



IRB Protocol Module
For Researchers

Table of Contents

I: For a General Audience	1
Overview of the IRB Protocol & Committee Modules.....	1
Section I Contents.....	1
Using This Guide	1
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
II: For Investigators and Other Protocol Preparers	6
Section II Contents.....	6
Initiating & Submitting a New Protocol	8
Initiating a New IRB Protocol.....	8
Updating the Protocol Tab	10
Updating the Personnel Tab.....	18
Updating the Questionnaire Tab.....	22
Updating the Custom Data Tab.....	23
Updating the Special Review Tab	23
Updating the Permissions Tab	25
Adding Notes & Attachments	26
Validating and Submitting a Protocol.....	29
Understanding Available Actions after Initial Submission	32
Recalling a Protocol	32
Withdrawing a Protocol.....	34
Deleting a Protocol.....	34
Editing a Returned Protocol	36
Accessing a Protocol Returned Before Committee Review	36
Accessing a Protocol Formally Returned for Revisions	36
Reviewing Reasons for the Return	38

Resubmitting the Protocol	39
Understanding Streamlyne Amendments & Renewals	41
Starting from a Copy.....	41
Differences in Naming Convention	41
Merging Amendments and Renewals	41
Using the Summary & History Section	42
Creating & Submitting an Amendment	43
Creating & Submitting a Renewal	46
Creating & Submitting a Renewal with Amendment	48
Communicating with the IRB	52
Notifying the IRB	52
Requesting to Close a Protocol	54
Requesting to Suspend a Protocol.....	55
Requesting to Close Enrollment on a Protocol.....	57
Requesting to Re-Open Enrollment on a Protocol	59
Requesting to Identify a Protocol in a Data Analysis Only Phase	60
Requesting to Terminate a Protocol.....	62
Appendix A: IRB Roles and Permissions.....	65
Appendix B: IRB Protocol Workflow Overview	66
Appendix C: All IRB Protocol Actions	67

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.....	1
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

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.

II: For Investigators and Other Protocol Preparers

The second section provides a step-by-step guide to prepare, submit, and follow up on an IRB Protocol in Streamlyne Research.

Section II Contents

Initiating & Submitting a New Protocol.....	8
Initiating a New IRB Protocol.....	8
Updating the Protocol Tab	10
Updating the Personnel Tab.....	18
Updating the Questionnaire Tab.....	22
Updating the Custom Data Tab.....	23
Updating the Special Review Tab	23
Updating the Permissions Tab	25
Adding Notes & Attachments	26
Validating and Submitting a Protocol.....	29
Understanding Available Actions after Initial Submission	32
Recalling a Protocol	32
Withdrawing a Protocol.....	34
Deleting a Protocol	34
Editing a Returned Protocol	36
Accessing a Protocol Returned Before Committee Review	36
Accessing a Protocol Formally Returned for Revisions	36
Reviewing Reasons for the Return.....	38
Resubmitting the Protocol.....	39
Understanding Streamlyne Amendments & Renewals	41
Starting from a Copy	41
Differences in Naming Convention	41
Merging Amendments and Renewals	41
Using the Summary & History Section	42
Creating & Submitting an Amendment.....	43
Creating & Submitting a Renewal	46
Creating & Submitting a Renewal with Amendment	48
Communicating with the IRB	52
Notifying the IRB.....	52
Requesting to Close a Protocol.....	54
Requesting to Suspend a Protocol.....	55
Requesting to Close Enrollment on a Protocol.....	57

Requesting to Re-Open Enrollment on a Protocol.....	59
Requesting to Identify a Protocol in a Data Analysis Only Phase.....	60
Requesting to Terminate a Protocol.....	62

Initiating & Submitting a New Protocol

This section will describe the steps to initiate and submit a new IRB Protocol document in Streamlyne Research. Principal Investigators, other researchers or their support staff typically initiate and submit these documents. If you will be initiating or submitting IRB protocols, use this section to begin using the IRB module productively.

If your role does not require you to initiate or submit IRB protocols, use this section to familiarize yourself with the entire process in order to effectively edit, review, approve or administer documents as they are routed to you.

For a flowchart of the standard lifecycle of a protocol, see [Appendix B: IRB Protocol Workflow Overview](#).

Initiating a New IRB Protocol

If your goal is to quickly initiate and save a protocol for later editing, be sure to have the following information available, as these 5 fields must be completed for the document to save without validation errors:

Tab	Section	Field Name	Description	Instructions
Protocol	Document Overview	Description	A short description of the protocol's key details The data entered here returns in search results.	Enter freeform text.
Protocol	Required Fields for Saving	Protocol Type	Differentiates the type of protocol. Defaults to Standard.	Select from dropdown (e.g., Full Board, Exempt, Expedited).

Tab	Section	Field Name	Description	Instructions
Protocol	Required Fields for Saving	Principal Investigator (Internal User Name Search)	Person ID of the investigator leading the effort recorded in the IRB protocol.	Use the magnifying glass to look up and select return value of the appropriate ID.
Protocol	Required Fields for Saving	or Principal Investigator (External Address Book Search)	Address Book ID of the non-employee investigator leading the effort recorded in the IRB protocol.	Note: Validation rules require that one of these fields must be populated, but not both.
Protocol	Required Fields for Saving	Title	Full project title	Enter freeform text.
Protocol	Required Fields for Saving	Lead Unit	Unit ID of the department leading the project.	<p>If the PI is an employee, the Lead Unit field automatically populates with their assigned Unit ID.</p> <p>If this is not the correct value, or if the PI not an employee, click the magnifying glass to look up and select return value of the appropriate Unit ID.</p>

Navigation

Main Menu > IRB > IRB Actions > IRB Protocol > +

To quickly initiate and save a Protocol, follow these steps:

1. Initiate a new document by following the navigation path here, as above:
Main Menu > IRB > IRB Protocol > +
2. Complete the Minimum Required Fields for Saving detailed in the preceding table.
3. Click the Save button. 

Result A protocol number is automatically assigned.

Note Once the document is saved, it will remain on your Action List as a pending item with a COM symbol, prompting you to complete the document at your convenience.

The protocol will remain on your Action List as a COM pending item until you submit it, delete it, or withdraw it.

Access the IRB Protocol again by clicking on the corresponding Id hyperlink next the COM item on your Action List.

Updating the Protocol Tab

If you have just initiated and saved a new protocol, simply continue updates in the open Protocol tab.

Otherwise, initiate a new document by navigating as follows:

Navigation

Main Menu > IRB > IRB Actions > IRB Protocol > +

Protocol Tab > Required Fields for Saving Document

1. The **Protocol Type** is used to designate the level of IRB review required. The types as well as the default value are configurable by your institution.

Click the arrow next to the **Protocol Type** field, and then select the appropriate option from the dropdown list.

2. Look up the internal or external user serving as **Principal Investigator** by clicking the magnifying glass  to search for and select return value of the desired record.

3. Enter a descriptive title for the project in the **Title** field.

4. The **Lead Unit** defaults to the unit assigned to the Principal Investigator.

If this is not the correct department for the project, enter the Unit Number into the **Lead Unit** field. If necessary, use the dropdown to select the correct value. Only Units associated with the PI and/or the protocol Initiator will be offered.

select
105020 - Medicine
105021 - Cardiology
105022 - Hematology & Medical Oncology

5. Click the Save button. 

Result Streamlyne Research will generate a Protocol Number that will display in both the Document Header and the Status & Dates section. The protocol number is ten digits in length. The first two digits represent the year of the creation date, the next two digits represent the month of the creation date, and the remaining six digits are assigned sequentially, as follows: YYMM123456.

The Initiator and Last Updated timestamp will be updated in the Document Header as well:

Document Number : 32277	Document Status : Pending/In Progress
Initiator: Last Updated : irbadmin : 01:30 PM 07/06/2018	Submission Status :
Protocol # : 1807002998	Expiration Date :

Protocol Tab > Statuses & Dates

▼
Status & Dates

Status & Dates
?

Protocol # : 1807002998	Protocol Status : Pending/In Progress
Approval Date : Generated on Approval	Last Approval Date : Generated on Renewal Approval
Initial Submission Date : Generated on Initial Submission	Expiration Date : Generated on Approval

This section contains read-only data recording milestones in the lifecycle of the protocol along with routinely referenced information such as Protocol # and Protocol Status.

To view this information, click the header to review the Status & Dates section.

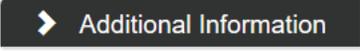


Protocol Tab > Additional Information > Areas of Research

Area of Research
?

	Code/Description	Actions
add:	(select) 🔍	
1	000001:All Research Areas	<div style="background-color: #e67e22; color: white; padding: 2px 5px; border-radius: 3px; display: inline-block;">Delete</div>

1. Click on the header to expand the Additional Information section.



- The Areas of Research automatically populates with 00001: All Research Areas.

Your institution may use this data to assign protocols to Committees or their individual Members based on Areas of Research, to report on protocols submitted by Areas of Research, or both.

If your institution has elected to use this feature, click the magnifying glass  to search for and select appropriate area in the Research Areas Lookup.

Otherwise, skip to the next section.

Research Areas Lookup

* required field

Research Area Code:

Has Children Flag: Yes No Both

Active: Yes No Both

Parent Research Area Code:

Code/Description:

- Use the available fields to enter search criteria, then click the Search button.

1855 items found. 200 items retrieved. Please refine your search criteria to narrow down your search.

Currently viewing page 1 of 2 (rows 1 to 100).

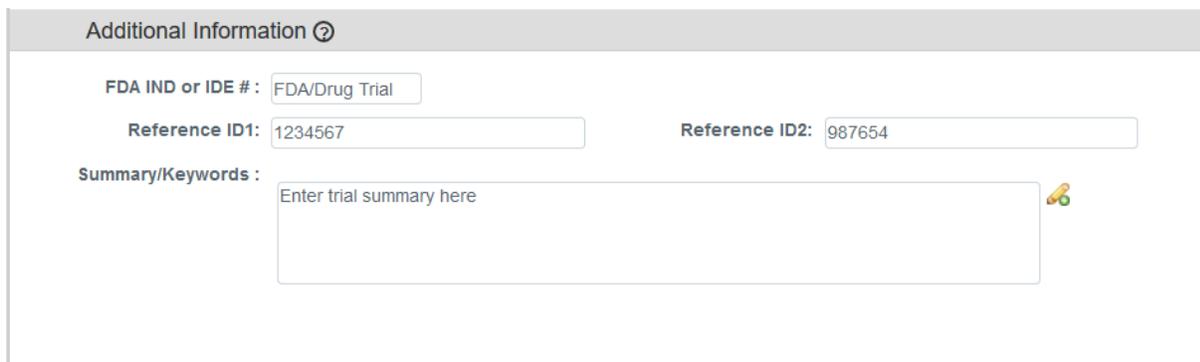
Go to page: 1

Select?	Research Area Code	Parent Research Area Code	Has Children Flag	Code/Description	Active
<input type="checkbox"/>	000001	000000	Yes	All Research Areas	Yes
<input type="checkbox"/>	01.	000001	Yes	AGRICULTURE, AGRICULTURE OPERATIONS, AND RELATED SCIENCES	Yes
<input type="checkbox"/>	01.0000	01.	Yes	Agriculture, General	Yes
<input type="checkbox"/>	01.01	01.	Yes	Agricultural Business and Management	Yes
<input type="checkbox"/>	01.01.01	01.0000	No	under agriculture	Yes
<input type="checkbox"/>	01.0101	01.01	No	Agricultural Business and Management, General	Yes
<input checked="" type="checkbox"/>	01.0102	01.01	No	AgribusinessAgricultural Business Operations	Yes
<input type="checkbox"/>	01.0103	01.01	No	Agricultural Economics	Yes
<input type="checkbox"/>	01.0104	01.01	No	FarmFarm and Ranch Management	Yes
<input type="checkbox"/>	01.0105	01.01	No	AgriculturalFarm Supplies Retailing and Wholesaling	Yes
<input checked="" type="checkbox"/>	01.0106	01.01	No	Agricultural Business Technology	Yes
<input type="checkbox"/>	01.0199	01.01	No	Agricultural Business and Management, Other	Yes

- From the Lookup window, click the checkboxes next to one or more applicable Research Area Codes/Descriptions, and then click the Return selected results button.

5. If you added any Research Area Codes in error, click the Delete button next to the extraneous row(s) to remove them. 

Protocol Tab > Additional Information > Additional Information Subsection



The panel above is used to track identifiers related to the work performed on the project, such as FDA Investigational New Drug number, or Investigational Device number. The fields labelled **Reference ID1** and **Reference ID2** can be configured by your institution to capture any other identifier you wish (e.g., such as ClinicalTrials.gov # or iEdison #). These identifiers will not apply to every protocol.

1. If this research effort involves an FDA Investigational New Drug, or Investigational Device, enter the numeric identifier in the **FDA IND or IDE #** field.
Otherwise, skip to the next process.
2. Enter the trial reference number(s) in one or both of the **Reference ID** fields.
3. Enter any additional information related to the **FDA #s** or **Reference IDs** in the **Summary/Keywords** field.

Protocol Tab > Additional Information > Other Identifiers

The Other Identifiers subsection is specifically intended to capture alternate protocol numbers for this project. If this project has a protocol number with an external IRB or an external research network, capture the entity, the identifier, and associated dates in this section. This will not apply to every protocol.

The values in the dropdown list are determined by your institution during your implementation.

Other Identifiers ?				
* Type	* Other Identifier	Application Date	Approval Date	Actions
add: <input type="text" value="select"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="button" value="Add"/>
Comment:		<input type="text"/>		

- If this project is associated with an external research network or external IRB, click the arrow next to the **Type** field and select the corresponding acronym from the dropdown list. Some examples of common networks that IRBs can work with are:

 - Cancer and Leukemia Group B (CALGB)
 - Radiation Therapy Oncology Group (RTOG)
 - Online IRB Administration sites (IRBNet)
 - Clarification of Optimal Anticoagulation Through Genetics research network (COAG)
- Enter the identifying number assigned by the external organization in the **Other Identifier** field.
- Populate the **Application Date** and/or the **Approval Date** in MM/DD/YYYY format or click the calendar icon to select the date.
- Enter any supplemental or descriptive information in the **Comments** field.
- Click the Add button to add the entry to the protocol.

- select
- CALGB
- RTOG
- IRBNet
- COAG

Protocol Tab > Organizations

The Organizations section allows you to indicate which, if any, outside institutions may be performing some aspect of the study activities. Organizations that are configured in the system have identified contacts, called IRB Correspondents, who may be listed on the Personnel Tab and are eligible to receive autogenerated, email correspondence as the protocol moves through its lifecycle.

Organization profiles are configured and maintained from

Main Menu > Settings> Organizations.

Access to create, update, or inactivate Organization profiles is governed by a role assigned to the user's Person record.

* Organization Id	* Organization Type	Contact	Human Sub Assurance	Actions
Add: <input type="text"/> <input type="text" value="select"/> <input type="button" value="Add"/>				
1 000001 Streamlyne Institution	Performing Organization	Director, GCO: 2020 Camino del Rio N., Suite 700 , San Diego, CA 92108-1545 <input type="button" value="Clear organization address"/>	FWA00000045	<input type="button" value="Delete Organization"/>

1. If other organizations are collaborating on this research, click on the header to expand the Organizations section.

Otherwise, skip to the next process.

2. Enter the **Organization ID** or click the magnifying glass to search for and select return value of the corresponding organization.

3. Click the arrow next to the **Organization Type** field to identify this organization as the organization performing the research, an external organization, or the single IRB of Record (sIRB).

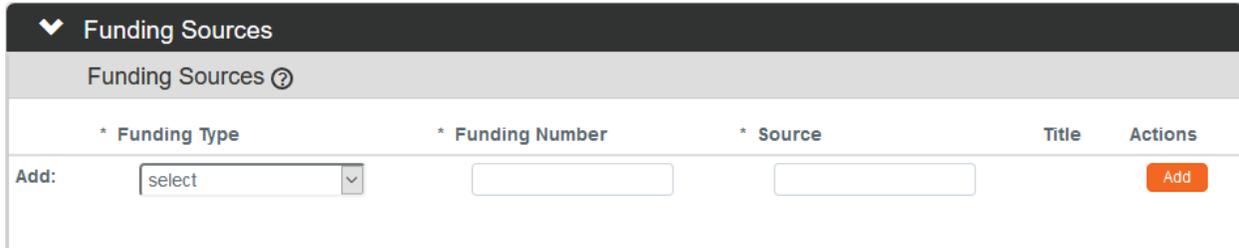
- select
- External
- IRB of Record (sIRB)
- Performing Organization

4. Click the Add button to complete the action.

5. Repeat Steps 2 through 4 until all collaborating institutions are included on the protocol document.

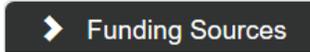
Protocol Tab > Funding Sources

The Funding Sources section internally links the protocol to one or more proposals, awards, or departments within Streamlyne Research.

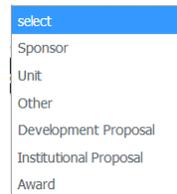


* Funding Type	* Funding Number	* Source	Title	Actions
Add: <input type="text" value="select"/>	<input type="text"/>	<input type="text"/>		<input type="button" value="Add"/>

1. Click on the header to expand the Funding Sources section.



2. Click the arrow next to the **Funding Type** field to select the source from the dropdown list.



Note If your institution is using the Streamlyne Research Pre-Award and/or Post-Award suites, the **Funding Number** field dynamically integrates to these modules greatly facilitating congruency checks.

If you selected a Funding Type of Development Proposal, Institutional Proposal, or Award, Streamlyne Research will prompt you to link the specific document to the Protocol using the magnifying glass next to the **Funding Number** field to search for and select the desired value.

If your funding is coming directly from a Sponsor or a Department/Unit within your institution, Streamlyne Research will prompt you to identify the Sponsor or Unit instead of a Funding Number.

Entering this information will also display the Proposal, Institutional Proposal, and/or Award on the Streams page for easy access between different administrators who need to view the linked documents (if permissions allow).

3. Enter a **Funding Number** or click the magnifying glass  to search for and select the corresponding return value.
4. Click the Add button to complete this action.

- Repeat Steps 2 through 4 until all Funding Sources are identified.

Protocol Tab > Participant Types

In the Participant Types section, the types of participants and number involved can be tracked.

Participant Types		
Participant Types ?		
* Type	* Count	Actions
Add: <input type="text" value="select"/>	<input type="text"/>	<input type="button" value="Add"/>
1 Students	<input type="text" value="250"/>	<input type="button" value="Delete"/>
Total Participants:		250

- Click on the header to expand the Participant Types section.
- Click the arrow next to the **Type** field to select the best participant descriptor from the dropdown list.

Participant Types

- select
- Children
- Other
- Decisionally impaired
- Employees
- Prisoners
- Pregnant women
- Fetuses
- Adults (18yr +)
- Wards of the state

- Enter a projected number of participants for this participant group into the **Count** field.
- Click the Add button to complete this action.
- Repeat Steps 3 and 4 until all Participant Types and counts are identified for the protocol.

Total Participants will update as participant types are added.

Updating the Personnel Tab

- If your institution's process requires you to identify project personnel in addition to the Principal Investigator, click on the tab header to access the Personnel tab.

Personnel

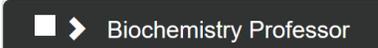
- Click the radio button next to either **Internal User Name** or **External Address Book ID**. You may enter the username for the person you would like to add (typically the first part of their institutional email address) and click the magnifying glass.

You can also search for a person by clicking the magnifying glass  to look up the **Internal User Name** or **External Address Book ID**.

- Click the arrow next to the **Protocol Role** field to select the team member's role from the dropdown list.

- Click the Add button to complete this action. 

Result A new section will be created for each person with subsections for Person Details, Contact Information, Attachments and Unit Details.

- Click the section header to expand the user section. 

- Click the Show button to expand the Person Details subsection. 

▼ **Biochemistry Professor** Principal Investigator
 Biochemistry Professor ⓘ
Hide Person Details

Protocol Role : Update View
 Affiliation Type :
 Trained : No

7. Click the arrow next to the **Protocol Role** field to edit if necessary.

8. Click the arrow next to the **Affiliation Type** field to select the appropriate affiliation from the list.

Affiliate
 Faculty
 Supervisor
 Non-Faculty
 Student Investigator

9. Click the Show button to expand the Contact Information. Show

Hide Contact Information

Full Name : Biochemistry Professor	User Name : bioprofessor
Email Address : <input type="text" value="ekualitiuser@gmail.com"/>	Office Phone : <input type="text" value="102-456-1079"/>
Primary Title : <input type="text" value="Biochemistry Professor"/>	Directory Title : <input type="text" value="Biochemistry Professor"/>
Home Unit : 105010	School : Medicine University
NSF ID :	CITI User Name :
eRA Commons User <input type="text"/>	Fax : <input type="text" value="102-456-2079"/>
Name :	Mobile : <input type="text"/>
Pager : <input type="text"/>	Secondary Office
Office Location : <input type="text" value="Suite 779"/>	Location :
Address Line 1 : <input type="text" value="2020 Camino del Rio N."/>	Address Line 2 : <input type="text" value="Suite 779"/>
Address Line 3 : <input type="text"/>	City : <input type="text" value="San Diego"/>
County : <input type="text" value="San Diego"/>	State : <input type="text" value="CALIFORNIA"/>
Postal Code : <input type="text" value="92108-1545"/>	Country : <input type="text" value="United States"/>

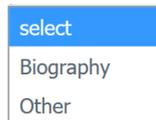
10. Update defaulted contact information if necessary.

11. If you need to attach personnel-specific documents, click the Show button to expand the Attachments subsection. Show

Hide Attachments

Update Timestamp	Updated By	* Attachment Type	* Description	* File Name	Actions
Add:		<input type="text" value="select"/>	<input type="text"/>	<input type="text" value="Browse..."/> No file selected.	Add

12. Click the arrow next to the **Attachment Type** field to select the appropriate attachment type from the list. Your institution may configure the selections in the dropdown.



select
Biography
Other

13. Enter a description for the attachment in the **Description** field.
14. Click the Browse button to access files on your computer. Follow your operating system's prompts.
15. Click the Add button to add the Attachment. 
16. Click the Show button to expand the Unit Details subsection. 



	Unit Name	* Unit Number	* Lead	Actions
Add:	(select) 	<input type="text"/>	<input type="checkbox"/>	
1	Biochemistry	105010	<input checked="" type="radio"/>	

17. Click the magnifying glass  to search for an additional Unit or enter the unit number in the **Unit Number** field if you know it. Adding additional units is rarely necessary.
18. Click the **Lead** box to indicate if this Unit is the lead unit for this investigator.
19. Click the Add button to add the Unit. 
20. You can click the Delete button to remove a Unit if entered in error. 
21. Repeat these steps until all personnel are identified and the appropriate information is added.

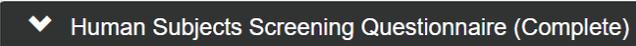
Note



If you find that you have added a team member in error, simply click the checkbox on the section header, and then click the Delete Selected button at the bottom of the page.

Updating the Questionnaire Tab

The Questionnaire functionality in Streamlyne Research allows your institution to interview Principal Investigators and collect additional required information at the time of submission. This feature is very customizable and your institution has configured questions to match internal processes. The content within this function is, thus, unique to each institution. The particular questions presented to the user are also dependent on the Protocol Type selected in the Protocol tab. The sample screenshots below will familiarize you with the purpose and function of the Questionnaire tab but will not match your institution's application. Please consult with your local IRB administrator for details.

1. Click on the tab header to access the Questionnaire tab. 
 2. Click on the section header to expand the Questionnaire section. (The section header will vary depending on the required Questionnaire(s).) 
 3. Read each item carefully and provide a response. Enter detailed descriptions or explanations where prompted. You may be directed to upload an attachment. Additional instructions on doing so can be found in the [Adding Notes & Attachments](#) section. Yes No
- Note** New questions may appear based on your answers.
4. Click the More Information button to the right of each question to review any Explanation, Policy or Regulation references where pertinent. 
 5. Click the Save button at any time to save your work. 
 6. The Questionnaire status will change to Complete once all questions are answered. 

If the questionnaire is required, you will not be able to submit your protocol until all questions are answered and the Complete status displays.

Updating the Custom Data Tab

As the name implies this section contains customized fields tailored to your institution.

If applicable, click the header to reveal the Custom Data section.

Complete any fields required by your institution. An asterisk (*) preceding a field label indicates the data element is required.

An orange rectangular button with the text "Custom Data" in white.

Updating the Special Review Tab

The Special Review functionality is designed to record other reviews or administrative efforts linked to your IRB protocol in such instances as:

- Data sharing between projects that are tracked on separate IRB protocol documents.
- Project-related animal research protocols that are tracked on IACUC protocol documents.
- Technology/data protections for your project that are recorded on Intellectual Property Review documents.
- Biosafety and/or Environmental Health & Safety reviews
- Research-related facilities requests or clearances for your projects, such as space requests, lab transfers or material handling requests.

Note If you add an IRB or IACUC protocol that is also maintained in Streamlyne Research, these protocols will also show up in Streams for easy access between different users and administrators, per their permissions.

All Special Review Types are determined by your institution.

Your institution may also elect to configure Streamlyne to automatically notify people or groups of Special Reviews when the protocol is submitted.

1. Click on the tab header to access the Special Review tab.

An orange rectangular button with the text "Special Review" in white.

2. Click the arrow next to the Special Review **Type** field to choose from the dropdown list configured for your institution.

- Human Subjects
- Animal Usage
- Recombinant DNA
- Radioactive Isotopes
- Biohazard Materials
- International Programs
- Space Change
- Tech Licensing: No conflict (A)
- Tech Licensing: Reviewed, no conflict (B1)
- Tech Licensing: Potential Conflict (B2)
- Tech Licensing: Previously Reviewed
- Foundation Relations
- Export Control
- Biosafety

3. When your institution uses Streamlyne Research for IRB or IACUC protocols, the **Approval Status** field will auto-populate based on the protocol Status of the document whose Protocol Number you will identify in Step 4. Continue to the next step.

Otherwise, click on the arrow next to the **Approval Status** field to select the appropriate Approval Status from the dropdown list.

4. When your institution uses Streamlyne Research for IRB or IACUC protocols, click the magnifying glass  next to the **Protocol Number** field to look up this value.

Otherwise, enter your institution's custom document tracking number in the **Protocol Number** field.

5. Enter the **Application Date**, **Approval Date**, and **Expiration Date** of your linked project, if known. Type these values in MM/DD/YYYY format or click the calendar icon  to select the date.

6. If you have linked to an IRB protocol, and the human subjects research falls under one of the eight categories of Exempt Research per the Common Rule (45 CFR 46.101(b)), identify the **Exemption #** by clicking the arrows next to the field and selecting the correct number from the list.

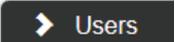
- Click the Add button to complete this action. 
- Repeat Steps 2 through 7 until all related reviews are recorded.

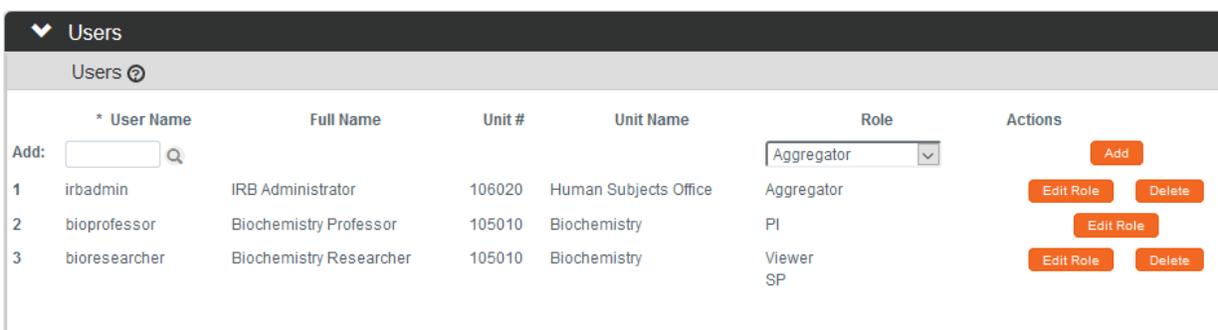
Note Only fields marked with an asterisk (*) are required.

Updating the Permissions Tab

The Permissions tab contains read-only user role and project role data for the personnel identified in the previous sections. For example, the protocol's default Aggregators (or editors) will be identified as the Principal Investigator and the Initiator (if different from the PI).

An Initiator or IRB Administrator can also grant access to ad hoc users who might not normally have access to protocol documents. This is especially useful to a researcher who would like to turn over Aggregating (editing) Rights to a coworker in an administrative support role. This feature is also commonly used to grant ad hoc Viewer Rights to users who do not normally have access to protocols.

- Click on the tab header to access the Permissions section. 
- Scroll down to the Users section. If it is not already expanded, click on the header to expand the section. 



	* User Name	Full Name	Unit #	Unit Name	Role	Actions
Add:	<input type="text"/>				Aggregator	<input type="button" value="Add"/>
1	irbadmin	IRB Administrator	106020	Human Subjects Office	Aggregator	<input type="button" value="Edit Role"/> <input type="button" value="Delete"/>
2	bioprofessor	Biochemistry Professor	105010	Biochemistry	PI	<input type="button" value="Edit Role"/>
3	bioresearcher	Biochemistry Researcher	105010	Biochemistry	Viewer SP	<input type="button" value="Edit Role"/> <input type="button" value="Delete"/>

- If you need to add an ad hoc user, click the magnifying glass  next to the **User Name** field to search for and select the correct value.

4. Click the arrow next to the **Role** field to select a permissions level for the ad hoc user.



5. Click the Add button to complete the action.



6. Repeat Steps 3 through 5 until all ad hoc users are added to the protocol.

7. If you need to remove a user, click the Delete button.

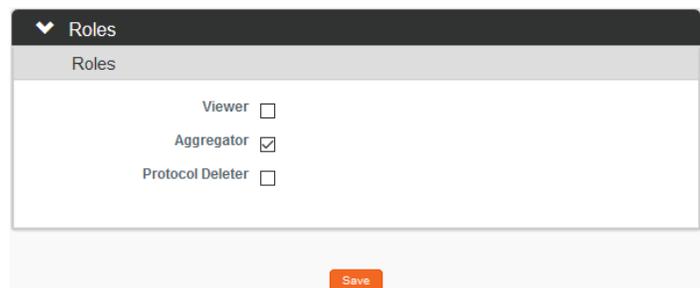


8. If you need to change the nature of a user's access to the protocol, click the Edit Role button next to the user's name.



Otherwise, skip to the next section.

9. Streamlyne Research will display a pop-up window listing the three permissions levels for a protocol.



Indicate whether the user should have permissions to view the document, to

aggregate (edit) document data, or to delete the document by clicking the corresponding checkbox.

Alternatively, you also have the option to remove defaulted or previously granted permissions by unchecking the corresponding boxes.

10. Click the Save button to commit your changes.



Note The functionality of this section becomes more limited once the protocol is submitted into workflow. After submitting a document, the system limits Permissions changes to the addition of users with view-only privileges.

Adding Notes & Attachments

The Notes & Attachments section provides a place to track supporting content collected during the life of the protocol document.

1. Click on the tab header to access the Notes & Attachments section.

Notes & Attachments

2. To upload an attachment, click on the Protocol Attachments header to expand the section.

Protocol Attachments (1)

To add a Note only, skip to Step 11.

3. Click the arrow next to the **Attachment Type** field to select an appropriate option from the dropdown.

- select
- Adverse Event
- Advertisement
- Children's Assent Form
- HIPAA Research Authorization Form
- HIPAA Waiver of Research Authorization Form
- Informed Consent Document
- Investigator Brochure
- Other
- Protocol Narrative
- Recruitment Brochure

4. Click the arrow next to the **Status** field to select the current status of the Attachment.

- select
- Complete
- Incomplete

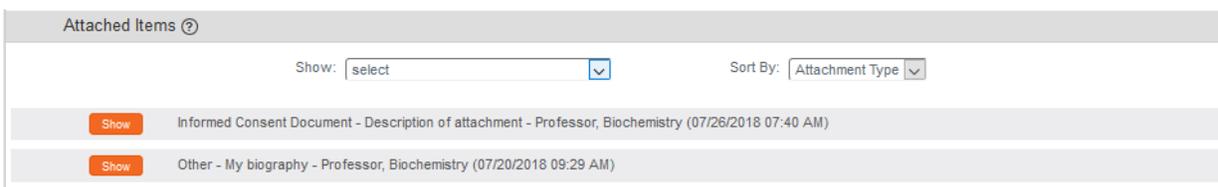
5. Enter freeform text in the **Description** field to describe the attachment if necessary.

6. Enter information in the remaining **Email, Contact Name, Phone** and **Comments** fields if needed.

7. Click the **Browse** button to access your operating system's Choose File or File Upload dialog box. Complete this action by following your operating system's prompts.

8. Click the add button. 
9. Repeat Steps 3 through 8 until all attachments are added to the protocol.

Result The system compiles a list of attachments in the Attached Items subsection.



10. If you wish to view or update an attachment, click the Show button. 

You may then change the Status or edit the Description. You may also View, Replace, or Delete the attached file.   

Note The **Show** and **Sort By** fields can be used to filter or organize a long list of Attachments.

11. To enter a Note, click on the Notes header to expand the section. 



12. In the **Note Topic** field enter a short description of what the note is about.
13. In the **Note Text** field enter or paste a complete note.
14. Click the **Restricted** checkbox if the Note should be restricted from users with View Only privileges.
15. Click the Add button to add the Note to the database. 
16. Repeat Steps 11 through 15 until all Notes are added.

Validating and Submitting a Protocol

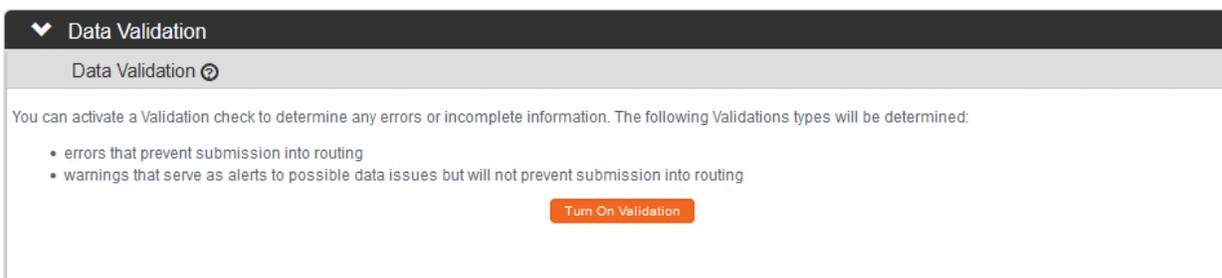
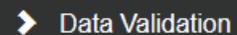
When a new protocol is complete, the Request an Action options available on the Protocol Actions tab include submitting the protocol for review or deleting the protocol. Data Validation is also available. These processes are defined in this section. A complete list of all available protocol actions is available in [Appendix C: All IRB Protocol Actions](#).

Validating the Protocol

1. Click the tab header to access the Protocol Actions tab.



2. Click the header to access the Data Validation section.



▼ Data Validation

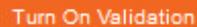
Data Validation ⓘ

You can activate a Validation check to determine any errors or incomplete information. The following Validations types will be determined:

- errors that prevent submission into routing
- warnings that serve as alerts to possible data issues but will not prevent submission into routing

Turn On Validation

3. Click the Turn On Validation button.



4. Streamlyne Research will run a series of validation steps to make sure all fields are populated correctly and that field entries do not conflict wherever possible. This same validation routine automatically runs when the protocol is submitted.

If errors are found, Streamlyne Research will display a red error message at the top of the page and display a list of errors found on the document.



If errors exist, click the Fix button next to the first listed error.



Otherwise, skip to the next process.

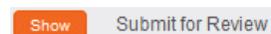
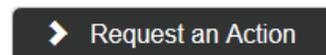
5. Streamlyne Research returns to the document section where the problem resides. Make your corrections and save the updated document.
6. Repeat Steps 4 and 5 as many times as necessary to resolve all errors.

Note This same validation routine is automatically run each time you submit the protocol into workflow. If it is the case that your submission is interrupted because of errors, you must resubmit the document by following the steps outlined in the very next process.

Submitting the Protocol Document to the IRB

Follow these steps to submit your protocol to the IRB. This submission action will enter the document into your institution's predefined workflow. Workflow stops, called nodes, generally begin with departmental and institutional approvals. This workflow is predefined by your institution and can vary from department to department. Once these approvals are in place, the workflow continues to the IRB Office for administrative review followed by Committee review (if applicable) and final approval before research activities can begin. You can access the workflow status at any time via the Route Log.

1. Click on the tab header to access the Protocol Actions tab.
2. Click on the header to expand the Request an Action tab.
3. Click the Show button next to the Submit for Review option under the Available Actions subsection.



The screenshot shows a dark grey header with a downward arrow and the text "Request an Action". Below this is a light grey bar with "Available Actions" and a refresh icon. A white bar contains a red "Hide" button and the text "Submit for Review". The form area has a white background and contains several dropdown menus: "* Submission Type:" (select), "* Submission Review Type:" (select), "Type Qualifier:" (select), "Committee:" (select), and "Schedule Date:" (select). A red "Submit" button is centered at the bottom of the form.

4. Streamlyne Research will display the Submit for Review subsection.

Click the arrows next to the **Submission Type** field and select the Initial Protocol Application for Approval option from the dropdown list.

Note If you are submitting an Amendment or Renewal these will show as options, if applicable.

- Click the arrow next to the **Submission Review Type** field to select the IRB submission type from the dropdown list, if known.

- If you selected a **Submission Review Type** of Expedited or Exempt in Step 5, Streamlyne Research will present predefined checklists, also known as Categories.

Make your selection(s) by clicking the corresponding checkbox(es) based on the explanations provided, or skip to the next step.

Note If you select the incorrect categories, this can be changed by the IRB Administrator.

- The **Type Qualifier** field will offer options in the dropdown based on **Submission Type** selected. If no dropdown options appear, skip to Step 8.

- Select a **Committee** and a **Schedule Date** if your institution asks you to complete this information at this stage.

If not, this will be supplied by your IRB Administrator.

- Click the Submit button to send the IRB protocol into workflow. 

Special Note If someone other than the PI submits a protocol, then the PI will be inserted as the first reviewer in workflow. Please see [FOR DEPARTMENTAL REVIEWERS AND APPROVERS](#) for more information on the review and approval process.

Note If you would like to confirm your submission was successful, verify that the Document Status in the Document Header has updated to Submitted to IRB.

Document Number : 32277	Document Status : Submitted to IRB
Initiator: Last Updated : irbadmin : 07:35 AM 07/18/2018	Submission Status : Pending
Protocol # : 1807002998	Expiration Date :

At this point, you can also confirm the document was sent to the correct users for approval. Do this by expanding the Route Log Section on the Protocol Actions tab and making sure the correct approvers are included in the Pending Action Requests and Future Action Requests sections.

For more information on the use of this common function, refer to the **Navigation, the Action List, and Common Document Elements** manual.

Understanding Available Actions after Initial Submission

There are approximately 15 actions that are conditionally available, depending on A.) where the protocol document is in its lifecycle; and B.) which actions were performed along the way. A complete list of all available protocol actions is in [Appendix C: All IRB Protocol Actions](#).

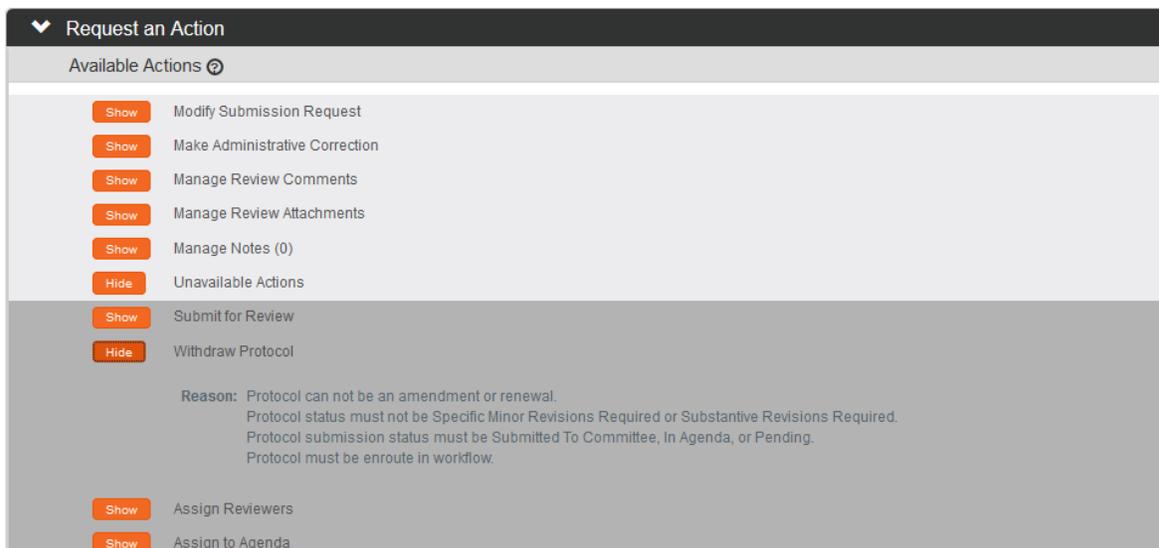
Available Actions

After initial submission, there are very few Available Actions for the user who has submitted the protocol. The Available Actions section will change over time as the protocol is reviewed, returned and eventually approved.

Note: If you would like to recall your protocol from the workflow for further edits, please see the [Recalling a Protocol](#) section.

Unavailable Actions

If you click the Show button next to any Unavailable Action you will be able to see the reason that Action is currently unavailable.



Recalling a Protocol

This action can only be performed after a document has been submitted into workflow and there are other users who need to approve the protocol before it is received by the IRB Administrator. This action will deliver the document back into Action List of the user who created/initiated the protocol. You can then make edits to the document and submit the document back into workflow. If

your protocol has been submitted and you would like to recall the submission, follow these instructions to recall the document.

Note There is a similar function called Withdraw Protocol but this action is reserved for instances in which the protocol has already reached the IRB Administrator for review and approval and you no longer wish to have the protocol reviewed. Recall is used for instances in which you would like the protocol back for further edits before approvals and subsequent IRB review.

1. Click on the tab header to access the Protocol Actions tab.



2. Scroll to bottom of the page and click the Recall button.



Are you sure you want to recall this document to the action list?

* Please enter the reason below:

YesReturn to Document

3. Enter an explanation in the field provided.
4. If you are satisfied with your explanation continue to the next Step. Otherwise, click the Return to Document button to cancel the recall action.
5. Click the Yes button.



Note The Document Status and the Submission Status will be updated to Recalled in Routing.

Document Number : 32277	Document Status : Recalled in Routing
Initiator:Last Updated : irbadmin : 07:35 AM 07/18/2018	Submission Status : Recalled in Routing
Protocol # : 1807002998	Expiration Date :

Withdrawing a Protocol

If you have submitted an IRB protocol that has reached the IRB Administrator for review and approval, but you no longer wish to have it reviewed, you can use the Withdraw action to stop the approval and review process. Once the review process has begun, however, only the IRB Administrator will be able to withdraw the protocol.

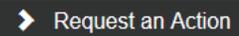
1. Using Lookups, locate the protocol you would like to Withdraw.

2. Click the edit hyperlink.

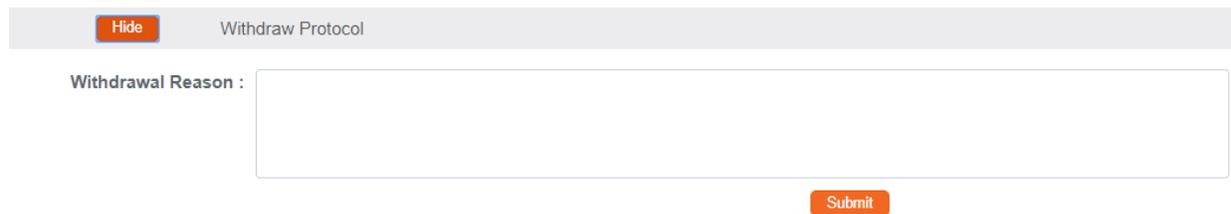
3. Click on the tab header to access the Protocol Actions tab.



4. Click on the header to expand the Request an Action tab.



5. Click the Show button next to Withdraw Protocol.



The form shows a 'Hide' button and the title 'Withdraw Protocol'. Below is a text input field labeled 'Withdrawal Reason :'. At the bottom right of the form is a 'Submit' button.

6. Enter freeform text in the **Withdrawal Reason** field.

7. Click the Submit button to finalize your withdrawal.



Result The IRB Administrator will be notified that the protocol has been withdrawn.

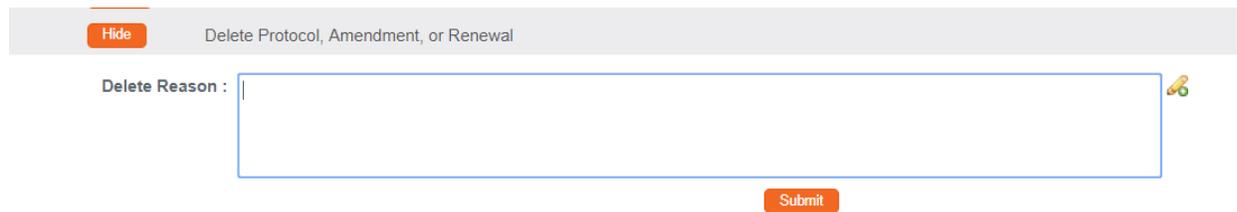
Note If you would like to proceed with review of this protocol in the future, you must create a new protocol document or use the copy function to reuse the information on the Withdrawn protocol.

Deleting a Protocol

If you initiate a Protocol, Amendment or Renewal, but then decide you will not be submitting it to the IRB Committee after all, then follow these steps to delete the document from the system. This

action can only be performed when a document has not yet been submitted. Please note that you will no longer be able to access this document and it will not be included in your list of protocols.

1. Within the Protocol, click on the tab header to access the Protocol Actions tab. 
2. Click on the header to expand the Request an Action section. 
3. Click the Show button next to Delete Protocol, Amendment, or Renewal.



Hide Delete Protocol, Amendment, or Renewal

Delete Reason :

Submit

4. Enter an explanation in the **Delete Reason** field.
5. Click the Submit button. 
6. Streamlyne Research will prompt you to confirm the action.
Click the Yes button to confirm the deletion. 

Result The Protocol Status will be updated to Deleted.
†

Editing a Returned Protocol

Sometimes a protocol is returned to the Principal Investigator by an IRB Administrator because it is incomplete, contains errors, or needs revisions based on committee feedback. Generally, a protocol is returned at two specific points in the process:

- When an institution has pre-review procedures in place to vet protocols before assigning protocol reviews to committee members;
- After formal review, when either a committee member or the full committee request specific minor or substantive revisions before approval can be granted.

The information available to the Principal Investigator and the manner in which he or she accesses the protocol document is influenced by the action taken by the administrator to return the protocol. This section will describe the scenarios in which a protocol could be returned.

Accessing a Protocol Returned Before Committee Review

This first scenario occurs when an IRB Administrator sends the protocol document back to the PI using the Return to PI Action, as described in [Returning the Protocol to the PI](#). This option is only available before any type of formal review has occurred.

Follow these steps when the title of the FYI Notification reads “Protocol Returned to PI Action,” as shown in the image here:

		32320	Streamlyne Research Notification	Protocol Returned to PI Action	FINAL		11:57 AM 07/20/2018
---	---	-------	----------------------------------	--------------------------------	-------	--	------------------------

1. When a protocol is returned to the PI through the Return to PI Action, Streamlyne Research will send two items to your Action List: An FYI Notification and a COM Notification, indicating the document requires completion.
2. You can access the protocol by clicking on the hyperlink  32319 | IRB Protocol within the message body of the FYI Notification, however the quickest way to access the protocol is by clicking the hyperlinked document number in the ID column of the COM item.

Accessing a Protocol Formally Returned for Revisions

This second scenario occurs when an IRB Administrator sends the protocol document back after at least one committee member has determined that the study cannot be approved as it is currently

documented. More specifically, this occurs when one or more committee members records a determination of Specific Minor Revisions or Substantive Revisions Required.

Follow these steps when the title of the FYI Notification reads Substantive revisions requested or Specific minor revisions requested as shown in the image below:

Show	FYI	32306	Streamlyne Research Notification	Specific minor revisions requested.	FINAL	12:26 PM 02/10/2015
------	-----	-------	--	--	-------	------------------------

1. When revisions are specifically requested, Streamlyne Research will send two items to your Action List: an FYI Notification and a COM Notification, indicating the document requires completion.
2. Click the Show button to open the FYI Notification.

Id: 1904
From: admin
Recipients: pedsprofessor
Channel: KC Notification Channel
Producer: Notification System
Type: FYI
Priority: Normal
Send Date: 2015-02-16T17:07:24.000-08:00
Removal Date: none

Title: Specific minor revisions requested.
Content:

The IRB protocol number [1502001123](#) has requested specific minor revisions. [view correspondence](#)

3. Based on your institutional configuration, Streamlyne Research may generate a Correspondence Letter each time a formal determination is recorded for a protocol. The purpose of the letter is to formally document and communicate the reason for the determination.

Click the view correspondence hyperlink in the body of the message, if appropriate.

4. You may then review the reason for the determination as documented in the Correspondence.
5. If you choose, you may download and save the PDF for your records.

Note The correspondence is also stored within the protocol document. See [Accessing Correspondence](#) for more information.

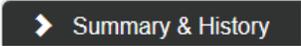
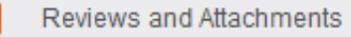
6. Return to the body of the FYI Notification and click the hyperlinked protocol number to open the document.

Reviewing Reasons for the Return

There are two places that an IRB Administrator and/or Reviewers can log comments describing the reasons for returning the protocol: in Correspondence (as shown in the previous process) and/or in Review Comments.

Accessing Review Comments

The IRB Administrator logs the reason for the return and/or the requested changes in the Review Comments subsection. Follow these steps to access this information:

1. Click on the header to access the Protocol Actions tab. 
2. Click on the header to access the Summary & History section. 
3. Click on the Show button to expand the Reviews and Attachments section.  
4. Read through the comments to understand the kinds of changes that are required to the resubmit the document to the IRB.

Note For instructions to navigate through the tabs and sections of the protocol to perform the requested updates, see [Updating the Protocol Tab](#).

When you are ready, follow the steps outlined in [Resubmitting the Protocol](#).

Accessing Correspondence

We have already seen the process to access correspondence from the FYI Notification. Follow this process to access the correspondence from within the protocol document.

1. Click on the header to access the Protocol Actions tab. 
2. Click on the header to access the Summary & History section. 

History						
View Action Date Range: Beginning On <input type="text"/> Ending On <input type="text"/> Filter Clear						
Description	Date	Action Date	Comments	Updated By	Update Time	
<input type="radio"/> Specific Minor Revisions Required	07/23/2018 01:37 PM	07/23/2018	Substantive Revision is not needed. Only the minor revision was agreed to be required.	irbadadmin	07/23/2018 01:37 PM	
Show Correspondences (1)						
<input type="radio"/> Record Committee Decision	07/23/2018 01:27 PM	07/23/2018		irbadadmin	07/23/2018 01:27 PM	
<input type="radio"/> Assigned to Agenda	07/23/2018 08:39 AM	07/23/2018	Comment entered during Assign to Agenda action.	irbadadmin	07/23/2018 08:39 AM	
Show Notifications (1)						
<input type="radio"/> Submitted to IRB	07/20/2018 01:10 PM	07/20/2018	Submitted to IRB	bioprofessor	07/20/2018 01:10 PM	
Show Notifications (1)						
Show Questionnaires (1)						

3. Locate the most recent determination Description in the History subsection.

4. Click the Show button to expand the Correspondence section to access the letter and review the reasons for the determination.

Note For instructions to navigate through the tabs and sections of the protocol to perform the requested updates, see [Updating the Protocol Tab](#).

When you are ready, follow the steps outlined in [Resubmitting the Protocol](#).

Resubmitting the Protocol

1. Once your changes are complete and you are ready to resubmit your protocol, click on the header to access the Protocol Actions tab.

Protocol Actions

2. Click on the header to access the Request an Action section.

Request an Action

3. Click on the Show button next to the Submit for Review subsection.

Show

Submit for Review

Hide Submit for Review

* Submission Type : Resubmission ▼

* Submission Review Type : Full Board ▼

Type Qualifier : select ▼

Committee : Full Board IRB Committee ▼

Schedule Date : 08-03-2018, [no location], 12:00 PM ▼

Submit

4. Click the arrow next to the **Submission Type** field and select Resubmission from the dropdown list.
5. Click the arrow next to the **Submission Review Type** field, and then select the correct value from the dropdown list.
6. Click the Submit button. 

Result The following updates occur:

†

- The Protocol Status updates to Submitted to IRB, and the Submission Status updates to Pending.
- The protocol will enter workflow again as if it had been newly submitted.
- After all predefined departmental and institutional approvals are complete, the IRB Administrator will be able to perform all actions available before the document was returned.

Understanding Streamlyne Amendments & Renewals

The purpose of this section is to help you understand how Streamlyne treats Amendments and Renewals with respect to the original approved protocol.

Amendment

Streamlyne allows an approved protocol to be amended at any time. The purpose of the amendment is to notify the IRB of any changes to a previously approved human subjects study.

Renewal

Streamlyne allows an approved protocol to be renewed at any time. The purpose of the renewal is to garner the IRB's approval to extend the study beyond the current expiration date.

Streamlyne allows for both Renewals and Renewals with Amendments, as it may be necessary to amend the approved human subjects study at renewal time.

Starting from a Copy

When user initiates an Amendment or Renewal, Streamlyne creates the document by copying the original protocol content into a new version.

Document Number : 26792	Document Status : Amendment Incorporated into Protocol	Copied from Document Header Id : 26732
Initiator:Last Updated : crimprofessor : 03:01 PM 02/21/2018	Submission Status : Approved	
Protocol # : 1802003135A001	Expiration Date : 02/20/2019	

Streamlyne will identify the source of the copy in the Document Header, as shown above in the Copied from Document Header ID field.

Differences in Naming Convention

Streamlyne identifies Renewals and Amendments by appending unique identifiers to the original protocol number, following the format RNNN or ANNN respectively. For example, the Protocol # above of 1802003135A001 indicates this is the first amendment submitted for Protocol #1802003135.

Merging Amendments and Renewals

After the review process is complete, and the amendment or renewal is approved, the system versions the original protocol and merges the new information into the original document.

Streamlyne updates the Document Status to either Amendment Incorporated into Protocol or Renewal Incorporated into Protocol.

Document Status : Amendment Incorporated into Protocol

Using the Summary & History Section

When the amendment or renewal is first submitted, you can access the entire history of the project by navigating to Protocol Actions > Summary & History.

Identifying Changes in the Review Process

The screenshot shows the 'Amendment Details' section. At the top left is a 'Hide' button. Below it is a 'Summary' field containing the text 'test'. Underneath the summary is an 'Amend:' section with a grid of checkboxes. The first column contains: General Info, Funding Source, Protocol References & Other Identifiers, Protocol Organizations, Subjects, and Questionnaire. The second column contains: Add/Modify Notes & Attachments (checked), Areas of Research, Special Review, Protocol Personnel, and Others.

For Amendments, the system will display the Amendment Details section, which contains a **Summary** of changes as marked sections to indicate where changes were made.

For Renewals, the system will display the Renewal Details section, which contains only the **Summary** of progress to date.



You may wish to compare to previous versions. For a quick view of the changes made to the protocol, the system will highlight all new data in red when you click the Compare to Previous Sequence button.

Viewing Amendments/Renewals After Approval is Granted

After the approval has been granted, the renewal and amendment information can then be viewed in the future from the Amendment/Renewal History section in Protocol Actions > Summary & History.

Click Show to view more details:



Amendments/Renewals				
Type	Version Number	Summary	Status	Created Date
Amendment	0	manual	Amendment Incorporated into Protocol	02/21/2018
		Show Amendment Summary - 1802003135A001		
		Show Amendment Questionnaires - 1802003135A001		

Creating & Submitting an Amendment

The PI or the protocol creator can amend a protocol any time after initial approval. The review process for amendments is like the review process for initial submissions. This section will only cover the differentiators specific to creating and submitting an amendment.

The recommended way to initiate an amendment is from within the existing, active protocol: IRB Actions > Amend or Renew IRB Protocol. Clicking this menu option will display all protocols available to the user that currently qualify for an amendment or renewal.

Navigation

Main Menu > IRB > IRB Actions > Amend or Renew IRB Protocol

Actions	Protocol #	Protocol Type	Investigator	Title	Protocol Status	Approval Date	Expiration Date	Last Approval Date	Initial Submission Date	Lead Unit	Lead Unit Name	Summary/Keywords	Active
perform action	1412000227	Expedited	Biochemistry Professor	Expedited Test	Expired	12/19/2014	12/18/2015		12/19/2014	105010	Biochemistry		Yes
perform action	1502000810	Full Board	Biochemistry Professor	Boston College IRB Demo 3	Active - Open to Enrollment	05/01/2015	04/30/2016		02/03/2015	105010	Biochemistry		Yes
perform action	1506002204	Expedited	Biochemistry Professor	America's Genetic Mutations: A Meta Data Analysis from 1980-2010	Active - Open to Enrollment	07/10/2015	07/09/2016		06/17/2015	105010	Biochemistry		Yes
perform action	1508002365	Expedited	Biochemistry Professor	Nature vs Nurture and PTSD.	Active - Open to Enrollment	10/02/2015	10/01/2016		09/02/2015	105010	Biochemistry		Yes

1. Locate the protocol that you would like to amend.
2. Click the corresponding perform action hyperlink.

Result Streamlyne will open the protocol to Protocol Actions > Request an Action panel. The Available Actions will display multiple options for you.

3. Click the Show button next to Create Amendment.

Show

Create Amendment

[Hide](#) Create Amendment

* Summary:

*Amend:

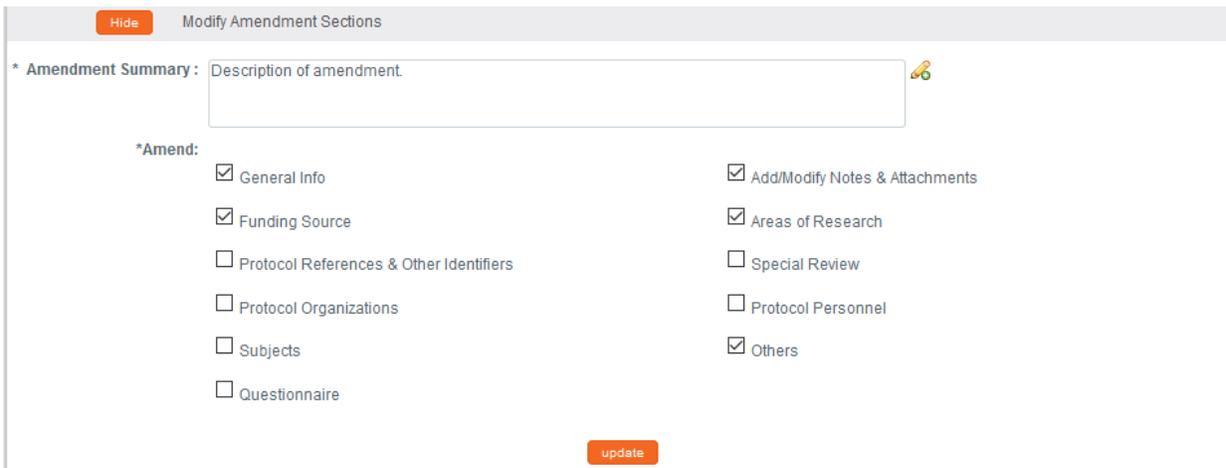
<input type="checkbox"/> General Info	<input type="checkbox"/> Add/Modify Notes & Attachments
<input type="checkbox"/> Funding Source	<input type="checkbox"/> Areas of Research
<input type="checkbox"/> Protocol References & Other Identifiers	<input type="checkbox"/> Special Review
<input type="checkbox"/> Protocol Organizations	<input type="checkbox"/> Protocol Personnel
<input type="checkbox"/> Subjects	<input type="checkbox"/> Others
<input type="checkbox"/> Questionnaire	

[create](#)

4. Describe the purpose and content of the amendment in the **Summary** field. If necessary, click on the edit button  to access a text editor with character count.
5. In the **Amend** section, check all boxes for sections you wish to amend. Protocol sections with checked boxes will be opened for editing. Those not selected will remain read-only.
6. Click the Create button. 

Result Streamlyne will open a new Amendment document. You will be able to make edits in the areas you selected in Step 5.

7. If you would like to edit further sections in addition to those previously selected, navigate back to Protocol Actions > Request an Action > Available Actions.
8. Click the Show button next to Modify Amendment Sections.  



9. Select the applicable sections and click the Update button. 
10. Make all applicable changes to the information displayed on the protocol document as needed.

Note Your institution may have chosen to configure an Amendment Questionnaire – or a series of interview questions displayed only for amendments. If so, you **MUST** complete this questionnaire before submitting the document.

11. When ready to submit, navigate back to Protocol Actions > Request an Action> Submit for Review.

12. Click the Show button next to Submit for Review.

Show

Submit for Review

13. Complete the required fields of **Submission Type** (e.g., Amendment) and **Submission Review Type** (e.g., Full Board).

Notes For Exempt and Expedited protocols, a Checklist will display. Select all categories that apply to your amendment.

14. Click the Submit button to submit your amended protocol for the required workflow approvals.

Submit

Result The delivered Data Validation routine will display any errors or warnings that pertain to this document. Be sure to complete the Questionnaire. If necessary, fix the errors and click the Submit button again to revalidate and submit.

Otherwise, the system will change the Document Status to Submitted to IRB.

Document Number : 32282	Document Status : Submitted to IRB	Copied from Document Header Id : 7490
Initiator:Last Updated : bioprofessor : 10:33 AM 07/18/2018	Submission Status : Pending	
Protocol # : 1501000500A001	Expiration Date : 03/17/2016	

See [Understanding Streamlyne Amendments & Renewals](#) for what Amendment details will be made available in the Summary & History section.

Creating & Submitting a Renewal

Renewals can be submitted by the PI or the protocol creator at any time after initial approval has occurred. However, the timeline for submitting a Renewal depends on both the expiration date and institutional business practices. The review process for Renewals is like the review process for initial submissions. This section will only cover the differentiators that are specific to creating and submitting a protocol for Renewal.

You can access the protocol you would like to renew through various Lookups. However, the recommended way to initiate a Renewal is through IRB Actions > Amend or Renew IRB Protocol. Clicking this menu option will display all protocols available to the user that currently qualify for an amendment or renewal.

Navigation

Main Menu > IRB > IRB Actions > Amend or Renew IRB Protocol

Actions	Protocol #	Protocol Type	Investigator	Title	Protocol Status	Approval Date	Expiration Date	Last Approval Date	Initial Submission Date	Lead Unit	Lead Unit Name	Summary/Keywords	Active
perform action	1412000227	Expedited	Biochemistry Professor	Expedited Test	Expired	12/19/2014	12/18/2015		12/19/2014	105010	Biochemistry		Yes
perform action	1502000810	Full Board	Biochemistry Professor	Boston College IRB Demo 3	Active - Open to Enrollment	05/01/2015	04/30/2016		02/03/2015	105010	Biochemistry		Yes
perform action	1506002204	Expedited	Biochemistry Professor	America's Genetic Mutations: A Meta Data Analysis from 1980-2010	Active - Open to Enrollment	07/10/2015	07/09/2016		06/17/2015	105010	Biochemistry		Yes
perform action	1508002365	Expedited	Biochemistry Professor	Nature vs Nurture and PTSD.	Active - Open to Enrollment	10/02/2015	10/01/2016		09/02/2015	105010	Biochemistry		Yes

1. Locate the protocol you wish to renew.
2. Click the corresponding perform action hyperlink.

Result Streamlyne will open the protocol to the Protocol Actions > Request an Action section.

3. Click the Show button next to Create Renewal without Amendment.

Hide Create Renewal without Amendment

* Summary:

create

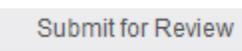
4. Describe the progress of the project and the purpose of the renewal in the **Summary** field. If necessary, click on the edit button to access a text editor with character count.

5. Click the Create button. 

Result This will open a new Renewal in Progress document.

Note Your institution may have chosen to configure a Renewal Questionnaire. If so, you will need to complete this questionnaire before submitting the document.

6. When ready to submit, navigate back to Protocol Actions > Request an Action> Submit for Review.

7. Click the Show button next to Submit for Review.  

8. Complete the required fields of **Submission Type** (e.g., Continuing Review/Continuation without Amendment) and **Submission Review Type** (e.g., Full Board).

Notes For Exempt and Expedited protocols, a Checklist will display. Select all categories that apply to your submission.

9. Click the Submit button to submit your protocol into workflow. 

Result The delivered Data Validation routine will display any errors or warnings that pertain to this document. If necessary, fix the errors and click the Submit button again to revalidate and submit.

Otherwise, the system will change the Document Status to Submitted to IRB.

Document Number : 32288	Document Status : Submitted to IRB	Copied from Document Header Id : 21071
Initiator:Last Updated : bioprofessor : 06:45 AM 07/19/2018	Submission Status : Pending	
Protocol # : 1701002734R001	Expiration Date : 02/05/2018	

See [Understanding Streamlyne Amendments & Renewals](#) for what Renewal details will be made available in the Summary & History section.

Creating & Submitting a Renewal with Amendment

While the system will allow a PI or the protocol creator to submit a Renewal with Amendment protocol at any time after initial approval, the timeline for submitting a Renewal depends on both the expiration date on the protocol and institutional business practices. The review process for Renewals with Amendments is similar to the review process for initial submissions. This section will only cover the differentiators that are specific to creating and submitting a protocol for both renewal and amendment.

The recommended way to initiate an amendment is from within the existing, active protocol: IRB Actions > Amend or Renew IRB Protocol. Clicking this menu option will display all protocols available to the user that currently qualify for an amendment or renewal.

Navigation

Main Menu > IRB > IRB Actions > Amend or Renew IRB Protocol

Actions	Protocol #	Protocol Type	Investigator	Title	Protocol Status	Approval Date	Expiration Date	Last Approval Date	Initial Submission Date	Lead Unit	Lead Unit Name	Summary/Keywords	Active
perform action	1412000227	Expedited	Biochemistry Professor	Expedited Test	Expired	12/19/2014	12/18/2015		12/19/2014	105010	Biochemistry		Yes
perform action	1502000810	Full Board	Biochemistry Professor	Boston College IRB Demo 3	Active - Open to Enrollment	05/01/2015	04/30/2016		02/03/2015	105010	Biochemistry		Yes
perform action	1506002204	Expedited	Biochemistry Professor	America's Genetic Mutations: A Meta Data Analysis from 1980-2010	Active - Open to Enrollment	07/10/2015	07/09/2016		06/17/2015	105010	Biochemistry		Yes
perform action	1508002365	Expedited	Biochemistry Professor	Nature vs Nurture and PTSD.	Active - Open to Enrollment	10/02/2015	10/01/2016		09/02/2015	105010	Biochemistry		Yes

1. Locate the protocol you like to renew and amend.
2. Click the corresponding perform action hyperlink.

Result Streamlyne will open the protocol to Protocol Actions > Request an Action panel. The Available Actions section will display multiple options for you.

3. Click the Show button next to Create Renewal with Amendment.

Show

Create Renewal with Amendment

Hide Create Renewal with Amendment

* Summary: 

*Amend:

<input type="checkbox"/> General Info	<input type="checkbox"/> Add/Modify Notes & Attachments
<input type="checkbox"/> Funding Source	<input type="checkbox"/> Areas of Research
<input type="checkbox"/> Protocol References & Other Identifiers	<input type="checkbox"/> Special Review
<input type="checkbox"/> Protocol Organizations	<input type="checkbox"/> Protocol Personnel
<input type="checkbox"/> Subjects	<input type="checkbox"/> Others
<input type="checkbox"/> Questionnaire	

create

4. Describe the purpose and content of the amendment in the **Summary** field. If necessary, click on the edit button  to access a text editor with character count.
5. In the **Amend** section, check all boxes for sections you wish to amend. Protocol sections with checked boxes will be opened for editing. Those not selected will remain read-only.
6. Click the Create button. 

Result Streamlyne will open a new Renewal In Progress. You will be able to make edits in the areas you selected in Step 5.

7. If you would like to re-select the boxes to be able to edit further sections, navigate back to Protocol Actions > Request an Action > Available Actions.
8. Click the Show button next to Modify Amendment Sections.  

Hide Modify Amendment Sections

* Amendment Summary : Description of amendment. 

*Amend:

<input checked="" type="checkbox"/> General Info	<input checked="" type="checkbox"/> Add/Modify Notes & Attachments
<input checked="" type="checkbox"/> Funding Source	<input checked="" type="checkbox"/> Areas of Research
<input type="checkbox"/> Protocol References & Other Identifiers	<input type="checkbox"/> Special Review
<input type="checkbox"/> Protocol Organizations	<input type="checkbox"/> Protocol Personnel
<input type="checkbox"/> Subjects	<input checked="" type="checkbox"/> Others
<input type="checkbox"/> Questionnaire	

update

9. Select the applicable sections and click the Update button. 

10. Make all applicable changes to the information displayed on the protocol document as needed.

Note Your institution may have chosen to configure an Amendment Questionnaire, a Renewal Questionnaire, or both. If so, you will need to complete these questionnaires before submitting the document.

11. When ready to submit, navigate back to Protocol Actions > Request an Action> Submit for Review.

12. Click the **Show** button next to Submit for Review.  

13. Complete the required fields of **Submission Type** (e.g., Continuing Review/Continuation with Amendment) and **Submission Review Type** (e.g., Full Board).

Notes For Exempt and Expedited protocols, a Checklist will display. Select all categories that apply to your submission.

14. Click the Submit button to submit your amended protocol for the required workflow approvals. 

Result The delivered Data Validation routine will display any errors or warnings that pertain to this document. If necessary, fix the errors and click the Submit button again to revalidate and submit.

Otherwise, the system will change the Document Status to Submitted to IRB.

Document Number : 32282	Document Status : Submitted to IRB	Copied from Document Header Id : 7490
Initiator:Last Updated : bioprofessor : 10:33 AM 07/18/2018	Submission Status : Pending	
Protocol # : 1501000500A001	Expiration Date : 03/17/2016	

See [Understanding Streamlyne Amendments & Renewals](#) for what details will be made available in the Summary & History section.

Communicating with the IRB

Streamlyne delivers a number of features to facilitate communication from the study team to the IRB regarding any study activity.

The benefit to leveraging these features is that all communication will be captured in the Summary and History sections of the protocol.

This chapter will review the purpose of each of these features, and provides the steps to execute each.

Notifying the IRB

This process applies to all instances in which the PI needs to notify the IRB Committee of an event that occurred that may require further review or scrutiny by an IRB Administrator and/or IRB Committee. The most common occurrences are adverse events, unanticipated problems or protocol deviations. However, there are a variety of events that may be applicable. Not all will be covered in this manual, but the steps to submit a Notify IRB action are the same.

Access the protocol through IRB Actions > Notify the IRB on a Protocol. Clicking this menu option will display all the protocols that qualify for this action.

Navigation

Main Menu > IRB > IRB Actions > Notify IRB on a Protocol

1. Locate the protocol that you would like to notify the IRB about.
2. Click the perform action hyperlink on the corresponding row.

Result This will open the protocol on the Protocol Actions > Request an Action > Available Actions subsection.

Note You may alternatively navigate to Protocol Actions > Request an Action > Available Actions subsection, if you are already in the protocol for which you would like to take action.

3. Under Available Actions, the Notify IRB section will display.

Request an Action

Available Actions

Hide Notify IRB

Details

Submission Type Qualifier :

Committee :

Submission Review Type :

Comment :

Attachments

	Attachment	Description	Actions
Add:	<input type="button" value="Browse..."/> No file selected.	<input type="text"/>	<input type="button" value="add"/>

- In the **Submission Type Qualifier** field, use the dropdown to select the appropriate option.

Note **Submission Review Type** will default to FYI and cannot be changed.

- In the **Committee** field select the committee that reviews your protocol if known. If not, proceed to the next Step.
- In the **Comment** field, enter freeform text regarding the reason for the notification.
- In the Attachments subsection, upload an attachment by clicking the Browse button and following your operating system's prompts if needed.
- In the **Description** field enter a description of the attachment if needed.
- Click the add button.
- Repeat Steps 7 through 9 until all necessary attachments are added.
- Click the Submit button to finalize the Notify IRB action.

Result A notification and attachments if present will go to the IRB Administrator and/or IRB Committee for review as applicable to the event. You may not have any available Actions while your request is being processed.

Note Once the review is complete, the user should receive a response indicating that the IRB has acknowledged the event. The format of the response and any accompanying correspondence will be based on your institution's workflow configuration. It may display as an FYI in your Action List. You can always access this information in Protocol Actions>Summary & History. The IRB may request further information before full acknowledgment takes place.

Requesting to Close a Protocol

Your institution may require PI's to formally close protocols once the research is complete, is no longer being executed, or the PI is transferring to a different institution.

Navigation	Main Menu > IRB > IRB Lookups > All My Protocols
-------------------	--

1. Locate the protocol you would like to close.
2. Click the edit hyperlink on the corresponding row.

Result This will open the protocol so only the Available Actions section is available for editing. The remainder of the protocol is in a view-only state.

3. Navigate to Protocol Actions > Request an Action > Available Actions.

4. Click the Show button next to Request to Close. Show Request To Close

Hide Request To Close

Details

Committee : <input type="text" value="select"/>	Reason : <input style="width: 95%;" type="text"/>
---	---

Attachments

	Attachment	Description	Actions
Add:	<input type="button" value="Browse..."/> No file selected.	<input style="width: 95%;" type="text"/>	<input type="button" value="add"/>

5. In the **Committee** field select the Committee that reviews your protocol if known. If not, proceed to the next Step.
6. In the **Reason** field, enter freeform text to describe the reason you would like to close the protocol.
7. In the Attachments subsection, upload an attachment by clicking the Browse button and following your operating system's prompts, if needed.
8. In the **Description** field enter a description of the attachment if needed.
9. Click the add button. 

Notes Repeat Steps 7 through 9 until all necessary attachments are added.

10. Click the Submit button to finalize the Request to Close action. 

Result The request and supplemental information will go to the IRB office for IRB Administrator and/or IRB Committee review as applicable.

Note Once the IRB Administrator has received the Request to Close and the request has been approved, the user should receive a response indicating that your protocol has officially been closed. The format of the response and any accompanying correspondence will be based on your institution's workflow configuration. It may display as an FYI in your Action List. You can always access this information in Protocol Actions>Summary & History. The IRB may request further information before this action takes place.

Requesting to Suspend a Protocol

Your institution may require PI's to formally request to suspend a protocol. A PI may wish to pause a study for a variety of reasons, however, the steps to request a suspension are the same regardless of reason or previous actions taken on the protocol.

Navigation

Main Menu > IRB > IRB Lookups > All My Protocols

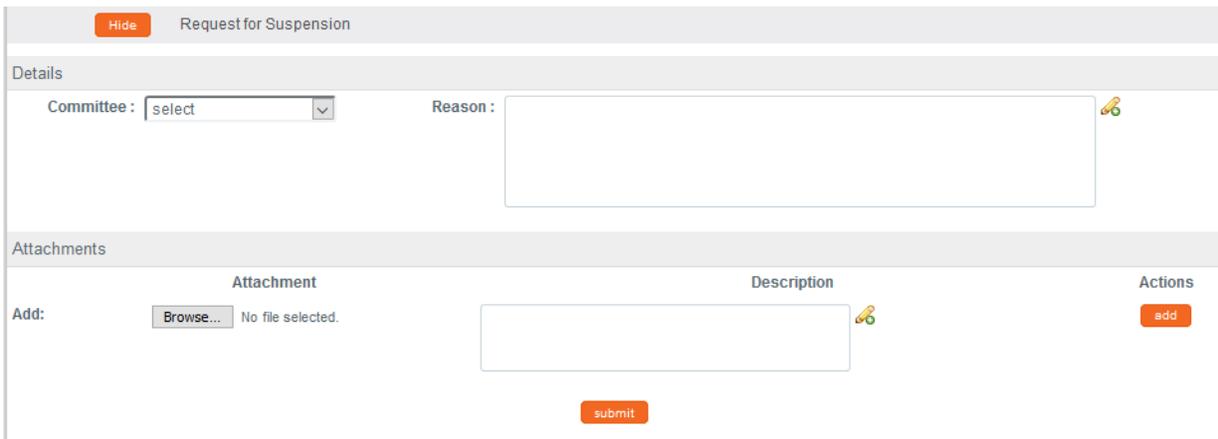
1. Locate the protocol you would like to suspend.

2. Click the edit hyperlink on the corresponding row.

Result This will open the protocol so only the Available Actions section is available for editing. The remainder of the protocol is in a view-only state.

3. Navigate to Protocol Actions > Request an Action > Available Actions.

4. Click the Show button next to Request for Suspension.  



5. In the **Committee** field select the Committee that reviews your protocol if known. If not, proceed to the next Step.

6. In the **Reason** field, enter freeform text to describe the reason you would like to suspend the protocol.

7. In the Attachments subsection, upload an attachment by clicking the Browse button and following your operating system's prompts if needed.

8. In the **Description** field enter a description of the attachment if needed.

9. Click the add button. 

Notes Repeat Steps 7 through 9 until all necessary attachments are added.

10. Click the Submit button to finalize the Request for Suspension action. 

Result The request and supplemental information will go to the IRB office for IRB Administrator and/or IRB Committee review as applicable.

Note Once the IRB Administrator has received the Request for Suspension and the request has been approved, the user should receive a response indicating that your protocol has officially been suspended. The format of the response and any accompanying correspondence will be based on your institution's workflow configuration. It may display as an FYI in your Action List. You can always access this information in Protocol Actions>Summary & History. The IRB may request further information before this action takes place.

Requesting to Close Enrollment on a Protocol

Your institution may require PI's to formally request to close enrollment of subjects for your protocol. This will occur once you are no longer actively recruiting research subjects for your protocol.

Navigation

Main Menu > IRB > IRB Lookups > All My Protocols

1. Locate the protocol where you would like to close enrollment.
2. Click the edit hyperlink on the corresponding row.

Result This will open the protocol so only the Available Actions section is available for editing. The remainder of the protocol is in a view-only state.

3. Navigate to Protocol Actions > Request an Action > Available Actions.

4. Click the Show button next to Request to Close Enrollment.

Show

Request to Close Enrollment

5. In the **Committee** field select the Committee that reviews your protocol if known. If not, proceed to the next Step.
6. In the **Reason** field, enter freeform text to describe the reason you would like to close enrollment on the protocol.
7. In the Attachments subsection, upload an attachment by clicking the Browse button and following your operating system's prompts if needed.
8. In the **Description** field enter a description of the attachment if needed.
9. Click the add button. 

Notes Repeat Steps 7 through 9 until all necessary attachments are added.

10. Click the Submit button to finalize the Request to Close Enrollment action. 

Result The request and supplemental information will go to the IRB office for IRB Administrator and/or IRB Committee review as applicable.

Note Once the IRB Administrator has received the Request to Close Enrollment and the request has been approved, the user should receive a response indicating that your protocol has officially been closed for enrollment of subjects. The format of the response and any accompanying correspondence will be based on your institution's workflow configuration. It may display as an FYI in your Action List. You can always access this information in Protocol Actions>Summary & History. The IRB may request further information before this action takes place.

Requesting to Re-Open Enrollment on a Protocol

Your institution may require PI's to formally request to re-open enrollment of subjects for your protocol. This request will only be available if the current status of your protocol is Active-Closed to Enrollment.

Navigation

Main Menu > IRB > IRB Lookups > All My Protocols

1. Locate the protocol where you would like to re-open enrollment.
2. Click the edit hyperlink on the corresponding row.

Result This will open the protocol so only the Available Actions section is available for editing. The remainder of the protocol is in a view-only state.

3. Navigate to Protocol Actions > Request an Action > Available Actions.

4. Click the Show button next to Request to Re-open Enrollment.

Show Request to Re-open Enrollment

Hide Request to Re-open Enrollment

Details

Committee : Reason :

Attachments

Attachment	Description	Actions
Add: <input type="button" value="Browse..."/> No file selected.	<input type="text"/>	<input type="button" value="add"/>

5. In the **Committee** field select the Committee that reviews your protocol if known. If not, proceed to the next Step.
6. In the **Reason** field, enter freeform text to describe the reason you would like to re-open enrollment on the protocol.

7. In the Attachments subsection, upload an attachment by clicking the Browse button and following your operating system's prompts if needed.
8. In the **Description** field enter a description of the attachment if needed.
9. Click the add button. 

Notes Repeat Steps 7 through 9 until all necessary attachments are added.

10. Click the Submit button to finalize the Request to Re-open Enrollment action. 

Result The request and supplemental information will go to the IRB office for IRB Administrator and/or IRB Committee review as applicable.

Note Once the IRB Administrator has received the Request to Re-open Enrollment and the request has been approved, the user should receive a response indicating that your protocol has officially been re-opened for enrollment of subjects. The format of the response and any accompanying correspondence will be based on your institution's workflow configuration. It may display as an FYI in your Action List. You can always access this information in Protocol Actions>Summary & History. The IRB may request further information before this action takes place.

Requesting to Identify a Protocol in a Data Analysis Only Phase

Your institution may require PI's to formally request to transition a study into a data analysis only phase when you reach that point in the study. This will occur when only data analysis is being conducted and data collection and interaction with human subjects has ceased.

Navigation

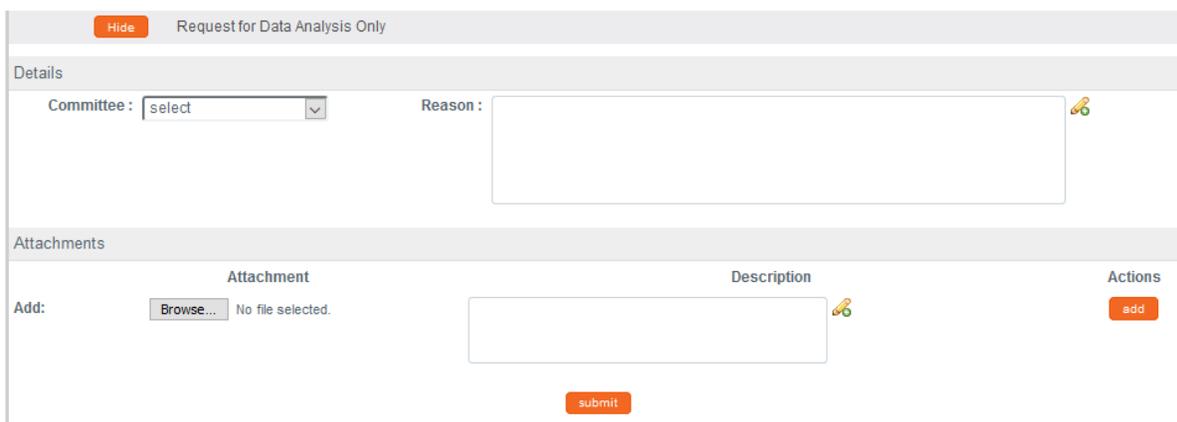
Main Menu > IRB > IRB Lookups > All My Protocols

1. Locate the protocol where you would like to request a data analysis only phase.
2. Click the edit hyperlink on the corresponding row.

Result This will open the protocol so only the Available Actions section is available for editing. The remainder of the protocol is in a view-only state.

3. Navigate to Protocol Actions > Request an Action > Available Actions.

4. Click the Show button next to Request for Data Analysis Only.



5. In the **Committee** field select the Committee that reviews your protocol if known. If not, proceed to the next Step.

6. In the **Reason** field, enter freeform text to describe the reason you would like to transition the protocol to a data analysis only phase.

7. In the Attachments subsection, upload an attachment by clicking the Browse button and following your operating system's prompts if needed.

8. In the **Description** field enter a description of the attachment if needed.

9. Click the add button. 

Notes Repeat Steps 7 through 9 until all necessary attachments are added.

10. Click the Submit button to finalize the Request for Data Analysis Only action. 

Result The request and supplemental information will go to the IRB office for IRB Administrator and/or IRB Committee review as applicable.

Note Once the IRB Administrator has received the Request for Data Analysis Only and the request has been approved, the user should receive a response indicating that your protocol has officially transitioned to a data analysis only phase. The format of the response and any accompanying correspondence will be based on your institution's workflow configuration. It may display as an FYI in your Action List. You can always access this information in Protocol Actions>Summary & History. The IRB may request further information before this action takes place.

Requesting to Terminate a Protocol

Your institution may require PI's to formally request to terminate the study. This action can occur for a variety of reasons, however, the steps to request a termination are the same regardless of reason or previous actions taken on the protocol.

Navigation

Main Menu > IRB > IRB Lookups > All My Protocols

1. Locate the protocol you would like to terminate.
2. Click the edit hyperlink on the corresponding row.

Result This will open the protocol so only the Available Actions section is available for editing. The remainder of the protocol is in a view-only state.

3. Navigate to Protocol Actions > Request an Action > Available Actions.

4. Click the Show button next to Request for Termination.

Show

Request for Termination

5. In the **Committee** field select the Committee that reviews your protocol if known. If not, proceed to the next Step.
6. In the **Reason** field, enter freeform text to describe the reason you would like to terminate the protocol.
7. In the Attachments subsection, upload an attachment by clicking the Browse button and following your operating system's prompts if needed.
8. In the **Description** field enter a description of the attachment if needed.

9. Click the add button. 

Notes Repeat Steps 7 through 9 until all necessary attachments are added.

10. Click the Submit button to finalize the Request for Termination action. 

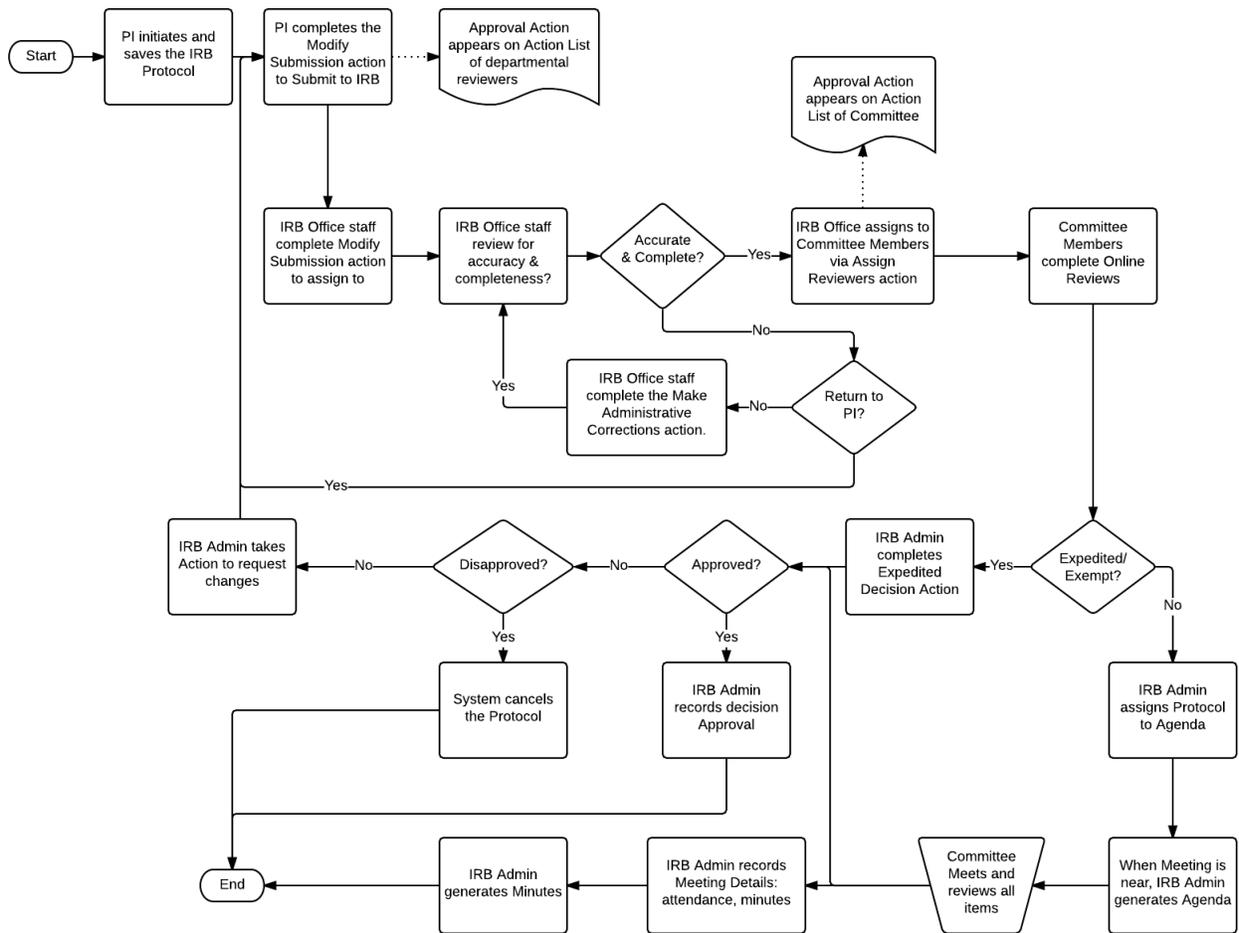
Result The request and supplemental information will go to the IRB office for IRB Administrator and/or IRB Committee review as applicable.

Note Once the IRB Administrator has received the Request for Termination and the request has been approved, the user should receive a response indicating that your protocol has been terminated. The format of the response and any accompanying correspondence will be based on your institution's workflow configuration. It may display as an FYI in your Action List. You can always access this information in Protocol Actions>Summary & History. The IRB may request further information before this action takes place.

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.