



IRB Protocol & Committee Modules
Committee Member User Manual
University of Northern Colorado

Table of Contents

Table of Contents	1
I: For a General Audience	1
Overview of the IRB Protocol & Committee Modules.....	1
Section I Contents.....	1
Using This Guide.....	2
A Stepwise Approach.....	2
Navigation and Common Elements	2
Every Installation Is Different	2
Searching with IRB Lookups.....	3
All My Protocols.....	3
All My Reviews.....	3
All My Schedules	4
Protocol Submissions.....	4
Pending Protocols	4
Protocols Pending PI Action	4
Protocols Pending Committee Action	5
Protocol Online Review	5
IRB Committee Schedules	5
IV: For IRB Committee Members	6
Section IV Contents.....	6
Completing IRB Committee Reviews.....	7
Completing an Assigned Online Review	7
Viewing Previous Review Information.....	9
Preparing for Committee Meetings	10
Appendix A: IRB Roles and Permissions	13
Appendix B: IRB Protocol Workflow Overview.....	14
Appendix C: All IRB Protocol Actions	15

I: For a General Audience

The first section of the IRB Manual contains information for all audiences.

Overview of the IRB Protocol & Committee Modules

Streamlyne’s IRB Protocol & Committee Modules are designed to facilitate the institutional processes that ensure compliance with the federally-mandated protection of human subjects participating in research activities. Principal Investigators initiate and submit IRB protocols, amendments, and renewals within the system. Protocols are automatically routed to the appropriate departments and corresponding IRBs for review and approval. Reviewers and Committee Members have access to the protocols online where their comments and decisions are preserved. IRB administrators have all the tools they need to track protocols, coordinate reviews, manage committee meetings, maintain associated correspondence, and properly administer protocols throughout their lifecycles.

Section I Contents

Using This Guide	Error! Bookmark not defined.
A Stepwise Approach.....	Error! Bookmark not defined.
Navigation and Common Elements	Error! Bookmark not defined.
Every Installation Is Different	Error! Bookmark not defined.
Searching with IRB Lookups	Error! Bookmark not defined.
All My Protocols.....	Error! Bookmark not defined.
All My Reviews.....	Error! Bookmark not defined.
All My Schedules	Error! Bookmark not defined.
Protocol Submissions.....	Error! Bookmark not defined.
Pending Protocols	Error! Bookmark not defined.
Protocols Pending PI Action	Error! Bookmark not defined.
Protocols Pending Committee Action	Error! Bookmark not defined.
Protocol Online Review	Error! Bookmark not defined.
IRB Committee Schedules	Error! Bookmark not defined.

Using This Guide

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

A Stepwise Approach

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-level processes that meet your institution's unique needs.

Navigation and Common Elements

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

Every Installation Is Different

Streamlyne Research is highly configurable. If you are currently in the implementation process, it is likely your institution will perform some level of analysis to identify which features you would like to use, which values you would like to change to reflect your institution's terminology, and which features you will skip altogether.

Given this, the processes detailed in this document are representative of general IRB practices and do not necessarily represent the exact manner in which your institution will choose to use the application.

Let's begin!

Searching with IRB Lookups

To assist you in locating IRB Protocols and Committees within Streamlyne Research, IRB search windows, called lookups, are available from the Main Menu. Access to these lookups depends on the IRB roles assigned to you in your Person record, or user profile. Most users at an institution will have the necessary permissions to prepare and submit a protocol, while only IRB administrators will have access to the various administrative functions related to IRB protocols and committees. Some users (such as Department Chairs or IRB Committee Members) may also be involved in approving or reviewing protocols. See [Appendix A: IRB Roles and Permissions](#) for a complete list.

To search for items using IRB lookups, simply navigate from the Main Menu to the corresponding IRB Lookup as indicated below. Results will be displayed at the bottom of the page. If you wish to refine these results, enter further criteria in the Lookup fields and click the Search button.

All My Protocols

Navigation

Main Menu > IRB > IRB Lookups > All My Protocols

This lookup will generate a list of all the protocols you have ever submitted and any protocols where you are listed as personnel, regardless of the document status. 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.

All My Reviews

Navigation

Main Menu > IRB > IRB Lookups > All My Reviews

This lookup is useful to those who are regularly assigned to review IRB protocol documents. When you access this option, the system will automatically return a list of all the protocol documents currently assigned to you as a Reviewer.

All My Schedules

Navigation

Main Menu > IRB > IRB Lookups > All My Schedules

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.

Protocol Submissions

Navigation

Main Menu > IRB > IRB Lookups > Protocol Submissions

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

Pending Protocols

Navigation

Main Menu > IRB > IRB Lookups > Pending Protocols

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.

Protocols Pending PI Action

Navigation

Main Menu > IRB > IRB Lookups > Protocols Pending PI Action

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.

Protocols Pending Committee Action

Navigation

Main Menu > IRB > IRB Lookups > Protocols Pending Committee Action

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

Protocol Online Review

Navigation

Main Menu > IRB > IRB Lookups > Protocol Online Review

This IRB Administrator lookup allows the administrator to search and view a list of all assigned reviews in order to capture the review status and further manage the review process. The system will default to a review status of Saved but the status can be changed to display results of reviews in a Final status or a Cancelled status.

IRB Committee Schedules

Navigation

Main Menu > IRB > IRB Lookups > IRB Committee Schedules

This IRB Administrator lookup gives the administrator quick access to a list of the Committee schedules without having to access the schedule through the IRB Committee Document.

IV: For IRB Committee Members

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.

Section IV Contents

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

Completing IRB Committee Reviews

Based on our institution's specific Policies & Procedures, IRB Committee Members may be assigned to review and comment on assigned protocols, approve expedited protocols online, and/or attend scheduled committee meetings to approve protocols.

Some institutions, including ours, will assign a select number of IRB Members to review and comment on certain protocols prior to the committee meeting. To facilitate this function, Streamlyne Research makes a new Online Review tab available within these protocols for both reviewers and administrators. Once the IRB Administrator completes the Assign Reviewers action, the protocol becomes available to the selected committee Members. For IRB protocols that will not go on to a Full Board Committee Review, such as Exempt or Expedited protocols, this Online Review step is the point at which the committee members can render an official decision.

Completing an Assigned Online Review

A committee member should complete this process upon receiving a Review Assignment from the IRB Administrator. This required assignment will appear on the committee member's Action List as shown:

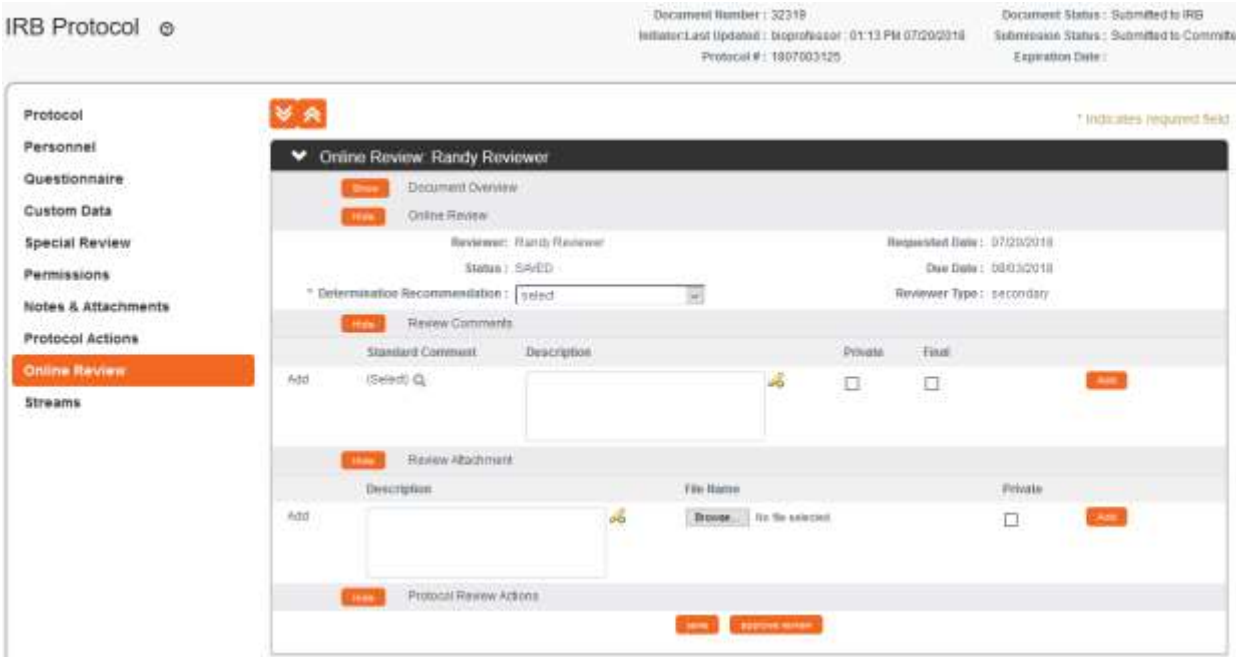



The screenshot shows a row in an Action List with a light blue background. On the left, there is a red pill-shaped icon with the text 'APP' and a mouse cursor pointing to the number '32329'. The main text of the row is 'IRB Protocol Review'. To the right of this text, there is a smaller text string 'IRB Protocol Review - Professor/Protocol# 1807003125'. Further right, the status 'ENROUTE' is displayed. On the far right, the time '01:43 PM' and the date '07/20/2018' are shown.

APP 32329	IRB Protocol Review	IRB Protocol Review - Professor/Protocol# 1807003125	ENROUTE	01:43 PM 07/20/2018
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1. From the Action List, access the item by clicking the hyperlinked Id.

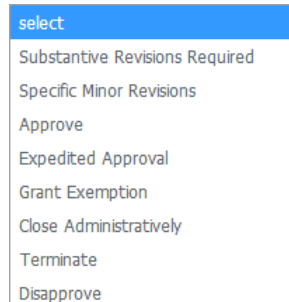
Result Streamlyne Research automatically opens to the Online Review tab.






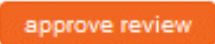
- To review the content of the protocol, click through the other tabs, sections, comments, and attachments. You may want to familiarize yourself with protocol documents and how a PI initiates and submits a new protocol, amendment, renewal or request by referencing the [FOR PRINCIPAL INVESTIGATORS](#)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



5. 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.
6. Click the Add button to register your comments. 

7. The Review Attachments subsection is optional.
If you chose to put your extended comments in an attachment, include this document by clicking the Browse button and following your operating system's uploading instructions.
8. Click the Add button to complete the attachment process. 
9. When you are ready to complete the review, click the Approve Review button. 

Result Streamlyne Research will generate an FYI Notification to the IRB Administrator to advise them that the Committee Member's Online Review is complete.

Viewing Previous Review Information

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.

Preparing for Committee Meetings

Once the IRB Administrator has sent an agenda, members of the committee will receive a notification indicating that meeting agenda has been created. They will be able to access both the PDF version of the agenda as well as an interactive Meeting page. It is on this Meeting page that they will be able to access the protocols that will be reviewed at the meeting. Only specifically-assigned reviewers will be able to make official review comments via the Online Review functionality.


1. Access the Agenda and Meeting page from your Action List or through the All My Meetings Lookup.
2. From the Action List click the Show button next to the FYI notification Agenda created for committee. 

Action	Id	Type	Title	Route Status	Delegator	Date Created	Group Request	Actions	Le
	32410	Streamlyne Research Notification	Agenda created for committee Full Board IRB Committee	FINAL		10:07 AM 07/23/2018		 NONE 	

id: 3487
From: irhadren
Recipients: boresearcher, medichair, researchaan, reviewer1, reviewer2
Channel: Notification Channel
Producer: Notification System
Type: FYI
Priority: Normal
Send Date: 2018-07-23T10:07:27.000-07:00
Removal Date: none

Title: Agenda created for committee Full Board IRB Committee
Content:
An Agenda has been created for committee Schedule meeting on 2018-08-03. Click [here](#) for a printable version of the agenda.



3. If you wish to view the Meeting page, click on the Schedule meeting on YYYY-MM-DD hyperlink. 

Otherwise skip to Step 7.

Result The Meeting page will open.

†

Protocol Submitted							
Protocol Submitted ⓘ							
Protocol No	PI	Protocol Title	Submission Type	Sub. Type Qualifier	Sub. Review Type	Submission Status	Submission Date
1	1807003125	Biochemistry Professor	Project for Documentation Involving Human Subjects	Resubmission	Full Board	In Agenda	07/20/2018

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

➤ Protocol Submitted

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

View

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.

6. Review any other pertinent information on the Meeting page to help prepare for the committee meeting.
7. If you wish to view the the PDF Agenda, click on the here hyperlink from the Action List page.

An Agenda has been created for committee Schedule meeting on 2018-08-03. Click [here](#) for a printable version of the agenda.

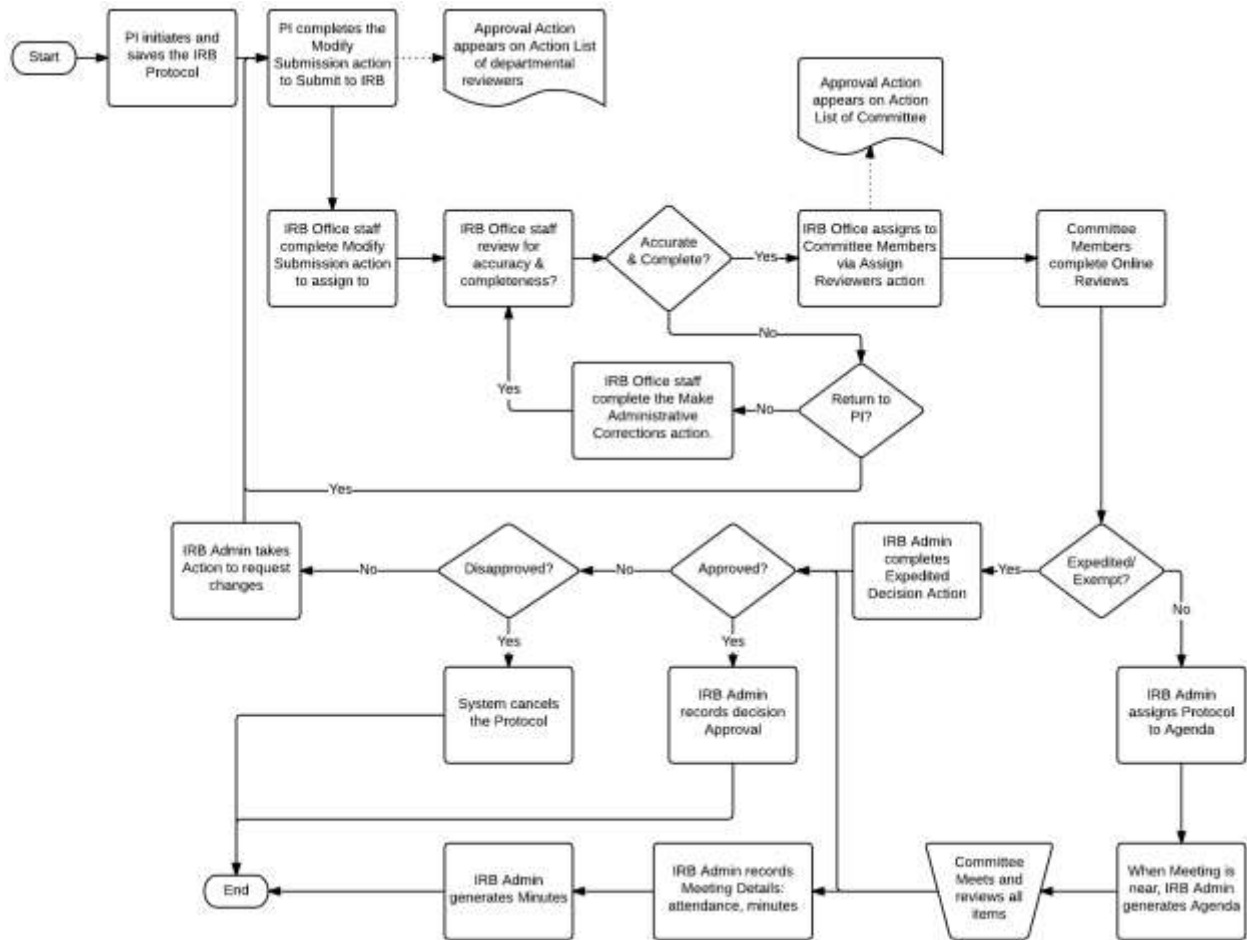
Note The Meeting page may be updated as preparations continue. A revised agenda can be sent as needed by the IRB Administrator. An additional FYI notification will be sent if this occurs.

Each Expedited and Full Board protocol has to be assigned to a meeting, so you will likely see monthly Committee Meetings even when the board is not meeting in person. If the location is indicated as “N/A”, you will know this is not a scheduled meeting, but just set up for Expedited Protocols.

Appendix A: IRB Roles and Permissions

Role	IRB Protocol & Committee Permissions
Protocol Viewer	Ability to view IRB protocols with read-only privileges
Protocol Creator	Ability to initiate IRB protocol documents
Protocol Aggregator	Ability to edit IRB protocol documents
Protocol Approver	Ability to receive workflow approval requests and render departmental/institutional approvals for IRB protocols
IRB Administrator	Ability to perform all administrative Actions related to IRB protocols and committees
Maintain IRB Questionnaire	Ability to create and make system-wide updates to the questions posed in the custom Questionnaires that are part of each IRB Protocol
IRB Approver	Ability to perform Online Reviews and record determinations

Appendix B: IRB Protocol Workflow Overview



Appendix C: All IRB Protocol Actions

Action	Role	Description	Prerequisites	Result
Abandon	Investigator	Used to cancel a protocol that has been returned for revisions by IRB Administrators or Reviewers, but the PI no longer intends to pursue the study.	Both Submission Status and Protocol Status must be one of the following: Specific Minor Revisions, Substantive Revisions Required.	Protocol Status is updated to Abandoned.
Approve Action	IRB Admin	Used to record approval of a protocol following full committee review. (See also: Record Committee Decision)	Record Committee Decision must be performed with Motion Type set to Approve. Submission Status must be In Agenda.	Protocol Status updates to Active-Open to Enrollment. Submission Status updates to Approved.
Assign Reviewers	IRB Admin	Used to select primary and secondary reviewer assignments from a system display of active IRB Committee Members.	Protocol Status must be Submitted to IRB. Submission Status must be Submitted to Committee or In Agenda. Action appears when protocol is assigned to a committee (for Designated Member review) or assigned to a committee and a schedule (for Full Board review).	Upon submission, the Protocol will appear in each reviewer's Action List.

Action	Role	Description	Prerequisites	Result
Assign to Agenda	IRB Admin	Used to assign a protocol to the agenda of a committee meeting for review. (See also: Modify Submission Request)	Protocol must be assigned to a committee and a schedule. Protocol Status must be Submitted to IRB. Submission Status must be Submitted to Committee.	No change other than the Protocol will appear on the IRB Agenda.
Close	IRB Admin	Used to indicate all protocol activities have been completed. (See also: Request to 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.	If an Investigator initiated the request, Protocol Status updates to Closed by Investigator. If an Investigator did not initiate the request, the Protocol Status updates to Closed Administratively. Submission Status updates to Closed.
Close Enrollment	IRB Admin	Used to indicate that no new human subjects will be enrolled for participation on an active protocol. (See also: Request to Close Enrollment)	Protocol Status must be Active-Open to Enrollment.	Protocol Status updates to be Active-Closed to Enrollment. Submission Status updates to Closed for Enrollment.

Action	Role	Description	Prerequisites	Result
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.
Create Renewal without Amendment	Investigator	Used to renew a protocol set to expire when no changes need to be incorporated.	Protocol Status must be one of the following: Active-Open to Enrollment, Active-Closed to Enrollment, Active-Data Analysis Only, Exempt, Expired, Closed Administratively (for lack of response), Closed by Investigator, Suspended by Investigator, Suspended by IRB.	Protocol Status updates to Renewal in Progress.

Action	Role	Description	Prerequisites	Result
Data Analysis Only	IRB Admin	Used to indicate the study has entered a phase where only data analysis is being conducted. Data collection and interaction with human subjects has ceased. (See also: Request for Data Analysis Only)	Protocol Status must be Active-Open to Enrollment or Active-Closed to Enrollment.	Protocol Status updates to Active-Data Analysis Only. Submission Status updates to Data Analysis Only.
Defer Action	IRB Admin	Used to indicate that the IRB Committee has chosen during its meeting to defer review of a protocol for want of more information.	Protocol Status may not be Final. Submission Status must be Submitted to Committee or In Agenda.	Submission Status updates to Deferred
Delete Protocol, Amendment or Renewal	Investigator	Used to delete a protocol, amendment, or renewal prior to submission, because the PI no longer intends to pursue the study.	Protocol Status must be one of the following: Pending/In Progress, Renewal In Progress, Amendment in Progress.	Protocol Status updates to Deleted. Protocol is marked as Inactive, and therefore will only appear in search results for Inactive documents.

Action	Role	Description	Prerequisites	Result
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.

Action	Role	Description	Prerequisites	Result
Grant Exemption	IRB Admin	Used to indicate that a submitted protocol has been determined to be exempt from IRB review.	Submission Review Type must be Exempt. Protocol Status must be Submitted to IRB. Submission Status must be Pending or Submitted to Committee.	Protocol Status updates to Exempt. Submission Status updates to Exemption Granted.
IRB Acknowledgement	IRB Admin	Used to formally acknowledge the receipt of an FYI submission from the Investigator. (See also: Notify IRB)	Submission Review Type must be FYI. Submission Status must be Submitted to Committee.	Submission Status updates to IRB Acknowledgement.
Make Administrative Correction	IRB Admin	Used sparingly to make minor administrative corrections to a submitted protocol.	Protocol Status can be anything except but Pending.	Streamlyne Research maintains an audit trail of all changes within the Action History section.
Manage Notes	Investigator and IRB Admin	Used to add and edit notes associated with a protocol. Administrators cannot edit Investigator notes, but Administrators can control visibility using the restricted checkbox.	None.	Notes are updated.

Action	Role	Description	Prerequisites	Result
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.
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.	Attachments are updated.
Modify Amendment Sections	Investigator	Used to modify specified sections for amendment when submitting an Amendment or Renewal with Amendments.	Protocol Status must be Amendment in Progress or Renewal in Progress.	Amendment sections are updated.
Modify Submission Request	IRB Admin	Used to confirm the Protocol Submission Review Type and assign a protocol to committee and schedule, making it eligible for review.	Protocol Status must be Submitted to IRB or Submission Status is Submitted to Committee.	Protocol is routed for review and approval according to the process defined for the Review Type.

Action	Role	Description	Prerequisites	Result
Notify Committee	IRB Admin	Used to list an expedited approval on a full board meeting schedule, usually after the Expedited Approval action is complete. (See also: Expedited Approval)	Submission Review Type must be Expedited. Protocol Status must be Submitted to IRB.	Expedited Approval listed on Full Board Meeting Schedule.
Notify IRB	Investigator	Used to inform the IRB of an event or change that may not require committee review.	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, Withdrawn, Suspended by DSMB, Expired, Disapproved, Terminated by IRB, Suspended by IRB, Suspended by DSMB.	Submission Status updates to Submitted to IRB or Pending.

Action	Role	Description	Prerequisites	Result
Record Committee Decision	IRB Admin	Used to record the decision of a full IRB committee review of a protocol, specifically: Approve, Disapprove, Specific Minor Revisions, or Substantive Revisions Required.	Protocol must have been assigned to an agenda. Submission Status must be In Agenda.	No change to statuses. Streamlyne Research records the number of yes/no votes, the names of members who recused themselves, and the names of members who abstained from voting in the Protocol's history.
Reopen for Enrollment	IRB Admin	Used to indicate that the enrollment of human subjects has reopened on a study after having been closed for a period of time. (See also: Request to Reopen Enrollment)	Protocol Status must be Active-Closed to Enrollment.	Protocol Status updates to Active-Open to Enrollment. Submission Status updates to Open to Enrollment.
Request for Data Analysis Only	Investigator	Used to notify the committee that the study has entered a phase where only data analysis is being conducted. Data collection and interaction with human subjects has ceased. (See also: Data Analysis Only)	Protocol Status must be Active-Open to Enrollment or Active-Closed to Enrollment.	Submission Status updates to Pending.

Action	Role	Description	Prerequisites	Result
Request for Suspension	Investigator	Used to request suspension of an active protocol, usually when researchers have identified new risks that require investigation before proceeding. (See also: Suspend)	Protocol Status must be in one of the following statuses: Active-Open to Enrollment, Active-Closed to Enrollment, Active-Data Analysis Only, Exempt.	Submission Status updates to Pending.
Request for Termination	Investigator	Used to request termination of protocol, usually when researchers have determined that it is no longer safe to continue. (See also: 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.	Submission Status updates to Pending.
Request to Close	Investigator	Used to request protocol closure when all activities pertaining to the study are complete. (See also: Close)	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.	Submission Status updates to Pending.

Action	Role	Description	Prerequisites	Result
Request to Close Enrollment	Investigator	Used to request that enrollment on a study be formally closed, as no new human subjects will be enrolled for participation on an active protocol. (See also: Close Enrollment)	Protocol Status must be Active-Open to Enrollment.	Submission Status updates to Pending.
Request to Reopen Enrollment	Investigator	Used to request that the enrollment of human subjects is reopened on a study after having been closed for a period of time. (See also: Reopen Enrollment)	Protocol Status must be Active-Closed to Enrollment.	Submission Status updates to Pending.
Response Approval	IRB Admin	Used to approve a protocol resubmission.	Submission Review Type must be Response.	Protocol Status updates to Active-Open to Enrollment.

Action	Role	Description	Prerequisites	Result
Return for Specific Minor Revisions	IRB Admin	<p>Used to indicate a committee decision where the investigator needs to make changes to a protocol before the committee will approve the study.</p> <p>Action is performed based committee’s evaluation that the study poses minimal risk, and that requested changes are specific and minor.</p>	<p>The Record Committee Action must be completed with a Motion Type of Specific Minor Revisions.</p> <p>Protocol Status must be Submitted to IRB.</p> <p>Submission Status must be In Agenda.</p>	<p>Protocol Status updates to Specific Minor Revisions Required.</p> <p>Submission Status updates to Specific Minor Revisions Requested.</p>
Return for Substantive Revisions Required	IRB Admin	<p>Used to indicate a full board decision requiring the PI to make significant changes to a protocol before the committee will approve the study, usually due to the committee’s assessment of a “greater than minimal” risk.</p>	<p>The Record Committee Action must be completed with a Motion Type of Substantive Revisions Required.</p> <p>Protocol Status must be Submitted to IRB.</p> <p>Submission Status must be In Agenda.</p>	<p>Protocol Status updates to Substantive Revisions Required.</p>

Action	Role	Description	Prerequisites	Result
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 Committee and Schedule Actions must be completed. Protocol Status must be Submitted to IRB.	Protocol Status updates to Return to PI. Submission Status updates to Returned to PI.
Review Comments	Reviewer	Used to enter comments during an Assigned Review.	The Assign to Reviewers actions must be completed.	Comments are updated.
Review Not Required	IRB Admin	Used when reviewers determine that the nature of study does not actually qualify as human subject research, and therefore review by the committee is not necessary.	The Assign to Committee and Schedule actions must be completed. Protocol Status must be Submitted to IRB.	Protocol Status updates to IRB Review Not Required. Submission Status updates to IRB Review Not Required.

Action	Role	Description	Prerequisites	Result
Submit for Review	Investigator	Used to submit a protocol, amendment, or renewal to the IRB for review.	Protocol status must be In Progress, Specific Minor Revision Required, Substantive Revision Required, Amendment In Progress, Renewal In Progress, Deferred, or Withdrawn.	Protocol Status updates to Submitted to IRB. Submission Status updates to Pending.
Suspend	IRB Admin	Used to suspend an active protocol, usually at the behest of researchers that have identified new risks that require investigation before proceeding. (See also: Request for Suspension)	Protocol Status must be in one of the following: Active-Open to Enrollment, Active-Closed to Enrollment, Active-Data Analysis Only, Exempt.	Protocol Status updates to Suspended by Investigator when the suspension is executed in response to a request action, or Suspended by IRB when no such request is present. Submission Status updates to Suspended.
Suspend by DSMB	IRB Admin	Used to suspend an active protocol, usually at the behest of the Data Safety Monitoring Board (DSMB).	Protocol Status must be in one of the following: Active-Open to Enrollment, Active-Closed to Enrollment, Active-Data Analysis Only, Exempt.	Protocol Status updates to Suspended by DSMB.

Action	Role	Description	Prerequisites	Result
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, Withdrawn, Amendment Approval, Renewal Approval, Administrative Correction.	Protocol Status and Submission Status revert to previous states.
Withdraw Protocol	IRB Admin	Used to withdraw a protocol from consideration by the IRB.	Protocol Status must be Submitted to IRB. Submission Status must be Submitted to Committee or Pending.	Protocol Status and Submission Status update to Withdrawn.

Action	Role	Description	Prerequisites	Result
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.

