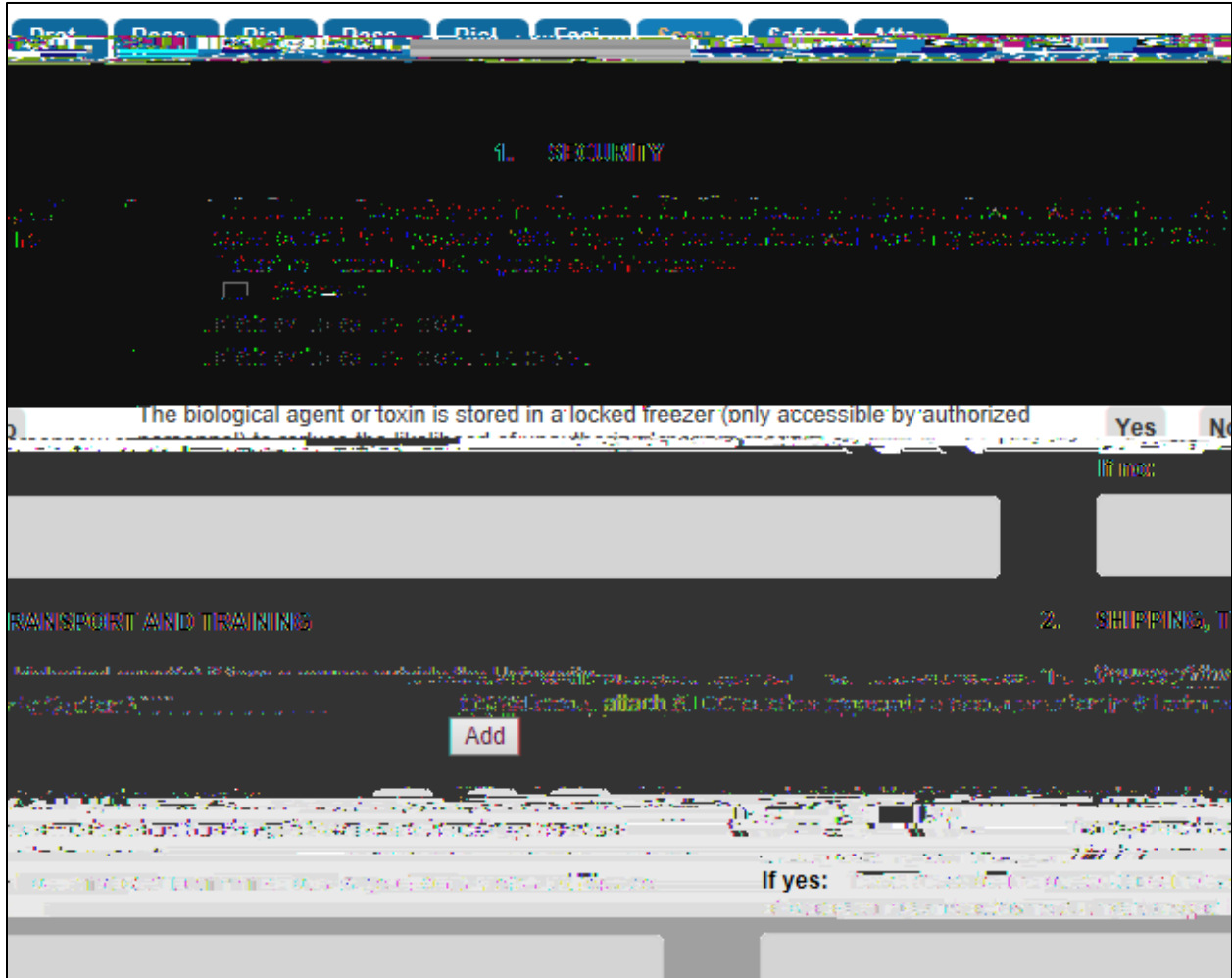


Figure 224.3.6 Security, Shipping, Transport, and Training

4.3.8 Attachments

As you create your protocol, various attachments are either required or optional. Attachments are uploaded as shown in Figure 24: Attachments.

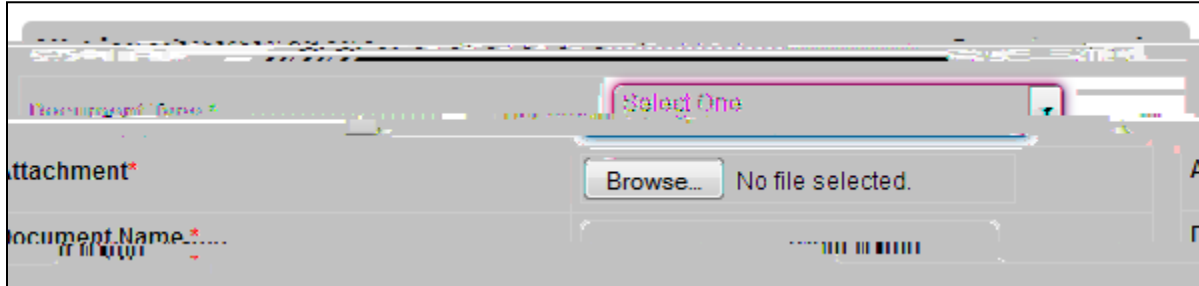


Figure 24: Attachments

Various document types can be selected from the drop-down box such as an explanatory diagram or safety information. Attachment of documents is encouraged dependent upon your selections as you go through the protocol application. For example, if you had a statistician determine the required biological materials in your protocol, it would be beneficial to upload this report. If your response to certain questions is too long, such as the potential value of your research, eProtocol will prompt you to add the information as an attachment.

Use **Browse** to search for the appropriate file on your computer and then name your uploaded document in the **Document Name** field. Acceptable Attachment formats are: MS Word, MS Excel, MS PowerPoint, MS Visio, PDF, GIF, TIF, and JPEG. and Adobe Acrobat .PDF formats.

4.4 Certifications

The IBC must enforce research compliance to the biosafety regulations governing the subject in research and instruction. Here, you, the Principle Investigator, must read and agree to abide by the assurances. Check the box on the bottom left of the page to continue with your application.



Figure 25: Certifications page

4.5 Check for Completeness

Clicking the **Check for Completeness** tab will initiate a check to ensure that all required and mandatory fields within the form are completely filled. The sections that are incomplete are displayed as shown in Figure 26: Check for Completeness.

Figure 26: Check for Completeness

Click a section link under **Resolution** to navigate to the corresponding section and complete the required details.

4.6 Submit Form

Click the **Submit Form** tab in the left navigation pane after completing all the required and mandatory details of the protocol application. A confirmation window pops up. Click the

4.7 Print View

The Print View feature allows you to print the protocol, the comments related to it, or both in PDF format. Click the **Print View** tab in left navigation pane of the form. The **Print View** window pops up as shown in Figure 28: Print View

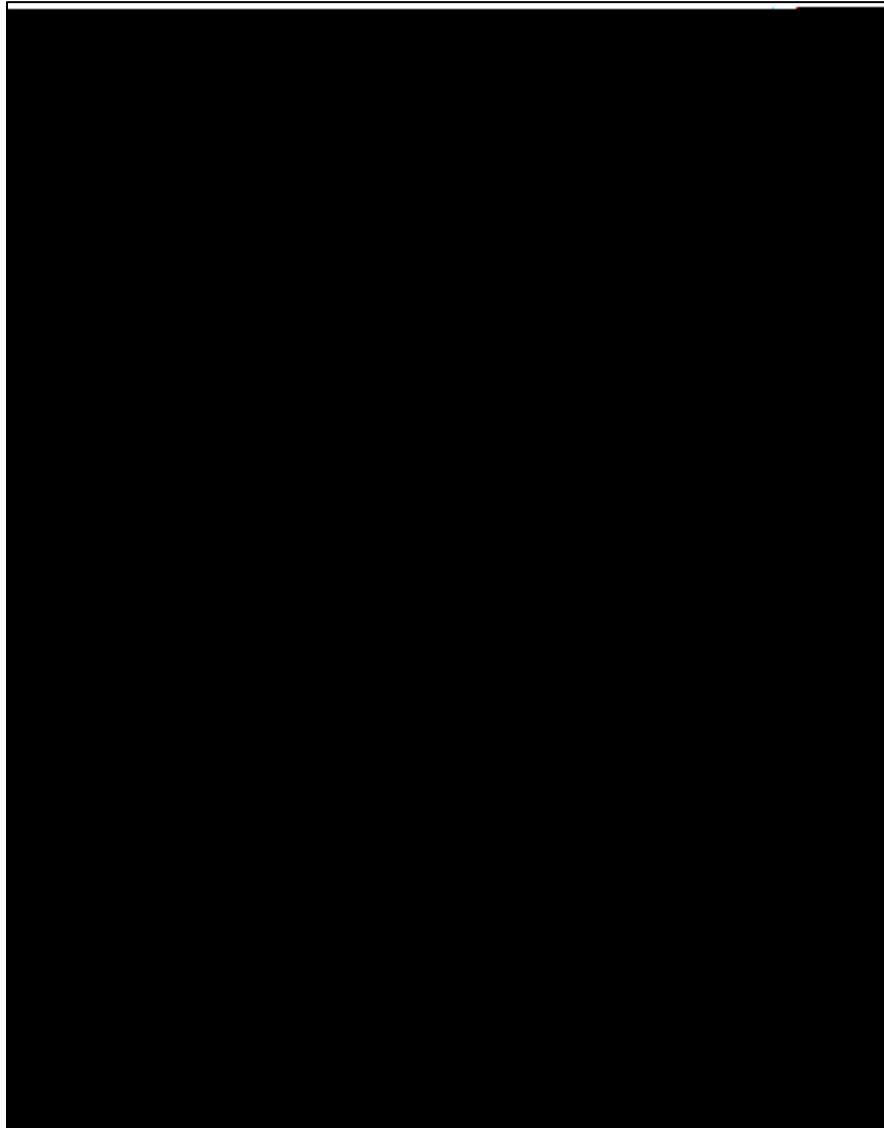


Figure 28: Print View

Select one of the print options with the radio buttons at the top of the page. Select the sections you want to print by checking the boxes on the left-hand side of the window. By default, all the sections except Event History are selected for printing. The orientation of the pages can also be changed by selecting Portrait or Landscape for the section(s) you would like to print. Orientation is set to Portrait by default. Once you have selected the sections you want printed and their orientation, click **OK**. A PDF is generated and can be printed.

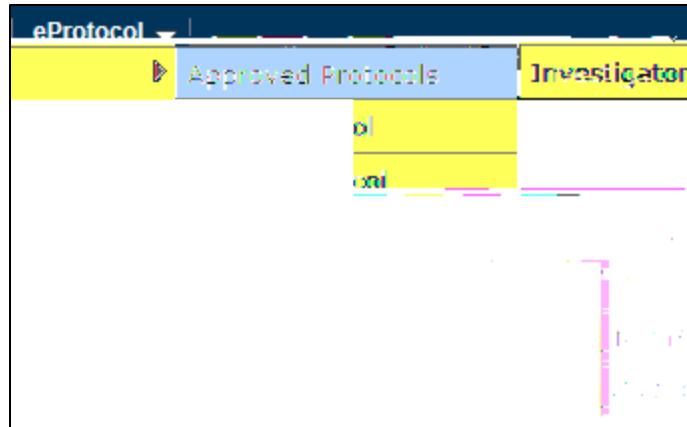


Figure 33: Viewing Approved Protocols

You are directed to the **Approved Protocols** page as shown in Figure 34: Approved Protocols.

Figure 34: Approved Protocols

Once in the Approved Protocol section, select a **Protocol ID**.

The Approved Protocol Decision window pops up with various options including: Open in View Mode, Protocol Details, Start Amendment, Start Continuing Review, and Close Protocol as shown in Figure 35: Approved Protocol Decision Window.

Figure 35: Approved Protocol Decision Window

6.1 Open in View Mode

To open protocols in **View** mode, select **View Mode** and click **OK**. This will open the protocol for viewing, but not editing. You can view the various sections of the protocol. This is useful if you are trying to determine a protocol for cloning.

6.2 Protocol Details

To view the details of different forms created for the protocol, select **Protocol Details**, and click the **OK** button. You are directed to the **Details** page where you can view the complete history of the protocol as shown in Figure 36: Details of Approved Protocols

Figure 36: Details of Approved Protocols

There are several links within the page. Form Type can be used to view the protocol. The

Figure 37: Amendments

Amendments are defined here as minor or significant depending upon the types of changes requested and may result in further review of the protocol. The Amendment can be Saved or undergo a Spell Check by using the buttons in the upper right-hand corner.

To submit your amendments, click the Submit Form tab in the left-hand navigation pane. This sends a summary of the amendments to the IBC Coordinator.

6.4 Start Continuing Review

A Continuing Review is used to initiate an annual review and renewal of a protocol. Normally, protocols within your institution are approved for three years. However, the protocols must be reviewed and renewed annually. Prior to a protocol's expiration date, select Continuing Review in the Approved Protocol Decision window as shown in Figure 35: Approved Protocol Decision Window

1. Select the checkbox next to the **Protocol ID** link and click the **Delete Protocol** button. Select **Yes** in confirmation pop-up to confirm the deletion.

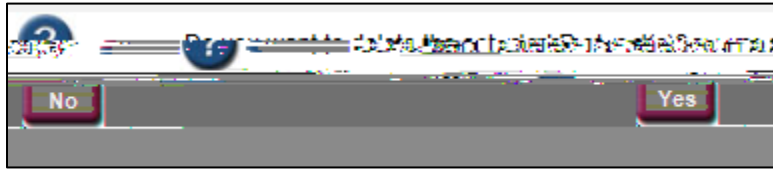


Figure 39: Confirmation window for deleting a protocol



6.7 Searching for a Protocol

You can search for a specific protocol or a set of protocols that meet criteria you select, once you have found the desired protocol(s) you can open and review them by clicking the protocol ID link.

To search for a Protocol:

1. Point to the **eProtocol> Manager** on top left corner of the homepage and click on the **Search Protocol** sub menu (Figure 2: Investigator submenu) to open the **Search Protocol** page.

On this page, you will find several fields you can use in your search : you can use one (for example, Protocol ID or Study Title) or several (for example, Principle Investigator, Sponsor, and Protocol Status).



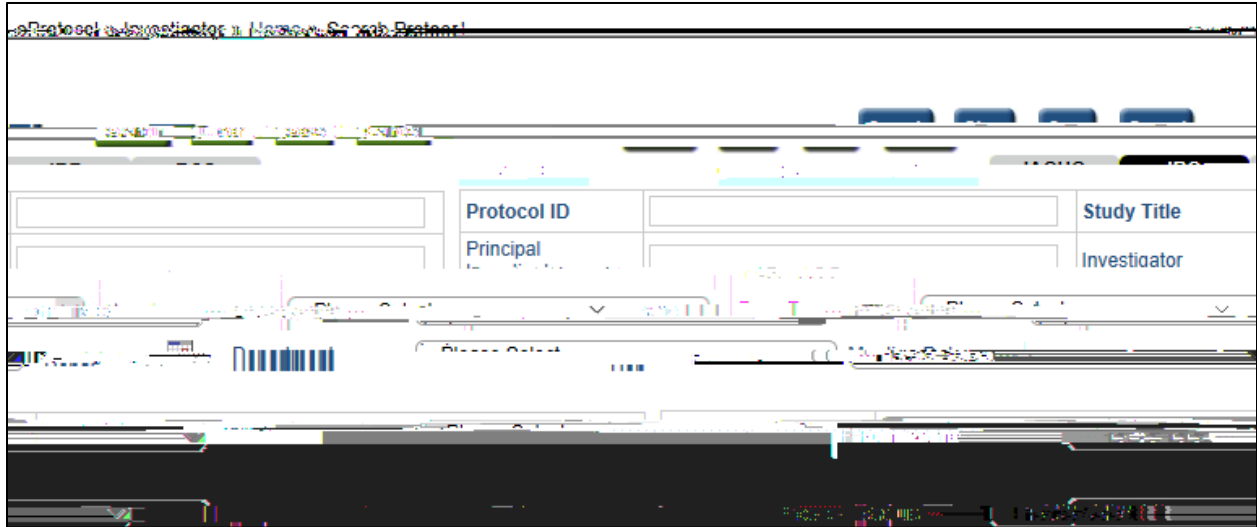
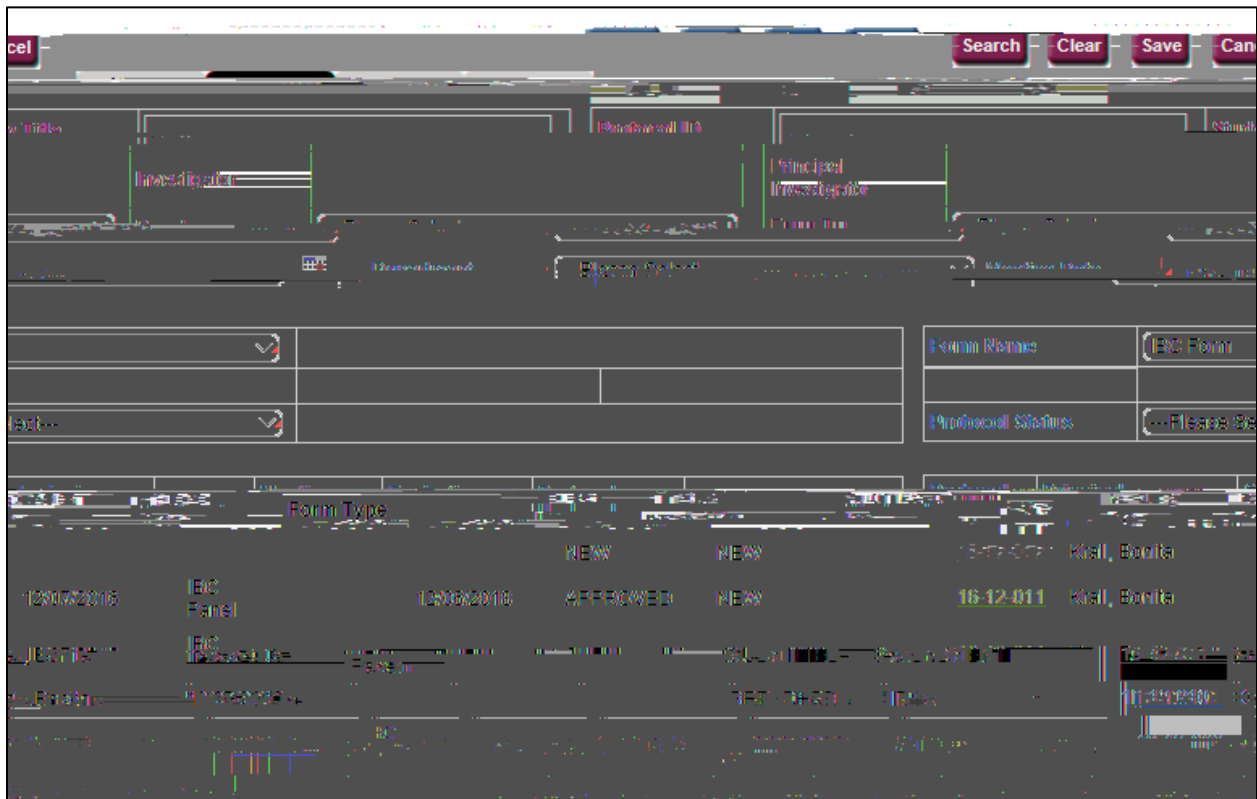


Figure 40: Search Protocol page

2. Enter/Select any of the details/fields and click **Search**, the matching protocol(s) appear below the search criteria as shown in Figure 41: Protocol Search Results.



Form Type	Status	Location
NEW	NEW	16-12-011 Kral, Borita
120072016 IBC Panel	APPROVED	16-12-011 Kral, Borita

Figure 41: Protocol Search Results



6.8 Viewing the Non-Active Protocols

You can view the protocols which are not in active state. The non-active statuses are closed, withdrawn, expired, and not preapproved.

1. Navigate to the **Non Active Protocols** page by pointing to the **eProtocol>Manager** and clicking the **Non Active Protocols** on sub menu (Figure 2: Investigator submenu).

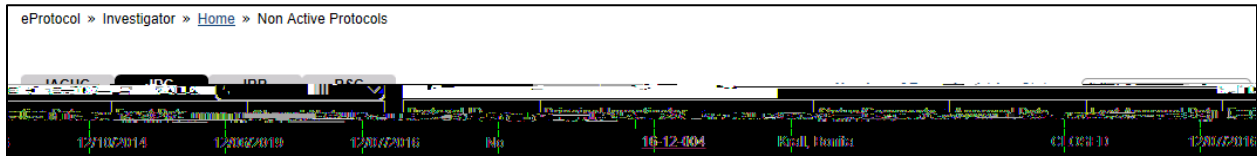


Figure 44: Non Active protocols page

This page shows the protocol details like PI, Status, Approval Date, last Approval Date etc.

2. Select the **Status** from the dropdown list, to view the respective protocols, as shown in Figure 45.

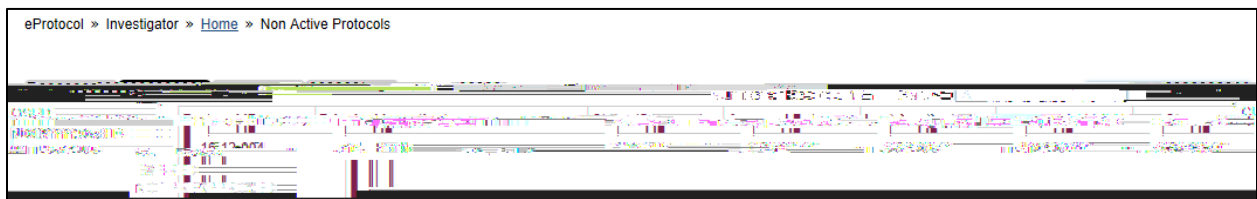


Figure 45: Selecting the status to view the respective protocols

Description of the protocol statuses:

Status	Description
Closed	The protocol is closed by the IBC based on your request. It can be reactivated by the Panel Manager.
Not Approved	The protocol is not approved by the Panel Manager.
Withdrawn	The protocol is withdrawn by the Panel Manager.
Expired	The protocol has crossed the expiration date as no Continuing Review form was submitted for it. It can be reactivated by the Panel Manager.
Not Preapproved	The protocol is not pre-approved.



7 Appendix A -

8 Appendix B - Getting Started Tips

8.1 Disabling Pop-ups

To view pop-ups in the application, you must set browser to allow pop-ups for the application.

8.1.1 For Mozilla

1. A dialogue box appears once you login for first time, Click

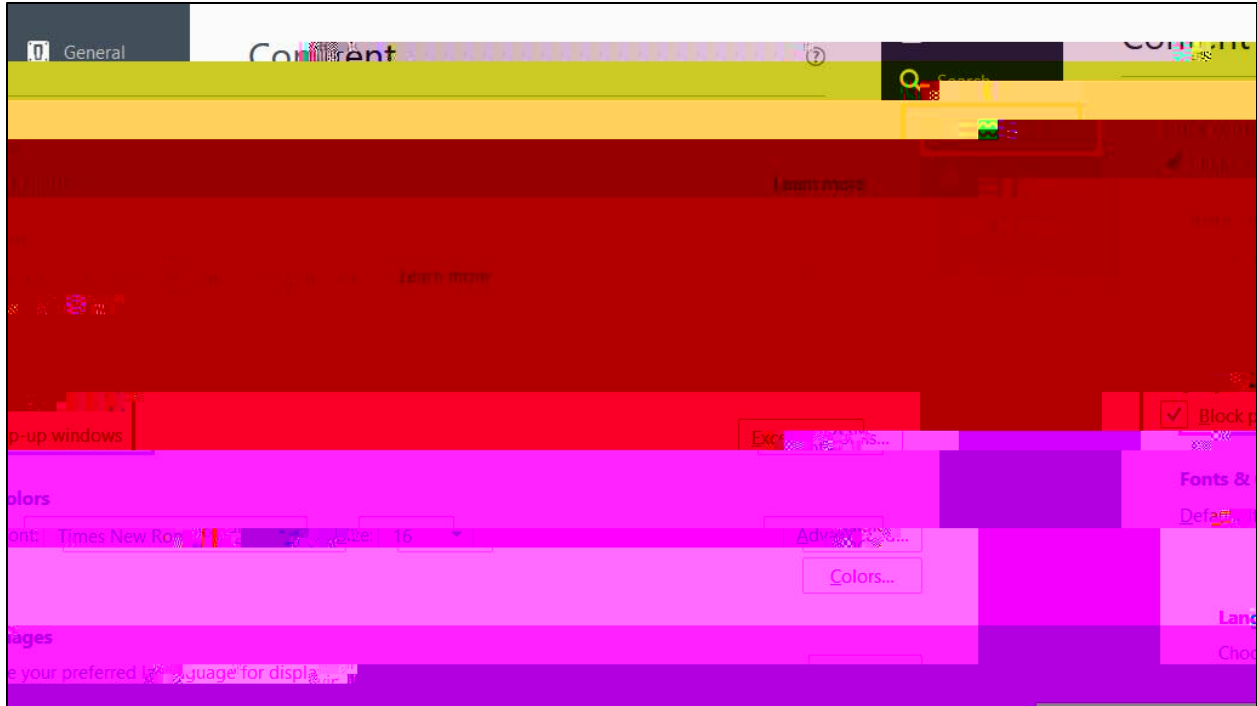


Figure 49: Pop-ups check box

8.1.2 For Internet Explorer

1. A dialogue box appears once you login for first time, Click **Ok** to confirm.

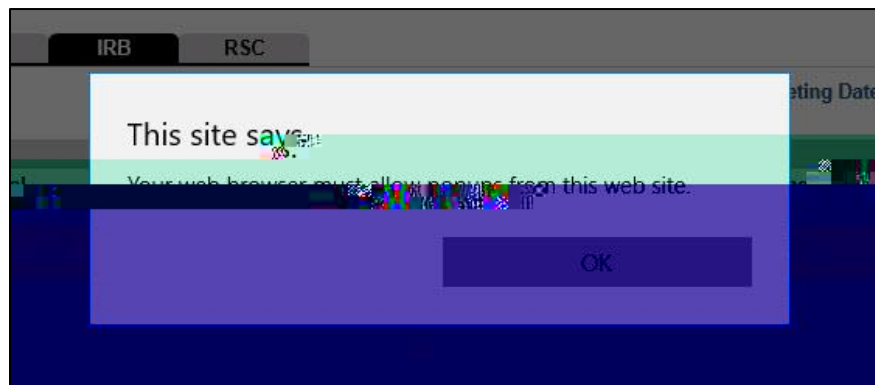


Figure 50: Allow pop-ups

2. A confirmation dialogue box appears on bottom of the page, Click **Allow Once** or **Always Allow** to confirm.

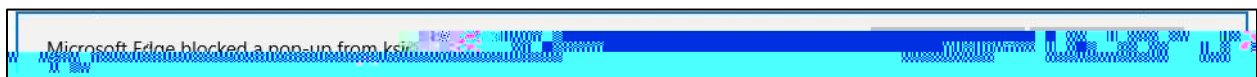


Figure 51: Confirmation box

8.1.3 For Chrome

1. A dialogue box appears once you login for first time, Click **Ok** to confirm.

Figure 52: Allow pop-ups

2. A pop-ups blocker icon appears on the right corner of the URL field. Click on icon and select the **Allow pop-ups** radio option and click **Done**.

Figure 53: Pop-up dialogue box

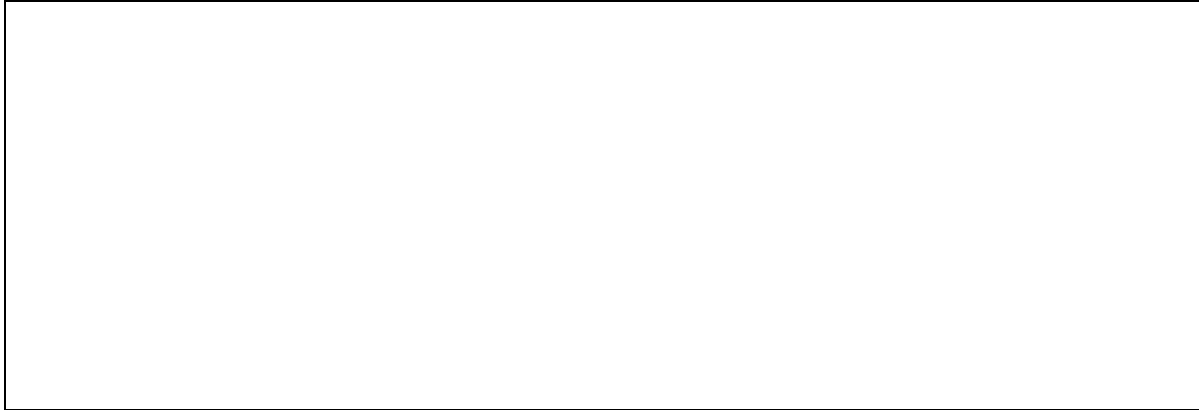


Figure 58: Forgot Password Fields

2. The **Click here**

4. Click on the URL to open the **Reset Password** page.
5. Enter your **UserID** and **Email ID** (the email id on which you will receive a new password).
6. Select the **Hint Question** from the drop-down list and enter an answer for the question.
7. Click the **Submit** button. The details are submitted. An email with the new password is sent to the specified email id.

You can use [this link](#) to reset your password.

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