



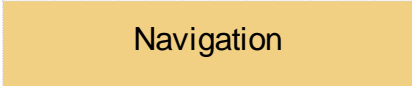
Please keep the following things in mind as you use this guide:

These guides are designed to facilitate immediate productivity for new users in a complex and unfamiliar system. To achieve this end, the processes are broken down into manageable sections with the steps to each process laid out sequentially.

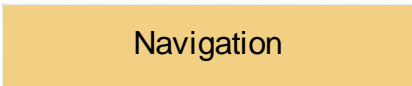
By practicing the steps and experimenting in the application at the detail level, you will gain the knowledge you need to master your role or design high-unique needs.

This guide assumes you are familiar with the common features and basic navigation as presented in the manual. Please use that manual as a companion to this one, as we have tried to eliminate redundancy wherever possible.

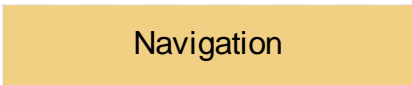
Streamlyne Research is highly configurable. If you are currently in the



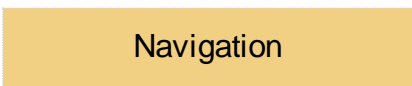
This lookup is useful to IRB Committee members who regularly attend Committee meetings. The results will show a schedule of meetings where your attendance is expected based on your Committee membership status.



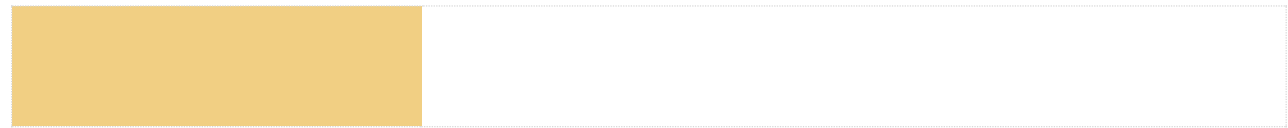
This IRB Administrator lookup will generate a list of protocol submissions for approval, amendment, renewal, notifications, action requests, and acknowledgements in various statuses.



This lookup will generate a list of protocols that are in various statuses pending approval. The search results will include any protocols where you are listed as personnel. If you are not the Principal Investigator or do not have permissions to edit the document, you will only be able to view the protocol document.



This lookup will generate a list of protocols that are pending action from the Principal Investigator. Typically, these are protocols that have been returned to the PI for revisions. The search results will include any protocols where you are listed as personnel. If you are not the Principal Investigator or do not have permissions to edit the document, you will only be able to view the protocol document.



This lookup will generate a list of protocols that have been submitted and are awaiting Committee review and approval. The search results will include

The fourth section provides IRB Committee Members a step-by-step guide to prepare, review, submit assigned Online Reviews, along with information needed to prepare for committee meetings.

Completing IRB Committee Reviews..... Error! Bookmark not defined.
 Completing an Assigned Online Review
 Viewing Previous Review Information.....
 Preparing for Committee Meetings



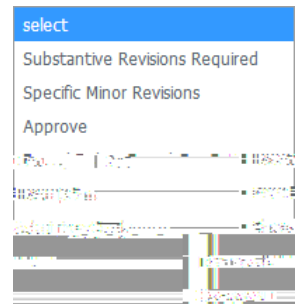
To review the content of the protocol, click through the other tabs, sections, comments, and attachments. You may want to familiarize yourself with protocol documents and how a PI initiates and submits a new protocol, amendment, renewal or request by referencing the [FOR PRINCIPAL INVESTIGATORS](#) section.


When you are ready to render a decision, return to the **Online Review** tab by clicking the tab header.



In the **Online Review** subsection, indicate your **Determination Recommendation** by clicking the arrows next to the field and selecting from the dropdown list.


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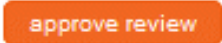
In the **Review Comments** section, click the **magnifying glass**  to search for a standard comment or summarize your determination in the **Description** field with a freeform comment.

Click the **Add** button to register your comments. 

The **Review Attachments** subsection is optional.

If you chose to put your extended comments in an attachment, include this document by clicking the **Browse**  instructions.

Click the **Add** button to complete the attachment process. 

When you are ready to complete the review, click the **Approve Review**  button.

Streamlyne Research will generate an **FYI Notification** to the IRB Administrator to advise them that the  Online Review is complete.

Often the assigned reviewer is reviewing a protocol that has already been reviewed by themselves or a different member of their committee. Prior to a re-review, it is helpful to view previous determinations, comments, or the official correspondence outlining the changes that were needed. These comments can be viewed a few different ways:

Quick Steps:

1. Access the official correspondence letter by going to **Protocol Actions > Summary & History > History** and viewing the section that corresponds with the last **Return for Revisions** action.
2. Access the Reviewer information and comments by going to **Protocol Actions > Summary & History > Reviews and Attachments**.

Note: Only Final Review comments will be visible unless made by the reviewer currently assigned.

The **Meeting** page will open.

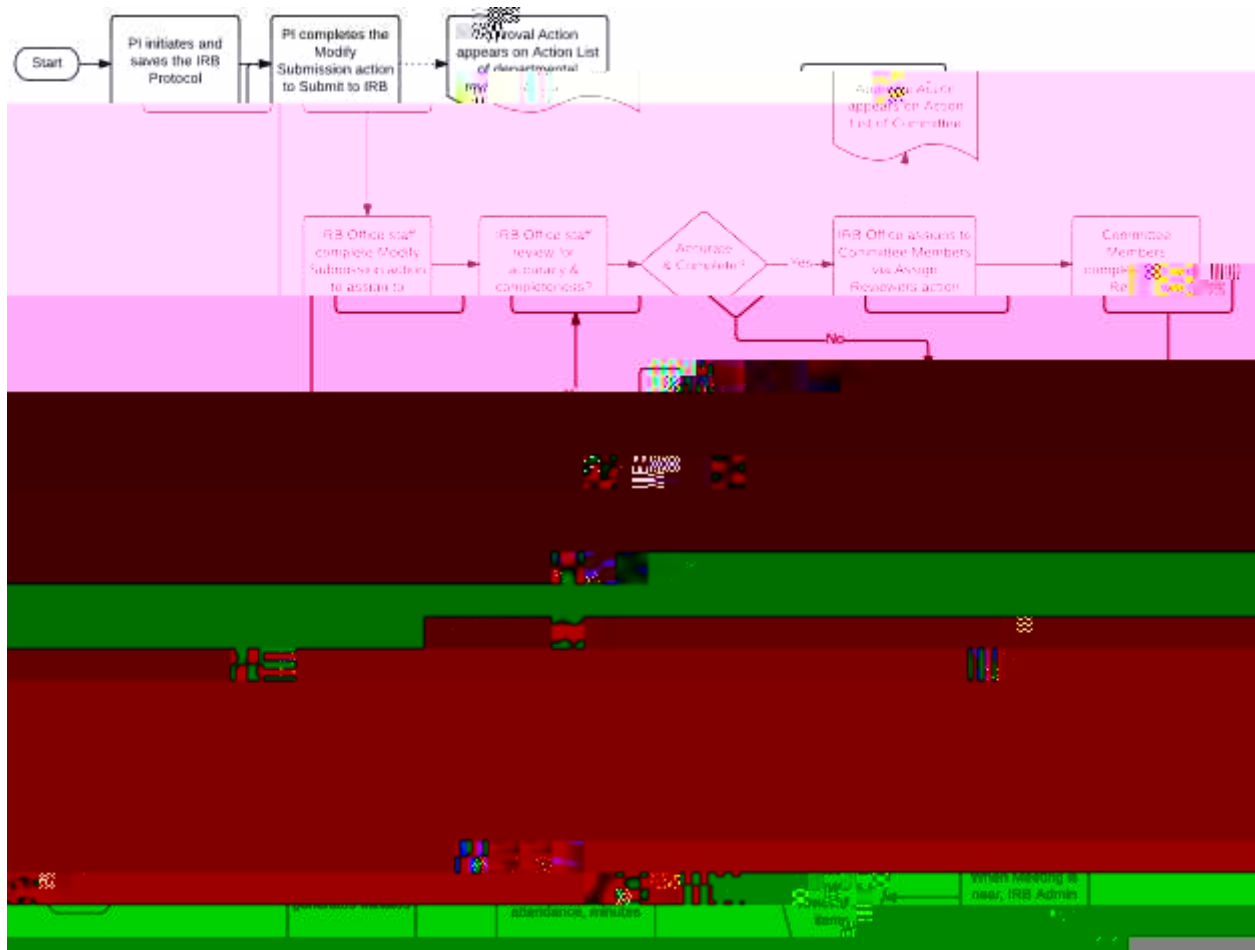
Click the section header to expand the **Protocol Submitted** section.


Click the **View** button for access to the protocol.

You may want to familiarize yourself with protocol documents and how a PI initiates and submits a new protocol, amendment, renewal or request by referencing the [FOR PRINCIPAL INVESTIGATORS](#) section.

If you are not assigned as a reviewer, the protocol will open with read only access.


Review any other pertinent information on the **Meeting** page to help prepare for the committee meeting.





Abandon Investigator Used to cancel a
protocol

Create Amendment	Investigator	Used to request an amendment to a previously approved protocol, incorporating minor administrative changes through changes to study design.	Protocol Status must be one of the following: Active-Open to Enrollment, Active-Closed to Enrollment, Active-Data Analysis Only, Exempt.	Protocol Status updates to be Amendment in Progress.
Create Renewal with Amendment	Investigator	Used to both renew a protocol set to expire, AND to incorporate various changes to the protocol. (See also: Create Renewal without Amendment and Create Amendment)	Protocol Status must be one of the following: Active-Open to Enrollment, Active-Closed to Enrollment, Active-Data Analysis Only, Exempt.	Protocol Status updates to Renewal in Progress.




Data Analysis Only	IRB Admin	Used to indicate the study has entered a phase where only data analysis is
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Disapprove	IRB Admin	Used to record disapproval of a protocol following full committee review. (See also: Record Committee Decision)	Record Committee Decision must be performed with Motion Type set to Disapprove. Protocol Status must be Submitted to IRB. Submission Status must be In Agenda.	Protocol Status updates to Disapproved. Submission Status updates to Disapproved.
Expedited Approval	IRB Admin	Used to record approval of a protocol following expedited review.	Protocol Status must be Submitted to IRB. Submission Status must be Pending or Submitted to Committee.	Protocol Status updates to Active-Open to Enrollment. Submission Status updates to Approved.
Expire	IRB Admin	Used to indicate that approval of a protocol has expired and no human subject activities may proceed until a renewal is approved. Alternatively, the study may close.	Protocol Status must be one of the following: Active-Open to Enrollment, Active-Closed to Enrollment, Active-Data Analysis Only, Exempt, Suspended by Investigator, Suspended by IRB, Request to Close.	Protocol Status updates to Expired.




Manage Review Comments	IRB Admin	Used as a single point of access for all reviewer and administrator comments. Comments can be added, deleted, or modified.	None.	Comments are updated.
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Manage Review Attachments	IRB Admin	Used as a single point of access for all reviewer and administrator attachments. Attachments can be added, deleted, or modified.	None.	
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Record Committee Decision	IRB Admin	Used to record the decision of a full IRB committee review of a protocol, specifically: Approve,
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Request for Investigator Used to request
Suspension



Request to
Close
Enrollment



Return to PI	IRB Admin	Used to return a protocol to the investigator for corrections prior to formal committee review. Similar actions requesting revisions can only be sent after the committee decision is recorded. (See also: Return for Substantive Revisions Required and Return for Specific Minor Revisions)	The Assign to
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Terminate	IRB Admin	Used to formally terminate a study when the either the investigators or the IRB determine it is unsafe to continue. Often occurs in response to a Request to Terminate action. (See also: Request to Terminate)	Protocol Status must be in one of the following statuses: Active-Open to Enrollment, Active-Closed to Enrollment, Active-Data Analysis Only, Exempt, Suspended by Investigator, Suspended by IRB, Expired.	Protocol Status updates to Terminated by IRB.
Undo Last Action	IRB Admin	Used to revert a protocol to its state prior to the last action taken, including deleting any correspondence associated with the last action.	Protocol Status must not be in one of the following: Protocol Created, Submitted to IRB, Renewal Created, Amendment Created, Expired,	

Withdraw Submission	IRB Admin	Used to withdraw a protocol submission request from consideration.	<p>Protocol must have a pending Request to Close, Request to Suspend, Request to Close Enrollment, Request to Re-Open Enrollment, Request for Data Analysis Only, or Request to Terminate Action.</p> <p>Submission Status will be Pending.</p>	Submission Status only updates to Withdrawn.
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