



eProtocol Reviewer

User Guide

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1 Introduction

eProtocol is the Keys Solutions software tool used to manage the life of a protocol. eProtocol helps eliminate errors and improves collaboration, communication, and efficiency.

This user guide is intended to be used in conjunction with the eProtocol application for those with the role of Reviewer. The Reviewer has several duties that are described in this document, including how to:

- Search for a protocol
- Review a protocol
- Use the reviewer checklist
- Send comments to the PI
- Recommend protocols for approval

Depending on your institution and the type of protocol you are reviewing, your screens may differ from the screenshots you see here.

Key Solutions makes improvements to its software on a regular basis.

Key Solutions is interested in making documentation more useful to people that use the eProtocol software and is always interested in feedback—both supportive and constructive. For comments and feedback, please email techpubs@keyusa.com.

1.1 General Information

Table 1 displays the **Note** and **Caution** icons that are used throughout this guide. Heed these icons as they contain beneficial information that will assist you while you use eProtocol. Furthermore, you will encounter certain terms and acronyms in this guide and eProtocol – refer to Table 2 for clarification.

Table 1 Icons in this Guide



Note: *This is the Note icon. It indicates that the information that follows this icon requires special attention.*



Caution: *This is the Caution icon. It indicates that the information that follows this icon is a problem that must be avoided.*

Table 2 Common Acronyms and Terms

Acronym/Term	Stands For	Definition
Committee		A compliance group that receives and reviews protocols. Depending on your institution, there may be multiple

Acronym/Term	Stands For	Definition
		committees, e.g., an IRB, IACUC, IBC, CS, CSC, or RSC.
NPR	Non-Primary Reviewer	An individual who attends the review and discussion of the protocol.
PI	Principal Investigator	An individual who is responsible for creating and completing a protocol and ultimately responsible for all activities associated with the research described in the protocol.
PDF	Portable Document Format	The Adobe file type accepted by eProtocol.
PM	Panel Manager	An individual responsible for coordinating the overall review process. Responsibilities include: <ul style="list-style-type: none"> • Assigning reviewers • Reviewing and forwarding comments to the PIs • Reviewing and returning responses to Reviewers from the PI • Generating meeting agendas and meeting minutes • Approving protocols
PR	Primary Reviewer	The primary person requested to review a protocol. Comments cannot be forwarded to the PI until all PRs have provided their comments to the protocol.
Protocol ID	Protocol Identification Number	A unique ID assigned to a protocol when it is created. This is used mainly for identification purposes. The ID stays with the protocol throughout its life.
SR	Secondary Reviewer	A committee member assigned a protocol for review for a second opinion. Comments may be forwarded to the PI without the SR's comments.



Note: When a figure or hyperlink (in [blue](#)) is referenced in this guide, you may navigate to the referenced point by holding CTRL on your keyboard and clicking the figure or hyperlink.

2 Getting Started

When you log in to eProtocol, the Reviewer homepage is displayed. The homepage consists of shortcuts that allow you to navigate to specific locations or functions.



Caution: Do not use the browser's forward and backward arrows to navigate. Since eProtocol is a secure application, using the forward and backward arrows results in a security violation, an unrecoverable error, and you are logged out of eProtocol.



Note: If you have trouble logging in, contact your institution's admin.

2.1 Reviewer Homepage

The Reviewer homepage is divided into two sections: the header and the body. Each section has their own shortcuts.

2.1.1 Header Shortcuts

At the top of the page is the header. On the left-side of the header is the Reviewer submenu. To navigate to the Reviewer submenu, hover over **eProtocol** and then **Reviewer**. From this submenu, you may perform the following functions (refer to the red reference numbers in Figure 1):

1. View information resources
2. Navigate to the homepage
3. Search for a protocol



Figure 1 Reviewer Submenu

On the right-side of the header, you can perform the following functions (refer to the blue reference numbers in Figure 1):

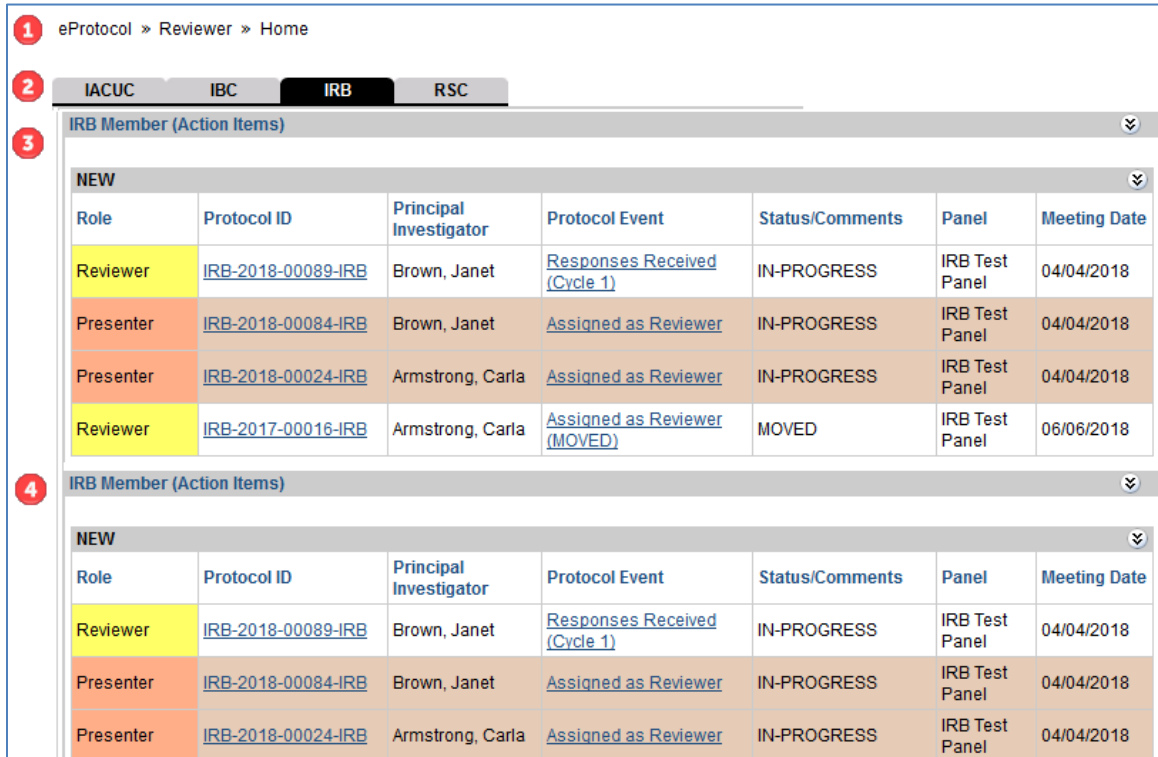
4. View the eProtocol version number.
5. Change your password.
6. Sign out of eProtocol.
7. Display a pop-up that will help you with the homepage.

i **Note:** A Help button is located on every page in eProtocol, including the pages in a protocol. Click the Help button at any time for tips about the current page.

2.1.2 Homepage Body Shortcuts

The homepage body is located below the header. In the homepage body, you can view and perform the following functions (refer to Figure 2’s reference numbers):

1. Know your location in eProtocol by viewing the breadcrumbs.
2. Switch between committees by clicking on a committee name, if applicable.
3. View protocols from the “Action Items” table.
 - a. These protocols require your attention for a review or approval decision. For example, a protocol that has new responses from the PI appears here for you to review.
4. View protocols from the “Protocols for Review” table.
 - a. You have viewed and provided feedback for these protocols. For example, a protocol that you recommended for approval appears here.



1 eProtocol » Reviewer » Home

2 IACUC IBC **IRB** RSC

3 IRB Member (Action Items)

NEW						
Role	Protocol ID	Principal Investigator	Protocol Event	Status/Comments	Panel	Meeting Date
Reviewer	IRB-2018-00089-IRB	Brown, Janet	Responses Received (Cycle 1)	IN-PROGRESS	IRB Test Panel	04/04/2018
Presenter	IRB-2018-00084-IRB	Brown, Janet	Assigned as Reviewer	IN-PROGRESS	IRB Test Panel	04/04/2018
Presenter	IRB-2018-00024-IRB	Armstrong, Carla	Assigned as Reviewer	IN-PROGRESS	IRB Test Panel	04/04/2018
Reviewer	IRB-2017-00016-IRB	Armstrong, Carla	Assigned as Reviewer (MOVED)	MOVED	IRB Test Panel	06/06/2018

4 IRB Member (Action Items)

NEW						
Role	Protocol ID	Principal Investigator	Protocol Event	Status/Comments	Panel	Meeting Date
Reviewer	IRB-2018-00089-IRB	Brown, Janet	Responses Received (Cycle 1)	IN-PROGRESS	IRB Test Panel	04/04/2018
Presenter	IRB-2018-00084-IRB	Brown, Janet	Assigned as Reviewer	IN-PROGRESS	IRB Test Panel	04/04/2018
Presenter	IRB-2018-00024-IRB	Armstrong, Carla	Assigned as Reviewer	IN-PROGRESS	IRB Test Panel	04/04/2018

Figure 2 Homepage Body

The protocols are color coded depending on the protocol or role status. Table 3 displays the descriptions of each color.

Table 3 Color Code Descriptions

Color	Description
Light Brown	The protocol is assigned for a Full Committee Review.
Pink	The protocol is assigned for Designated Review process and the reviewers have not submitted their feedback.
Yellow	Only shown in the Role column. Yellow is displayed when (1) you need to perform a Review Decision or (2) you are assigned as a PR or SR by the PM.
Peach	Only shown in the Role column. Peach is displayed when you are assigned as a Presenter by the PM.

The protocols are sorted in different columns. Table 4 displays the descriptions of each column.

Table 4 Column Names and Descriptions

Column Names	Descriptions
Role	The type of role (Reviewer or Presenter) that the PM assigned to you appears here.
Protocol ID	A unique ID assigned to a protocol when it is created. This is used mainly for identification purposes. The ID stays with the protocol throughout its life.
Principal Investigator	The individual who created and submitted the protocol.
Protocol Event	<p>The current status of the protocol:</p> <ul style="list-style-type: none"> • Assigned as Reviewer: You are assigned as a Reviewer for the protocol and you have either (1) not yet started the review or (2) have started the review, but have not sent your approval decision or comments to the PM. • Recommended for Approval: You have recommended the protocol for approval. • Comments Sent (Cycle 1): You have submitted comments for the protocol. If more comment/response cycles occur, the cycle number increases in the status accordingly, e.g., Comments Sent (Cycle 2), Comments Sent (Cycle 3). • Responses Received (Cycle 1): The PM forwarded the PI's responses to you. If more comment/response cycles occur, the

Column Names	Descriptions
	<p>cycle number increases in the status accordingly, e.g., Responses Received (Cycle 2), Responses Received (Cycle 3).</p> <ul style="list-style-type: none"> • Moved: The protocol’s meeting date was moved to another date. You may continue the review process as normal. • Tabled: A protocol may be tabled because (1) the committee could not make a decision on the protocol and is requiring the PI to submit additional information in order to proceed with the review process, (2) the committee ran out of time and could not make a decision, or (3) there was an unresolved issue during the meeting. • Contingent: The protocol is approved as long as the PI satisfies your recommendations. Once the criteria have been met, the protocol is approved. You cannot continue the review process at this stage.
Panel	The name of the panel that is assigned to review the protocol.
Meeting Date	The date that the meeting is scheduled to be reviewed.

2.2 Reviewer Functions

There are many functions that a Reviewer must perform. The functions include:

- [Selecting a Full Review or Designated Review for a protocol](#)
- [Using the Reviewer Checklist](#)
- [Sending comments to the PI](#)
- [Reviewing responses from the PI](#)
- [Recommending a protocol for approval](#)
- [Searching for a protocol](#)

2.2.1 Select Full Review or Designated Review

This section is only applicable to IACUC protocols. As a Reviewer, you need to decide if a protocol should undergo a Full Review or Designated Review.

To give a decision on the type of a review, perform the following tasks:

1. Click the **Assigned as Reviewer** link in the Protocol Event column. The Comments page appears.
2. View the protocol by selecting the **Protocol ID** link on the left or **Get Protocol** on the right-side of the page (Figure 3).



Figure 3 View a Protocol

3. Click **Review Decision** on the right. This opens the **Review Decision** pop-up.
4. Select **Designated Review** or **Full Review** and add notes to the text field.
5. Click **Submit** (Figure 4).

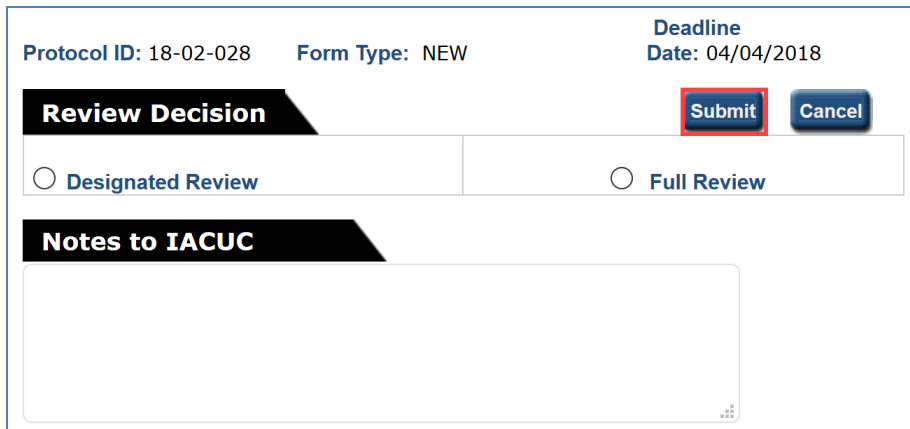


Figure 4 Submit a Review Decision

Once you submit your review decision, the protocol disappears from the homepage. The protocol reappears on your homepage if the PM assigns you as a Reviewer of the protocol.

2.2.2 Use the Reviewer Checklist

Depending on your institution, you may not have a reviewer checklist. The Reviewer Checklist is intended to help you review a protocol. The checklist consists of various items that should be considered when doing a review and making a recommendation for approval.

To use the reviewer checklist, perform the following tasks:

1. Open the Comments page by selecting the Protocol Event status.
2. Select **Checklist**. The Reviewer Checklist appears.
3. Select the Protocol ID link to view the protocol.

4. Use the checkboxes to answer the questions. When you select a checkbox, the comments field is enabled for you to provide additional information.
5. It is a good idea to periodically save your responses; just click **Save** (Figure 5).

Protocol ID: [IRB-2018-00084-IRB](#) (Brown, Janet) [Print](#)

Study Title: Monitoring Heart Rates in College Students

Reviewer Checklist

[Save](#)
[Close](#)

	Yes	No	N/A	Comments
Is the population defined clearly, both for subjects (participants) and stimulus (intervention), and is it sufficiently detailed to permit the study to be replicated?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Figure 5 Reviewer Checklist



Note: *You don't have to complete the review in a single sitting, you can Save, Close, and come back later.*

2.2.3 Send Comments to the PI

The first step of a Comment/Response Cycle is writing comments to the PI. Once the comments are sent to the PI (via the PM) the PI can respond. The responses, including any changes to the protocol, are returned (via the PM) to the reviewers which completes the Comment/Response Cycle. The review process may consist of zero or more review cycles – zero cycles if the protocol is recommended for approval as is (there are no comments) and one or more cycles depending on the necessary changes.

Writing comments allows you to request more information or a revision on any part of the protocol. The PM reviews and consolidates all comments prior to submitting them to the PI.

2.2.3.1 Write Comment(s) on Comments Page

To write comments to the PI through the Write Comment(s) button, perform the following tasks:

1. Click the **Assigned as Reviewer** link in the Protocol Events column. The Comments page appears.
2. Select the **Protocol ID** link or **Get Protocol** to view the protocol.
3. Click **Write Comment(s)** (Figure 6).



Figure 6 Comments Page

4. Use the **Select Section** dropdown to select a section of the protocol.
5. Enter the comments in the text field provided.
6. Select **Response Necessary for Approval** or **Suggestion Not Necessary for Approval**.
 - a. Response Necessary for Approval: The PI's response to the comment is mandatory.
 - i. The Recommend for Approval button is disabled when this type of comment is selected.
 - b. Suggestion Not Necessary for Approval: The PI's response to the comment is optional.
 - i. The Submit to (Committee) button is disabled if all comments are set to this type.
7. Click **Save and Add Comment**. Continue to add comments as necessary.
8. Enter notes to the committee in the appropriate text field, e.g., Notes to IRB. Then, click **Save**.
9. Click **Submit to (Committee)**, e.g., Submit to IRB. Then, **OK** to proceed.

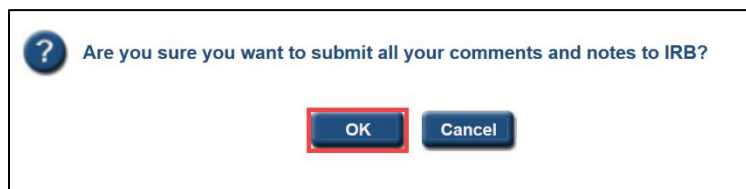


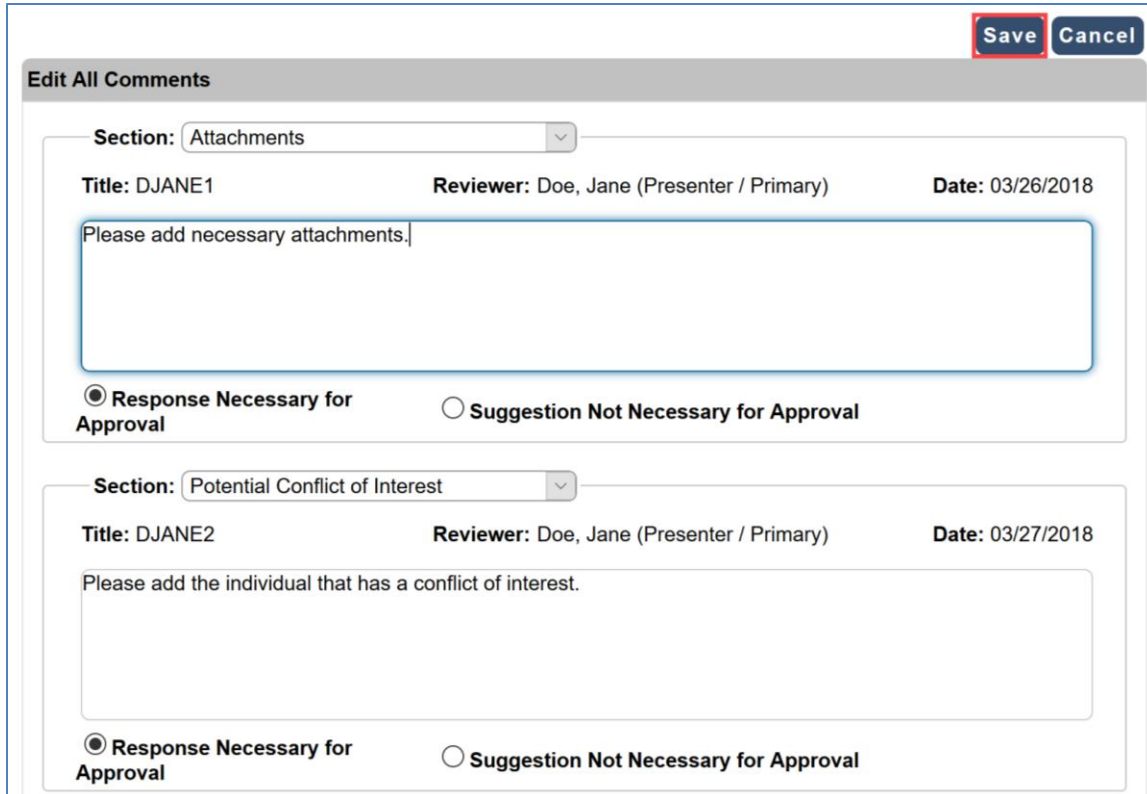
Figure 7 Submit Comments

The protocol moves to the Protocols for Review table on the homepage and the Protocol Event status updates to Comments Sent (Cycle 1).

2.2.3.2 Edit Comments on the Comments Page

To edit comments on the comments page, perform the following tasks:

1. Select **Edit All Comments**. The Edit All Comments page appears.
2. Modify all comments, as appropriate. Then, click **Save** (Figure 8).



The screenshot shows a web interface titled "Edit All Comments" with a "Save" button highlighted in red and a "Cancel" button. The interface contains two comment entries, each with a "Section" dropdown, "Title", "Reviewer", "Date", a text area for editing, and radio buttons for response status.

Comment 1:
 Section: Attachments
 Title: DJANE1
 Reviewer: Doe, Jane (Presenter / Primary)
 Date: 03/26/2018
 Text area: Please add necessary attachments.
 Radio buttons: Response Necessary for Approval, Suggestion Not Necessary for Approval

Comment 2:
 Section: Potential Conflict of Interest
 Title: DJANE2
 Reviewer: Doe, Jane (Presenter / Primary)
 Date: 03/27/2018
 Text area: Please add the individual that has a conflict of interest.
 Radio buttons: Response Necessary for Approval, Suggestion Not Necessary for Approval

Figure 8 Edit All Comments

2.2.4 Review Responses from the PI

When you receive a response from the Investigator, the protocol event changes to Comments Received (Cycle 1). If more comment/response cycles occur, the cycle number increases accordingly.

To review responses from the PI, perform the following tasks:

1. Click **Responses Received (Cycle 1)** in the Protocol Event column. The Comments page appears. The responses appear below your original comment (Figure 9).

Comments

Section: Subject Population (a-f)

Title: DJANE1 **Reviewer:** Doe, Jane (Presenter / Primary) **Date:** 03/26/2018

More information is needed on question b.

Response Necessary for Approval
 Suggestion Not Necessary for Approval

Response **Date:** 03/26/2018

Question b updated.

Figure 9 View Response

2. Click **Get Protocol** to open the protocol. The first entry in the left-side navigation pane is Updates and the **Updates (Current)** page appears.
3. Click on the links to view the changes made in the listed section (Figure 10).

Updates	Updates(Current)
Personnel Information	Subject Population 6(a-g)
Subject Checklist	

Figure 10 Link to the Changes

4. You are navigated to the page where changes were made (Figure 11).

5. Subject Population

a) How many subjects do you intend to enroll and/or how many subject records do you intend to access?

i. At this site

# of subjects		100
# of records		100

ii. At all sites **N/A**

# of subjects	30
# of records	30

Figure 11 Changes to Protocol

5. Click the folder icon () to view the previous and current responses. A pop-up appears. For example, Figure 12 displays that the previous response has changed. Under the Current Response column, a deletion is represented by crossed-out text and a red background. The current response (i.e., modified text) has a green background and underlined text. The Previous Response column displays the unedited previous version for comparison.
 - a. You may only view one pop-up at a time.

Cycle 1			Version History		
Caption	Current Response	Previous Response	Caption	Current Response	Previous Response
# of subjects	130100	130	# of records	130100	130

Figure 12 Two Examples of a Previous and Current Response

- If you are satisfied with the changes, continue to the next section (2.2.5 Recommend the Protocol for Approval). If not, begin another comment/response cycle with the PI by sending a comment to the PI – refer to section 2.2.3.1 for more details on how to Write Comment(s) on Comments Page.

2.2.5 Recommend the Protocol for Approval

Once you have reviewed a protocol and believe it is ready for approval, you need to recommend it for approval.

To recommend a protocol for approval, perform the following task:

- Open the comments page by selecting the link under the Protocol Event column.
- Click Recommend for Approval (Figure 13). The Approval Notes page appears.

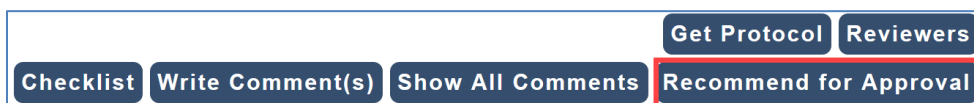
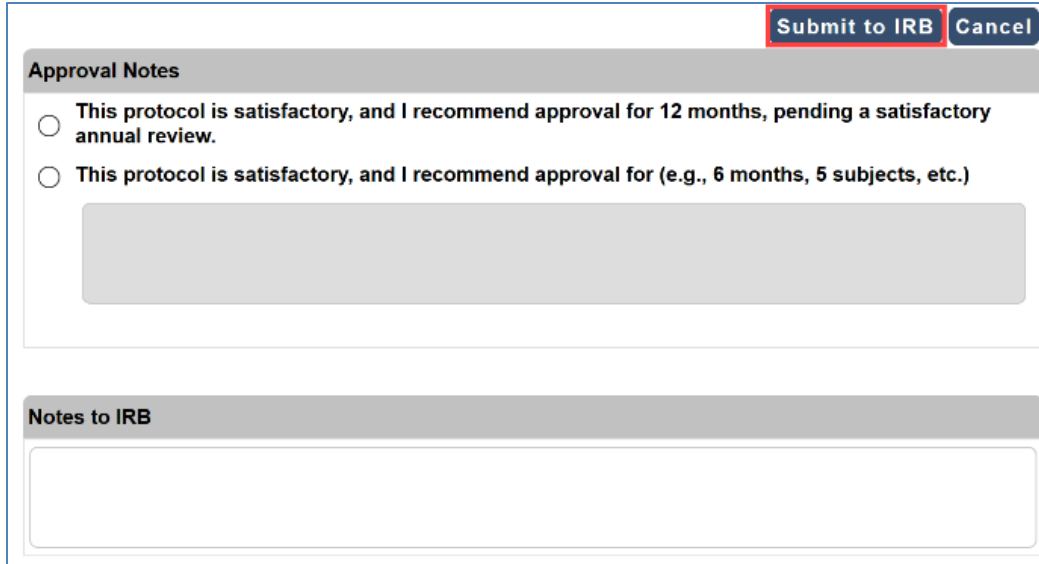


Figure 13 Recommend for Approval

- Select the appropriate option. If necessary, add notes to the committee. Then, click **Submit to (Committee)** (Figure 14).



Submit to IRB **Cancel**

Approval Notes

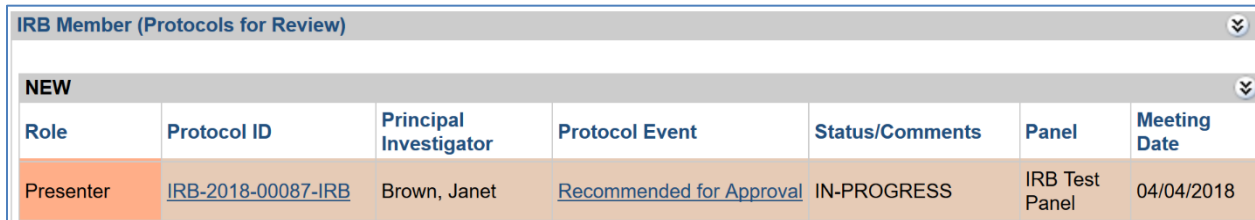
This protocol is satisfactory, and I recommend approval for 12 months, pending a satisfactory annual review.

This protocol is satisfactory, and I recommend approval for (e.g., 6 months, 5 subjects, etc.)

Notes to IRB

Figure 14 Approval Notes

- The protocol moves to the Protocols for Review section and the Protocol Event status changes to Recommend for Approval (Figure 15).



IRB Member (Protocols for Review)						
NEW						
Role	Protocol ID	Principal Investigator	Protocol Event	Status/Comments	Panel	Meeting Date
Presenter	IRB-2018-00087-IRB	Brown, Janet	Recommended for Approval	IN-PROGRESS	IRB Test Panel	04/04/2018

Figure 15 Recommended for Approval



Caution: You cannot add comments once you recommend the protocol for approval. Email the committee with any issues or concerns.

2.2.6 Search 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 may review them by clicking the protocol ID link.

To search for a protocol, perform the following tasks:

- Navigate to the Reviewer submenu and click **Search Protocol**. The Search Protocol page appears (Figure 16).

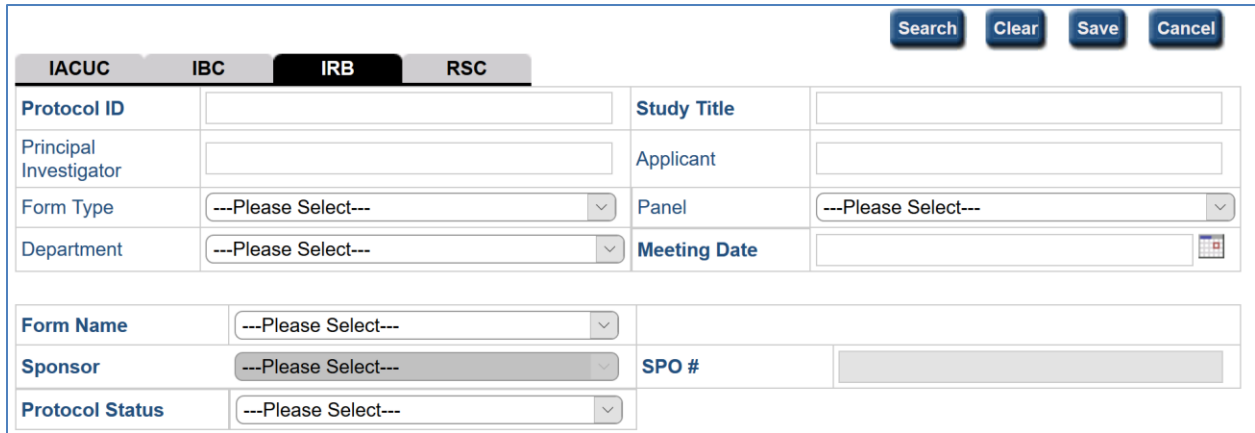


Figure 16 Search Protocol

2. Select a committee tab. Then, refine your search by entering information into the text fields and/or using the dropdowns.
3. Click **Search**.
4. Click the Protocol ID link to view the protocol.

To save the Search Criteria for re-use in the future, perform the following tasks:

1. Click **Save** in the upper-right above the search table. The Search Criteria text field appears below the table of search filters.
2. Enter in a name that you would like to use to refer to the set of search criteria in the future. Then, click **Save** (Figure 17).

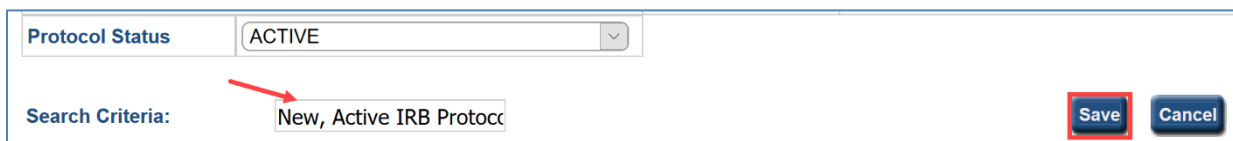


Figure 17 Save Search Criteria