IACUC Protocol & Committee Modules

Last Updated May 1, 2019

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Login in to Streamlyne

Before you start using Streamlyne, please make sure you are using **Google Chrome OR Firefox**
And avoid using special characters in the text boxes.

1. Go to https://research.ponce.streamlyne.org
2. Login with your username and password.

If you do not have a username and password, fill a the **StreamLyne Account Creation Form at http://j.mp/2Atz5pC

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.

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.

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 ofgeneral IACUC practices and do not necessarily represent the exact way your institution will choose to use the application.

Let's begin

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.

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. Note: Validation rules require that one of these fields must be populated, but not both.
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.	
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.	If the PI is an employee, the **Lead Unit** field automatically populates with their assigned Unit ID. 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.

Tab	Section	Field Name	Description	Instructions
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.

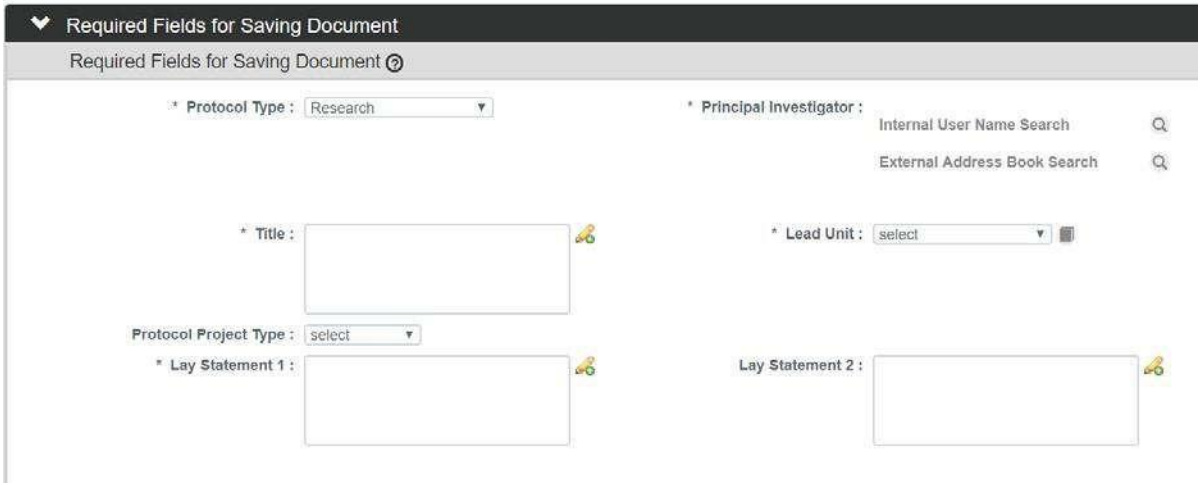
3. Click the Save button. 

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.

Protocol Tab > Required Fields for Saving Document



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.

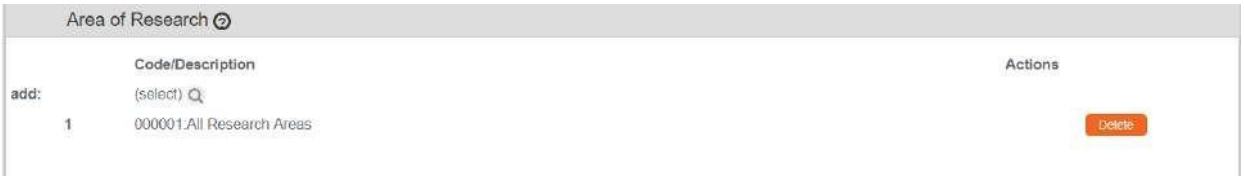
5. The **Protocol Project Type** is optional and is used to provide a further description of the project type (e.g., Agricultural, Behavioral, Biomedical, Field Studies).

   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. 

Protocol Tab > Additional Information > Areas of Research



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

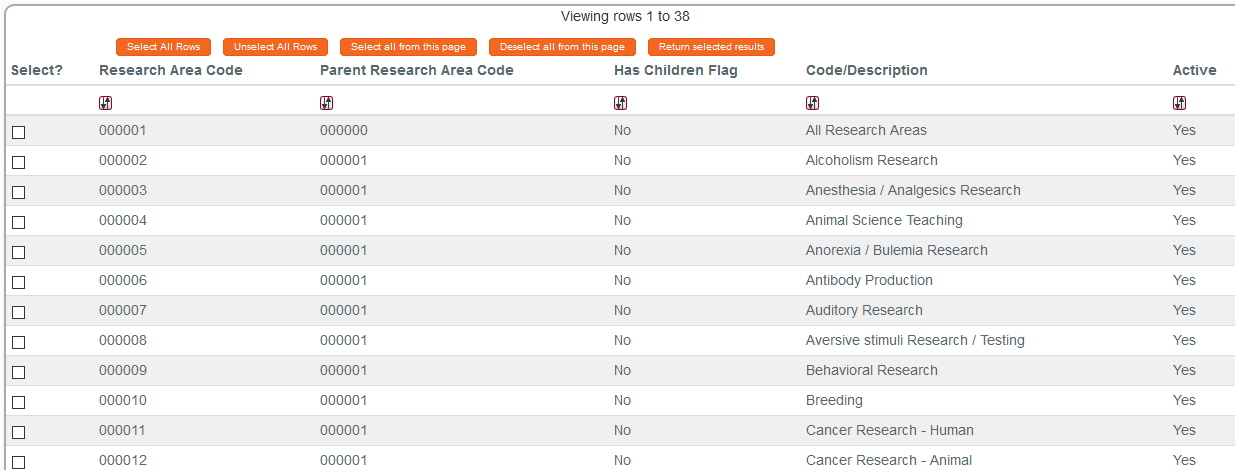
2. The Areas of Research list automatically populates with 00001: All Research Areas.

   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.

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



Select?	Research Area Code	Parent Research Area Code	Has Children Flag	Code/Description	Active
☐	000001	000000	No	All Research Areas	Yes
☐	000002	000001	No	Alcoholism Research	Yes
☐	000003	000001	No	Anesthesia / Analgesics Research	Yes
☐	000004	000001	No	Animal Science Teaching	Yes
☐	000005	000001	No	Anorexia / Bulemia Research	Yes
☐	000006	000001	No	Antibody Production	Yes
☐	000007	000001	No	Auditory Research	Yes
☐	000008	000001	No	Aversive stimuli Research / Testing	Yes
☐	000009	000001	No	Behavioral Research	Yes
☐	000010	000001	No	Breeding	Yes
☐	000011	000001	No	Cancer Research - Human	Yes
☐	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. Return selected results

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

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 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.

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.

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.

Protocol Tab > Organizations

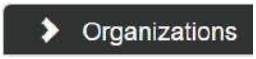
The Organizations section allows you to indicate which, if any, outside institutions may be performing some aspect of the study activities. Organizations that are configured in the system have identified contacts, called IACUC Correspondents, who may be listed on the Personnel Tab and are eligible to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

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



Otherwise, skip to the next process.

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

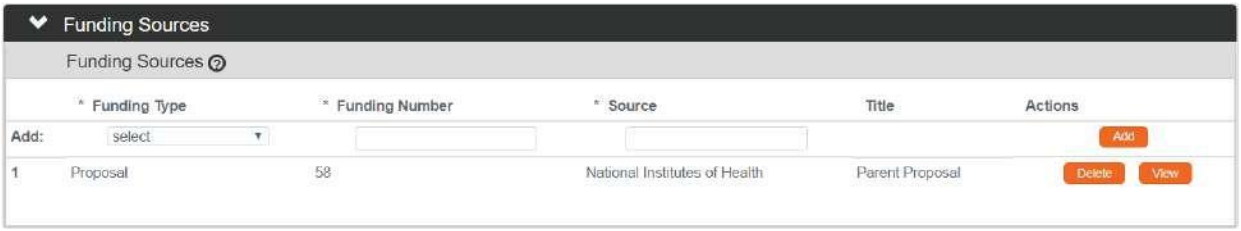
3. Click the arrow next to the **Organization Type** field to identify this organization as either an external organization or the organization performing the research.

4. Click the Add button to complete the action. 

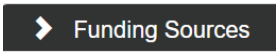
5. Repeat Steps 2 through 4 until all collaborating institutions are included on the protocol document.

Protocol Tab > Funding Sources

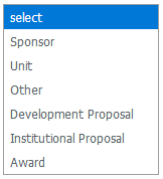
The Funding Sources section internally links the protocol to one or more proposals, awards or departments within Streamlyne Research.



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



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



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

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

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

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

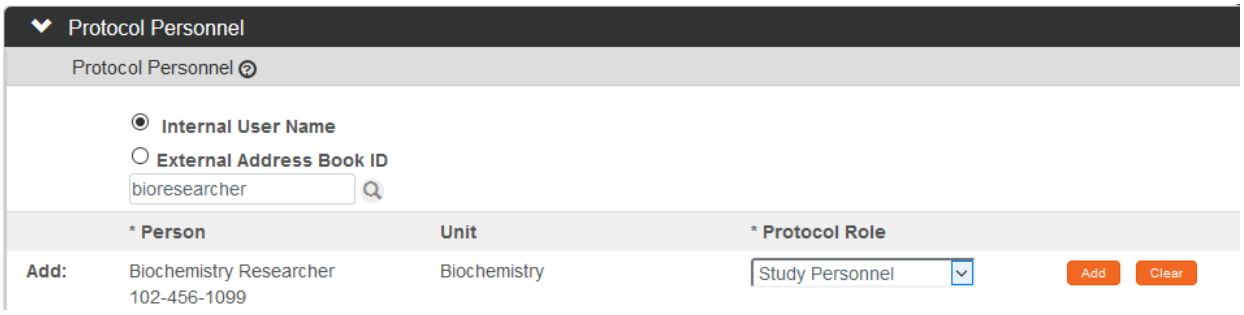
3. Enter a **Funding Number** or click the magnifying glass to search for and select the corresponding return value.

4. Click the Add button to complete this action. 

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

Updating the Personnel Tab

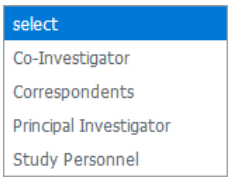
1. If your institution's process requires you to identify project personnel in addition to the Principal Investigator, click on the tab header to access the Personnel tab.



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

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

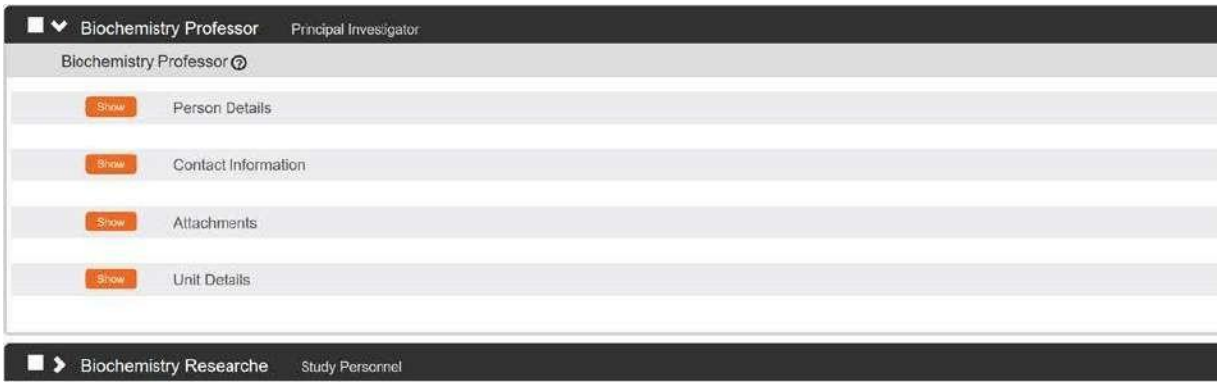
3. Click the arrow next to the **Protocol Role** field to select the team member's role from the dropdown list.



4. Click the Add button to complete this action. 

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

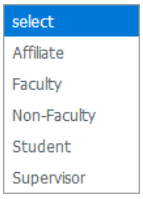
5. Click the section header to expand the user section.



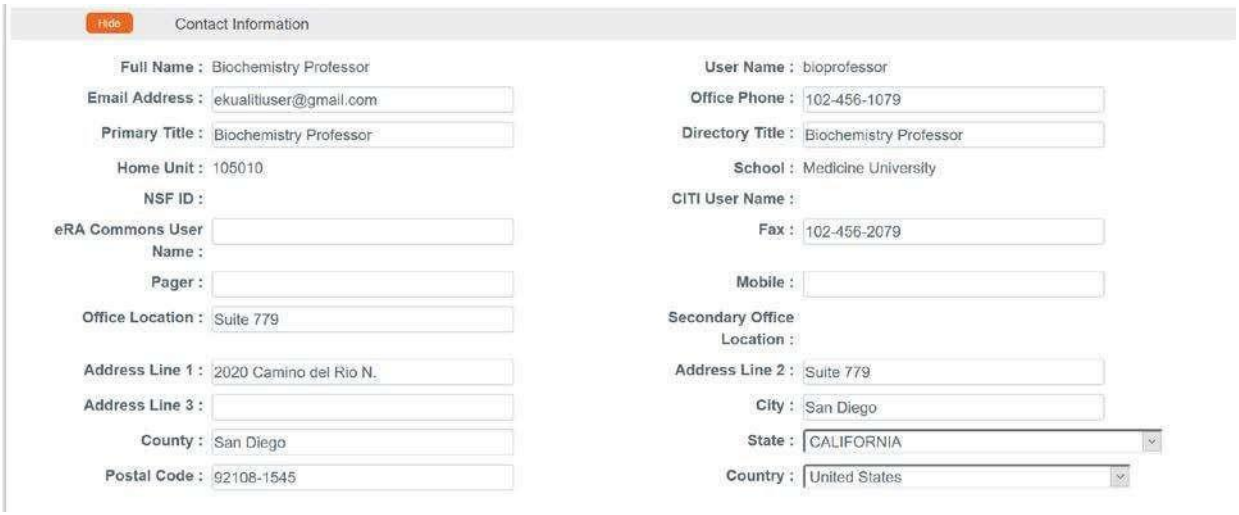
6. Click the Show button to expand the Person Details subsection. 

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.



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



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.

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.

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. 

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.

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.

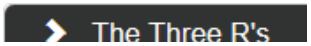
Additionally, this tab allows the investigator to identify literature searches conducted during the design of their proposed study. This is especially useful in documenting the specific literature searches that they are required to perform in their efforts to find alternatives to any procedures likely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

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



3. In the **Principles of Reduction** field, enter freeform text to justify the number of animals used and how this minimal number was determined.

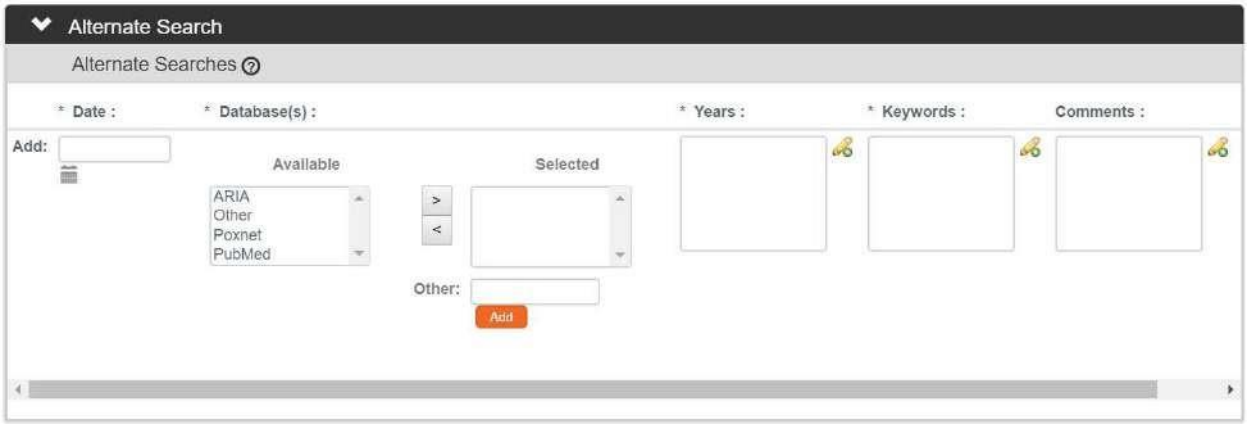
4. In the **Principles of Refinement** field, enter freeform text to describe the methods that will be employed to minimize discomfort, distress, and pain.

5. In the **Principles of Replacement** field, enter freeform text to justify the use of this 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 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. 

Note New questions may appear based on your answers.

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

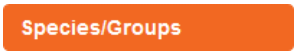
5. Click the Save button to save your work. 

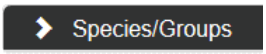
6. The Questionnaire status will change to Complete once all questions are answered. 

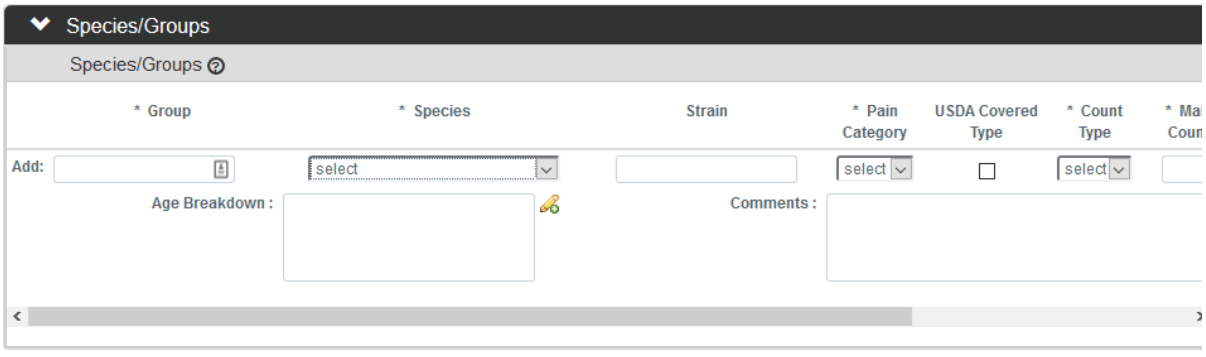
   If the questionnaire is required, you will not be able to submit your protocol until all questions are answered and the Complete status displays.

Updating the 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.

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

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



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.

   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.

USDA PAIN CATEGORIES

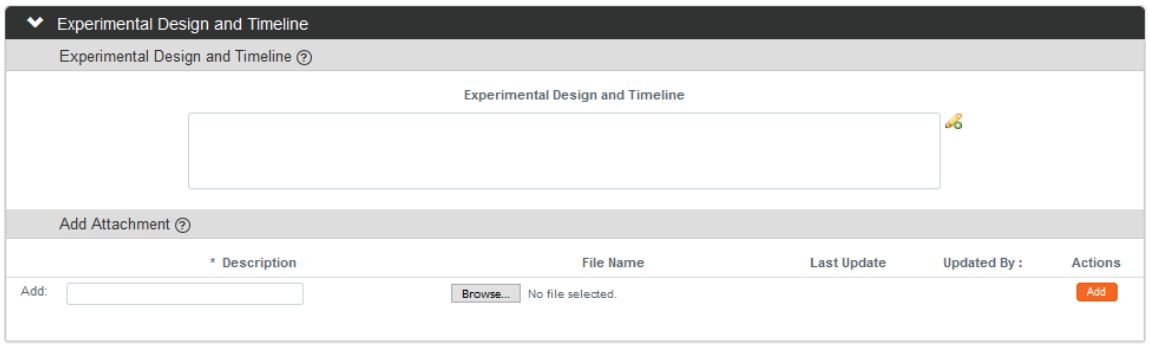
B Animals housed for breeding or other purposes where no experimental manipulations are required.

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.

Procedures Tab > Experimental Design and Timeline



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

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.

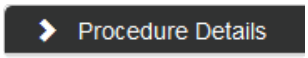
Once you select one or more procedures from the included categories listing, the system will expand the fields to allow data entry related to each procedure in the following sub tabs:

- 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.

Sub Tab > Procedures

1. If it is not already expanded, click on the section header to expand the Procedure Details section.



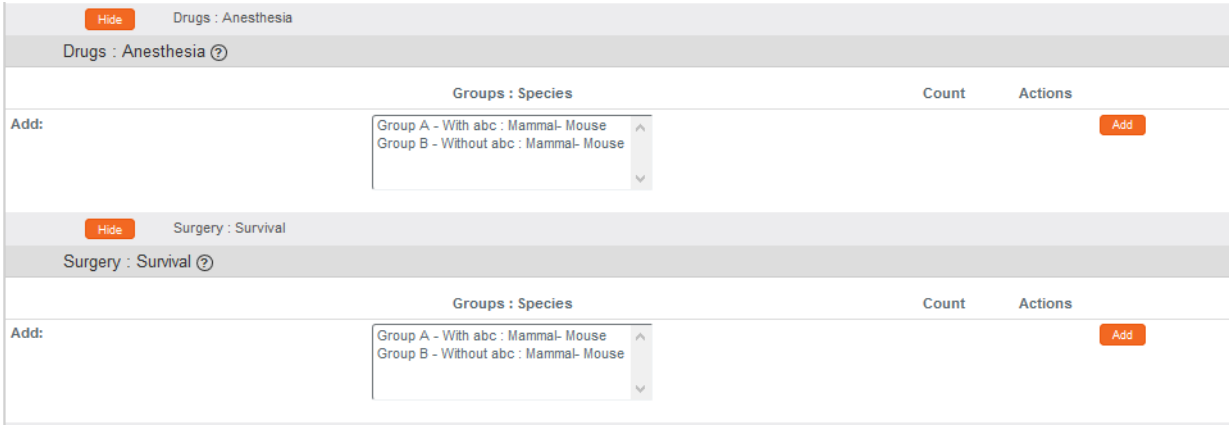
2. Check the box(es) next to each procedure that will be utilized over the course of the study.

Result Streamlyne Research will create a subsection for each Procedure you select. Subsections will appear below the Included Categories subsection.

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

Otherwise, proceed to the next Step.

Note: PLEASE AVOID SPECIAL CHARACTERS IN THE RESPONSE TEXT BOX

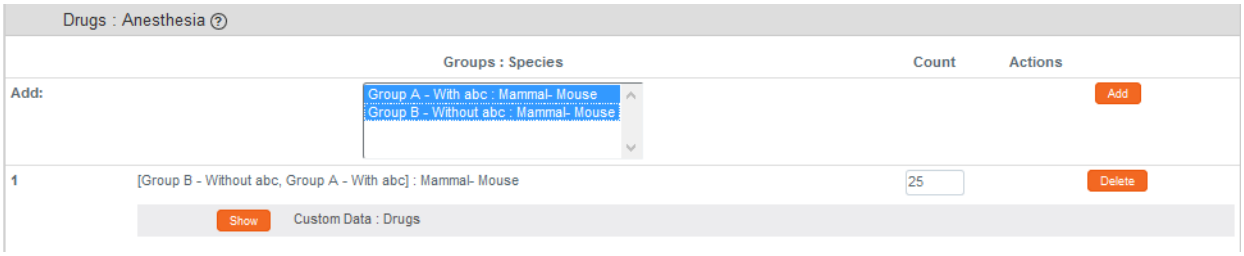


3. Select the group(s) in the **Groups:Species** field on which the procedure will be performed. Hold down the Ctrl key to select more than one group.

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 subsection 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. Save

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. View Training Details

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

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.

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 variouis 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.

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. Add

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.

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.

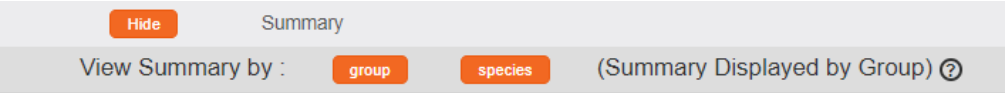
8. Check each procedure that will be performed at the location or click the checkbox next to ALL PROCEDURES to automatically select all procedures.

9. Click the Save button. Save

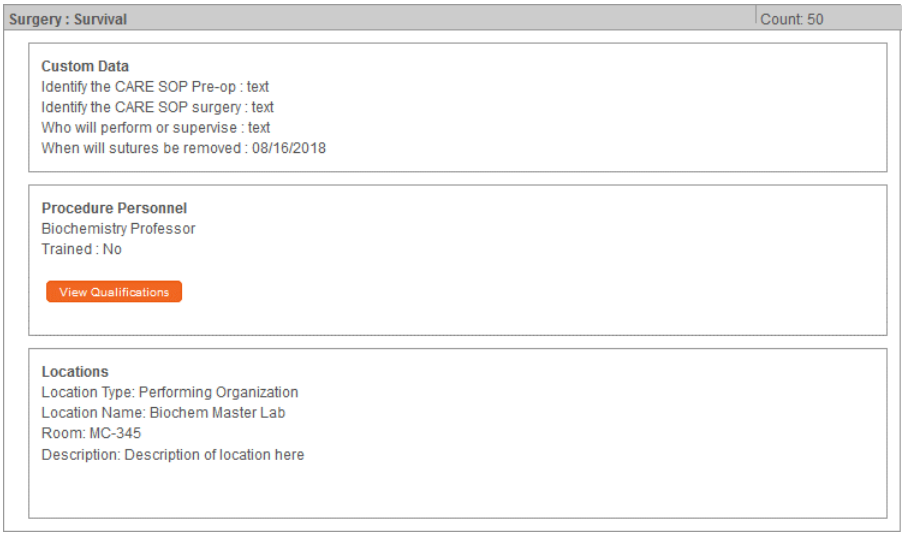
10. Complete Steps 2 through 9 for any additional Locations.

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.



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



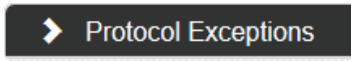
Updating the Protocol Exceptions Tab

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*.

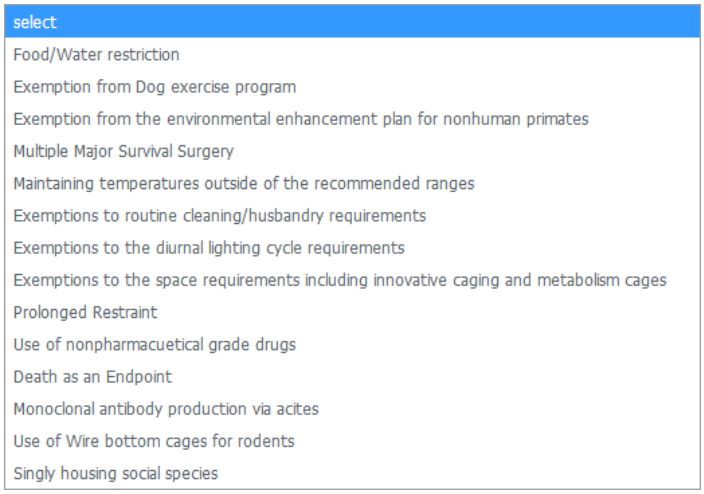
For example, the Guide might state that if dogs are to be used as laboratory animals, they need to be exercised a certain number of times in a day. If the proposed research involving dogs cannot adhere to this standard, you need to provide justification within the Protocol Exception section.

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

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



3. Click the arrow next to the **Exception** field for a dropdown list of options to select. These are configurable by your institution.



4. Click the arrow next to the **Species** field to choose the species for which you will be deviating from standard procedure.

5. Enter freeform text in the **Exception Justification and Description** field to describe the reason or justification for departing from standard procedures.

6. Enter digits in the **Exception Count** field indicating the number of animals that will be affected.

7. Click the Add button. 

8. Repeat Steps 3 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.

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:

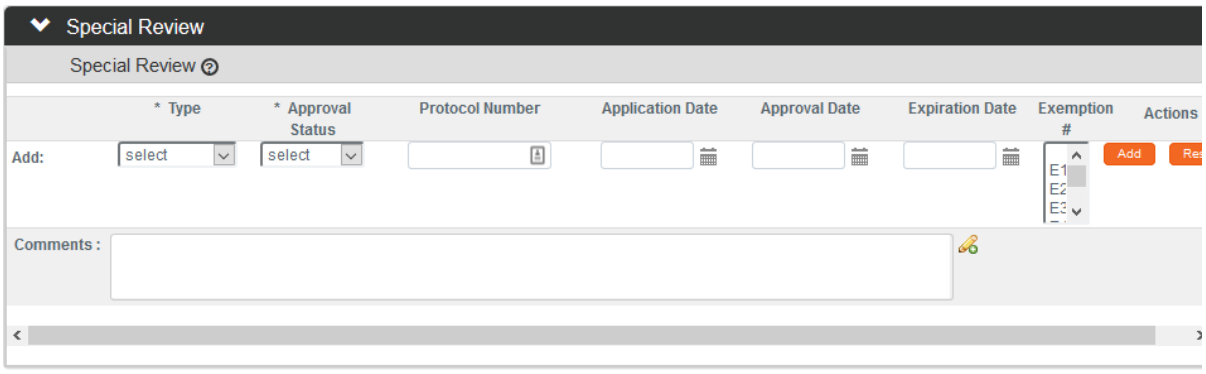
- Data sharing between projects that are tracked on separate IACUC protocol documents.
- Project-related human research protocols that are tracked on IRB protocol documents.
- Technology/data protections for your project that are recorded on Intellectual Property Review documents.
- Biosafety and/or 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.

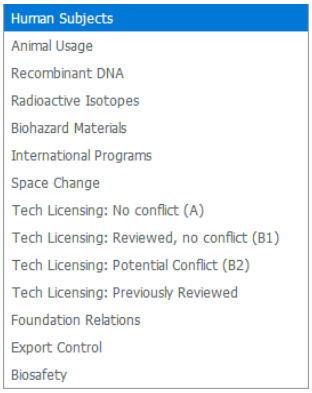
All Special Review Types are determined by your institution.

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.



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. Add

8. Repeat Steps 2 through 7 until all related reviews are recorded.

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

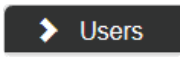
Updating the Permissions Tab

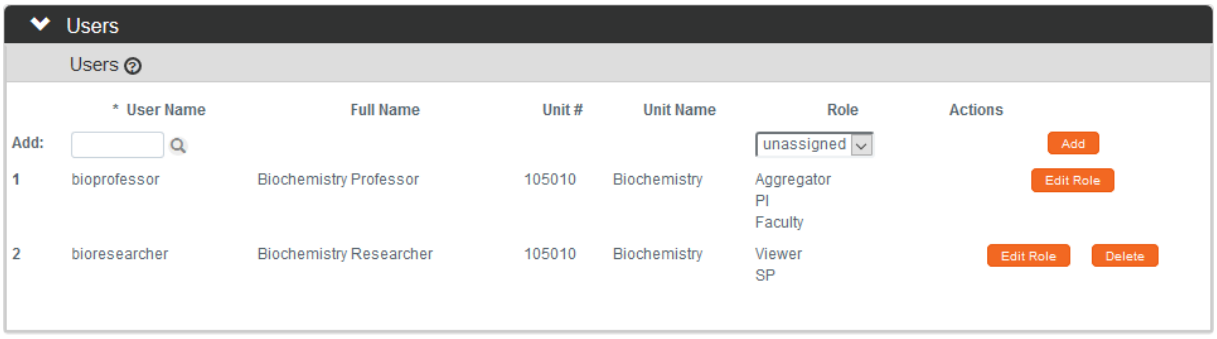
The Permissions tab contains read-only user role and project role data for the personnel identified in the previous sections. For example, the protocol's default Aggregators (or editors) will be identified as the Principal Investigator and the Initiator (if different from the PI).

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.

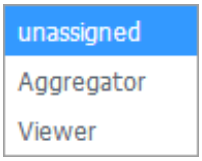
2. Scroll down to the Users section. If it is not already expanded, click on the header to expand the section.





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.

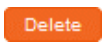
4. Click the arrow next to the **Role** field to select a permissions level for the ad hoc user.

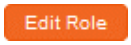


5. Click the Add button to complete the action.

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

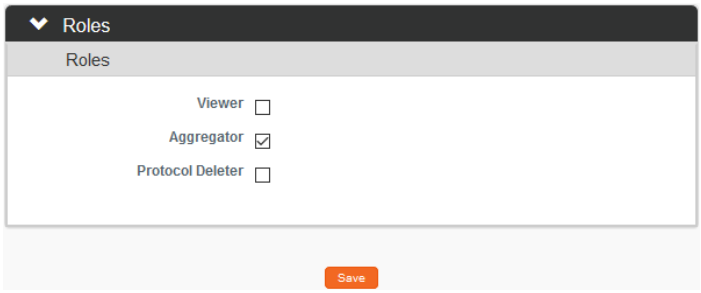
7. If you need to remove a user, click the Delete button.



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

   Otherwise, skip to the next section.

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



   Indicate whether the user should have permissions to view the document, to aggregate (edit) document data, or to delete the document by clicking the corresponding checkbox.

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

10. Click the Save button to commit your changes. 

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

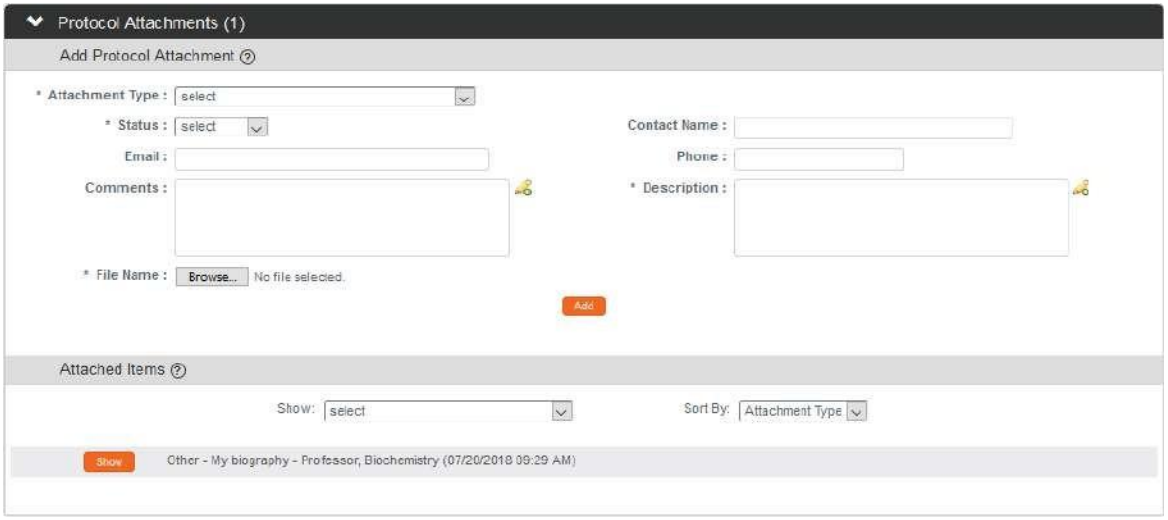
Adding Notes & Attachments

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

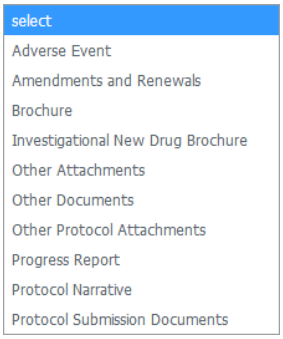
1. Click on the tab header to access the Notes & Attachments section. 

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

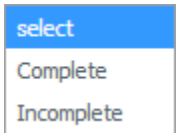
   To add a Note only, skip to Step 11.



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



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



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

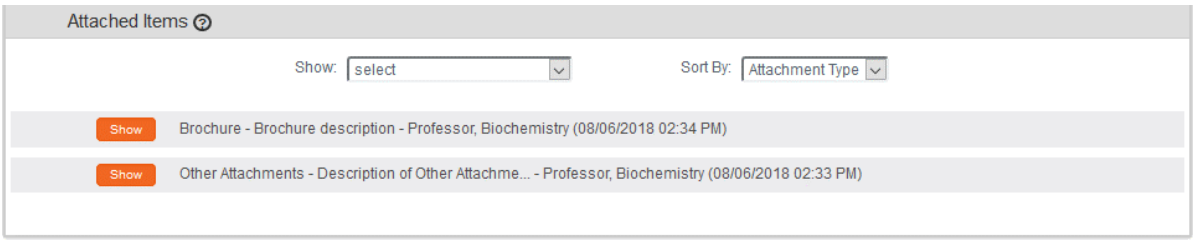
6. Enter information in the remaining **Email, Contact Name, Phone** and **Comments** fields if needed.

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

8. Click the add button. 

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

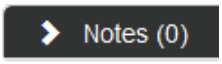
Result The system compiles a list of attachments in the Attached Items subsection.



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

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

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

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

12. In the **Note Topic** field enter a short description of what the note is about.

13. In the **Note Text** field enter or paste a complete note.

14. Click the **Restricted** checkbox if the Note should be restricted from users with View Only privileges.

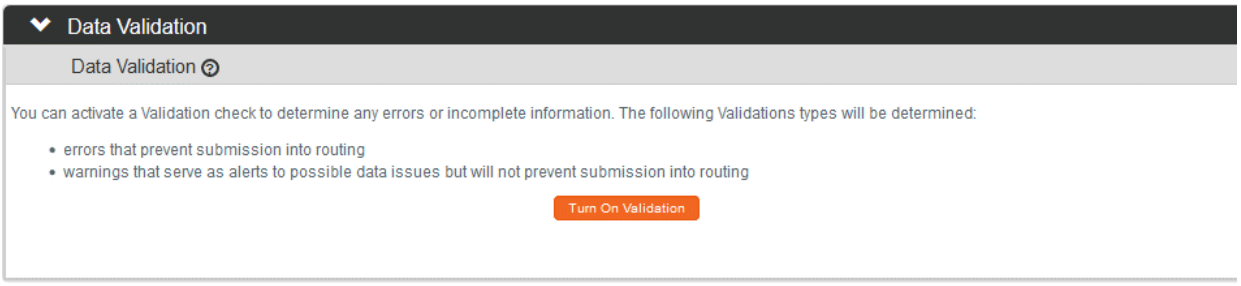
15. Click the Add button to add the Note to the database. 

16. Repeat Steps 11 through 15 until all Notes are added.

Validating the Protocol

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

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



3. Click the Turn On Validation button. 

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

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

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

   Otherwise, skip to the next process.

5. Streamlyne Research returns to the document section where the problem resides.

   Make your corrections and save the updated document.

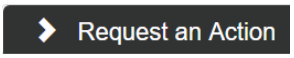
6. Repeat Steps 4 and 5 as many times as necessary to resolve all errors.

Submitting the Protocol Document to the IACUC

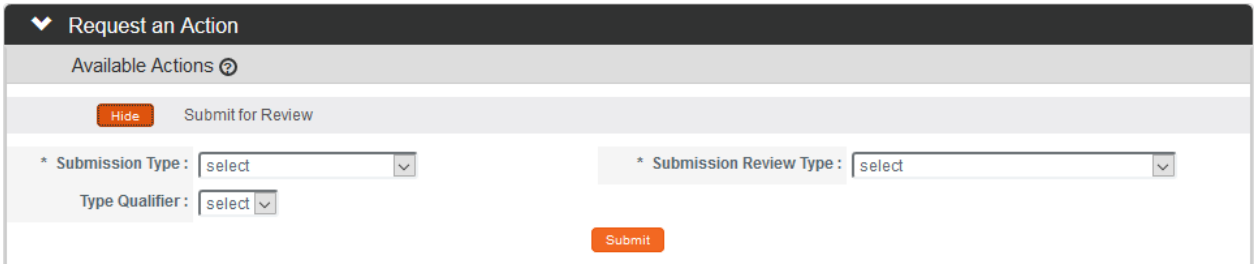
Follow these steps to submit your Protocol to the IACUC. This submission action will enter the document into your institution's predefined workflow. Workflow stops, called nodes, generally begin with departmental and institutional approvals. This workflow is predefined by your institution and can vary 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

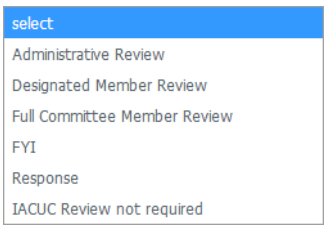


4. Streamlyne Research will display the Submit for Review subsection.

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.



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. 

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.