



IRB Protocol & Committee Modules

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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.

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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 **NEW USER MANUAL: Navigation, the Action List, and Common Document Elements**. 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.

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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

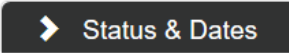
▼ **Status & Dates**

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.

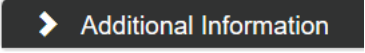


Protocol Tab > Additional Information > Areas of Research

Area of Research ?


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

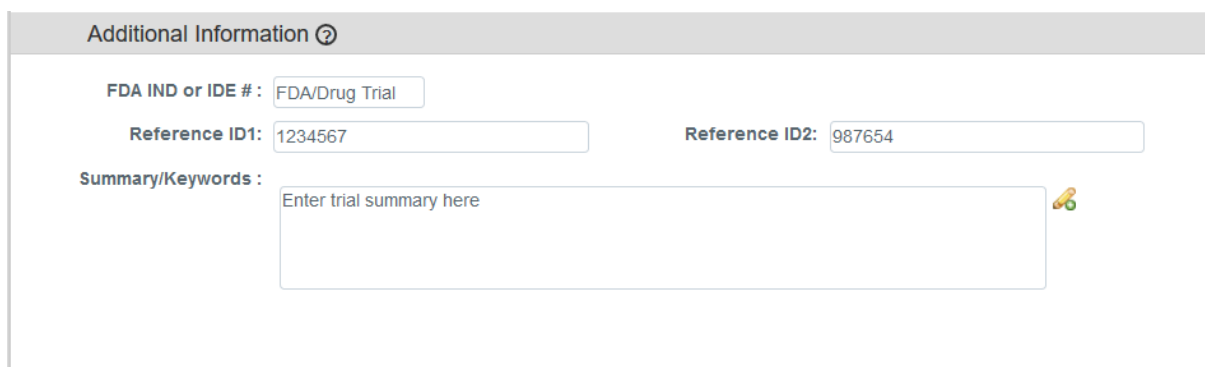
Go to page: 1

Select?	Research Area Code	Parent Research Area Code	Has Children Flag	Code/Description	Active
<input type="checkbox"/>	00001	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.

	* Type	* Other Identifier	Application Date	Approval Date	Actions
add:	select				Add
Comment:					

1. 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)
2. Enter the identifying number assigned by the external organization in the **Other Identifier** field.
3. Populate the **Application Date** and/or the **Approval Date** in MM/DD/YYYY format or click the calendar icon  to select the date.
4. Enter any supplemental or descriptive information in the **Comments** field.
5. Click the Add button to add the entry to the protocol. 

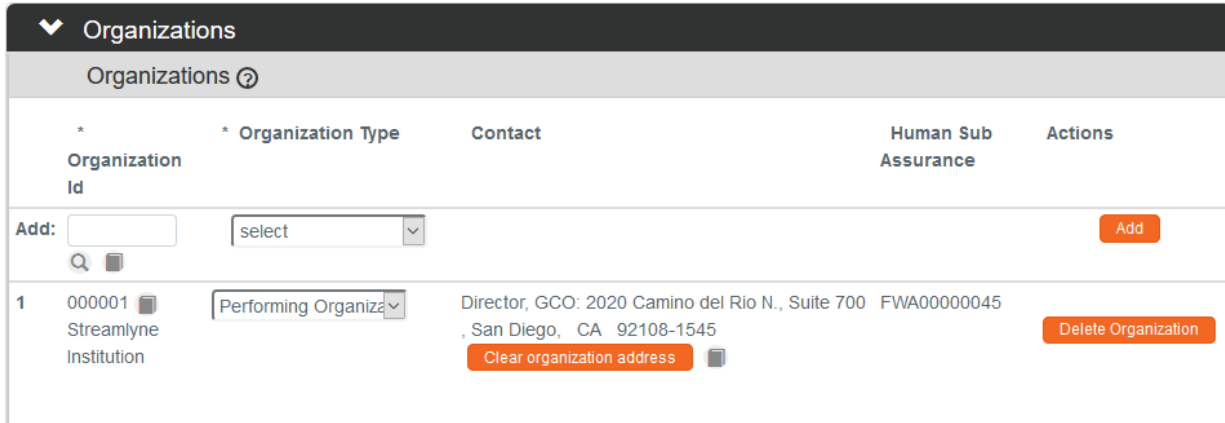
- select
- CALGB
- RTOG
- IRBNet
- COAG

Protocol Tab > Organizations

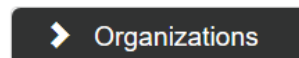
The Organizations section allows you to indicate which, if any, outside institutions may be performing some aspect of the study activities. Organizations that are configured in the system have identified contacts, called IRB Correspondents, who may be listed on the Personnel Tab and are eligible to receive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



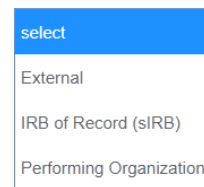
1. If other organizations are collaborating on this research, click on the header to expand the Organizations section.




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).

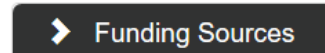


4. Click the Add button to complete the action. 
5. Repeat Steps 2 through 4 until all collaborating institutions are included on the protocol document.

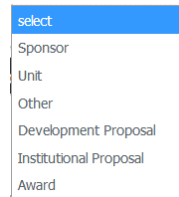
Protocol Tab > Funding Sources

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

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. 

5. 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

1. Click on the header to expand the Participant Types section.
2. 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

3. Enter a projected number of participants for this participant group into the **Count** field.
4. Click the Add button to complete this action.
5. 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


1. 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

2. 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**.

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

4. 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.

5. Click the section header to expand the user section.

6. 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 :

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
 Email Address :
 Primary Title :
 Home Unit : 105010
 NSF ID :
 eRA Commons User Name :
 Pager :
 Office Location :
 Address Line 1 :
 Address Line 3 :
 County :
 Postal Code :
 User Name : bioprofessor
 Office Phone :
 Directory Title :
 School : Medicine University
 CITI User Name :
 Fax :
 Mobile :
 Secondary Office Location :
 Address Line 2 :
 City :
 State :
 Country :

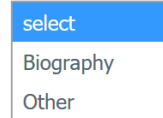
10. Update defaulted contact information if necessary.

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.



A dropdown menu with a blue header containing the word "select". Below the header, two options are listed: "Biography" and "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. 



A table titled "Unit Details" with a "Hide" button in the top left corner. The table has four columns: "Unit Name", "* Unit Number", "* Lead", and "Actions". The first row is for adding a new unit, with a "(select)" dropdown for the unit name, an empty input field for the unit number, an unchecked checkbox for the lead status, and an "Add" button. The second row shows an existing unit with the number "1", the name "Biochemistry", the unit number "105010", a checked radio button for the lead status, and a "Delete" button.

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.

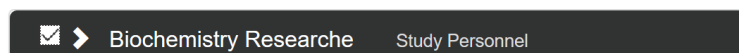
18. Click the **Lead** box to indicate if this Unit is the lead unit for this investigator.

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




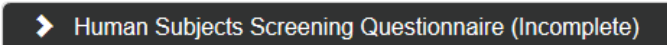

A dark grey horizontal bar containing a checked checkbox, a right-pointing arrow, and the text "Biochemistry Researche Study Personnel".



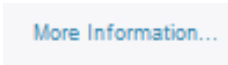

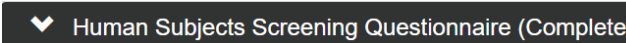
If you find that you have added a team member in error, simply click the checkbox on the section header, and then click the Delete Selected button at the bottom of the page.

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. 

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.

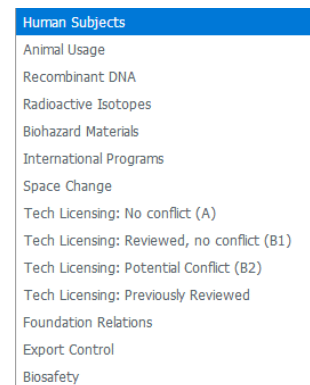
All Special Review Types are determined by your institution.

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.

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




- 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.

- 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.

- 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.

- 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.

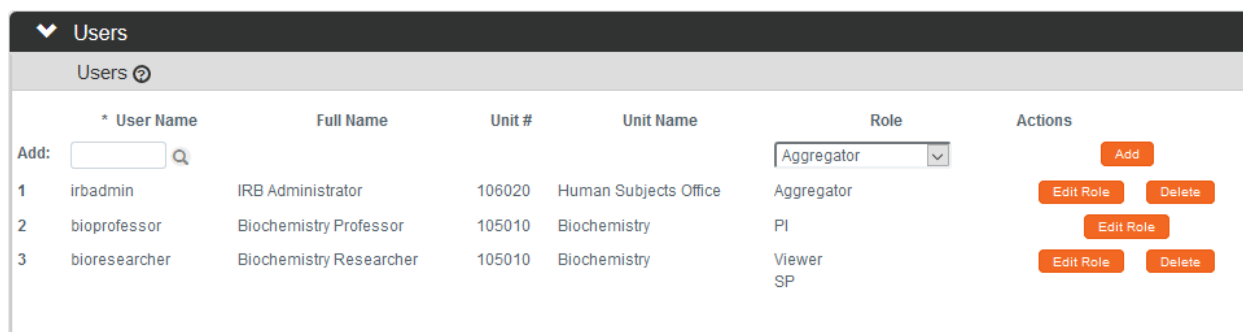
Note Only fields marked with an asterisk (*) are required.







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).

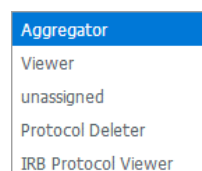
An Initiator or IRB Administrator can also grant access to ad hoc users who might not normally have access to protocol documents. This is especially useful to a researcher who would like to turn over Aggregating (editing) Rights to a coworker in an administrative support role. This feature is also commonly 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	
1	irbadmin	IRB Administrator	106020	Human Subjects Office	Aggregator	 
2	bioprofessor	Biochemistry Professor	105010	Biochemistry	PI	
3	bioresearcher	Biochemistry Researcher	105010	Biochemistry	Viewer SP	 

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



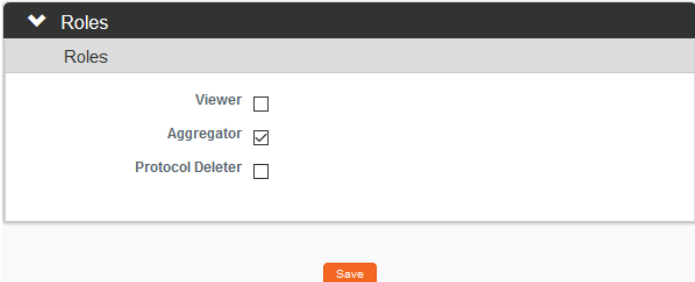
Aggregator
Viewer
unassigned
Protocol Deleter
IRB Protocol Viewer

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.

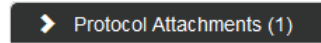
Adding Notes & Attachments

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.

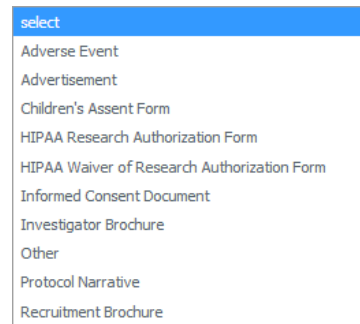


- To upload an attachment, click on the Protocol Attachments header to expand the section.

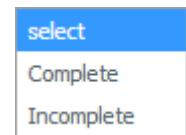


To add a Note only, skip to Step 11.

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

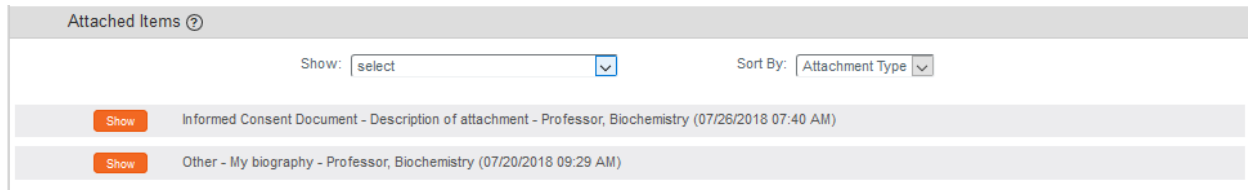



- Click the arrow next to the **Status** field to select the current status of the Attachment.






- Enter freeform text in the **Description** field to describe the attachment if necessary.
- Enter information in the remaining **Email, Contact Name, Phone** and **Comments** fields if needed.
- 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.
- Click the add button.
- 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.

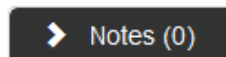


10. If you wish to view or update an attachment, click the Show button. 

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

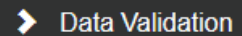
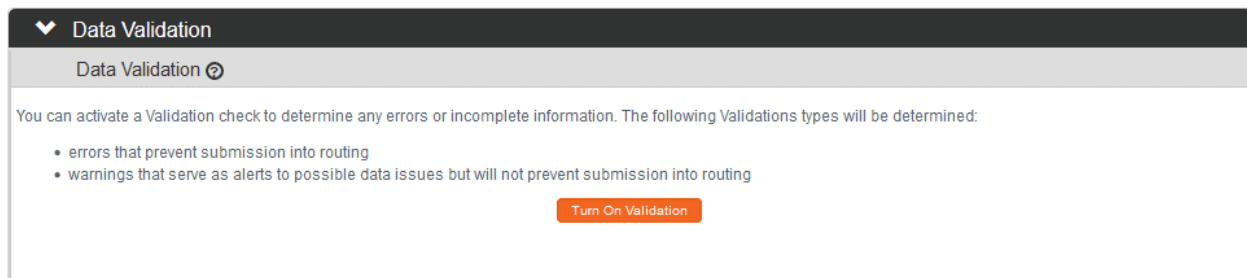
When a new protocol is complete, the Request an Action options available on the Protocol Actions tab include submitting the protocol for review or deleting the protocol. Data Validation is also available. These processes are defined in this section. A complete list of all available protocol actions is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

Validating the Protocol

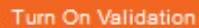
1. Click the tab header to access the Protocol Actions tab.

An orange rectangular button with the text "Protocol Actions" in white.

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

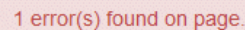
A dark grey header with a white right-pointing arrow and the text "Data Validation" in white.

3. Click the Turn On Validation button.

An orange rectangular button with the text "Turn On Validation" in white.

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.

A light red rectangular message box with the text "1 error(s) found on page." and a small red 'x' icon in the top right corner.

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

An orange rectangular button with the text "Fix" in white.

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.

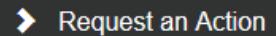
Submitting the Protocol Document to the IRB

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.

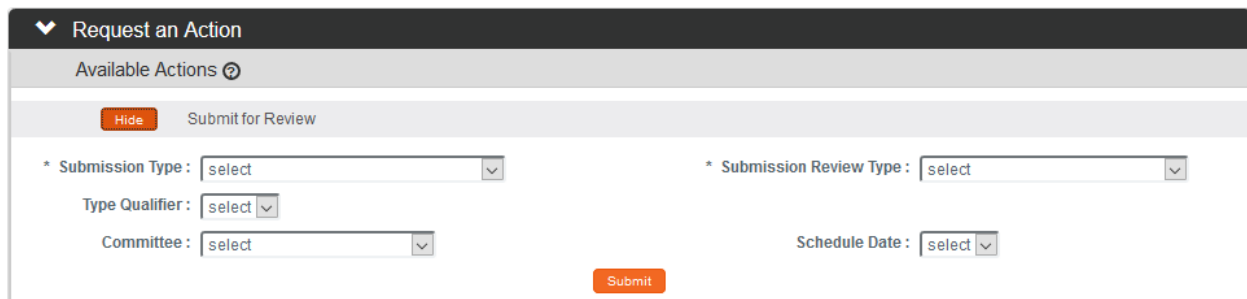
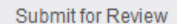
1. Click on the tab header to access the Protocol Actions tab.



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.



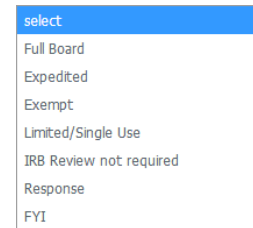
The screenshot shows a web interface for 'Request an Action'. Under the 'Available Actions' section, the 'Submit for Review' option is expanded. It contains several dropdown menus: 'Submission Type', 'Submission Review Type', 'Type Qualifier', 'Committee', and 'Schedule Date'. A 'Submit' button is located at the bottom of this section.

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.

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



select
Full Board
Expedited
Exempt
Limited/Single Use
IRB Review not required
Response
FYI

6. 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.

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

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.

9. 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](#).

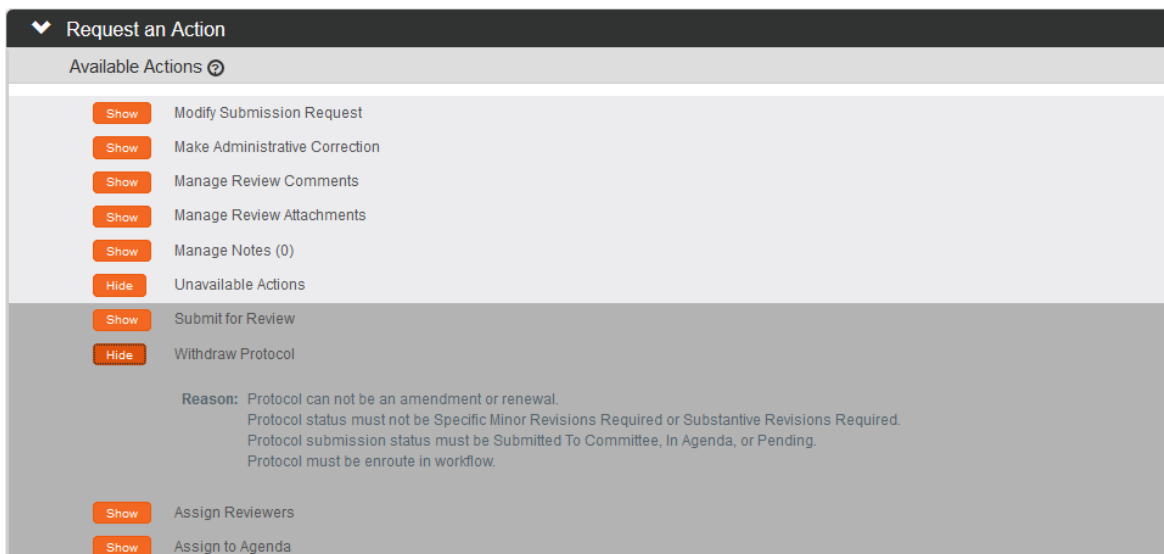
Available Actions

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.

Protocol Actions

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

Recall

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

* Please enter the reason below:

Yes

Return 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.

Yes

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 screenshot shows a user interface for withdrawing a protocol. At the top, there is a tab labeled "Protocol Actions" in an orange box. Below it, a dark grey button with a right-pointing arrow and the text "Request an Action" is visible. Underneath, a light grey bar contains a "Show" button in an orange box and the text "Withdraw Protocol". Below this bar, there is a "Hide" button in an orange box and the text "Withdraw Protocol". The main area features a text input field labeled "Withdrawal Reason :". To the right of the input field is a small yellow pencil icon. Below the input field is a "Submit" button in an orange box.

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.

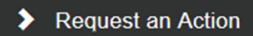
Deleting a Protocol

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.

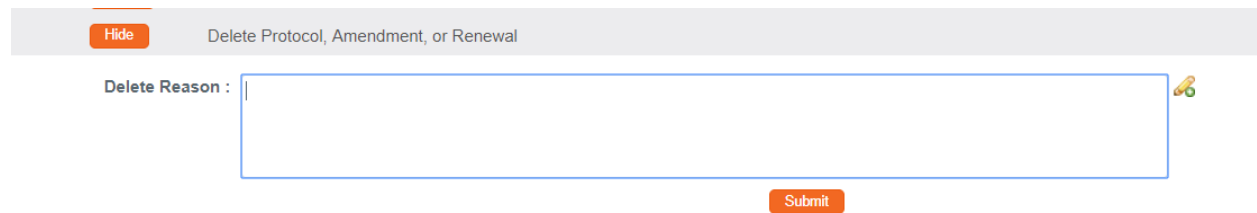
1. Within the Protocol, click on the tab header to access the Protocol Actions tab.



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



3. Click the Show button next to Delete Protocol, Amendment, or Renewal.



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.


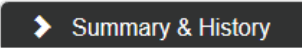
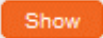
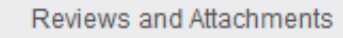
6. Return to the body of the FYI Notification and click the hyperlinked protocol number to open the document.

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:


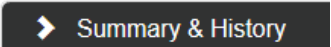
1. Click on the header to access the Protocol Actions tab. 
2. Click on the header to access the Summary & History section. 
3. Click on the Show button to expand the Reviews and Attachments section.  
4. Read through the comments to understand the kinds of changes that are required to the resubmit the 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.	irbadmin	07/23/2018 01:37 PM	
Show Correspondences (1)						
<input type="radio"/> Record Committee Decision	07/23/2018 01:27 PM	07/23/2018		irbadmin	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.	irbadmin	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.
2. Click on the header to access the Request an Action section.
3. Click on the Show button next to the Submit for Review subsection.

Protocol Actions

Request an Action

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

Hide Amendment Details

* Summary: test

* Amend:

- General Info
- Funding Source
- Protocol References & Other Identifiers
- Protocol Organizations
- Subjects
- Questionnaire
- Add/Modify Notes & Attachments
- Areas of Research
- Special Review
- Protocol Personnel
- 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.

Show Compare to Previous Sequence

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:

Show Amendment/Renewal History

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

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.

Hide Modify Amendment Sections

* Amendment Summary : Description of amendment.

*Amend:

- General Info
- Add/Modify Notes & Attachments
- Funding Source
- Areas of Research
- Protocol References & Other Identifiers
- Special Review
- Protocol Organizations
- Protocol Personnel
- Subjects
- Others
- Questionnaire


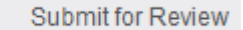
update

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.

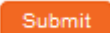
Note Your institution may have chosen to configure an Amendment Questionnaire – or a series of interview questions displayed only for amendments. If so, you **MUST** complete this questionnaire before submitting the document.

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.  

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. 

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.


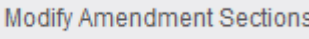
3. Click the Show button next to Create Renewal with Amendment.


Show

Create Renewal with Amendment

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.


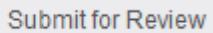
7. If you would like to re-select the boxes to be able to edit further sections, navigate back to Protocol Actions > Request an Action > Available Actions.
8. Click the Show button next to Modify Amendment Sections.  

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.

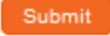
Note Your institution may have chosen to configure an Amendment Questionnaire, a Renewal Questionnaire, or both. If so, you will need to complete these questionnaires before submitting the document.

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 style="width: 100%;" type="text"/>	<input style="background-color: #f4a460; color: white; padding: 2px 5px; border-radius: 3px;" type="button" value="add"/>

4. 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.

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

6. In the **Comment** field, enter freeform text regarding the reason for the notification.

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.

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

11. 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


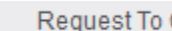
Your institution may require PI's to formally close protocols once the research is complete, is no longer being executed, or the PI is transferring to a different institution.

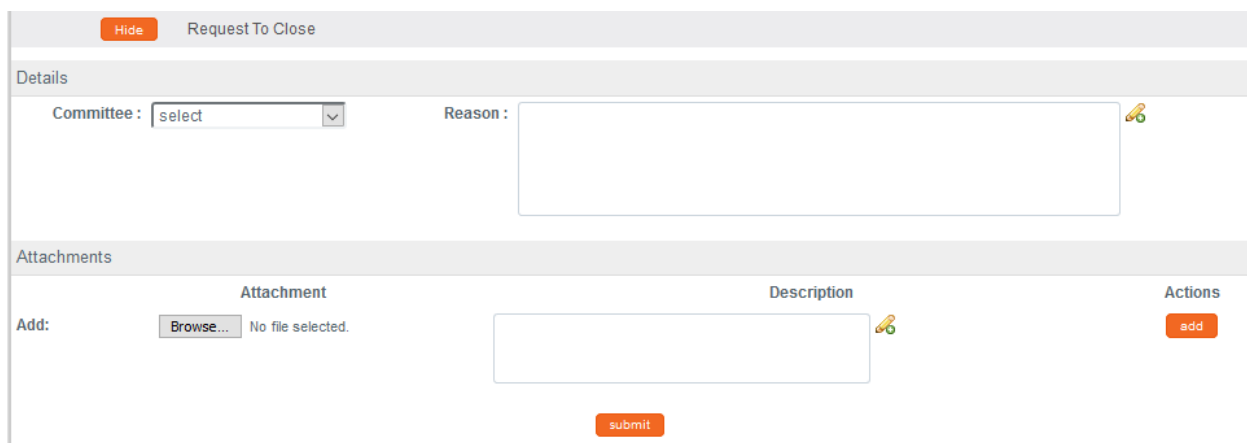
Navigation

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.  



The screenshot shows a web form titled "Request To Close". At the top left, there is a "Hide" button. Below the title is a "Details" section with a "Committee:" dropdown menu (currently showing "select") and a "Reason:" text area with a pencil icon. Below this is an "Attachments" section with a table header: "Attachment", "Description", and "Actions". Under "Attachment", there is a "Browse..." button and the text "No file selected.". Under "Description", there is a text area with a pencil icon. Under "Actions", there is an "add" button. At the bottom center of the form is a "submit" button.

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.

Show Request for Suspension

Hide Request for Suspension

Details

Committee : select Reason :

Attachments

Attachment	Description	Actions
Add: Browse... No file selected.		add

submit

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. add

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

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

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

Request to Close Enrollment

Hide

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 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

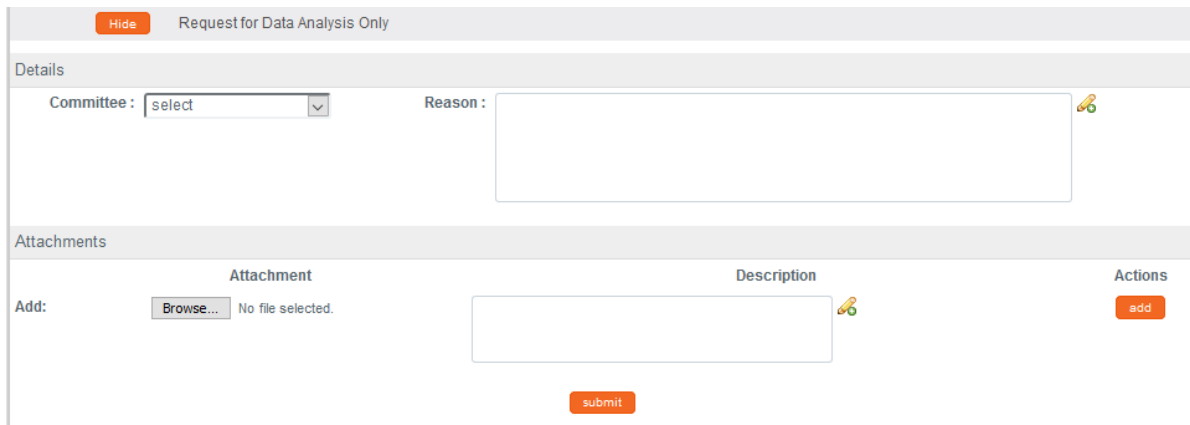
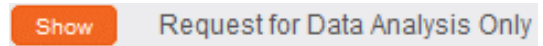
Main Menu > IRB > IRB Lookups > All My Protocols

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.

III: For Departmental Reviewers & Approvers

Based on your institution's specific Policies & Procedures, Principal Investigators, Department Chairs, College Deans, administrators, or other institutional officials may be required to approve IRB protocols and IRB-related requests in a hierarchy prior to final submission to the IRB. To facilitate this process, Streamlyne Research routes submitted protocol documents and requests to the appropriate Action Lists of those specified in your institution's IRB workflow configuration for review and approval.

A typical approval progression might route a protocol from the Department Administrator to the PI, the Department Chair, and perhaps even to the Dean before an IRB Administrator will take action on the protocol. Amendments, renewals, and IRB requests could follow the same workflow route or it may be different, depending on your institution's internal business practices. The steps to complete a review and approval in workflow remain the same regardless of the submission type.

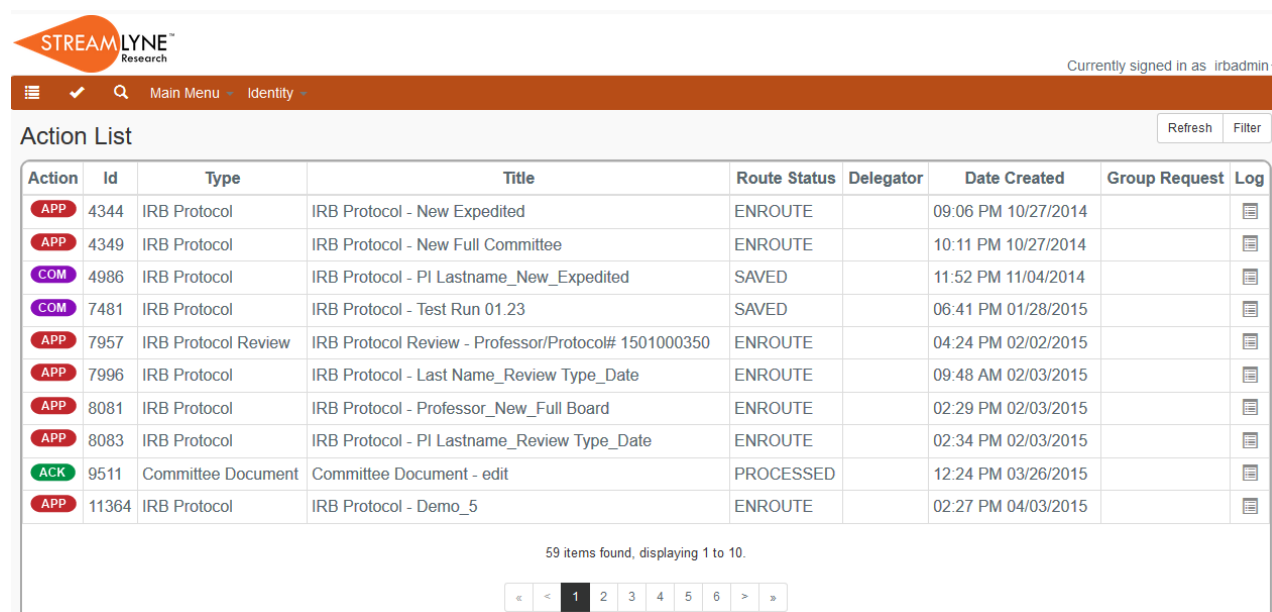
Departmental reviews are configurable and optional. If your institution has chosen to route submitted protocols through Chairs and Deans, follow the steps included in this section to complete those reviews.

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Reviewing and Approving Protocols in Workflow

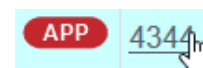
This section will describe the steps to review and approve an IRB protocol for departmental and other institutional reviewers and approvers. These users will typically have read-only access to the protocol to enable them to review the information before taking approval action.



Action	Id	Type	Title	Route Status	Delegator	Date Created	Group Request	Log
APP	4344	IRB Protocol	IRB Protocol - New Expedited	ENROUTE		09:06 PM 10/27/2014		
APP	4349	IRB Protocol	IRB Protocol - New Full Committee	ENROUTE		10:11 PM 10/27/2014		
COM	4986	IRB Protocol	IRB Protocol - PI Lastname_New_Expedited	SAVED		11:52 PM 11/04/2014		
COM	7481	IRB Protocol	IRB Protocol - Test Run 01.23	SAVED		06:41 PM 01/28/2015		
APP	7957	IRB Protocol Review	IRB Protocol Review - Professor/Protocol# 1501000350	ENROUTE		04:24 PM 02/02/2015		
APP	7996	IRB Protocol	IRB Protocol - Last Name_Review Type_Date	ENROUTE		09:48 AM 02/03/2015		
APP	8081	IRB Protocol	IRB Protocol - Professor_New_Full Board	ENROUTE		02:29 PM 02/03/2015		
APP	8083	IRB Protocol	IRB Protocol - PI Lastname_Review Type_Date	ENROUTE		02:34 PM 02/03/2015		
ACK	9511	Committee Document	Committee Document - edit	PROCESSED		12:24 PM 03/26/2015		
APP	11364	IRB Protocol	IRB Protocol - Demo_5	ENROUTE		02:27 PM 04/03/2015		

1. Access your Action List by clicking the Action List button  on the Menu Bar.

2. Documents currently requiring your approval will be noted with the Approval symbol in the Action column.



Click the hyperlinked Document ID number in the Id column to open the document in a new browser tab


3. Drill into as many tabs and sections as necessary to fully review the document according to your institution's procedures. You may want to familiarize yourself with protocol documents and how a PI initiates and submits a new protocol, amendment, renewal or request by referencing the [FOR PRINCIPAL INVESTIGATORS](#) section.

4. When you are ready to execute an action, click the Protocol Actions tab.

Protocol Actions



5. If you wish to approve the protocol, click the Approve button located at the bottom of the page. Otherwise, skip to the next Step. 

Result If you have selected Approve, the document will be routed to the next user in the workflow.


6. If you wish to disapprove the protocol, click the Disapprove button located at the bottom of the page. 

Are you sure you want to **disapprove** this document?


* Please enter the reason below:


 

7. If you are sure you want to disapprove the protocol, enter explanatory comments in the field provided and continue to the next Step. Otherwise skip to Step 9.

8. Click the Yes button to Disapprove this document. 

Result Once the Disapprove action is complete, the Submission Status will update to Rejected in Routing.

9. Click the No button to return to the protocol without disapproving. 

10. If you are now ready to approve the protocol, click the Approve button located at the bottom of the page. 

Result If you have selected Approve, the document will be routed to the next user in the workflow.

Printing a Protocol Document for Review

This section describes the steps to print a protocol document. Though you may print a protocol at any time, reviewers frequently choose to print a protocol document at this point to facilitate easier reading, or to file a hardcopy according to departmental processes.

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

Protocol Actions

Print

2. Click on the header to expand the Print section.

Show

Protocol Details

3. Click the Show button next to the Protocol Details subsection.

The screenshot shows a 'Print' window with a 'Print' icon and a 'Print' label. Below this is a 'Hide' button and the text 'Protocol Details'. The main content area is titled 'Protocol Summary' and contains a grid of checkboxes for various document sections. Under 'Questionnaires', there are two checkboxes: 'New IRB Protocol' and 'IRB Screening Questionnaire (Optional)'. At the bottom of the window, there are three buttons: 'Print Selected', 'Select All', and 'Select None'.

Section	Item	Checked
Protocol Summary	Document Overview	<input checked="" type="checkbox"/>
	References	<input checked="" type="checkbox"/>
	Subjects	<input checked="" type="checkbox"/>
	Correspondents	<input checked="" type="checkbox"/>
	Protocol Roles	<input checked="" type="checkbox"/>
	Review Comments	<input checked="" type="checkbox"/>
	Protocol Details	<input checked="" type="checkbox"/>
	Organization	<input checked="" type="checkbox"/>
	Investigator	<input checked="" type="checkbox"/>
	Other Data	<input checked="" type="checkbox"/>
Questionnaires	New IRB Protocol	<input checked="" type="checkbox"/>
	IRB Screening Questionnaire (Optional)	<input checked="" type="checkbox"/>
	Area of Research	<input checked="" type="checkbox"/>
	Funding Source	<input checked="" type="checkbox"/>
	Study Personnel	<input checked="" type="checkbox"/>
	Special Review	<input checked="" type="checkbox"/>
	Action History	<input checked="" type="checkbox"/>

4. Indicate which sections you would like to print by checking or unchecking the boxes next to the names of the document subsections.

5. Click the Print Selected button.

Print Selected

6. Streamlyne Research will generate a PDF of the selected protocol sections. Follow your browser's prompts to open, save, or print this document.

7. To print additional sections of the protocol document, repeat Steps 3 through 5 for the Attachments, Questionnaires and/or Correspondences subsections.

IV: For IRB Committee Members

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

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Completing IRB Committee Reviews

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

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

Completing an Assigned Online Review

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

APP	32329 IRB Protocol Review	IRB Protocol Review - Professor/Protocol# 1807003125	ENROUTE	01:43 PM 07/20/2018
-----	---	---	---------	------------------------

1. From the Action List, access the item by clicking the hyperlinked Id.

Result Streamlyne Research automatically opens to the Online Review tab.

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

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

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

This field is required for saving.

- select
- Substantive Revisions Required
- Specific Minor Revisions
- Approve
- Expedited Approval
- Grant Exemption
- Close Administratively
- Terminate
- Disapprove

Review Comments					
Standard Comment	Description	Private	Final		
Add	20	The language of the informed consent should invite rather than assume participation.	<input type="checkbox"/>	<input type="checkbox"/>	Add

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

6. Click the Add button to register your comments.

Review Attachment				
Description	File Name	Private		
Add		<input type="button" value="Browse..."/> No file selected.	<input type="checkbox"/>	Add

7. The Review Attachments subsection is optional.

If you chose to put your extended comments in an attachment, include this document by clicking the Browse button and following your operating system's uploading instructions.

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

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

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

Viewing Previous Review Information

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


Quick Steps:






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


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

Preparing for Committee Meetings

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

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

Action	Id	Type	Title	Route Status	Delegator	Date Created	Group Request	Actions	Log
 	32410	Streamlyne Research Notification	Agenda created for committee Full Board IRB Committee	FINAL		10:07 AM 07/23/2018		NONE  	
<p>Id: 3487 From: irbadmin Recipients: bioresearcher , medicinechair , researchdean , reviewer1 , reviewer2 Channel: Notification Channel Producer: Notification System Type: FYI Priority: Normal Send Date: 2018-07-23T10:07:27.000-07:00 Removal Date: none</p> <p>Title: Agenda created for committee Full Board IRB Committee</p> <p>Content:</p> <p>An Agenda has been created for committee Schedule meeting on 2018-08-03. Click here for a printable version of the agenda.</p> <p></p>									

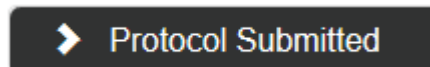
3. If you wish to view the Meeting page, click on the Schedule meeting on YYYY-MM-DD hyperlink. 

Otherwise skip to Step 7.

Result The Meeting page will open.

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

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



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



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

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

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

7. If you wish to view the the PDF Agenda, click on the here hyperlink from the Action List page.

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

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

V: For IRB Administrators

The fifth section of this manual provides targeted content for IRB Administrators. This section contains step-by-step processes for creating and assigning Online Reviews, for returning protocols for revisions, for maintaining review comments, for administering correspondences, and for creating and maintaining everything related to IRB Committees and their meetings.

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Administering an IRB Protocol

Streamlyne Research provides robust administrative functionality to support the protocol's path through the administrative and IRB committee review process. Generally, a user would not use these administrative features until after all departmental and institutional approvals were in place. Such a user would need the IRB Administrator role assigned to their profile to take advantage of these features.

Review this section to understand the most commonly used administrative features, called Actions, available within the IRB Protocol module. A complete list of all available protocol actions is available in [Appendix C: All Protocol Actions](#).

Accessing an Existing IRB Protocol


Using the Action List

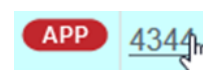
If you are an IRB Administrator, all open protocol documents can be found on your Action List.

Action	Id	Type	Title	Route Status	Delegator	Date Created	Group Request	Log
APP	4344	IRB Protocol	IRB Protocol - New Expedited	ENROUTE		09:06 PM 10/27/2014		
APP	4349	IRB Protocol	IRB Protocol - New Full Committee	ENROUTE		10:11 PM 10/27/2014		
COM	4986	IRB Protocol	IRB Protocol - PI Lastname_New_Expedited	SAVED		11:52 PM 11/04/2014		
COM	7481	IRB Protocol	IRB Protocol - Test Run 01.23	SAVED		06:41 PM 01/28/2015		
APP	7957	IRB Protocol Review	IRB Protocol Review - Professor/Protocol# 1501000350	ENROUTE		04:24 PM 02/02/2015		
APP	7996	IRB Protocol	IRB Protocol - Last Name_Review Type_Date	ENROUTE		09:48 AM 02/03/2015		
APP	8081	IRB Protocol	IRB Protocol - Professor_New_Full Board	ENROUTE		02:29 PM 02/03/2015		
APP	8083	IRB Protocol	IRB Protocol - PI Lastname_Review Type_Date	ENROUTE		02:34 PM 02/03/2015		
ACK	9511	Committee Document	Committee Document - edit	PROCESSED		12:24 PM 03/26/2015		
APP	11364	IRB Protocol	IRB Protocol - Demo_5	ENROUTE		02:27 PM 04/03/2015		

59 items found, displaying 1 to 10.

« 1 2 3 4 5 6 »

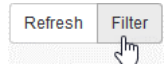
1. Access your Action List by clicking the Action List button  on the Menu Bar.
2. Access the document you wish to review by clicking the hyperlinked Document ID number in the Id column.



Using the Action List Filter

You can use the Action List Filter function to narrow down the number of documents you see on your Action List based on a variety of filter criteria.

1. Click the Filter button at the top right-hand corner of the Action List to access the Action List Filter.



Action List Filter

Parameters	
Document Title	<input type="text"/> <input type="checkbox"/> Exclude?
Document Route Status	<input type="text" value="All"/> <input type="checkbox"/> Exclude?
Action Requested	<input type="text" value="All"/> <input type="checkbox"/> Exclude?
Action Requested Group	<input type="text" value="No Filtering"/> <input type="checkbox"/> Exclude?
Document Type	<input type="text"/> <input type="checkbox"/> Exclude?
Date Created	from: <input type="text"/> <input type="text"/> to: <input type="text"/> <input type="text"/> <input type="checkbox"/> Exclude?
Date Last Assigned	from: <input type="text"/> <input type="text"/> to: <input type="text"/> <input type="text"/> <input type="checkbox"/> Exclude?

2. Streamlyne Research will display search criteria available to narrow your Action List results.
3. Enter the criteria by which you would like the Action List to filter and click the Filter button.



Using the Protocol Lookup Function

You can access an existing protocol from a variety of predefined search lookups. The lookups offered will vary depending on the roles assigned to you. For more information on these lookups, see [Searching with IRB Lookups](#).

1. Access the Protocol Lookups by navigating to Main Menu > IRB > IRB Lookups and choose the appropriate Lookup for your current search. The example below is for Protocol Submissions.

Protocol Submission Lookup

Protocol #:

Submission Type:

Submission Date From:

Title:

Schedule Date To:

Committee Id:

Sequence Number:

Submission Status:

Submission Date To:

Schedule Date From:

Sub. Review Type:

2. This page will allow you to search for a protocol document by such data elements as **Submission Type**, **Submission Status**, assigned **Committee**, or range of **Dates** during which the review may be scheduled.

Enter the relevant criteria, and then click the Search button .

Result Streamlyne Research will display all the documents that meet your criteria.

3. Click the edit hyperlink next to the protocol you wish to access.

Executing Administrative Protocol Actions

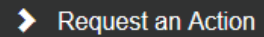
There are approximately 48 administrative actions that are conditionally available, depending on where the protocol document is in its lifecycle and which actions were performed along the way. This section will address the most commonly used actions: Modify Submission Request, Make Administrative Correction, and Return to PI. Many of these actions are called different things but require similar steps within the system. A complete listing of all actions is contained in [Appendix C: All Protocol Actions](#). It may be helpful to review this section before proceeding.

All subsequent processes detailed in this section will begin from the Protocol Actions tab. Click on the tab header on the left-hand side of the page to access the Protocol Actions tab.

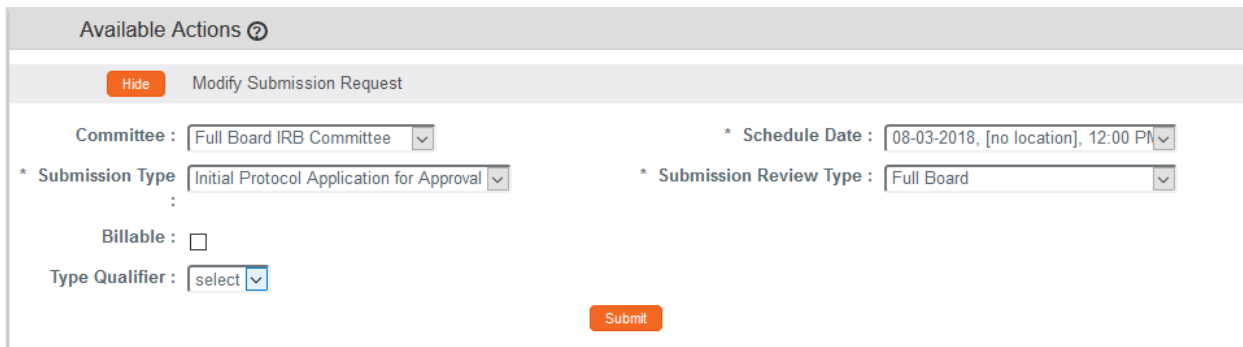
Assigning an IRB Committee and Meeting Date

The Modify Submission Request action is used to allow the IRB Administrator to assign a committee (for Full Board and Expedited protocols) and a schedule date, as well as to correct the Submission Review Type if needed. Assigning a committee and choosing a schedule date is a prerequisite to most other administrative functions that are available with the exception of Exempt protocols.

1. From the Protocol Actions tab, click the section header to expand the Request an Action section. In some cases, this section may appear expanded by default.



2. Click the Show button next to the Modify Submission Request action.

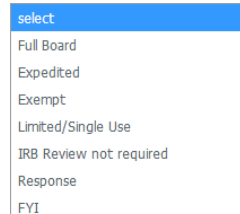


3. Click the arrow next to the **Committee** field to select the committee that will review the document. This can be changed by the IRB Administrator in the future if the committee changes.
4. Click the arrow next to the **Schedule Date** field to select a tentative date for the anticipated board meeting during which the protocol will be reviewed.

This date can be changed.

Note If a protocol is on an agenda but being deferred, refer to [Deferring a Protocol](#).

5. Click the arrow next to the **Submission Review Type** to change the Submission Review Type if necessary.



6. If you changed the **Submission Review Type** to Expedited or Exempt in Step 5, Streamlyne Research will present pre-defined checklists, also known as Categories. In addition, if the incorrect categories were selected, you may edit them now.

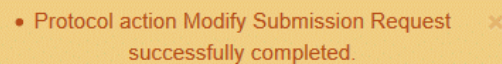
Identify the research categories that apply to the Expedited or Exempt protocol by clicking the corresponding checkbox next to the best-matching explanation.

Continue to the next step if this does not apply to your document.

7. Click the Submit button.



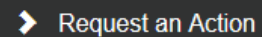
Result Streamlyne Research will display a message at the top of the page to let you know your action completed as expected. The document's Submission Status will update to Submitted to Committee.



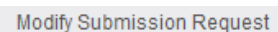
Determining an IRB Review is not Required

This action is reserved for instances where a protocol has been submitted but does not qualify as human subjects research or if further review is otherwise not required. This determination may be made by the IRB Administrator

1. From the Protocol Actions tab, click the section header to expand the Request an Action section. In some cases, this section may appear expanded by default.



2. Click the Show button next to the Modify Submission Request action.



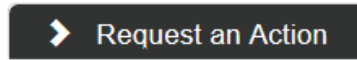
3. Click the arrow next to the **Submission Review Type** field to select IRB Review not required.

Making Administrative Corrections

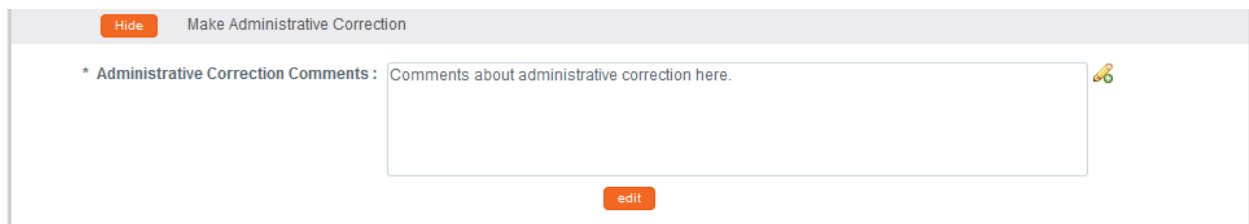
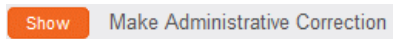
Streamlyne Research allows the IRB Administrator to make corrections to the protocol document. Ideally, these changes would correct problems that are typographical or procedural in nature and not material to the scientific details or research design. Changes related to science or design should always be left to the Principal Investigator.


The Administrative Correction action becomes available for use once the Document Status is Submitted to IRB.

1. From the Protocol Actions tab, click the section header to expand the Request an Action section. In some cases, this section may appear expanded by default.



2. Click the Show button next to the Make Administrative Correction action.



3. Enter a detailed description of the changes you wish to make into the **Administrative Correction Comments** field.
4. Click the edit button. 
5. Streamlyne Research will open all fields for editing. These fields will remain open for editing until the document is reloaded either by clicking the Reload button or by exiting and re-accessing the document.

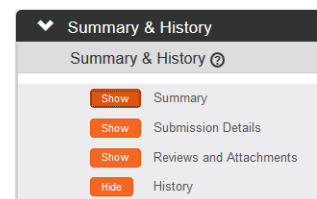
Click through the tabs and sections of the document and make any necessary changes.

6. Save your work by clicking the Save button.



Note This action is recorded in the Summary & History section of the Protocol Actions tab.

Click Show on the History subsection to review the audit trail for this protocol.



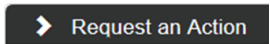
Returning the Protocol to the PI

To return a submitted protocol to the Principal Investigator so that they can make changes either in conjunction with (or in lieu of) an Administrative Correction action, use the Return to PI Action.

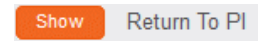
Like the Administrative Correction action, the Return to PI action may only be used prior to formal committee review. Typically, this action might be used as part of a pre-review or administrative process conducted by IRB Office staff members.

The Document Status must be Submitted to IRB and all departmental or institutional approvers must approve to use the Return to PI function.

1. From the Protocol Actions tab, click the section header to expand the Request an Action section. In some cases, this section may appear expanded by default.



2. Click the Show button next to the Return to PI action.

A screenshot of a web form for returning a protocol to the PI. It features a large text area for "Comments" with a placeholder "Comments about why this is returning to the PI." and a small icon. Below is an "Action Date" field with a calendar icon and the date "07/20/2018". At the bottom, there are three buttons: "Show", "Review Comments", and "Submit".

3. Enter a detailed description in the **Comments** field to explain the changes required.
4. Click the Submit button to return the protocol to the PI.
5. Depending on your institution's configuration, Streamlyne Research may display the Notification Editor function.



If applicable, edit the Notification Recipients section using the Add and Delete buttons.

If the Notification Editor does not appear, proceed to Step 8.

Notification Editor

Notification Recipients

Add:

Role Search	Q	Add
Employee Search	Q	
Internal User Name Search	Q	

1	KC-PROTOCOL:PI	Delete
2	KC-PROTOCOL:SP	Delete
3	KC-PROTOCOL:CRC	Delete
4	KC-PROTOCOL:CA	Delete

Notification Message

Subject: Protocol Returned to PI Action

Message: The protocol number 1807003125 has had the action "Return to PI" performed on it.


Include Document Link

Send Cancel

6. If desired, update the Notification Message section with a detailed description of the changes required for the protocol to be considered or any other information that you would like to convey to the PI.





7. Click the Send button. 

Result Streamlyne Research will reload the protocol and unlock the document for editing.

8. Click the Close button to ensure the document will be available for editing by the Principal Investigator. 

Note Upon completion of these steps, Streamlyne Research automatically performs the following actions:

- The Return to PI action is recorded in the audit trail listed in the Summary & History section of the document.
- The protocol's Document Status updates to Return to PI, and the Submission Status updates to Returned to PI.
- A COM action appears on the Action List of the Principal Investigator, alerting them of the need to make changes.
- An FYI Notification appears on the Action Lists of the recipients, including the Principal Investigator.

	Action	Id	Type	Title	Route Status	Delegator	Date Created	Group Request	Actions	Log
		32320	Streamlyne Research Notification	Protocol Returned to PI Action	FINAL		11:57 AM 07/20/2018		NONE 	

For more information on what the PI needs to do in order to edit the returned protocol, see [Editing a Returned Protocol](#).

Administering Online Reviews

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

Some institutions will assign a select number of IRB Members to review and comment on certain protocols prior to the committee meeting. To facilitate this function, Streamlyne Research makes a new Online Review tab available within these protocols for both reviewers and administrators. Once the IRB Administrator completes the Assign Reviewers action, the protocol becomes available to the selected committee Members. While each reviewer (committee member) can only access their own individual review from the Online Review tab, the IRB Administrator can access and manage all the assigned reviews through this same tab.

For IRB protocols that will not go on to a Full Board Committee Review, such as Exempt or Expedited protocols, this Online Review step is the point at which the committee members can render an official decision.

Additionally, an IRB Administrator can manage committee member reviews using the Accept, Return, or Delete Review Comments actions once reviews are complete. For more information, you may reference [Appendix C: All Protocol Actions](#).

Assigning Reviewers to a Protocol

Once the protocol has been assigned to a committee, the system makes the document available for the IRB Administrator to Assign Reviewers. Reviewers are members of the committee you selected when you assigned the protocol to a committee ([Assigning an IRB Committee and Meeting Date](#)).

1. From the Protocol Actions tab, click the Show button next to the Assign Reviewers action.


Show Assign Reviewers

The screenshot shows a user interface for assigning reviewers. At the top left, there is a 'Hide' button and the title 'Assign Reviewers'. Below this is a table with two columns of reviewer information. Each row contains a reviewer's name and a dropdown menu for their role. At the bottom center of the table is a 'Submit' button.

Reviewer Name	Role	Reviewer Name	Role
Rachel Reviewer	secondary	Research A Dean	secondary
Randy Reviewer	secondary	Biochemistry Researcher	secondary
Medicine Chair	primary		

Result Streamlyne Research will display the names of members of the Committee assigned to the protocol. For more information on assigning users to Committees, refer to [Creating a New Committee](#).


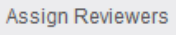
2. Assign one or more reviewers by clicking the arrow next to each **Name** field and indicating whether the committee member is a primary or secondary reviewer.

3. Click the Submit button to complete the action. 

Result The newly assigned protocol will now appear on the Action Lists of the assigned reviewers. [Completing an Assigned Online Review](#) contains information on how they will complete this kind of review.

Deleting Reviewers from a Protocol

If the reviewer assigned by the IRB Administrator is determined to be not appropriate or is not available to complete the review for any reason, the IRB Administrator can delete the reviewer from the protocol. This action can be taken on either the Protocol Actions tab or the Online Review tab. This action cannot be taken after a reviewer has submitted their review.

1. From the Protocol Actions tab, click the Show button next to the Assign Reviewers action.  

2. Click the dropdown next to the name of each Reviewer you wish to delete and change to Select.

3. Click the Submit button.

Result The Reviewer will receive a notification indicating that they are no longer assigned to the review and this action will also be logged in the Reviews and Attachments section within the Summary & History section of Protocol Actions for audit purposes.

Reviews and Attachments				
Reviewers				
Sequence	Reviewer	Reviewer Type	Determination Recommendation	Due Date
1	Lead Professor (Deleted)	primary		03/06/2018

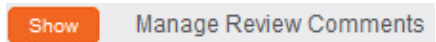
Managing Review Comments & Attachments


The IRB Administrator has access to add, update, restrict, and finalize comments and attachments using the actions described in this section. These comments and attachments can be added at various times during the review process:

- During pre-review by the IRB Office staff
- By online reviewers once they have been assigned
- By an administrator during the committee review process.

Managing review comments can be done in the Manage Review Comments section of the Protocol Actions tab or in the Online Review tab prior to approving a review.

1. Click the Show button next to the Manage Review Comments action.



2. If you need to enter a new comment, you may either type a freeform entry into the **Comments** field or click the magnifying glass  to search for a standardized value.

The lookup will allow you to search for and select **Standard Protocol Contingency Code/Description**.




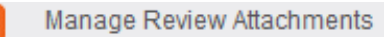
3. If applicable, mark the comment as Private by clicking the checkbox.



The private flag on a review comment indicates that protocol personnel will not be able to view the comment. By default, all reviewer entered comments will have the Private flag checked. The IRB Administrator can override the private flag setting on a review comment. Click within the checkbox to select the item. A check mark appears within the checkbox to indicate the item is selected. Click within the checkbox again to clear the mark and deselect the item.



4. If applicable, mark the comment as Final by clicking the checkbox.
- | Private | Final |
|--------------------------|-------------------------------------|
| <input type="checkbox"/> | <input checked="" type="checkbox"/> |
- The final flag on a review comment indicates that the IRB Administrator has processed the comment and it can appear on all official communication related to the protocol if it is a non-private comment. By default all reviewer entered comments are marked as non-Final. The IRB Administrator can override the final flag setting on a review comment. Click within the checkbox to select the item. A check mark appears within the checkbox to indicate the item is selected. Click within the checkbox again to clear the mark and deselect the item.

Note See the [Review Comment Matrix](#) for information about how the Private and Final checkboxes affect the view of each type of user.

5. Click the Add button to finalize the comment. 
6. Update or edit any existing comments, including updating the **Private** and **Final** checkboxes where necessary.
- Otherwise, skip to Step 8.
7. If you chose to edit or update an existing comment, click the Submit button to save those changes. 
8. Click the Show button next to the Manage Review Attachments action.  
9. If you need to attach a new document, summarize the purpose of the document in the **Description** field.
- Otherwise, skip to Step 13.
10. If applicable, indicate that the attachment should be private by clicking the **Private** checkbox.
- When you check the private flag on an attachment, the study team will not be able to view the attachment or the Description. The IRB Administrator can override the private flag setting on a review attachment.

11. Upload a new attachment by clicking the Browse button and following your operating system's prompts.
12. Click the Add button to complete the upload. 
13. If you need to make changes to the content of an attachment, access the document from your institution's network, make changes to the original, and upload a new copy using Steps 9 through 12.
14. If you need to update a **Description** or a **Private** flag for an existing entry, make your changes now.
15. If you made changes to an existing entry in the previous step, click the Submit button to register those changes to the database. 

Result Reviewer information and comments are stored in the Summary & History section > Reviews and Attachments. This allows for a historical review of previous comments, as well as a place to view statuses and determinations for all reviewers assigned to the protocol.

REVIEW COMMENT MATRIX

You will be able to view comments when your role is...	And the Comments are marked...			
	Final Not Private	Final Private	Not Final Not Private	Not Final Private
IRB Administrators	YES	YES	YES	YES
Assigned Reviewer	YES	YES	YES	YES
Other Reviewers	YES	YES	YES	NO
Active Committee Members	YES	YES	NO	NO
PI	YES	NO	NO	NO

Returning and Accepting Review Comments

After an assigned reviewer has completed and approved their review of the comments, the IRB Administrator will receive an FYI notification indicating that the review is complete. In addition, the APP button for that particular review will remain on the IRB Administrator's Action List until

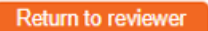
they accept the review to finalize it. This final step integrates the review comments into correspondences and official meeting minutes.

Take these steps to Return or Accept the assigned review.


1. Access the APP action for the assigned review from your Action List.

Result The protocol will open to the Online Review page.

2. Review comments and recommendations as needed.

If the review needs to be returned to the reviewer, click the Return to Reviewer button to send the review back to the assigned reviewer. 

Result The reviewer will receive another FYI notification and an APP action in their Action List directing them to review and re-approve their review but all review comments will remain intact as long as the IRB Administrator did not edit them before returning the review.

3. Once the online review is ready to be accepted (see section [Managing Review Comments & Attachments](#)), click the accept review comments button to finalize this review document. 

The IRB Administrator can access the full detail of all Assigned Reviews from the Online Review tab. From this page, the IRB Administrator can perform a variety of actions on the Online Review, such as:

- Submitting the review on behalf of the assigned reviewer
- Entering comments on behalf of the reviewer
- Accepting review comments
- Deleting the review
- Returning the review to the assigned reviewer for further changes
- Updating the private and/or final settings
- Viewing the history of review comments

Approving an Online Review

As each assigned reviewer completes his or her assigned review, the system aggregates the details of each completed review onto the IRB Administrator's Online Review tab within the protocol document.

An IRB Administrator will perform a review of these details after receiving an FYI Notification that a committee member has completed his or her Online Review. Follow the steps below to approve an Online Review.

Show	FYI	32373	Streamlyne Research Notification	Protocol 1807003125 Review Complete	FINAL	07:19 AM 07/23/2018
----------------------	------------	-------	----------------------------------	-------------------------------------	-------	------------------------

1. From the Action List, click the Show button next to the item. [Show](#)

2. Streamlyne Research displays a high-level document summary, as well as a message indicating that the Committee Member has completed his or her review. Click the hyperlinked Protocol Number to open the document.

Title: Protocol 1807003125 Review Complete
 Content:
 Researcher, Biochemistry has approved review comments for protocol [1807003125](#)

3. Click on the tab header to open the Online Review tab. [Online Review](#)

▼ Online Review: Randy Reviewer

[Show](#) Document Overview
[Hide](#) Online Review

Reviewer: Randy Reviewer Requested Date: 07/20/2018
 Status: FINAL Due Date: 08/03/2018
 * Determination Recommendation: Specific Minor Revisions Reviewer Type: secondary

[Hide](#) Review Comments

	Standard Comment	Description	Private	Final	
Add	(Select) 🔍	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	Add
1	20 🔍	The language of the informed consent should invite rather than assume participation.	<input type="checkbox"/>	<input type="checkbox"/>	Delete

Created by Randy Reviewer Updated By Randy Reviewer Last Updated 07/23/2018 06:33 AM

[Hide](#) Review Attachment

Description	File Name	Private	
<input type="text"/>	Browse... No file selected.	<input type="checkbox"/>	Add

[Hide](#) Protocol Review Actions

[save](#) [accept review comments](#) [Return to reviewer](#)

4. Review the content of the completed reviews.

As IRB Administrator you can edit the content. Doing so will mark the comments as Last Updated By which will include the name of the administrator who made the change.

5. If applicable, mark the comment as Private by clicking the checkbox.

Private	Final
<input checked="" type="checkbox"/>	<input type="checkbox"/>

The private flag on a review comment indicates that protocol personnel will not be able to view the comment. By default, all reviewer entered comments will have the Private flag checked. The IRB Administrator can override the private flag setting on a review comment. Click within the checkbox to select the item. A check mark appears within the checkbox to indicate the item is selected. Click within the checkbox again to clear the mark and deselect the item.

6. If applicable, mark the comment as Final by clicking the checkbox.

Private	Final
<input type="checkbox"/>	<input checked="" type="checkbox"/>

The final flag on a review comment indicates that the IRB Administrator has processed the comment and it can appear on all official communication related to the protocol if it is a non-private comment. By default all reviewer entered comments are marked as non-Final. The IRB Administrator can override the final flag setting on a review comment. Click within the checkbox to select the item. A check mark appears within the checkbox to indicate the item is selected. Click within the checkbox again to clear the mark and deselect the item.

Note See the [Review Comment Matrix](#) for information about how the Private and Final checkboxes affect the view of each type of user.

7. Render your decision by clicking one of the Action Buttons at the bottom of the page.

save	accept review comments	Return to reviewer
------	------------------------	--------------------

8. Repeat Steps 4 through 7 for each completed review.

Note This process is a prerequisite for actions used to enter a decision such as: Grant Exemption, Expedited Approval, Recording Committee Decision and Approve Protocol.

Revisions and Approvals for Exempt & Expedited Protocols

The manner in which Exempt and Expedited protocols are returned for revisions and approved differs from protocols that go through formal Committee Review. Use this section to learn how to record decisions for Exempt and Expedited protocols.

Returning a Protocol for Specific Minor Revisions

The Return for Specific Minor Revisions action should only be taken after the Online Reviews are completed by committee members and approved by the IRB Administrator. All review comments that are marked as Final will be included in the official correspondence that is generated for this action.

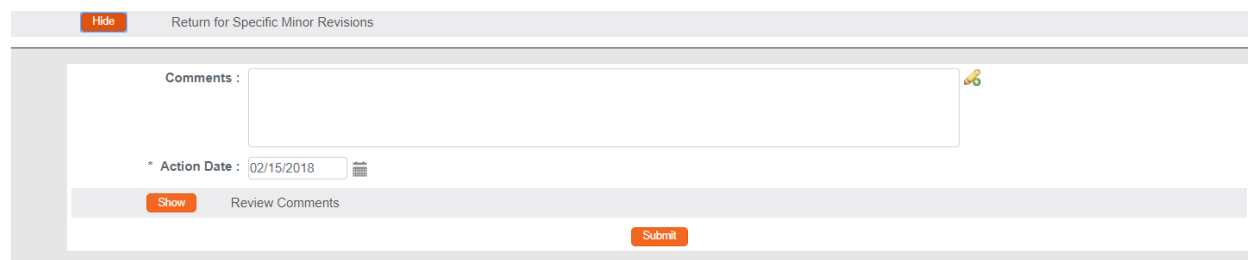
1. From the Protocol Actions tab, click the section header to expand the Request an Action section. In some cases, this section may appear expanded by default.

Request an Action

2. Click the Show button next to the Return for Specific Minor Revisions action.

Show

Return for Specific Minor Revisions



3. Enter detailed **Comments** in the freeform field provided. These are not official review comments, just administrative notes to be kept with this action, if needed.


4. Click the Show button next to the Review Comments action to view all official review comments.

Show

Review Comments

5. Ensure all review comments are marked appropriately. See [Managing Review Comments & Attachments](#) for more information on these settings.

Note Only comments marked as Final will be included on the official correspondence and viewable by the PI. See [Managing Review Comments & Attachments](#) for more information on these settings.

6. Click the Submit button to record the decision and send the protocol back for Specific Minor Revisions. 

Result Correspondence screen will open.

7. Review the Correspondence and mark the **Final** box once the correspondence is verified.

8. Click the Save button. 

Result Upon completion of this process, Streamlyne Research sends an FYI Notification to inform all interested parties that the protocol requires revisions as well as a Specific Minor Revisions Letter (Correspondence) with review comments and the protocol's Document Status updates to Specific Minor Revisions Required, and the Submission Status updates to Specific Minor Revisions Required.

Returning a Protocol for Substantive Revisions

The Return for Substantive Revisions action should only be taken after the Online Reviews are completed by committee members and approved by the IRB Administrator.

All review comments that are marked as Final will be included in the official correspondence that is generated for this action.

1. From the Protocol Actions tab, click the section header to expand the Request an Action section. In some cases, this section may appear expanded by default.

Request an Action

2. Click the Show button next to the Return for Substantive Revisions Required action.



Return for Substantive Revisions Required


Hide Return for Substantive Revisions Required

Comments :



* Action Date : 02/15/2018

Show Review Comments

Submit

3. Enter detailed **Comments** in the freeform field provided. These are not official review comments, just administrative notes to be kept with this action, if needed.
4. Click the Show button next to the Review Comments action to view all official review comments.  Review Comments
5. Ensure all review comments are marked appropriately. See [Managing Review Comments & Attachments](#) for more information on these settings.

Note Only comments marked as Final will be included on the official correspondence and viewable by the PI. See [Managing Review Comments & Attachments](#) for more information on these settings.

6. Click the Submit button to record the decision and send the protocol back for Substantive Revisions. 
7. Review the correspondence and check the Final box to finalize the communication.
8. Click the Save button. 

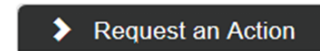
Result Upon completion of this process, Streamlyne Research sends an FYI Notification to inform all interested parties that the protocol requires revisions as well as a Substantive Revisions Letter (Correspondence) with review comments and the protocol's Document Status updates to Substantive Revisions Required, and the Submission Status updates to Substantive Revisions Requested.

Approving Expedited Protocols

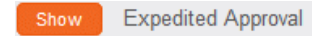
The Expedited Approval action should only be taken after the Online Reviews are completed by committee members and approved by the IRB Administrator.

Follow these steps to grant approval to an Expedited protocol.

1. From the Protocol Actions tab, click the section header to expand the Request an Action section. In some cases, this section may appear expanded by default.



2. Click the Show button next to the Expedited Approval action.

A screenshot of a web form titled "Expedited Approval" with a "Hide" button. The form contains several fields: "Approval Date" (07/24/2018), "Expiration Date" (07/23/2019), a "Comments" text area, "Include in an agenda?" (checked), "Committee" (IRB), "Schedule Date" (07-31-2018, [no location], 05:00 PM), and "Action Date" (07/24/2018). At the bottom, there are three buttons: "Show Enter Risk Level", "Show Review Comments", and "Submit".

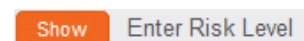
3. Streamlyne Research displays the Expedited Approval action window.

Note that the **Action Date** and the **Approval Date** default to today's date, and that the protocol's **Expiration Date** is set to the last day of a rolling calendar year that begins on the **Approval Date**.

These fields are editable. Should you need to alter these dates, do so by typing new values in MM/DD/YYYY format.

4. Enter detailed **Comments** in the freeform field provided.
5. Note that the **Include in an agenda?** checkbox defaults to checked, and that the **Committee** field is populated with the value identified in the Modify Submission Request step. Federal regulation requires all Expedited protocols be formally announced or a report provided at a Committee Meeting. Identify the meeting date on which this Expedited Approval will be announced or reported by clicking the arrows next to the **Schedule Date** field to select a value.

6. Click the Show button next to the Enter Risk Level action.



Hide Enter Risk Level

* Risk Level	* Date Assigned	Date Inactivated	* Status	Comments	Actions
Add: <input type="text" value="select"/>	<input type="text" value="07/24/2018"/>		active	<input type="text"/>	<input type="button" value="add"/>

- Click the arrow next to the **Risk Level** field, and then select a value from the dropdown list that best represents the study's risk to human subjects.

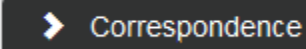
select

- Greater than minimal risk but potential for direct benefit for participant
- High Risk
- Moderate Risk
- No greater than minimal risk.
- Research involving greater than minimal risk, with no potential for benefit to participant, but likely to yield generalizable knowledge about the participant's condition

- Enter any pertinent information regarding this risk assessment into the **Comments** field.
- Click the add button to commit the risk assessment to the database.
- Click the Submit button to record the Expedited Approval.


Result A Correspondence section will appear with an Expedited Approval Letter available to View and finalize.

Correspondence			
Correspondence ?			
Protocol Number	Correspondence	Final	Action
1807003222	Expedited Approval Letter	<input type="checkbox"/>	<input type="button" value="View"/>

- Click the header to expand the Correspondence section. 
- Click the View button to review and/or save the correspondence as a PDF.
- Check the **Final** box to finalize the communication.
- Click the Save button.

Result Upon completion of this process, Streamlyne Research sends an FYI Notification to inform all interested parties that the protocol has been approved along with the official Approval Letter (Correspondence) and the protocol's Document Status updates to Active-Open to Enrollment, and the Submission Status updates to Approved.

15. Depending on your institution's configuration, you may see a Notification Editor screen allowing you to select additional recipients and edit the content of the notification.

Click the Send button to send the notification. 

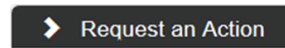
Granting an Exemption

Exemptions are granted to studies where the research poses no risk whatsoever to human subjects. In some cases, IRB protocols with Submission Types of Exempt are created simply because the sponsor requires the project to be registered with the IRB. In addition, revised Common Rule regulations allow for Exemptions to be granted without committee member review and therefore can be registered by an IRB Administrator as soon as the protocol is received in workflow.


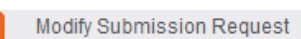
Follow these steps to grant an exemption.

APP	32450	IRB Protocol	IRB Protocol - New Exempt Protocol for Documentation	ENROUTE	09:24 AM 07/25/2018	IRBAdmin
-----	-------	--------------	--	---------	------------------------	----------

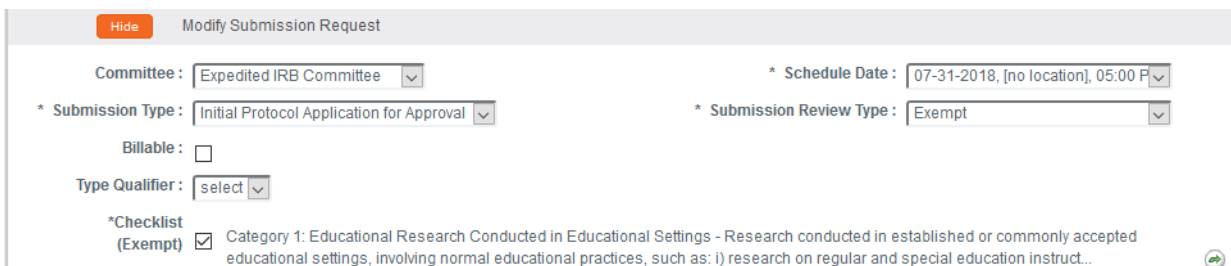
1. From the Protocol Actions tab, click the section header to expand the Request an Action section. In some cases, this section may appear expanded by default.



2. If the Grant Exemption action is not available, click the Show button next to the Modify Submission Request action.

If the Grant Exemption action is available, proceed to Step 6.



Hide Modify Submission Request

Committee: Expedited IRB Committee

* Submission Type: Initial Protocol Application for Approval

Billable:

Type Qualifier: select

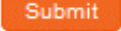
* Checklist (Exempt) Category 1: Educational Research Conducted in Educational Settings - Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: i) research on regular and special education instruct...

* Schedule Date: 07-31-2018, [no location], 05:00 P

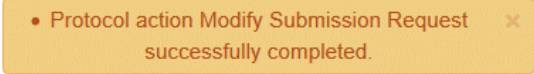
* Submission Review Type: Exempt

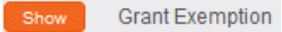
3. Click the arrow next to the **Committee** field to select the committee that will receive the announcement about the exempt protocol.

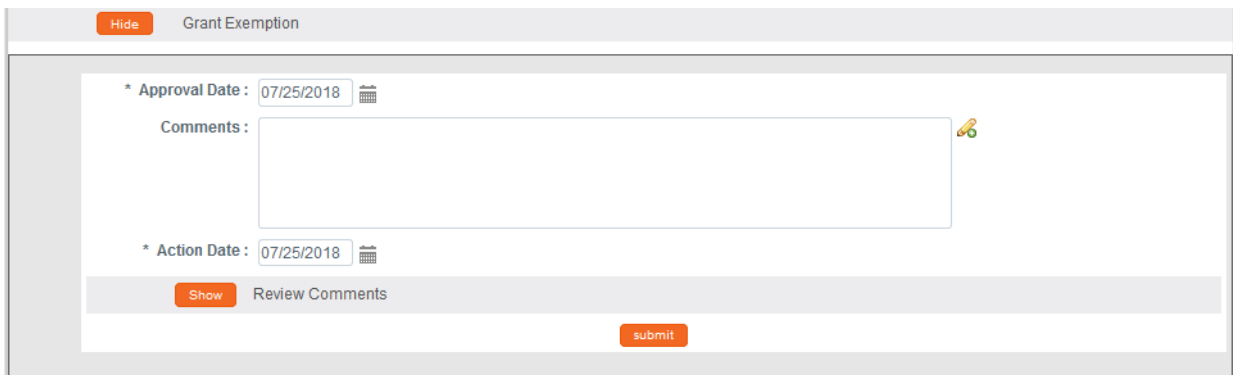
4. Click the arrow next to the **Schedule Date** field to select a tentative date for the board meeting during which the exempt protocol will be announced.

5. Click the Submit button. 

Result Streamlyne Research will display a message at the top of the page to let you know your action completed as expected. The document's Submission Status will update to Submitted to Committee and the Grant Exemption action item will appear.



6. If it is not already expanded, click the Show button next to the Grant Exemption action. 

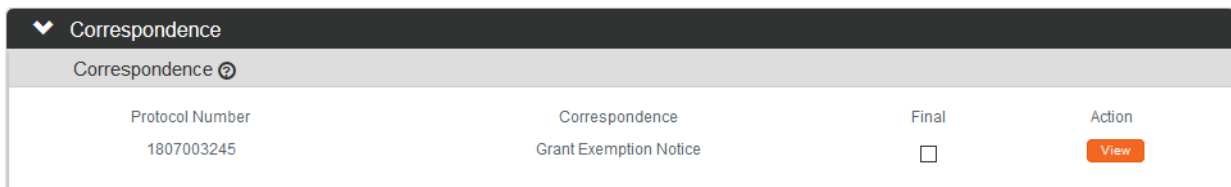



7. Note that the **Approval Date** and the **Action Date** default to today's date. If these dates should be changed for any reason, type in the new values in MM/DD/YYYY format.

8. Enter a justification for the exemption in the **Comments** field.

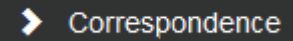
9. Click the Submit button to record the Exemption. 

Result A Correspondence section will appear with a Grant Exemption Notice available to view and finalize.



Protocol Number	Correspondence	Final	Action
1807003245	Grant Exemption Notice	<input type="checkbox"/>	

10. Click the header to expand the Correspondence section.

A dark grey rectangular button with a white right-pointing chevron icon followed by the text "Correspondence" in white.

11. Click the View button to review and/or save the correspondence as a PDF.


12. Check the **Final** box to finalize the communication.

13. Click the Save button. 

Result Upon completion of this process, Streamlyne Research sends an FYI Notification to inform all interested parties that the exemption has been granted and the protocol's Document Status updates to Exempt, and the Submission Status updates to Exemption Granted.

Note Amendments and Renewals cannot be submitted for Exempt protocols. If the Exempt protocol changes in any way that may impact the risk to subjects, a new protocol must be submitted.

14. Depending on your institution's configuration, you may see a Notification Editor screen allowing you to select additional recipients and edit the content of the notification.

Click the Send button to send the notification. 

Preparing & Maintaining IRB Committees

This section describes the processes for preparing committees and meetings.

Creating a New Committee

It is recommended that institutions have at least one committee for Full Committee protocols and one committee for Expedited protocols (even if Expedited protocols are not reviewed at a formal meeting). Follow these steps to set up a new IRB Committee and to assign users to that committee. Skip this section if you have already performed this configuration step.


Navigation

Main Menu > IRB > IRB Actions > IRB Committee > +

Updating the Committee Tab


The screenshot shows the 'Committee' configuration form in Streamlyne Research. The form is titled 'Committee' and has a search icon. It contains the following fields and options:

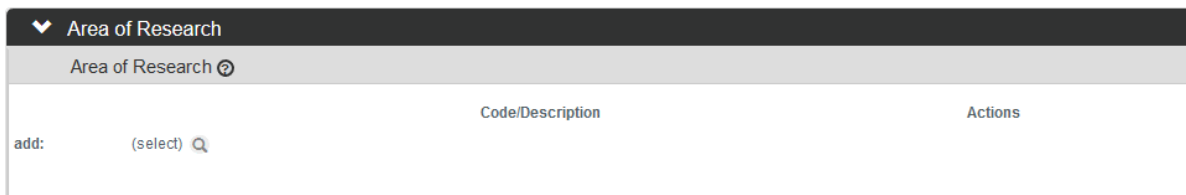
- * Committee ID: [Text input field]
- * Committee Name: [Text input field]
- * Home Unit: [Text input field with search icon] (select)
- Type: IRB
- Committee Description: [Text area with edit icon]
- Schedule Description: [Text area with edit icon]
- * Min Members for Quorum: [Text input field]
- * Review Type: [Dropdown menu with 'select' option]
- * Maximum Protocols: [Text input field]
- Last Updated: [Text input field]
- * Adv Submission Days: [Text input field]
- Updated User: [Text input field]
- Active:

1. Streamlyne Research defaults to the Committee section of the Committee  tab.


Complete the Document Overview section according to the steps in the **Navigation, the Action List, and Common Document Elements** manual. A Description is required.

2. In the Committee section, enter a unique identifier in the **Committee ID** field. A three-digit number is recommended.
3. Enter a name for the committee in the **Committee Name** field.


4. Enter the Unit ID that represents the committee's departmental affiliation in the **Home Unit** field or click the magnifying glass  to look up the correct value.
5. Enter the minimum number of committee members that must be present for a decision in the **Min Members for Quorum** field.
6. Click the arrow next to the **Review Type** field to indicate the type of protocols that this committee will review.
7. In the **Maximum Protocols** field, enter the maximum number of documents that will be reviewed at any given Committee Meeting.
8. In the **Adv Submission Days**, enter the number of days that a protocol must be submitted prior to a scheduled Committee Meeting for that protocol to be added to a Committee Agenda.





The screenshot shows a dropdown menu titled 'Area of Research'. Below the title is a search bar containing the text 'add: (select) Q'. Below the search bar is a table with two columns: 'Code/Description' and 'Actions'.

9. In the optional Area of Research section, click the magnifying glass  to look up and select the Areas of Research **Codes** and **Descriptions** that this Committee will specifically address.

Updating the Members Tab

1. Click the tab header to access the Members tab.
2. Click the magnifying glass  next to the **Employee Search** or **Non-Employee Search** fields to look up and select the Person ID of a Committee Member.
3. Click the Add Member button to complete the action.

Members

* Person: Internal User Name Search 
 External Address Book Search 

Clear Add Member

Add Member

Committee ⊙

Members Add IRB Member

Schedule

* Person: Internal User Name Search
 External Address Book Search

⌵ ⌶

* Indicates required field

- ▣ ▶ Rachel Reviewer (inactive)
- ▣ ▶ Randy Reviewer (inactive)
- ▣ ▶ Medicine Chair (inactive)
- ▣ ▶ Research A Dean (inactive)
- ▣ ▶ Biochemistry Researche (inactive)

Result Once the member is added they will default to an “Inactive” status and a new section will be created for them.

4. Expand the section for each committee member to access required fields in each of four subsections. ▣ ▶ Rachel Reviewer (inactive)

5. Click the Show button under each subsection and complete all fields marked with an asterisk (*) as required.

▣ ▾ Rachel Reviewer (active) Term 01/01/2018 - 12/31/2021

Rachel Reviewer ⊙

Person Details

Person Name : Rachel Reviewer * Term Start Date : 01/01/2018

* Membership Type : Voting Member
 (paid member) * Term End Date : 12/31/2021

Contact Notes : Training Notes :

Contact Information

Roles

Expertise

Training

Result Once all required fields are complete, the member will be marked as “Active” as denoted in the tab header and will be ready to participate in the system as an assigned committee member.

Note Each committee must have a Chair. The Chair is indicated in the ROLES subsection. Federal requirements may also mandate that other roles with specific expertise or diversity be included (e.g., scientist, lay person, unaffiliated, prisoner or child advocate).

6. Repeat Steps 2 through 5 for each committee member.

Updating the Schedule Tab

The Schedule section of the Committee Schedule page has two subsections.

- Add to Schedule is used to add meeting events to the Schedule.
- Schedule is where all scheduled events are viewable.

1. Click the tab header to access the Schedule tab.

Schedule

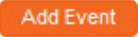
The screenshot shows a web form for adding a meeting event. The form is titled "Schedule" and "Add to Schedule". It includes the following fields and options:

- Date:** 08/03/2018 (with a calendar icon)
- Start Time:** 12:00 (with AM/PM radio buttons, PM is selected)
- Place:** Conference Room (with a location pin icon)
- Recurrence:** Radio buttons for Never, Daily, Weekly, Monthly (selected), and Yearly.
- Expanded Recurrence Section:** Radio buttons for "Day 6 of every 1 month(s)" and "The first Friday of every 1 month(s)" (selected). There are dropdown menus for "first" and "Friday", and a text input for "1".
- Ending on:** 07/31/2025 (with a calendar icon)
- Buttons:** "Add Event" (orange)

2. In the **Date** field, enter the date of the first committee meeting in MM/DD/YYYY format or use the calendar icon

3. In the **Start Time** field, enter the meeting's start time.

4. If the meeting's location is available, enter this into the **Place** field.

5. If this meeting will recur on a regularly scheduled basis, select the type of Recurrence by clicking the radio button next to the desired interval.
6. If you selected a Recurrence interval, Streamlyne Research will prompt you to refine the schedule criteria. The criteria will vary based on the interval selected in Step 5.
7. Click the Add Event button. 

Result The Schedule subsection will populate with each recurring meeting event per the criteria set in the Steps above.

8. Click the Submit button to complete the setup of a committee. 

Preparing & Maintaining Committee Meetings

The initial steps to preparing for an IRB Committee meeting are:

1. Assigning protocols to an agenda
2. Generating the agenda in advance of the committee meeting

This section will describe these processes.

Assigning a Protocol to a Meeting Agenda

Protocols must be assigned to a Meeting Agenda if the Submission Type is Expedited or Full Board. Though procedures vary by institution, this step generally takes place after the protocol has been assigned to committee members for review. Some institutions choose to wait until the Online Reviews are complete.

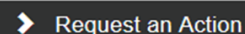
Follow these steps to assign a protocol to a Committee Meeting Agenda.

1. Access a protocol from your Action List or by using a Lookup.

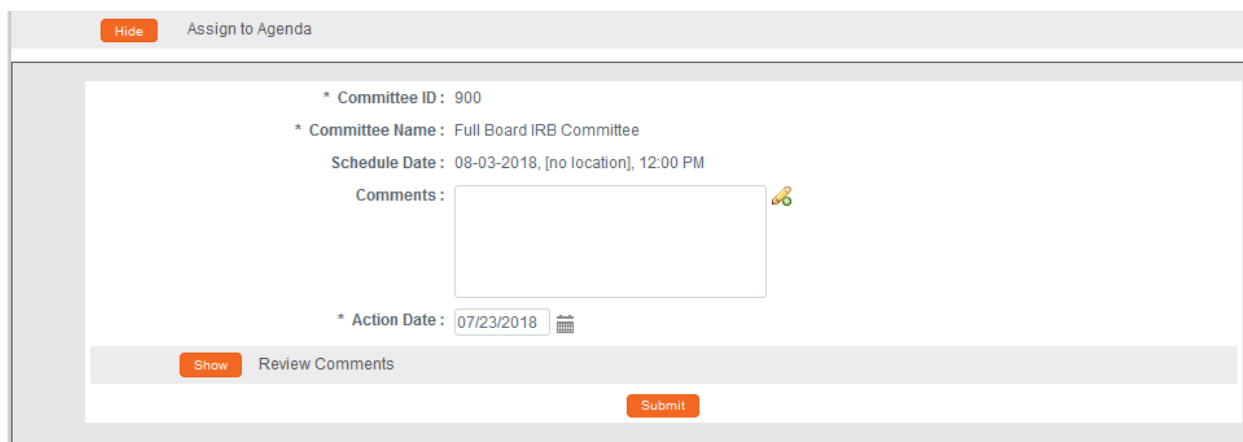
2. Click the tab header to access the Protocol Actions tab.



3. Click the header to access the Request an Action section.



4. Click the Show button next to the Assign to Agenda action.



The screenshot shows a web interface for assigning a protocol to a meeting agenda. At the top, there is a 'Hide' button and the title 'Assign to Agenda'. The form contains the following fields and labels:

- * Committee ID: 900
- * Committee Name: Full Board IRB Committee
- Schedule Date: 08-03-2018, [no location], 12:00 PM
- Comments: A text area with a pencil icon for editing.
- * Action Date: 07/23/2018 with a calendar icon.

At the bottom of the form, there is a 'Show' button next to the text 'Review Comments' and a 'Submit' button.

5. Streamlyne Research displays the Schedule data based on the assignment you made when you performed the Modify Submission action.

If this meeting assignment is correct, proceed to the next step.

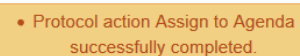
If this meeting assignment is incorrect, refer to [Assigning an IRB Committee and Meeting Date](#) to reschedule the protocol's review.

6. Enter any relevant information in the **Comments** field.

7. Click the Submit button to complete the action.



Result The system will return a message stating the protocol action of Assign to Agenda was successfully completed and the document's Submission Status will update to In Agenda.



Document Number : 32319

Initiator:Last Updated : bioprofessor : 08:39 AM 07/23/2018

Protocol # : 1807003125

Document Status : Submitted to IRB

Submission Status : In Agenda

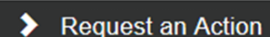
Expiration Date :

Deferring a Protocol

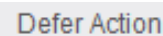
The IRB Administrator may want to defer review of a protocol if there is not enough information to make a decision about a protocol. There are a variety of reasons why this may happen: comments/revision requests have been sent to an investigator, but a response was not provided by the time of an IRB meeting; a protocol was tabled at an IRB meeting and put on the agenda for a subsequent meeting, but the investigator was not able to provide revisions by the time of the meeting, so the protocol review was deferred to another subsequent meeting.

Using this action, the IRB Administrator can move a protocol that has been submitted for a committee review to either a different committee or a different schedule for the same committee.

1. From the Protocol Actions tab, click the section header to expand the Request an Action section. In some cases, this section may appear expanded by default.

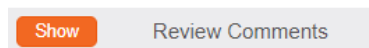


2. Click the Show button next to Defer Action.



3. Enter detailed **Comments** in the freeform field provided. These are not official review comments, just administrative notes to be kept with this action, if needed.
4. Note that the **Action Date** defaults to today's date. This field is editable. Should you need to alter this date, click the calendar icon 📅 or enter a new value in MM/DD/YYYY format.

5. Click the Show button next to the Review Comments action to view all official review comments.



6. Ensure all review comments are marked appropriately. See [Managing Review Comments & Attachments](#) for more information on these settings.

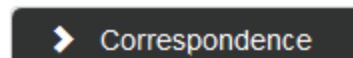
Note Only comments marked as Final will be included on the official correspondence and viewable by the PI. See the [Review Comment Matrix](#) for information about how the Private and Final checkboxes affect the view of each type of user.

7. Click the Submit button to record the Defer Action.



Result A Correspondence section will appear with correspondence letter listed to View and finalize.

8. Click the header to expand the Correspondence section.



9. Click the View button to review and/or save the correspondence as a PDF.
10. Check the **Final** box to finalize the communication.

11. Click the Save button.



Note Upon completion of this process, Streamlyne Research sends an FYI Notification to inform all interested parties that the protocol has been deferred.

15. Depending on your institution's configuration, you may see a Notification Editor screen allowing you to select additional recipients and edit the content of the notification.

Click the Send button to send the notification.

Send

Preparing and Generating Committee Meeting Agendas

In addition to reviewing protocols, IRB meetings often entail other pieces of business that need to be discussed with members. The IRB Meeting page contains five sections:

- Meeting Details
- Protocol Submitted
- Other Actions
- Attendance
- Minutes

Each allows for the entry, selection, and/or viewing of information pertaining to a particular meeting. Information included on an Agenda will be pulled from this page. It is important to enter the information here before generating the agenda.

This section describes the steps to finalize and disseminate a Meeting Agenda. This step is taken after all protocols to be reviewed at the meeting are assigned to the meeting date for this particular agenda.

Navigation

Main Menu > IRB > IRB Lookups > IRB Committee Schedules

1. Enter **Date** or **Committee** information into the Lookup window to narrow your search results to the specific committee meeting you would like to work with, and then click the Search button.

Search

2. Click the edit hyperlink next to the desired row.

3. Click on the tab header to access the Meeting tab.

Meeting

- Click the section header to expand the Other Actions section to enter any additional agenda items if applicable. Otherwise, skip to Step 8.



Other Actions

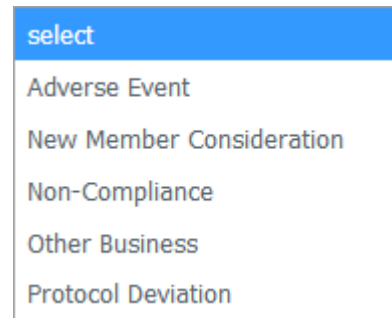
Other Actions ⓘ

* Type * Description

Add:

1 New Member Consideration A new Reviewer will be considered.

- Click the arrow next to the **Type** field to select the appropriate action from the dropdown.



- Enter a description of the action in the **Description** field and click the Add button. Note that as you add Other Actions, you may reorder them using the up and down arrows or delete them entirely using the Delete button.

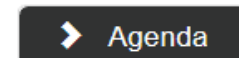
1	Other Business	Other Business	<input type="button" value="Up"/>	<input type="button" value="Down"/>	<input type="button" value="Delete"/>
2	Other Business	More Business	<input type="button" value="Up"/>	<input type="button" value="Down"/>	<input type="button" value="Delete"/>

- Review the other Sections on the Meeting page.

- Once the Meeting page has been reviewed, click the tab header to access the Meeting Actions tab.



- Click the section header to expand the Agenda section.



- Click the Submit button next to the Generate Agenda action.

Generate Agenda ⓘ

Generate Agenda

Result A PDF version of the agenda is created. This PDF can be viewed by clicking the view agenda button.

View Agenda ⓘ		
Version	Date Created	Actions
1	Jul 23, 2018 10:00:05 AM	send agenda view agenda

11. Click the Send Agenda button to send a PDF version of the agenda, including a list of protocols along with their comments via an FYI Notification to the Action List of each committee member. [send agenda](#)

12. Click OK to acknowledge the action.


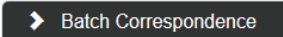
Batch Correspondence

IRB Batch Correspondence functionality provides a means for institutions to configure automated reminder notifications to go out to researchers to remind them on a timely basis of certain actions they need to take related to their protocols. These reminder notifications are triggered manually by a designated IRB staff member and are done so based on the institutions standard operating procedures. Streamlyne Research provides Batch Correspondence functionality for the following two scenarios.

- **Protocol Renewal Reminders** – Batch correspondences related to renewal reminders serve to remind researchers when they need to renew their protocol because their protocol's expiration date is approaching.
- **Reminder to IRB Notifications** – Batch correspondences related to Reminder to IRB notifications remind researchers to revise and re-submit their protocols when it has been returned for revisions (Specific Minor Revisions or Substantive Revisions Required).

Batch Correspondences are sent out based on committee first and then protocols that are either expiring or need resubmission based on that committee.

In addition to generating reminders for the researcher, the Batch Correspondence also allows institutions to set up a final action to be taken on the protocol by the system at the time of the final reminder. The most common examples are expiring a protocol after the final renewal reminder or withdrawing a protocol after the final reminder to IRB Notification.

1. Enter information into the search criteria or click Search to view all committees.
2. Locate the committee and click the view active hyperlink.
3. Click the tab header to access the Actions tab. 
4. Click the header to access the Batch Correspondence section. 

▼
Batch Correspondence

Generate Batch Correspondence ⓘ

Committee ID: 950

*Batch Type: ▼

Committee Name: Expedited IRB Committee

*Date: from to

Batch Correspondence History ⓘ

Committee ID: 950

*Batch Type: ▼

Committee Name: Expedited IRB Committee

Run Date: from to

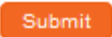
5. To generate new notifications, in the Generate Batch Correspondence section, click the arrow next to the **Batch Type** field and make the appropriate selection.

▼
select

Protocol Renewal Reminders

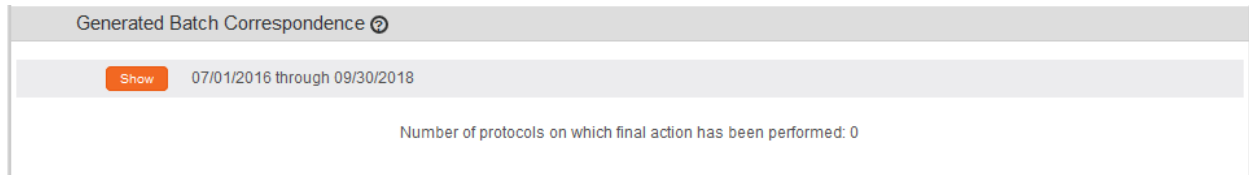
Reminder to IRB Notifications

To just view Batch Correspondence History, skip to Step 11.

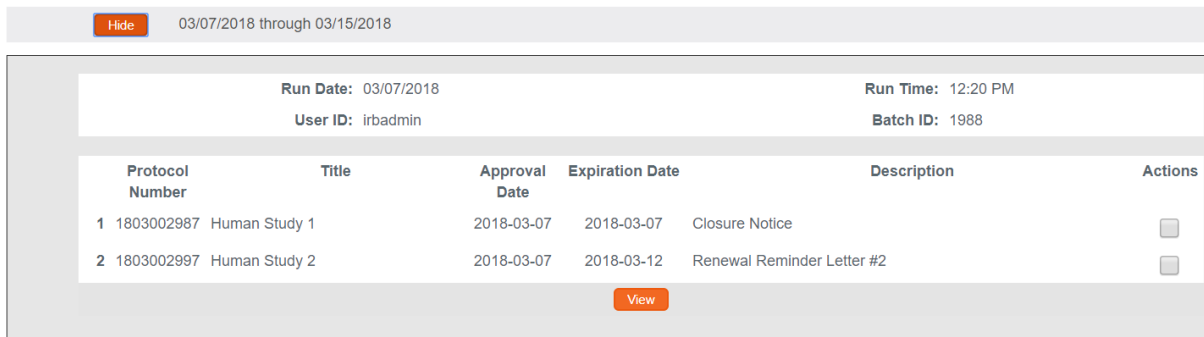
6. Enter the date parameters for the protocols that need reminders.
7. Click the Submit button. 

Result Notifications will be sent to the PI and applicable study team members for all qualifying protocols based on the time intervals set up by the system administrator. For example, 15 days to expiration or 30 days to expiration.

A new section called Generated Batch Correspondence will be created and will include a message with the number of protocols that Final Action has been taken on. Final Action examples are Expired, Closed or Termination. No further actions can be taken by the PI or the study team on these protocols.



8. To see the list of protocols that received the notification and correspondence, click the Show button next to the date range that populated.

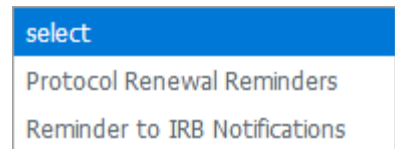


9. Click on the Protocol Number hyperlink to open the protocol for more information.

10. To view the correspondence letter, click the Actions box and then click the View button. Multiple correspondences can be selected at the same time.



11. To view Batch Correspondence History, click the arrow next to the **Batch Type** field and make the appropriate selection.



12. Enter the date parameters for the which the batch correspondence was sent.

13. Click the filter button.



Batch Type: Protocol Renewal Reminders ⓘ

Show 03/01/2015 through 03/07/2018

Show 03/01/2015 through 03/07/2018

Show 03/01/2016 through 03/07/2017

Hide 03/07/2018 through 03/15/2018

Run Date: 03/07/2018 **Run Time:** 12:20 PM
User ID: irbadmin **Batch ID:** 1988

Protocol Number	Title	Approval Date	Expiration Date	Description	Actions
1 1803002987	Human Study 1	2018-03-07	2018-03-07	Closure Notice	<input type="checkbox"/>
2 1803002997	Human Study 2	2018-03-07	2018-03-12	Renewal Reminder Letter #2	<input type="checkbox"/>

View

14. Click on the Protocol Number hyperlink to open the protocol for more information.

Note The batch correspondence letters, notifications, time intervals and final actions are pre-determined by your IRB office and system administrators based on your IRB office's standard operating procedures. Each institution will vary. These settings can be configured with the appropriate permissions.

Recording Full Committee Minutes & Decisions

The IRB Administrator will perform the Record Committee Decision action after the committee members have convened, discussed, and voted on the protocol and attendance information has been entered.

Note that the final decision cannot be recorded unless the protocol has been assigned to a meeting agenda. Refer to [Assigning a Protocol to a Meeting Agenda](#) if you missed this step.

Entering Attendance Information

Before committee decisions can be recorded for the specific protocols reviewed, the IRB Administrator must update the Meeting page with attendance information. This information includes both voting and non-voting members present.


The total number of those who were present and voting must match the total number of votes recorded when entering the committee decision within each specific protocol.

Navigation

Main Menu > IRB > IRB Lookups > IRB Committee Schedules

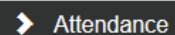
1. If you need to navigate to a new meeting, select Main Menu > IRB Protocols > IRB Committee Schedules from the Menu Bar.

If you are already in the meeting record, make sure you are on the main page by clicking the header on the Meeting tab, then skip to Step 3.

2. Enter **Date** or **Committee** information into the lookup window to narrow your search results to the specific Committee Meeting you would like to work with, and then click the Search button. 

3. Click the edit hyperlink next to the committee meeting you wish to select.

4. Click on the header to access the Attendance section.



Attendance

Attendance

Voting Members Present: 0

Person Name	Alternate For	Comments	Actions
Others Present: 0			
Add: Internal User Name Search External Address Book Search			
Add			
Person Name	Role	Comments	Actions
Members Absent or Available: 5			
Name	Role	Comments	Actions
1 Biochemistry Researcher			present Voting present Other
2 Medicine Chair			present Voting present Other
3 Rachel Reviewer			present Voting present Other
4 Randy Reviewer			present Voting present Other
5 Research A Dean			present Voting present Other

- Click present voting or present other depending on each member's status. Do this for all members.



You must indicate whether each of the Committee Members is voting or not before you can indicate whether the member is or was absent.

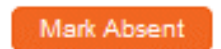
Attendance

Attendance

Voting Members Present: 5




Person Name	Alternate For	Comments	Actions
1 Biochemistry Researcher		<input type="text"/>	Mark Absent
2 Medicine Chair		<input type="text"/>	Mark Absent
Others Present: 2			

- As each person is marked, they will move to the top of the section indicating that their attendance has been completed and a Mark Absent button will become available for each person.



If you mistakenly added a Person as present, you can click the Mark Absent button to indicate that a member was in fact not present.

Note You may have to use the scroll bar located to the right of the present members to see all members.


7. Add a guest by clicking the magnifying glass  next to **Internal User Name Search** or **External Address Book Search** to access the lookup functions.
8. Click the Add button. 
9. Repeat Steps 7 and 8 until all guests are recorded. You may need to make a note and add these people to the system at a later time.
10. It is important to click the Save button once all attendance has been entered. 

Recording Committee Decisions

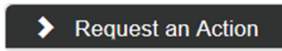
There are four possible motion types, or committee decisions in Streamlyne Research:

Motion Type	Definition
Approve	Used to indicate the protocol has the full support of the IRB Committee to proceed with research activities as documented on the protocol.
Disapprove	Used to indicate the protocol does not have the support of the IRB Committee and cannot proceed.
Specific Minor Revisions	Used to indicate that the protocol requires small, clearly detailed changes before the committee can grant approval. Some institutions regard it as a conditional approval.
Substantive Revisions Required	Used to indicate that the protocol requires major re-work from the Principal Investigator before the committee will consider it again for formal review.

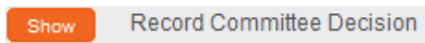
Follow these steps to complete the Record Committee Decision Action.

1. Access a protocol from your Action List, via a Document Lookup, or from the Meeting Agenda document.
2. Click the tab header to access the Protocol Actions tab. 

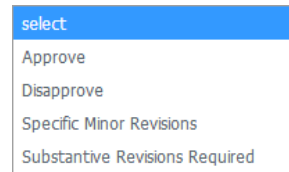
3. Click the header to access the Request An Action section.



4. Click the Show button next to the Record Committee Decision action.

A screenshot of a web form titled "Record Committee Decision". At the top left is a "Hide" button. The form contains a dropdown menu for "Motion Type" currently set to "Specific Minor Revisions". Below this are input fields for "No" (value 1), "Yes" (value 4), "Abstain" (value 0), and "Recused" (value 0). There is also a "Voting Comments" text area. At the bottom, there are three "Show" buttons for "Abstainers", "Recused", and "Review Comments", and a "submit" button.

5. Click the arrow next to the **Motion Type** field to select a value from the dropdown list.

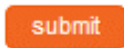


6. Enter the number of **No** and **Yes** votes.

Note that indicating these votes is a requirement, and the total number of votes must match the total number of voting members in attendance. (See [Entering Attendance Information](#) for details). The system will validate these numbers as well as account for those who abstained or recused themselves during the vote.

Note There are subsections here to record Abstainers, and Recused members and to Review Comments.

7. Click the Submit button.



Note Upon completion of these steps, the system will generate an FYI Notification to inform all interested parties of the decision.

8. If the Committee voted to approve the protocol, proceed to [Approving a Full Board Protocol](#).

9. If the Committee voted to return the protocol for revisions, proceed to the next section, [Returning a Full Committee Protocol for Revisions](#).

Returning a Full Board Protocol for Revisions

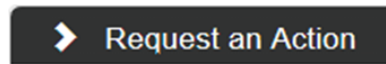
After the committee decision has been entered, the protocol can be returned for minor or substantive revisions. These two options will show in the Available Actions section after the committee decision has been entered.

Returning a Protocol for Specific Minor Revisions

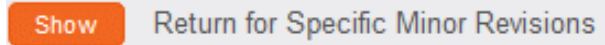
The Return for Specific Minor Revisions action is only available after the Record Committee Decision has been entered.

All review comments that are marked as Final will be included in the official correspondence that is generated for this action.

1. From the Protocol Actions tab, click the section header to expand the Request an Action section. In some cases, this section may appear expanded by default.



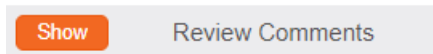
2. Click the Show button next to the Return for Specific Minor Revisions action.



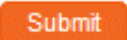
3. Streamlyne Research displays the Return for Specific Minor Revisions action window.

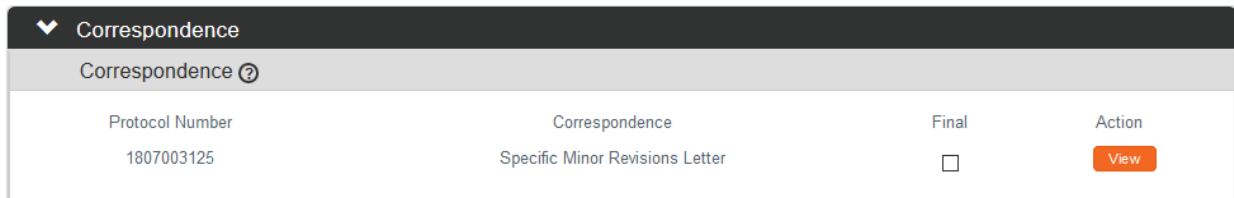
A screenshot of a web application window titled "Return for Specific Minor Revisions". At the top left, there is a "Hide" button. Below the title bar, there is a large text area labeled "Comments :". Below the text area, there is a field for "Action Date" with the value "07/23/2018" and a calendar icon. At the bottom of the window, there is a "Show" button next to the text "Review Comments" and a "Submit" button.


4. Enter detailed **Comments** in the freeform field provided. These are not official review comments, just administrative notes to be kept with this action, if needed.
5. Click the Show button next to the Review Comments action to view all official review comments.
6. Ensure all review comments are marked appropriately. See [Managing Review Comments & Attachments](#) for more information on these settings.



Note Only comments marked as Final will be included on the official correspondence and viewable by the PI. See the [Review Comment Matrix](#) for information about how the Private and Final checkboxes affect the view of each type of user.

7. Click the Submit button to record the decision and send the protocol back for Specific Minor Revisions. 




Protocol Number	Correspondence	Final	Action
1807003125	Specific Minor Revisions Letter	<input type="checkbox"/>	

8. A Correspondence section will now appear to preview the official correspondence that will be sent to the PI. View the correspondence and mark the Final box once the correspondence is verified in order to finalize the communication.

Result Upon completion of this process Streamlyne Research sends an FYI Notification to inform all interested parties that the protocol requires revisions as well as a Specific Minor Revisions Letter (Correspondence) with review comments.

The protocol's Document Status updates to Specific Minor Revisions Required and the Submission Status updates to Specific Minor Revisions Required.

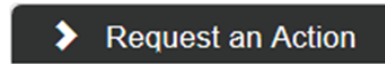
9. Click the Save button. 
10. Depending on your institution's configuration, you may be offered a Notification Editor screen.
If so, make any necessary edits and click Send.

Returning a Protocol for Substantive Revisions

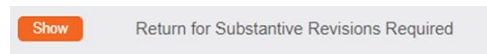
The Return for Substantive Revisions action can only be taken after the Record Committee Decision has been entered.

All review comments that are marked as Final will be included in the official correspondence that is generated for this action.

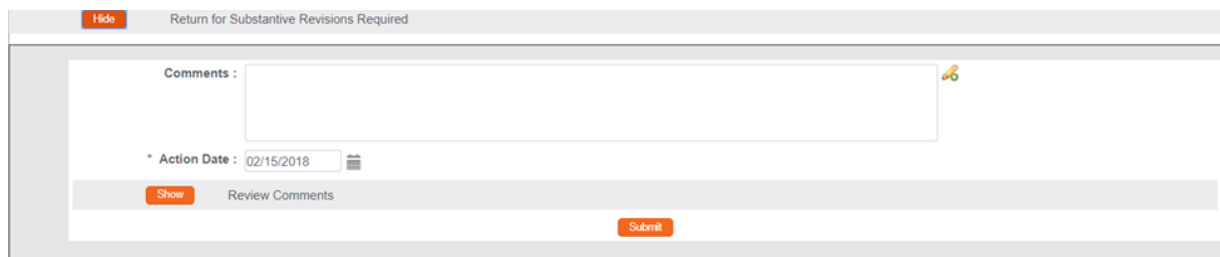
1. From the Protocol Actions tab, click the section header to expand the Request an Action section. In some cases, this section may appear expanded by default.



2. Click the Show button next to the Return for Substantive Revisions Required action.

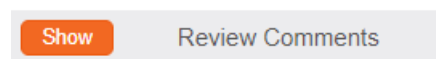


3. Streamlyne Research displays the Return for Substantive Revisions Required action window.



4. Enter detailed **Comments** in the freeform field provided. These are not official review comments, just administrative notes to be kept with this action, if needed.

5. Click the Show button next to the Review Comments action to view all official review comments.



6. Ensure all review comments are marked appropriately. See [Managing Review Comments & Attachments](#) for more information on these settings.

Note Only comments marked as Final will be included on the official correspondence and viewable by the PI.

7. Click the Submit button to record the decision and send the protocol back for Substantive Revisions.




8. A Correspondence section will now appear to preview the official correspondence that will be sent to the PI. View the correspondence and mark the Final box once the correspondence is verified in order to finalize the communication.

Result Upon completion of this process, Streamlyne Research sends an FYI Notification to inform all interested parties that the protocol requires revisions as well as a Substantive Revisions Required Letter (Correspondence) with review comments.

The protocol's Document Status updates to Substantive Revisions Required and the Submission Status updates to Substantive Revisions Requested.

9. Click the Save button. 

10. Depending on your institution's configuration, you may be offered a Notification Editor screen.

If so, make any necessary edits and click Send. 

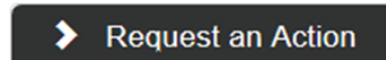
Otherwise, this process is complete.

Approving a Full Board Protocol

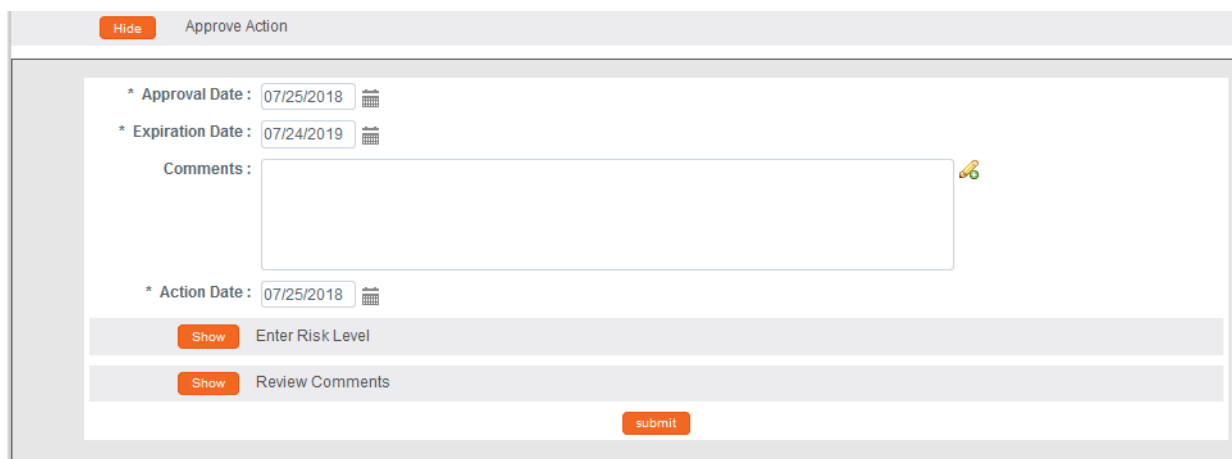
The Approve Action is the final step performed before enrollment for a study can begin for Full Committee protocols.

The Approve Action will not appear under Available Actions until the Recording Committee Decision Action is complete. See [Recording Committee Decisions](#).


1. From the Protocol Actions tab, click the section header to expand the Request an Action section. In some cases, this section may appear expanded by default.



2. Click the Show button next to Approve Action.  Approve Action

A screenshot of a web form titled "Approve Action". At the top left is a "Hide" button. The form contains several fields: "Approval Date" with a date picker set to 07/25/2018, "Expiration Date" with a date picker set to 07/24/2019, and "Comments" with a large text area and a paperclip icon. Below these is "Action Date" with a date picker set to 07/25/2018. At the bottom are two rows, each with a "Show" button and a label: "Enter Risk Level" and "Review Comments". A "submit" button is centered at the very bottom.

- Note that the **Action Date** and the **Approval Date** default to today's date, and that the protocol's **Expiration Date** is set to the last day of a rolling calendar year that begins on the **Approval Date**.

These fields are editable. Should you need to alter these dates, do so by using the calendar icon  or typing new values in MM/DD/YYYY format.

- Enter detailed **Comments** in the freeform field provided.

- Click the Show button next to the Enter Risk Level action.



* Risk Level	* Date Assigned	Date Inactivated	* Status	Comments	Actions
Add: <input type="text" value="select"/>	<input type="text" value="07/25/2018"/>		active	<input type="text"/>	<input type="button" value="add"/>

- Click the arrow next to the **Risk Level** field, and then select a value from the dropdown list that best represents the study's risk to human subjects.

- Enter any pertinent information regarding this risk assessment into the **Comments** field.

- Click the add button to commit the risk assessment to the database.



- Click the Submit button to record the Approval.



Correspondence			
Correspondence ⓘ			
Protocol Number	Correspondence	Final	Action
1807003268	Approval Letter	<input type="checkbox"/>	<input type="button" value="View"/>

10. A Correspondence section will now appear to preview the official correspondence that will be sent to the PI. View the correspondence and mark the Final box once the correspondence is verified in order to finalize the communication.

Result Upon completion of this process Streamlyne Research sends an FYI Notification to inform all interested parties that the protocol has been Approved.

The protocol's Document Status updates to Active-Open to Enrollment and the Submission Status updates to Approved and the protocols expiration date will now be included in the Document Header.

Document Number : 32465	Document Status : Active - Open to Enrollment
Initiator:Last Updated : medicineprofessor : 03:18 PM 07/25/2018	Submission Status : Approved
Protocol # : 1807003268	Expiration Date : 07/24/2019

11. Depending on your institution's configuration, you may see a Notification Editor screen allowing you to select additional recipients and edit the content of the notification.

Click the Send button to send the notification. 


Closing a Meeting Record

After a Committee has convened, the system expects a series of processes to be performed to close out the meeting record. These processes are designed for Full Board Meetings, though these steps can also be performed for meetings of Committees reviewing Expedited protocols.

Updating Meeting Details

The IRB Administrator can log additional meeting details after the meeting has occurred. This is in addition to recording the Attendance information discussed in [Entering Attendance Information](#).

Navigation	Main Menu > IRB > IRB Lookups > IRB Committee Schedules
-------------------	---

1. Enter **Date** or **Committee** information into the look up window to narrow your search results to the specific Committee Meeting you would like to work with, and then click the Search button. 
2. Click the edit hyperlink next to the desired row.

Meeting Details

Meeting Details

Committee ID : 900

Schedule Date : 07/25/2018

Place :

Max Protocols : 20

Agenda Generation: 07/25/2018

Start Time : 12:00 AM PM

Available to reviewers :

Comments :

Committee Name : Full Board IRB Committee


* Meeting Date : 07/25/2018

Time : 03:00 AM PM

* Deadline : 07/25/2018

Status : Scheduled

End Time : 12:00 AM PM

- In the Meeting Details window, update the actual **Meeting Date** versus the Schedule Date, the **Place** the meeting took place, the scheduled meeting **Time**, the actual **Start Time**, the **End Time**, and the **Status** of this meeting per your institution's procedures.
- Click the Save button to save your changes. 

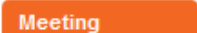
Recording Meeting Minutes

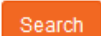
The Minutes section of the Meeting document allows you to select from a predefined list of entry types and then enter textual descriptions for each. Minutes entries can be marked as either Private or Final prior to being added as numbered line items.


The Minutes section also includes all review comments entered through the Online Review process or through the management of review comments by the IRB Administrator over the course of the protocol's review.

Recording Meeting Minutes is not a system prerequisite for approving or rejecting a protocol, but it is highly recommended.

- If you need to navigate to a new meeting, select Main Menu > IRB Protocols > IRB Committee Schedules from the Menu Bar.

If you are already in the meeting record, make sure you are on the main page by clicking the header on the Meeting tab, then skip to  Step 3.

- Enter **Date** or **Committee** information into the lookup window to narrow your search results to the specific Committee Meeting you would like to work with, and then click the Search button. 

- Click on the header to access the Minutes section. 

Minutes


Minutes ?

* Entry Type	Entry Type Detail	* Description	Standard Review Comment	Private	Final	Last Updated By	Created By	Actions
Add: <input type="text" value="select"/>		<input type="text"/>		<input type="checkbox"/>	<input type="checkbox"/>			<input type="button" value="Add"/>
General Comments		Opening Remarks		<input type="checkbox"/>	<input checked="" type="checkbox"/>	IRB Administrator 07/22/2019 10:35 AM	IRB Administrator 07/22/2019 10:35 AM	<input type="button" value="Up"/> <input type="button" value="Down"/>
Other Business	Other Business: Other Business	Other Business Remarks		<input type="checkbox"/>	<input checked="" type="checkbox"/>	IRB Administrator 07/22/2019 10:38 AM	IRB Administrator 07/22/2019 10:38 AM	<input type="button" value="Up"/> <input type="button" value="Down"/>
Other Business	Other Business: More Business	More Business Remarks		<input type="checkbox"/>	<input checked="" type="checkbox"/>	IRB Administrator 07/22/2019 10:39 AM	IRB Administrator 07/22/2019 10:39 AM	<input type="button" value="Up"/> <input type="button" value="Down"/>
Protocol	1812003792	This should be identified as Exempt # 4.		<input type="checkbox"/>	<input checked="" type="checkbox"/>	IRB Administrator 12/28/2018 10:49 AM	IRB Administrator 12/28/2018 10:49 AM	<input type="button" value="Delete"/>

- Click the arrow next to the **Entry Type** field to indicate the kind of agenda item being covered.

select

- General Comments
- Attendance
- Adverse Events
- Other Business
- Protocol
- Regulatory Findings
- Conflicts of Interest
- Tabled Discussions

- If you selected an **Entry Type** of Protocol in the previous step, select the **Protocol Number** from the dropdown box.
- Enter discussion content into the **Description** field.
- Indicate whether the item is **Private**, **Final**, or both, by clicking the checkboxes.
- Click the add button to commit the discussion details to the database. 

9. Repeat Steps 4 through 8 for each item on the Minutes. Note that as you add items, you may reorder them using the up and down arrows or delete them entirely using the Delete button. Protocols are listed at the end.


10. Click the Save button. 


If the minutes are ready to be disseminated, proceed to the next section to generate meeting minutes.

Generating Meeting Minutes


This section describes the steps to finalize and disseminate meeting minutes. These minutes can also be reviewed at the subsequent Full Committee meeting.


1. If you need to navigate to a new meeting, select Main Menu > IRB Protocols > IRB Committee Schedules from the Menu Bar.

If you are already in the meeting record, make sure you are on the main page by clicking the header on the Meeting Actions tab, then skip to Step 3. 

2. Enter **Date** or **Committee** information into the lookup window to narrow your search results to the specific Committee Meeting you would like to work with, and then click the Search button. 

3. Click the edit hyperlink next to the desired row.

4. Click the tab header to access the Meeting Actions tab. 

5. Click the section header to expand the Minutes section. 

6. Click the Submit button next to the Generate Minutes action.  

7. Click the Send Minutes button to send a PDF version of meeting minutes to all committee members and guests. 

8. Click OK to acknowledge the action. 

Administering & Maintaining Active Protocols

The full lifecycle of a protocol after initial approval varies greatly.

For the major transactions such as amendments and renewals, Streamlyne Research handles the IRB submission, administration and committee review processes much like the steps taken for initial submissions and reviews.

For example, when an amendment is submitted for an expedited protocol, the amendment will get assigned to a committee and then to a reviewer from that committee, as needed. Whereas, an amendment that qualifies for Full Committee review will need to be assigned to an agenda and reviewed at a convened meeting. The same goes for renewals.

This section will not cover the step-by-step process of managing the review process of amendments and renewals as they have already been covered. This section will cover various other important actions that the IRB Administrator may facilitate over the lifecycle of an IRB protocol.

These administrator level actions are all found under the Available Actions within the Protocol Actions page.

- Incorporating Amendments and Renewals
- Reviewing and Acknowledging a Notify IRB Action
- Withdrawing a Protocol
- Closing a Protocol
- Expiring a Protocol
- Closing Enrollment on a Protocol
- Re-opening Enrollment on a Protocol
- Identifying a Protocol in a Data Analysis Only Phase
- Suspending a Protocol
- Suspending a Protocol by DSMB
- Terminating a Protocol

A complete list of all available protocol actions is available in [Appendix C: All Protocol Actions](#).

Reviewing and Acknowledging a Notify IRB Action

The [Notify IRB Action](#) is used by the Principal Investigator to inform the IRB of an event or provide new information about the protocol that does not require an amendment. This is an umbrella action that encompasses things such as adverse events, unanticipated problems, protocol

deviations, and other events or transactions that a Principal Investigator or study team member may want to notify their IRB about for review and acknowledgment.

This action can be escalated to a committee member for review (Assign Reviewer) or can be included on an Agenda (Assign to Agenda) for review at a convened committee meeting.

1. Once the Notify IRB Action is taken by the Principal Investigator, the IRB Administrator will receive an FYI Notification as well as an ACK Notification in their Action List.

Action List

	Action	Id	Type
Show	FYI	26742	Streamlyne Research Notification
	ACK	26732	IRB Protocol

2. From the Action List, click on the Id number next to the ACK symbol.

3. From the Protocol Actions tab, click the section header to expand the Request an Action section. In some cases, this section may appear expanded by default.

Request an Action

4. To assign to a committee or to a committee member to review, click on the SHOW button next to Modify Submission Request.

Show Modify Submission Request

If committee or committee member review is not required, skip to Step 9.

5. Use the **Committee** and **Schedule Date** fields to indicate when the Notification will be reviewed.

6. Click the arrow in the **Type Qualifier** field to change the Type Qualifier if applicable.

select

- Revision to Exempt Protocol
- Unanticipated Problems
- Adverse Event
- Annual Scheduled by IRB
- Contingent/Conditional Approval/Deferred Approval/Non-Approval
- Protocol-Related COI Report
- Report of Noncompliance

7. Click the Submit button when ready to Submit.

Submit

8. Proceed with assigning a committee member to review and/or assigning the Notification to an agenda as applicable.

9. Once the Notification has been sufficiently reviewed, click the Show button next to IRB Acknowledgement.

Show

IRB Acknowledgement

The screenshot shows a web interface for IRB Acknowledgement. At the top, there is a header bar with a 'Hide' button and the text 'IRB Acknowledgement'. Below this is a large text area labeled 'Comments :'. Underneath the comments area is a field for '* Action Date : 07/24/2018' with a calendar icon. At the bottom of the form, there is a 'Show Review Comments' button and a 'Submit' button.

10. Use the **Comments** field to record any applicable comments.
11. Click the Show button next to Review Comments to finalize any review comments if Committee review took place.
12. Once all information is correct, click the Submit button to finalize the communication.

Result The PI will be notified of the Acknowledgment. The format of the response and any accompanying correspondence will be based on your institution's workflow configuration. The correspondence will include any review comments or follow up action that was marked as Final. The PI will be able to proceed with submission of amendments or renewals as needed.

Withdrawing a Protocol

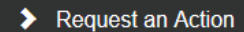
If a protocol has reached the IRB Office, but needs to be withdrawn because the PI no longer wants the study to be considered for review or the study is no longer eligible for review, then the IRB Administrator can withdraw the protocol. Once the protocol is scheduled for review, the Withdraw action can only be taken by the IRB Administrator. The PI will automatically be notified, if the Withdraw Action is taken.

1. Using the Lookups, locate the protocol you would like to Withdraw.
2. Click the edit hyperlink.

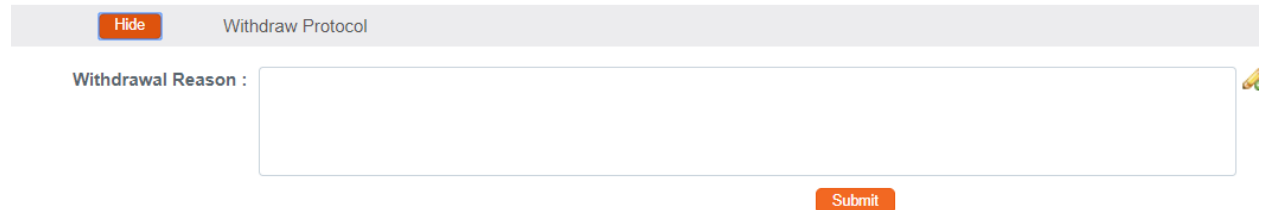
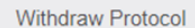
3. Click on the tab header to access the Protocol Actions tab.



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 'Withdraw Protocol' header with a 'Hide' button. Below the header is a text input field labeled 'Withdrawal Reason :'. To the right of the input field is a small yellow pencil icon. Below the input field is a 'Submit' button.

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

7. Click the Submit button to finalize your withdrawal.



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

Note To review this protocol in the future, a new protocol document must be created or the copy function can be utilized to reuse the information on the Withdrawn protocol.

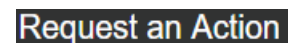
Closing a Protocol

If a PI [Requests to Close a Proposal](#), or it is determined that the study will close, the IRB Administrator can close the protocol. Closing a protocol can also be done through Final Actions tied to Batch Correspondence, in which a protocol is automatically closed due to non-response. See [Batch Correspondence](#) for more information.

The steps below explain how to manually close a protocol if the Close action is not tied to Batch Correspondence.

1. Use the Lookups to search for the protocol.

2. From the Protocol Actions tab, click the section header to expand the Request an Action section. In some cases, this section may appear expanded by default.



3. Click on the Show button next to Close.





Close

Comments :

* Action Date : 07/25/2018

Submit

4. Enter detailed **Comments** in the freeform field provided. These are not official review comments, just administrative notes to be kept with this action, if needed.
5. The **Action Date** field will default to today. Change the date if necessary using the calendar icon  or enter the date in a MM/DD/YYYY format.
6. Click the Submit button to record the decision. 

Result The PI should receive a response indicating that their 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 their Action List. You can always access this information in Protocol Actions>Summary & History.

Note This is a Final Action and will change the Document Status to Closed. A new protocol must be submitted for further review.

Expiring a Protocol

Protocols must be manually expired by an IRB Administrator unless this Final Action is set up as part of your committee maintenance and triggered as part of the Batch Correspondence process. See [Batch Correspondence](#) for more information. This is often an action that is taken after multiple renewal reminders have been sent to the PI.



The steps below explain how to manually expire a protocol if the expiration action is not tied to Batch Correspondences.

1. Use the Lookups to search for the protocol.
2. From the Protocol Actions tab, click the section header to expand the Request an Action section. In some cases, this section may appear expanded by default.

Request an Action

3. Click on the Show button next to Expire.

A screenshot of a web form titled 'Expire'. At the top left, there is a 'Hide' button and the word 'Expire'. Below this is a large text area labeled 'Comments:' with a yellow icon in the top right corner. Underneath the text area is a field for '* Action Date:' with the value '07/25/2018' and a calendar icon. At the bottom of the form, there is a grey bar containing a 'Show' button and the text 'Review Comments'. Below this bar is a 'Submit' button.

4. Enter detailed **Comments** in the freeform field provided. These are not official review comments, just administrative notes to be kept with this action, if needed.
5. The **Action Date** field will default to today. Change the date if necessary using the calendar icon  or enter the date in a MM/DD/YYYY format.
6. Click the Show button next to Review Comments to finalize any review comments if committee review took place.
7. Click the Submit button to record the decision. 

Result The PI should receive a response indicating that their protocol has officially been expired. 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 their Action List. You can always access this information in Protocol Actions>Summary & History.

Note This is a Final Action and will change the Document Status to Expired. A new protocol must be submitted for further review.

Closing Enrollment on a Protocol

This is the IRB Administrator's response to a PI's [Request to Close Enrollment on a Protocol](#). It changes the status of the document to Active – Closed for Enrollment.

This action can also be taken by the IRB Administrator without a request from the researcher.

1. Use the Lookups to search for the protocol.

- From the Protocol Actions tab, click the section header to expand the Request an Action section. In some cases, this section may appear expanded by default.

Request an Action

- Click on the Show button next to Close Enrollment.

Show

Close Enrollment

The screenshot shows a web interface for the 'Close Enrollment' action. At the top left, there is a 'Hide' button and the text 'Close Enrollment'. Below this is a large text area labeled 'Comments:' with a yellow pencil icon for editing. Underneath the comments field is an 'Action Date' field with the value '07/19/2018' and a calendar icon. At the bottom of the form, there is a 'Show' button next to the text 'Review Comments', and a 'Submit' button centered below it.

- Enter detailed **Comments** in the freeform field provided. These are not official review comments, just administrative notes to be kept with this action, if needed.

- Click the Show button next to the Review Comments action to view all official review comments.

Show

Review Comments

- Ensure all review comments are marked appropriately. See [Managing Review Comments & Attachments](#) for more information on these settings.

Note Only comments marked as Final will be included on the official correspondence and viewable by the PI. See the [Review Comment Matrix](#) for information about how the Private and Final checkboxes affect the view of each type of user.

- Click the Submit button to record the decision.

Submit

Result The PI should receive a response indicating that their 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 their Action List. You can always access this information in Protocol Actions>Summary & History.

Note The PI may submit a Request to Reopen Enrollment. See next section for details on responding to this type of request.

Re-Opening Enrollment on a Protocol

This Action can be taken on any protocol that has a current status of Active-Closed to Enrollment in which case the PI has [Requested to Re-Open Enrollment](#).

This action can also be taken by the IRB Administrator without a request from the researcher.

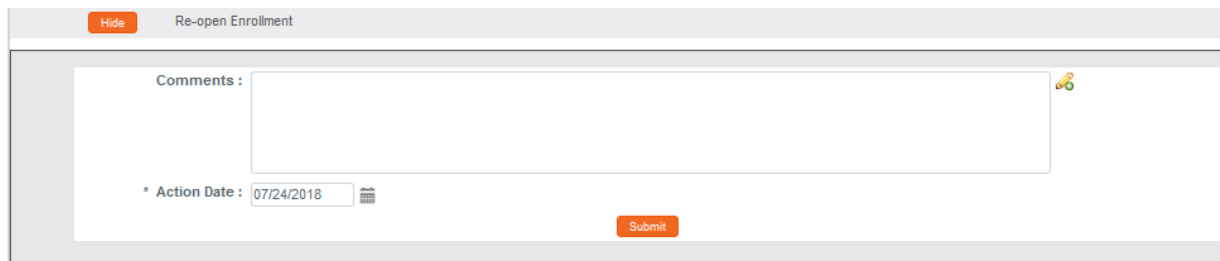
1. Use the Lookups to search for the protocol.
2. From the Protocol Actions tab, click the section header to expand the Request an Action section. In some cases, this section may appear expanded by default.

Request an Action

3. Click on the Show button next to Re-open Enrollment.

Show

Re-open Enrollment



4. Enter detailed **Comments** in the freeform field provided. These are not official review comments, just administrative notes to be kept with this action, if needed.
5. Click the Show button next to the Review Comments action to view all official review comments.
6. Ensure all review comments are marked appropriately. See [Managing Review Comments & Attachments](#) for more information on these settings.

Show

Review Comments

Note Only comments marked as Final will be included on the official correspondence and viewable by the PI. See the [Review Comment Matrix](#) for information about how the Private and Final checkboxes affect the view of each type of user.

7. Click the Submit button to record the decision.

Submit

Result The PI should receive a response indicating that their 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 their Action List. You can always access this information in Protocol Actions>Summary & History.

Identifying a Protocol in a Data Analysis Only Phase

This is the IRB Administrator's response to a Principal Investigator's [Request for Data Analysis Only](#). This action indicates that that the human participant portion of the study is complete and only data analysis remains to be completed. Often this will allow Full Committee protocols to be review at an Expedited level.

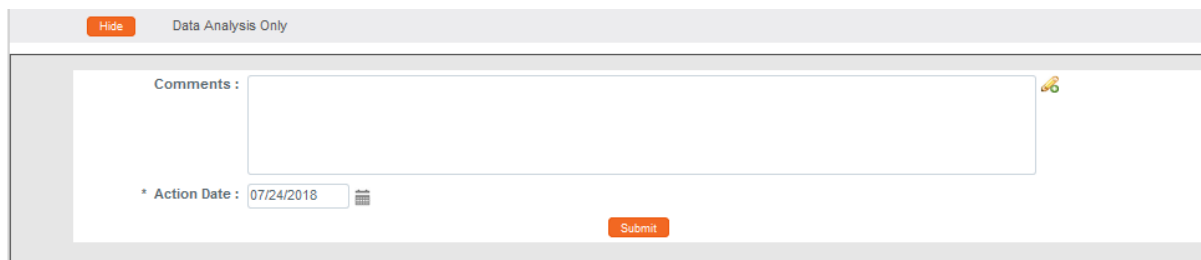
This action can also be taken by the IRB Administrator without a request from the researcher.

1. Use the Lookups to search for the protocol.
2. From the Protocol Actions tab, click the section header to expand the Request an Action section. In some cases, this section may appear expanded by default.
3. Click on the Show button next to Data Analysis Only.

Request an Action

Show

Data Analysis Only



Hide Data Analysis Only

Comments :

* Action Date : 07/24/2018

Submit

4. Enter detailed **Comments** in the freeform field provided. These are not official review comments, just administrative notes to be kept with this action, if needed.
5. Click the Submit button to record the decision..

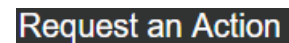
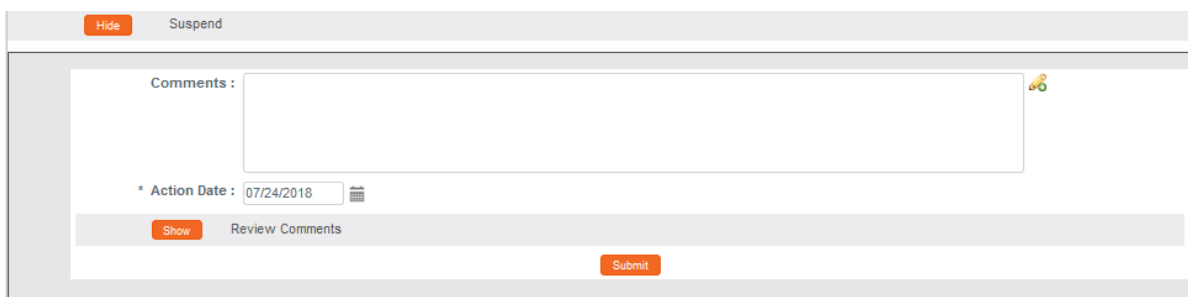
Submit

Result The PI should receive a response indicating that their 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 their Action List. You can always access this information in Protocol Actions>Summary & History.

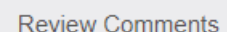
Suspending a Protocol

Sometimes an IRB Administrator will need to suspend a protocol. This action may be in response to a Principal Investigator's [Request to Suspend a Protocol](#). This action can also be taken by the IRB Administrator without a request from the researcher. A protocol is suspended when risk to human subjects has been identified and further investigation is required prior to letting the research continue. This action is typically driven by regulatory obligation and indicates temporary suspension of research activities.

1. Use the Lookups to search for the protocol.
2. From the Protocol Actions tab, click the section header to expand the Request an Action section. In some cases, this section may appear expanded by default.
3. Click on the Show button next to Suspend.

A dark grey rectangular button with the text "Request an Action" in white.A small orange button with the text "Show" in white.A light grey button with the text "Suspend" in dark grey.A screenshot of a web form titled "Suspend". At the top left is a "Hide" button. Below it is a large text area labeled "Comments:" with a small icon on the right. Underneath the comments area is a field for "Action Date:" with the value "07/24/2018" and a calendar icon. At the bottom of the form are three buttons: "Show", "Review Comments", and "Submit".

4. Enter detailed **Comments** in the freeform field provided. These are not official review comments, just administrative notes to be kept with this action, if needed.
5. Click the Show button next to the Review Comments action to view all official review comments.
6. Ensure all review comments are marked appropriately. See [Managing Review Comments & Attachments](#) for more information on these settings.

A small orange button with the text "Show" in white.A light grey button with the text "Review Comments" in dark grey.

Note Only comments marked as Final will be included on the official correspondence and viewable by the PI. See the [Review Comment Matrix](#) for information about how the Private and Final checkboxes affect the view of each type of user.

7. Click the Submit button to record the decision. 

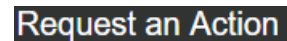
Results The PI should receive a response indicating that their protocol has been suspended. The format of the response and any accompanying correspondence will be based on your institution's workflow configuration. It may display as an FYI in their Action List. You can always access this information in Protocol Actions>Summary & History.

Note After a protocol has been suspended, the approval of any amendment, renewal or amendment with renewal that occurs after the suspend action will lift the suspension. The protocol will revert to the status that it was in prior to the suspension.

Suspending a Protocol by DSMB

An IRB Administrator may also suspend a protocol on behalf of the Data Safety Monitoring Board (DSMB). This action is used if the DSMB has called for the suspension.


1. Use the Lookups to search for the protocol.
2. From the Protocol Actions tab, click the section header to expand the Request an Action section. In some cases, this section may appear expanded by default.



3. Click on the Show button next to Suspend By DSMB.  



4. Enter detailed **Comments** in the freeform field provided. These are not official review comments, just administrative notes to be kept with this action, if needed.

5. Click the Submit button to record the decision. 

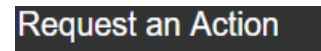
Results The PI should receive a response indicating that their protocol has been suspended. The format of the response and any accompanying correspondence will be based on your institution's workflow configuration. It may display as an FYI in their Action List. You can always access this information in Protocol Actions>Summary & History.

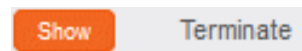
Note After a protocol has been suspended, the approval of any amendment, renewal or amendment with renewal that occurs after the suspend action will lift the suspension. The protocol will revert to the status that it was in prior to the suspension.

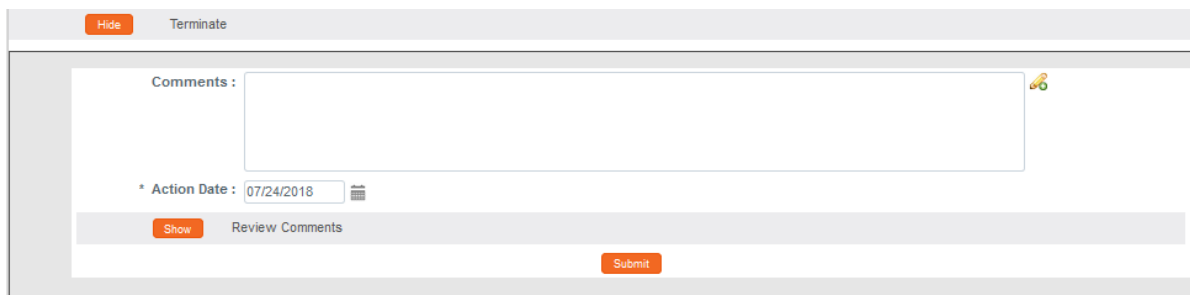
Terminating a Protocol

Termination will sometimes follow a suspension. When an IRB Administrator terminates a protocol, the research is no longer allowed. The action may also be in response to a Principal Investigator's [Request to Terminate a Protocol](#).

1. Use the Lookups to search for the protocol.
2. From the Protocol Actions tab, click the section header to expand the Request an Action section. In some cases, this section may appear expanded by default.
3. Click on the Show button next to Terminate.

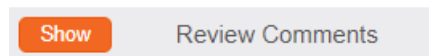







The screenshot shows a web interface for the 'Terminate' action. At the top left, there is a 'Hide' button and the title 'Terminate'. Below this is a large text area labeled 'Comments :'. Underneath the comments area is an 'Action Date' field with the value '07/24/2018' and a calendar icon. At the bottom of the form, there is a 'Show' button next to the text 'Review Comments', and a 'Submit' button centered below it.

4. Enter detailed **Comments** in the freeform field provided. These are not official review comments, just administrative notes to be kept with this action, if needed.
5. Click the Show button next to the Review Comments action to view all official review comments.



6. Ensure all review comments are marked appropriately. See [Managing Review Comments & Attachments](#) for more information on these settings.

Note Only comments marked as Final will be included on the official correspondence and viewable by the PI. See the [Review Comment Matrix](#) for information about how the Private and Final checkboxes affect the view of each type of user.

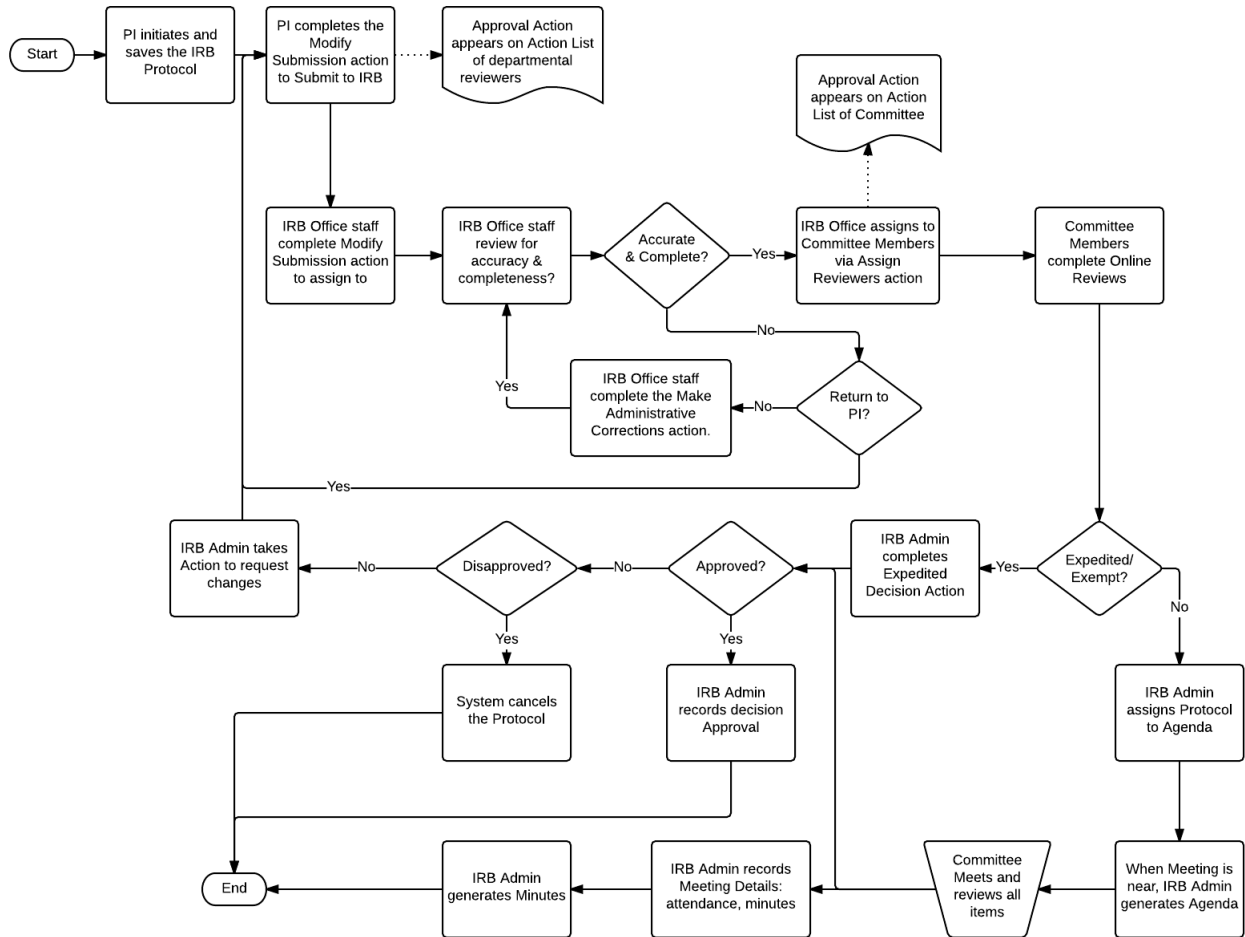
7. Click the Submit button to record the decision. 

Results The PI should receive a response indicating that their 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 their Action List. You can always access this information in Protocol Actions>Summary & History.

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	Used to indicate a committee decision where the investigator needs to make changes to a protocol before the committee will approve the study. Action is performed based committee's evaluation that the study poses minimal risk, and that requested changes are specific and minor.	The Record Committee Action must be completed with a Motion Type of Specific Minor Revisions. Protocol Status must be Submitted to IRB. Submission Status must be In Agenda.	Protocol Status updates to Specific Minor Revisions Required. Submission Status updates to Specific Minor Revisions Requested.
Return for Substantive Revisions Required	IRB Admin	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.	The Record Committee Action must be completed with a Motion Type of Substantive Revisions Required. Protocol Status must be Submitted to IRB. Submission Status must be In Agenda.	Protocol Status updates to Substantive Revisions Required.

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.

Appendix D: Editing Correspondences

The purpose of this section is to educate the user on how to perform basic edits to Protocol Correspondence templates.

Protocol Correspondences are generated by taking an XML representation of the protocol data and merging it with an XSL Template via a process called XSL Translation. Modifying the appearance and some of the static content of the correspondences is achieved by editing the XSL Template. These XSL Templates describe the layout of the final correspondence along with some of the static content.

Understanding XML Basics

XSL is very similar to HTML in its syntax and layout. An XSL document consists of a series of nested tags. Each tag is a word or words surrounded by '<' and '>'. All tags appear either in pairs or as single, freestanding tags. For pairs, the second or closing tag is the same as the opening tag with the addition of a '/' character at the beginning of the tag. For single tags, the closing '>' is preceded by a '/'. Tags of the first kind (pairs) may contain data and other tags nested between the opening and closing tags.

Some tags also contain attributes contained within the tag. In the case of a pair of tags, these attributes only appear in the opening tag. They appear as key-value pairs expressed as follows: key="value". These often include layout data such as dimensions or styles.

Understanding Correspondence Template Layouts

Note: All examples in this document come from the default Approval Letter template.

All of the delivered correspondence templates begin with a brief layout section describing a body, named "xsl-region-body"; a header, named "xsl-region-before"; and a footer, named "xsl-region-after"; as shown here:

```
<xsl:variable name="fo:layout-master-set">
  <fo:layout-master-set>
    <fo:simple-page-master master-name="default-page"
page-height="11in" page-width="8.5in" margin="0.5in">
      <fo:region-body region-name="xsl-region-
body" margin-top="1in" margin-bottom="0.25in" />
```

```

        <fo:region-before region-name="xsl-region-
before" extent="1in" />

        <fo:region-after region-name="xsl-region-
after" extent="0.25in" />

    </fo:simple-page-master>

</fo:layout-master-set>

</xsl:variable>

```

This section is followed by the main template. This main template is divided into two (2) static blocks, delineated by the tag “<fo:static-content>”, and a third, longer section delineated by the tag “<fo:flow>”. The static sections further define the header and footer while the third section is the main content of the correspondence.

Generally speaking, the first half of the correspondence section creates the headers of the correspondence such as the “To” and “From” lines. Protocol data is included here as well. These items are formatted using “<fo:table-row>” tags which are analogous to “<tr>” tags in HTML. If you wish to remove any of these items from the table, be sure to remove everything between and including the “<fo:table-row>” tag pair.

In the following excerpt, for example, in order to remove the “Action Date” from the correspondence, you would remove everything between and including the highlighted lines:

```

...
<fo:table-row>
    <fo:table-cell>
        <fo:block>
            <fo:inline font-weight="bold">Action:</fo:inline>
        </fo:block>
    </fo:table-cell>
    <fo:table-cell>
        <fo:block>
            <fo:inline font-weight="bold">Approval</fo:inline>
        </fo:block>
    </fo:table-cell>
</fo:table-row>
<fo:table-row>
    <fo:table-cell>

```

```

        <fo:block>
            <fo:inline font-weight="bold">Action Date: </fo:inline>
        </fo:block>
    </fo:table-cell>
<fo:table-cell>
    <fo:block>
        <xsl:for-each select="nl:Protocol">
            <xsl:for-each select="nl:Submissions">
                <xsl:for-each select="nl:SubmissionDetails">
                    <xsl:for-each select="nl:ActionType">
                        <xsl:for-each select="nl:ActionDate">
                            <xsl:value-of select="format-
number(substring(., 6, 2), '00')" />
                            <xsl:text></xsl:text>
                            <xsl:value-of select="format-
number(substring(., 9, 2), '00')" />
                            <xsl:text></xsl:text>
                            <xsl:value-of select="format-
number(substring(., 1, 4), '0000')" />
                        </xsl:for-each>
                    </xsl:for-each>
                </xsl:for-each>
            </xsl:for-each>
        </fo:block>
    </fo:table-cell>
</fo:table-row>
<fo:table-row>
    <fo:table-cell>
        <fo:block>
            <fo:inline font-weight="bold">Protocol #: </fo:inline>
        </fo:block>
    </fo:table-cell>

```



```

<fo:table-cell>
  <fo:block>
    <xsl:for-each select="nl:Protocol">
      <xsl:for-each select="nl:ProtocolMasterData">
        <xsl:for-each select="nl:ProtocolNumber">
          <fo:inline>
            <xsl:apply-templates />
          </fo:inline>
        </xsl:for-each>
      </xsl:for-each>
    </xsl:for-each>
  </fo:block>
</fo:table-cell>
</fo:table-row>
...

```

Beyond these correspondence header sections are the sections that define the actual textual contents of the Correspondence. In many cases, the text of a correspondence is different based on an attribute of the protocol such as SubmissionTypeCode. These different sections are all contained within an “<xsl:choose>” block and each different choice is separated out within that block in “<xsl:when>” blocks. Sometimes a final “<xsl:otherwise>” block is defined as a case when none of the when blocks are selected. The text within these normally appears as formatted plain-text and can be edited directly.

Beneath this section is a section containing public comment entries and another that lists personnel on the protocol.

Finally, there is a large section at the end that contains what appears to be random text. This block of text contains the encoded version of the header image and should not be edited by hand.