



IACUC Protocol & Committee Modules

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I: For a General Audience

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

Overview of the IACUC Protocol & Committee Modules

Streamlyne's IACUC Protocol & Committee Modules are designed to facilitate the institutional processes that safeguard the welfare of laboratory animals and ensure compliance with the federally-mandated humane care and use of animals involved in research, research training, and biological testing activities. Principal Investigators initiate and submit IACUC protocols, amendments, and continuations within the system. Protocols are automatically routed to the appropriate departments and corresponding IACUCs for review and approval. Reviewers and Committee Members have access to the protocols online where their comments and decisions are preserved. IACUC 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 **Navigation, the Action List, and Common Document Elements** manual. Please use that manual as a companion to this one, as we have tried to eliminate redundancy wherever possible.

Every Installation Is Different

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

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

Let's begin!

Searching with IACUC Lookups

To assist you in locating IACUC Protocols and Committees within Streamlyne Research, IACUC search windows, called lookups, are available from the Main Menu. Access to these lookups depends on the IACUC 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 IACUC administrators will have access to the various administrative functions related to IACUC protocols and committees. Some users (such as Department Chairs or IACUC Committee Members) may also be involved in approving or reviewing protocols. See [Appendix A: IACUC Roles and Permissions](#) for a complete list.

To search for items using IACUC lookups, simply navigate from the Main Menu to the corresponding IACUC 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 > IACUC > IACUC 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 > IACUC > IACUC Lookups > All My Reviews
------------	--

This lookup is useful to those who are regularly assigned to review IACUC 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 > IACUC > IACUC Lookups > All My Schedules

This lookup is useful to IACUC 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 > IACUC > IACUC Lookups > Protocol Submissions

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

Pending Protocols

Navigation

Main Menu > IACUC > IACUC 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 > IACUC > IACUC 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 > IACUC > IACUC 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.

IACUC Online Review

Navigation

Main Menu > IACUC > IACUC Lookups > IACUC Online Review

This IACUC Administrator lookup allows the administrator to search and view 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.

IACUC Committee Schedules

Navigation

Main Menu > IACUC > IACUC Lookups > IACUC Committee Schedules

This IACUC Administrator lookup gives the administrator quick access to a list of the Committee schedules without having to access the schedule through the IACUC 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 IACUC 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 IACUC protocols, use this section to begin using the IACUC module productively.

If your role does not require you to initiate or submit IACUC 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: IACUC Protocol Workflow Overview](#).

Initiating a New IACUC Protocol

If your goal is to quickly enter 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 Research.	Select from dropdown.

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>
Protocol	Required Fields for Saving	Lay Statement 1	A short summary of the project in layman's terms so that it can be understood by anyone.	Enter freeform text.

Navigation

Main Menu > IACUC > IACUC Actions > IACUC Protocol > +

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

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

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 IACUC Protocol again by clicking on the corresponding Id hyperlink next to 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 > IACUC > IACUC Actions > IACUC Protocol > +

Protocol Tab > Required Fields for Saving Document

Required Fields for Saving Document

Required Fields for Saving Document ⓘ

* Protocol Type : Research ▼

* Principal Investigator : Internal User Name Search 🔍
External Address Book Search 🔍

* Title : ⓘ

* Lead Unit : select ▼ ⓘ

Protocol Project Type : select ▼

* Lay Statement 1 : ⓘ

Lay Statement 2 : ⓘ

1. The **Protocol Type** is used to designate the level of IACUC 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 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. The **Protocol Project Type** is optional and is used to provide a further description of the project type (e.g., Agricultural, Behavioral, Biomedical, Field Studies).

Select the appropriate option from the dropdown list.

6. Enter a lay statement into the **Lay Statement 1** field. If you have an additional lay statement, use the **Lay Statement 2** field, as necessary.

7. Click the Save button. Save

Note 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 : 32500	Document Status : Pending/In Progress
Initiator:Last Updated : bioprofessor : 09:29 AM 08/03/2018	Submission Status :
Protocol # : 1808000216	Expiration Date :

Protocol Tab > Statutes & Dates

▼ Status & Dates	
Status & Dates ⓘ	
Protocol # : 1808000216	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

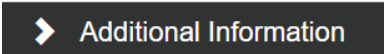

This section contains read-only data recording milestones in the lifecycle of the protocol along with routinely referenced information such as **Protocol #** and **Protocol Status**.

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

▶ Status & Dates

Protocol Tab > Additional Information > Areas of Research

Area of Research ⓘ		
	Code/Description	Actions
add:	(select) 🔍	
1	000001:All Research Areas	Delete

1. Click on the header to expand the Additional Information section. 
2. The Areas of Research list 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 areas in the Research Areas Lookup.
Otherwise, skip to the next section.

IACUC Research Areas Lookup

* required field


Research Area Code:

Parent Research Area Code:

Has Children Flag: ☐ Yes ☐ No ☒ Both

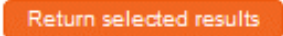
Code/Description:

Active: ☒ Yes ☐ No ☐ Both

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

Viewing rows 1 to 38

Select?	Research Area Code	Parent Research Area Code	Has Children Flag	Code/Description	Active
<input type="checkbox"/>	000001	000000	No	All Research Areas	Yes
<input type="checkbox"/>	000002	000001	No	Alcoholism Research	Yes
<input type="checkbox"/>	000003	000001	No	Anesthesia / Analgesics Research	Yes
<input type="checkbox"/>	000004	000001	No	Animal Science Teaching	Yes
<input type="checkbox"/>	000005	000001	No	Anorexia / Bulimia Research	Yes
<input type="checkbox"/>	000006	000001	No	Antibody Production	Yes
<input type="checkbox"/>	000007	000001	No	Auditory Research	Yes
<input type="checkbox"/>	000008	000001	No	Aversive stimuli Research / Testing	Yes
<input type="checkbox"/>	000009	000001	No	Behavioral Research	Yes
<input type="checkbox"/>	000010	000001	No	Breeding	Yes
<input type="checkbox"/>	000011	000001	No	Cancer Research - Human	Yes
<input type="checkbox"/>	000012	000001	No	Cancer Research - Animal	Yes

4. 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.

Delete

Protocol Tab > Additional Information > Additional Information Subsection

Additional Information ⓘ

Reference ID1:

Reference ID2:

Summary/Keywords :

This panel is used to track identifiers related to the work performed on the project. The fields labelled **Reference ID1** and **Reference ID2** can be configured by your institution to capture any other identifier you wish. These identifiers will not apply to every protocol.

1. Enter the applicable identifiers in one or both of the **Reference ID** fields.
2. Enter any additional information related to the **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 IACUC 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 this dropdown list are determined by your institution during your implementation.

Other Identifiers ⓘ

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

1. If this project is associated with an external research network or external IACUC, click the arrow next to the **Type** field and select the appropriate option.

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

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 IACUC 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.

▼ Organizations


Organizations ⓘ

	* Organization Id	* Organization Type	Contact	Animal Welfare Assurance	Actions
Add: <input style="width: 100px;" type="text"/> select Add					
1	000001 Streamlyne Institution	Performing Organiz ▼	Director, GCO: 2020 Camino del Rio N., Suite 520 , San Diego, CA 92108-1545 FWA00000045 Clear Contact		Delete Organization

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

➤ Organizations

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 either an external organization or the organization performing the research.

select


External



Performing Organization

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

Protocol Tab > Funding Sources

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

▼ Funding Sources				
Funding Sources ?				
	* Funding Type	* Funding Number	* Source	Title
Add:	select			
1	Proposal	58	National Institutes of Health	Parent Proposal

1. Click on the header to expand the Funding Sources section.
2. Click the arrow next to the **Funding Type** to select the source from the dropdown list.

➤ Funding Sources

select

Sponsor

Unit


Other

Development Proposal

Institutional Proposal



Award

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**.

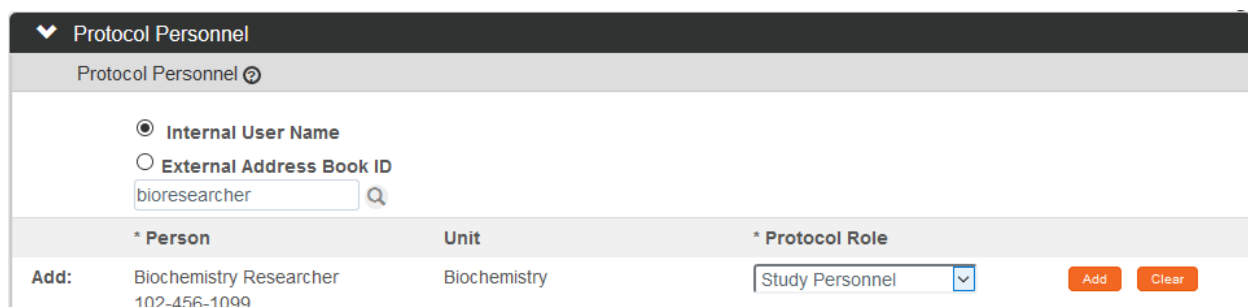
Entering this information will also display the Proposal, Institutional Proposal, and/or Award on the Streams page for easy access between different administrators who need to view the linked documents (if permissions allow).

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.

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

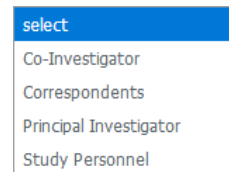


* Person	Unit	* Protocol Role
Add: Biochemistry Researcher 102-456-1099	Biochemistry	Study Personnel

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.



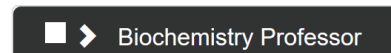
A dropdown menu with a blue header labeled 'select'. Below the header are four options: 'Co-Investigator', 'Correspondents', 'Principal Investigator', and 'Study Personnel'.

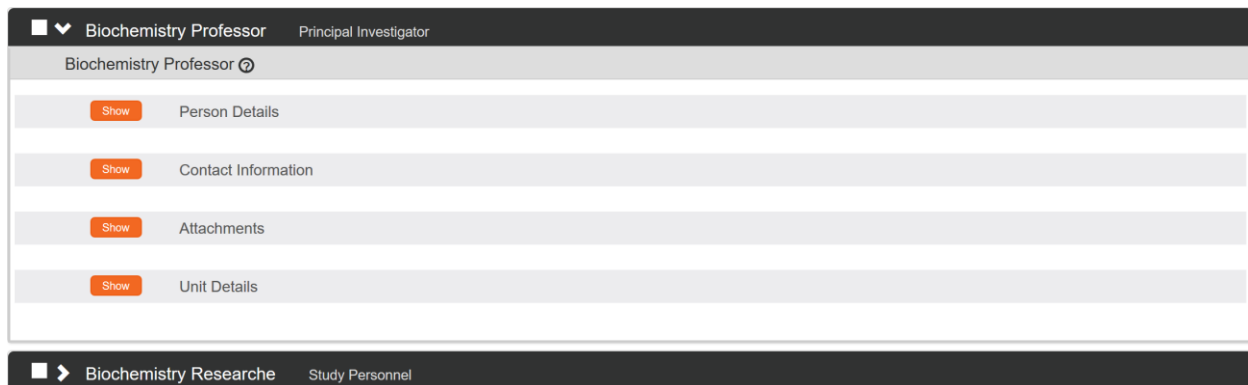
4. Click the Add button to complete this action.



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.

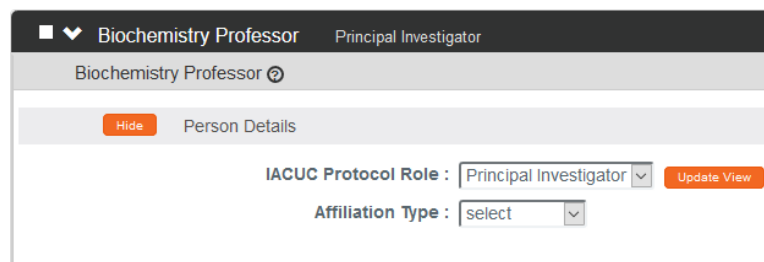




A screenshot of the 'Biochemistry Professor' user section. The header shows 'Biochemistry Professor' with a dropdown arrow and 'Principal Investigator'. Below the header is a list of subsections: 'Person Details', 'Contact Information', 'Attachments', and 'Unit Details'. Each subsection has a 'Show' button to its left.

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





A screenshot of the expanded 'Person Details' subsection. The header shows 'Biochemistry Professor' with a dropdown arrow and 'Principal Investigator'. Below the header is a 'Hide' button. The main content area contains two fields: 'IACUC Protocol Role' with a dropdown menu showing 'Principal Investigator' and an 'Update View' button, and 'Affiliation Type' with a dropdown menu showing 'select'.

7. Click the arrow next to the **IACUC 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.

select

- Affiliate
- Faculty
- Non-Faculty
- Student
- Supervisor

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

Show

Hide Contact Information

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

10. Update defaulted contact information if necessary.
11. If you need to attach personnel-specific documents, click the Show button to expand the Attachments subsection.

Show

Hide Attachments

Update Timestamp	Updated By	* Attachment Type	* Description	* File Name	Actions
Add:		select		Browse... No file selected.	Add

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

select

- Biography
- Other



13. Enter a description for the attachment in the **Description** field.
14. Click the Browse button to access files on your computer. Follow your operating system's prompts.


15. Click the Add button to add the Attachment. 

16. Click the Show button to expand the Unit Details subsection. 



The screenshot shows a form titled "Unit Details" with a "Hide" button. The form has four columns: "Unit Name", "* Unit Number", "* Lead", and "Actions". The "Unit Name" column has a dropdown menu with "(select)" and a magnifying glass icon. The "Unit Number" column has a text input field. The "Lead" column has a checkbox. The "Actions" column has "Add" and "Delete" buttons. Below the header, there is a row with the following data: "1" in the first column, "Biochemistry" in the second, "105010" in the third, a radio button in the fourth, and a "Delete" button in the fifth.

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

17. Click the magnifying glass  to search for an additional Unit or enter the unit number in the **Unit Number** field if you know it. Adding additional units is rarely necessary.

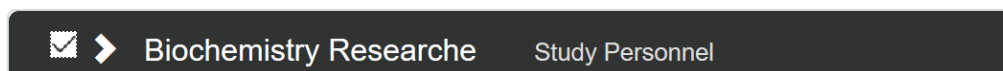
18. Click the **Lead** box to indicate if this Unit is the lead unit on for this investigator.

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



The screenshot shows a dark grey bar with a checkbox, a right arrow, and the text "Biochemistry Researche" and "Study Personnel".

☒ ➔ 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 Three R's Tab

The Three R's tab is used by the investigator to describe how they have applied the ethical concept of the three R's (Reduction, Refinement and Replacement) in the design of their proposed study, taking into consideration the welfare of the animals and thoroughly justifying the use and care of animals in their research. This ensures that investigators comply with federal regulations in using the minimal number of animals necessary, minimizing any pain or distress that may be incurred, and exploring the possibility of using alternative models (*in vivo* or *in vitro*) instead of the species described in the proposed research.

Additionally, this tab allows the investigator to identify literature searches conducted during the design of their proposed study. This is especially useful in documenting the specific literature searches that they are required to perform in their efforts to find alternatives to any procedures likely to produce pain or distress in the animals.

Refer to the National Research Council's [Guide for the Care and Use of Laboratory Animals](#) for further definitions and guidelines for the Three R's.

Three R's Tab > The Three R's

1. Click on the tab header to access the The Three R's tab.

The Three R's

2. Click on the section header to expand the The Three R's section.

> The Three R's

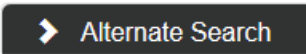

The screenshot shows a web interface for 'The Three R's'. At the top is a dark header with a dropdown arrow and the text 'The Three R's'. Below this is a light gray bar with the text 'Principles' and a small circular icon. The main content area contains three text input fields, each with a label on the left and a small icon on the right. The labels are 'Principles of Reduction:', 'Principles of Refinement:', and 'Principles of Replacement:'. The icons are small, stylized figures of people.


3. In the **Principles of Reduction** field, enter freeform text to justify the number of animals used and how this minimal number was determined.
4. In the **Principles of Refinement** field, enter freeform text to describe the methods that will be employed to minimize discomfort, distress, and pain.
5. In the **Principles of Replacement** field, enter freeform text to justify the use of this particular animal model in relation to other possible alternatives.
6. Click the Save button.



Save



Three R's Tab > Alternate Search

In the Alternate Search section, you can identify your literature searches for alternatives conducted during the design of the proposed study.

1. Click on the section header to expand the Alternate Search section. 
2. Enter the date the database search was performed in the **Date** field using a MM/DD/YYYY format or click the calendar icon  to select the date.
3. Select from the list of databases in the **Available** field. You can choose multiple databases by holding down the Ctrl key while selecting.


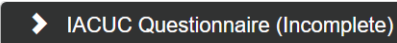

If a database you used to perform the search is not listed in the **Available** field, skip to Step 5.
4. Click the right arrow to move the selected database(s) from the **Available** field to the **Selected** field. 

Click the left arrow if you need to move a database in the **Selected** field, back to the **Available** field. 
5. Enter a database name in the **Other** field if a database you used is not listed in the **Available** field.
6. Click the Add button to move this database to the **Selected** field. 
7. Specify the publication years or date parameters that the literature search was performed against in the **Years** field.

8. Specify keywords that were used in performing the database search in the **Keywords** field.
9. Enter freeform text in the **Comments** field to provide a summary of the database search performed. Describe whether alternatives were found and, if so, reasons for designing your study in the ways you did.
10. Click the Add button once all information has been entered. 
11. Repeat Steps 2 through 10 until all alternate searches have been entered.
12. Click the Save button. 

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 IACUC administrator for details.

1. Click on the tab header to access the Questionnaire tab. 
2. Click on the section header to expand the IACUC 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.

- Click the More Information button to the right of each question to review any Explanation, Policy or Regulation references where pertinent.

[More Information...](#)

- Click the Save button to save your work.

Save

- The Questionnaire status will change to Complete once all questions are answered.

▼ IACUC Questionnaire (Complete)

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 Species/Groups Tab

The Species/Groups section captures details of the species of animals in each experimental group that is part of the study. Experimental groups should be based on the different procedures that will be performed. The same species might be grouped into multiple experimental groups, if each experimental group undergoes a different procedure. For example, if the researcher plans to conduct surgery on one group of mice and administer drugs to another group of mice, the user should define two experimental groups: one group with a species of mice and a procedure of surgery, and another group with a species of mice and a procedure of drugs. Each experimental species/group combination can list multiple procedures.

- Click on the tab header to access the Species/Groups tab.

Species/Groups

- Click on the header to expand the Species/Groups section.

➤ Species/Groups

▼ Species/Groups

Species/Groups ⓘ


* Group	* Species	Strain	* Pain Category	USDA Covered Type	* Count Type	* Male Count	* Female Count	* Species Count	Actions
Add: <input type="text"/>	<input type="text" value="select"/>	<input type="text"/>	<input type="text" value="select"/>	<input type="checkbox"/>	<input type="text" value="select"/>	<input type="text"/>	<input type="text"/>	<input type="text" value="0"/>	<input type="button" value="Add"/>
Age Breakdown : <input type="text"/>		Comments : <input type="text"/>							

3. Enter the name you want to give the experimental group in the **Add: Group** field.


Each experimental group will consist of one species and one or more procedures being performed on that species. The experimental group names within a protocol must be unique and the naming convention to be used is often decided by the implementing institution.
4. Click on the arrow next to the **Species** field to choose from the dropdown list configured for your institution.
5. Enter text in the **Strain** field to further define the species strain for this experimental group.
6. Click on the arrow next to the **Pain Category** field to select the level of pain the species will go through when they undergo procedures.

Select from the [USDA Pain Categories](#) B, C, D, E, or your institution's predefined pain categories as listed. If the study involves an experimental group where multiple procedures will be performed, the pain category should reflect the most painful procedure.
7. Check the **USDA Covered Type** box, if the species is covered by the USDA Animal Welfare Act. This field may autopopulated if configured by your institution.

USDA defines covered as "any live or dead dog, cat, nonhuman primate, guinea pig, hamster, rabbit, or any other warm-blooded animal."
8. Click on the arrow next to the **Count Type** field to select the form (e.g., animal, embryo, egg) of the species you will be using for this group.
9. Enter the number of males within the group in the **Male Count** text field.
10. Enter the number of females within the group in the **Female Count** text field.
11. The **Species Count** field will auto-calculate the total based on what is entered in the male and female count fields.
12. Enter freeform text in the **Age Breakdown** field to provide additional details or justifications regarding the planned age breakdown of group members.

13. Enter freeform text in the **Comments** field to provide any additional information you feel is pertinent in describing the makeup of the group.
14. Click the Add button. 
15. Repeat Steps 3 through 14 for any additional experimental groups.

As Species/Groups are added, note that the Species Totals by Count Type panel is populated to tally the number of species and total number of animals. If necessary, click the Recalculate button if the panel does not appear to be syncing when you add or remove Species/Groups.

▼ Species Totals by Count Type			
Count Type: Animal			
Species - Strain	Male Count	Female Count	Species Count
Mouse - C57BL/6	<input type="text" value="10"/>	<input type="text" value="10"/>	<input type="text" value="20"/>
Guinea Pig - Hartley	<input type="text" value="10"/>	<input type="text" value="10"/>	<input type="text" value="20"/>
	Total Male Count	Total Female Count	Total Species Count
	20	20	40
Grand Total			
	Grand Total Male Count	Grand Total Female Count	Grand Total Species Count
	20	20	40
			

USDA PAIN CATEGORIES

- B** Animals housed for breeding or other purposes where no experimental manipulations are required.
- C** Animals will not undergo procedures or experience conditions that would normally cause more than momentary or slight pain or distress. Note that euthanasia before significant pain and distress could be C. Include all animals that will be euthanized because they fall under the category of “wastage” (e.g., the wrong genotype) in this category.
- D** Animals may potentially experience more than momentary or slight pain or distress and will receive some corrective measure, such as anesthetics, analgesics, or tranquilizers during or after the procedure to prevent more than minor pain or distress. **Use this category if euthanasia is delayed until the onset of significant pain or distress.**

- E** Animals may potentially experience more than momentary or slight pain or distress and will not receive a corrective measure, such as anesthetics, analgesics, tranquilizers, or other therapies to alleviate pain or distress. One possibility is if euthanasia is purposefully delayed for scientific reasons until significant pain or distress has occurred.

Updating the Procedures Tab

The Procedures tab is for capturing details of the procedures that will be performed on each experimental group. The details include personnel involved in performing each procedure, the location where the procedure will be performed, and specific information related to the procedure that your institution may require. The Procedures page allows you to attach a high-level timeline and overview of all the procedures that will be conducted as part of the research project.

The Procedures tab is split into two main sections:

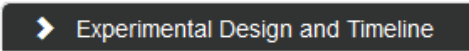

- **Experimental Design and Timeline:** This section captures a summary of all procedures and a timeline of when the procedures will be performed and allows you to add attachments with further detail.
- **Procedure Details:** This section is robust and further divided into subsections for details regarding the procedures such as: each procedure that will be performed on each experimental group, personnel who will be performing each procedures, the location where each procedure will be performed, and information related to each procedure that your institution may require.

Procedures Tab > Experimental Design and Timeline



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

1. Click on the tab header to access the Procedures tab.

Procedures

2. If it is not already expanded, click on the section header to expand the Experimental Design and Timeline section. 
3. In the **Experimental Design and Timeline** field enter a summary. You may do this by hand keying the text directly into the freeform text field, by copying and pasting from a source document, or by clicking the pencil icon  to open a text editor in a pop-up window. There is a character limit of 2,000.
4. Enter text in the **Description** field in the Add Attachment subsection to briefly describe your attachment.
5. 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.

Note PDF format is required for attachments in the Add Attachment subsection.

6. Click the add button. 
7. Repeat Steps 4 through 6 until all attachments are added.
8. Click the Save button at the bottom of the screen to save your work. 

Procedures Tab > Procedure Details

The Procedure Details section requires you to select the procedure or procedures you plan to perform on each Group defined in the Species/Group tab.

Once you select one or more procedures from the included categories listing, the system will expand the fields to allow data entry related to each procedure in the following sub tabs:

- Procedures
- Personnel
- Location

There is also a Summary sub tab to consolidate and present all of the information entered in the Procedures, Personnel, and Location tabs in a single view.

▼ Procedure Details

procedures

personnel

location

summary

Sub Tab > Procedures

Hide

Procedures

Included Categories ⓘ

Surgical Procedures

☐ Minor Survival Surgery
 ☐ Major Survival Surgery
 ☐ Multiple Survival Surgeries
 ☐ Non-Survival Surgery
 ☐ Medical Device Testing

Other Procedures

☐ Aversive Stimuli
 ☐ Antibody Production
 ☐ Immunization
 ☐ Blood/Tissue Sample Collection
 ☐ Other

Drugs

☐ Analgesics
 ☐ Anesthetics
 ☐ Paralytics
 ☐ Antibiotics
 ☐ Experimental Drugs

Hazardous Agents

☐ Radiation/Radioactive Isotopes
 ☐ Hazardous Substances
 ☐ Infectious Agents

Restraint

☐ Physical Restraint
 ☐ Chemical Restraint

Environment

☐ Food/Fluid Restrictions
 ☐ Nutritional Studies
 ☐ Abnormal Environmental Conditions

Euthanasia

☐ Chemical Method
 ☐ Physical Method

Update

- If it is not already expanded, click on the section header to expand the Procedure Details section.
- Check the box(es) next to each procedure that will be utilized over the course of the study.

▼ Procedure Details

procedures

personnel

location

summary

Hide

Procedures

Included Categories ⓘ

Surgical Procedures

☐ Minor Survival Surgery
 ☒ Major Survival Surgery
 ☐ Multiple Survival Surgeries
 ☐ Non-Survival Surgery
 ☐ Medical Device Testing

Other Procedures

☐ Aversive Stimuli
 ☐ Antibody Production
 ☐ Immunization
 ☐ Blood/Tissue Sample Collection
 ☐ Other

Drugs

☐ Analgesics
 ☐ Anesthetics
 ☐ Paralytics
 ☐ Antibiotics
 ☒ Experimental Drugs

Hazardous Agents

☐ Radiation/Radioactive Isotopes
 ☐ Hazardous Substances
 ☐ Infectious Agents

Restraint

☐ Physical Restraint
 ☒ Chemical Restraint

Environment

☐ Food/Fluid Restrictions
 ☐ Nutritional Studies
 ☐ Abnormal Environmental Conditions

Euthanasia

☒ Chemical Method
 ☐ Physical Method

Update

> Surgical Procedures : Major Survival Surgery

> Drugs : Experimental Drugs

> Restraint : Chemical Restraint

> Euthanasia : Chemical Method

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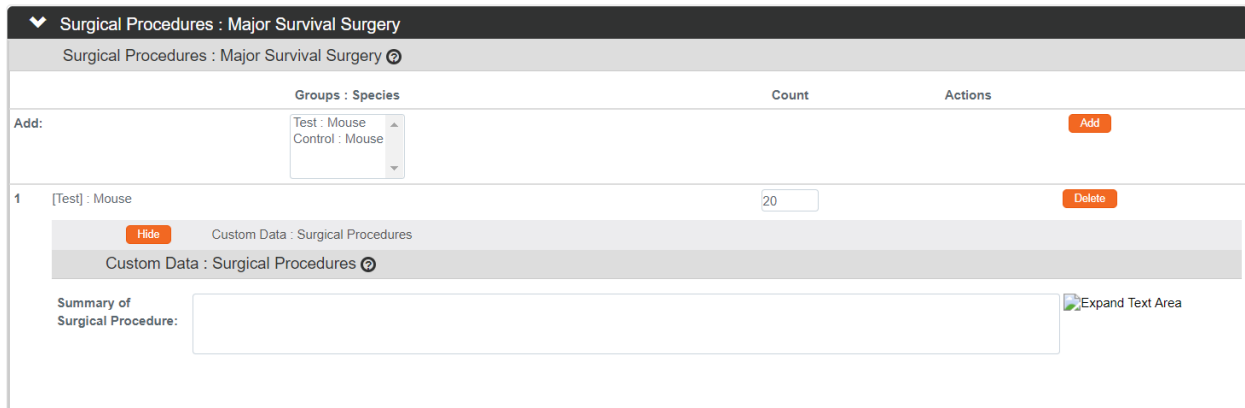
29

Result Note that Streamlyne Research creates a panel for each Procedure you select. Panels will appear below the Procedure Details panel.


If necessary, click the Update button if the panels do not appear to be syncing when you add or remove checkboxes in the Included Categories subsection.



Otherwise, proceed to the next Step.



3. Select the group(s) in the **Groups:Species** field on which the procedure will be performed. Hold down the Ctrl key to select more than one group.

4. Click the Add button. 


Result The system will display the count of species (retrieved from data entered in the Species/Group tab) and create a Custom Data subsection with fields for additional procedure information for each group or set of groups.

The system provides one set of Custom Data fields for all groups selected this way.

5. Update the **Count** field with the number of animals in the group that will have this procedure performed, if applicable.

6. Click the Show button next to the Custom Data procedure to reveal fields to provide additional information determined by your institution to be relevant to this procedure.

7. Complete the Custom Data fields.

8. Repeat Steps 3 through 7 for each procedure selected in Step 2.
9. To remove a Procedure, uncheck the Procedure in the Included Categories section. This will remove the Procedure panel generated by the system below the Included Categories section, but will preserve the data. Check the Procedure again from within Included Categories to make it re-appear.
10. Click the Save button. 


Sub Tab > Personnel

The Personnel sub tab allows you to indicate personnel who will be performing the different procedures.





1. Click the personnel button under the Procedure Details header.

Result The system displays a subsection with each of the personnel listed in the Personnel tab for the protocol. Streamlyne Research dynamically updates the Personnel subsection in the Procedure Details section with any personnel changes made in the Personnel tab.

2. Click the View Training Details button to view training details for the person identified. This information is maintained by your institution. Check with your IACUC Administrator for further information. 

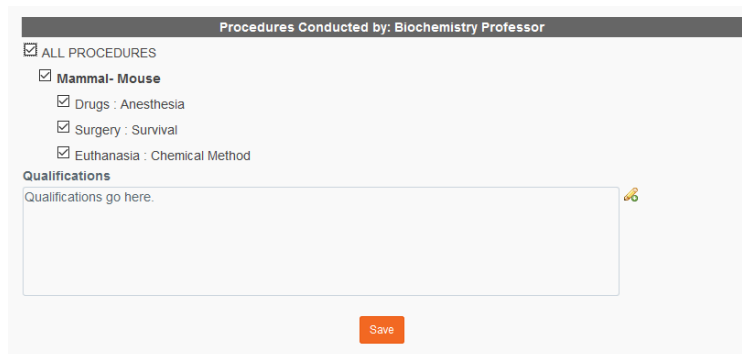
Result A window will open displaying the person's training information if it is maintained.


Training Details for : Biochemistry Professor								
Procedure Description	Species Name	Training Number	Training	Description	Date Requested	Date Submitted	Date Acknowledged	
Minor Survival Surgery	Mouse	3	2095	CITI ACU Animal Specific: Working with Mice in Research Settings	2019-01-01	2019-01-29	2019-01-29	

Person Name	Qualifications	Procedures	Actions
1 Biochemistry Professor			 

3. Tap the Esc button or click anywhere outside the window to close the Training Details window.
4. Click the Edit Procedure button. 

Result A window will open to add details related to the procedure(s) this individual will be performing or will be involved in. Items will be grouped by Species or Group, based on settings determined by your institution.



5. Check each procedure that person will perform or click the checkbox next to ALL PROCEDURES to automatically select all procedures.
6. In the Qualifications field, enter freeform text to describe how the person performing the procedure is qualified to perform the procedure.
7. Click the Save button once all applicable procedures are marked and the qualifications are adequately described. 

Result The system will display the information on the Personnel sub tab.

Personnel ⓘ			
Person Name	Qualifications	Procedures	Actions
1 Biochemistry Professor View Training Details	Trained in all procedures.	Mouse - Surgical Procedures:Major Survival Surgery Mouse - Drugs:Experimental Drugs Mouse - Restraint:Chemical Restraint Mouse - Euthanasia:Chemical Method	Edit Procedure

8. Click the Edit Procedure button again to edit this information if changes are needed.
9. Complete Steps 2 through 7 for each person listed on the Personnel sub tab.

Sub Tab > Location


The Location section allows you to provide location details of where the procedures will be performed. You can provide multiple locations, if the procedures will be conducted at various sites. For each location added, you are required to select the procedures that will be performed at that location.



1. Click the location button under the Procedure Details header.

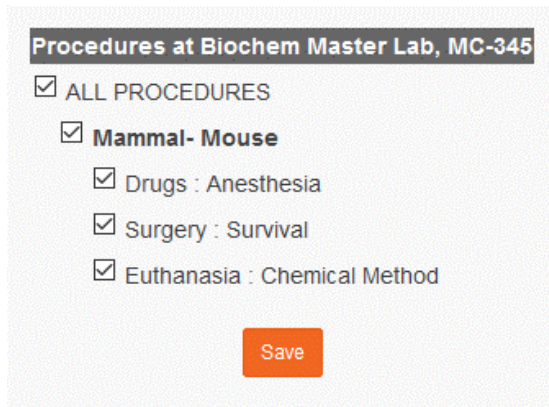
Result The system displays a Location subsection.

A screenshot of a web application showing a 'Location' subsection. At the top, there is a 'Hide' button and the title 'Location'. Below this is a table with four columns: '* Type', '* Name', 'Room', and 'Description'. The 'Add' button is located on the far right of the table. The table has a scroll bar at the bottom.

2. To enter a location, first click the arrow in the **Type** field to display the Location Type dropdown and make a selection. Location Types are configurable by your institution.
3. Click the arrow in the **Name** field to display the Location Name dropdown and make a selection. Location Names offered depend on the Location Type selection and are configurable by your institution.
4. Enter freeform text in the **Room** field depending on your institution's business practices.
5. Enter freeform text in the **Description** field depending on your institution's business practices.
6. Click the Add button on the far right. Use the scroll bar at the bottom of the Location subsection if necessary. 

Result An Edit Procedure and a Delete button will appear on the far right side of the Location entry line.

7. Click the Edit Procedure button.



Procedures at Biochem Master Lab, MC-345

☒ ALL PROCEDURES

☒ **Mammal- Mouse**


☒ Drugs : Anesthesia

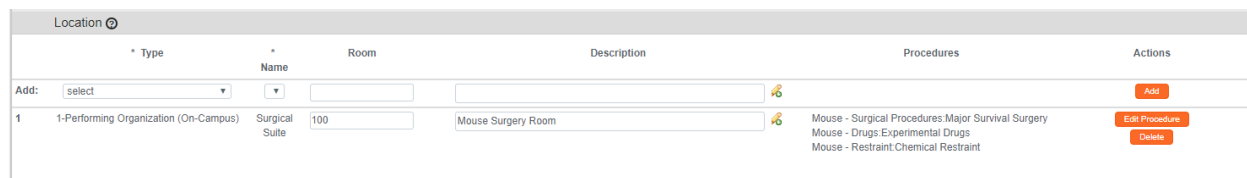
☒ Surgery : Survival

☒ Euthanasia : Chemical Method

Save

Result A window will open to add details related to the procedure(s) that will take place in this location. Items will be grouped by Species or Group, based on settings determined by your institution.

8. Check each procedure that will be performed at the location or click the checkbox next to ALL PROCEDURES to automatically select all procedures.
9. Click the Save button. 
10. Complete Steps 2 through 9 for any additional Locations.



	* Type	* Name	Room	Description	Procedures	Actions
Add:	select					Add
1	1-Performing Organization (On-Campus)	Surgical Suite	100	Mouse Surgery Room	Mouse - Surgical Procedures:Major Survival Surgery Mouse - Drugs:Experimental Drugs Mouse - Restraint Chemical Restraint	Edit Procedure Delete

Sub Tab > Summary

The Summary sub tab in the Procedure Details section consolidates all the data entered in the Procedures, Personnel, and Location sub tabs. The data displayed within Summary is in read only mode and is dynamically updated. You can choose to view data within Summary organized by Species or by Groups. The system will inform you which view is displayed. Summary Displayed by Group is the default.

Hide

Summary

View Summary by :

group

species

(Summary Displayed by Group) ⓘ

For each Species/Group, each procedure is described to include species count, custom data, procedure personnel, and locations.

Surgical Procedures : Major Survival SurgeryCount: 20

Custom Data

Summary of Surgical Procedure : Surgery will be performed on mice.

Procedure Personnel

Biochemistry Professor

View Training Details

View Qualifications

Locations

Location Type: 1-Performing Organization (On-Campus)

Location Name: Surgical Suite

Room: 100

Description: Mouse Surgery Room

Updating the Protocol Exceptions Tab

The Protocol Exception section is used to document any deviation or departure from standard procedures as stated by the National Research Council's [Guide for the Care and Use of Laboratory Animals](#).

For example, the Guide might state that if dogs are to be used as laboratory animals they need to be exercised a certain number of times in a day. If the proposed research involving dogs cannot adhere to this standard, you need to provide justification within the Protocol Exception section.

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

Protocol Exception
2. If it is not already expanded, click on the section header to expand the Protocol Exceptions section.

> Protocol Exceptions
3. If there are no Protocol Exceptions and your institution requires certification, check the Certification checkbox indicating that there are no Protocol Exceptions.

Protocol Exceptions

Protocol Exceptions ⓘ

	* Exception	* Species	* Exception Justification and Description	Exception Count	Actions
Add:	<input type="text" value="select"/>	<input type="text" value="select"/>	<input type="text"/>	<input type="text"/>	<input type="button" value="Add"/>

Certification: ☒ I certify that there are no Protocol Exceptions. No Procedures deviate from the standards established in the NRC Guide for the Care and Use of Laboratory Animals.

- If there are Protocol Exceptions to report, click the arrow next to the **Exception** field for a dropdown list of options to select. These are configurable by your institution.

select

- Food/fluid regulation or restriction
- Environmental temperature or humidity levels outside of recommended ranges
- Air quality/ventilation exception
- Noise/vibration exception
- Lighting intensity/photo period exception
- Exception to space requirements, including use of innovative or metabolic caging
- Exception to husbandry recommendations, including atypical diet or bedding
- Routine sanitation/waste disposal/pest control exception
- Use of wire bottom cages for rodents
- Singly housing social species
- Dog exercise program exception
- Non-human primate environmental enhancement plan exception
- Use of non-pharmaceutical-grade chemicals and other substances
- Prolonged restraint
- Multiple survival surgical procedures
- Monoclonal antibody production via ascites
- Death as an endpoint
- Method of euthanasia inconsistent with AVMA Guidelines
- Other exception

- Click the arrow next to the **Species** field to choose the species for which you will be deviating from standard procedure.
- Enter freeform text in the **Exception Justification and Description** field to describe the reason or justification for departing from standard procedures.
- Enter digits in the **Exception Count** field indicating the number of animals that will be effected.
- Click the Add button.
- Repeat Steps 4 through 7 if there are additional Protocol Exceptions to identify.

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. The asterisk (*) preceding each field label indicates the data element is required.

Custom Data

Updating the Special Review Tab

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

- Data sharing between projects that are tracked on separate IACUC protocol documents.
- Project-related human research protocols that are tracked on IRB 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.

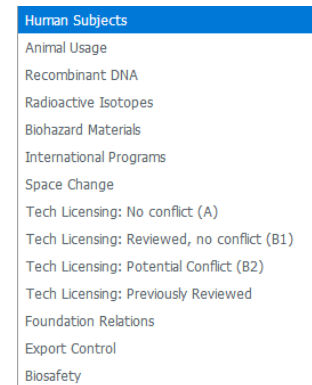
Your institution may also elect to configure Streamlyne to automatically notify people or groups of Special Reviews when the protocol is submitted.

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

Special Review

The screenshot shows the 'Special Review' tab interface. At the top, there is a dark header with a dropdown arrow and the text 'Special Review'. Below this is a light gray bar with the text 'Special Review' and a help icon. The main area contains a table with the following columns: '* Type', '* Approval Status', 'Protocol Number', 'Application Date', 'Approval Date', 'Expiration Date', 'Exemption #', and 'Actions'. The 'Add:' row shows dropdown menus for '* Type' and '* Approval Status', input fields for 'Protocol Number', 'Application Date', 'Approval Date', and 'Expiration Date', and a dropdown for 'Exemption #' with options E1, E2, and E3. To the right of the table are 'Add' and 'Reset' buttons. Below the table is a 'Comments:' section with a text area and a pencil icon. At the bottom, there is a horizontal scrollbar.

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




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

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

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

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

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

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

7. Click the Add button to complete this action. 

8. 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.

1. Click on the tab header to access the Permissions section.

Permissions

2. Scroll down to the Users section. If it is not already expanded, click on the header to expand the section.

Users

Users						
Users						
	* User Name	Full Name	Unit #	Unit Name	Role	Actions
Add:	<input type="text"/>				unassigned	<button>Add</button>
1	bioprofessor	Biochemistry Professor	105010	Biochemistry	Aggregator PI Faculty	<button>Edit Role</button>
2	bioresearcher	Biochemistry Researcher	105010	Biochemistry	Viewer SP	<button>Edit Role</button> <button>Delete</button>

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

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

unassigned
Aggregator
Viewer

5. Click the Add button to complete the action.

Add

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.

Delete

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. 

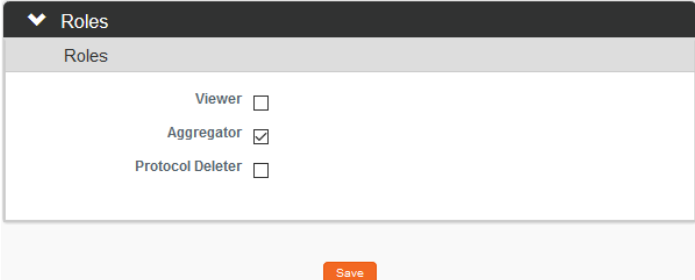
Otherwise, skip to the next section.

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.



The image shows a pop-up window titled 'Roles' with a dropdown arrow on the left. Inside the window, there is a table with three rows: 'Viewer' with an unchecked checkbox, 'Aggregator' with a checked checkbox, and 'Protocol Deleter' with an unchecked checkbox. At the bottom right of the window is a 'Save' button.

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.

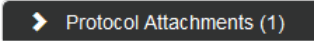
Adding Notes & Attachments

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.



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



To add a Note only, skip to Step 11.

▼ Protocol Attachments (1)

Add Protocol Attachment ?

* Attachment Type :

* Status :

Email :

Comments :

* File Name : No file selected.

Contact Name :

Phone :

* Description :

Attached Items ?

Show: Sort By:

Other - My biography - Professor, Biochemistry (07/20/2018 09:29 AM)

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

select

- Adverse Event
- Amendments and Renewals
- Brochure
- Investigational New Drug Brochure
- Other Attachments
- Other Documents
- Other Protocol Attachments
- Progress Report
- Protocol Narrative
- Protocol Submission Documents

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

select

- Complete
- Incomplete

- 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.

Attached Items ?	
Show: select	Sort By: Attachment Type
Show	Brochure - Brochure description - Professor, Biochemistry (08/06/2018 02:34 PM)
Show	Other Attachments - Description of Other Attachme... - Professor, Biochemistry (08/06/2018 02:33 PM)


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.

 Notes (0)

Notes ?					
Created By	Updated By	* Note Topic	* Note Text	Restricted?	Actions
Add:				<input type="checkbox"/>	

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 Proposal

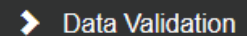
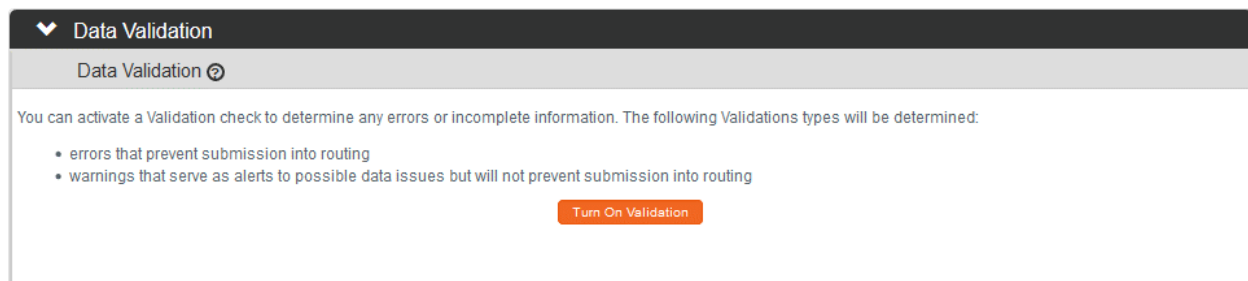
When a new protocol is complete, the Request an Action options available on the IACUC Protocol Actions tab include submitting the protocol for review or deleting the protocol. Data Validation is also available. These processes are defined in this section. A complete list of all available protocol actions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

Validating the Protocol

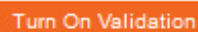
1. Click the tab header to access the IACUC Protocol Actions tab.

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

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

A dark grey rectangular button 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 notification box with rounded corners, containing the text "1 error(s) found on page." in red.

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

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


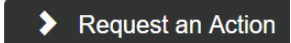
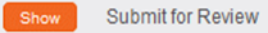
Otherwise, skip to the next process.

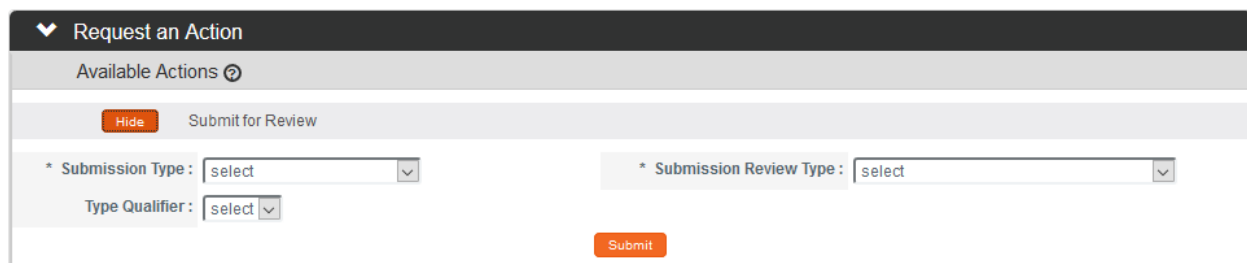
5. Streamlyne Research returns to the document section where the problem resides. Make your corrections and save the updated document.
6. Repeat Steps 4 and 5 as many times as necessary to resolve all errors.

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 IACUC

Follow these steps to submit your Protocol to the IACUC. 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 IACUC 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.

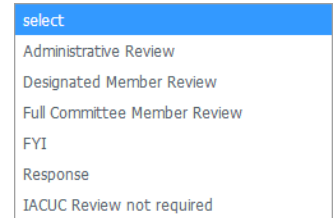
1. Click on the tab header to access the IACUC Protocol Actions tab. 
2. Click on the header to expand the Request an Action tab. 
3. Click the Show button next to the Submit for Review option under the Available Actions subsection. 



4. Streamlyne Research will display the Submit for Review subsection.
Click the arrow 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 Continuation, these will show as options, if applicable.

5. Click the arrow next to the **Submission Review Type** field to select the IACUC submission type from the dropdown list.



A screenshot of a dropdown menu for 'Submission Review Type'. The menu is open, showing a list of options: 'select' (highlighted in blue), 'Administrative Review', 'Designated Member Review', 'Full Committee Member Review', 'FYI', 'Response', and 'IACUC Review not required'.

6. The **Type Qualifier** field will offer options in the dropdown based on **Submission Type** selected. If no dropdown options appear or if none are applicable, skip to Step 7.

7. Click the Submit button to send the IACUC Protocol into workflow.

Submit

Result A Holding Page will appear for several seconds and then return to the submitted protocol. You can click the Return to Action List button if you do not wish to return to your protocol.

Holding Page

The document is being processed.
You will be returned to the document once processing is complete.
You can also return to the Action List by clicking below.

[Return to Action List](#)

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 IACUC.

Document Number : 32500	Document Status : Submitted to IACUC
Initiator:Last Updated : bioprofessor : 02:54 PM 08/06/2018	Submission Status : Pending
Protocol # : 1808000216	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 IACUC Protocol Actions tab and making sure the correct approvers are included in the Pending Action Requests and Future Action Requests sections.

For more information 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 IACUC Protocol Actions](#).

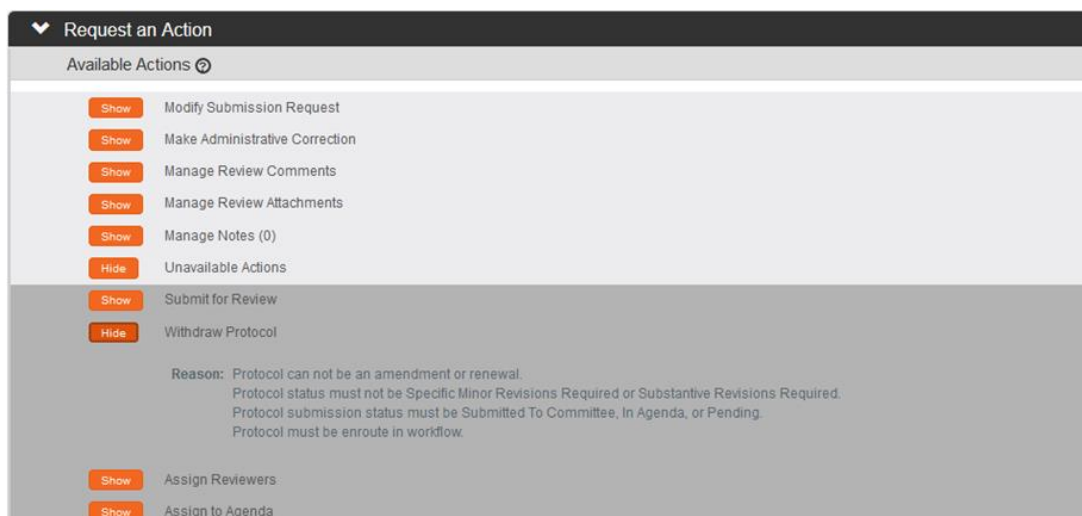
Available Actions

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 IACUC Administrator. This action will deliver the document back into the Action List of the user who

created/initiated the protocol. You can then make edits 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 IACUC 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 IACUC review.

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

IACUC 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 : 32758

Initiator:Last Updated : medicineprofessor : 11:35 AM 08/15/2018

Protocol # : 1808000222

Document Status : Recalled in Routing

Submission Status : Recalled in Routing

Expiration Date :

Withdrawing a Protocol

If you have submitted an IACUC protocol that has reached the IACUC 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 IACUC Administrator will be able to withdraw the protocol.

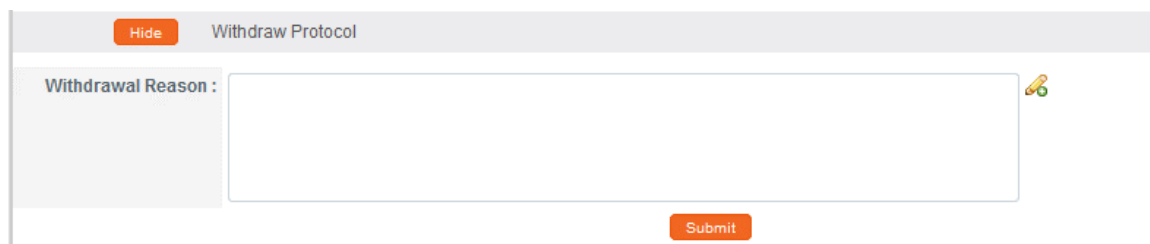
1. Using Lookups, locate the protocol you would like to Withdraw.
2. Click the edit hyperlink.
3. Click on the tab header to access the IACUC Protocol Actions tab.
4. Click on the header to expand the Request an Action tab.
5. Click the Show button next to Withdraw Protocol.

IACUC Protocol Actions

➤ Request an Action

Show

Withdraw Protocol



Hide Withdraw Protocol

Withdrawal Reason :

Submit

6. Enter freeform text in the **Withdrawal Reason** field.
7. Click the Submit button to finalize your withdrawal.

Submit

Result The IACUC 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 or Amendment, but then decide you will not be submitting it to the IACUC 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 IACUC Protocol Actions tab.

IACUC Protocol Actions

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

➤ Request an Action

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

Show

Delete Protocol, Amendment, or Renewal

Hide Delete Protocol, Amendment, or Renewal

Delete Reason :

Submit

4. Enter an explanation in the **Delete Reason** field.
5. Click the Submit button.

Submit
6. Streamlyne Research will prompt you to confirm the action.
Click the Yes button to confirm the deletion.

Yes

Note The Protocol Status will be updated to Deleted.

Editing a Returned Protocol

Sometimes a protocol gets sent back to the Principal Investigator by an IACUC Administrator because it is incomplete, contains errors, or needs revisions based on committee feedback. Generally, a protocol is returned at a 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 major or minor revisions before approval can be granted.

The information available to the Principle 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 IACUC 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:

Show	FYI	28439 Streamlyne Research Notification	Protocol Returned to PI Action	FINAL	03:44 PM 03/29/2018	NONE	
------	-----	--	--------------------------------	-------	------------------------	------	--

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 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.



COM	24099	IACUC Protocol
-----	-------	----------------

Accessing a Protocol Formally Returned for Revisions

This second scenario occurs when an IACUC 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 Minor Revisions Requested or Major Revisions Required.

Follow these steps when the title of the FYI Notification reads “Major revisions required” or “Minor revisions requested” as shown in the image below:

		32761	Streamlyne Research Notification	Major revisions required	FINAL	10:25 AM 08/15/2018
---	---	-------	----------------------------------	--------------------------	-------	------------------------

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.



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.


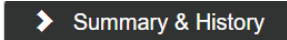
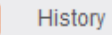

6. Return to the body of the FYI Notification and click the hyperlinked protocol number to open the document.

Reviewing Reasons for the Return

There are two places that an IACUC 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 IACUC Administrator logs the reason for the return and/or the requested changes in the Review Comments subsection. Follow these steps to access this information:


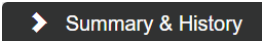
1. Click on the header to access the IACUC Protocol Actions tab.
2. Click on the header to access the Summary & History section.
3. Click on the Show button to expand the History section.
4. Read through the comments to understand the kind of changes that are required to the resubmit the document to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

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

History ⓘ

View Action Date Range: Beginning On  Ending On  Filter Clear

Description	Date	Action Date	Comments	Updated By	Update Time
<input type="radio"/> Major Revisions Required	08/15/2018 10:07 AM	08/15/2018	Administrative comments for Return for Major Revisions	iacucadmin	08/15/2018 10:07 AM
Show Correspondences (1)					
Show Notifications (1)					
<input type="radio"/> Record Committee Decision	08/15/2018 09:58 AM	08/15/2018		iacucadmin	08/15/2018 09:58 AM
<input type="radio"/> Assigned to Agenda	08/15/2018 09:28 AM	08/15/2018	Comments during Assign to Agenda step.	iacucadmin	08/15/2018 09:28 AM
<input type="radio"/> Modify Protocol Submission	08/15/2018 09:27 AM	08/15/2018	ModifyProtocolSubmission	medicineprofessor	08/15/2018 11:06 AM
<input type="radio"/> Assigned to Agenda	08/13/2018 01:20 PM	08/13/2018	Comments during Assign to Agenda step.	iacucadmin	08/13/2018 01:20 PM
Show Notifications (7)					
<input type="radio"/> Modify Protocol Submission	08/13/2018 12:18 PM	08/13/2018	ModifyProtocolSubmission	medicineprofessor	08/15/2018 11:06 AM
<input type="radio"/> Submitted to IACUC	08/13/2018 08:16 AM	08/13/2018	SubmittedToIACUC	medicineprofessor	08/13/2018 08:16 AM
Show Notifications (2)					
Show Questionnaires (1)					
Protocol Created	08/13/2018 07:52 AM	08/13/2018	Protocol created	medicineprofessor	08/13/2018 07:52 AM
Show Notifications (1)					

Load Load selected node into Summary View, above

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

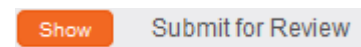
1. Once your changes are complete and you are ready to resubmit your protocol, click on the header to access the IACUC Protocol Actions tab.


IACUC Protocol Actions

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

➤ Request an Action

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

A screenshot of a web form titled 'Request an Action'. It has a dark header with a dropdown arrow and the title. Below is a section 'Available Actions' with a 'Hide' button and the text 'Submit for Review'. The form contains two dropdown menus: 'Submission Type' with 'Response to Previous IACUC Notification' selected, and 'Submission Review Type' with 'select' selected. There is also a 'Type Qualifier' dropdown with 'select' and a 'Submit' button.

4. Click the arrows next to the **Submission Type** field and select Response to Previous IACUC Notification from the dropdown list.
5. Click the arrows next to the **Submission Review Type** field, and then select the correct value from the dropdown list.
6. Click the Submit button. 

Result A Holding Page will appear for several seconds and then return to the submitted protocol. You can click the Return to Action List button if you do not wish to return to your protocol.

Holding Page

A screenshot of a 'Holding Page' with a light grey background. It contains a white box with the text: 'The document is being processed. You will be returned to the document once processing is complete. You can also return to the Action List by clicking below.' Below the text is an orange button labeled 'Return to Action List'.

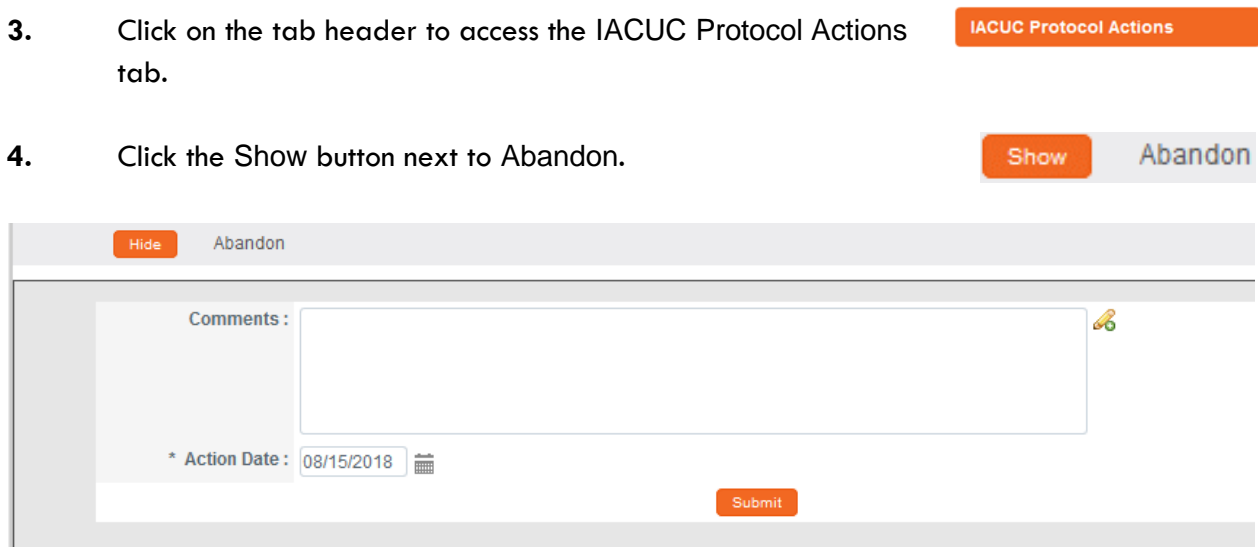
Note Upon completion of this action, the following updates occur:

- The Protocol Status updates to Submitted to IACUC, 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 IACUC Administrator will be able to perform all actions available before the document was returned.


Abandoning a Protocol

An IACUC Protocol can be abandoned if it has been returned for major or minor revisions, but the PI no longer intends to pursue the study. After the Abandoned action has been taken, the protocol is considered inactive and no further action can be performed on it.

1. Locate the Protocol on your Action List.
2. Click the hyperlinked Document ID number in the Id column to open the document in a new browser tab.
3. Click on the tab header to access the IACUC Protocol Actions tab.
4. Click the Show button next to Abandon.



The screenshot shows the 'IACUC Protocol Actions' tab with a sub-tab 'Abandon'. The form includes a 'Comments' field, an 'Action Date' field with a calendar icon, and a 'Submit' button. The 'Action Date' is set to 08/15/2018.

5. In the **Comments** field, enter freeform text to describe the reason you would like to abandon the protocol.
6. 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.
7. Click the Submit button to finalize the Abandon action.

Result The PI should receive a response indicating that their protocol has officially been abandoned. 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 Abandoned. A new protocol must be submitted for further review.

Understanding Streamlyne Amendments & Continuations

The purpose of this section is to help you understand how Streamlyne treats Amendments and Continuations 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 IACUC of any changes to a previously approved study.

Continuation

Streamlyne allows an approved protocol to be continued after a set period of time (e.g., one year). For example, some institutions may require that a Continuation be submitted on an annual basis, regardless of the expiration date. Streamlyne allows for both Continuations and Continuations with Amendments, as it may be necessary to amend the approved animal study at the same time.

Starting from a Copy

When a user initiates an Amendment or Continuation, 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 for the copy in the Document Header, as shown above in the **Copied from Document Header ID** field.

Differences in Naming Convention

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

Merging Amendments and Continuations

After the review process is complete, and the amendment or continuation 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 Continuation Incorporated into Protocol.

Document Status : Amendment Incorporated into Protocol

Using the Summary & History Section

When the Amendment or Continuation is first submitted, reviewers can access the entire history of the project by navigating to IACUC Protocol Actions > Summary & History.

Identifying Changes in the Review Process

Hide Create Amendment

* Summary:

*Amend:

- ☐ General Info
- ☐ Funding Source
- ☐ Protocol References & Other Identifiers
- ☐ Protocol Organizations
- ☐ Questionnaire
- ☐ Species/Groups
- ☐ Protocol Exception
- ☐ Add/Modify Notes & Attachments
- ☐ Areas of Research
- ☐ Special Review
- ☐ Protocol Personnel
- ☐ Three R's
- ☐ Procedures
- ☐ Others

Create

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 Continuations, the system will display the Continuation 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/Continuations After Approval is Granted

After the approval has been granted, the Continuation and amendment information can then be viewed in the future from the Amendment/Continuation History section in IACUC 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: IACUC Actions > Amend or Continue IACUC Protocol. Clicking this menu option will display all protocols available to the user that qualify for an amendment or continuation.

Navigation

Main Menu > IACUC > IACUC Actions > Amend or Continue IACUC Protocol

Actions	Protocol #	Protocol Type	Sequence Number	Investigator	Title	Protocol Status	Approval Date	Expiration Date	Last Approval Date	Initial Submission Date	Lead Unit	Lead Unit Name	Summary/Keywords	Active
perform action	1505000098	Breeding	0	Biochemistry Professor	Testing XML	Administratively Approved	06/10/2015	06/09/2018		05/27/2015	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 IACUC Protocol Actions > Request an Action panel. The Available Actions will display multiple options for you.


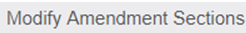
3. Click the Show button next to Create Amendment.

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 IACUC Protocol Actions > Request an Action > Available Actions.
8. Click the Show button next to Modify Amendment Sections.  

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


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

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

11. When ready to submit, navigate back to IACUC 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**.

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 IACUC.

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

Creating & Submitting a Continuation

Continuations can be submitted by the PI or protocol creator at any time after initial approval has occurred. However, the timeline for submitting a Continuation depends on both the expiration date and institutional business practices. Typically, these are required annually. The review process for Continuations 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 Continuation without Amendment.

You can access the protocol you would like to initiate a Continuation through various Lookups. However, the recommended way to initiate a Continuation is through IACUC Actions > Amend or Continue IACUC Protocol. Clicking this menu option will display all protocols available to the user that currently qualify for a continuation.

Navigation

Main Menu > IACUC > IACUC Actions > Amend or Continue IACUC Protocol

Actions	Protocol #	Protocol Type	Sequence Number	Investigator	Title	Protocol Status	Approval Date	Expiration Date	Last Approval Date	Initial Submission Date	Lead Unit	Lead Unit Name	Summary/Keywords	Active
perform action	1505000098	Breeding	0	Biochemistry Professor	Testing XML	Administratively Approved	06/10/2015	06/09/2018		05/27/2015	105010	Biochemistry		Yes

1. Locate the protocol you wish to initiate a Continuation.
2. Click the corresponding perform action hyperlink.

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

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


Show Create Continuation without Amendment

Hide

Create Continuation without Amendment

* Summary:

Create

4. Describe the progress of the project and the purpose of the continuation 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 Continuation document.

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

6. When ready to submit, navigate back to IACUC 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** and **Submission Review Type**.

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 IACUC.

See [Understanding Streamlyne Amendments & Continuations](#) for details about the Summary & History section.

Creating & Submitting a Continuation with Amendment

While the system will allow a PI or the protocol creator to submit a Continuation with Amendment protocol at any time after initial approval has occurred, the timeline for submitting a Continuation depends on both the expiration date on the protocol and institutional business practices. Typically, a Continuation is required annually. The review process for Continuations 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 Continuation with Amendment.

You can access the protocol you would like to initiate a Continuation through various Lookups. However, the recommended way to initiate a Continuation is through IACUC Actions > Amend or Continue IACUC Protocol. Clicking this menu option will display all protocols available to the user that currently qualify for a continuation.

Navigation

Main Menu > IACUC > IACUC Actions > Amend or Continue IACUC Protocol

Actions	Protocol #	Protocol Type	Sequence Number	Investigator	Title	Protocol Status	Approval Date	Expiration Date	Last Approval Date	Initial Submission Date	Lead Unit	Lead Unit Name	Summary/Keywords	Active
perform action	1505000098	Breeding	0	Biochemistry Professor	Testing XML	Administratively Approved	06/10/2015	06/09/2018		05/27/2015	105010	Biochemistry		Yes


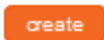
1. Locate the protocol you wish to initiate a Continuation.
2. Click the corresponding perform action hyperlink.

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

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

Show

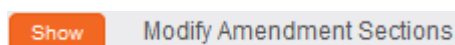
Create Continuation with Amendment



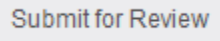

4. Describe the purpose and content of the amendment in the **Summary** field. If necessary, click on the edit button  to access a text editor with character count.
5. In the **Amend** section, check all boxes for sections you wish to amend. Protocol sections with checked boxes will be opened for editing.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

Result Streamlyne will open a new Continuation document. 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 IACUC 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 a Continuation Questionnaire, an Amendment Questionnaire, or both. If so, you will need to complete these questionnaires before submitting the document.
11. When ready to submit, navigate back to IACUC 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** and **Submission Review Type**.
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 IACUC.

See [Understanding Streamlyne Amendments & Continuations](#) for details about the Summary & History section.

Communicating with the IACUC

Streamlyne delivers a number of features to facilitate communication from the study team to the IACUC 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 provide the steps to execute them.

Notifying the IACUC

This process applies to all instances in which the PI needs to notify the IACUC of an event that occurred that may require further review or scrutiny by an IACUC Administrator and/or IACUC 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 IACUC action are the same.

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

Navigation

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

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

Result This will open the protocol on the IACUC 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 IACUC section will display.

▼ Request an Action

Available Actions ⓘ

Hide Notify IACUC

Details

Submission Type Qualifier: Modification/Amendments/revision/Significant New F

Committee:



* Submission Review Type: Administrative Review

Comment:

Attachments

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

Submit

4. In the **Submission Type Qualifier** field, use the dropdown to select the appropriate option.
5. In the **Submission Review Type** field, use the dropdown to select the appropriate option.
6. In the **Committee** field select the committee that reviews your protocol, if known. If not, proceed to the next Step.
7. In the **Comment** field, enter freeform text regarding the reason for the notification.
8. In the Attachments subsection, upload an attachment by clicking the Browse button and following your operating system's prompts if needed.
9. In the **Description** field enter a description of the attachment if needed.
10. Click the Add button. 
11. Repeat Steps 8 through 10 until all necessary attachments are added.
12. Click the Submit button to finalize the Notify IACUC action. 

Result A notification and attachments if present will go to the IACUC Administrator and/or IACUC 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 will receive a response indicating that the IACUC 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 IACUC may request further information before full acknowledgment takes place.

Request 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 > IACUC > IACUC 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 IACUC 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

Add:

Attachment

Browse...


No file selected.

Description


Actions

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. 

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

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

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

Note Once the IACUC 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.

Request to Deactivate a Protocol

Your institution may require PI's to formally deactivate their protocols once they are no longer actively working on your animal protocol.

Navigation

Main Menu > IACUC > IACUC Lookups > All My Protocols

1. Locate the protocol you would like to deactivate.

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 IACUC Protocol Actions > Request an Action > Available Actions.

4. Click the Show button next to Request to Deactivate.

Hide Request to Deactivate

Details

Reason :

Attachments

Add: Choose File No file chosen

Attachment Description Actions

Submit

5. In the **Reason** field, enter freeform text to describe the reason you would like to deactivate the protocol.
6. In the Attachments subsection, upload an attachment by clicking the Browse button and following your operating system's prompts, if needed.
7. In the **Description** field enter a description of the attachment if needed.
8. Click the add button. **add**

Notes Repeat Steps 6 through 8 until all necessary attachments are added.

9. Click the Submit button to finalize the Request to Deactivate action. **submit**

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

Note Once the IACUC Administrator has received the Request to Deactivate and the request has been approved, the user should receive a response indicating that your protocol has officially been deactivated. 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 IACUC 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 IACUC protocols and IACUC-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 IACUC 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 IACUC Administrator will take action on the protocol. Amendments, continuations, and IACUC 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


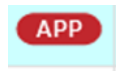

This section will describe the steps to review and approve an IACUC Protocol for departmental and other institutional reviewers and approvers. These users will typically have read-only access to the protocol to enable them to review the information before taking approval action.




   Main Menu - Identity -  Reporting

Action List


Action	Id	Type	Title
	6873	IACUC Protocol Review	IACUC Protocol Review - Professor/Protocol# 1501000027
	7258	IACUC Protocol	IACUC Protocol - New IACUC Protocol
	13640	Common Committee Document	Common Committee Document - edit
	14363	IACUC Protocol	IACUC Protocol - IACUC DEMO
	14376	IACUC Protocol Review	IACUC Protocol Review - Professor/Protocol# 1505000079
	14379	IACUC Protocol	IACUC Protocol - IACUC DEMO 2
	15569	IACUC Protocol Review	IACUC Protocol Review - Researcher/Protocol# 1506000120
	15607	IACUC Protocol	IACUC Protocol - MASTER DEMO PROTOCOL
	15612	IACUC Protocol Review	IACUC Protocol Review - Professor/Protocol# 1509000149
	15733	IACUC Protocol	IACUC Protocol - Revisions demo

1. Access your Action List by clicking the Action List button  on the Menu Bar.
2. Documents 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, continuation or request by referencing the [FOR PRINCIPAL INVESTIGATORS](#) section.
4. When you are ready to execute an action, click the IACUC Protocol Actions tab header. 

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:


Yes


No

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. 

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


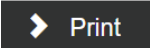

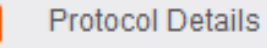
9. Click the No button to return to the protocol without disapproving. 

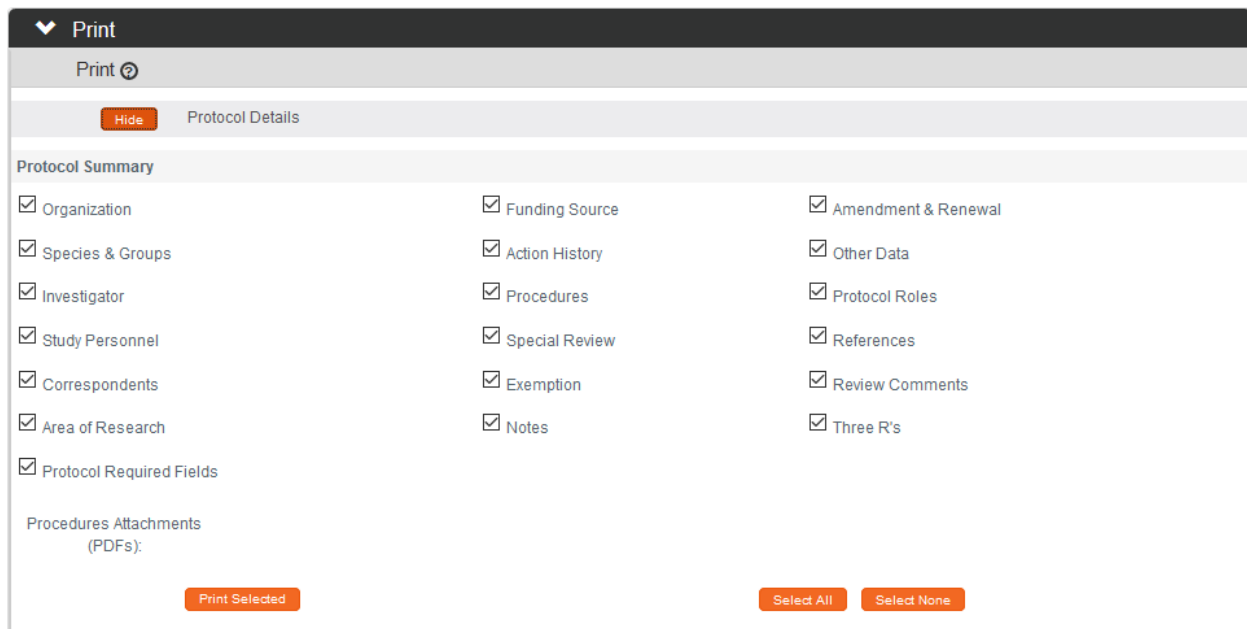
10. If you are ready to approve the protocol, click the Approve button located at the bottom of the page. 

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 IACUC Protocol Actions tab. 
2. Click on the header to expand the Print section. 
3. Click the Show button next to the Protocol Details subsection.  



The screenshot shows the 'Print' section of the IACUC Protocol Actions tab. The 'Print' section is expanded, and the 'Protocol Details' subsection is visible. The 'Protocol Summary' section contains a list of subsections with checkboxes:

Subsection	Checkbox
Organization	<input checked="" type="checkbox"/>
Species & Groups	<input checked="" type="checkbox"/>
Investigator	<input checked="" type="checkbox"/>
Study Personnel	<input checked="" type="checkbox"/>
Correspondents	<input checked="" type="checkbox"/>
Area of Research	<input checked="" type="checkbox"/>
Protocol Required Fields	<input checked="" type="checkbox"/>
Funding Source	<input checked="" type="checkbox"/>
Action History	<input checked="" type="checkbox"/>
Procedures	<input checked="" type="checkbox"/>
Special Review	<input checked="" type="checkbox"/>
Exemption	<input checked="" type="checkbox"/>
Notes	<input checked="" type="checkbox"/>
Amendment & Renewal	<input checked="" type="checkbox"/>
Other Data	<input checked="" type="checkbox"/>
Protocol Roles	<input checked="" type="checkbox"/>
References	<input checked="" type="checkbox"/>
Review Comments	<input checked="" type="checkbox"/>
Three R's	<input checked="" type="checkbox"/>

Below the list of subsections, there is a section for 'Procedures Attachments (PDFs):'. At the bottom of the 'Print' section, there are three buttons: 'Print Selected', 'Select All', and 'Select None'. The 'Print Selected' button is highlighted.

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. 
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 IACUC Committee Members

The fourth section provides IACUC 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 Review Type Determinations

The Public Health Service Policy on Humane Care and Use of Laboratory Animals assurances require that all IACUC committee members vote on what type of review a given IACUC protocol should undergo. The IACUC Administrator or Committee Chair is responsible for contacting each committee member, giving them a deadline to respond, and then following the majority's recommendation for a review type (e.g., Administrative Review, Designated Review, or Full Committee Review). This activity is called a Review Determination.

Once the IACUC Administrator completes either the Review Type Determination or the Assign Reviewer action, a notification is sent and the protocol becomes available to the appropriate committee members. To facilitate the Review Type Determination function, Streamlyne Research creates a separate Review Type Determination tab within the protocol for both reviewers and administrators.

Completing a Review Type Determination

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

Show	FYI	32602	Streamlyne Research Notification	IACUC Protocol 1808000216 Review Type Determination Action	FINAL	01:30 PM 08/10/2018
------	-----	-------	----------------------------------	--	-------	------------------------

1. From the Action List, access the contents of the notification by clicking the Show button.

Id: 3696
From: iacucadmin
Recipients: iacucadmin , iacucadmin2 , iacucdirector , medicinechair , researchdean , reviewer1 , reviewer2
Channel: Notification Channel
Producer: Notification System
Type: FYI
Priority: Normal
Send Date: 2018-08-13T08:38:58.000-07:00
Removal Date: none

Title: IACUC Protocol 1808000222 Review Type Determination Action
Content:

The protocol number 1808000222, Principal Investigator Medicine Professor has had the action "Review Type Determination" performed on it.
The action was executed by Administrator, IACUC. Determination is due by 13-Aug-2018. Additional information and further actions can be accessed through the system.

IACUC Protocol Number: 1808000222 - Document Number: 32666
This notification was generated by IACUC Administrator.

FYI

2. Click the protocol number hyperlink within the message to access the actual protocol.

3. 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, continuation or request by referencing the [FOR PRINCIPAL INVESTIGATORS](#) section.

4. When you are ready to render a decision, navigate to the Review Type Determination tab by clicking the tab header.

Review Type Determination

▼ Determine Review Type: Rachel Reviewer

Hide Determine Review Type

Review Type Determination : select

Determination Due Date : 04/26/2018

Updated By : Last Update :

save

5. In the Determine Review Type subsection, indicate your **Review Type Determination** by clicking the arrow next to the field and selecting from the dropdown list.

select

Administrative Review

Designated Member Review

Full Committee Member Review

6. Click Save to finalize your Determination.

save

Note No other action is required after you have saved your Determination. A separate Review Assignment will be sent to you if you are selected to formally review the protocol.

Completing IACUC Committee Reviews

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

Some institutions will assign a select number of IACUC 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 IACUC Administrator completes the Assign Reviewers action, the protocol becomes available to the selected committee Members. For IACUC protocols that will not go on to a Full Committee Review, such as Designated Member Review, 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 IACUC Administrator. This required assignment will appear on the committee member's Action List as shown:

APP	32702	IACUC Protocol Review	IACUC Protocol Review - Professor/Protocol# 1808000222	ENROUTE		01:06 PM 08/13/2018
-----	-------	-----------------------	--	---------	--	------------------------

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

Result Streamlyne Research automatically opens to the Online Review tab.

Protocol

Personnel

The Three R's

Questionnaire

Species/Groups

Procedures

Protocol Exception

Custom Data

Special Review

Permissions

Notes & Attachments

IACUC Protocol Actions

Review Type Determination

Online Review

Streams

* Indicates required field

Online Review: Rachel Reviewer

Show Document Overview

Hide Online Review

Reviewer: Rachel Reviewer Requested Date : 08/13/2018

Status : SAVED Due Date :

* Determination Recommendation : select Reviewer Type : primary

Hide Review Comments

Standard Review Comment	Description	Private	Final
Add (Select) Q		<input type="checkbox"/>	<input type="checkbox"/>

Hide Review Attachment

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

Hide Protocol Review Actions

save approve review

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, continuation 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.

Online Review

Hide Online Review

Reviewer: Rachel Reviewer Requested Date : 08/13/2018

Status : SAVED Due Date :

* Determination Recommendation : select Reviewer Type : primary

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

This field is required for saving.


select


Major Revisions Required

Minor Revisions Required


Approved

Disapproved

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

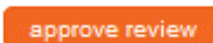
5. In the Review Comments section, click the magnifying glass  to search for a standard comment or summarize your determination in the **Description** field with a freeform comment.

6. Click the Add button to register your comments. 

Review Attachment			
Description	File Name	Private	
Add	 <input type="text" 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 IACUC 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 IACUC Protocol Actions > Summary and History > History and viewing the correspondence that corresponds with the last Return for Revisions action.
2. Access the Reviewer information and comments by going to IACUC Protocol Actions > Summary and 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 IACUC Administrator has sent the 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 the 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. However, only specifically-assigned reviewers will be able to make official review comments via the Online Review functionality.

Show	FYI	32803	Streamlyne Research Notification	Agenda created for committee IACUC Full Board	FINAL		08:38 AM 08/16/2018
----------------------	------------	-------	----------------------------------	---	-------	--	------------------------

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

[Show](#)

Id: 3795
From: admin
Recipients: medicinechair , researchdean , reviewer1 , reviewer2
Channel: Notification Channel
Producer: Notification System
Type: FYI
Priority: Normal
Send Date: 2018-08-16T08:38:00.000-07:00
Removal Date: none

Title: Agenda created for committee IACUC Full Board

Content:

An Agenda has been created for committee Schedule meeting on 2018-08-16. Click here for a printable version of the agenda.

[FYI](#)

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

An Agenda has been created for committee [Schedule meeting on 2018-08-03](#)

Otherwise skip to Step 7.

Result The Meeting page will open.

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

> Protocol Submitted

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

View

You may want to familiarize yourself with protocol documents and how a PI initiates and submits a new protocol, amendment, continuation 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 PDF Agenda, click on the here hyperlink from the Action List page.

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

V: For IACUC Administrators

The fifth section of this manual provides targeted content for IACUC 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 IACUC Committees and their meetings.

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Administering an IACUC Protocol

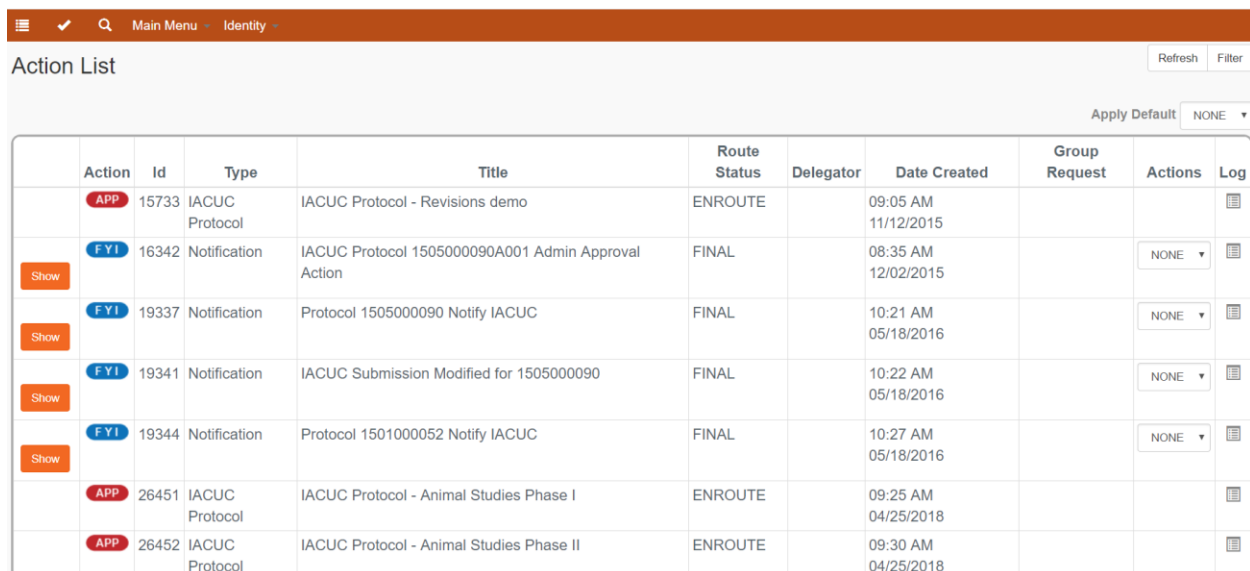
Streamlyne Research provides robust administrative functionality to support the protocol's path through the administrative and IACUC committee review process. Generally, a user would not use these administrative features until after all departmental and institutional approvals were in place. Such a user would need the IACUC 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 IACUC Protocol module. A complete list of all available protocol actions is available in [Appendix C: All Protocol Actions](#).


Accessing an Existing IACUC Protocol

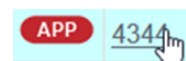
Using the Action List

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



Main Menu - Identity										
Action List										
										Refresh Filter
										Apply Default NONE
Action	Id	Type	Title	Route Status	Delegator	Date Created	Group Request	Actions	Log	
APP	15733	IACUC Protocol	IACUC Protocol - Revisions demo	ENROUTE		09:05 AM 11/12/2015				
Show	FYI	16342	Notification	IACUC Protocol 1505000090A001 Admin Approval Action	FINAL	08:35 AM 12/02/2015		NONE		
Show	FYI	19337	Notification	Protocol 1505000090 Notify IACUC	FINAL	10:21 AM 05/18/2016		NONE		
Show	FYI	19341	Notification	IACUC Submission Modified for 1505000090	FINAL	10:22 AM 05/18/2016		NONE		
Show	FYI	19344	Notification	Protocol 1501000052 Notify IACUC	FINAL	10:27 AM 05/18/2016		NONE		
APP	26451	IACUC Protocol	IACUC Protocol - Animal Studies Phase I	ENROUTE		09:25 AM 04/25/2018				
APP	26452	IACUC Protocol	IACUC Protocol - Animal Studies Phase II	ENROUTE		09:30 AM 04/25/2018				

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"/> <input type="checkbox"/> Exclude? to: <input type="text"/> <input type="text"/>
Date Last Assigned	from: <input type="text"/> <input type="text"/> <input type="checkbox"/> Exclude? to: <input type="text"/> <input type="text"/>

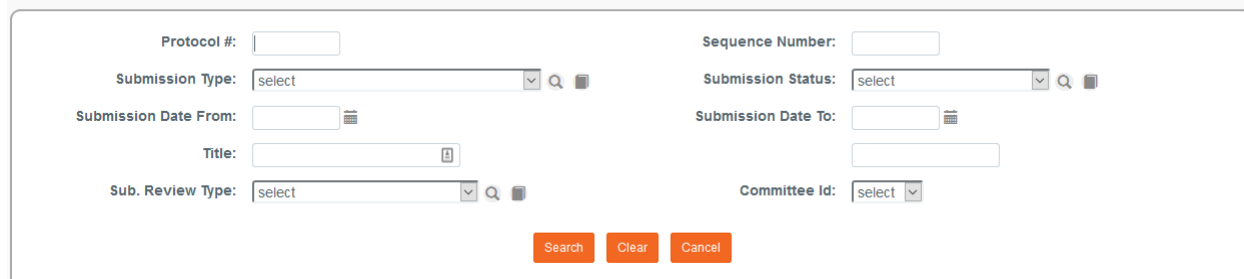
2. Streamlyne Research will display search criteria available to narrow your Action List results.
3. Enter the criteria by which you would like the Action List to filter and click the Filter button.

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 IACUC Lookups](#).

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

IACUC Protocol Submission Lookup



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.

Search

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. 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 IACUC Protocol Actions](#). It may be helpful to review this section before proceeding.

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

IACUC Protocol Actions

Assigning an IACUC Committee and Meeting Date

The Modify Submission Request action is used to allow the IACUC Administrator to assign a committee 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.

1. From the IACUC 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 Modify Submission Request action.

Show

Modify Submission Request

Hide Modify Submission Request

Committee : IACUC Full Board

* Submission Type : Initial Protocol Application

Billable : ☐

Type Qualifier : select

Review Type Determination: No recommendations so far.

Schedule Date : 08-11-2018, Conference Room, 01:

* Submission Review Type : Full Committee Member Review

Determination Due Date :

Submit Send Notification

3. Click the arrow next to the **Committee** field to select the committee that will review the document. This can be changed by the IACUC 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 board meeting during which the protocol will be reviewed.

This date can be changed.

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

select

- Administrative Review
- Designated Member Review
- Full Committee Member Review
- FYI
- Response
- IACUC Review not required

Note The Public Health Service Policy on Humane Care and Use of Laboratory Animals requires that all IACUC committee members vote on what type of review a given IACUC Protocol should undergo. If you need to request a Review Type Determination at this point, choose Designated Member Review from the list and proceed to Step 5 in [Sending Review Type Determination Requests](#).

Otherwise, proceed to the next step.

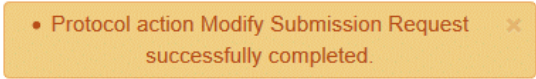
6. If you changed the **Submission Review Type** to something (other than Designated Member Review) that warrants qualification or further explanation, click the arrow next to the **Type Qualifier** field to select an appropriate option.

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

7. Click the Submit button.

A rectangular orange button with the word "Submit" in white text.

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.

A yellow rectangular box with a black border. It contains a bullet point followed by the text "Protocol action Modify Submission Request successfully completed." and a small 'x' icon in the top right corner.

• Protocol action Modify Submission Request successfully completed. x

Sending Review Type Determination Requests

The Public Health Service Policy on Humane Care and Use of Laboratory Animals assurances require that all IACUC committee members vote on what type of review a given IACUC protocol should undergo. The IACUC Administrator or Committee Chair is responsible for contacting each committee member, giving them a deadline to respond, and then following the majority's recommendation for a review type (e.g., Administrative Review, Designated Review, or Full Committee Review). This activity is called a Review Type Determination.

The IACUC Administrator can complete either the Review Type Determination or the Assign Reviewer action to send a notification to the appropriate committee members indicating that the protocol is available for review. To facilitate the Review Type Determination function, Streamlyne Research creates a separate Review Type Determination tab within the protocol for both reviewers and administrators.

Once the IACUC Administrator has the majority opinion from the Review Determinations, they can then proceed to execute the recommendation – either by assigning online reviews for Designated Reviews or by assigning the protocol to an agenda for Full Committee Reviews.

Hide

Modify Submission Request

Committee : IACUC Committee A ▼

Schedule Date : select ▼

* Submission Type : Initial Protocol Application ▼

* Submission Review Type : Designated Member Review ▼

Billable : ☐

Type Qualifier : select ▼

Reviewers:

Comp1 Reviewer

committee ▼

Comp3 Reviewer

committee ▼

Comp2 Reviewer

committee ▼

Review Type Determination: No recommendations so far.

Determination Due Date :


Send Notification

- From the IACUC 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 the Show button next to the Modify Submission Request action.

Hide

Modify Submission Request
 - If you haven't already done so click the arrow next to the **Committee** field to select from the dropdown list the Committee ID of the board that will make the review determination.
 - If you haven't already done so, click the arrow next to the **Schedule Date** field to select a tentative date for the board meeting during which the document will be reviewed.

A tentative schedule date is required before sending the Review Type Determination notification. If scheduling is not firm, this date can be changed later.
 - If you haven't already done so, click the arrow next to the **Submission Review Type** field and select Designated Member Review.
- Result** The names of the members of the Committee will appear in the **Reviewers** section with a dropdown next to each member's name. The default value will display as Committee. Do not change this value until after the Review Type Determination process is complete. You will change the value when selecting a designated reviewer, if applicable.
- Select a **Determination Due Date** which will assign a deadline to each reviewer for their response. Enter a date in a MM/DD/YYYY format or click on the calendar icon  to use the date selector feature.

7. Click the Send Notification button to send the Review Type Determination request.

Send Notification

8. Click the Yes button to finalize this action.

Yes

Note After the notification has been sent, the reviewer names will display at the bottom of this section. This serves to keep a tally on determinations as they are submitted by each Committee member.

9. 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 12.

10. 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 Principal Investigator.

11. Click the Send button.

Send

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

12. If any other changes were made to the **Schedule Date, Committee, or Submission Type**, be sure to click the Submit button to render those changes.

Submit

Note Streamlyne Research will display a message at the top of the page to let you know your action completed as expected.

• Protocol action Modify Submission Request successfully completed.

Managing Review Type Determinations

An IACUC Administrator can manage the Review Recommendation process prior to a formal review. After a Review Type Determination request has been sent out to all Committee members, they can complete their Determinations by following the steps in [Completing a Review Type Determination](#). The IACUC Administrator can review these decisions and can also record decisions for Reviewers in the Review Type Determination tab. The decisions can also be seen in the IACUC Protocol Actions tab.

The Review Type Determination Tab

1. Click on the tab header to access the Review Type Determination tab.

Review Type Determination

2. If it is not already expanded, click on the section header to expand the Determine Review Type section for the first Reviewer.

➤ Determine Review Type: Rachel Reviewer

▼ Determine Review Type: Rachel Reviewer

Hide

Determine Review Type

Review Type Determination : Full Committee Member Review

Determination Due Date : 08/13/2018

Updated By : reviewer1

Last Update : 08/13/2018 08:56 AM

save

▼ Determine Review Type: Randy Reviewer

Hide

Determine Review Type

Review Type Determination : select

Determination Due Date : 08/13/2018

Updated By : iacucadmin

Last Update : 08/13/2018 09:09 AM

save

▼ Determine Review Type: Medicine Chair

Hide

Determine Review Type

Review Type Determination : select

Determination Due Date : 08/13/2018

Updated By : iacucadmin

Last Update : 08/13/2018 09:09 AM

save

Result If a Committee member has saved their Determination, it will display on the Review Type Determination dropdown list under their name.

3. To complete the determination on behalf of the Committee Member, locate the member and use the dropdown next to the **Review Type Determination** field to select the appropriate response.

4. Click the Save button.

save

Result Changes made to Determinations will reflect in the read only **Updated By** and **Last Update** fields.

5. Repeat Steps 3 and 4 for additional Committee Member Determinations.

IACUC Protocol Actions Tab

1. From the IACUC 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 Modify Submission Request action.

Show

Modify Submission Request

▼ Request an Action

Available Actions ⓘ

Show Withdraw Protocol

Hide Modify Submission Request

Committee: IACUC Full Board

* Submission Type: Initial Protocol Application

Billable: ☐

Type Qualifier: select

Schedule Date: (past deadline) 08-11-2018, Conference Room

* Submission Review Type: Full Committee Member Review

Review Type Determination: Rachel Reviewer-Full Committee Member Review
Randy Reviewer-Full Committee Member Review
Medicine Chair-Full Committee Member Review
Research A Dean-Full Committee Member Review

Determination Due Date: 08/13/2018

Send Notification

Submit

Result Information regarding Review Type Determinations will display next to each Committee member's name.

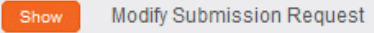
3. To make changes to Committee members Determinations, navigate to the Review Type Determination tab and follow the Steps in the previous section.

Determining an IACUC Review is not Required

This action is reserved for instances in which a protocol has been submitted but does not qualify as animal research or further review is otherwise not required.

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

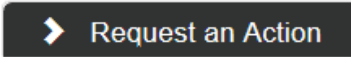
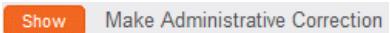
➤ Request an Action

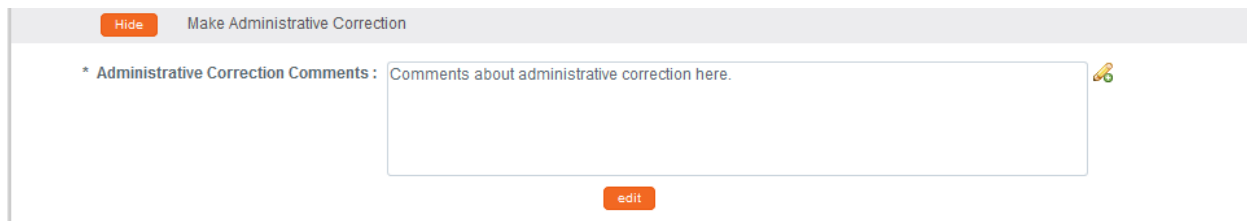
2. Click the Show button next to the Modify Submission Request action. 
3. Click the arrow next to the **Submission Review Type** field to select IACUC Review not required.


Making Administrative Corrections

Streamlyne Research allows the IACUC 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 IACUC.

1. From the IACUC 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 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.

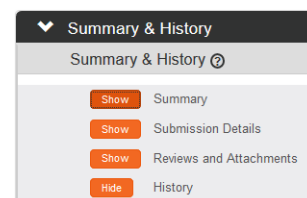
Click through the tabs and sections of the document and make any necessary changes.

6. Save your work by clicking the Save button.



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

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



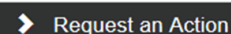
Returning the Protocol to the PI

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

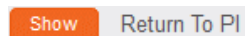
Like the Administrative Correction action, the Return to PI action may only be used prior to formal committee review. Typically, this action might be used as part of a pre-review or administrative process conducted by IACUC Office staff members.

The Document Status must be Submitted to IACUC and all departmental or institutional approvers must have approved the protocol in order to use the Return to PI function.

1. From the IACUC 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.




Comments : Comments about why this is returning to the PI.

* Action Date : 07/20/2018


Show Review Comments

Submit


3. Enter a detailed description in the **Comments** field to explain the changes required from the Principal Investigator.
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.

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
Show	FYI	32320	Streamlyne Research Notification	Protocol Returned to PI Action	FINAL		11:57 AM 07/20/2018		NONE	

For more information on what a 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, IACUC Committee Members may be assigned to review and comment on protocols, designated to review and approve protocols, and/or attend scheduled committee meetings to approve protocols.

Some institutions will assign a select number of IACUC 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 IACUC 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 IACUC protocols that will not go on to a Full Committee Review, such as Designated Member Review, 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 IACUC Administrator to Assign Reviewers. Reviewers are members of the committee you selected when you assigned the protocol to a committee ([Assigning an IACUC Committee and Meeting Date](#)).

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

Assign Reviewers	
Rachel Reviewer	<select></select>
Randy Reviewer	<select></select>
Medicine Chair	<select></select>
Research A Dean	<select></select>
<input type="button" value="Submit"/>	




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 IACUC Administrator is determined to be not appropriate or is not available to complete the review for any reason, the IACUC Administrator can delete the reviewer. This action can be taken on either the IACUC Protocol Actions tab or the Online Review tab. See [Completing Online Reviews](#) for information regarding the Online Review Tab. This action cannot be taken after a reviewer has submitted their review.

1. From the IACUC Protocol Actions tab, click the Show  Assign Reviewers  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 IACUC 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

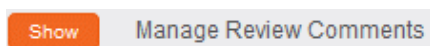
Managing Review Comments & Attachments


The IACUC 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 IACUC 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 IACUC Protocol Contingency 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 IACUC 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

The final flag on a review comment indicates that the IACUC 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 IACUC 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.

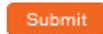
5. Click the Add button to finalize the comment.



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.



Manage Review Attachments


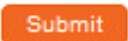
9. If you need to attach a new document, summarize the purpose of the document in the **Description** field.

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 IACUC 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
IACUC 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 IACUC 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 IACUC 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.

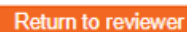
Take these steps to Return or Accept the assigned review.

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 IACUC 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.



4. 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.



Result The system will send the notification and return to the Online Review tab.

5. Repeat Steps 2 through 4 for each Online Review.

The IACUC Administrator can access the full detail of all Assigned Reviews from the Online Review tab. From this page, the IACUC Administrator can perform a variety of actions on the Online Review tab, 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 IACUC Administrator's Online Review tab within the protocol document.

An IACUC 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.

		32744	Streamlyne Research Notification	IACUC Protocol 1808000222 Review Complete Action	FINAL		01:27 PM 08/14/2018
---	---	-------	----------------------------------	--	-------	--	------------------------

1. From the Action List, click the Show button next to the item.



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.

Title: Protocol 1807003125 Review Complete
Content:

Researcher, Biochemistry has approved review comments for protocol [1807003125](#)

Click the hyperlinked Protocol Number to open the document.

3. Click on the tab header to open the Online Review tab.



▼

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="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	
Add		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 IACUC 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

☒ ☐

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 IACUC 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

☐☒

The final flag on a review comment indicates that the IACUC 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 IACUC 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: Recording Committee Decision and Approve Protocol.

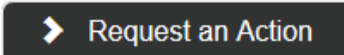
Revisions and Approvals for Administrative and Designated Member Reviews

The manner in which Administrative Review and Designated Member Review 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 Administrative Determinations and Designated Member Reviews.

Administrative Determination: Marking a Protocol as Incomplete

The Administrator can mark a protocol as Incomplete and send the protocol back to the Principal Investigator with reasons for the Incomplete determination. The PI will then be required to re-submit the protocol once the protocol is complete.

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

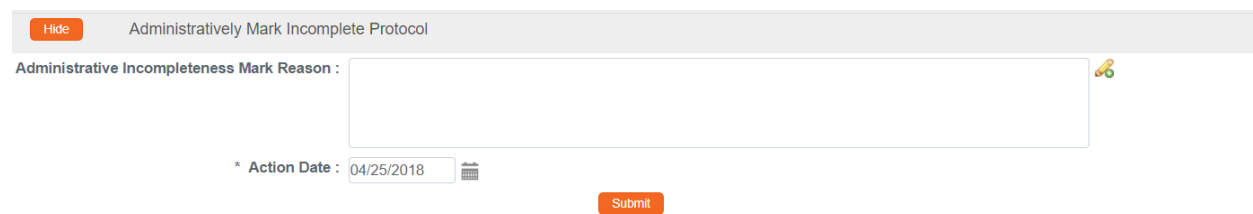
A dark grey button with a white right-pointing chevron icon and the text "Request an Action" in white.

2. Click on the Show button next to the Administrative Determination action.



A small orange button with the word "Show" in white.A light grey button with the text "Administrative Determination" in grey.

Result This will expand and reveal three additional Action buttons.

3. Click on the Show button next to the Administratively Mark Incomplete Protocol button.

A small orange button with the word "Show" in white.A light grey button with the text "Administratively Mark Incomplete Protocol" in grey.A screenshot of a web form titled "Administratively Mark Incomplete Protocol". At the top left is a "Hide" button. Below the title is a label "Administrative Incompleteness Mark Reason :" followed by a large text input field. To the right of the input field is a small icon of a pencil and a speech bubble. Below the input field is a label "* Action Date :" followed by a date input field containing "04/25/2018" and a calendar icon. At the bottom center is a "Submit" button.

4. Enter applicable freeform text in the **Administrative Incompleteness Mark Reason** field.

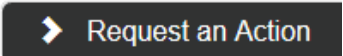
5. Note that the **Action Date** defaults to today's date. Should you need to alter this date, do so by using the calendar icon  or typing a new value in MM/DD/YYYY format.
6. Click the Submit button to render the protocol Incomplete and send it back to the Principal Investigator for editing and re-submission. 

Result The Document Status changes to Administratively Incomplete and the Submission Status changes to Administratively Incomplete.

Administrative Determination: Administratively Approve Protocol

The Administrative Approve action allows an IACUC Administrator to approve an IACUC protocol that has been marked for Administrative Review.

1. From the IACUC 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 on the Show button next to the Administrative Determination action.



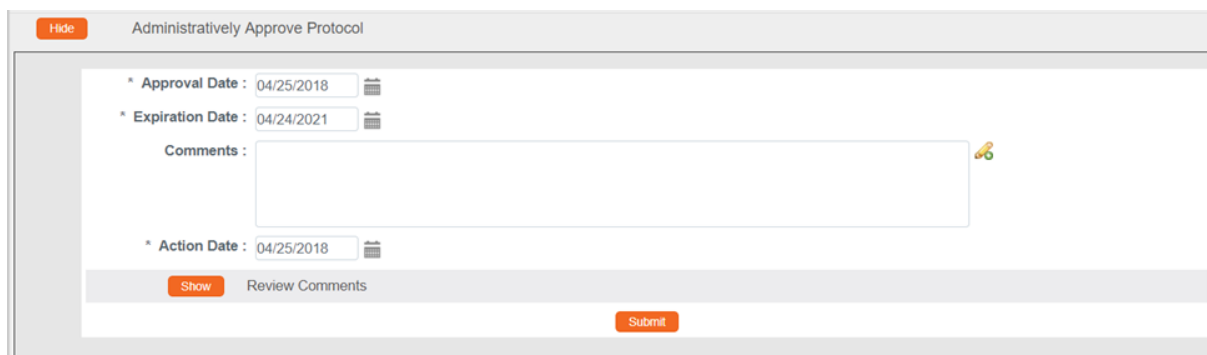
Administrative Determination

Result This will expand and reveal three additional Action buttons.


3. Click on the Show button next to the Administratively Approve Protocol button.


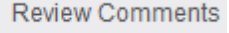
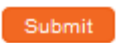


Administratively Approve Protocol



4. This will expand the section and allow you to enter an Approval and Expiration Date. The date will default to the current date for approval plus three years, minus a day for Expiration.

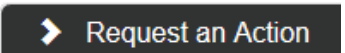

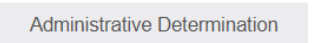
These dates can be edited to reflect the date the Approval Determination was officially made by using the calendar icon  or typing a new value in MM/DD/YYYY format.

5. Enter applicable freeform text in the **Comments** field. These are intended as administrative comments only.
6. If an assigned review was completed at any time for this protocol, click the Show button to review the Review Comments subsection.  
7. Click the Submit button to render the protocol Approved. 


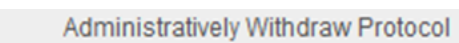
Result The Document Status changes to Administratively Approved and the Submission Status changes to Administratively Approved.


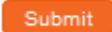
Administrative Determination: Administratively Withdraw Protocol

The Administrative Withdrawal action allows an IACUC Administrator to withdraw an IACUC protocol from submission. It is recommended that this action be used for Administrative level reviews instead of the other Withdraw action that may be available.

1. From the IACUC 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 on the Show button next to the Administrative Determination action.  

Result This will expand and reveal three additional Action buttons.

3. Click on the Show button next to the Administratively Withdraw Protocol button.  

4. Enter applicable freeform text in the **Administrative Withdrawal Reason** field.
5. Note that the **Action Date** defaults to today's date. Should you need to alter this date, do so by using the calendar icon  or typing a new value in MM/DD/YYYY format.
6. Click the Submit button to render the Protocol Incomplete and send it back to the Principal Investigator for editing and re-submission. 

Result The Document Status changes to Administratively Withdrawn and the Submission Status changes to Administratively Withdrawn.

A new Protocol must be submitted if further review is desired.

Returning a Protocol for Minor Revisions

This action allows the IACUC Administrator to return an IACUC protocol for minor revisions following a full committee review or a designated member review. The Minor Revisions determination indicates that an investigator needs to make changes to a protocol to secure IACUC approval. The changes requested by the IACUC office and/or reviewers are communicated to the investigator through review comments and the official correspondence.

The system will not allow the action until there is at least one review comment entered. All review comments that are marked as Final will be included in the official correspondence that is generated for this action. For an IACUC protocol needing a full committee review, this action only appears after the Record Committee Action has been performed on the protocol with a motion type of Minor Revisions. See [Recording Committee Decisions](#).

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

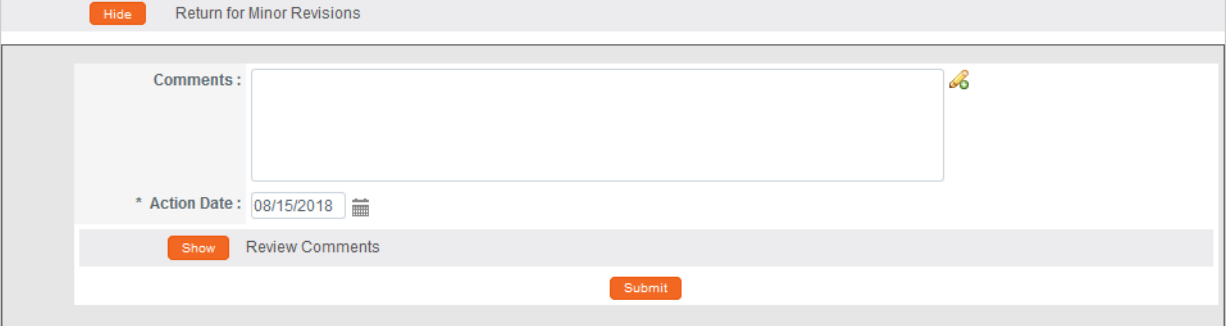
Request an Action

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

Show

Return for Minor Revisions

3. Streamlyne Research displays the Return for Minor Revisions 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.

Show

Review Comments

6. Ensure all review comments are marked appropriately.

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

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

Submit

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

9. Click the Save button.

Save

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

If so, make any necessary edits and click Send.

Send

Otherwise, this process is complete.

11. 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 Return for Minor Revisions Letter (Correspondence) with review comments.

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

Returning a Protocol for Major Revisions

The Return for Major Revisions action should only be taken after the Online Reviews are completed by Committee members and approved by the IACUC Administrator. The Record Committee Decision action with the motion to request major revisions must also have been taken. See [Recording Committee Decisions](#).

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

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

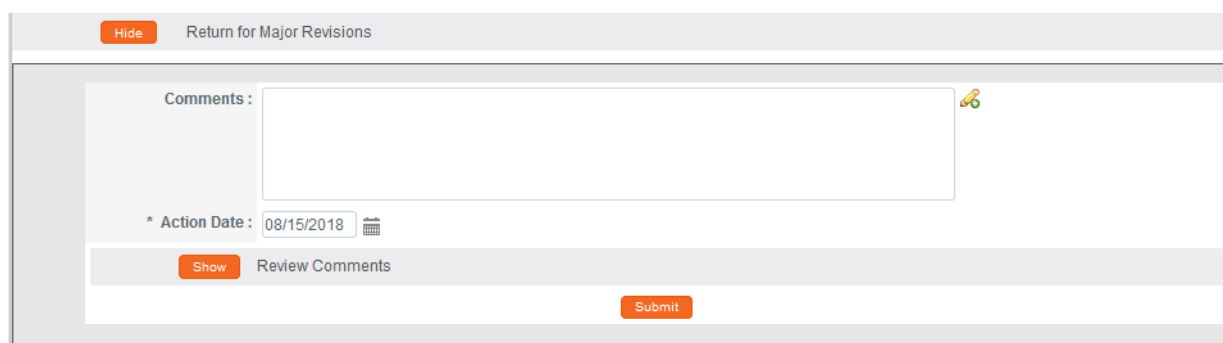
Request an Action

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

Show

Return for Major Revisions

3. Streamlyne Research displays the Return for Major Revisions 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.

Show

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 Principal Investigator.

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

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

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.

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 Return for Major Revisions Letter (Correspondence) with review comments.

The protocol's Document Status and Submission Status updates to Major Revisions Required.

Approving Designated Member Reviews

The Approval of a Designated Member Review should only be taken after the Online Reviews are completed by Committee Members and approved by the IACUC Administrator.

Follow these steps to grant approval to a Designated Member Review Protocol.

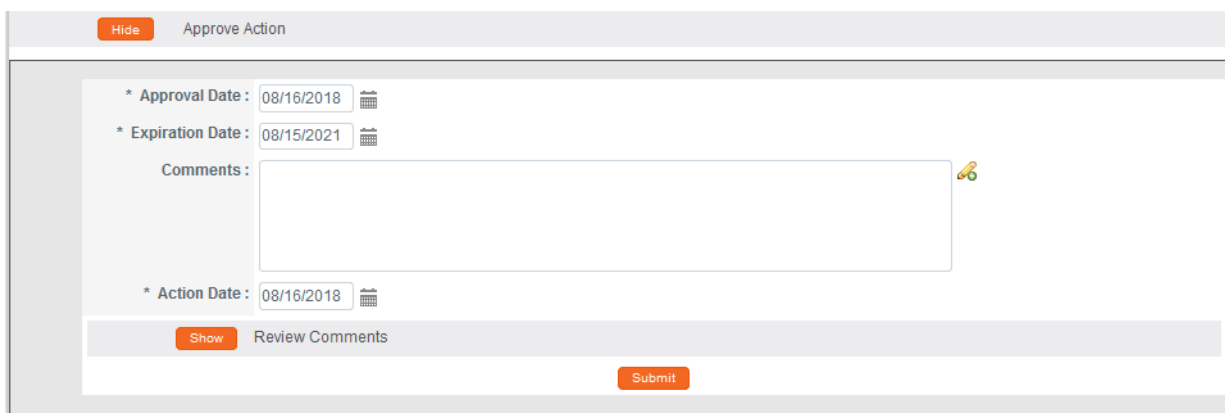
1. From the IACUC Protocol Actions tab, click the section header to expand the Request an Action section. In some cases, this section may appear expanded by default.

➤ Request an Action


2. Click the Show button next to Approve Action.

Show

Approve Action



3. 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 the third 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.

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

5. Click the Show button to Review Comments.

Show

Review Comments

6. Click the Submit button to record the Approval.

submit

Correspondence			
Correspondence ⓘ			
Protocol Number	Correspondence	Final	Action
1808000222	Approval Letter	<input checked="" type="checkbox"/>	View

7. A Correspondence section will now appear to preview the official correspondence that will be sent to the Principal Investigator. 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 and the Submission Status updates to Approved and the protocols expiration date will now be included in the Document Header.

Document Number : 32793	Document Status : Active
Initiator:Last Updated : medicineprofessor : 02:23 PM 08/16/2018	Submission Status : Approved
Protocol # : 1808000222	Expiration Date : 08/15/2021

8. 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 IACUC 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. Follow these steps to set up a new IACUC Committee and to assign users to that committee. Skip this section if you have already performed this configuration step.

Navigation

Main Menu > IACUC > IACUC Actions > IACUC Committee > +


Updating the Committee Tab

The screenshot shows the 'Committee' configuration form. It includes fields for Committee ID (100), Home Unit (100000, Streamlyne Institution), Committee Name (IACUC Full Committee A), Type (IACUC), Committee Description, Schedule Description, Min Members for Quorum (6), Maximum Protocols (10), Adv Submission Days (7), Review Type (Full Committee Member Review), Last Updated, Updated User, and an Active checkbox (checked).

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

Committee

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.

Area of Research

Area of Research

add: (select) 🔍

Code/Description	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.

Members

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.

* Person:

Internal User Name Search 🔍

External Address Book Search 🔍

Clear Add Member

3. Click the Add Member button to complete the action.

Add Member

Committee

Members

Schedule

Add IACUC Member

Internal User Name Search

External Address Book Search

Clear

Add Member

Show All Members

Rachel Reviewer (inactive)

Randy Reviewer (inactive)

Medicine Chair (inactive)

Research A Dean (inactive)

Biochemistry Researche (inactive)

Delete Selected

Submit

Save

Close

* Indicates required field

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

- Expand the section for each committee member to access required fields in each of four subsections.

Rachel Reviewer (inactive)

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

Show

Hide

Person Details

Person Name : Rachel Reviewer

* Term Start Date : 07/01/2017

* Membership Type : Voting member

* Term End Date : 06/30/2019

☐ (paid member)

Contact Notes :

Training Notes :

Show

Contact Information

Show

Roles

Show

Expertise

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., veterinarian, scientist, lay person, unaffiliated).

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

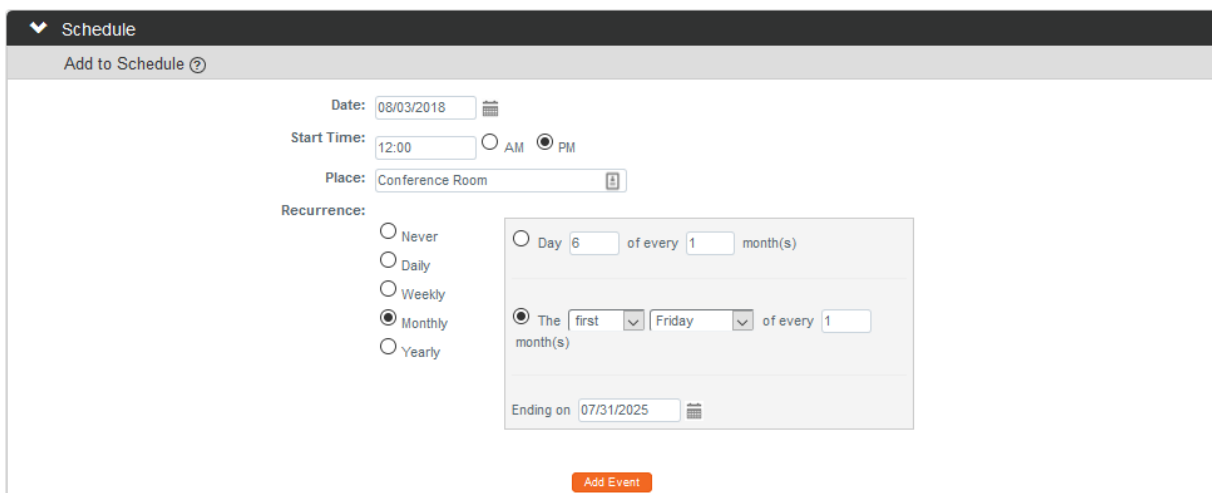
7. Click the Save button. 

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.

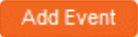
1. Click the tab header to access the Schedule tab. 



The screenshot shows the 'Add to Schedule' form within the 'Schedule' tab. The form 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:**
 - ☐ Never
 - ☐ Daily
 - ☐ Weekly
 - ☒ Monthly
 - ☐ Yearly
- Monthly Recurrence Details:**
 - ☐ Day 6 of every 1 month(s)
 - ☒ The first Friday of every 1 month(s)
- Ending on:** 07/31/2025 (with a calendar icon)
- Add Event** button

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 IACUC 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 Full Committee. 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 IACUC Protocol Actions tab.

IACUC Protocol Actions

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

Request an Action

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

Show

Assign to Agenda

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

- * Committee ID : 700
- * Committee Name : IACUC Full Board
- Schedule Date : 08-15-2018, Conference Room, 05:00 PM
- Comments : A text area with a small icon to its right.
- * Action Date : 08/13/2018 (with a calendar icon)
- At the bottom, there is a 'Show' button, a 'Review Comments' link, 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.

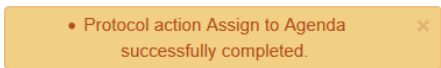
If this meeting assignment is incorrect, refer back to [Assigning an IACUC Committee and Meeting Date](#) to reschedule the protocol's review.

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.



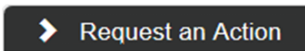
Document Number : 32666	Document Status : Submitted to IACUC
Initiator:Last Updated : medicineprofessor : 01:20 PM 08/13/2018	Submission Status : In Agenda
Protocol # : 1808000222	Expiration Date :

Deferring a Protocol

The IACUC 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 IACUC 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.



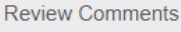
Using this action, the IACUC Administrator can move a protocol that has been submitted for a committee review to either a different committee or a different schedule for the same committee.

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.



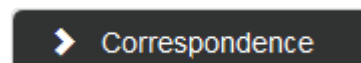
3. Enter detailed **Comments** in the freeform field provided. These are not official review comments, just administrative notes to be kept with this action, if needed.
4. Note that the **Action Date** defaults to today's date. This field is editable. Should you need to alter this date, click the calendar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

12. 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, IACUC meetings often entail other pieces of business that need to be discussed with members. The IACUC 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 that will be reviewed at the meeting are assigned to the meeting date for this particular agenda.

Navigation

Main Menu > IACUC > IACUC Lookups > IACUC 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

4. 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

The screenshot shows the 'Other Actions' section header with a dropdown arrow. Below it is a form titled 'Other Actions' with a help icon. The form has two main fields: '* Type' and '* Description'. The '* Type' field is a dropdown menu with 'select' as the current value. The '* Description' field is a large text area. To the right of the form is an 'Add' button. There is also a small icon of a notepad and pencil next to the description field.

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

The screenshot shows the dropdown menu for the 'Type' field. The menu is open, showing a list of options: 'select', 'Adverse Event', 'New Member Consideration', 'Non-Compliance', 'Other Business', and 'Protocol Deviation'. The 'select' option is currently selected and highlighted in blue.

6. 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.

The screenshot shows a list of two added 'Other Actions'. Each item has a number, a 'Type' field, a 'Description' field, and action buttons (up/down arrows and a 'Delete' button).

Item	Type	Description	Actions
1	Other Business	Other Business	Up/Down arrows, Delete
2	Other Business	More Business	Up/Down arrows, Delete

7. Review the other Sections on the Meeting page.

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

Meeting Actions

9. Click the section header to expand the Agenda section.

➤ Agenda

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

The screenshot shows the 'Generate Agenda' section header with a help icon. Below it is a form with a 'Generate Agenda' label and a 'submit' button.

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. [OK](#)

Batch Correspondence

IACUC 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 IACUC staff member and are done so based on the institution's standard operating procedures. Streamlyne Research provides Batch Correspondence functionality for the following two scenarios.

- **Protocol Continuation Reminders** – Batch correspondences related to continuation reminders serve to remind researchers when they need to continue their protocol because their protocol's expiration date is approaching.
- **Reminder to IACUC Notifications** – Batch correspondences related to Reminder to IACUC notifications remind researchers to revise and re-submit their protocols when it has been returned for revisions (Minor Revisions Requested or Major 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 continuation reminder or withdrawing a protocol after the final reminder to IACUC Notification.

Navigation

Main Menu > IACUC Actions > IACUC Committee

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.

Actions

4. Click the header to access the Batch Correspondence section.

➤ Batch Correspondence

Batch Correspondence

Generate Batch Correspondence ?

Committee ID: 700

*Batch Type: select

Committee Name: IACUC Full Board

*Date: from to

submit

Batch Correspondence History ?

Committee ID: 700

*Batch Type: select

Committee Name: IACUC Full Board

Run Date: from to

filter

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 IACUC 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.

Submit

Result Notifications will be sent to the Principal Investigator 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.

Generated Batch Correspondence ?

Show

08/01/2016 through 08/16/2018

view

Number of protocols on which final action has been performed: 0

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

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

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.

View

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

select

Protocol Renewal Reminders

Reminder to IRB Notifications

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

13. Click the filter button.

filter

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 IACUC office and system administrators based on your IACUC office's standard operating procedures. Each institution will vary. These settings can be configured with the appropriate permissions.

Recording Full Committee Decisions, Revisions & Approvals

The IACUC 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 IACUC Administrator must update the IACUC Meeting page with attendance information. This information includes both voting and non-voting members.


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 > IACUC > IACUC Lookups > IACUC Committee Schedules

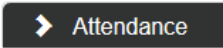
1. If you need to navigate to a new meeting, select Main Menu > IACUC Protocols > IACUC Committee Schedules from the Menu Bar.

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: 4			
Name		Actions	
1 Medicine Chair		present Voting present Other	
2 Rachel Reviewer		present Voting present Other	
3 Randy Reviewer		present Voting present Other	
4 Research A Dean		present Voting present Other	

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

present Votingpresent Other

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: 4




Person Name	Alternate For	Comments	Actions
1 Medicine Chair		<div></div>	Mark Absent
2 Rachel Reviewer		<div></div>	Mark Absent
Others Present: 0			

6. 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.

Mark Absent

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 IACUC Committee to proceed with research activities as documented on the protocol.
Disapprove	Used to indicate the protocol does not have the support of the IACUC Committee and cannot proceed.
Minor Revisions Required	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.
Major 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 IACUC Protocol Actions tab.

IACUC Protocol Actions

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

➤ Request an Action

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

Show

Record Committee Decision

Hide Record Committee Decision

* Major Revisid No: 0 Yes: 4 Abstain: 0 Recused: 0 Voting Comments: No additional comments.

Motion Type:

Show Abstainers

Show Recused

Show Review Comments

Submit

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

select
Approve
Disapprove
Minor Revisions
Major Revisions

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.

submit

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 Committee 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 Committee Protocol for Revisions

After the Committee Decision has been entered, the Protocol can be returned for Minor or Major Revisions. The appropriate option will show in the Available Actions after the Committee Decision has been entered.

Returning a Protocol for Minor Revisions

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

Request an Action

Show

Return for Minor Revisions

Hide Return for Minor Revisions

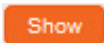
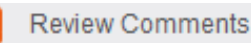
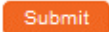

Comments:


* Action Date: 08/15/2018

Show Review Comments

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.
- 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 Minor 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.
 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.
 11. 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 Return for Minor Revisions Letter (Correspondence) with review comments.

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

Returning a Protocol For Major Revisions

The Return for Major 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 IACUC Protocol Actions tab, click the section header to expand the Request an Action section. In some cases, this section may appear expanded by default.

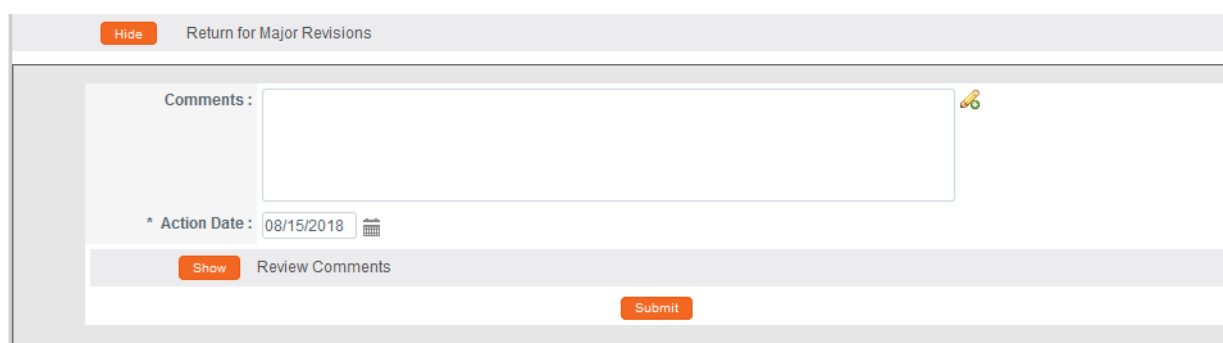
Request an Action

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

Show

Return for Major Revisions

3. Streamlyne Research displays the Return for Major Revisions 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.

Show

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 Major Revisions.

Submit

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.

9. Click the Save button.

Save

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

If so, make any necessary edits and click Send.

Send

Otherwise, this process is complete.

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 Return for Major Revisions Letter (Correspondence) with review comments.

The protocol's Document Status and Submission Status updates to Major Revisions Required.

Approving a Full Committee 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 IACUC 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 Approve Action.

Show

Approve Action


The screenshot shows a web interface for the 'Approve Action' step. At the top, there is a 'Hide' button and the title 'Approve Action'. The form contains several fields: 'Approval Date' with a date picker set to 08/16/2018, 'Expiration Date' with a date picker set to 08/15/2021, and a large 'Comments' text area with a pencil icon for editing. Below the comments area is the 'Action Date' field with a date picker set to 08/16/2018. At the bottom of the form, there is a 'Show' button, a 'Review Comments' link, and a 'Submit' button.


3. 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 the third 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.

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

5. Click the Show button to Review Comments.  

6. Click the Submit button to record the Approval. 

Correspondence			
Correspondence ⓘ			
Protocol Number	Correspondence	Final	Action
1808000222	Approval Letter	<input checked="" type="checkbox"/>	


7. A Correspondence section will now appear to preview the official correspondence that will be sent to the Principal Investigator. 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 and the Submission Status updates to Approved and the protocols expiration date will now be included in the Document Header.

Document Number : 32793	Document Status : Active
Initiator:Last Updated : medicineprofessor : 02:23 PM 08/16/2018	Submission Status : Approved
Protocol # : 1808000222	Expiration Date : 08/15/2021

8. 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.

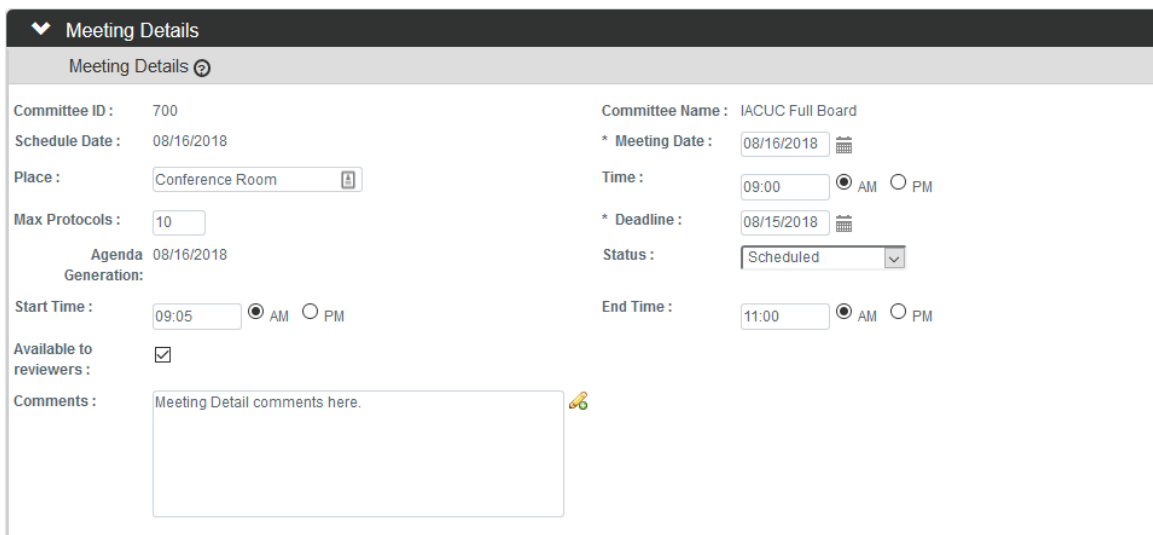
Updating Meeting Details

The IACUC 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 > IACUC > IACUC Lookups > IACUC 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.



The screenshot shows the 'Meeting Details' form. It is divided into two columns. The left column contains fields for Committee ID (700), Schedule Date (08/16/2018), Place (Conference Room), Max Protocols (10), Agenda Generation (08/16/2018), Start Time (09:05 AM), Available to reviewers (checked), and a Comments text area. The right column contains fields for Committee Name (IACUC Full Board), Meeting Date (08/16/2018), Time (09:00 AM), Deadline (08/15/2018), Status (Scheduled), and End Time (11:00 AM). A Save button is located at the bottom right of the form.

3. 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.
4. Click the Save button to save your changes. 

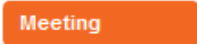
Recording Meeting Minutes


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 IACUC 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.

1. If you need to navigate to a new meeting, select Main Menu > IACUC Protocols > IACUC 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 on the header to access the Minutes section.

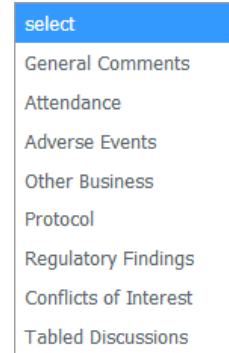


Minutes



Minutes

* Entry Type	Entry Type Detail	* Description	Standard Review Comment	Private	Final	Last Updated By	Created By	Actions
Add: select				<input type="checkbox"/>	<input type="checkbox"/>			Add
General Comments		Opening Remarks		<input type="checkbox"/>	<input checked="" type="checkbox"/>	IACUC Administrator 06/21/2019 12:09 PM	IACUC Administrator 06/21/2019 12:07 PM	<div>Up Arrow</div> <div>Down Arrow</div> <div>Delete</div>
Other Business	Other Business: Other Business	Other Business Remarks		<input type="checkbox"/>	<input checked="" type="checkbox"/>	IACUC Administrator 06/21/2019 12:09 PM	IACUC Administrator 06/21/2019 12:08 PM	<div>Up Arrow</div> <div>Down Arrow</div> <div>Delete</div>
Other Business	Other Business: More Business	More Business Remarks		<input type="checkbox"/>	<input checked="" type="checkbox"/>	IACUC Administrator 06/21/2019 12:09 PM	IACUC Administrator 06/21/2019 12:08 PM	<div>Up Arrow</div> <div>Down Arrow</div> <div>Delete</div>
Protocol	1811000339	The mandatory IACUC orientation program has not been completed. This must be done prior to this protocol being approved.		<input type="checkbox"/>	<input checked="" type="checkbox"/>	IACUC Administrator 06/21/2019 12:09 PM	IACUC Administrator 06/21/2019 12:09 PM	Delete

4. 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

5. If you selected an **Entry Type** of Protocol in the previous step, select the **Protocol Number** from the dropdown box and proceed to Step 7.
6. If the Agenda contained an entry in the Other Actions section, then use the **Entry Type** of Other Business and select the Agenda item from the dropdown that appears in the **Other Action** column.
7. Enter discussion content into the **Description** field.
8. Indicate whether the item is **Private**, **Final**, or both, by clicking the checkboxes. See [Review Comment Matrix](#).
9. Click the add button to commit the discussion details to the database. 
10. Repeat Steps 4 through 9 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.
11. Click the Save button. 

Proceed to [Generating Meeting Minutes](#) if the minutes are ready to be disseminated.

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 > IACUC Protocols > IACUC 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 5.


An orange rectangular button with the word "Meeting" in white text.

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.

An orange rectangular button with the word "Search" in white text.

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

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

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

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

A dark grey rectangular button with a white right-pointing chevron and the word "Minutes" in white text.

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

A blue button with the text "Generate Minutes" in blue.An orange rectangular button with the word "submit" in white text.

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

An orange rectangular button with the text "Send Minutes" in white.

8. Click OK to acknowledge the action.

A light blue rectangular button with the word "OK" in blue text.

Administering & Maintaining Active Protocols

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

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

For example, when an amendment is submitted for a Designated Review, 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 continuations.

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

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

- Incorporating Amendments and Continuations
- Reviewing and Acknowledging a Notify IACUC Action
- Withdrawing a Protocol
- Deactivating a Protocol
- Expiring a Protocol
- Suspending a Protocol
- Terminating a Protocol

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

Reviewing & Acknowledging a Notify IACUC Action

The [Notify IACUC Action](#) is used by the Principal Investigator to inform the IACUC 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 IACUC 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 IACUC Action is taken by the Principal Investigator, the IACUC Administrator will receive an FYI Notification in their Action List.

Show	FYI	32861	Streamlyne Research Notification	Protocol 1808000222 Notify IACUC	FINAL		03:01 PM 08/16/2018
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2. Click the Show button next to the FYI Notification.

Hide	FYI	32861	Streamlyne Research Notification	Protocol 1808000222 Notify IACUC	FINAL	03:01 PM 08/16/2018	NONE	
------	-----	-------	----------------------------------	----------------------------------	-------	------------------------	------	--

Id: 3848
From: medicineprofessor
Recipients: iacucadmin , iacucadmin2 , iacucdirector , medicineprofessor
Channel: Notification Channel
Producers: Notification System
Type: FYI
Priority: Normal
Send Date: 2018-08-16T15:01:20.000-07:00
Removal Date: none

Title: Protocol 1808000222 Notify IACUC
Content:

The IACUC protocol number 1808000222, Principal Investigator Medicine Professor has had the action "Notify IACUC" performed on it.
The action was executed by Professor, Medicine.
The Submission Type Qualifier is "Unanticipated problems".
The Submission Review Type is "Administrative Review".
The Committee name is "IACUC Full Board".
The comment on the action is "Comment for Unanticipated Problems for Administrative Review".
Additional information and further actions can be accessed through the system.

IACUC Protocol Number: 1808000222 - Document Number: 32793
This notification was generated by Medicine Professor

3. Click on the hyperlink for the Protocol number to open the Protocol in a new tab.

4. From the IACUC 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

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

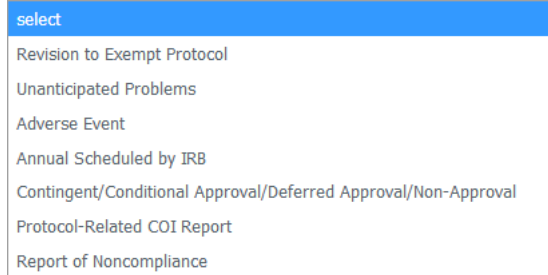
Show

Modify Submission Request

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

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

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



A dropdown menu with a blue header labeled 'select'. The menu lists the following options: Revision to Exempt Protocol, Unanticipated Problems, Adverse Event, Annual Scheduled by IRB, Contingent/Conditional Approval/Deferred Approval/Non-Approval, Protocol-Related COI Report, and Report of Noncompliance.

8. Click the Submit button when ready to Submit.

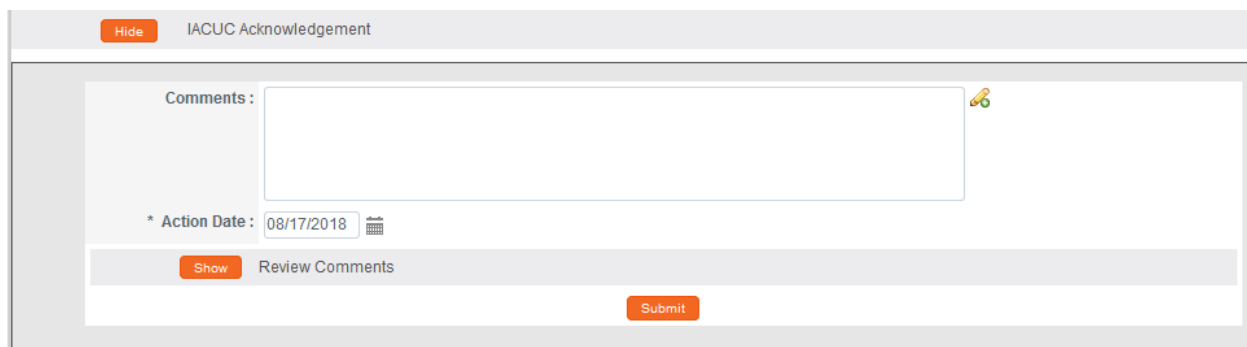
Submit

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


10. Once the Notification has been sufficiently reviewed, click the Show button next to IACUC Acknowledgement.

Show

IACUC Acknowledgement



The IACUC Acknowledgement form includes a 'Hide' button, a 'Comments' text area with a yellow pushpin icon, an 'Action Date' field set to '08/17/2018' with a calendar icon, a 'Show' button, a 'Review Comments' label, and a 'Submit' button.

11. Use the **Comments** field to record any applicable comments.
12. Note that the **Action Date** defaults to today's date. Should you need to alter this date, do so by using the calendar icon  or typing a new value in MM/DD/YYYY format.
13. Click the Show button next to Review Comments to finalize any review comments if Committee review took place.
14. 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 continuations as needed.

Withdrawing a Protocol

If a protocol has reached the IACUC 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 IACUC Administrator can withdraw the protocol. Once the protocol is scheduled for review, the Withdraw action can only be taken by the IACUC 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 IACUC Protocol Actions tab.

IACUC Protocol Actions

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

Request an Action

5. Click the Show button next to Withdraw Protocol.

Show

Withdraw Protocol

Hide Withdraw Protocol

Withdrawal Reason :

Submit

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

7. Click the Submit button to finalize the withdrawal.

Submit

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.

Deactivating a Protocol

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

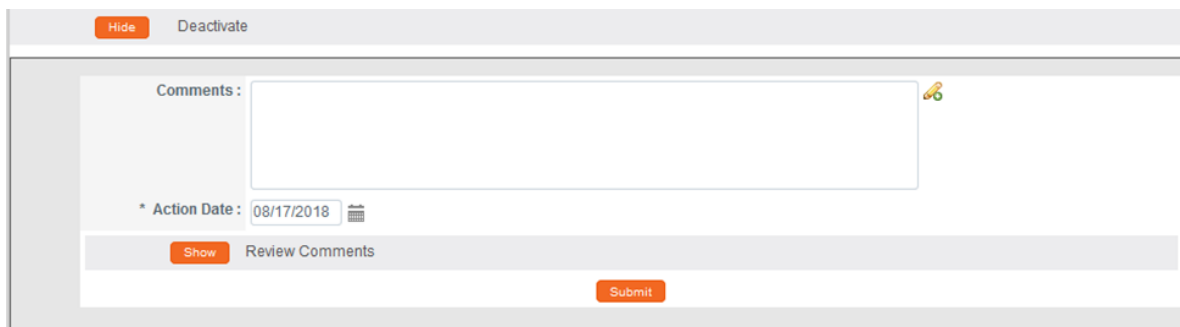
The steps below explain how to manually close a protocol if the Close action is not tied to Batch Correspondence.

1. Use the Lookups to search for the protocol.
2. From the IACUC 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 Deactivate.

Show Deactivate



The screenshot shows a web form for deactivating a protocol. At the top, there are two buttons: 'Hide' (orange) and 'Deactivate' (grey). Below these is a large text area labeled 'Comments:' with a small icon to its right. Underneath the comments area is a field for '* Action Date:' with the value '08/17/2018' and a calendar icon. At the bottom of the form, there is a 'Show' button (orange) next to the text 'Review Comments', and a 'Submit' button (orange) at the very bottom.

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 deactivated. 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 Deactivated. A new protocol must be submitted for further review.

Expiring a Protocol

Protocols must be manually expired by an IACUC 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](#). This is often an action that is taken after multiple continuation reminders have been sent to the Principal Investigator.

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

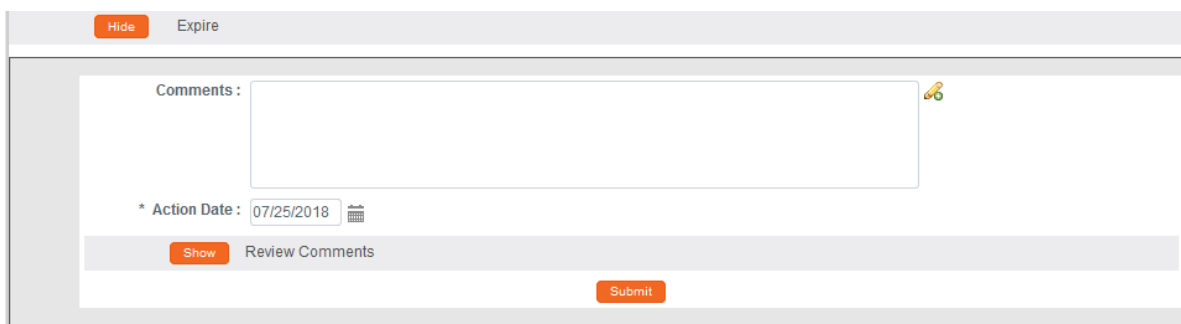
1. Use the Lookups to search for the protocol.
2. From the IACUC Protocol Actions tab, click the section header to expand the Request an Action section. In some cases, this section may appear expanded by default.


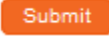
Request an Action

3. Click on the Show button next to Expire.







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. 

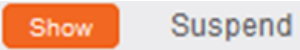
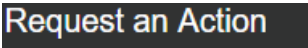
Result The PI should receive a response indicating that their protocol has officially been expired. The format of the response and any accompanying correspondence will be based on your institution's workflow configuration. It may display as an FYI in their Action List. You can always access this information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

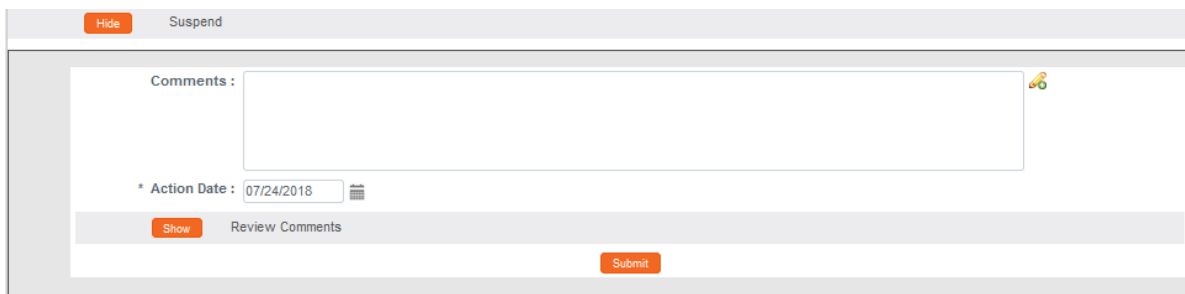
Note This is a Final Action and will change the Document Status to Expired. A new protocol must be submitted for further review.



Suspending a Protocol

Sometimes an IACUC 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 IACUC Administrator without a request from the researcher. A protocol is generally suspended when researchers identify new risks that require investigation before proceeding. This action is typically driven by regulatory obligation and indicates temporary suspension of research activities.

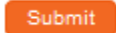
1. Use the Lookups to search for the protocol.
2. From the IACUC Protocol Actions tab, click the section header to expand the Request an Action section. In some cases, this section may appear expanded by default.
3. Click on the Show button next to Suspend.





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 the Review Comments  Review Comments action to view all official review comments.
7. 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 Principal Investigator. See the [Review Comment Matrix](#) for information about how the Private and Final checkboxes affect the view of each type of user.

8. Click the Submit button to record the decision. 

Result 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, continuation or amendment with continuation 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.

Putting a Protocol On Hold

Sometimes an IACUC Administrator will want to put a protocol On Hold rather than suspending the protocol. This can be used to temporarily delay work on an active protocol for minor reasons.

1. Use the Lookups to search for the protocol.
2. From the IACUC 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 Hold.

Request an Action

Show

Hold

Hide Hold

Comments :

* Action Date : 08/28/2018

Show Review Comments

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 Show button next to the Review Comments action to view all official review comments.
7. 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 Principal Investigator. See the [Review Comment Matrix](#) for information about how the Private and Final checkboxes affect the view of each type of user.

8. Click the Submit button to record the decision.

An orange rectangular button with the word "Submit" in white text.

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

If so, make any necessary edits and click Send.

An orange rectangular button with the word "Send" in white text.

Otherwise, this process is complete.

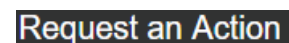
Result The PI should receive a response indicating that their protocol has been put on hold. The format of the response and any accompanying correspondence will be based on your institution's workflow configuration. It may display as an FYI in their Action List. You can always access this information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

Lifting the Hold on a Protocol

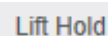
The IACUC Administrator may want to lift a hold on a protocol so that work may resume. This is accomplished through the Lift Hold action.

1. Use the Lookups to search for the protocol.


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

A dark grey rectangular button with the text "Request an Action" in white.

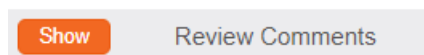
3. Click on the Show button next to Lift Hold.

An orange rectangular button with the word "Show" in white text.A light grey rectangular button with the text "Lift Hold" in dark grey.

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 the Review Comments action to view all official review comments.



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

8. Click the Submit button to record the decision.



Result 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.

Terminating a Protocol

Termination will sometimes follow a suspension. When an IACUC Administrator terminates a protocol, the research is no longer allowed. This usually occurs when either the investigators or the IACUC determine it is unsafe to continue with the study.


1. Use the Lookups to search for the protocol.
2. From the IACUC 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.

Request an Action

Show

Terminate

The screenshot shows a web form for terminating a protocol. At the top, there are two buttons: 'Hide' and 'Terminate'. Below these is a large text area labeled 'Comments :'. Under the comments area is a field for '* Action Date : 08/17/2018' with a calendar icon. At the bottom of the form, there 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. 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. 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.

Submit

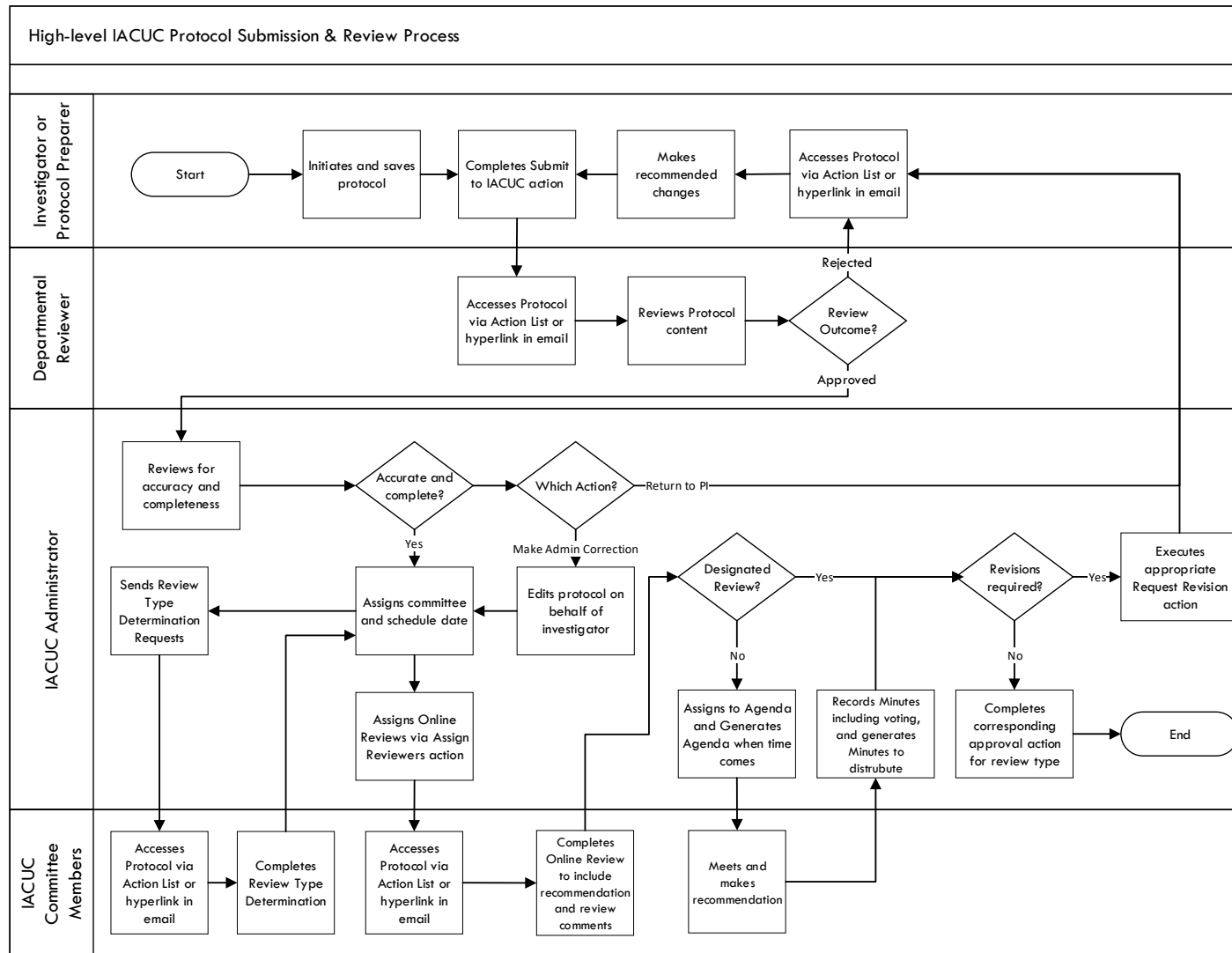
Results The PI should receive a response indicating that their protocol has been terminated. The format of the response and any accompanying correspondence will be based on your institution's workflow configuration. It may display as an FYI in their Action List. You can always access this information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

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

Appendix A: IACUC Roles and Permissions

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

Appendix B: IACUC Protocol Workflow Overview



Appendix C: All IACUC Protocol Actions

Action	Role	Description	Prerequisites	Result
Abandon	Investigator	Used to cancel a protocol that has been returned for revisions by IACUC 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: Minor Revisions Required, Major Revisions Required.	Protocol Status is updated to Abandoned.
Administrative Determination	IACUC Admin	Used to administratively approve, mark incomplete or withdraw a protocol. (See also: Administratively Approve Protocol, Administratively Mark Incomplete Protocol, Withdraw Protocol)	Protocol Status must be Submitted to IACUC or Submission Status is Submitted to Committee.	Options to Administratively Approve Protocol, Administratively Mark Incomplete Protocol, or Administratively Withdraw Protocol are offered when applicable.
Administratively Approve Protocol	IACUC Admin	Used to record approval of a protocol following administrative review.	Protocol Status must be Submitted to IACUC. Submission Status must be Pending or Submitted to Committee.	Protocol Status updates to Administratively Approved. Submission Status updates to Administratively Approved.

Action	Role	Description	Prerequisites	Result
Administratively Mark Incomplete Protocol	IACUC Admin	Used to administratively mark that a protocol is incomplete, so that the PI can make corrections and resubmit.	Protocol Status must be Submitted to IACUC. Submission Status must be Pending or Submitted to Committee.	Protocol Status updates to Administratively Incomplete. Submission Status updates to Administratively Incomplete.
Administratively Withdraw Protocol	IACUC Admin	Used to administratively withdraw a protocol from consideration by the IACUC.	Protocol Status must be Submitted to IACUC or Submission Status is Submitted to Committee.	Protocol Status updates to Administratively Withdrawn. Submission Status updates to Administratively Withdrawn.
Approve Action	IACUC 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 is updated to Active. Submission Status is updated to Approved.

Action	Role	Description	Prerequisites	Result
Assign Reviewers	IACUC Admin	Used to select primary and secondary reviewer assignments from a system display of active IACUC Committee Members.	<p>Protocol Status must be Submitted to IACUC.</p> <p>Submission Status must be Submitted to Committee or In Agenda.</p> <p>Action appears when protocol is assigned to a committee (for Designated Member review) or assigned to a committee and a schedule (for Full Committee review).</p>	Upon submission, the Protocol will appear in each reviewer's Action List.
Assign to Agenda	IACUC Admin	<p>Used to assign a protocol to the agenda of a committee meeting for review.</p> <p>(See also: Modify Submission Request)</p>	<p>Protocol must be assigned to a committee and a schedule.</p> <p>Protocol Status must be Submitted to IACUC.</p> <p>Submission Status must be Submitted to Committee.</p>	No change other than the Protocol will appear on the IACUC Agenda.
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, Active-On Hold, Suspended.	Protocol Status updates to be Amendment in Progress.

Action	Role	Description	Prerequisites	Result
Create Continuation with Amendment	Investigator	Used to both continue a protocol for another set period of time (e.g., one year), AND to incorporate various changes to the protocol. (See also: Create Continuation without Amendment and Create Amendment)	Protocol Status must be one of the following: Active, Active-On Hold, Suspended.	Protocol Status updates to Continuation in Progress.
Create Continuation without Amendment	Investigator	Used to continue a protocol for another set period of time (e.g., one year).	Protocol Status must be one of the following: Active, Active-On Hold, Suspended.	Protocol Status updates to Continuation in Progress.
Deactivate	IACUC Admin	Used to deactivate a protocol where all animal activities have been completed. (See also: Request to Deactivate)	Protocol Status must be Active, Administratively Approved, or Active-On Hold. Submission Status must be Submitted to Committee or Pending.	Protocol Status updates to Deactivated. Submission Status updates to Deactivated.

Action	Role	Description	Prerequisites	Result
Delete Protocol, Amendment or Continuation	Investigator	Used to delete a protocol, amendment, or continuation prior to submission, because the PI no longer intends to pursue the study.	Protocol Status must be one of the following: Pending/In Progress, Continuation 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.
Disapprove	IACUC 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 IACUC. Submission Status must be In Agenda.	Protocol Status updates to Disapproved. Submission Status updates to Disapproved.
Expire	IACUC Admin	Used to indicate that approval of a protocol has expired and no human subject activities may proceed beyond the expiration date. Alternatively, the study may close.	Protocol Status must be one of the following: Active, Active-On Hold, Deactivated, Suspended.	Protocol Status updates to Expired.

Action	Role	Description	Prerequisites	Result
Hold	IACUC Admin	Used to temporarily delay work on an active protocol for minor reasons. (See also: Lift Hold)	Protocol Status must be Active.	Protocol Status updates to Active-On Hold.
IACUC Acknowledgement	IACUC Admin	Used to formally acknowledge the receipt of an FYI submission from the Investigator (See also: Notify IACUC)	Submission Review Type must be FYI. Submission Status must be Submitted to Committee.	Submission Status updates to IACUC Acknowledgement.
Lift Hold	IACUC	Used to lift a hold on a protocol so that work may resume. (See also: Hold)	Protocol Status must be Active-On Hold.	Protocol Status updates to Active. Submission Status updates to Lift Hold.
Make Administrative Correction	IACUC Admin	Used sparingly to make minor corrections to a submitted protocol.	Protocol Status can be anything except Pending.	Streamlyne Research maintains an audit trail of all changes within the Action History section.

Action	Role	Description	Prerequisites	Result
Manage Notes	Investigator and IACUC 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.
Manage Review Comments	IACUC 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	IACUC 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 Continuation with Amendments	Protocol Status must be Amendment in Progress or Continuation in Progress.	Amendment sections are updated.

Action	Role	Description	Prerequisites	Result
Modify Submission Request	IACUC Admin	Used to change the Protocol Submission Review Type and assign a protocol to committee and schedule, making it eligible for review.	Protocol Status must be Submitted to IACUC or Submission Status is Submitted to Committee.	Protocol is routed for review and approval according to the process defined for the Review Type.
Notify Committee	IACUC Admin	Used to notify the Committee of various changes or provide important information regarding protocols not reviewed by the full committee.	Submission Review Type must be Administrative or Designated Member Review. Protocol Status must be Submitted to IACUC.	Notification will appear as FYI in each Committee Member's Action List.
Notify IACUC	Investigator	Used to inform the IACUC of an event or change that may not require committee review.	Protocol Status must be one of the following: Active, Active-On Hold, Withdrawn, Expired, Disapproved, Terminated, Suspended	Submission Status updates to Submitted to IACUC or Pending.

Action	Role	Description	Prerequisites	Result
Record Committee Decision	IACUC Admin	Used to record the decision of a full IACUC committee review of a protocol, specifically: Approve, Disapprove, Minor Revisions Required, or Major 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.
Request to Deactivate	Investigator	Used to notify the committee that the portion of the study involving animals has been deactivated. (See also: Deactivate)	Protocol Status must be in one of the following statuses: Active, Active-On Hold.	Submission Status updates to Pending
Request for Suspension	Investigator	Used to request a suspension of the existing study, usually when researchers identify new risks that require investigation before proceeding (See also: Suspend)	Protocol Status must be in one of the following statuses: Active, Active-On Hold.	Submission Status updates to Pending.

Action	Role	Description	Prerequisites	Result
Response Approval	IACUC Admin	Used to approve a proposal resubmission.	Submission Review Type must be Response.	Protocol Status updates to Active.
Return for Major Revisions	IACUC Admin	Used to indicate a full committee decision requiring the investigator to make significant changes to a protocol before the committee will approve the study, usually due to the committee's assessment of a "greater than minimal" risk.	<p>The Record Committee Action must be completed with a Motion Type of Major Revisions Required.</p> <p>Protocol Status must be Submitted to IACUC.</p> <p>Submission Status must be In Agenda.</p>	<p>Protocol Status updates to Major Revisions Required.</p> <p>Submission Status updates to Major Revisions Requested.</p>
Return for Minor Revisions	IACUC Admin	<p>Used to indicate a committee decision where the investigator needs to make changes to a Protocol before the committee will approve the study.</p> <p>Action is performed based on committee's evaluation that the study poses minimal risk, and that requested changes are minor.</p>	<p>The Record Committee Action must be completed with a Motion Type of Minor Revisions Required.</p> <p>Protocol Status must be Submitted to IACUC.</p> <p>Submission Status must be In Agenda.</p>	<p>Protocol Status updates to Minor Revisions Required.</p> <p>Submission Status updates to Minor Revisions Requested.</p>

Action	Role	Description	Prerequisites	Result
Return to PI	IACUC 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 Major Revisions and Return for Minor Revisions)	The Assign to Committee and Schedule Actions must be completed. Protocol Status must be Submitted to IACUC.	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	IACUC Admin	Used when reviewers determine that the nature of study does not actually qualify as animal 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 IACUC.	Protocol Status updates to IACUC Review Not Required. Submission Status updates to IACUC Review Not Required.

Action	Role	Description	Prerequisites	Result
Submit for Review	Investigator	Used to submit a protocol, amendment, or continuation to the IACUC for review.	Protocol status must be In Progress, Minor Revisions Required, Major Revisions Required, Amendment in Progress, Continuation in Progress, Deferred, or Withdrawn.	Protocol Status updates to Submitted to IACUC. Submission Status updates to Pending.
Suspend	IACUC 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 statuses: Active, Active-On Hold.	Protocol Status updates to Suspended. Submission Status updates to Suspended.
Table Protocol	IACUC Admin	Used to indicate that the IACUC 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

Action	Role	Description	Prerequisites	Result
Terminate	IACUC Admin	Used to formally terminate a study when either the investigators or the IACUC determine it is unsafe to continue.	Protocol Status must be in one of the following statuses: Active, Active-On Hold, Suspended, Expired.	Protocol Status updates to Terminated.
Undo Last Action	IACUC 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 statuses: Protocol Created, Submitted to IACUC, Amendment Created, Expired, Withdrawn, Amendment Approval, Administrative Correction.	Protocol Status and Submission Status revert to previous state.
Withdraw Protocol	IACUC Admin	Used to withdraw a protocol from consideration by the IACUC.	Protocol Status must be Submitted to IACUC. Submission Status must be Submitted to Committee or Pending.	Protocol Status and Submission Status update to Withdrawn.
Withdraw Submission	IACUC Admin	Used to withdraw a protocol submission request from consideration.	Protocol must have a pending Request to Deactivate, Request to Lift Hold, or Request to Suspend Action. Submission Status will be Pending.	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>
            </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.