



eProtocol IBC Principal Investigator User Guide

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1 Introduction

This guide explains how eProtocol, a Key Solutions Protocol Management System (PMS) tool, can assist a Principal Investigator (PI) in the submission, review and approval process associated with the Institutional Biosafety Committee (IBC).

Within eProtocol, PI is a functional role. The PI is responsible for creation and submission of the final IBC application and for adherence to the protocol parameters once the protocol has been approved. Co-PIs and other personnel can take an active role in preparing the application and in the review process. These permissions to prepare or edit the protocol are set by the Company Administrator.

Separate eProtocol guides are available to personnel assigned to the roles of Site Administrator, Committee Manager and Reviewer.

2 General Information

eProtocol is a Key Solutions Protocol Management System (PMS) tool used by a variety of institutional personnel to manage the submission, review and approval process for protocols used in a variety of research projects. The software helps eliminate application errors, and improves collaboration and communication among research teams.



Do not use the Back or Next buttons on your browser while using eProtocol, as this will result in you being logged out of the system. Instead, use the menu items found in the eProtocol module that you are working on.

This guide is specifically designed to assist the PI in successfully navigating through the eProtocol module, and in the submission of protocols to the IBC. An unabridged workflow is found in Figure 46: eProtocol Workflow Diagram.

2.1 About this Guide



This is the Note icon. It indicates information requiring special attention.



This is the Warning icon. It indicates a problem that must be avoided.

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.



The chevron symbol to the far right of the category headings on the homepage is used to expand or collapse the category of protocol application that you are working on.



Use the bread crumb links in the upper left-hand corner of each section to move up through the hierarchy of the eProtocol system. The links are so named because they show you exactly where you are and how to get back to where you were before.



eProtocol is a secure application. Do not use the Back or Next buttons on your browser while using eProtocol, as this will result in you being logged out of the system. Instead, use the menu items found in the eProtocol module that you are working on.



On some pages in eProtocol, information is requested that triggers additional, subordinate information later in the process. If you make an error entering this information, a message appears at the top of the page and you can neither save the contents of that page nor move to another page until you have corrected the error. You may close the page, but the contents will not be saved.

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.



The screenshot shows a login interface for eProtocol. At the top is a photograph of a man in a white lab coat and glasses looking through a microscope in a laboratory setting. Below the photo are two text input fields. The first is labeled 'User ID' and the second is labeled 'Password'. At the bottom of the form are two blue buttons: 'Login' on the left and 'Forgot Password' on the right.

Figure 1: eProtocol Login

3. Click Login.



If you forget your password, you request a new one via the regular process. If you are using the standard eProtocol authentication process (rather than your institution's single sign-on process), you will receive an email with a link to a website to reset your password.

3 Principal Investigator Home

Your Principle Investigator home page displays details of all ongoing protocol applications, approved protocols and amendments to protocols. Any protocols created by you and or in which you are a member are automatically displayed after their creation. From the home page, you can Create , Clone (copy) or Delete (prior to submission) protocols. Once created, from the home page you can open, modify, and submit protocols for review by the IBC.

You are automatically directed to the home page after login. However, you can navigate to the home page at any stage by pointing to **eProtocol > Investigator** in the top left corner of the

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

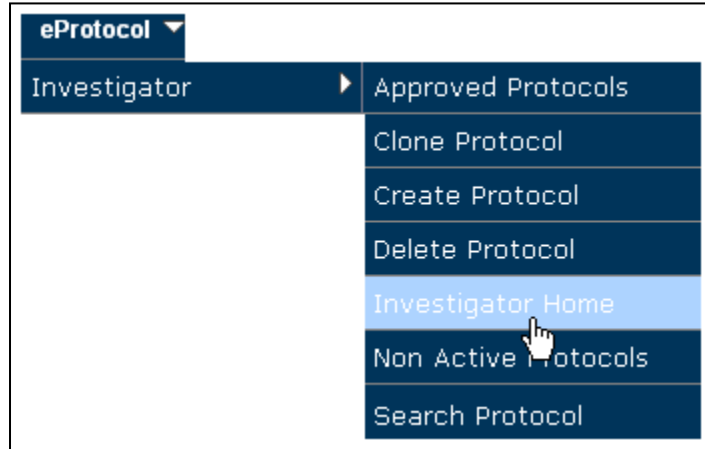


Figure 2: Investigator submenu

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.

IACUC	IBC	IRB	RSC		
Protocols (In Preparation / Submitted)					
NEW					
Protocol ID	Principal Investigator	Protocol Event	Status/Comments	Panel	Meeting Date
16-12-012	Krall, Bonita	Yet to Submit to IBC	NEW		
16-12-010	Krall, Bonita	Resubmit the Protocol	RETURNED		

Figure 3: New Protocol Applications



Please Note that whenever you want to view the protocol content click Protocol ID link.



To sort the protocols in ascending/descending order in a column, click the Column Header.



Please Note you can use the Show/Hide icons (up/down chevrons on the right side of the grey section headers) to view/hide the protocols list.

New protocol applications include applications that are incomplete and applications that have been submitted, but are still in the review process. The column heading definitions for New applications are found in Table 3: Investigator Homepage Category Definitions Following Protocol Approval.

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	The protocol stage in the review process. Events are displayed as: <ol style="list-style-type: none"> 1. Yet to Submit: protocols which are in progress and have been assigned a Protocol ID. 2. Submitted: submitted for review to the IBC. 3. Moved: meeting date has been changed. 4. Tabled: IBC discussion about the protocol is not complete. 5. Contingent: approved contingent specified changes being made. 6. Comments Received: response received from IBC. 7. Responses Sent: PI has responded to IBC comments. 8. Resubmit: protocol returned to PI for resubmission specifying changes to be made.
Status/ Comments	The current status of the protocol in the review process. Statuses include: <ol style="list-style-type: none"> 1. New: has not yet been submitted for review. 2. Submitted: submitted to the IBC. 3. In-Progress: under development. 4. Returned: IBC has requested changes and resubmission. 5. Moved: Different meeting date assigned. 6. Tabled: IBC discussion not complete; PI's response must be reviewed by full committee. 7. Approved with Stipulation: Contingent Approval of the protocol.
Panel	The name of the panel that is reviewing the protocol is displayed in the column.
Meeting Date	The date on which the protocol is scheduled to be discussed in the panel meeting.

3.1.2 Protocol Categories Following Approval

Following IBC approval of a new protocol, several other activity categories become important and are viewed on the home page as shown in Figure 4: Investigator Homepage Categories Following Protocol Approval. These include Amendments and Continuing Reviews, which have entered a review process, as well as a list of Approved Protocols and Non-Active Protocols.

AMENDMENT						
Protocol ID	Principal Investigator	Protocol Event	Status/Comments	Panel	Meeting Date	
13-10-N-00007	Jones, Simon	SUBMITTED TO IACUC	SUBMITTED	LC IACUC		

CONTINUING REVIEW						
Protocol ID	Principal Investigator	Protocol Event	Status/Comments	Panel	Meeting Date	Expiration Date
13-10-N-00011	Jones, Simon	Yet to Submit to IACUC	NEW	LC IACUC		10/11/2013

Approved Protocols						
Protocol ID	Principal Investigator	Approval Date	Last Approval Date	Expiration Date	Review Decision	Form Type
13-10-N-00011	Jones, Simon	10/12/2010	10/25/2012	10/11/2013	Administrative Review	AMENDMENT
13-10-N-00007	Jones, Simon	10/25/2013	10/25/2013	10/24/2016	Administrative Review	NEW

Non Active Protocols						
Protocol ID	Principal Investigator	Approval Date	Last Approval Date	Status/Comments	Form Type	
13-10-N-00008	Jones, Simon			NOT APPROVED	NEW	
13-10-N-00006	Jones, Simon			WITHDRAWN	NEW	

Figure 4: Investigator Homepage Categories Following Protocol Approval

Definitions of these categories are found in Table 3: Investigator Homepage Category Definitions Following Protocol Approval.

Table 3: Investigator Homepage Category Definitions Following Protocol Approval

Type	Description
Amendment	Revisions to the protocol following its approval.
Continuing Review	The annual renewal of an approved protocol usually must be approved prior to the first and second anniversaries of the initial approval.
Approved Protocols	Protocols approved by IBC.
Non-active Protocols	Protocols not approved, closed, withdrawn, temporarily inactive or expired.



New, Amendment and Continuing Review are primary protocol documents. Only one of these forms can be in preparation for a protocol at any point in time. Amendments can only be created following protocol approval. Similarly, a Continuing Review form can only be created following the approval of a protocol or an amendment and only during the specified period prior to the anniversary of the initial approval. Only one amendment can be active at a time, if an amendment has been submitted another amendment cannot be created until that amendment is approved, disapproved or withdrawn.

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.



By clicking the specific column headings on your home page, it is possible to arrange the protocols in ascending/descending order.

3.1.3 Home Page for the dual Principle Investigator and Reviewer

If you are assigned a Reviewer role along with the Investigator role by the Company Administrator, you will have two drop down options in your navigation panel as shown in Figure 5: Dual Reviewer and Investigator Roles.

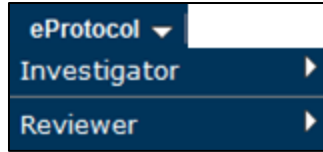


Figure 5: Dual Reviewer and Investigator Roles



The Company Administrator sets your roles within eProtocol. If you are a Committee or Panel Manager, that role will also appear in your navigation panel drop-down list. In order to work in a specific role within the system, you select your user role from this list and navigate to the user home page to perform your tasks.

From the Investigator Home Page, there are three main task buttons: Create Protocol, Clone Protocol and Delete Protocol. These are explained below.

3.2 Create a Protocol

Click **Create Protocol** in the upper right-hand corner to begin your protocol application (as seen in Figure 6: Investigator Homepage for IBC Protocol Creation).

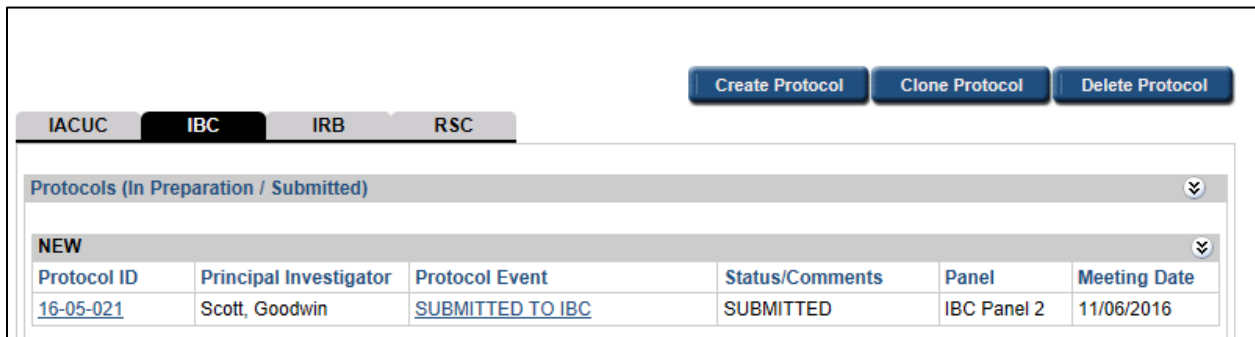


Figure 6: Investigator Homepage for IBC Protocol Creation



Please Note whenever you want to view the protocol, click the Protocol ID link.



To sort the protocols in ascending/descending order in a column, click the Column Header.

Alternatively, you can navigate to **eProtocol>Investigator** in the top left corner of the screen and then select **Create Protocol** from the sub menu as shown in Figure 2: Investigator submenu.

Once you select **Create Protocol**, the following fields must be completed prior to obtaining a Protocol ID and being able to save the protocol.

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



eProtocol » Investigator » [Home](#) » Create Protocol

Study Title Create Cancel

IBC form

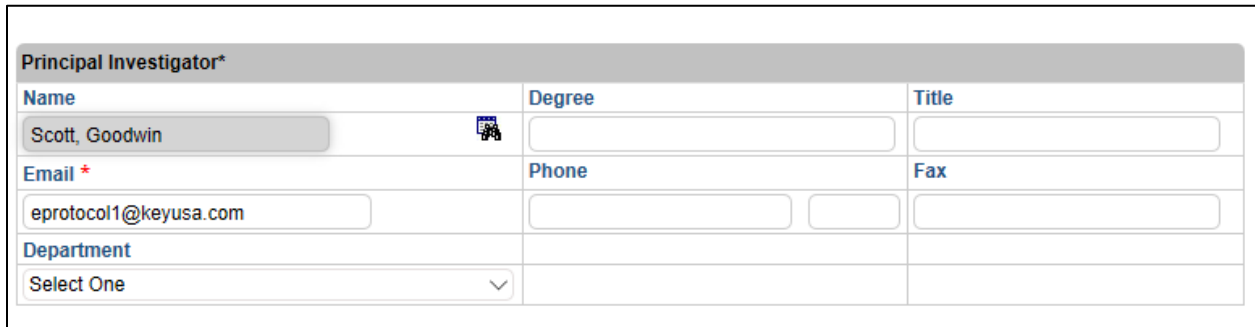
IACUC IBC IRB RSC

IBC

IBC Form

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 Investigator. Depending upon your system's configuration, there may be additional roles visible on the create protocol page (e.g., an optional Administrative Editor).



Principal Investigator*


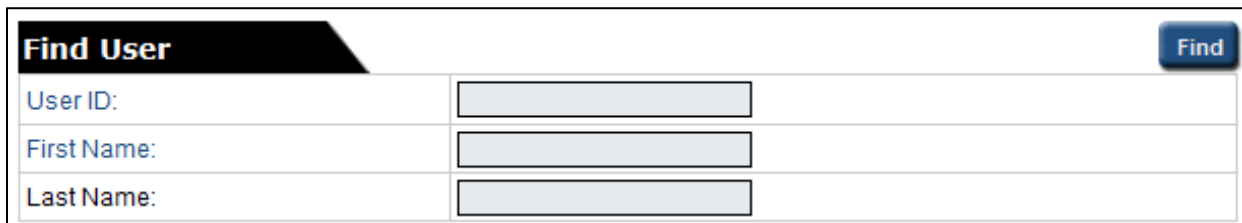
Name	Degree	Title
Scott, Goodwin 		
Email *	Phone	Fax
eprotocol1@keyusa.com		
Department		
Select One		

Figure 8: Principal Investigator Fields

If you want a different user to be the Principal Investigator, you can select them by clicking the binoculars icon to the right of the shaded Name field. The Find User window pops up as shown in Figure 9: Find User Field. Provide the User ID, First Name or Last Name, and click the **Find** button. Based on the selection criteria, user records are displayed. Select a user, click the **OK** button, and the user is added.



Find User Find

User ID:

First Name:

Last Name:

Figure 9: Find User Field

- 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 Submit to IBC**’ as shown in Figure 6: Investigator Homepage for IBC Protocol Creation.



When you log on as an **Investigator** and begin an application, the PMS eProtocol program automatically completes some entry fields, grays out others, and either gives you or denies you access to parts of the application based upon your answers to questions as you progress through the pages of the form.

3.3 Clone a Protocol

To create a protocol with similar content to that of an existing protocol, the Clone Protocol option can be used. This can speed up the protocol creation process. This is particularly useful for doing a de novo protocol. After cloning the protocol, you can modify it as little or as much as information as required to accurately reflect your research requirements. Once cloned, your new protocol is given a new Protocol ID and added to the Investigator Home Page. The new protocol has Protocol Event: ‘**Yet to Submit to IBC.**’

To start the Clone Protocol process, go to the Investigator Home Page. This screen has a list of all your protocols, either in preparation or submitted. The Clone Protocol tab is found in the upper right hand corner as shown in Figure 10: Selecting an IBC Protocol to Clone.

Alternatively, you can navigate to **eProtocol > Investigator** in the top left corner of the screen and then select Clone Protocol from the sub menu as shown in Figure 2: Investigator submenu

						Clone Protocol
IACUC	IBC	IRB	RSC	All		
Protocol ID	Principal Investigator	Protocol Event	Form Type	Panel	Meeting Date	
<input type="radio"/> IBC-16-12-077	Scott, Goodwin	NEW	NEW			
<input type="radio"/> 16-05-021	Scott, Goodwin	IN-PROGRESS	NEW	IBC Panel 2	11/06/2016	

Figure 10: Selecting an IBC Protocol to Clone

- Select the protocol you would like to clone using the radio button directly to the left of the Protocol ID as shown in Figure 10: Selecting an IBC Protocol to Clone.



If you are unsure of the Protocol ID of the protocol you need to clone, you can view the protocols prior to selection by clicking on the blue underlined Protocol ID link.

- Click **Clone Protocol**. A confirmation window appears as shown in Figure 11: Clone Protocol Confirmation. Select **Yes** to clone the protocol.

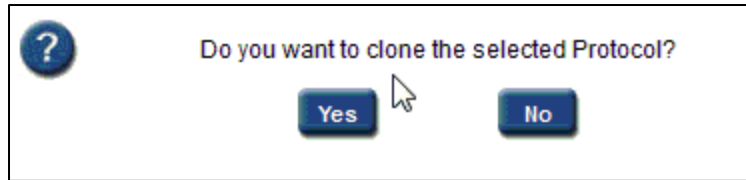


Figure 11: Clone Protocol Confirmation

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 that it is a cloned protocol is recorded in the Event History.

4 Completing and Submitting a New Protocol

Once you have added a title, the details of the Principle Investigator, your new protocol is created and given a Protocol ID as discussed in Create Protocol. The new protocol is described by the Protocol Event: Yet to Submit to IBC on your Investigator Home Page.

To complete and submit your protocol application, click the **Protocol ID** or the **Protocol Event** of the protocol you would like to edit. All of the fields to be completed as part of the application process are listed in the left-hand panel as shown in Figure 12: Left-Hand Navigation Pane.



Figure 12: Left-Hand Navigation Pane

While editing protocols for submission to IBC, you will notice a title bar and a toolbar as you proceed through or edit the protocol as shown in Figure 13: Toolbar Visible When Creating or Editing a Protocol. On the title bar is the form you are using, the ID and title of the Protocol you are working on. On the toolbar are action options: Save, Spell Check, Help and Close.

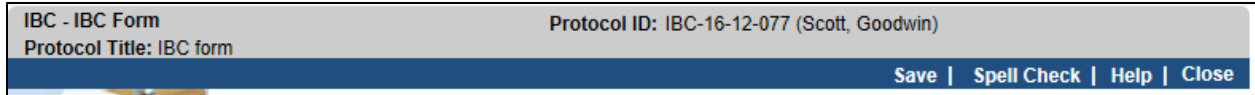


Figure 13: Toolbar Visible When Creating or Editing a Protocol

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 Figure 14: Confirmation of Close Selection.

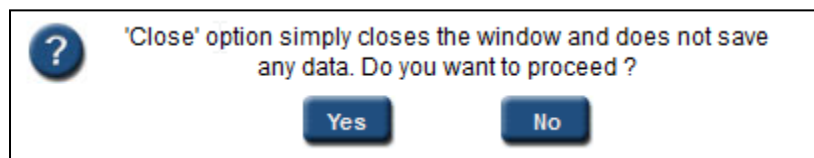


Figure 14: Confirmation of Close Selection

4.1 Personnel Information section

The Principle Investigator field is auto-populated with the information you provided when creating the protocol. However, you can edit this information and you may be required by the IBC to provide additional information on training for the species used in the protocol.

In addition to the PI, there may be other optional collaborating or assisting roles to complete, possibly including: one or more additional PIs, a Lab Supervisor, or a Study Coordinator. The Edit/View privileges and the Submit privileges for these roles are unique to your institution and are configured by the Company Administrator.

You can also enter Other Personnel working on the Protocol by clicking **Add** on the grey bar to the left of the title “Other Personnel.” You can add multiple users to various research roles.



To advance to the next section of the application, you can either choose another heading from the left-hand navigation pane or click **Next**. Selecting **Next** will auto-save the information added to the protocol up to this point.



Clicking **Next** checks all Items/questions with a red asterisk “*” to make sure they have been answered. If they have not, a message appears at the top of the page and you do not move to the next page. You must answer the items with a **red asterisk**

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.

Personnel Information	<div style="background-color: #cccccc; padding: 5px;">Project Registration</div> <p style="font-size: small; color: #0056b3;">Please check all that apply to this protocol. Items checked on this Registration List will determine subsequent sections in the form that will need to be answered.</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 30px; text-align: center;"><input checked="" type="checkbox"/></td> <td>Biological Agents.</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Recombinant or Synthetic Nucleic Acid molecules (rsNA).</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Biological Toxin Usage.</td> </tr> </table>	<input checked="" type="checkbox"/>	Biological Agents.	<input type="checkbox"/>	Recombinant or Synthetic Nucleic Acid molecules (rsNA).	<input type="checkbox"/>	Biological Toxin Usage.
<input checked="" type="checkbox"/>		Biological Agents.					
<input type="checkbox"/>		Recombinant or Synthetic Nucleic Acid molecules (rsNA).					
<input type="checkbox"/>		Biological Toxin Usage.					
Project Registration							
Protocol Information							
Certifications							
Check For Completeness							
Submit Form							
Print View							
Event History							

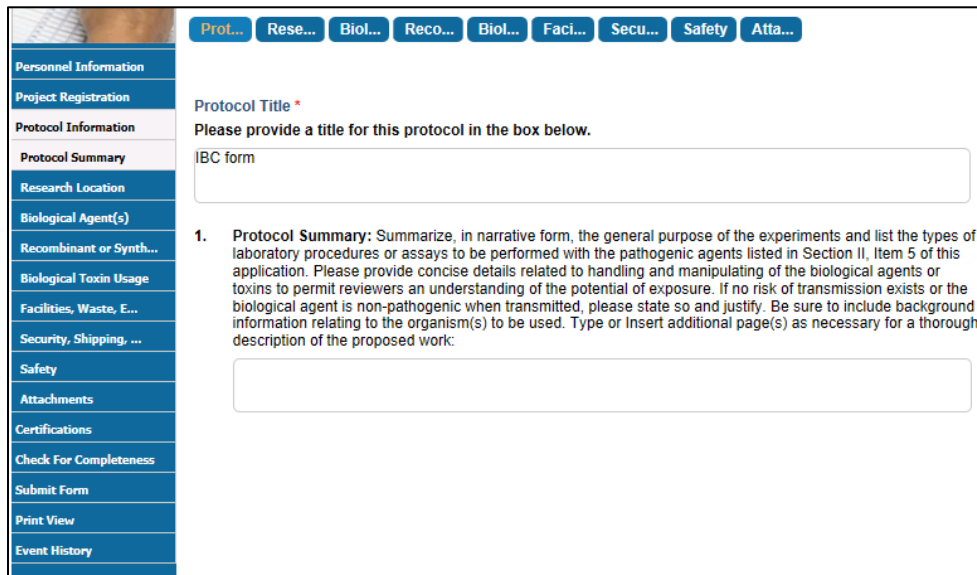
Figure 15: Project Registration section

4.3 Protocol Information section

In this section, you need to provide the necessary information for the various aspects of the research being undertaken. The researcher must provide a study title/project title; a protocol summary; and the various procedures that are to be followed during the research. It also ensures that the researcher follows all the compliance and regulations, if applicable, while conducting the research.



You can sequence through these sections by clicking **Next** when you have complete one, or you can use the navigation buttons at the top or navigation tabs to the left. Watching the which button at the top is highlighted gives you an idea of progress through the form.



The screenshot shows the 'Protocol Information' section of the eProtocol IBC system. At the top, there are navigation tabs: Prot..., Rese..., Biol..., Reco..., Biol..., Faci..., Secu..., Safety, and Atta... The 'Safety' tab is currently selected. On the left, a sidebar contains a list of sections: Personnel Information, Project Registration, Protocol Information (highlighted), Protocol Summary, Research Location, Biological Agent(s), Recombinant or Synth..., Biological Toxin Usage, Facilities, Waste, E..., Security, Shipping, ..., Safety, Attachments, Certifications, Check For Completeness, Submit Form, Print View, and Event History. The main content area displays the 'Protocol Title' field with a red asterisk and the instruction 'Please provide a title for this protocol in the box below.' The text 'IBC form' is entered in the text box. Below this is a numbered list item: '1. Protocol Summary: Summarize, in narrative form, the general purpose of the experiments and list the types of laboratory procedures or assays to be performed with the pathogenic agents listed in Section II, Item 5 of this application. Please provide concise details related to handling and manipulating of the biological agents or toxins to permit reviewers an understanding of the potential of exposure. If no risk of transmission exists or the biological agent is non-pathogenic when transmitted, please state so and justify. Be sure to include background information relating to the organism(s) to be used. Type or Insert additional page(s) as necessary for a thorough description of the proposed work:' followed by an empty text box.

Figure 16: Protocol Information section



You In the following Sections, where **Add** appears in a table header, clicking the **Add** opens a pop-up for you to provide additional information.

4.3.1 Research Location

[Prot...](#)
[Rese...](#)
[Biol...](#)
[Reco...](#)
[Biol...](#)
[Faci...](#)
[Secu...](#)
[Safety](#)
[Atta...](#)

Identify all laboratories, culture rooms, cold rooms, common equipment rooms, clinic areas or other areas in which the biological agent(s) or toxins will be stored or manipulated:

Research Location			Add	Delete
	Building Name	Floor	Room Number	
<input type="checkbox"/>	Building_1	FLOOR 2	1202	

Figure 17 Research Location

4.3.2 Biological Agents

[Prot...](#)
[Rese...](#)
[Biol...](#)
[Reco...](#)
[Biol...](#)
[Faci...](#)
[Secu...](#)
[Safety](#)
[Atta...](#)

1. Identify microorganisms you are proposing to use by listing them in the table below (Include all strains/variant)

Biological Agent (s)		Add	Delete
Please click on Add to add Biological Agent (s)			

Are there agents identified as select agents? Yes **No**

2. List the total liquid volumes of the biological agents that will be manipulated at a single time or in a single experiment

Please provide concise details related to handling and manipulating of the biological agents or toxins to permit reviewers an understanding of the potential of exposure. If no risk of transmission exists or the biological agent is non-pathogenic when transmitted, please state so and justify. Be sure to include background information relating to the organism(s) to be used. Type or Insert additional page(s) as necessary for a thorough description of the proposed work:

3. List the maximum concentrations or titers of the biological agents that will be manipulated

Please provide concise details related to handling and manipulating of the biological agents or toxins to permit reviewers an understanding of the potential of exposure. If no risk of transmission exists or the biological agent is non-pathogenic when transmitted, please state so and justify. Be sure to include background information relating to the organism(s) to be used. Type or Insert additional page(s) as necessary for a thorough description of the proposed work:

4. If viral, is the virus replication-competent? Yes No **N/A**

Figure 18 Biological Agents

4.3.3 Recombinant or Synthetic Nucleic Acid molecules (rsNA)

Prot...Rese...Biol...Reco...Biol...Faci...Secu...SafetyAtta...

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

a. List the total volume of bacterial cell culture containing Recombinant or Synthetic Nucleic Acid molecules (rsNA) grown at one time:

b. What will the plasmid express?

c. Vector(s) used:

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

Figure 19 4.3.3 Recombinant or Synthetic Nucleic Acid molecules

4.3.4 Biological Toxin Usage

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

1. Identify toxin(s) you are proposing to use by listing them in the table below

Biological Toxin Names

Please click on Add to add Biological Toxin Names

2. Is there a therapeutic agent (e.g., antidote) available for persons exposed to the toxin? Yes No N/A

a. **If yes:**

Is therapeutic agent stored within the laboratory (or)
 with Employee Health?

3. Is the toxin on the Select Agent List? Yes No N/A

a. **If yes:** Please check the appropriate box below

- Abrin
- Saxitoxin
- Botulinum neurotoxin
- Shiga-like ribosome inactivating proteins
- Clostridium perfringens epsilon toxin
- Shigatoxin
- Conotoxins
- Staphylococcal enterotoxins
- Diacetoxyscirpenol
- Tetrodotoxin
- Ricin
- T-2 toxin

Figure 20 Biological Toxins

4.3.5 Facilities, Waste, and Equipment

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

1. FACILITIES

a. Please provide a diagram of each laboratory and other areas with specific areas of biological or toxin agent use and/or storage identified. Attach the diagram to the application and label as Appendix F

b. All work with biological agent(s) or toxin(s) will be done in a HEPA-filtered (Class II) biological safety cabinet?

If no: Please explain what barrier system will be employed and justify its adequacy for the work performed (attach additional material if necessary):

c. Autoclaves used for sterilization are spore tested weekly and documented by a designated area individual.

i. Identify the individual responsible for documentation:

ii. Identify where documentation will be located:

d. Identify the disinfectant(s) you will use in conjunction with this work. PI's are allowed to choose more than one disinfectant:

- 10% (1 part stock bleach: 9 parts water-dilution) bleach solution prepared fresh daily.
- Envirocide; used according to product label (Product information sheet showing efficacy and MSDS attached).
- Sporklenz; used according to product label (Product information sheet showing efficacy and MSDS attached).

Figure 214.3.5 Facilities, Waste, and Equipment

4.3.6 Security, Shipping, Transport, and Training

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

1. SECURITY

Access to the laboratory or clinic areas is restricted to authorized personnel while work with the biological agent or toxin is in progress. Note: Open labs are restricted with proximity card access in the DRC. The following measures are in place to restrict access:

- Signage
- Laboratory doors are closed
- Laboratory doors are closed and locked

The biological agent or toxin is stored in a locked freezer (only accessible by authorized personnel) to reduce the likelihood of unauthorized access. Yes No

If no:

2. SHIPPING, TRANSPORT AND TRAINING

a. Source of the biological agent(s) if from a source outside the University (if applicable, [attach](#) ATCC or other appropriate documentation in Attachments Section.)

Add

b. Will materials containing, or contaminated by the biological agent or toxin be transported via a corridor or other thoroughfare which is used by persons not directly working with the agent? Yes No N/A

If yes: Please describe the precautions that will be employed to minimize breakage of containers and release of biological agents or toxins during transport:

Figure 224.3.6 Security, Shipping, Transport, and Training

4.3.7 Safety

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

Note to Investigators: Please read the attached document by clicking the link.

For further help and guidance go to the Safety IBC - [APPENDIX A: General Practices](#)

By checking "Yes", the investigator affirms he/she has read Appendix A: General Practices and agrees to abide by the rules established for protection and safety in the laboratory Yes No

Explain any deviations:

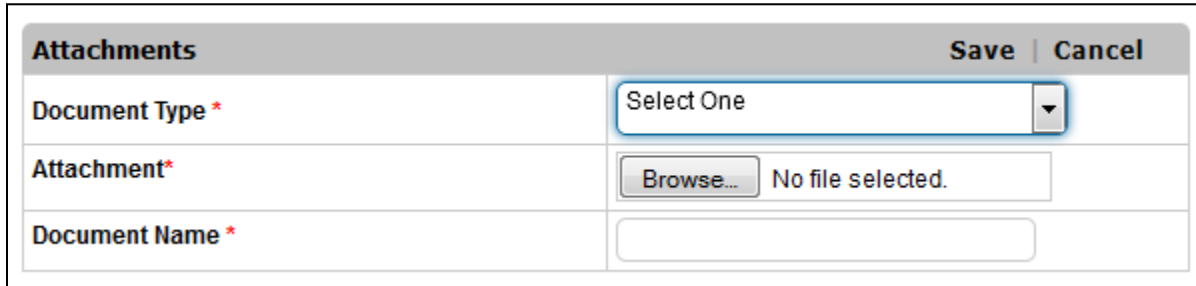
Splash and Exposure Procedure

- a. In the event of an accidental splash to skin or eye, flush for a full (timed) 15 minutes with running water/eye wash and seek medical attention
- b. In the event of an accidental exposure or injection with the biological agent, Recombinant or Synthetic Nucleic Acid molecules (rsNA), or toxin, the exposed skin or injection site will be washed with anti-microbial soap and water, and/or an approved alcohol base rub (containing >60% alcohol) will be applied to the site of injection or contact.
- c. The supervising PI and Biological Safety Officer will be notified.
- d. The employee will complete and Employee Report of Injury form.
- e. The employee will report to Employee Health during regular business hours. The employee should report to Client Hospital Emergency Department if injury is life threatening/severe or if acute treatment is required after business hours. If initial treatment is provided in the Emergency Room, the employee is to follow up with Employee Health on the next business day.

Figure 23 Safety

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.



Attachments		Save Cancel
Document Type *	Select One	
Attachment*	Browse... No file selected.	
Document Name *		

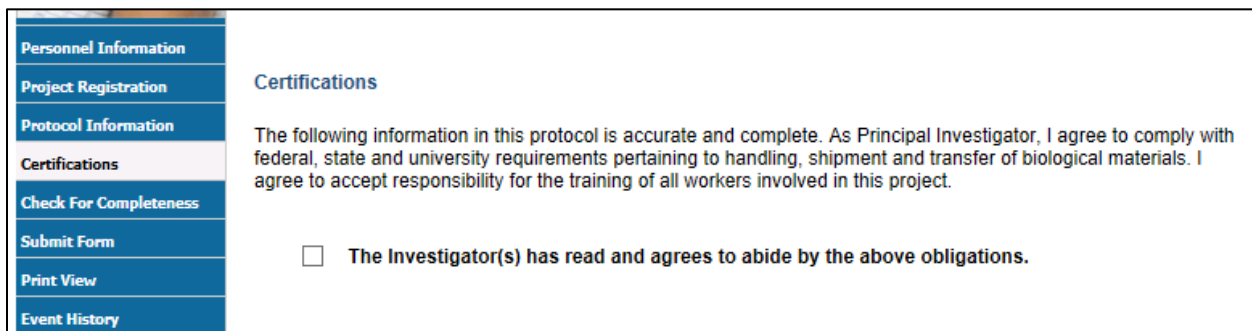
Figure 24: Attachments

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.



Personnel Information	<p>Certifications</p> <p>The following information in this protocol is accurate and complete. As Principal Investigator, I agree to comply with federal, state and university requirements pertaining to handling, shipment and transfer of biological materials. I agree to accept responsibility for the training of all workers involved in this project.</p> <p><input type="checkbox"/> The Investigator(s) has read and agrees to abide by the above obligations.</p>
Project Registration	
Protocol Information	
Certifications	
Check For Completeness	
Submit Form	
Print View	
Event History	

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.


 Search or enter web address	
Protocol ID: IBC-16-12-077	
Principal Investigator: Scott, Goodwin	
IBC Form	
S.No.	Resolution
1	Biological Agent(s) - Complete Questions (2) through (10). Specify N/A as appropriate.
2	Facilities, Waste, Equipment - Complete Questions (1) through (3). Specify N/A as appropriate.
3	Security, Shipping, Transport and Training - Complete Questions (1) and (2). Specify N/A as appropriate.
4	Protocol Summary - Complete Question (1). Specify N/A as appropriate.
5	Biological Agent(s) - Please add at least one record for 'Biological Agent(s)'.
6	Safety - Complete Section. Specify N/A as appropriate.
7	Please check the checkbox for 'Certifications' in Certifications section.

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

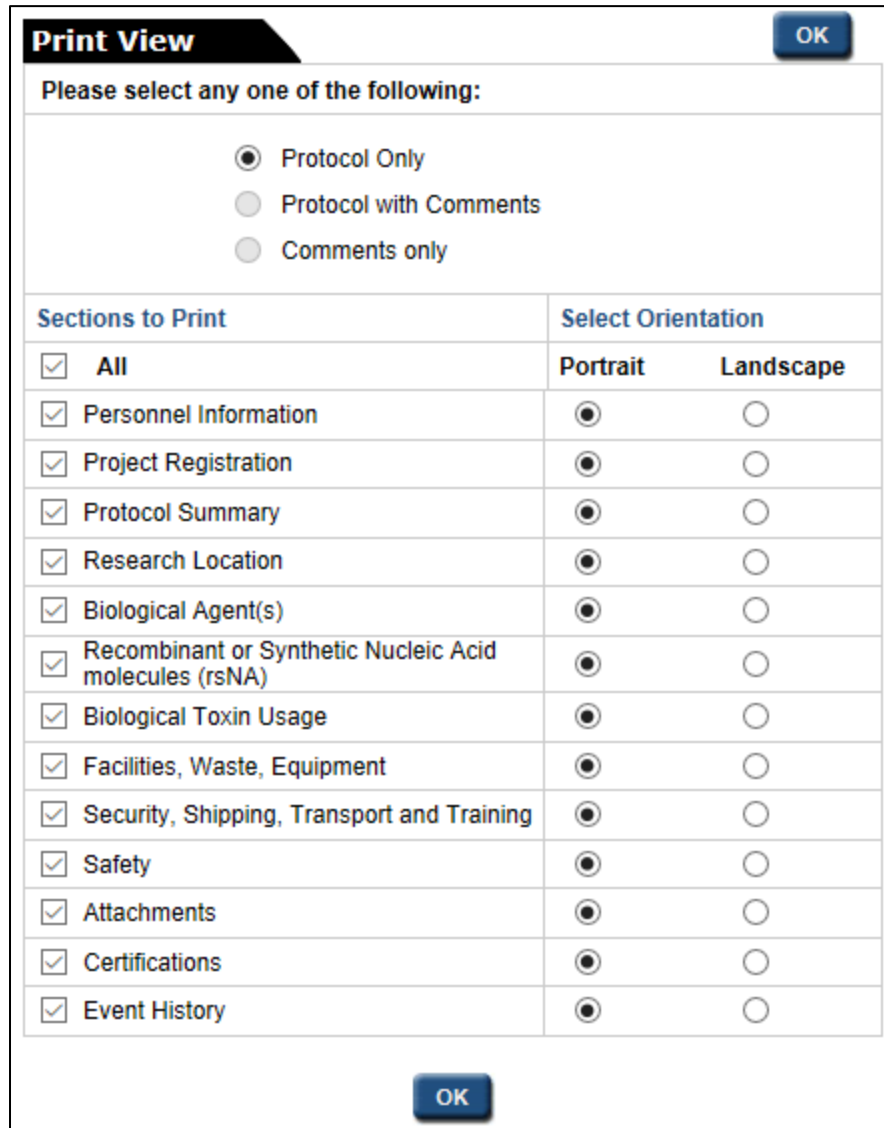
Click the **Submit Form** tab in the left navigation pane after completing all the required and mandatory details of the protocol application. A confirmation window pops up. Click the **Yes** button. In case there are any mandatory or required details that have not been entered, the **Check for Completeness** window pops up. Complete all details until the Check for Completeness tab displays “**IBC Application Form is complete**” and then click **Submit Form**. Following submission of your protocol, you are re-directed to your home page, where a message thanks you for submitting the protocol as shown in the top left of Figure 27: Submitted to .

Thank You for Submitting the Protocol 16-12-007. eProtocol » Investigator » Home					
<input type="button" value="Create Protocol"/> <input type="button" value="Clone Protocol"/> <input type="button" value="Delete Protocol"/>					
IACUC IBC IRB RSC					
Protocols (In Preparation / Submitted)					
NEW					
Protocol ID	Principal Investigator	Protocol Event	Status/Comments	Panel	Meeting Date
16-12-007	Scott, Goodwin	SUBMITTED TO IBC	SUBMITTED		
16-12-005	Scott, Goodwin	SUBMITTED TO IBC	SUBMITTED	IBC Panel	
16-12-003	Scott, Goodwin	Responses Sent (Cycle 1)	IN-PROGRESS	IBC Panel	

Figure 27: Submitted to IBC

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



Sections to Print		Select Orientation	
		Portrait	Landscape
<input checked="" type="checkbox"/>	All	<input checked="" type="radio"/>	<input type="radio"/>
<input checked="" type="checkbox"/>	Personnel Information	<input checked="" type="radio"/>	<input type="radio"/>
<input checked="" type="checkbox"/>	Project Registration	<input checked="" type="radio"/>	<input type="radio"/>
<input checked="" type="checkbox"/>	Protocol Summary	<input checked="" type="radio"/>	<input type="radio"/>
<input checked="" type="checkbox"/>	Research Location	<input checked="" type="radio"/>	<input type="radio"/>
<input checked="" type="checkbox"/>	Biological Agent(s)	<input checked="" type="radio"/>	<input type="radio"/>
<input checked="" type="checkbox"/>	Recombinant or Synthetic Nucleic Acid molecules (rsNA)	<input checked="" type="radio"/>	<input type="radio"/>
<input checked="" type="checkbox"/>	Biological Toxin Usage	<input checked="" type="radio"/>	<input type="radio"/>
<input checked="" type="checkbox"/>	Facilities, Waste, Equipment	<input checked="" type="radio"/>	<input type="radio"/>
<input checked="" type="checkbox"/>	Security, Shipping, Transport and Training	<input checked="" type="radio"/>	<input type="radio"/>
<input checked="" type="checkbox"/>	Safety	<input checked="" type="radio"/>	<input type="radio"/>
<input checked="" type="checkbox"/>	Attachments	<input checked="" type="radio"/>	<input type="radio"/>
<input checked="" type="checkbox"/>	Certifications	<input checked="" type="radio"/>	<input type="radio"/>
<input checked="" type="checkbox"/>	Event History	<input checked="" type="radio"/>	<input type="radio"/>

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.



The Protocols with Comments and Comments only radio buttons will only be enabled if the Comments/Response cycle has been initiated for the protocol.

4.8 Event History

Event History refers to the complete history of the protocol form submissions, and the major actions performed on the protocol (e.g. NEW FORM SUBMITTED, NEW FORM PANEL ASSIGNED, NEW FORM PROTOCOL CLONED, etc.). Event History is shown in Figure 29: Event History.

Event History			
2016 ▼			
Date	Status	View Attachments	Letters
12/07/2016	NEW FORM CREATED		
12/07/2016	NEW FORM SUBMITTED	View Attachments	
Email History			
2016 ▼			
Email Date	Email Type	Attachments	
12/07/2016	IBC Protocol has been submitted: 16-12-004, Krall, Bonita		

Figure 29: Event History and Email History

When you click the link in the **Status** column, you are directed to the Print View window. In Print View you can select the sections of the protocol to print and their orientation. Click **OK** and a **PDF** is created.

The links in the **View Attachments** column open the Attachments window. Select the document to view by checking the box on the far left. Then click the **Download** button (top right) to download the related attachments.

Links in the **Letters** column allow you to view the **Approval Letter/Acknowledgement Letter** in **PDF** format.

4.9 Email History

Email History contains the complete history of emails related to the protocol. This section is found at the bottom of the left navigation pane of the protocol. Clicking **Email History** opens a window as shown in Figure 29: Event History and Email History.

1. Click the link in the **Email Type** column to view the email in **PDF** format.

2. Click the link in the **Attachments** column to view the attachments, if any, in **PDF** format.

5 Responding to Comments

Once your Protocol is submitted, it enters the review process as described in Figure 46: eProtocol Workflow Diagram. The IBC Coordinator and Reviewers will review it as determined by its Review Type. Review Types include: Panel Manager Review, Designated Review and Committee Review as defined in Table 5- Review Types.

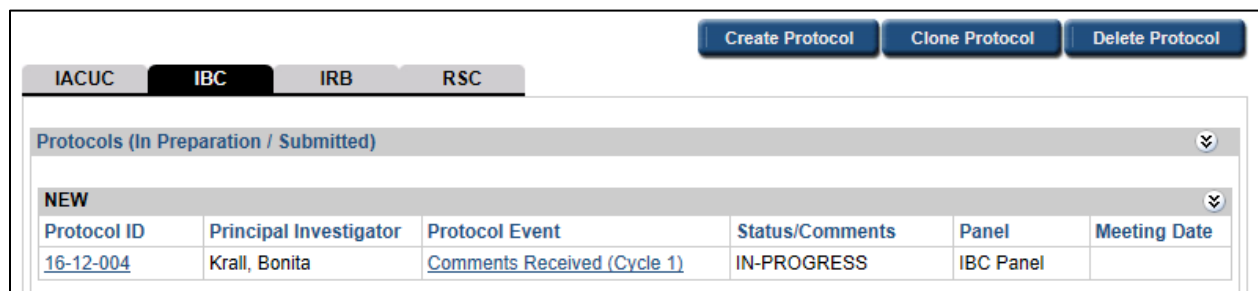
Table 5- Review Types

Review Type	Definition
Committee Review	Review by the IBC Coordinator and designated reviewers, normally the full panel.
Designated Review	Review by the IBC Coordinator and a designated reviewer(s). Responses are collated and viewed by the IBC Coordinator prior to sending them back to the PI.
Panel Manager Review	Review by the IBC Coordinator directly through a Comments/ Response cycle with the PI.

The IBC Coordinator submits his/her comments and also the comments from the Panel and/or designated Reviewers, as applicable. When you receive comments from the IBC Coordinator, the Protocol Event changes to ‘Comments Received (Cycle 1)’. You need to provide responses to the comments and also update the protocol form, if needed, and submit the responses to the IBC Coordinator.

Follow the steps given below to respond to the comments submitted by IBC Coordinator:

1. Navigate to the **Investigator Homepage** as shown in Figure 30: Investigator Homepage: Comments Received.



Protocol ID	Principal Investigator	Protocol Event	Status/Comments	Panel	Meeting Date
16-12-004	Krall, Bonita	Comments Received (Cycle 1)	IN-PROGRESS	IBC Panel	

Figure 30: Investigator Homepage: Comments Received

The link in the Protocol ID column will allow you to open your protocol application for editing or viewing. The link in Protocol Event **Comments Received (Cycle 1)** allows you to directly open the Comments window. Status/Comments for the protocol will now read In-Progress and the default panel will read *LC IBC*.

2. Click Protocol Event **Comments Received (Cycle 1)**. The Comments page opens as shown in Figure 31: Comments.

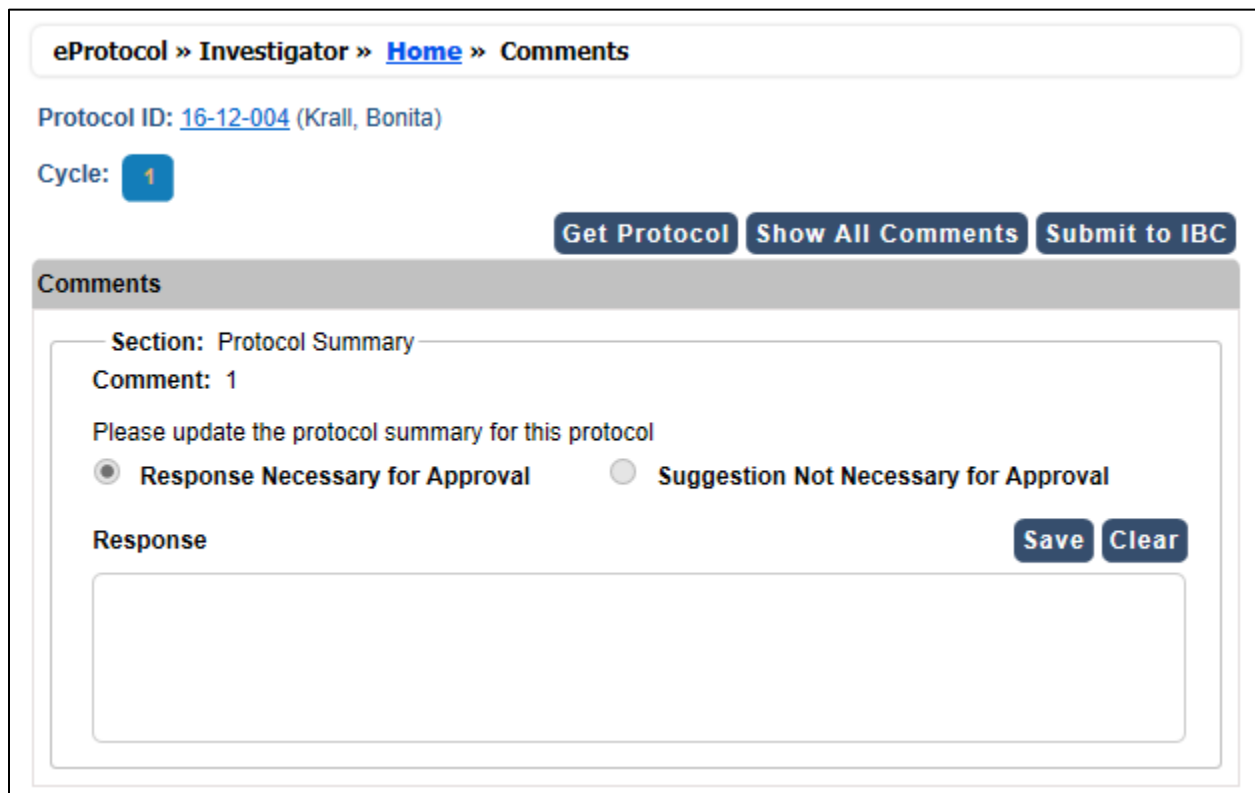


Figure 31: Comments page



On the Comments page you can:

- View the Comments and Responses of any cycle by clicking the **Cycle Number** icon on left side of the page.
- Delete the comments by clicking the **Delete** button.
- Modify the comments by clicking the **Edit** button.



You cannot edit or delete the comments from a previous cycle.



When you send a response to the comments, a Manager receives an email with all the details.

Only the first comment is displayed in Figure 31: Comments. However, multiple comments can be received and responded to. There are several buttons in this window. **Get Protocol** opens the protocol for viewing or editing. **Show all Comments** opens a table view of all comments received and their responses to date as shown in Figure 32: Show All Comments.

Comments OK				
Comment Title	Section Name	Comment/Response	Response Necessary	Panel Name
Cycle : 1				
1	Protocol Summary	Please update the protocol summary for this protocol Updated the protocol summary as requested	Yes	IBC Panel

Figure 32: Show All Comments

Comments are shown with a white background, while responses are shown lightly shaded. To leave this table view click **OK**.

3. Click **Input to IBC** when you have completed entering your responses. You will receive a message informing you that changes to the protocol cannot be made after re-submitting to IBC and that if changes were made to the protocol; both the protocol and responses to comments are submitted to the IBC Coordinator.
4. Click **OK**.

This review cycle of comments and responses may be repeated several times in the review process. Once a protocol has been approved, it is moved to the Approved Protocols section of the Investigator Home Page.

6 Processing of Approved Protocols

In order to view Approved Protocols, select **eProtocol>Investigator** in the top left corner of the home page and click **Approved Protocols** as shown in Figure 33: Viewing Approved Protocols.

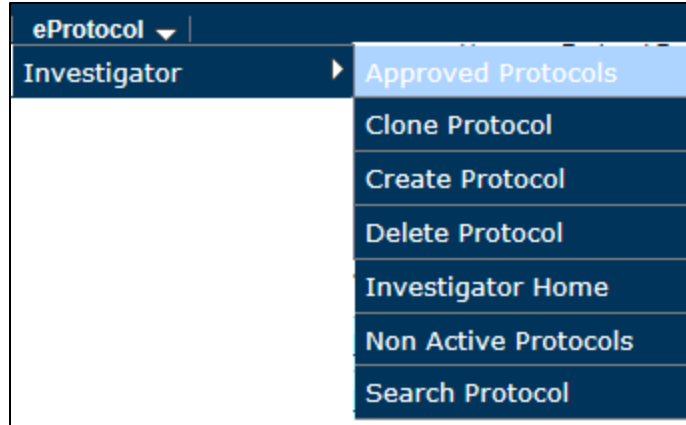


Figure 33: Viewing Approved Protocols

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

eProtocol » Investigator » [Home](#) » Approved Protocols

IACUC		IBC	IRB	RSC		
Protocol ID	Principal Investigator	Approval Date	Last Approval Date	Expiration Date	Review Decision	Form Type
16-12-004	Krall, Bonita	12/07/2016	12/07/2016	12/06/2019	Designated Review	NEW

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.

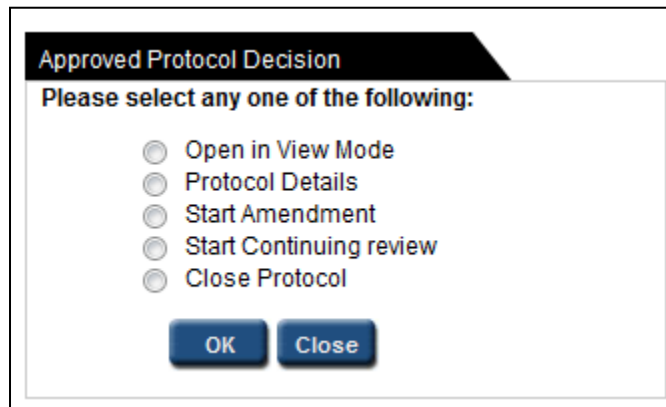


Figure 35: Approved Protocol Decision Window



The Continuing review radio option appears when the protocol approval period is about to complete (the protocol approval period is set by Site Admin).

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

Protocol ID: 16-12-004				Principal Investigator: Krall, Bonita			
Details							
Form Type	Submitted Date	Meeting Date	Status	Approval Date	Expiration Date	Comments	View Attachments
NEW	12/07/2016	01/02/2017	APPROVED	12/07/2016	12/06/2019	Comments	View Attachments

Figure 36: Details of Approved Protocols

There are several links within the page. Form Type can be used to view the protocol. The Comments link opens the review comments and responses for the selected protocol. View Attachments will open the Attachments page for viewing attachments for the specified protocol.

6.3 Start Amendment

An Amendment form is created when there are major changes in the protocol after it has been approved and IBC needs to be informed about it. Until the existing Amendment form is approved, you cannot create further Amendments or begin a Continuing Review form. To begin an Amendment, select **Start Amendment** and click **OK**. The application form window appears, where in addition to the information present in the Approved Protocol, the Amendment page is added to the protocol as shown in Figure 37: Amendments.

Amendment

1. Biosafety Level of Approved Work:

2. Original Biohazardous Agents Used:

3. Reason for Requested Amendment:

- Add/delete recombinant DNA molecules, biological agents or toxins
- Amend scope of work or procedure involving biohazardous agent use
- Add/delete principal investigator/lab personnel
 - Submit page indicating certification of lab workers with changes. Attach relevant training certificates and confirm OHP* enrollment.
- Add/delete the use of human subjects and recombinant DNA and/or biohazardous agents
- Add/delete CDC select agents
- Add/delete use of animals and recombinant DNA and/or biohazardous agents
- Project is complete; IBC approval no longer necessary

***Occupational Health Program**

4. Summary of Changes: (Attach supporting documentation)

No Updates available for current version

Previous
Next

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

Upon prompting, select Edit Protocol and you will be taken to the Continuing Review tab in the left navigation pane of the protocol application.

In Continuing Review, you are only allowed to make changes to certain sections of the protocol and the Protocol ID remains the same. If major changes are required when renewing a protocol (via Continuing Review), you are required to submit a separate Amendment. Sections that can be changed in a Continuing Review include: Record of Biological Material Usage, Protocol Status, and a Deviation Event.

When you have completed the Continuing Review questions, re-check the box in the Assurances section confirming your agreement to abide by Biosafety regulations. Click **Submit Form** in the left-hand navigation pane and confirm the submission of your protocol for Continuing Review.

6.5 Close Protocol

The Close Protocol option is used when you want to terminate a protocol. This request can be sent at any point in time after initial protocol approval, even when an Amendment or Continuing Review has been submitted. To close a protocol, select **Close Protocol** and click **OK**. The status of the protocol on the Approved Protocols page then changes to Close Requested. When the close request is approved, all other forms existing for the protocol are deleted and the closed form moves to the Non Active Protocols list on the Investigator Home Page.



Closed protocols can be reactivated by the IBC Coordinator.

6.6 Delete Protocol

You can delete a protocol before it is submitted to the IBC or once the protocol is returned by the IBC without being approved. Follow these steps to delete a protocol:

In order to delete a protocol, select **eProtocol>Investigator** in the top left corner of the home page and click **Delete Protocols**, this opens the **Delete Protocol** page.

eProtocol » Investigator » [Home](#) » Delete Protocol

IACUC		IBC	IRB	RSC		
<input type="checkbox"/>	Protocol ID	Principal Investigator	Protocol Event	Form Type	Panel	Meeting Date
<input type="checkbox"/>	16-12-012	Krall, Bonita	NEW	NEW		
<input type="checkbox"/>	16-12-010	Krall, Bonita	RETURNED	NEW		
<input type="checkbox"/>	16-12-008	Krall, Bonita	NEW	CONTINUING REVIEW	IBC Panel	

[Delete Protocol](#)

Figure 38: Delete Protocol page

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.

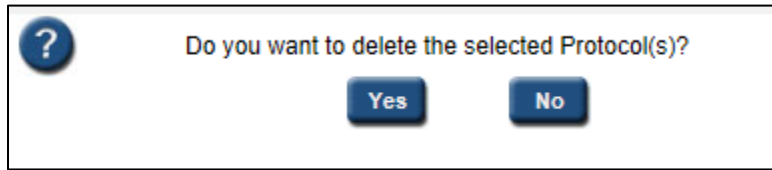


Figure 39: Confirmation window for deleting a protocol



The administrator can restore the deleted protocols. After restoring, the protocols reappear on the Homepage and Delete Protocol page of the protocol personnel.

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).



Depending on your organization the search fields may vary for what is shown here (Figure 40).

eProtocol » Investigator » [Home](#) » Search Protocol

Protocol ID	<input type="text"/>	Study Title	<input type="text"/>
Principal Investigator	<input type="text"/>	Investigator	<input type="text"/>
Form Type	---Please Select---	Panel	---Please Select---
Department	---Please Select---	Meeting Date	<input type="text"/>
Form Name	---Please Select---		
Protocol Status	---Please Select---		

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.

Protocol ID	<input type="text"/>	Study Title	<input type="text"/>
Principal Investigator	<input type="text"/>	Investigator	<input type="text"/>
Form Type	---Please Select---	Panel	---Please Select---
Department	---Please Select---	Meeting Date	<input type="text"/>
Form Name	IBC Form		
Protocol Status	---Please Select---		

Protocol ID	Principal Investigator	Submission Date	Panel	Meeting Date	Expiration Date	Protocol Status	Form Type
16-12-012	Krall, Bonita					NEW	NEW
16-12-011	Krall, Bonita	12/07/2016	IBC Panel		12/06/2018	APPROVED	NEW
16-12-011	Krall, Bonita	12/07/2016	IBC Panel			SUBMITTED	AMENDMENT
16-12-010	Krall, Bonita	12/07/2016				RETURNED	NEW
16-12-008	Krall, Bonita	12/07/2016	IBC Panel		12/03/2018	APPROVED	NEW
16-12-008	Krall, Bonita		IBC Panel			NEW	CONTINUING REVIEW

Figure 41: Protocol Search Results



To sort the protocols in ascending/descending order in a column, click the Column Header.



You can use the Show/Hide icons (up/down chevrons on the right side of the grey section headers) to view/hide the protocol lists.

3. Click on the **Protocol ID** link to open the desired protocol.



Use **Clear** to clear the search criteria entered and start new search.

4. If you want to save the Search Criteria to re-use in the future;
 - a. Click **Save** on search protocol page. This displays **Search Criteria** text field, plus the **Save**, and **Cancel** buttons, as shown in Figure 42.

Search Criteria: Save Cancel

Protocol ID	Principal Investigator	Submission Date	Panel	Meeting Date	Expiration Date	Protocol Status	Form Type
16-12-012	Krall, Bonita					NEW	NEW
16-12-011	Krall, Bonita	12/07/2016	IBC Panel		12/06/2018	APPROVED	NEW
16-12-011	Krall, Bonita	12/07/2016	IBC Panel			SUBMITTED	AMENDMENT
16-12-010	Krall, Bonita	12/07/2016				RETURNED	NEW

Figure 42: Search Criteria textbox

- b. Enter the name you want to use in the future to refer to these search criteria in the **Search Criteria** text field and click **Save**. This saves the search criteria with the given name and adds the name to the **Selected Search Criteria** drop-down list, as shown in Figure 43.

Selected Search Criteria:

Protocol ID	Principal Investigator	Date	Panel	Meeting Date	Expiration Date	Protocol Status	Form Type
16-12-012	Krall, Bonita					NEW	NEW
16-12-011	Krall, Bonita	12/07/2016	IBC Panel		12/06/2018	APPROVED	NEW
16-12-011	Krall, Bonita	12/07/2016	IBC Panel			SUBMITTED	AMENDMENT

Figure 43: Selected Search Criteria drop-down list

5. You can add other search criteria to the **Selected Search Criteria** drop down list, perform steps 2 thru 4.



To view the list of protocol searches, click the **Selected Search Criteria** from the drop-down.

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).

eProtocol » Investigator » Home » Non Active Protocols							
IACUC IBC IRB RSC				Number of Records: 1 / 1 Status: All			
Protocol ID	Principal Investigator	Status/Comments	Approval Date	Last Approval Date	Expiration Date	Event Date	Closed Notes
16-12-004	Krall, Bonita	CLOSED	12/07/2016	12/10/2014	12/06/2019	12/07/2016	No

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.

eProtocol » Investigator » Home » Non Active Protocols							
IACUC IBC IRB RSC				Number of Records: 1 / 1 Status: All			
Protocol ID	Principal Investigator	Status/Comments	Approval Date	Last Approval Date	Expiration Date	Event Date	Closed Notes
16-12-004	Krall, Bonita	CLOSED	12/07/2016	12/10/2014	12/06/2019	12/07/2016	All CLOSED NOTAPPROVED WITHDRAWN EXPIRED NOT PREAPPROVED

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 - eProtocol Workflow Diagram

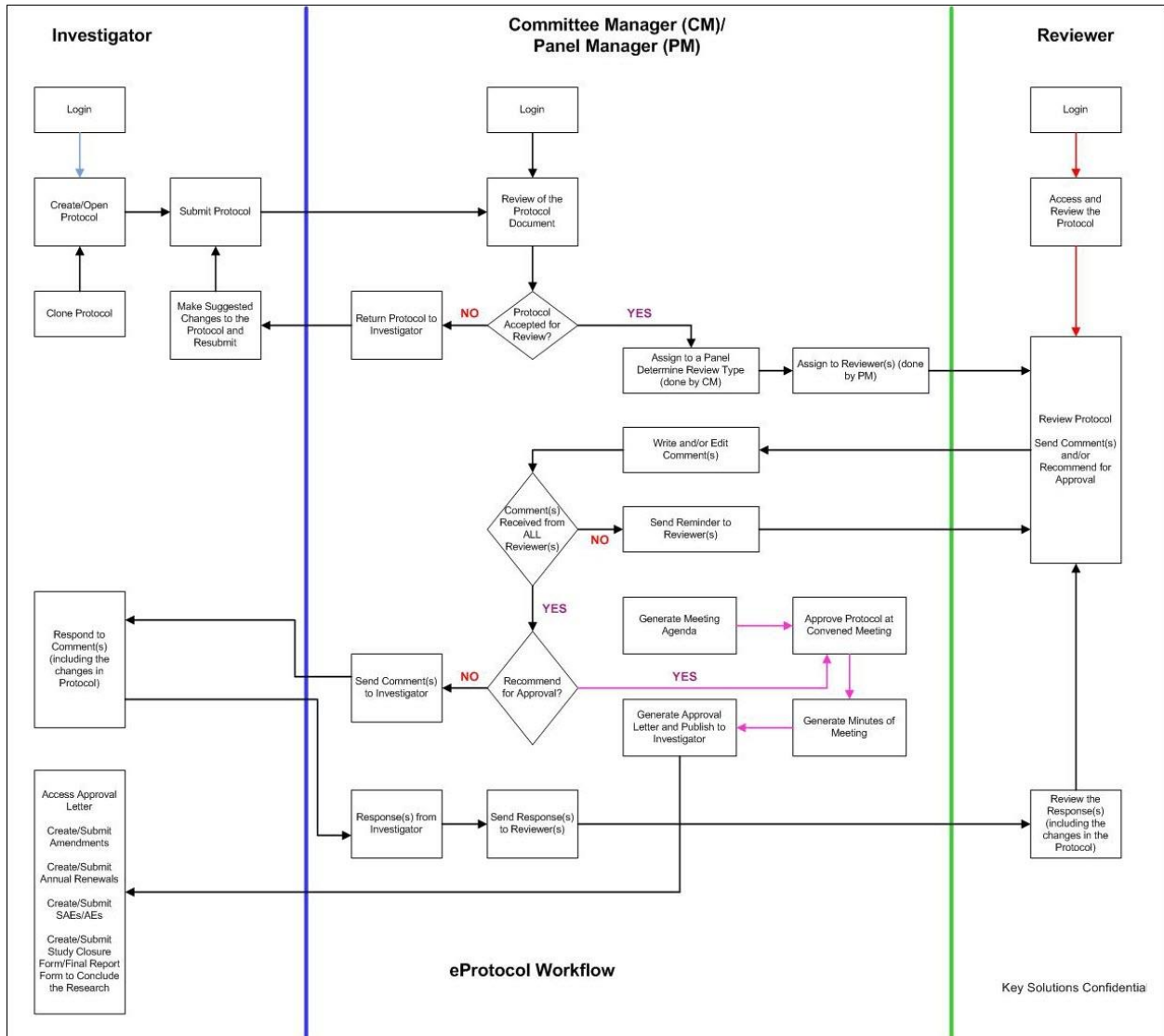


Figure 46: eProtocol Workflow Diagram

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 **Ok** to confirm.

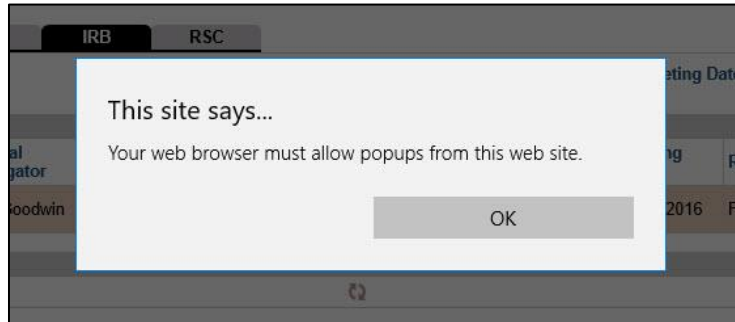


Figure 47: Allow pop-ups dialogue box

2. Click the right corner menu button on the screen and click **Options** as shown in Figure 48.

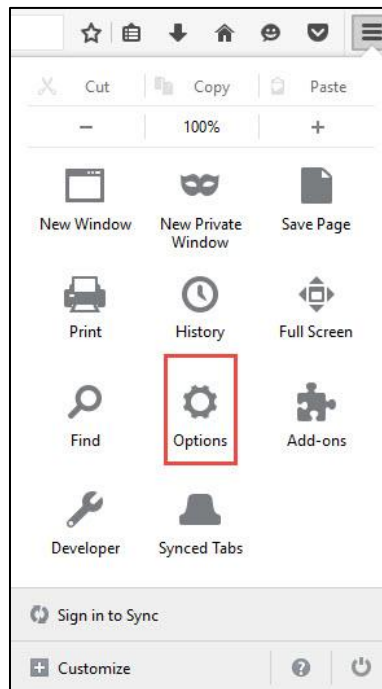


Figure 48: Choose options

3. Click **Content** on left navigation pane and check the **Pop-ups** check box as shown in Figure 49.

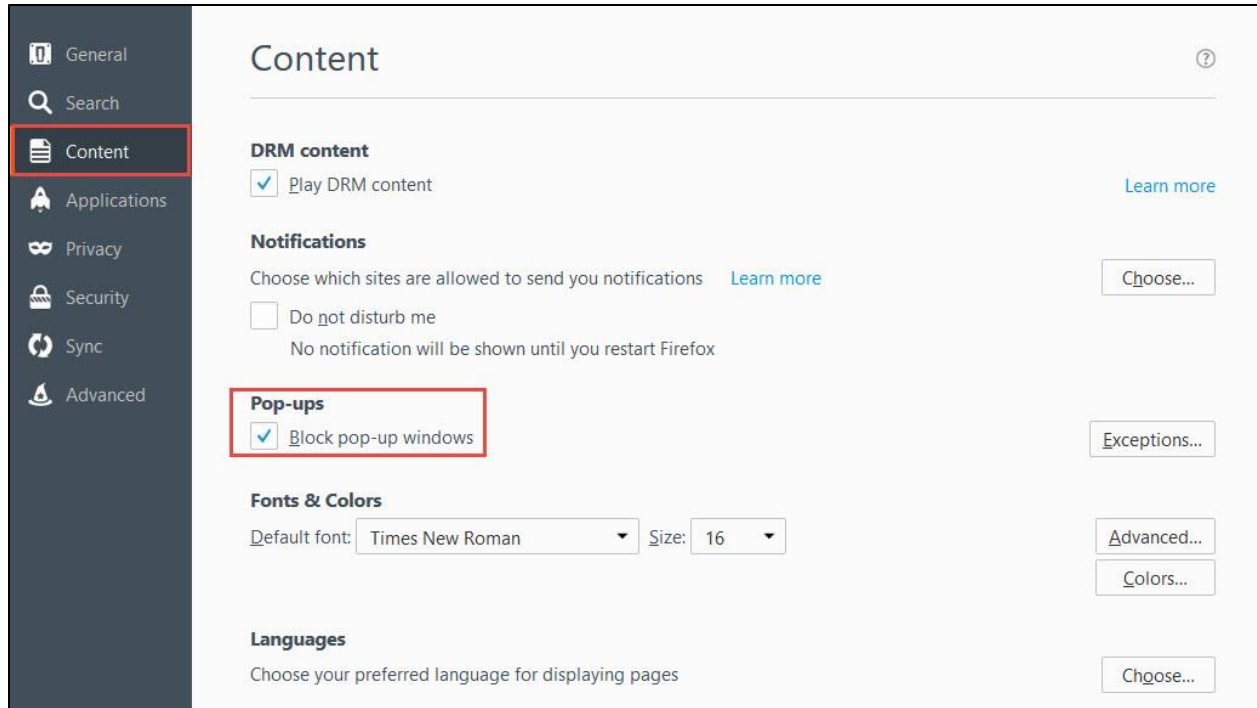


Figure 49: Pop-ups check box

8.1.2 For Internet Explorer

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

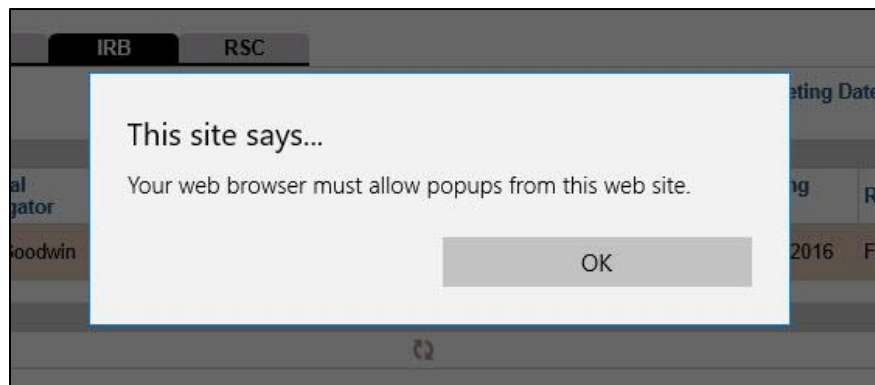


Figure 50: Allow pop-ups

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

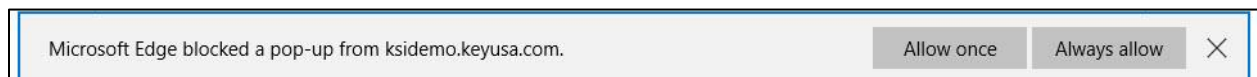


Figure 51: Confirmation box

8.1.3 For Chrome

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

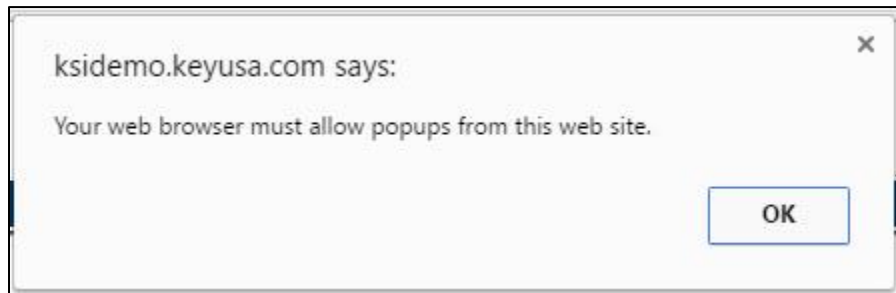


Figure 52: Allow pop-ups

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**.

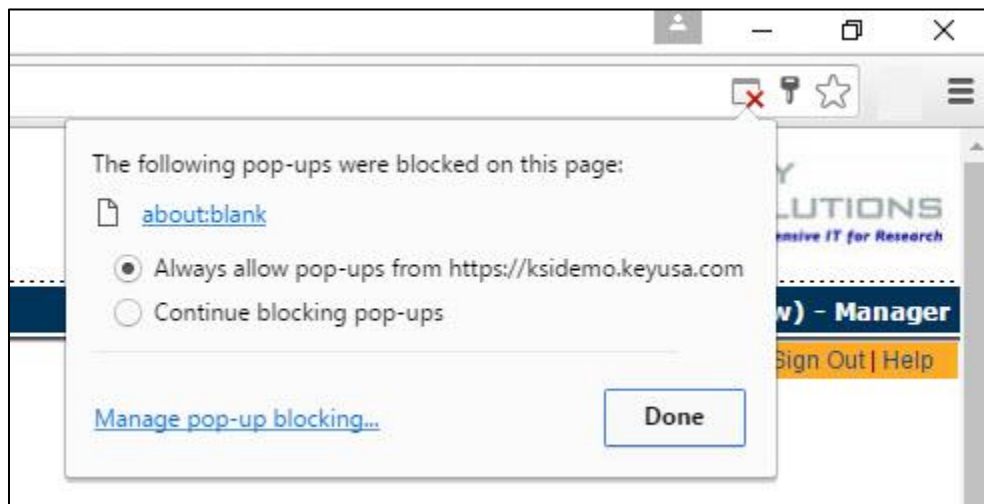



Figure 53: Pop-up dialogue box



Do not use the back button  of the browser while using the eProtocol application. Instead, use the navigation links at the top of the screen. This will lead you to the path that you have followed to navigate to where you are within eProtocol. You can click a link to go back to that page.

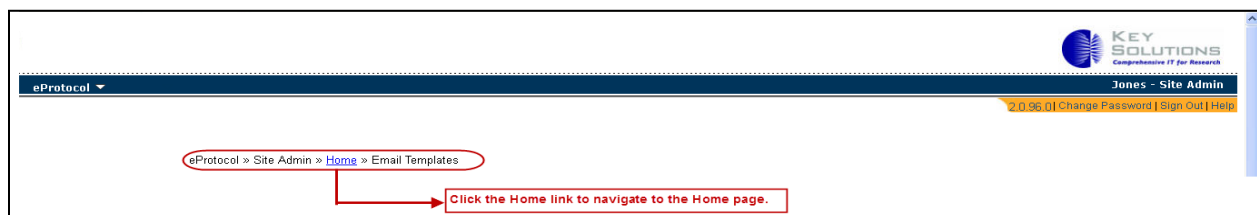


Figure 54: breadcrumb



Do not close the application without signing off. Click the Sign Out link to sign off from the eProtocol application



Figure 55: Sign Out link

Click the **Help** link to get help content (if implemented) for the page you are currently on.



Figure 56: Help Link

8.2 Password Management Assistance

8.2.1 Forgot Password

If you do not remember the password, click the **Forgot Password** button on login page to retrieve the password.



Figure 57: Forgot Password Icon

1. Enter the required details in the respective fields, select the **Hint Question** from the drop-down list and enter the answer in the **Answer** field to retrieve the password.

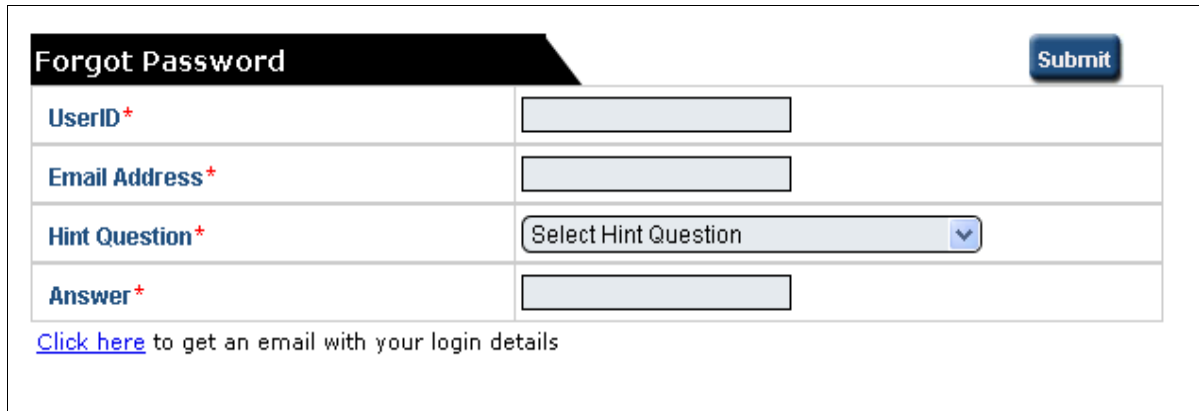


Figure 58: Forgot Password Fields

2. The **Click here** link helps the user to receive the login details to the registered email address.
3. Enter the **UserID** and **Email Address** in the respective fields and click **Submit** as seen in Figure 59.

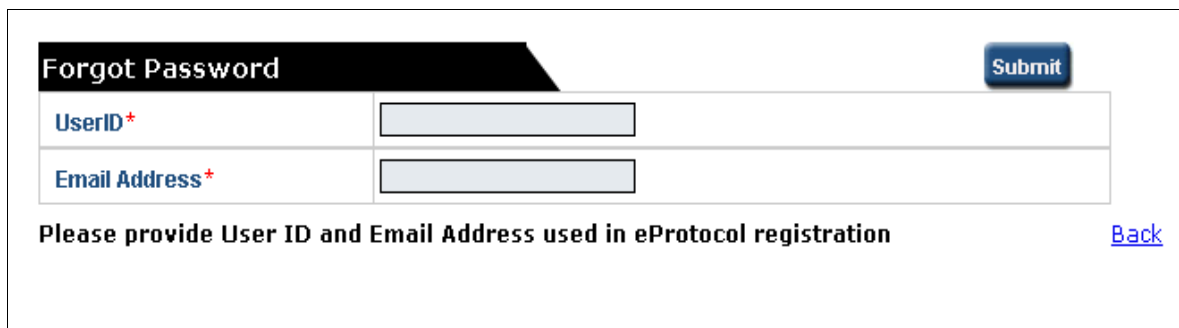


Figure 59: Retrieve Password using Credentials

The registered user now receives the email with a URL to change password.

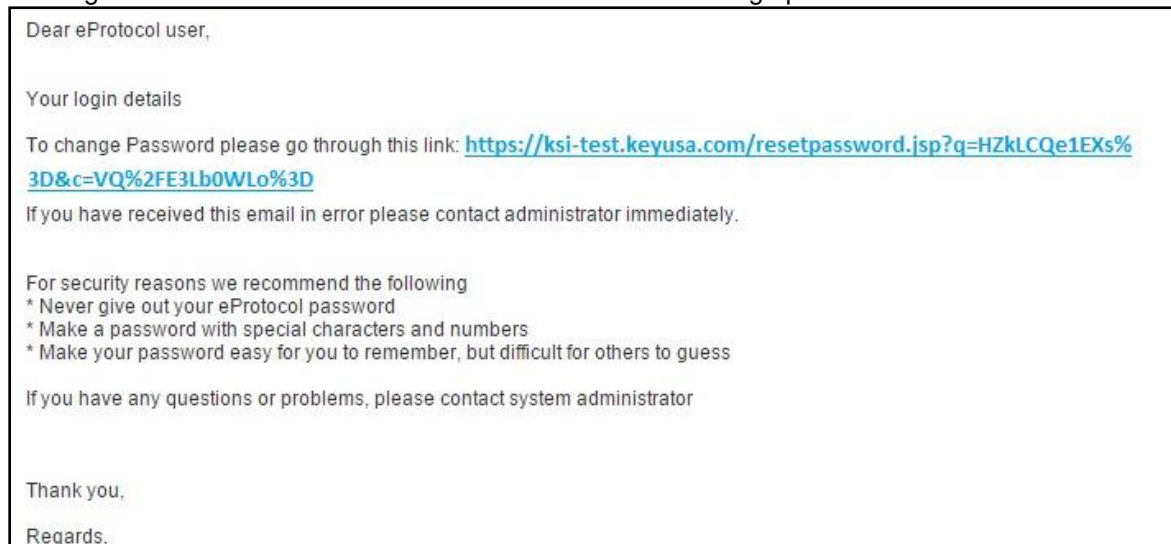


Figure 60: The email sent to a user

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 new password or change it by clicking the **Change Password** link on top right corner of the application.



Password Strength has been enhanced by adding certain attributes the password must contain

- ✓ At least 8 characters
- ✓ At least two of the following:
 - ✓ Uppercase Letters
 - ✓ Lowercase Letters
 - ✓ Numbers
 - ✓ Symbols

Password strength will be displayed beside the New Password field, if the strength is good then the color changes to green color.

8.2.2 Change Password

In the existing system, there is change password link in the upper right of the primary pages. Click it and a pop-up is displayed with the respective fields to help the user to the password as seen in Figure 62.



Figure 61: Change Password Link

The **Change Password** window pops up.

Change Password	
UserID	scott
Old Password*	<input type="text"/>
New Password*	<input type="text"/>
Confirm New Password*	<input type="text"/>
<p>Note : Passwords must have at least 8 characters and contain at least two of the following: uppercase letters, lowercase letters, numbers, and symbols.</p>	

[Change](#)

Figure 62: Change Password Fields

1. Enter the old password. Also, enter the new password and confirm it.
2. Click the **Change** button. The password is changed and you are directed to homepage.



The password must contain:

- ✓ At least 8 characters
- ✓ At least two of the following:
 - ✓ Uppercase Letters
 - ✓ Lowercase Letters
 - ✓ Numbers
 - ✓ Symbols

The password strength is displayed beside the New Password field, if the strength is acceptable then the color of the stars changes to green.



If you do not remember the old password, you can request a Company Administrator to initiate the changing of the password. Once a Company Administrator changes the password, you can login to the system with the password given by Company Administrator. The Change Password window pops up.

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