IRB QUESTIONNAIRE QUESTIONS

NOTE: This list includes ALL questions in the IRB questionnaire. Not all questions are relevant to your specific protocol. The entire list of questions is provided for your reference only. Completing this word document and attaching it to your protocol is not sufficient.

1. Please select the category that best describes your submission.
2. What is the main subject of your project?
3. Please provide a short lay abstract (or summary) of the project.
4. What do you hope to gain by doing this study? Mention specific outcomes.
5. Proposed Start Date of Protocol
6. Proposed End Date of Protocol
7. Anticipated Duration of Entire Study (years)
8. Does this protocol involve intervention or interaction with living individuals?
9. Describe the tasks/tests or procedures participants will be asked to complete.
10. Provide rationale for using vulnerable populations. Vulnerable groups are considered vulnerable or require special considerations by the federal regulatory agencies and by the IRB
11. Describe the tasks/tests or procedures participants will be asked to complete.
12. Please provide the duration of subject participation (#hours/ days/weeks) including number and duration of study visits.
13. Will participants receive inducements before or rewards after the study?
14. Will media advertisements be used?
15. Provide detail of steps to be taken to ensure additional protection of the rights and welfare of the identified vulnerable population(s)
16. Please provide the duration of subject participation (#hours/ days/weeks) including number and duration of study visits.
17. How, when and by whom will the inclusion / exclusion criteria be assessed?
18. Will physicians or staff refer subjects?
19. Please describe the referring physician's incentive below, if applicable
20. Describe any other recruitment methods:
21. Regarding the informed consent process, how will participants understanding be assessed? What questions will be asked to assess the participants understanding; will there be written responses; will understanding be assessed at other points in time?
22. Will the study use audio tapes, videotapes, or photographs?
23. Does this study use third party information such as family history or sexual contacts? If yes, describe protections for consent and privacy of third party.
24. Does this study collect incriminating or sensitive information regarding the following: Depression, Suicide, Mental illness, HIV/AIDS, Sexually transmitted diseases, Alcohol use Drug use
25. Please describe the incriminating or sensitive information
26. Does the study have a Certificate of Confidentiality (CoC)?
27. Number of Subjects for this Protocol:
28. Include statistical and clinical justification:
29. Gender of Subjects for this Protocol:
30. Is the activity biomedical, behavioral, clinical, or other project that collects or uses identifiable,

sensitive information (HIPAA identifiers)?

31. What type of waiver of HIPAA authorization, if any, are you requesting?
32. Does this study involve a Data Safety Monitoring Board (DSMB)?
33. Have all personnel completed the Health Information Privacy and Security (HIPS) and Human Subject Protections (Human Research) education requirement?
34. Are their respective certifications current and on file in the IRB office?
35. Are all personnel sufficiently trained to complete their respective duties on this protocol?
36. Does the proposed study involve human specimens (e.g., tissues, blood, urine, cell lines)? Provide a short description and indicate the source of the specimens.
37. Does the proposed project involve human embryonic stem cells (hESCs)?Indicate the stem cell line, source, and NIH HESC Registry number, if applicable.
38. Does the proposed project involve genetic testing of human specimens?
39. Does the proposed study involve medical data, documents, or records?
40. Is this a multicenter/multisite study?
41. Is this considered a clinical trial? If this research an applicable Clinical Trial that must be registered on Clinical Trails.gov, please provide the NCT number:
42. Is this an industry-sponsored clinical trial of an investigational product? Please attach the associated Investigator's Brochure in the Notes & Attachments section.
43. If this study has a "formal" designation (e.g., Phase I, II, III, or IV), indicate this below:
44. Does the proposed study involve an FDA Investigational New Drug (IND) application?
45. Does the proposed study involve an FDA Investigational Device Exemption (IDE)?
46. Please indicate if only adults 21+ years old will be involved in this protocol
47. Does this study involve vulnerable populations [e.g., children, prisoners, UPR-MSC Employees or Students, cognitively impaired individuals, pregnant women, fetuses, neonates, among others]?
48. Does this study involve students or employees of the institution?
49. What are the risks of this study? Why are they reasonable? What is the expected yield from the project?
50. Will study enrollment be limited to specific ethnic or social group(s)? If so, describe:
51. Federal regulations require that you include minorities in your research unless you can justify their exclusion. Are you including minorities? If not, please justify. Please provide justification for not including minorities in your study if applicable
52. Federal regulations require that you include non-pregnant Women in your study unless you can justify their exclusion. Are you including them? If not, justify. Please, provide justification for not including non-pregnant Women in your study if applicable.
53. Describe the inclusion and exclusion criteria for the study.
54. List any anticipated direct benefits of participation in this project.
55. What are the Informed Consent procedures?
56. What is the type of consent to be obtained for this study?
57. How, where, and when will consent be obtained?
58. If subjects are unable to give consent (e.g., children or cognitively impaired), describe how and by whom permission will be granted.
59. Is the activity biomedical, behavioral, clinical, or other project that collects or uses identifiable, sensitive information? NIH Policy for Issuing CoC).
60. Does this study involve questionnaires, interviews, or other interactions with individuals as part of a student class assignment in a university course?
61. Will the data contain any information that could personally link the subject to the study?

62. Describe how the data will be managed after it has been collected. How, where and who will oversee the research data (electronic and paper data) and for how long it will be stored. Specify the location where the data will be stored.
63. Describe specific procedures to be used to ensure confidentiality of subjects' data.
64. Will any biological materials (e.g., human tissue, blood, drugs) be transferred to or from another institution?
65. Are any approvals or authorizations from other review committees (e.g., biosafety, radiation) required prior to initiating this study?
66. Have you applied for or secured sufficient funding to complete this study, once all approvals are in place?
67. Does any participating member, staff, students (or his/her spouse or dependent Students and employees) have any financial interest such as royalty, equity, or any other payments (e.g., consulting, salary, etc...) in the sponsor or other entities having a financial interest in intellectual property, product, or service which is the subject of the proposed protocol?
68. Does/will any equity interest exceed $5,000 in current value or exceed 1% of ownership interest?
69. Does/will aggregate annual payments for royalty and other payments exceed $5,000?
70. If you answered yes to any of these questions, has your potential conflict of interest has been disclosed?

STREAMLYNE: EMAIL NOTIFICATION TYPES

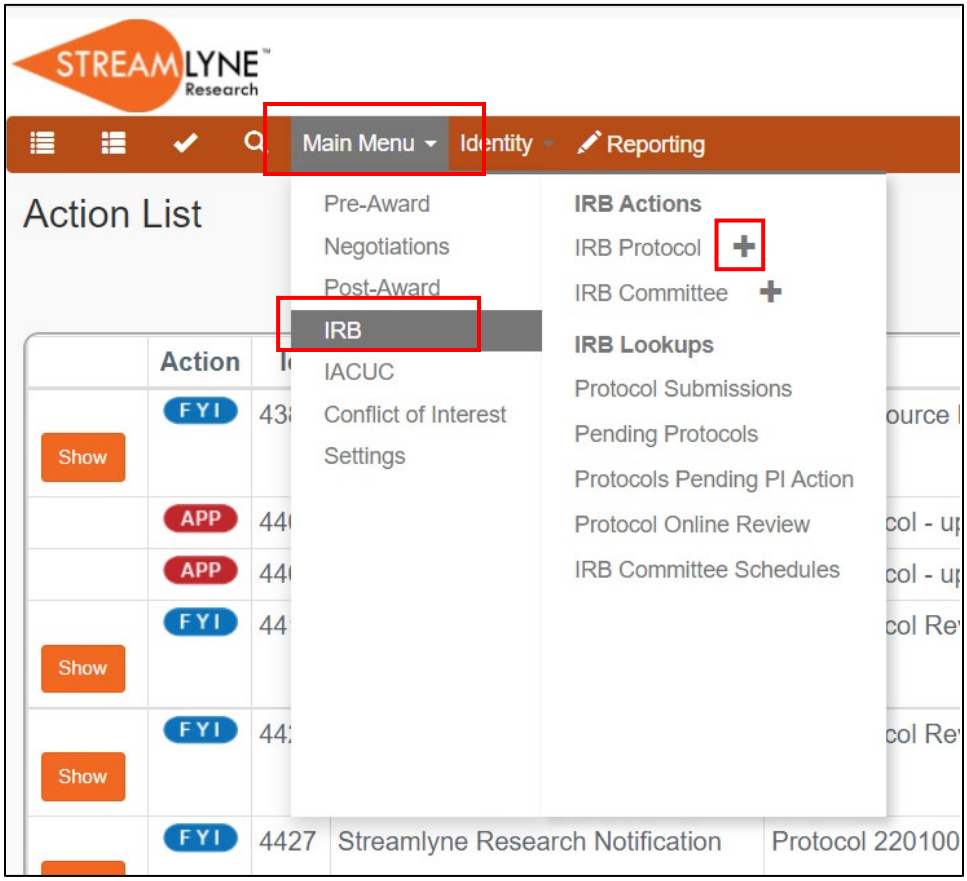
Email Notification Types	
Acknowledge ACK	This email is a notification that an item needs your acknowledgement before the routing process can be completed.
Action List	This email is a notification that an item is in your Streamlyne action list.
Approve APP	This email is a notification that an item needs your review. Upon review, you have the option to Approve, Disapprove, or Reject the document.
Complete COM	This email is a notification that you need to complete the document and submit it to begin the workflow (approval) routing process.
FYI FYI	This email is for your informational purposes only. Either of the following options will clear these messages from your Action List: 1) Within your Action List click the "Show" button to view details of the notification > click the FYI button at the bottom to clear the item from your action list, or 2) You can choose "FYI" from the "Apply Default"** drop-down menu on the far right of your Action List and scroll down to the bottom of the page and click the "Take Actions" button. This will clear away all FYI notifications currently on your Action List.

IRB: INITIATING A NEW PROTOCOL

1) **Login to Streamlyne.**

2) **Under the Streamlyne logo, hover over:**
   Main Menu > IRB > IRB Protocol > Click the + (plus sign) to create a new protocol

3) **Following these steps will open a new screen and allow you to create your new IRB Protocol.**

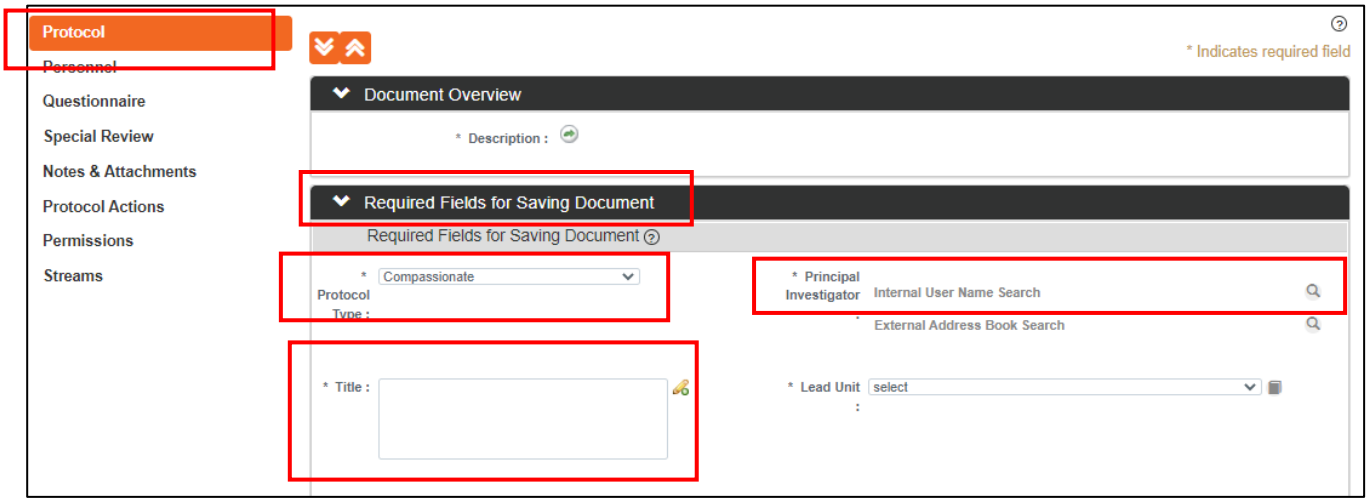


IRB: UPDATING THE PROTOCOL TAB

Once you have initiated a new protocol, as described in IRB: Initiating a New Protocol, follow the steps below to enter the required information in the Protocol Tab.
Before you can save an IRB Protocol in Streamlyne, you will need to complete the following five fields.

Document Overview & Required Fields for Saving

1) The **Description** of the IRB Protocol includes the protocol number an Principal Investigator name by default, therefore no action is needed in that section.
2) In the **Required Fields for Saving** tab, select the **Protocol Type** from the drop-down menu. This will designate the level of IRB review required. If unsure, leave it on the default type and the IRB Coordinator will correct it and notify you.
   NOTE: For details regarding the different levels of required IRB review, please go to the IRB webpage.
3) Enter the full **Title** of the protocol.
4) Search for the employee serving as the protocol's **Principal Investigator (PI)** by clicking the magnifying glass next to Person Lookup. Person Lookup
   a. To locate the PI in this search, enter their **UPR email address** (include @upr.edu) and leave all other search fields blank. Click **Search**.
   b. Below the Search button, locate the PI and click **Return Value** on the far left.
5) The **Lead Unit** should automatically populate with the unit assigned to the Principal Investigator. If it does not populate contact the Streamlyne Administrator.
6) After completing these required fields, scroll to the bottom of the page and click the **Save** button.



The next sections to review are: **Additional Information**, **Funding Sources** and **Participant Types**.

Additional Information > Other Identifiers

The only time you will need to update the **Additional Information > Other Identifiers** section is when an external IRB (not the University of Puerto Rico MSC IRB) has already reviewed and approved the protocol.
In that situation:

1) Select **External IRB** as the **Type**.
2) Enter the name of the external IRB in the **Other Identifier** field.
3) Enter the **Application Date** and **Approval Date.**
4) The **Comment** field is optional.
5) Click the **Add** but Add to add this information to the protocol.

Funding Sources

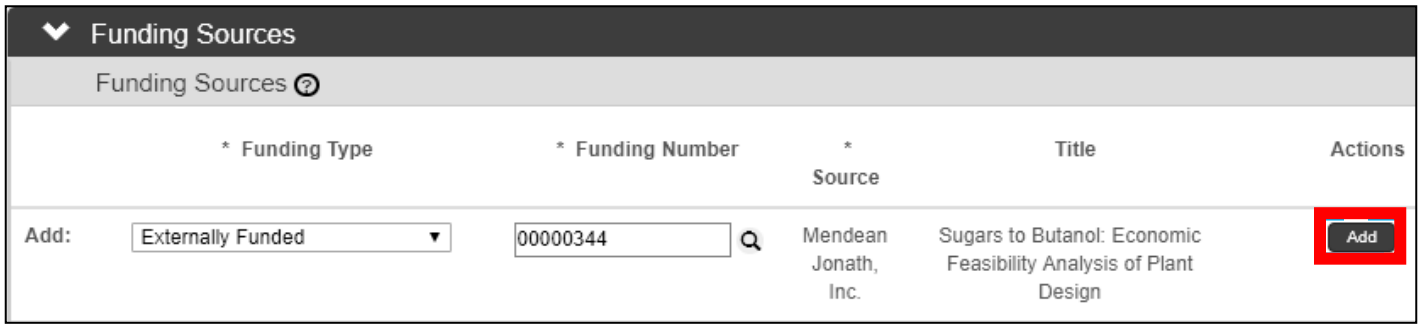
This section will be used to confirm congruency between the IRB Protocol and the Proposal. In addition, this section links your IRB Protocol to your Streamlyne Proposal/ Institutional Proposal (IP) and Award documents to reflect the status of your IRB review. NOTE: To ensure full functionality, list the IRB Special Review on your Proposal Development.

Select the **Funding Type** from the drop-down menu. Choose either **Externally** or **Internally Funded**:

1) Select **Externally Funded**, if your project is NOT being funded by your institution.
   a) Under **Funding Number**, click the magnifying glass to search and select the Institutional Proposal (IP) Number that corresponds with this protocol.
   b) Use the following fields to narrow the **Institutional Proposal (IP) Number** search:
      1) **Status** = Pending or Funded or Awarded
      2) **Principal Investigator Name** = Enter last name and click the Contains radio button
      3) Click the **Search** button Search , then click **Return Value** next to the IP you want to tie to the Protocol.

Return Value	Institutional Proposal Number	Proposal Type	Activity Type	Status	Lead Unit ID	Lead Unit Name	Account ID	Project Title	Sponsor ID	Sponsor Name
return value	00000344	New	Research	Pending	CHEG	Chemical Engineering		Sugars to Butanol: Economic Feasibility Analysis of Plant Design	100022	Mendean Jonath, Inc.

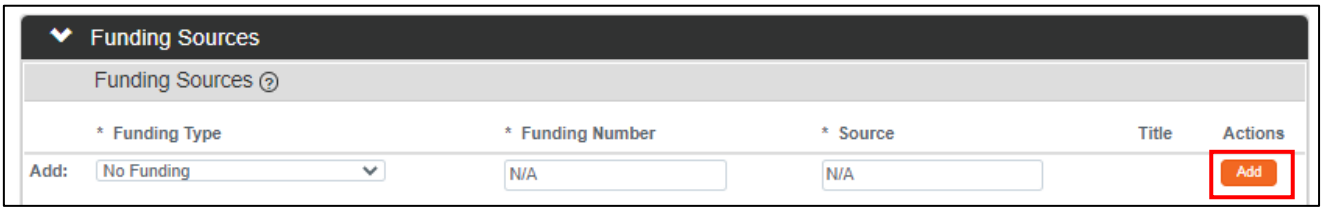
      4) Click the **Add** button Add , once you have returned to the Funding Source section.



Continue to the next page for information on **Internally Funded/Unfunded Research** and **Participant Types**.

2) Select **No Funding**, if:
    1) an internal department or school is funding your project,
    2) it is unfunded research, or
    3) the proposal was not entered into Streamlyne

a) Under **Funding Number**, enter N/A.
b) Under **Source**, enter N/A.
c) Click the **Add** button Add .

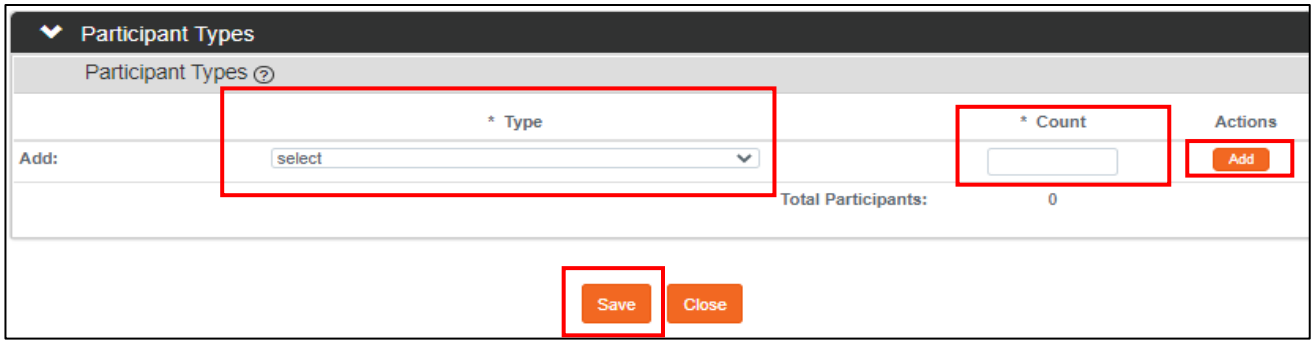


3) Scroll to the bottom of the page and click the **Save** button.

Participant Types

To submit your Protocol, you must enter the Participant Type information.

1) Under **Type**, click the drop-down menu to select the type of participants involved in this protocol.
2) In the **Count** box, enter the number of participants you are recruiting for this protocol.
3) Click the **Add** button Add .
4) If you have multiple participant types, follow the steps above to add each type and a count for each. The final number should total the number of participants estimated to be recruited for the protocol.
5) After adding all Participant Types, scroll to the bottom of the page and click the **Save** button.



IRB: UPDATING THE PERSONNEL TAB

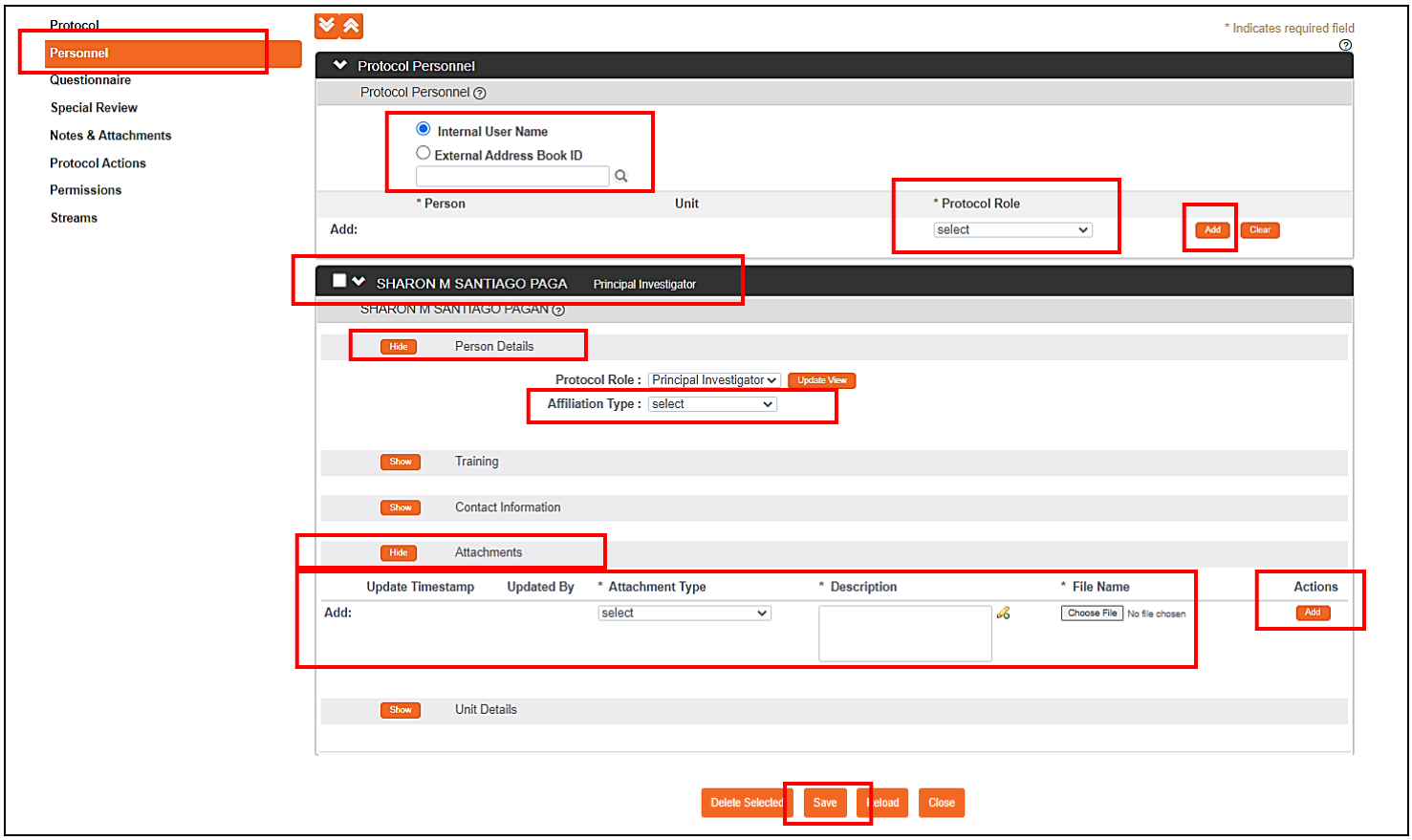
The Personnel Tab enables you to identify personnel working on this project, in addition to the Principal Investigator. Follow the steps below to enter the required information in the Personnel tab.

1) Click the **Personnel Tab**
    a. The Principal Investigator (PI) you selected from the Protocol tab will automatically be listed in this section.
2) Click the magnifying glass next to **Person User Name** to look up additional employees that should be listed on this protocol. Examples: Co-Investigator or Study Personnel.
    a. To locate the person in this search, click the magnifying glass and in the email address field enter their **UPR email address** (include: @upr.edu) and leave all other search fields blank. Click the **Search** button.
    b. Below the Search button, locate the person and click **Return Value**.
    c. Select the appropriate **Protocol Role** from the drop-down box.
    d. Click the **Add** button Add to add this information to the protocol.
    e. Repeat these steps until all personnel are identified.

3) Click the **Section Header** to access **Person Details**
    a. Click the **Show** button Show next to **Person Details.**
    b. Select the appropriate **Affiliation Type** such as Faculty, Supervisor, etc.

NOTE: If Student Investigator is chosen, a faculty MUST be added and given the Supervisor affiliation type.

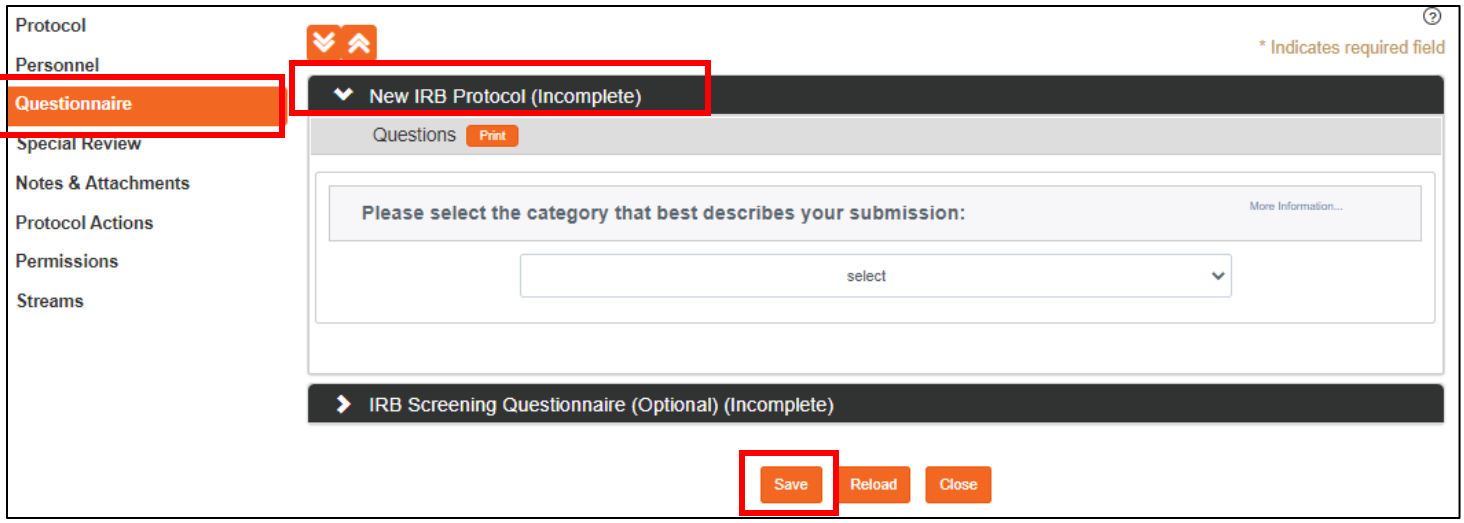
    c. Repeat this step for each person listed on the protocol.
4) Under the **Section Header,** you can also access Contact Information and Unit Details associated with each person listed on the protocol. You also have the option to add Attachments at the Personnel level, such as Resume, Curriculum Vitae, or Medical License, as needed.
5) Click the **Save** button.



IRB: UPDATING THE QUESTIONNAIRE TAB

The Questionnaire Tab enables Research Compliance to collect additional required information about the protocol. Based on the answer to a question, you may be presented with more questions.

1) Click the **Questionnaire Tab.**
2) Click the **New IRB Protocol header** to expand the section.
3) Answer the questions accordingly.
    a. If you are unclear how to respond to a question, please contact the IRB Coordinator at opphi.rcm@upr.edu or visit the IRB webpage.
4) For questions that require an attachment, click on the **Notes & Attachments tab** to upload the corresponding information.
5) Click the **Save button**.

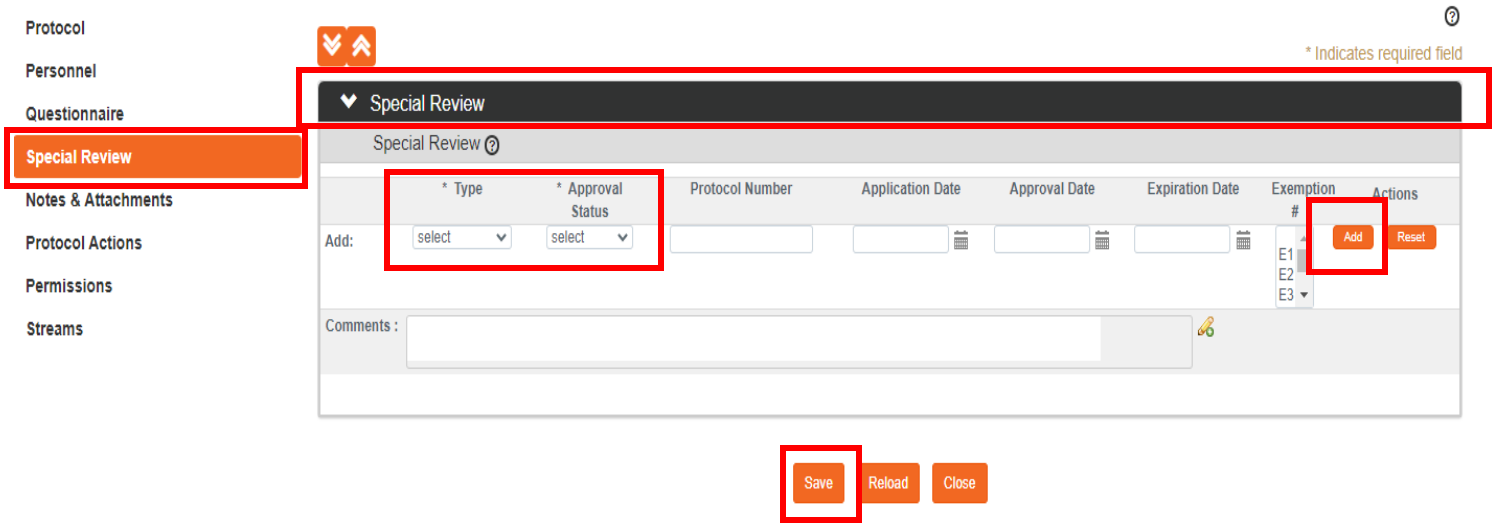


IRB: UPDATING THE SPECIAL REVIEW TAB (FOR PROTOCOLS)

The Special Review Tab (for protocols) is designed to record other special reviews linked to your IRB protocol. For example, your IRB protocol may also be linked to biosafety, animal research (IACUC), foreign travel, etc.

If you do not have additional special reviews linked to this protocol, leave this section blank.

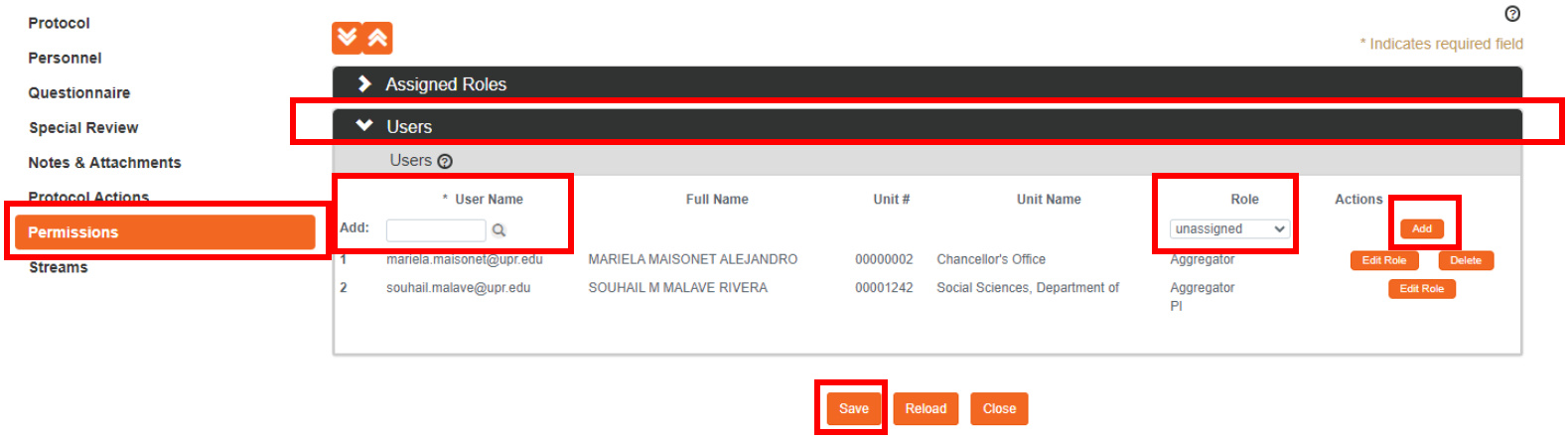
1) Click the **Special Review Tab.**
2) Click the **Special Review section header** to expand the section.
3) Under **Type,** click the drop-down menu to select the additional special review that corresponds with your protocol.
4) Under **Approval Status**, click the drop-down menu to select the appropriate status of your additional special review.
    a. Please DO NOT add 'Human Subjects IRB' as an additional special review to your IRB protocol.
5) Based on the approval status you selected, enter the additional Protocol Number, Application Date, Approval Date and Expiration Date if applicable. Comments are optional.
    a. If you select Animal Usage (IACUC), the only approval status option is 'Not yet applied'.
6) Click the **Add** button Add to add this information to the protocol.
7) Repeat the process for each additional special review linked to this protocol.
8) Click the **Save** button.



IRB: UPDATING THE PERMISSIONS TAB

Updating the Permission Tab is optional. The Permissions Tab is the place where the initiator (person that created the protocol) can grant access to additional users.

1) Click the **Permissions Tab.**
2) Scroll down to the **Users** section header, past the Assigned Roles section.
3) Click the magnifying glass under **User Name** to search for the person you want to add.
    a. To locate the person in this search, enter their **UPR email address** (include: @upr.edu,) and leave all other search fields blank. Then click the **Search** button.
    b. Below the Search button, locate the person and click **Return Value**.
4) Click the drop-down menu to select the **Role** you want to give the person.
    a. The **Viewer** or **IRB Protocol Viewer** role allows the user to view the protocol.
    b. The **Aggregator** role allows the user to view and edit the protocol.
5) Click the **Add** button Add to add this information to the protocol.
6) Repeat the process for each additional person you want to give permission to for this specific protocol.
7) Click the **Save** button.

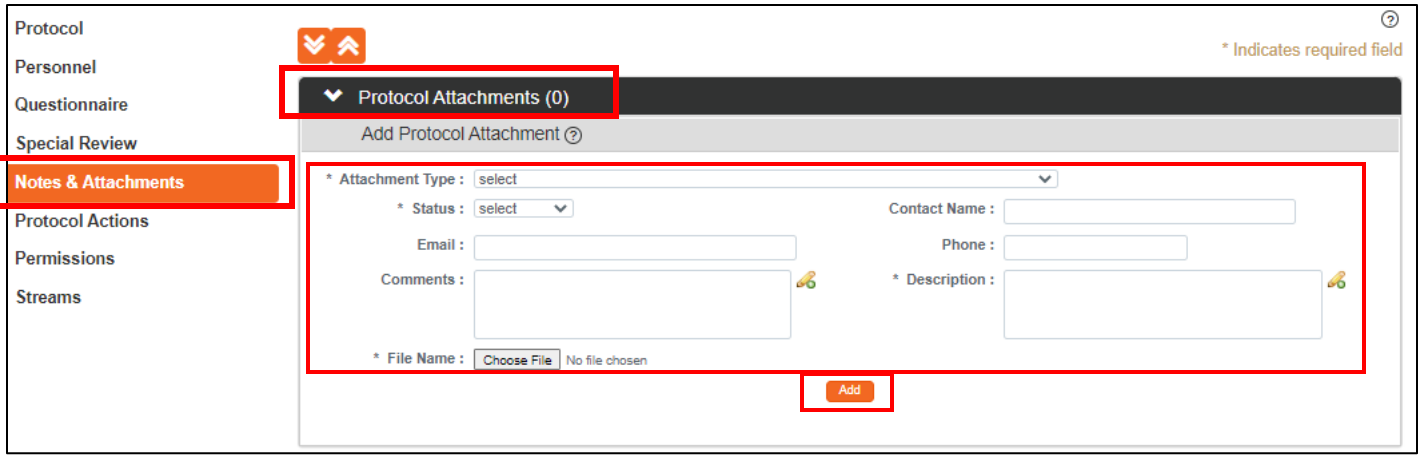


IRB: UPDATING THE NOTES & ATTACHMENTS TAB

The Notes & Attachments Tab is where you will attach all required documentation for the protocol.

Attachments

1) Click the **Notes & Attachments Tab.**
2) Click the **Protocol Attachments section header** to expand the section.
3) Click the drop-down menu next to **Attachment Type** to select the type.
4) Click the drop-down menu next to **Status** to identity if the attachment is complete or incomplete.
5) Enter a **Description** of the attachment.
6) Click the **Choose File** button to attach the file.
    a. You can drag and drop the file if you drop it directly on the **Choose File** button.
7) Click the **Add** button Add to add your attachments to the protocol.
8) Repeat this process for each additional attachment.
9) Click the **Save** button to ensure all attachments have been saved.



Notes (Optional)

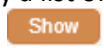
1) To add a Note, click the **Notes** section header to expand the section.
2) Add a **Note Topic,** a subject related to the note.
3) Enter the **Note Text**.
4) Click the **Add** button Add to add your notes to the protocol.
5) Repeat this process for additional notes.
6) Click the **Save** button to ensure all notes have been saved.

IRB: PROTOCOL ACTIONS TAB

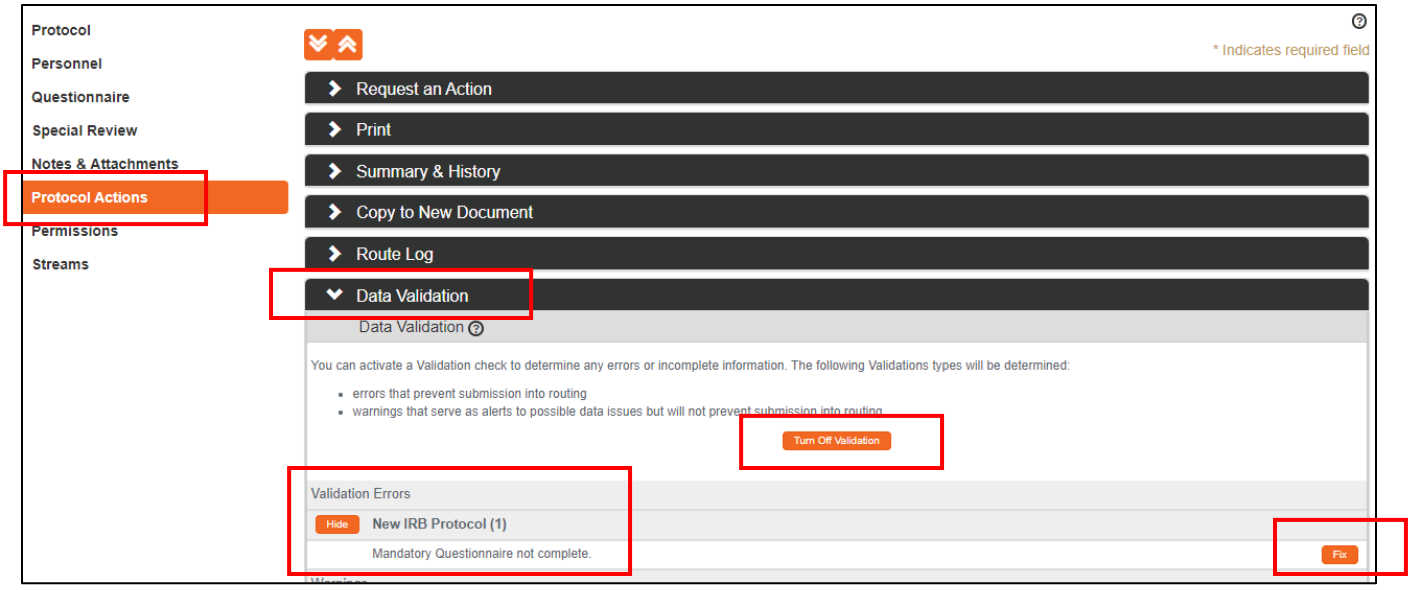
The Protocol Actions Tab is where you will go to finalize and submit the **new** protocol.

Data Validation

1) Click the **Protocol Actions Tab.**
2) Click the **Data Validation section header** to expand the section.
3) Click the **Turn On Validation** button. 

    a. The system will run a series of validation steps to ensure all required fields have been populated. This is the same validation the system automatically runs when the protocol is submitted.
    b. If errors are found, the system will display a list of the errors.
4) If there are multiple errors click the **Show** button 

to address each error one at a time.
5) Click the **Fix** button to resolve the issue.
    a. Clicking the **Fix** button will automatically take you to the tab and section that has an error.
    b. Correct the error, then click the **Save** button at the bottom of the page. Clicking the Save button automatically takes you back to the Data Validation section.
6) Repeat this process for each validation error.



Continue to the next page for information on the **Request an Action** section.

Request an Action

At this point in the process, the available Actions are limited to submitting or deleting the protocol.

1) Click the **Protocol Actions Tab.**

2) Click the **Request and Action section header** to expand the section.

3) **To submit the protocol**:

   a. Click the **Show** button Show next to the **Submit for Review** subsection.

   b. Click the drop-down menu next to **Submission Type** and select **Initial Protocol Application for Approval**.

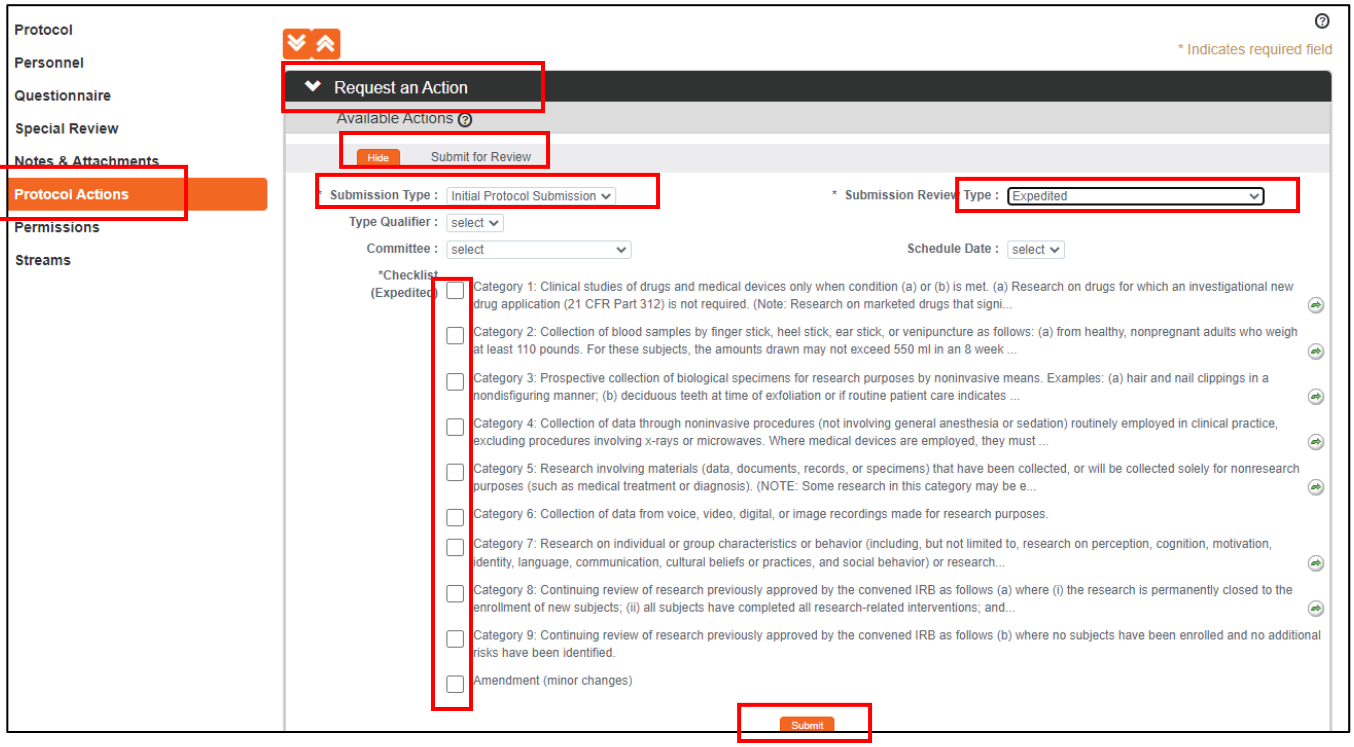
   c. The **Type Qualifier** field is optional. Select an option from the drop-down menu ifapplicable.

   d. Click the drop-down menu next to **Submission Review Type** and select the appropriate level of required IRB review for your protocol.

   NOTE*:* For details regarding different levels of required IRB review UPR faculty and staff can go to the IRB webpage or contact the IRB Coordinator at opphi.rcm@upr.edu for assistance.

   e. If you select a **Submission Review Type** of **Expedited** or **Exempt**, the system will present a checklist to qualify the submission type. Make your selection by clicking the appropriate checkbox(es) that correspond to your protocol.

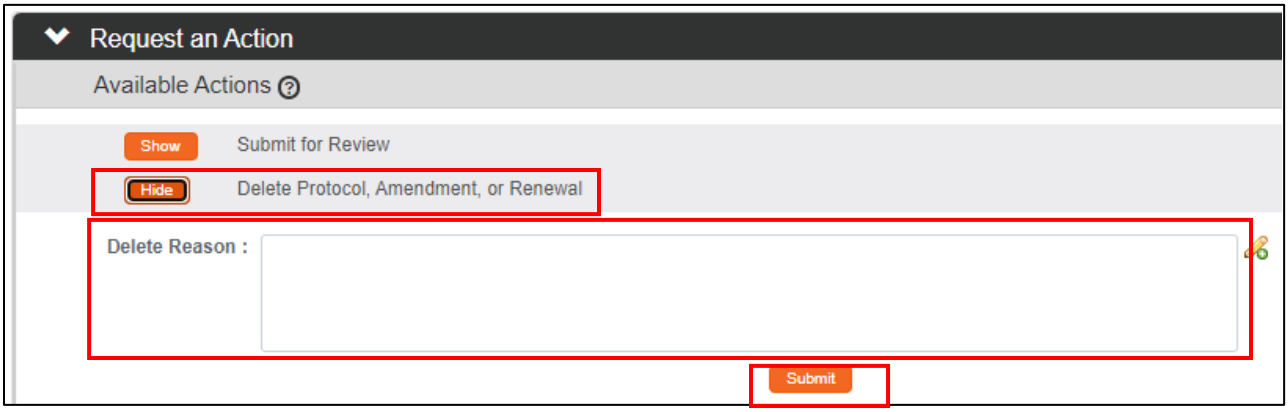
   f. Click the **Submit** button Submit to submit your IRB Protocol.



Continue to the next page for information on how to delete a protocol if you no longer want to submit it.

If you not longer want or need to submit this protocol, you can delete it.

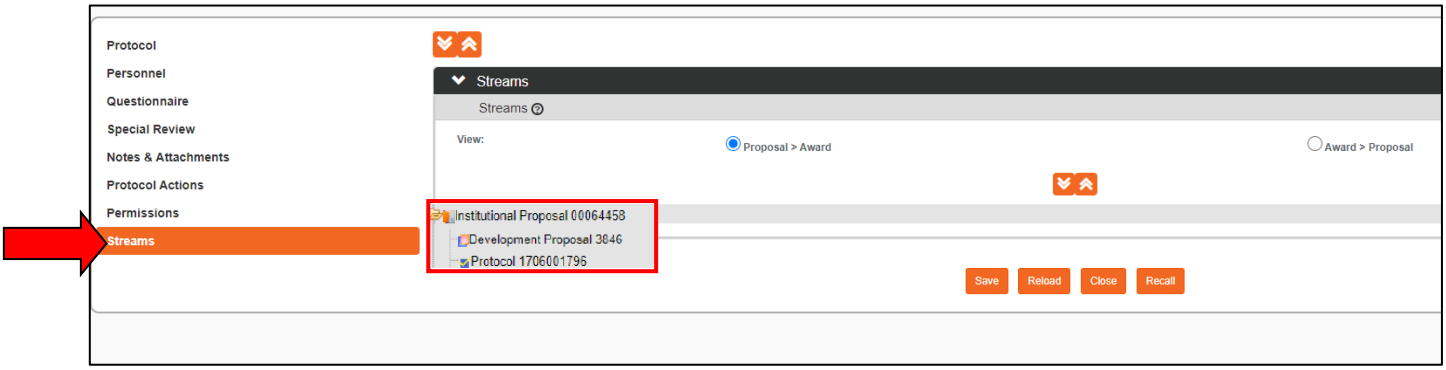
4) **To delete the protocol**:
   a. Click the **Show** button Show next to the **Delete Protocol, Amendment or Renewal** subsection.
   b. Enter a reason for deleting this protocol, amendment or renewal.
   c. Click the **Submit** button Submit to submit the deletion of the protocol.

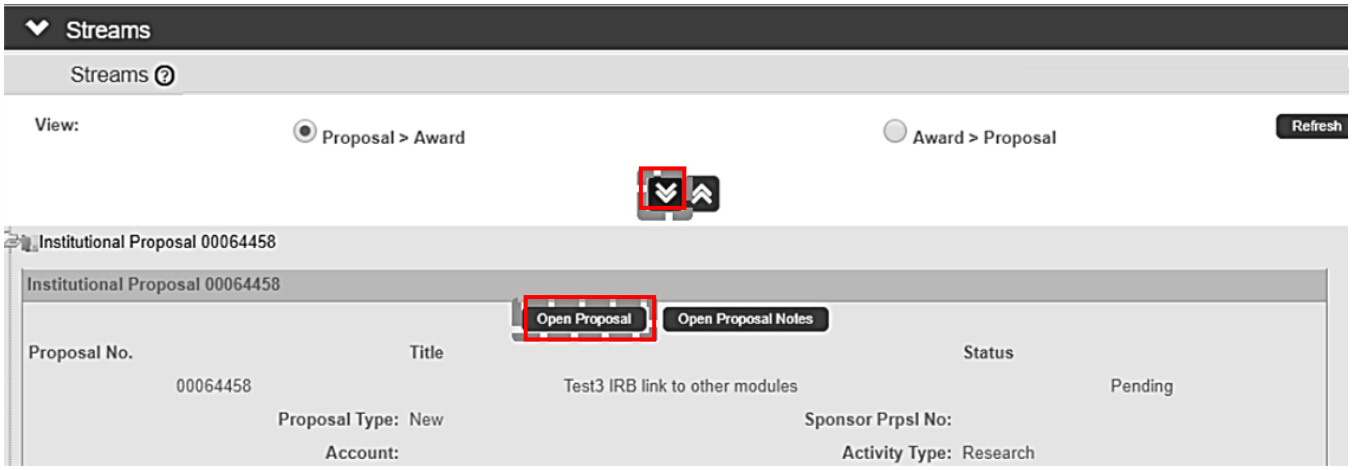


IRB: REVIEWING THE STREAMS TAB

The Streams Tab gathers and displays details of all other documents that are linked to this protocol.

1) Click the **Streams Tab**.
2) Click the **double up/down arrows** to expand or collapse the Streams view.
3) To view details of a linked document, click the **double down arrow** to expand the view.
4) Click the appropriate **Open** button in the document section to view details.





IRB: HOW TO APPROVE PROTOCOLS

When a protocol is submitted by the PI, anyone listed on the protocol as a COI or Supervisor will have to approve the protocol before it routes to the IRB Coordinator. Each person who must approve the protocol will receive an automated email notification after it is submitted.

NOTE: If someone other than the PI submits the protocol, **then the PI will also have to approve the protocol.**

How to Approve an IRB Protocol from the Email Notification

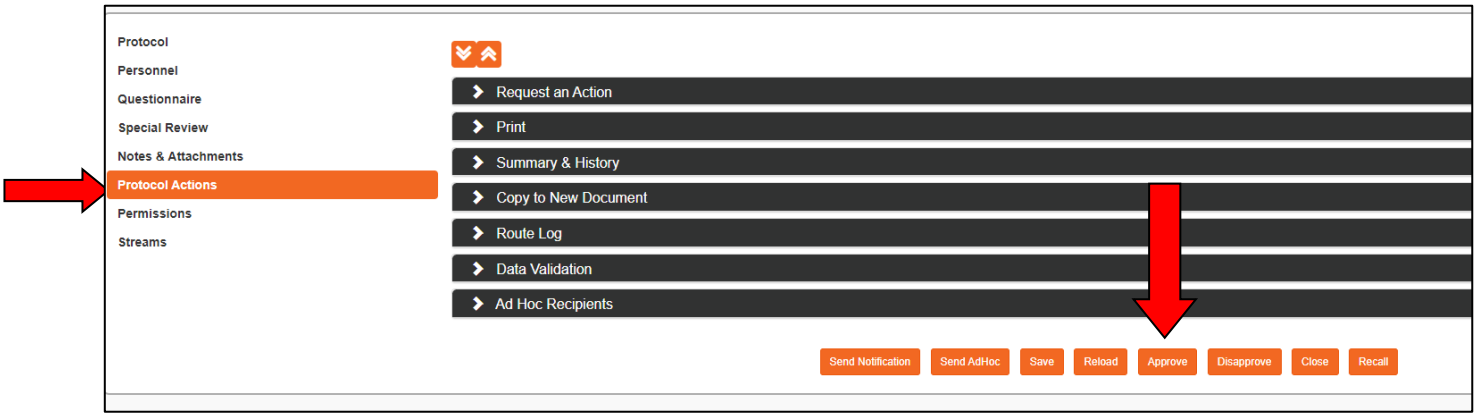
1) Click the first link in the email notification; this will take you to the Streamlyne central login page.
2) Sign in with your **institution email address and password** (@upr.edu).
3) The protocol should automatically open on the **Protocol** tab view.
4) Click the **Protocol Actions** tab (if you are not on that tab).
5) Click the **Approve** button on the bottom of that screen.

How to Approve an IRB Protocol without the Email Notification

1. Login to Streamlyne.
2. Sign in with your **institution email address and password** (@upr.edu).
3. On the Streamlyne Action List screen, **click the number in the ID column** to open the protocol.
4. Click the **Protocol Actions** tab (if you are not on that tab).
5. Click the **Approve** button on the bottom of that screen.

NOTE: To review the protocol before approving, follow the steps below.

a. Click the **Questionnaire** tab on the left. You can click the **Print** button to view the questions and responses in a PDF format.
b. Click the **Protocol Actions** tab > click the **Summary & History** section/ribbon > click the **Show** button next to the word **Summary**. From here you can review everything except the questionnaire.

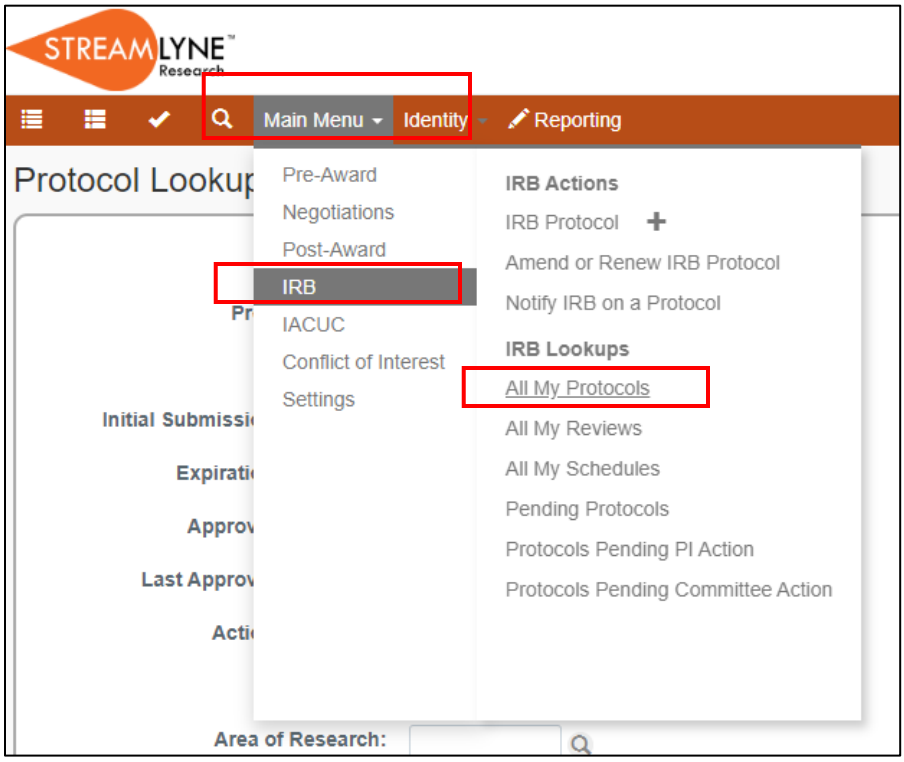


IRB: HOW TO SEARCH FOR AN IRB PROTOCOL

If you need to find your IRB protocol to see where it's at after you've submitted it, you can search for the protocol in Streamlyne.

How to Search for an IRB Protocol and View the Route Log

1) Login to Streamlyne.
2) Search under: **Main Menu** > **IRB** > and click **All My Protocols**
    a. You can also search using the IRB Protocol lookup feature by clicking the word **IRB Protocol**.
    b. In the Protocol Lookup search screen enter your last name in the **Investigator** field using asterisks. Example: *Rivera*
    c. Click the red **Search** button.
3) Scroll down past the Search button to locate the protocol you need, click the **view** link on the far left to open the protocol.

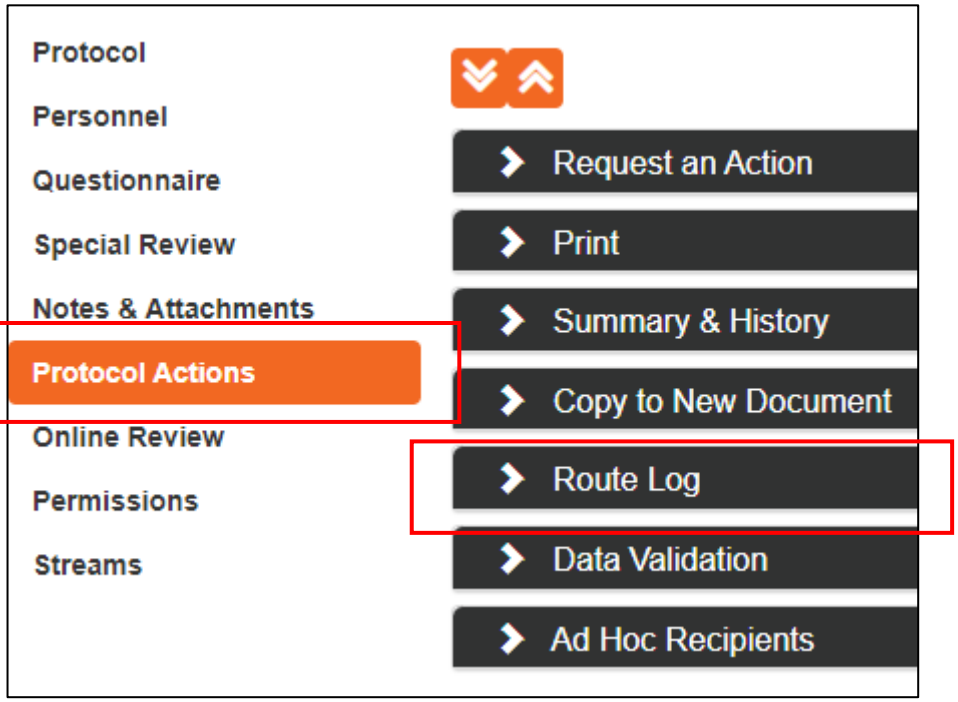


IRB: HOW TO SEARCH FOR PENDING ACTIONS

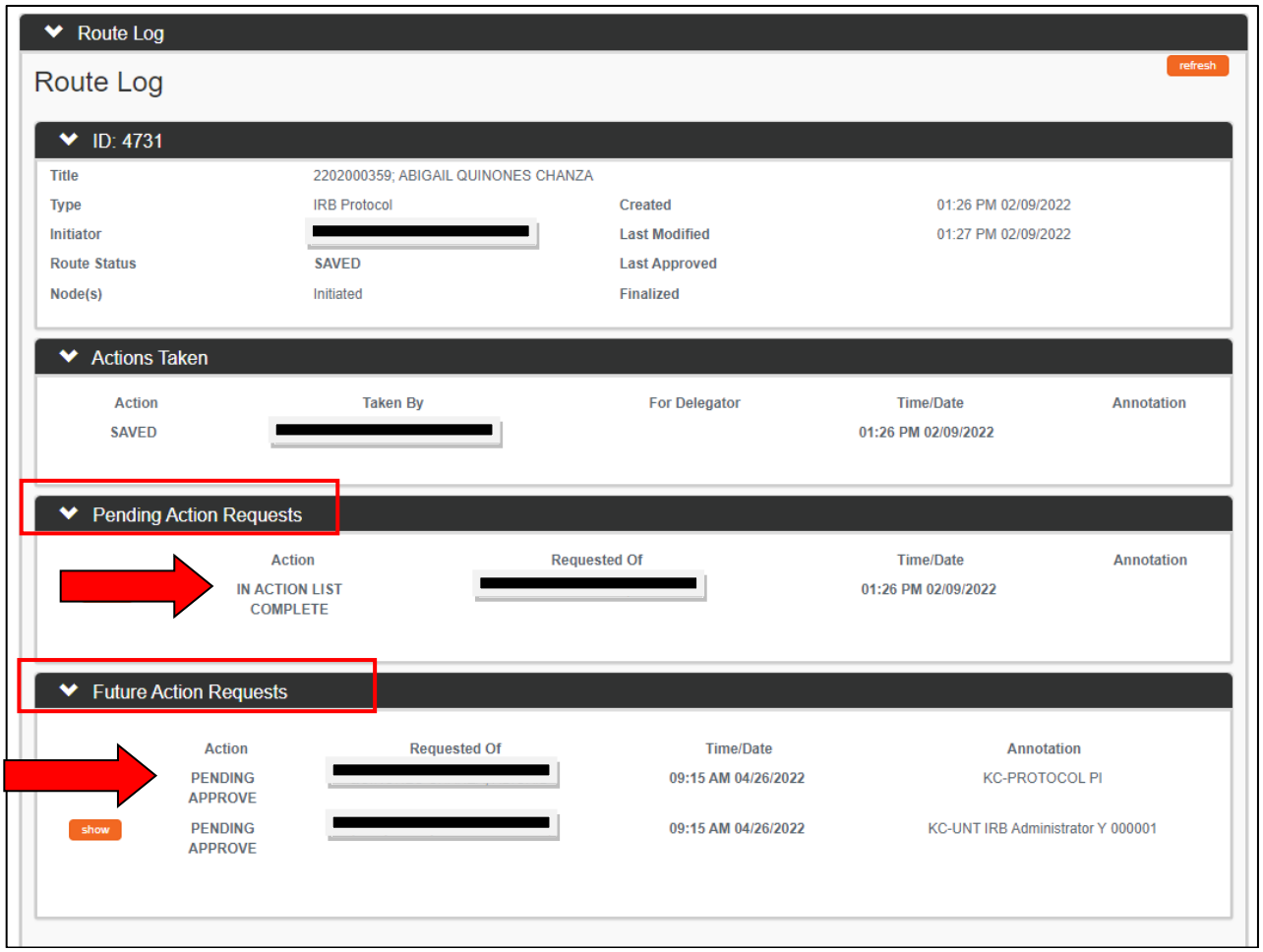
If you need to find your IRB protocol to see where it's at after you've submitted it, you can search for the protocol in Streamlyne.

How to Search for an IRB Protocol and View the Route Log

1) Login to Streamlyne.
2) Search under: **Main Menu** > **IRB** > and click **All My Protocols**
    a. You can also search using the IRB Protocol lookup feature by clicking the word **IRB Protocol**.
    b. In the Protocol Lookup search screen enter your last name in the **Investigator** field using asterisks. Example: *Rivera*
    c. Click the red **Search** button.
3) Scroll down past the Search button to locate the protocol you need, click the **view** link on the far left to open the protocol.
4) Click the **Protocol Actions** tab on the left side of the screen.
5) Click the **Route Log** ribbon.
6) Scroll down to the **Pending Action Requests** section. This shows where the protocol is and who needs to take action.
    a. If the pending action reads, "In Action List Approve" that means the protocol is on that person(s) Streamlyne Action List and waiting for them to review & approve it.
7) To see what will happen after the pending actions have been completed, click the **Future Action Requests** ribbon.



ROUTE LOG SCREENSHOT ON PAGE 2



IRB: HOW TO RESPOND TO A REVISION REQUEST

If the IRB Coordinator requests revisions to your protocol, the revision request could be sent with any of the following status': "Return to PI", "Specific Minor Revisions Required", or "Substantive Revisions Required". Follow the steps below to identify what revisions are necessary, make those changes and resubmit the protocol.

REMEMBER: Email notifications are sent to your institution email address (@upr.edu). If you do not check it regularly, we recommend creating an email rule to have your institution emails auto- forwarded to the email address you use.

How to Locate and Respond to a Revision Request

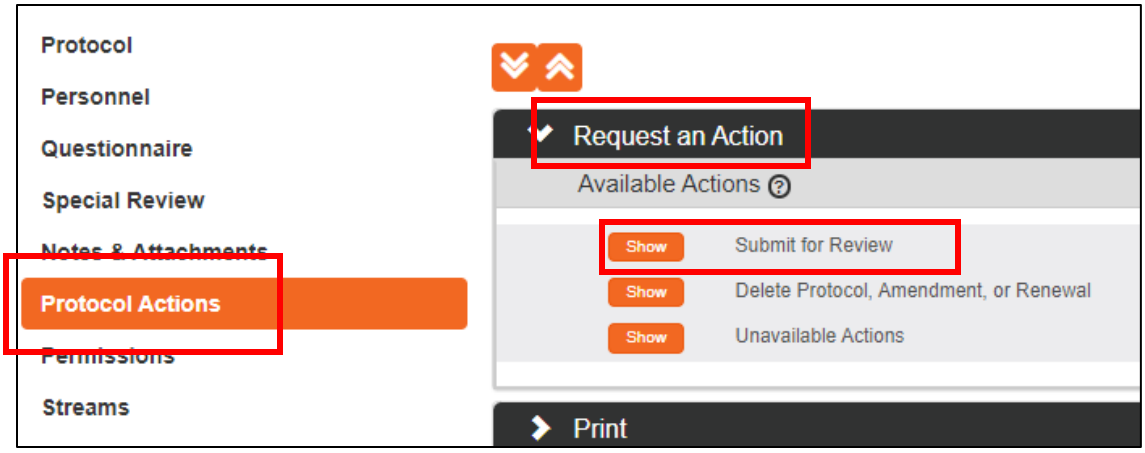
Locate the list of requested revisions using either step 1 or step 2.

1) If you receive an email notification requesting revisions, you can click the **View Correspondence** link in the email to view the letter listing the requested revisions. If needed, you can save the correspondence as a pdf document.
2) If you receive a "Return to PI" email notification requesting revisions, follow these steps to view the list of requested revisions. Click the **Protocol Number** link in the email to open the protocol or login to Streamlyne and open the protocol from your Action List. Once the protocol is open, click the **Protocol Actions** tab > **Summary & History** > **Review and Attachments** to access the **Review Comments**.

Respond to the revision request(s) by following steps 3 through 7.

3) Once you've identified the revisions that are needed, **login to Streamlyne** (if you are not logged in).
4) If you need to open the protocol it will be on your Action List. Click the number in the **ID column** to open the protocol. It will have a COM icon next to it.
5) Make the requested revisions to the attachments and/or to the protocol information. If attachments need to be revised, make sure to upload the revised copy.
6) Once all the revisions are complete, resubmit the protocol. Go to the **Protocol Actions** tab > **Request an Action** > and click the **Show** button Show next to **Submit for Review**.
7) Choose the **Submission Type** from the drop-down menu (there is only one option) and select the **Submission Review Type**. Select the same protocol/review type you originally selected. If the review type you selected has a Checklist, check the appropriate box(es). Then click the **Submit** button. Submit

NOTE: When you resubmit the protocol, it will re-route to anyone listed as a PI, COI or Supervisor and each person will have to approve again before the protocol routes to the IRB Coordinator.



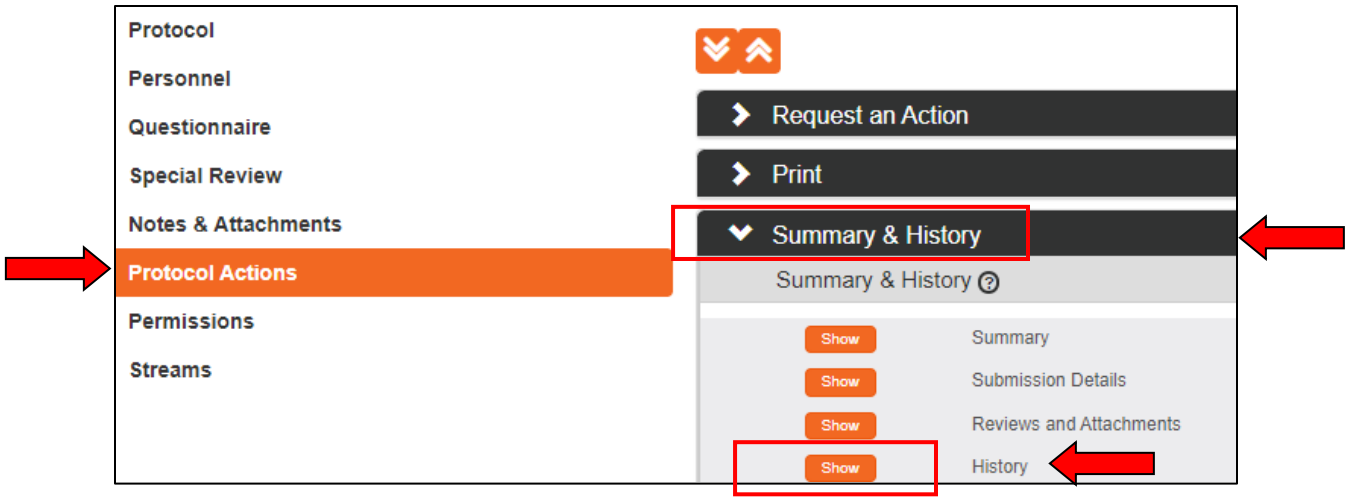
IRB: HOW TO LOCATE YOUR IRB APPROVAL LETTER

Once your IRB protocol has been approved, you can view or save the approval letter by opening the protocol in Streamlyne.

How to Search for an IRB Protocol and Locate the Approval Letter

1) Login to Streamlyne.
2) Search under: **Main Menu** > **IRB** > and click **All My Protocols**
    a. You can also search using the IRB Protocol lookup feature by clicking the word **IRB Protocol**.
    b. In the Protocol Lookup search screen enter your last name in the **Investigator** field using asterisks. Example: *Rivera*
    c. Click the red **Search** button.
3) Scroll down past the Search button to locate the protocol you need, click the **view or edit** link on the far left to open the protocol.
4) Click the **Protocol Actions** tab on the left side of the screen.
5) Click the **Summary & History** ribbon > click the **Show** button next to **History**
6) Scroll down and find the last approval, then click the **Show** button next to the word **Correspondences** on the grey bar.
7) Below Correspondences, click the **View** button on the right to view the approval letter. You can also save it as a pdf if needed.

NOTE: When the protocol was initially approved, the email notification you received had a link named "view correspondence", when you click that link it also opens the approval letter. Streamlyne refers to approval letters as correspondences.



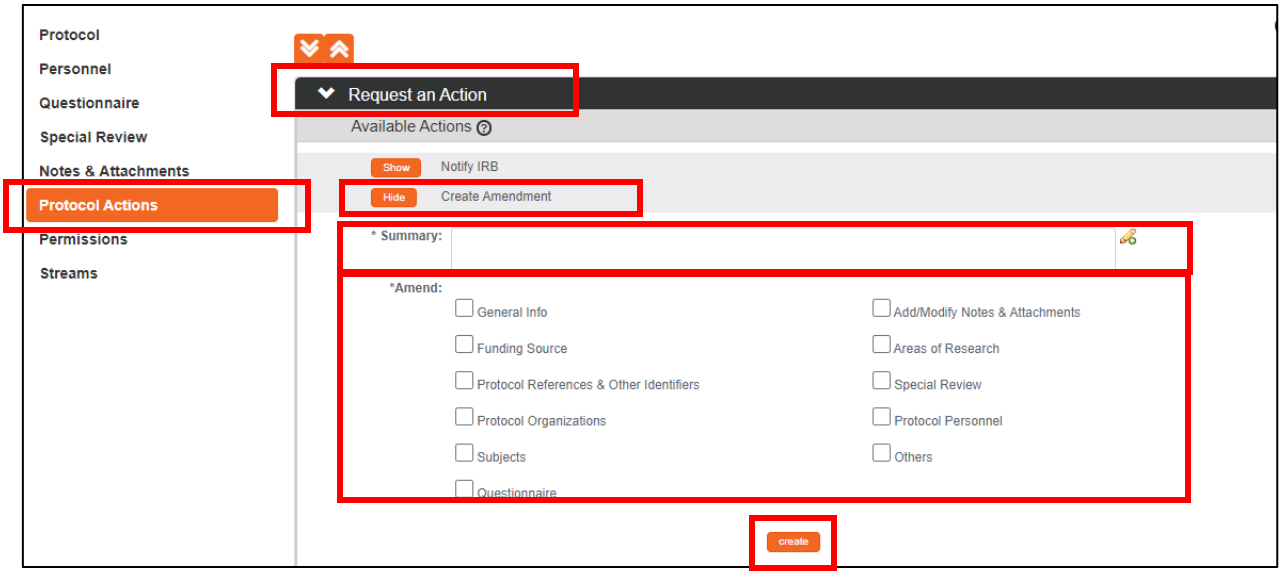
IRB: HOW TO CREATE AN AMENDMENT (MODIFICATION) TO AN IRB PROTOCOL

If you need to create a modification to an existing approved Expedited or Full Board IRB protocol, this is done via the amendment feature in Streamlyne. Follow the steps below to create and submit an amendment to your protocol. Remember, the amendment must be approved before you begin work using the requested changes.

NOTE: If making significant changes to a protocol approved as Exempt, a brand new protocol must be submitted.

How to Create and Submit an Amendment to an existing Expedited or Full Board IRB protocol

1) Login to Streamlyne.
1) Locate the protocol you need to amend. You can search under: **Main Menu** > **IRB** > and click **All My Protocols** or search using the IRB Protocol lookup feature.
2) Once you've located the protocol, click the **edit** link to open it in edit mode.
3) Navigate to the **Protocol Actions** tab > **Request an Action** section. There will be a list of Available Actions.
4) Click the **Show** button next to **Create Amendment**. If your protocol is up for renewal and you need to amend it, click the Show button next to Create Renewal with Amendment.
   NOTE: You should only renew and amend if your protocol is up for annual review.
5) Enter a summary of the amendments you are making to the protocol in the **Summary** box.
6) In the **Amend** section, check the box next to each section of the protocol that you need to amend. You can check multiple boxes if needed.
7) Next click the **create** button to create your amendment. Now the protocol and the sections you selected under Amend are open for editing.



8) Once you have entered all your amendments you need to submit this amended protocol. Go to the **Protocol Actions** tab > **Request an Action** > and click the **Show** button Show next to **Submit for Review**.

9) Choose the **Submission Type** from the drop-down menu (there is only one option) and select the **Submission Review Type**. Select the same protocol/review type you originally selected. If the review type you selected has a Checklist, check the appropriate box(es). Then click the **Submit** button. Submit

NOTE: When you submit the amendment, it will re-route to anyone listed as a PI or Supervisor and each person will have to approve before the protocol routes to the IRB Coordinator.

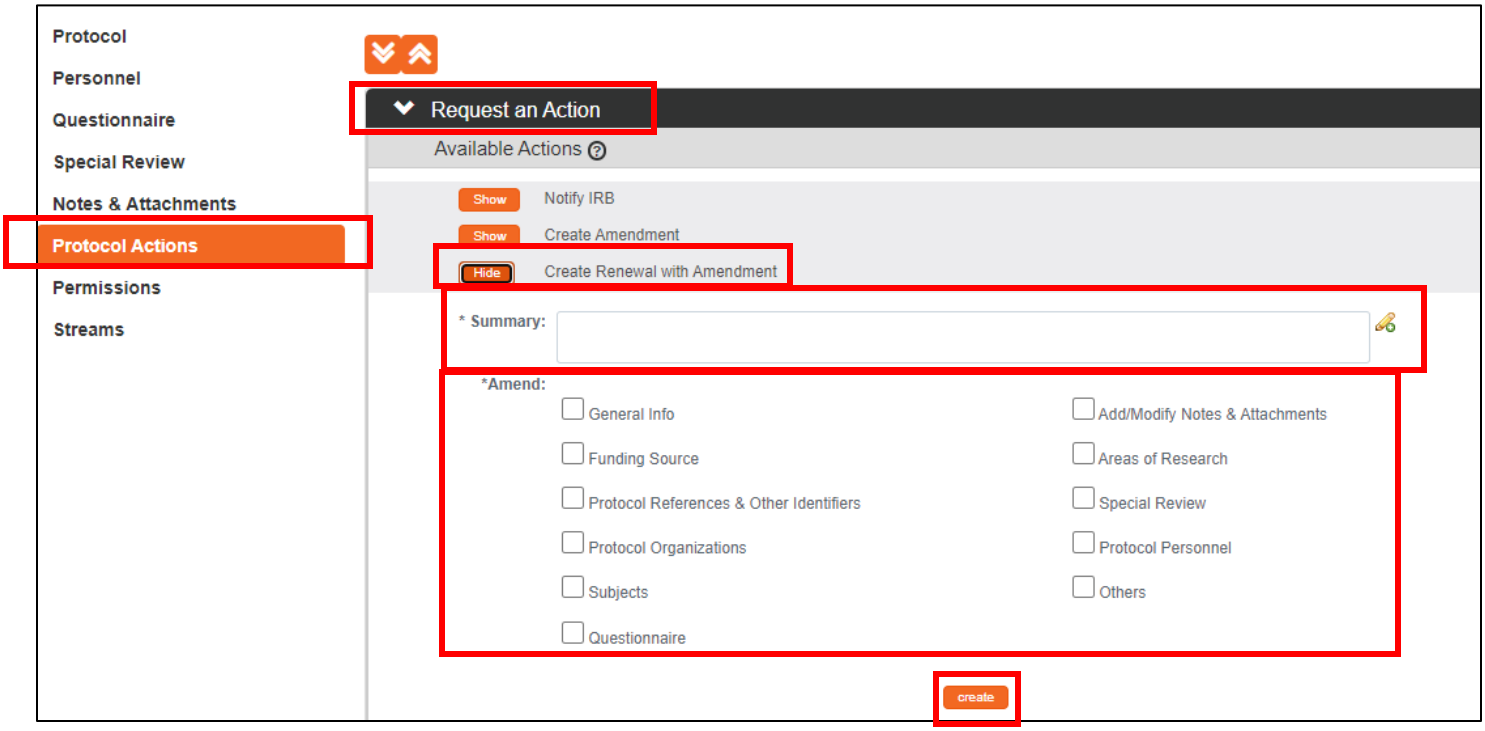
IRB: HOW TO CREATE AN IRB RENEWAL WITH AMENDMENT OR WITHOUT AMENDMENT

If you need to renew an existing approved Expedited or Full Board IRB protocol, this is done via the Create Renewal with/without Amendment feature in Streamlyne. Follow the steps below to create and submit a renewal. If your protocol expires and you have not renewed it, you need to stop work until it is renewed.

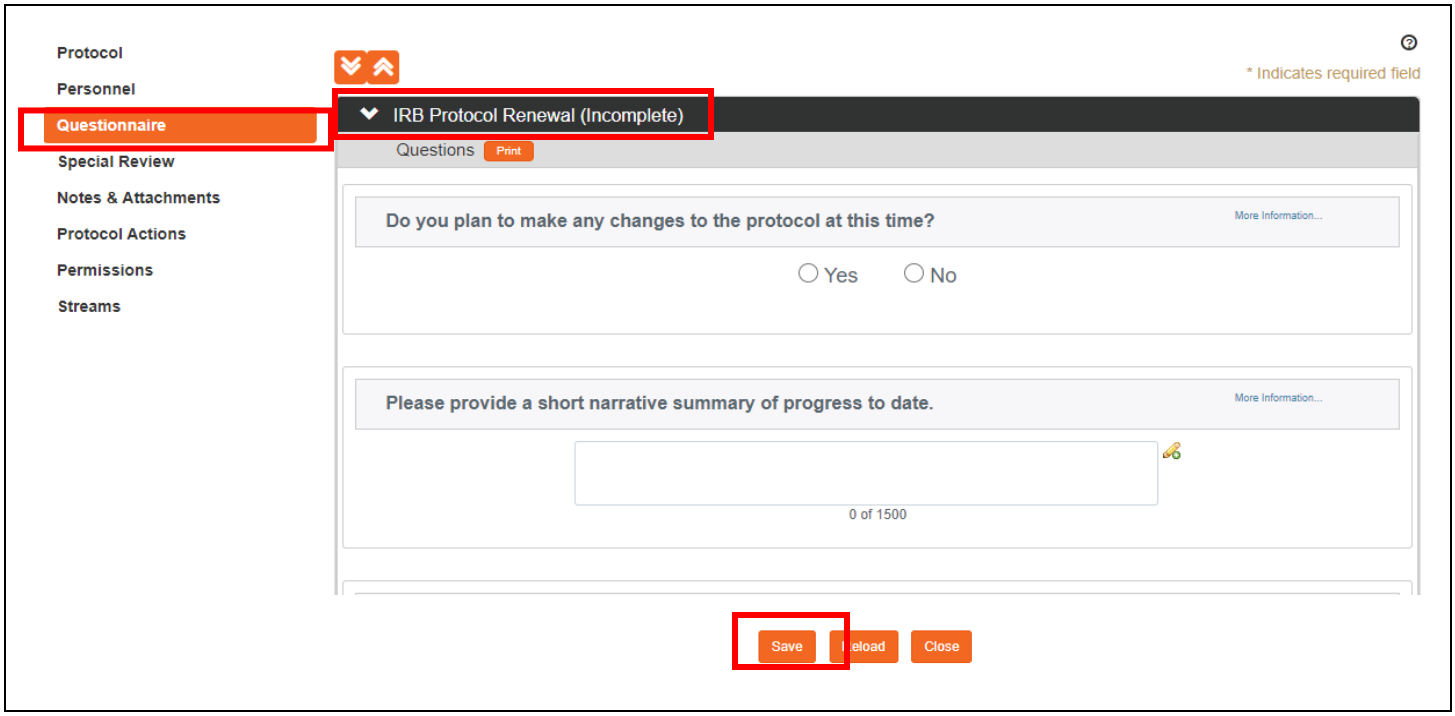
NOTE: IRB protocols approved as Exempt have no expiration date. If you significantly change the scope of the project, then a brand-new protocol must be submitted.

How to Renew AND Amend (modify) an Existing Expedited or Full Board IRB Protocol

1) Login to Streamlyne.
2) Locate the protocol you need to renew. You can search under: **Main Menu** > **IRB** > and click **All My Protocols** or search using the IRB Protocol lookup feature.
3) Once you've located the protocol, click the **edit** link to open it in edit mode.
   Navigate to the **Protocol Actions** tab > **Request an Action** section. There will be a list of Available Actions.
4) Click the **Show** button next to **Create Renewal with Amendment**. If you only need to renew with no changes, go to page 3 for instructions.
5) Enter a summary of the amendments you are making to the protocol in the **Summary** box.
6) In the **Amend** section, check the box next to each section of the protocol that you need to amend. You can check multiple boxes if needed.
7) Next click the **create** button to create your renewal with amendment. Now the protocol and the sections you selected under Amend are open for editing. You may go to each section and Amend as needed.



Navigate to the **Questionnaire** Tab > **IRB Protocol Renewal Interview (incomplete)** section. You will need to fill out (and **save** at the bottom of the page) the questions prior to submission of the renewal.



8) Once you have entered all your amendments you need to submit this amended protocol. Go to the **Protocol Actions** tab > **Request an Action** > and click the **Show** button Show next to **Submit for Review**.

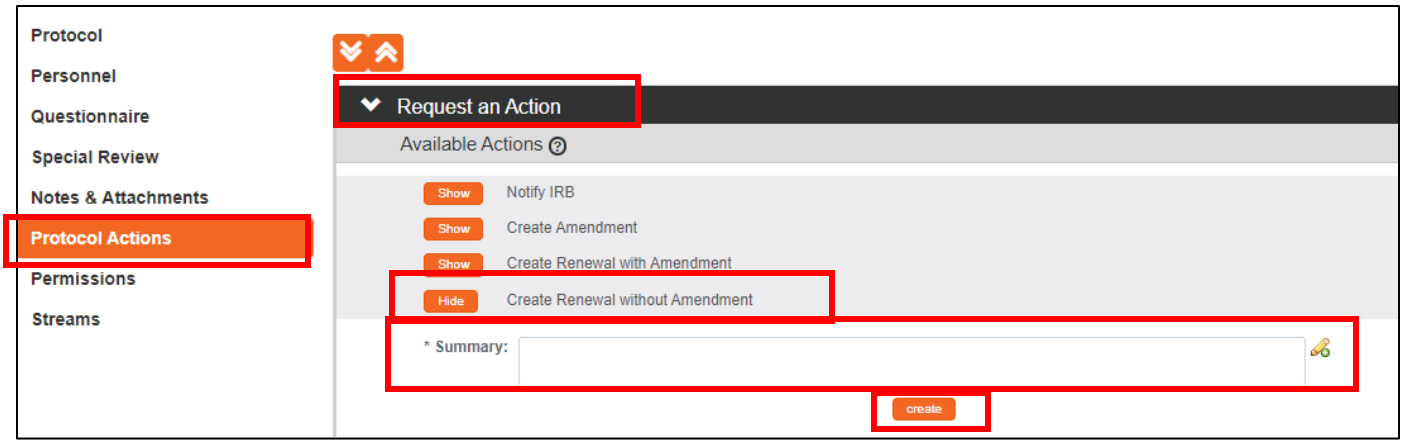
9) Choose the **Submission Type**- **Continuing Review/Continuation with Amendment** from the drop-down menu. Select the **Submission Review Type**. Select the same protocol/review type you originally selected. If the review type you selected has a Checklist, check the appropriate box(es). Then click the **Submit** button.

NOTE: Only **minor amendments** will be allowed to be submitted along with a renewal submission. Minor amendments include updated in: General Information, Funding Source, Protocol Organizations, Areas of Research, Special Review, and Protocol Personnel.

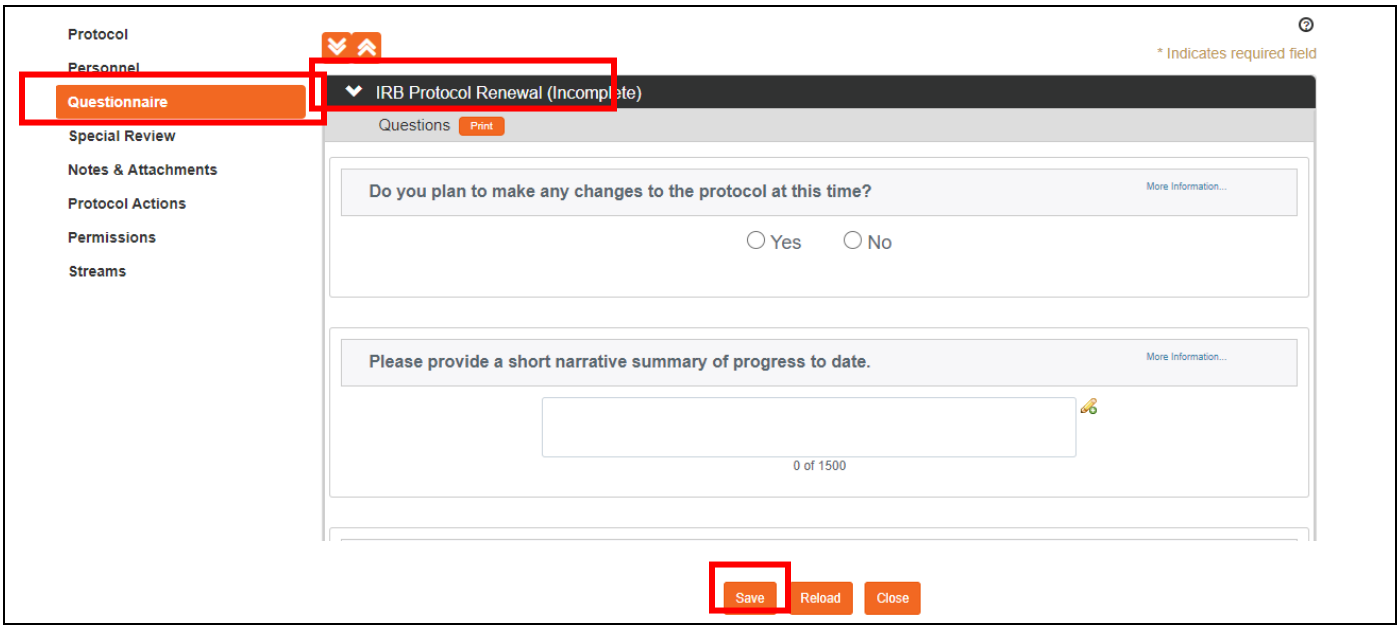
NOTE: When you submit any renewal, it will re-route to anyone listed as a PI, COI or Supervisor and each person will have to approve before the protocol routes to the IRB Coordinator.

How to Renew an Existing Expedited or Full Board IRB Protocol with No Amendments

1. Login to Streamlyne.
2. Locate the protocol you need to renew. You can search under: **Main Menu** > **IRB** > and click **All My Protocols** or search using the IRB Protocol lookup feature.
3. Once you've located the protocol, click the **edit** link to open it in edit mode.
4. Navigate to the **Protocol Actions** tab > **Request an Action** section. There will be a list of Available Actions.
5. Click the **Show** button next to **Create Renewal without Amendment**. If you need to make changes to the protocol as well as renewing it, go back to page 1 for instructions.
6. Enter a summary for the renewal you are submitting in the **Summary** box.
7. Next click the **create** button to create your renewal without an amendment



Navigate to the **Questionnaire** Tab > **IRB Protocol Renewal Interview (incomplete)** section. You will need to fill out (and **save** at the bottom of the page) the questions prior to submission ofthe renewal.



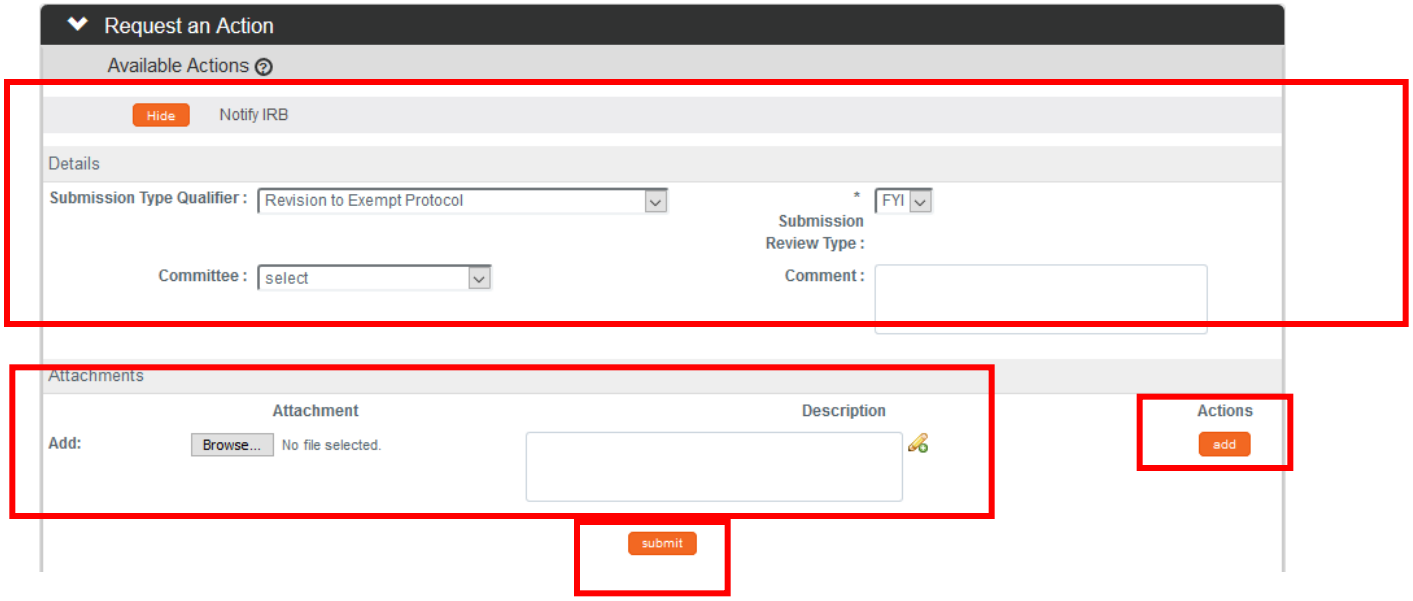
8. Go to the **Protocol Actions** tab > **Request an Action** > and click the **Show** button Show next to **Submit for Review**.
9. Choose the **Submission Type-Continuing Review/Continuation without Amendment** from the drop-down menu. Select the **Submission Review Type**. Select the same protocol/review type you originally selected. If the review type you selected has a Checklist, check the appropriate box(es). Then click the **Submit** button.

IRB: HOW TO NOTIFY IRB ON A PROTOCOL

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

How to Notify IRB on a Protocol

1) Login to Streamlyne.
2) Locate the protocol you need to renew. You can search under: **Main Menu** > **IRB** > and click **All My Protocols** or search using the IRB Protocol lookup feature.
3) Once you've located the protocol, click the **edit** link to open it in edit mode.
   Navigate to the **Protocol Actions** tab > **Request an Action** section. There will be a list of Available Actions.
4) Under Available Actions, the **Notify IRB** section will display.



5) In the **Submission Type Qualifier** field, use the dropdown to select the appropriate option:

- External Site Progress Report
- Revision to Exempt Protocol
- Request for Eligibility Exception
- Report of Insignificant Problems
- Report of Adverse Event
- Supplemental Documents
- Report of Unanticipated Delay
- Report of Unanticipated Adverse Device Effects (UADE)
- Report of Complaint
- Report of Significant Protocol Deviation
- Protocol-Related COI Report
- Report of Noncompliance
- Other

NOTE: If Other is selected, you must include a description in the comment text box.

NOTE: Submission Review Type will default to Request/Notification and cannot be changed.

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.

For Adverse Events, please attach the UPR MSC IRB ADVERSE EVENT / UNANTICIPATED PROBLEM REPORT form complete. The form is available in our web page under section Resources > Forms > Adverse Event / Unanticipated Problem Report: https://irbrcm.rcm.upr.edu/wp-content/uploads/sites/21/2020/12/ADVERSE-EVENT-UNANTICIPATED-PROBLEM_-REPORTInvestigator-24oct17.pdf

9)Click the add button. 

10) Repeat Steps 8 through 9 until all necessary attachments are added.

11) Click the Submit button to finalize the Notify IRB 

action.

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

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