

# eProtocol Reviewer Quick Guide

## Allina Hospitals & Clinics

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## Terminology Differences

Some of the terms used in eProtocol differ from those of Allina's IRBs and research community. Here are the words to note:

- Designated Reviewer  
The *designated* reviewer is eProtocol's term for *expedited* reviewer.
- Investigator  
In eProtocol everyone on the research team—principal investigators, study coordinators, other personnel—enters the system as “Investigator.”
- Panel  
eProtocol uses the word *panel* to refer to the IRB committee.
- Panel Manager  
At Allina the *panel manager* refers to IRB administrative staff.
- Protocol  
In eProtocol, the word *protocol* has two meanings; in its general sense, it refers to the entire study, but it is also used in a specific sense to refer to the document that describes the details of the study.

## Accessing eProtocol

You may access eProtocol through the URL link on the IRB/SPA Submission page. The eProtocol log-in page appears. Enter your user ID and password; then click **Login**.

Follow the tips outlined below when using the system.

**1. Use a recommended browser.**

If you are using Windows, eProtocol works best when using **Internet Explorer (7)**. If you are using a Mac, eProtocol works best when using **Safari**.

**2. Allow pop-up windows.**

Pop-up blocking software prevents the eProtocol application from opening certain windows. You'll need to make sure that your browser has all pop-up blocking software disabled while using eProtocol.

**3. Avoid using your browser's BACK button.**

Instead, use the menus and links within the application to navigate.

**4. SAVE frequently.**

eProtocol will time out after 45 minutes of inactivity. Only actions that cause the page to refresh or reload (such as saving or navigating to a new section) are indications to the system that your session is active.

**5. Be patient.**

Some processes can take a minute to run. Although data is loading, your browser may not indicate activity.

**6. Read the Instructions.**

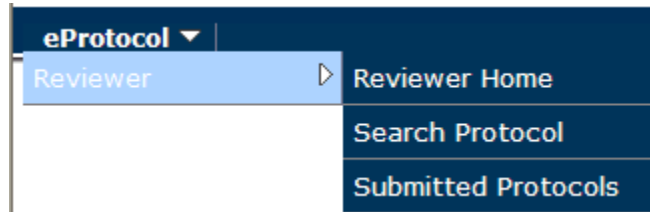
Many pages in the application offer instructions on the page to guide you. You can also check the [FAQ](#) page for answers to eProtocol questions.

**7. Sign out.**

To protect private information, always log off and shut down your browser completely (close all browser windows) when you are finished using eProtocol.

## Reviewer Home Page

After logging in, you'll be directed to the **Home** page. You can return to the **Home** page at any time by clicking **Reviewer Home** on the main menu. (If you are a researcher, you will access your protocols by clicking "Investigator Home.")



The protocols for your review will appear on your Home page.

IRB Member (Protocols for Review)						
<b>NEW</b>						
Role	Protocol ID	Principal Investigator	Protocol Event	Status/Comments	Panel	Meeting Date
Presenter	<a href="#">2009-03-050</a>	Atherton, Michael	<a href="#">MOVED</a>	MOVED	IRB	08/02/2009
NPR	<a href="#">2009-01-031</a>	michael	<a href="#">Assigned as Reviewer</a>	IN-PROGRESS	IRB	02/01/2009
Presenter	<a href="#">2009-01-109</a>	Atherton, Michael	<a href="#">Assigned as Reviewer</a>	IN-PROGRESS	IRB	02/01/2009
<b>AMENDMENT</b>						
Role	Protocol ID	Principal Investigator	Protocol Event	Status/Comments	Panel	Meeting Date
Presenter	<a href="#">2009-01-171</a>	Goodwin, Scott	<a href="#">Comments Sent (Cycle 1)</a>	IN-PROGRESS	IRB	02/01/2009
<b>CONTINUING REVIEW</b>						
Role	Protocol ID	Principal Investigator	Protocol Event	Status/Comments	Panel	Meeting Date
Presenter	<a href="#">2009-01-174</a>	Goodwin, Scott	<a href="#">Comments Sent (Cycle 1)</a>	IN-PROGRESS	IRB	02/01/2009
<b>REPORT</b>						
Role	Protocol ID	Principal Investigator	Protocol Event	Status/Comments	Panel	Meeting Date
Presenter	<a href="#">2009-01-188</a>	Atherton, Michael	<a href="#">CONTINGENT</a>	CONTINGENT	IRB	02/01/2009
<b>DEVIATION</b>						
Role	Protocol ID	Principal Investigator	Protocol Event	Status/Comments	Panel	Meeting Date
Reviewer	<a href="#">2009-02-261</a>	Colbert, Barbara	<a href="#">Assigned as Reviewer</a>	IN-PROGRESS	IRB	03/01/2009
<b>FINAL REPORT</b>						
Role	Protocol ID	Principal Investigator	Protocol Event	Status/Comments	Panel	Meeting Date
Presenter	<a href="#">2009-01-193</a>	Jones, Simon	<a href="#">Comments Sent (Cycle 1)</a>	IN-PROGRESS	IRB	01/03/2010

## Reviewer Functions

### Enter Comments About a Protocol

On the **Home** page, access the protocol (study) by clicking the link under **Protocol ID** to review the study. To enter your comments, click the link under **Protocol Event**.

Click the link under "Protocol Event."

IRB		SPA				
NEW						
Protocol ID	Principal Investigator	Protocol Event	Status/Comments	Panel	Meeting Date	
<a href="#">2008-12-058</a>	Goodwin, Scott	<a href="#">Assigned as Reviewer</a>	IN-PROGRESS	IACUC	02/01/2009	
<a href="#">2008-11-052</a>	Atherton, Michael	<a href="#">CONTINGENT</a>	CONTINGENT	IACUC	04/05/2009	

The **Comments** pop-up will appear. On it are several buttons, each of which is explained below.

#### Reviewers

Clicking the **Reviewers** button will open a pop-up list of the reviewers assigned to the study.

Reviewer Name	Presenter	PR	SR	Member Type
Atherton, Michael	Yes	No	No	VOTING
Johnson, David	No	Yes	No	VOTING
Rumsey, Yvonne	No	No	Yes	VOTING

Presenter	This designation is not currently used at Allina's IRBs.
PR	Primary Reviewer
SR	Secondary Reviewer
Member Type	Indicates whether an individual is a voting or non-voting member of the IRB

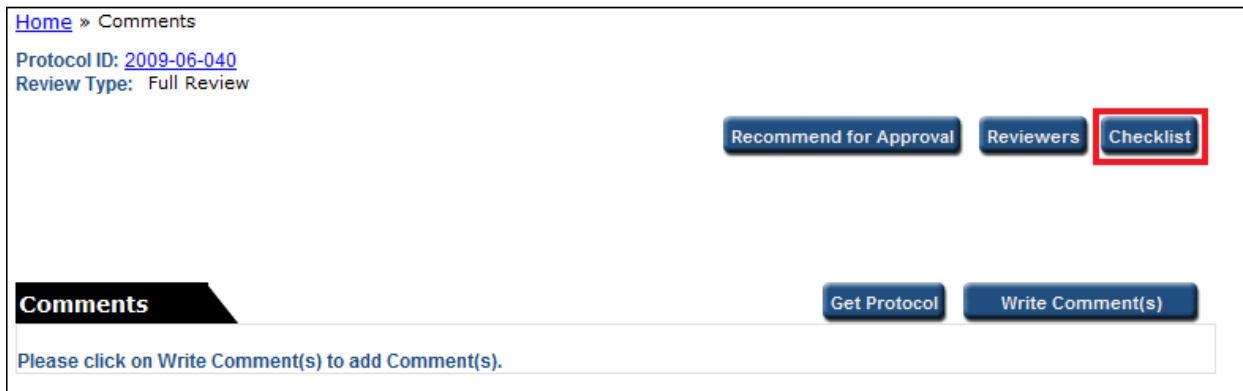
Click **Close** to exit the reviewer list.

### Get Protocol



The study (protocol) information will appear in a pop-up when you click the **Get Protocol** button.

### Checklist



### Using the Reviewer's Checklist

1. Click **Checklist** to access the Reviewer's Checklist for new studies.
2. Enter your responses to the questions by clicking the boxes under Yes, No, or NA (Not Applicable). If you wish to print a hard copy, click **Print** in the upper right corner.
3. Click **Save** before exiting the checklist. (See the figure below.)

**Reviewers Checklist** [Save](#) [Cancel](#) [Next](#)

	Yes	No	N/A	Comments
Does this study pose a risk or risks to participants?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Would the participants experience these risks if they were not part of the study?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Has the investigator attempted to minimize the risks?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are the risks reasonable in relation to the potential benefit(s) to the participants or the scientific knowledge to be gained?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Does the study use procedures that are consistent with sound research design and do not unnecessarily expose subjects to risk?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
If appropriate, does the study use procedures already being performed on the subjects for diagnostic or treatment purposes?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

*Write Comments*

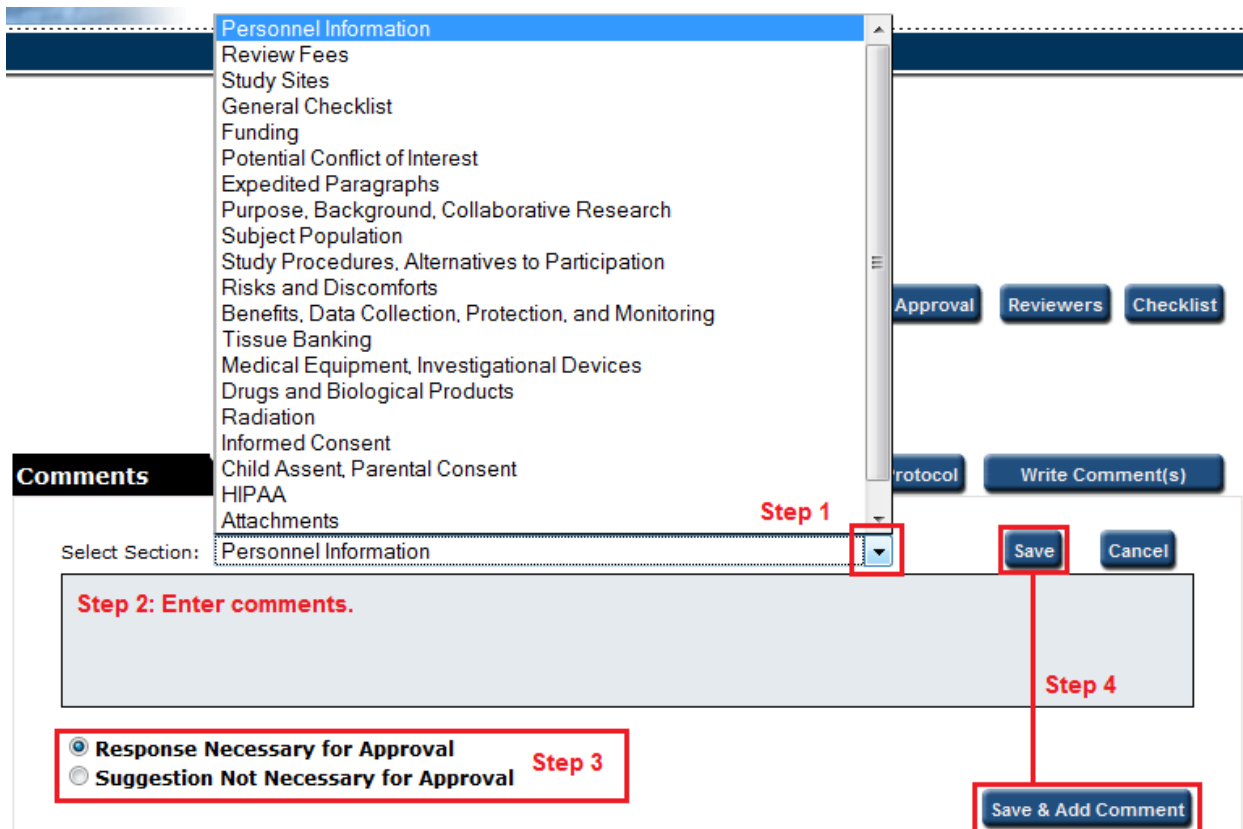
[Home](#) » Comments  
 Protocol ID: [2009-06-040](#)  
 Review Type: Full Review

[Recommend for Approval](#) [Reviewers](#) [Checklist](#)

**Comments** [Get Protocol](#) [Write Comment\(s\)](#)

Please click on [Write Comment\(s\)](#) to add Comment(s).

To record your comments about the study, click **Write Comment(s)**. The **Comments** pop-up will appear.



### Entering Comments

1. Click the down arrow to select the section about which you wish to make comments.
2. Enter your comments about that section of the protocol (study).
3. Select whether a response to your comment is necessary for approval or whether your comment is a suggestion that does not require a response
4. Click **Save & Add Comment** to add comments about other sections of the study. Or click **Save** at the top of the Comments text box when you have added all the comments you wish to make.

Reviewers Checklist

Cycle: 1

**Comments**    Get Protocol    Write Comment(s)    Show All Comments    **Submit to IRB**

Title: YR2    Select Section: Personnel Information    Edit    Delete

Provide information concerning the co-investigator.

Response Necessary for Approval  
 Suggestion Not Necessary for Approval

Select Section: Subject Population    Save    Cancel

Consider using a short form with this subject population.

Response Necessary for Approval  
 Suggestion Not Necessary for Approval

Save & Add Comment

You may **Edit** or **Delete** comments if you wish. When you have entered all of your comments, click the **Submit to IRB** button. The **Notes to IRB** pop-up will appear.

eProtocol - Allina Health System - Notes to Manager - Mozilla Firefox

keyusa.com https://allina.eppilot.keyusa.com/noteToManager.do

**Notes to IRB**    Submit to IRB    Cancel

Enter any comments you wish to make to the IRB.

Done

When you have entered your comments to the IRB, click the **Submit to IRB** button.

IRB Member (Protocols for Review)						
NEW						
Role	Protocol ID	Principal Investigator	Protocol Event	Status/Comments	Panel	Meeting Date
Presenter	<a href="#">2009-03-081</a>	Krall, Bonita	<a href="#">Comments Sent (Cycle 1)</a>	IN-PROGRESS	IRB	04/05/2009

After you send your comments to the IRB, the Protocol Event for the study changes to “Comments Sent (Cycle 1).”

If the IRB staff forward the researcher’s responses to your comments, the Protocol Event for the study changes to “Responses Received (Cycle 1).”

NEW						
Role	Protocol ID	Principal Investigator	Protocol Event	Status/Comments	Panel	Meeting Date
Presenter	<a href="#">2009-03-081</a>	Krall, Bonita	<a href="#">Responses Received (Cycle 1)</a>	IN-PROGRESS	IRB	04/05/2009

**Click on Protocol Event.  
Comments page is displayed.**

## Recommend the Protocol for Approval

If you wish to recommend approval for a protocol (study), begin by clicking the **Assigned as Reviewer** link under “Protocol Event” on your **Home** page.

**Click the "Assigned as Reviewer" link.**

Role	Protocol ID	Principal Investigator	Protocol Event	Status/Comments	Panel	Meeting Date
Presenter	<a href="#">2009-03-050</a>	Atherton, Michael	<a href="#">MOVED</a>	MOVED	IRB	08/02/2009
NPR	<a href="#">2009-01-031</a>	michael	<a href="#">Assigned as Reviewer</a>	IN-PROGRESS	IRB	02/01/2009
Presenter	<a href="#">2009-01-109</a>	Atherton, Michael	<a href="#">Assigned as Reviewer</a>	IN-PROGRESS	IRB	02/01/2009

The **Comments** pop-up will appear. Click the **Recommend for Approval** button.

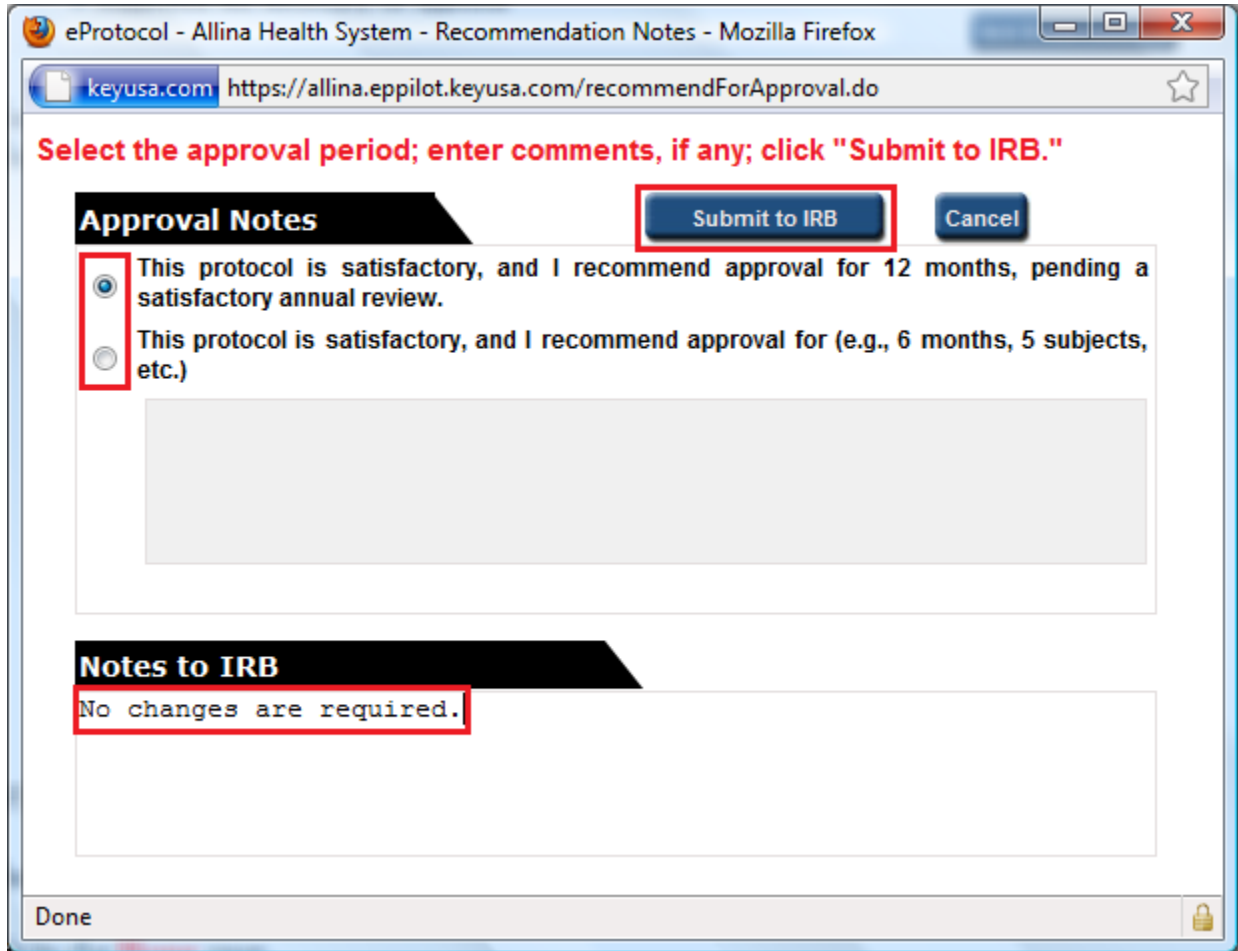
[Home](#) » Comments  
Protocol ID: [2009-06-040](#)  
Review Type: Full Review

**Recommend for Approval** **Reviewers** **Checklist**

**Comments** **Get Protocol** **Write Comment(s)**

Please click on Write Comment(s) to add Comment(s).

The **Approval** pop-up will appear.



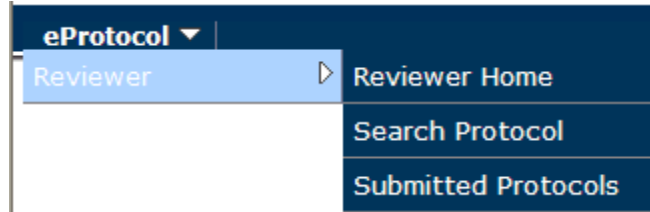
### Recommending Approval

1. Select the approval period for the study. If you believe that an approval period of less than one year is warranted, click the second radio button and enter your recommended interval before the next review.
2. Enter notes to the IRB, if any.
3. Click **Submit to IRB**.
4. After you send your comments to the IRB, the Protocol Event for the study changes to “Recommended for Approval.”

NEW						
Role	Protocol ID	Principal Investigator	Protocol Event	Status/Comments	Panel	Meeting Date
Reviewer	<a href="#">2009-03-436</a>	Atherton, Michael	<a href="#">Recommended for Approval</a>	IN-PROGRESS	IRB	04/05/2009

## Search Protocol

From the left navigation menu, go to the **Search Protocol** page.



The Search Protocol page displays.

[Home](#) » Search Protocol

IRB SPA Search Clear Save Cancel

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-----
Meeting Date	<input type="text"/>	SPO #	<input type="text"/>
Sponsor	-----Please Select-----		

Provide your search criteria; then click **Search**. Your search results will display.

[Home](#) » Search Protocol

**Click "Save." The "Search Criteria" textbox is enabled.**

IRB SPA Search Clear Save Cancel

Protocol ID	<input type="text"/>	Study Title	<input type="text"/>
Principal Investigator	<input type="text"/>	Investigator	<input type="text"/>
Form Type	NEW	Panel	-----Please Select-----
Meeting Date	<input type="text"/>	SPO #	<input type="text"/>
Sponsor	-----Please Select-----		

Protocol ID	Principal Investigator	Title	Panel	Meeting Date	Expiration Date	Form Type
<a href="#">2009-06-048</a>	Smith, Kevin	Beta Blocker Post-Marketing Follow-up Study	KSI IRB Practice			NEW
<a href="#">2009-06-029</a>	Rumsey, Yvonne	Perceptions of Research Participation: A Qualitative Study	KSI IRB Practice			NEW

[Home](#) » Search Protocol

**IRB** SPA Search Clear Save Cancel

Protocol ID	<input type="text"/>	Study Title	<input type="text"/>
Principal Investigator	<input type="text"/>	Investigator	<input type="text"/>
Form Type	NEW	Panel	-----Please Select-----
Meeting Date	<input type="text"/>	SPO #	<input type="text"/>
Sponsor	-----Please Select-----		

**Search Criteria:**  **Enter "Search Criteria"; click "Save."** Save Cancel

Protocol ID	Principal Investigator	Title	Panel	Meeting Date	Expiration Date	Form Type
<a href="#">2009-06-048</a>	Smith, Kevin	Beta Blocker Post-Marketing Follow-up Study	KSI IRB Practice			NEW
<a href="#">2009-06-029</a>	Rumsey, Yvonne	Perceptions of Research Participation: A Qualitative Study	KSI IRB Practice			NEW

Enter additional **Search Criteria** if you wish. When you click **Save**, the criteria will be added to the **Selected Search Criteria** drop-down menu.

[Home](#) » Search Protocol

**IRB** SPA Search Clear Save Cancel

Protocol ID	<input type="text"/>	Study Title	<input type="text"/>
Principal Investigator	<input type="text"/>	Investigator	<input type="text"/>
Form Type	NEW	Panel	-----Please Select-----
Meeting Date	<input type="text"/>	SPO #	<input type="text"/>
Sponsor	-----Please Select-----		

**Selected Search Criteria:** -----Please Select-----  
-----Please Select-----  
Study **The criteria is added to the "Selected Search Criteria" drop-down menu.** Save Cancel

Protocol ID	Principal Investigator	Title	Panel	Meeting Date	Expiration Date	Form Type
<a href="#">2009-06-048</a>	Smith, Kevin	Beta Blocker Post-Marketing Follow-up Study	KSI IRB Practice			NEW
<a href="#">2009-06-029</a>	Rumsey, Yvonne	Perceptions of Research Participation: A Qualitative Study	KSI IRB Practice			NEW