



**KEY
SOLUTIONS**
Comprehensive IT for Research

eProtocol Viewer

User Guide

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1 Introduction

eProtocol is used by a variety of institutional personnel to manage Protocols – reviews, approvals, event recording, reporting, and closure, for a variety of research projects. It helps eliminate application errors and improves collaboration and communication among research teams.

eProtocol also allows the compliance office to share access to approved protocols with other people or departments in the organization with a legitimate need. For example, the Sponsored Projects Office may need to confirm that a protocol has been approved in order to accept a grant. With access to eProtocol, the check can be done in a timely fashion independent of the compliance office, saving time in both areas.

This guide is intended for someone given the role of Viewer in eProtocol in order to access (in a read-only mode) documents associated with one or more compliance committees at an institution.

Viewer is not a job title or professional label, but a functional role. As a Viewer, you can scan a list of approved documents or use the search function to find the desired protocol or protocols and view them. This document explains how to use eProtocol, the Key Solutions' Protocol Management System (PMS) to accomplish these tasks online.

Table 1 - Icons You Will Encounter in this Guide



This is the Note icon, and it indicates that the information requires special attention.



This is the Warning icon, and it indicates a problem that must be avoided.

2 Getting Started

This section describes how to login to the system and how to use the Homepage.

There are two basic functions available to a Viewer: viewing protocol documents and searching for specific protocol documents. The sections 3 and 4, respectively, describe how to perform those functions.

This guide is not a standalone guide and is best used in conjunction with the eProtocol software application.

2.1 Definitions

You will encounter following terms as you use this guide:

Table 2 - Acronyms

Term	Definition
Principal Investigator (PI)	The person responsible for creating and completing a Protocol, and ultimately for the research and reporting performed related to the protocol.
Panel	A panel can be an entire committee or a subset of the full committee depending up on the size of the institution and the number of protocols actively managed by the committee.

2.2 Starting and logging into eProtocol



Make sure you have your eProtocol user ID and password along with the web address (URL) for the eProtocol application.

Bring up one of the following web browsers: **Firefox**, Chrome, or Safari. Disable the browser's pop-up blocker, and open the Key Solutions eProtocol web page.



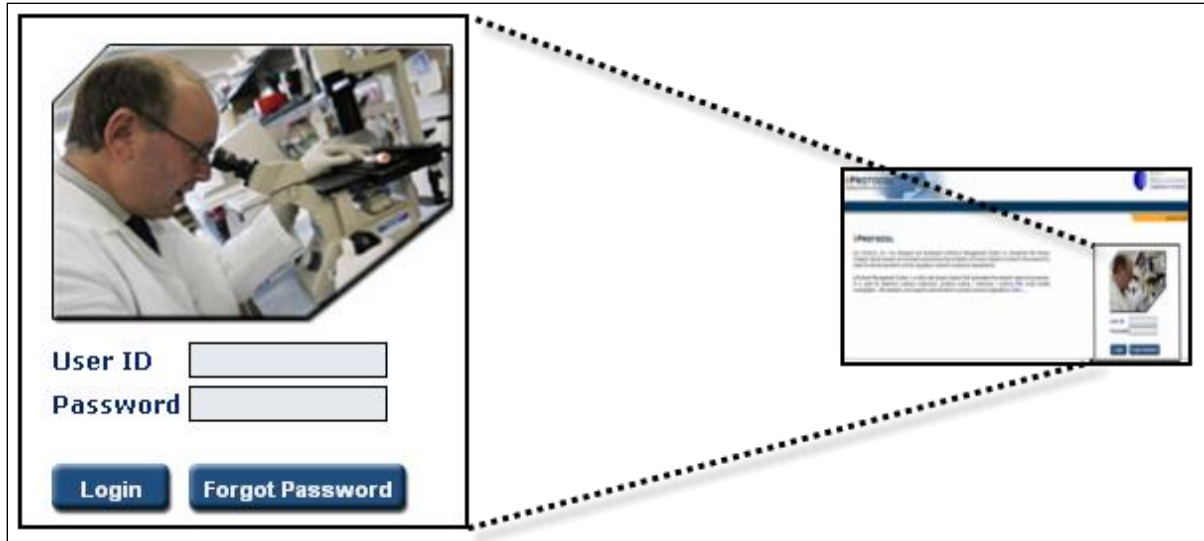
If you log in to eProtocol and then deactivate the browser's pop-up blocker, you may have to log in again to have the pop-ups deactivated for your session.



If your institution uses Single Sign-on (SSO), after sign-on the Homepage (described below) is displayed. Skip the remainder of this section.

1. Enter your login and password in the spaces provided on the far right of the page, as shown in the following figure.

Figure 1: eProtocol Login



2. Click **Login**.



If user id and/or password are incorrect, this displays a message “**Login Failed. Invalid User ID or Password**”.

2.3 The **Viewer** Home Page

Most of your work is initiated from the homepage.

All approved protocol documents are displayed in the Homepage body described in section 2.3.2.2.

To open a specific protocol, click on the Protocol ID link and the protocol is opened for viewing in a separate window.

2.3.1 Navigating to the Homepage

You are automatically directed to the **Homepage** after login. You can go to the **Homepage** at any time by clicking on **Viewer** on the menu bar or by clicking on **Viewer Home** in sub-menu as shown in Figure 2.

Figure 2 Viewer Home tab



2.3.2 The look of the Homepage

On the upper right side of the homepage, your last name, your location, and your role are displayed as shown in Figure 3.

Figure 3 User Identification on the Homepage – Name and Role



2.3.2.1 Committee Tabs

All the committees to which you have access are identified in tabs above the body of the homepage, as shown in Figure 4

Note that the IRB tab is darker than the others. This indicates the protocols displayed are IRB protocols.



If your institution has multiple compliance committees and you are granted access to more than one, you will see more than one committee tab at the top of the page. Click the tab of the committee to see the protocols approved by that committee.

Figure 4 Committee Tabs



The approved protocols are grouped on the Homepage based on Form Types (New, Amendment, Continuing Review, Report, SAE Report, Protocol Violation, and Final Report). This allows you to scan the page and focus on particular types of documents, should you so choose. Section 2.3.3 describes the form types.

If you want to search for a specific protocol or group of protocols, use the Search Protocol function described in section 4.

Figure 5 – Viewer Home Page

eProtocol » Viewer » Home

IRB

NEW				
Protocol ID	Principal Investigator	Panel	Meeting Date	Approval Date
14-08-058	Atherton, Michael	ABC	08/18/2014	08/14/2014
14-08-057	Atherton, Michael	ABC	08/18/2014	08/10/2011
14-08-056	Atherton, Michael	ABC		08/13/2014
14-08-055	Atherton, Michael	ABC		08/10/2011
13-10-009	Atherton, Michael	XYZ		07/18/2006
14-07-042	Atherton, Michael	ABC	07/21/2014	07/16/2013
13-10-019	Atherton, Michael	ABC		03/24/2014
13-11-030	Atherton, Michael	ABC	11/18/2013	11/18/2013
13-11-028	Atherton, Michael	ABC		10/01/2011

AMENDMENT				
Protocol ID	Principal Investigator	Panel	Meeting Date	Approval Date
14-08-054	Atherton, Michael	ABC	08/18/2014	08/12/2014
14-07-040	Atherton, Michael	ABC		07/17/2011
13-11-032	Atherton, Michael	ABC		03/01/2013
13-10-021	Atherton, Michael	ABC	11/18/2013	10/30/2013

2.3.2.2 The Home Page Body

The body of the Homepage displays a row of summary information for each protocol document. The summary columns are:

- Protocol ID** A unique identifier assigned to a Protocol when it is created. It stays with the Protocol throughout its lifecycle.
- Principal Investigator** The person responsible for creating and completing a Protocol, and ultimately for the research and reporting performed related to the protocol.
- Panel** The name of the panel to which the Protocol is assigned. A panel may be the entire committee or a subset of the full committee depending up on the size of the institution and the number of protocols actively managed by the committee.
- Meeting Date** The date of the meeting on which the Protocol form was reviewed.
- Approval Date** The date the Protocol was approved.



Whenever you want to view the content of a protocol, click Protocol ID link.



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



You can use the Show/Hide icons (up/down chevrons on the right side of the gray group headers) to view/hide the protocols list.

2.3.3 Form Types

The form types available vary by committee. The common ones are listed in Table 3. The first three (New, Amendment, and Continuing Review) are available for all committees. The remainder listed only apply to the IRB.

Table 3 - Different Protocol Form Types

Common Form Types	
New	Protocols which have been approved, but have not been amended or gone through a continuing review.
Amendment	Protocols which have approved amendments.
Continuing Review	Approved protocols which have most recently been through a Continuing Review.

Additional Form Types Unique to the IRB	
Serious Adverse Event Form/SAE Form	The serious adverse event forms created for reporting an incident of deviation or violation or participant non-compliance for approved Protocols are displayed.
Report	The report forms created for approved Protocols reporting the events or new information that may pose risks to subjects or others and alter the risks, benefits, or alternatives to subjects are displayed.
Final Report	The final report forms created for closing the approved Protocols for which the research is concluded are displayed.

3 Viewing a Protocol Document

This section describes how to view and print a protocol.


To Open a protocol document, click on the protocol ID link in the rightmost column of a protocol summary row. The protocol opens in a separate window (Figure 6) for viewing.

Figure 6 Protocol viewing window

IRB - IRB Form
Protocol ID: 16-05-025 (Scott, Goodwin)

Protocol Title: IRB Form
Help | Close

Previous Next



- Personnel Information
- Subject Checklist
- Study Location
- General Checklist
- Funding
- Protocol Information
- Obligations
- Print View
- Event History

* Starred items indicate required fields.

Principal Investigator*

Client defines "Investigator" as an individual who conducts a research study. If the study is conducted by a team of individuals, the Investigator is the responsible leader of the team. Students, fellows and residents may not act as a Principal Investigator.

Name of Principal Investigator *	Degree (MD/PhD/BSN/etc.)	Title
Scott, Goodwin		
Email *	Phone	Fax
eprotocol1@keyusa.com		
Research Department	Client Status Check ALL that apply *	Mailing Address
Communication	<input checked="" type="checkbox"/> Faculty <input type="checkbox"/> Staff <input type="checkbox"/> Other	

ALL research personnel are required to complete Human Subject Research training from CITI within the last 2 years prior to engaging in any research-related activities. Go to [CITI Program](#) to complete. The Research Compliance Office will verify the last date of completion below.

CITI Training Date *	Type of CITI training completed. *
05/13/2016	Group 2 Social/Behavioral

There are two ways to go through the protocol. The first is page-by-page using the **Next** button on the upper right of the page. (You can use the **Previous** button to go back to the previous page.) The second method is to use the navigation menu on the left side of the page to jump to a page of interest.



Since eProtocol is a secure application, using the **Back** or **Next** buttons on your **web browser** while navigating the form may result in an unrecoverable error. Should this happen, you must log in again to continue.

Should you want to have printed copy of the protocol, click the Print View tab on the left side navigation menu. This opens a new window (Figure 7) where you can select which sections of the protocol you would like to print.

Figure 7 Print View page

Print View
OK

Please select any one of the following:

- Protocol Only
- Protocol with Comments
- Comments only

Sections to Print	Select Orientation	
<input checked="" type="checkbox"/> All	Portrait	Landscape
<input checked="" type="checkbox"/> Personnel Information	<input checked="" type="radio"/>	<input type="radio"/>
<input checked="" type="checkbox"/> Subject Population	<input checked="" type="radio"/>	<input type="radio"/>
<input checked="" type="checkbox"/> Study Location	<input checked="" type="radio"/>	<input type="radio"/>
<input checked="" type="checkbox"/> General Checklist	<input checked="" type="radio"/>	<input type="radio"/>
<input checked="" type="checkbox"/> Funding	<input checked="" type="radio"/>	<input type="radio"/>
<input checked="" type="checkbox"/> Exempt Categories	<input checked="" type="radio"/>	<input type="radio"/>
<input checked="" type="checkbox"/> Summary of Activities	<input checked="" type="radio"/>	<input type="radio"/>
<input checked="" type="checkbox"/> Subject Population, Compensation, Recruitment	<input checked="" type="radio"/>	<input type="radio"/>
<input checked="" type="checkbox"/> Recruitment & Confidentiality	<input checked="" type="radio"/>	<input type="radio"/>
<input checked="" type="checkbox"/> International Research	<input checked="" type="radio"/>	<input type="radio"/>
<input checked="" type="checkbox"/> Research in Schools	<input checked="" type="radio"/>	<input type="radio"/>
<input checked="" type="checkbox"/> Informed Consent	<input checked="" type="radio"/>	<input type="radio"/>
<input checked="" type="checkbox"/> HIPPA Requirements	<input checked="" type="radio"/>	<input type="radio"/>
<input checked="" type="checkbox"/> Attachments	<input checked="" type="radio"/>	<input type="radio"/>
<input checked="" type="checkbox"/> Obligations	<input checked="" type="radio"/>	<input type="radio"/>
<input checked="" type="checkbox"/> Event History	<input checked="" type="radio"/>	<input type="radio"/>

OK

4 Searching for a Protocol

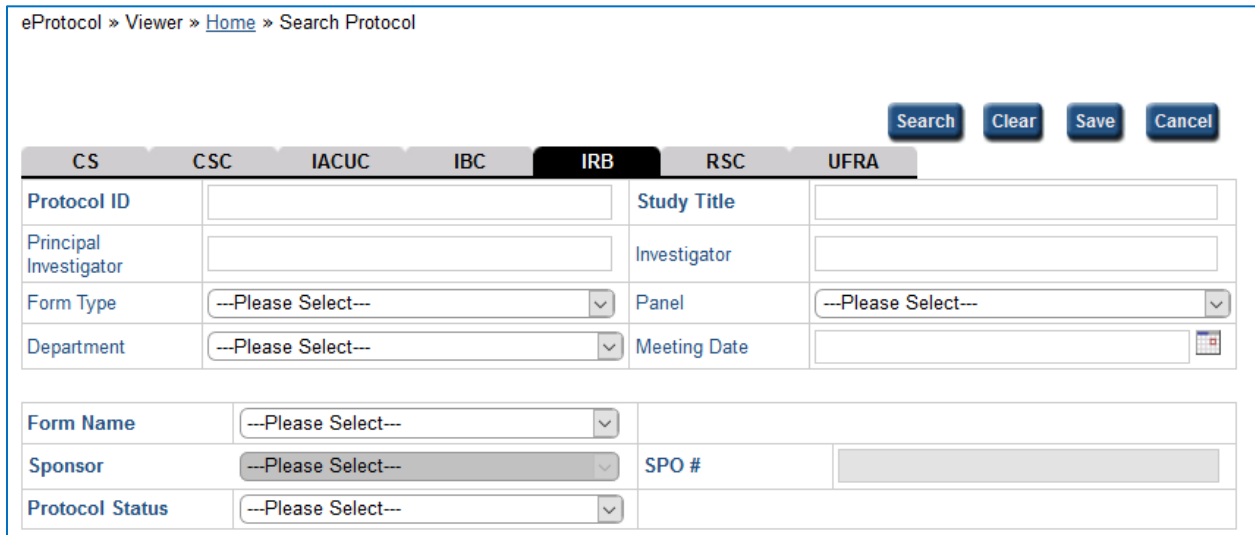
Some institutions have many protocols and scanning the list to find the desired one can be difficult. A solution to this is to look for it using the **Search Protocol** function available via the Viewer sub-menu as shown in Figure 8. On the **Search Protocol** page, you can select the specific search criteria you want to use to find your protocol. Search options include searching by a specific

Protocol ID, Study Title, Investigator, or choosing a Form Type, Panel, Department, Meeting Date, or Form Name. Figure 9 **Error! Reference source not found.** is an example. Your system may be different, but it is likely that most of these criteria are included.

Figure 8 Viewer sub-menu Search Protocol option



Figure 9 Search Protocol page



The screenshot shows the 'Search Protocol' page. At the top, there is a breadcrumb trail: 'eProtocol » Viewer » Home » Search Protocol'. Below this, there are four buttons: 'Search', 'Clear', 'Save', and 'Cancel'. A tabbed interface is visible with tabs for 'CS', 'CSC', 'IACUC', 'IBC', 'IRB' (selected), 'RSC', and 'UFRA'. The search criteria are organized into two columns:

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---		
Sponsor	---Please Select---	SPO #	<input type="text"/>
Protocol Status	---Please Select---		

Enter any of the search criteria and click the **Search** button. The results of the search are displayed on the same page below the search criteria as shown in Figure 10.

Figure 10 Search Protocol results

eProtocol » Viewer » [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	IRB Test
Department	---Please Select---	Meeting Date	<input type="text"/>

Form Name	---Please Select---
Sponsor	---Please Select---
Protocol Status	---Please Select---

Protocol ID	Principal Investigator	Submission Date	Panel	Meeting Date	Expiration Date	Protocol Status	Form Type
IRB-2017-00015-IRB	Scott, Goodwin	06/23/2017	IRB Test	07/02/2017		IN-PROGRESS	NEW
IRB-2017-00013-IRB	Scott, Goodwin	06/14/2017	IRB Test	07/02/2017		IN-PROGRESS	NEW
IRB-2017-00012-IRB	Scott, Goodwin	06/12/2017	IRB Test	07/02/2017		IN-PROGRESS	NEW

4.1 Saving Search Criteria for Future Use

When you have several protocols to examine it may take longer than a single session. If you used the search function to identify the group of protocols to view, you can name and save the set criteria and use them for a search at a later time.

Once you have selected the desired search criteria, click the Save button. A **Search Criteria** field is displayed just above the results of the search.

Figure 11 Search Criteria row

Search Criteria:

Protocol ID	Principal Investigator	Submission Date	Panel	Meeting Date	Expiration Date	Protocol Status	Form Type
-------------	------------------------	-----------------	-------	--------------	-----------------	-----------------	-----------

Enter the **Name** you want to give to the set of search criteria and click the **Save** button on the same row. This adds the name to the Search Criteria drop-down list that appears on the Search Protocol page.

To select the saved set of criteria, select it from the Search Criteria drop-down list as shown in Figure 12. Once selected, the search results are displayed.

Figure 12 - Selected Search Criteria drop-down list

Selected Search Criteria:		<div style="border: 1px solid red; padding: 2px;"> --Please Select-- --Please Select-- Florence Michael IRB </div>					
Protocol ID	Principal Investigator	Meeting Date	Expiration Date	Protocol Status	Form Type		
17-06-185	mason, mason			NEW	NEW		
17-06-182	Florence, Long	06/12/2017	IRB Panel	07/04/2017	IN-PROGRESS	NEW	



To view the Protocol, click Protocol ID link.



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



You can save any number of search results using the 'Save' feature and you can view them at any time using the Search Criteria drop-down list.