

# Streamlyne: IRB Protocol Manual for Researchers UPRCCC

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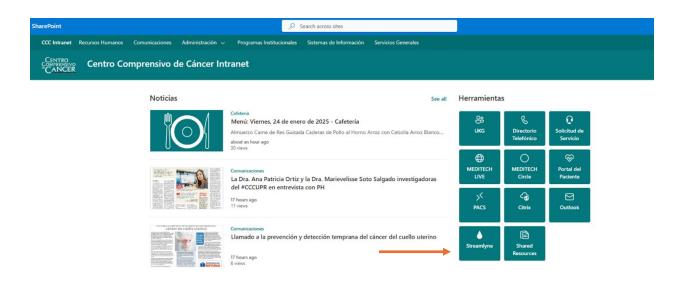
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# **How to Access the Streamlyne Platform**

There are two ways to access the platform:

#### Steps:

1. Via SharePoint: If you are CCC personnel, log in to your SharePoint portal and click the Streamlyne icon.



2. Via CCC Website: Visit www.cccupr.org and click the Streamlyne icon.

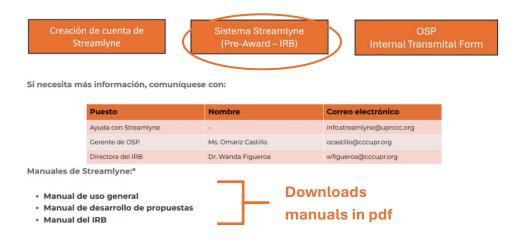


La administración de los proyectos de investigación puede ser complicada y requerir mucho tiempo. Para facilitar este proceso, el Centro Comprensivo de Cáncer de la Universidad de Puerto Rico usa Streamlyne para gestionar la administración de los proyectos subvencionados. Todos los proyectos subvencionados (grants, contratos, y subawards), así como las solicitudes a la Junta de Revisión Institucional (IRB, por sus siglas en inglés) se registran, dirigen/aprueban, someten y gestionan a través de esta plataforma. Por ende, la documentación de Streamlyne de cada proyecto servirá como récord permanente de su cumplimiento y su historia de fondos externos en el CCCUPR.

#### Once clicked:

You'll be redirected to a second page. On this page, click on the icon labeled "Sistema Streamlyne (Pre-Award-IRB)" to proceed.

You'll also find downloadable manuals in PDF format for reference.



3.If you have CCC credentials, you can log in using Single Sign-On (SSO). If you are an externally affiliated researcher, select the option to log in using a local Streamlyne Research account.



4. This will lead you to Action List page. This section displays the list of protocols initiated by the Principal Investigator (PI). It also appears in the action list for each of the study personnel.



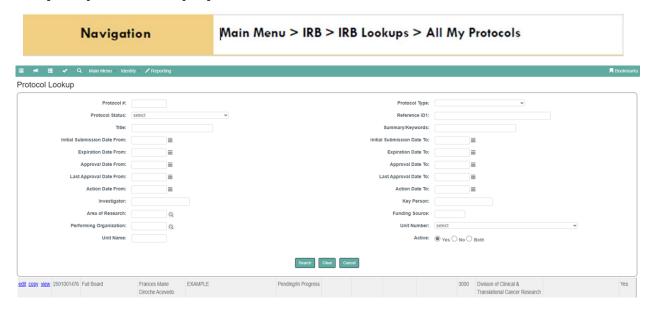
# **Searching for Protocols**

#### Steps:

#### From the Main Menu:

1. Navigate to IRB > IRB Lookups > All My Protocols.

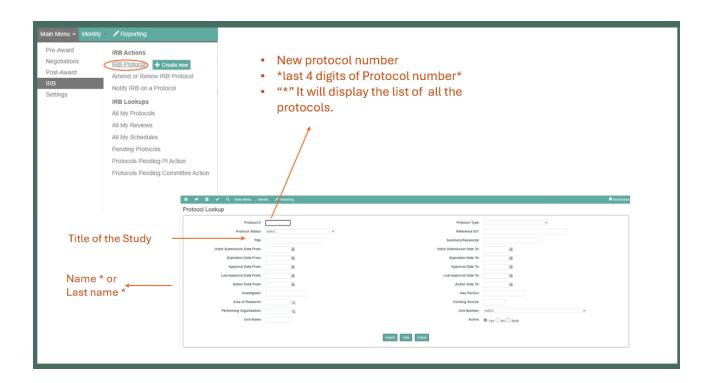
This will open the Protocol Lookup tab. Under the search bar, you will see a list of all your protocols displayed.



2. Alternatively, go to IRB > IRB Protocol.

This section also includes the protocol lookup feature.

- 1. Search Options:
  - Full protocol number
  - Asterisk + last 4 digits (e.g., \*1234)
  - Tittle of the Study
  - PI'S firswt or last name (eg., \*Simth\*)
  - Use \* to view all protocols.

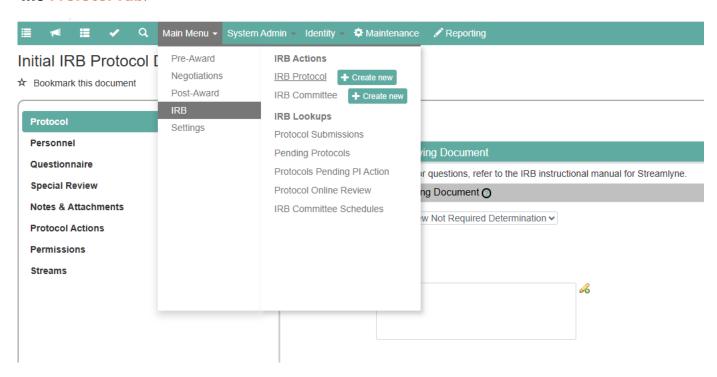


# Initiating and Submitting a New IRB protocol

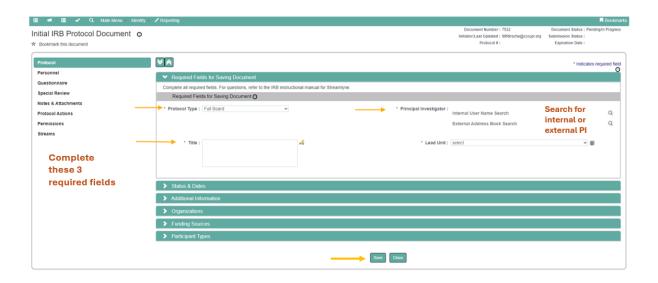
# Steps:

#### From the Main Menu:

1. Navigate to IRB >IRB Protocol> + Create New. This action will direct you to the Protocol Tab.



# Protocol Tab > Required Fields for Saving Document



#### Steps:

1. In the Protocol Type section, select the type of protocol you are submitting to the IRB. Choose from the available drop-down options



- 2. Enter your title in the Title section.
- 3. In the principal investigator search for an internal or external PI.

#### How to search for the internal and external username

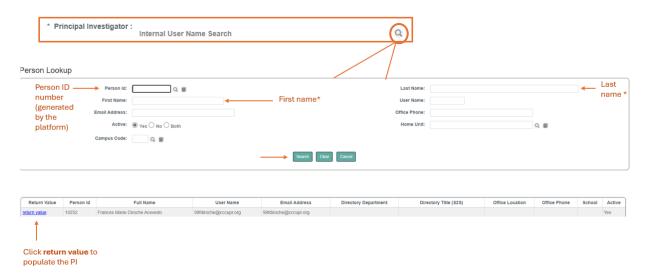
#### Principal Investigator (PI) Selection Instructions

#### Steps:

#### For Affiliated Principal Investigators

- 1. Enter the PI's first or last name, followed by an asterisk (\*) to perform a wildcard search.
- 2. Click on Return Value to automatically populate the Principal Investigator (PI) field with the appropriate information.

#### Internal username search: Personnel Affiliated to CCC.



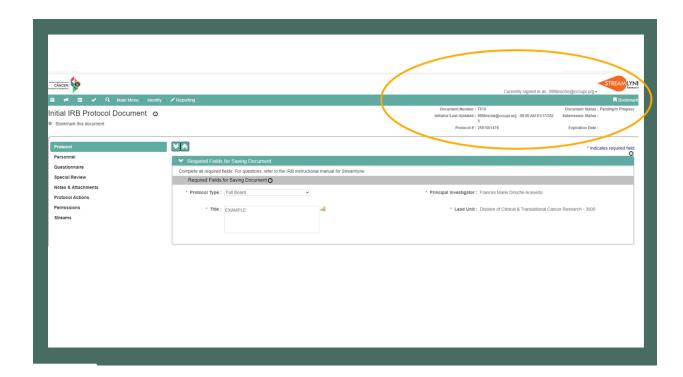
#### For Non-Affiliated Principal Investigators

- 1. If the PI is non-affiliated, search using the External Address Book ID.
- 2. Follow the same steps as those used for searching by internal username.

Once all required fields on the Protocol tab are completed, click Save to finalize the entry.

# After saving all the required fields, the following information will be displayed at the top:

- Document Number: Unique 4 digits.
- Initiator: Email of the initiator + the last time and date the protocol was accessed.
- Protocol #: Last two digits of the current year + two digits of the current month + sequential number.



# Protocol Tab > Status & Dates

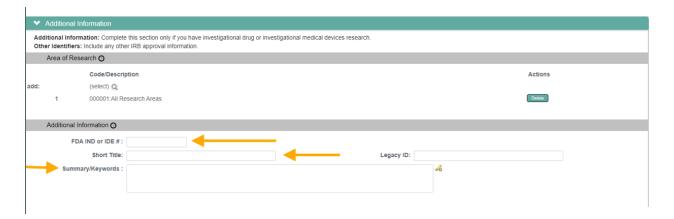
1. The information is autogenerated by the system. Subsequent data will be generated based on the actions taken on the protocol.



# **Protocol Tab> Additional Information**

#### Steps:

- FDA Investigational Number: If your study involves an FDA Investigational New Drug (IND) or Investigational Device Exemption (IDE), enter the corresponding number in the designated field.
- 2. Short Title of the Study: Provide a concise and descriptive title for the study. This title will be used for reference throughout the protocol documentation.
- 3. Study Keywords: Enter relevant keywords that best describe the study. These keywords will assist in categorizing and retrieving the protocol during searches.

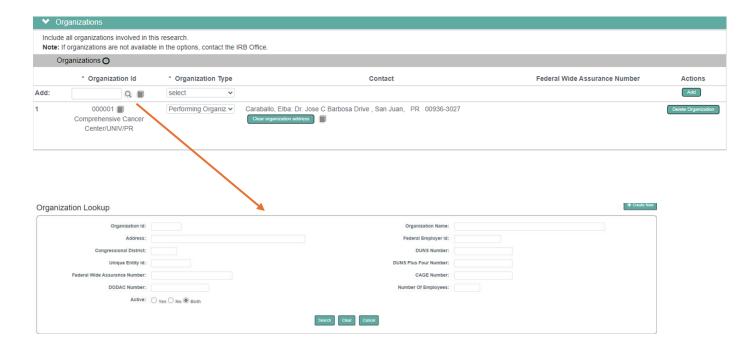


# **Protocol Tab> Other Identifiers**

- 1. If you have an external IRB, select it from the dropdown list.
- 2. In the "Other Identifier" field, include the External IRB number.
- 3. Fill in the Application Date and Approval Date.
- 4. Click "Add" and then click "Save."



# **Protocol Tab> Organizations**



- 1. Select the "Magnifying Glass icon" to access the "Organization Lookup" search bar.
- 2. Enter the organization number ID if known or part of the organization name followed by an asterisk (\*).

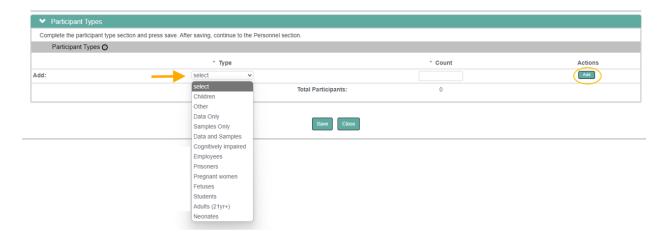
- 3. Once the organization appears, select "Return Value" to populate the field.
- 4. In the "Organization Type" section, choose whether the organization is External or the Performing Organization.
- 5. After entering all the information, click "Add" and then "Save".

# **Protocol Tab> Funding Sources**



- 1. From the dropdown list, select "Sponsor." This will lead you to the sponsor lookup search bar.
- 2. You can search for the sponsor by entering the sponsor code or sponsor name followed by an asterisk (\*).
- 3. Once you find the sponsor, select "Return Value" to populate it back to the main section.
- 4. Click "Add" and then click "Save."

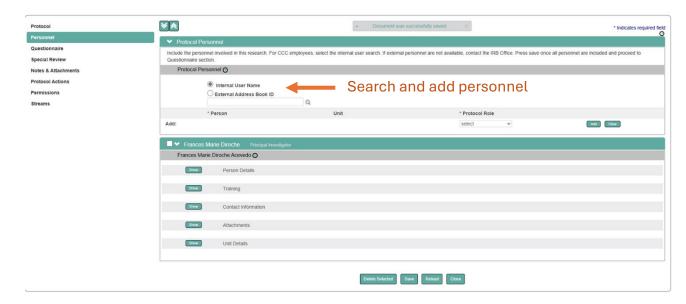
# **Protocol Tab> Participant Types**



#### Steps:

- 1. Add the type of participants according to their category individually, along with an approximate count.
- 2. Click "Add" and then click "Save."

# **Personnel Tab> Protocol Personnel**

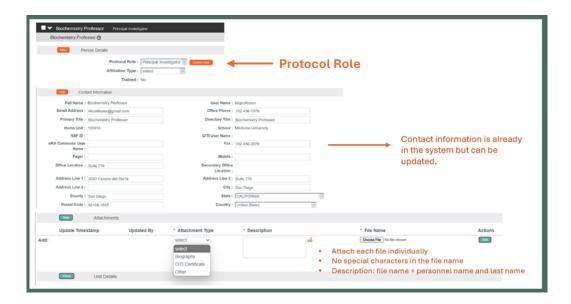


#### Steps

- 1. Principal Investigator is auto populated.
- 2. Add CCC personnel using internal username
- 3. Add external personnel via external address book

# On the Personnel Tab: Review the Following for Each Individual

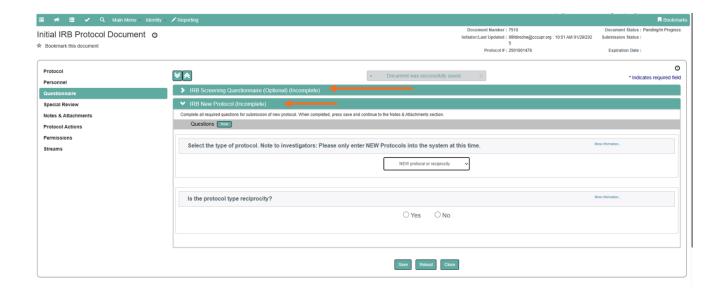
- 1. Under each personnel entry, verify the protocol role.
- 2. Update the contact information as needed.
- In the Attachments section, upload each file individually (e.g., CV, CITI
  certificates, medical licenses). Ensure that file names do not contain special
  characters.
- 4. After uploading each document separately, click "Add".
- 5. Once all documents have been uploaded for each personnel, make sure to click "Save".



# **Questionnaire Tab**

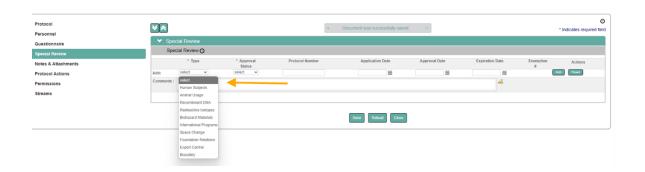
#### Steps:

- 1. Complete both questionnaires and provide notes and attachments as requested.
- 2. After completing both questionnaires click "Save".



# **Special Review Tab**

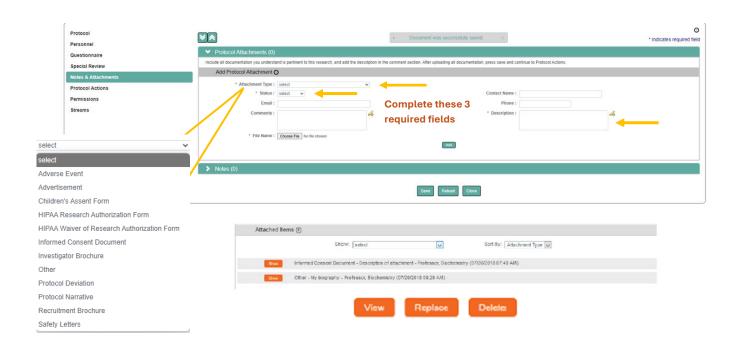
- 1. Include any additional reviews associated with your IRB protocol, such as biosafety, IACUC, biohazard materials, etc. (excluding human subjects).
- 2. After entering the required information, click "Add", then click "Save" to ensure all changes are recorded.



#### **Notes and Attachments**

In this section, include all documentation related to the protocol.

- 1. Select attachment type (e.g., Consent Form, Protocol Narrative)...
- 2. Set the Status to Completed
- 3. Upload each document individually. Avoid using special characters in file names (e.g., %, &, #, @), as they are not recognized by the system and may cause upload errors.
- 4. Provide a concise description of the document in the Description field to facilitate review and identification. Once all required fields are completed, upload the document.
- 5. After uploading, each document will be listed in the following format: Title Description Uploaded By Date/Time of Upload
- 6. For each uploaded document, you will have three available actions:
  - a. View: Click the icon to download the document to your computer.
  - b. Replace: Update the document while retaining its original metadata (Attachment Type, Status, and Description).
  - c. Delete: Permanently remove the document from the protocol.
- 7. After uploading all documents, click "Save" to finalize.



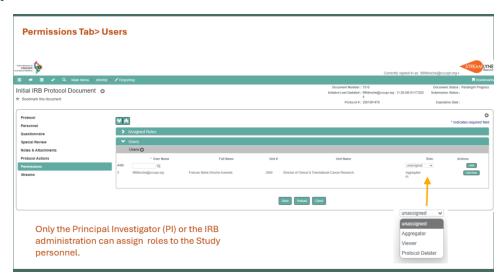
# **Permissions Tab > Users**

This section displays all personnel involved in the protocol.

If you are the Principal Investigator (PI), you may assign roles to other team members as follows:

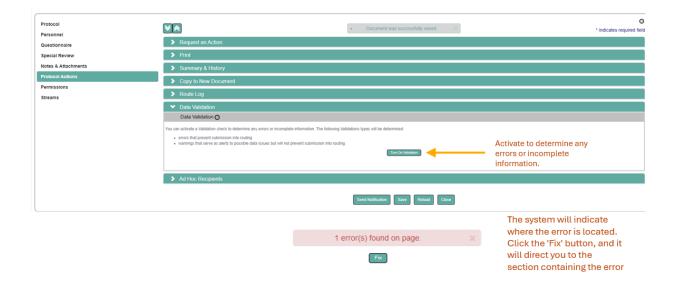
- Viewer: Can view the protocol but cannot make edits.
- Aggregator: Can edit and manage protocol content.

<u>A Recommendation</u>: To minimize the risk of simultaneous edits, it is advised that only the PI or the designated Coordinator hold the role of Aggregator. All other personnel should remain as Viewers.



# **Protocol Actions Tab> Data Validation**

- 1. In the Data Validation section, click the "Turn on Validation" button to enable the system to check for any errors or incomplete fields.
- 2. If an error is detected, the system will display a notification and indicate the affected section under "Validation Errors."
- 3. Click the "Fix" button. The system will automatically redirect you to the section that requires correction or completion.



# Protocol Actions> Request an Action> Submit Protocol for Review

This section allows you to submit your protocol to the IRB Committee.

#### Steps:

1. Submission Type:

From the dropdown menu, select the appropriate submission type:

- Initial Protocol Application for Approval
- Continuing Review / Continuation without Amendment
- Amendment
- Resubmission, etc.
- 2. Committee Selection:

**Under the Committee section, select:** 

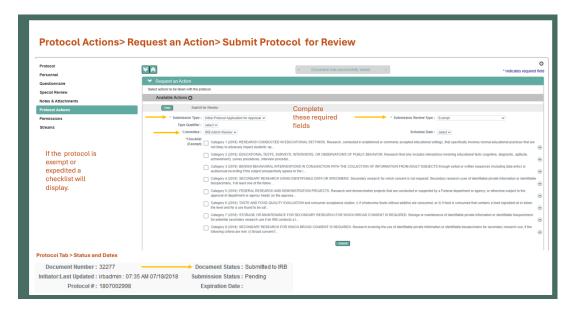
- IRB Committee Review
- 3. Submission Review Type:

From the dropdown menu, choose the applicable review type:

- Full
- Expedited
- Exempt, etc.

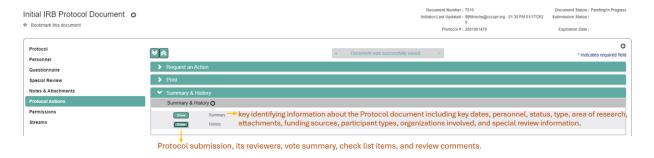
- 4. Category Checklist (for Exempt and Expedited protocols):
  If your protocol qualifies as Exempt or Expedited, a checklist of categories will be displayed. Select the category that best corresponds to your study.
- Schedule Date: Choose the next available date for the IRB Committee meeting.
- 6. Submit Protocol: Once all required fields are completed, click the "Submit" button. This action will notify the IRB Administrator that the protocol is ready for review.

Note: If you are the study coordinator, when you submit the protocol, it will automatically generate a notification to the Principal Investigator (PI) requesting final approval. Once the PI provides approval, the protocol will be routed to the IRB Administrator for further review.



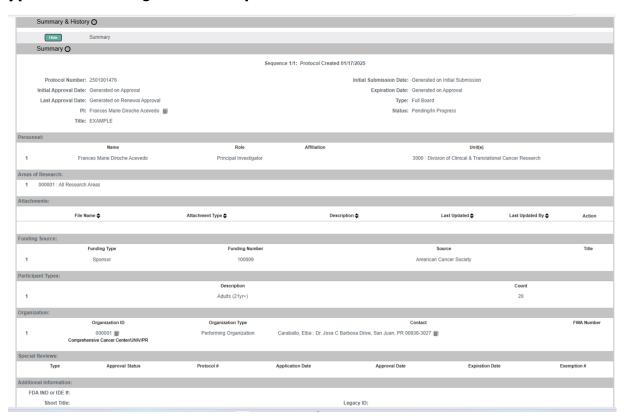
# **Protocol Actions> Summary and History**

In the section of Summary and History you can review all the information put on the protocol tab and all the actions taken in the history of the protocol.



#### **Summary**

This section provides a comprehensive summary of the protocol, including key details such as personnel, research area, attachments, funding sources, participant types, affiliated organizations, special reviews, and more.



#### History

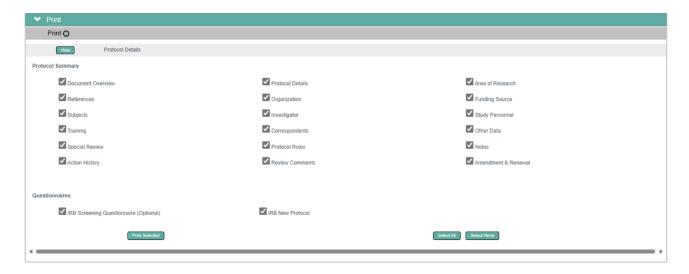
This section displays all actions associated with the protocol, including its creation, submission to the IRB, and final approval.

Under the Approval Action section, you can access your official approval letter. Simply click the "View" button to download the document directly to your computer.



#### **Protocol Actions> Print**

In this section, you can print the entire protocol or choose specific sections to print based on your preferences or requirements.



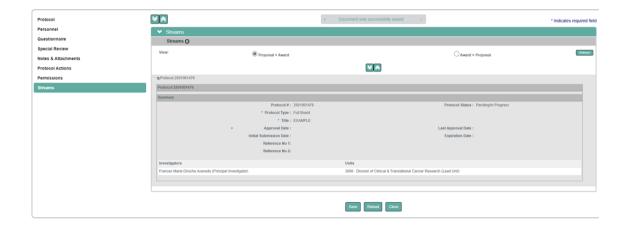
# **Protocol Actions> Route Log**

In this section, the routing status of the protocol will be displayed. It will show the actions that have been taken, as well as any pending action requests.



# **Streams Tab**

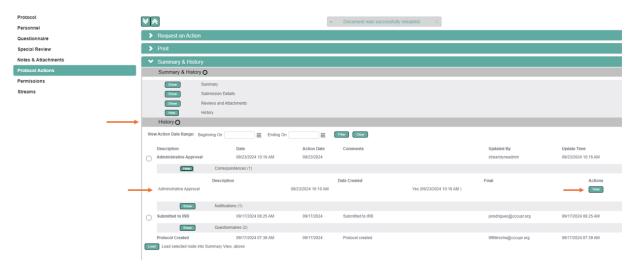
The Streams tab collects and displays details of all documents linked to a specific protocol.



# **IRB Approval Letter**

In this section, you can access and download the approval letter for your protocol. Steps:

- 1. Navigate to:
  - Protocol Actions > History > Approval
- 2. Then, click the "View" button. The document will be downloaded directly to your computer.



# Other Available Actions after initial submission

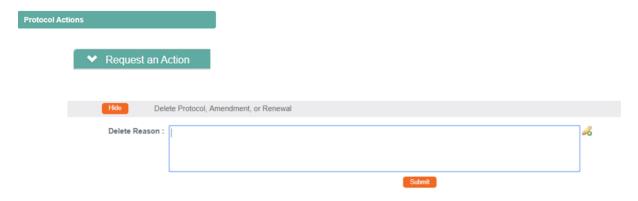
# **Deleting a Protocol**

To delete a protocol, it must be in an editable format.

The Protocol Status must be one of the following:

- Pending / In Progress
- Amendment in Progress
- Renewal in Progress
- Withdrawn

#### Only protocols with these statuses can be deleted.



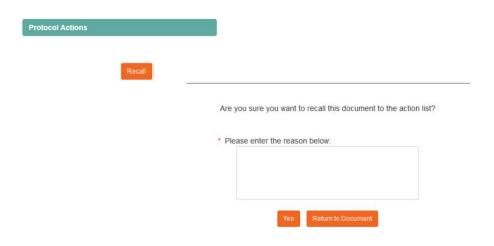
Result: The Protocol Status will be updated to Deleted.

#### **Recall Protocol**

This refers to the process of retracting a submission that has already been routed for review or approval by other users but has not yet been received or processed by the IRB Administrator.

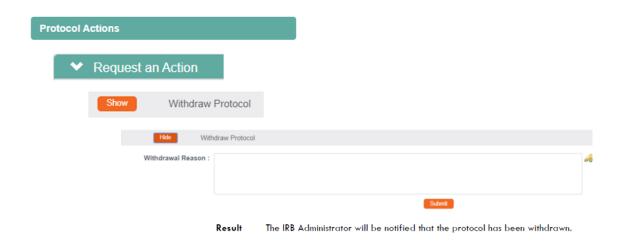
Recalling a submission allows the submitter to make necessary changes or corrections before resubmitting it for consideration.

When performing this action, please provide a brief explanation for recalling the protocol.



# **Withdrawing Protocol**

This applies when a protocol has reached the IRB Administrator, but the investigator decides not to proceed.



# **Editing a Returned Protocol**

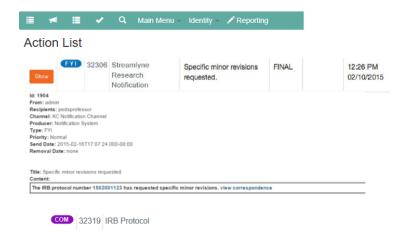
When a protocol is returned for revisions, the Principal Investigator (PI) will receive two notifications in the Action List:

- 1.An FYI notification indicating that the protocol has been returned.
- 2. The protocol itself, now available for editing.

Additionally, the PI will receive an email notification informing them that the protocol requires revisions.

Protocols may be returned due to:

- Errors
- Incomplete information
- Required modifications based on IRB feedback.



# **Accessing Review Comments**

In this section, you will be able to review the comments provided by the IRB Committee.

These comments are intended to guide you in making the necessary revisions based on the committee's recommendations.



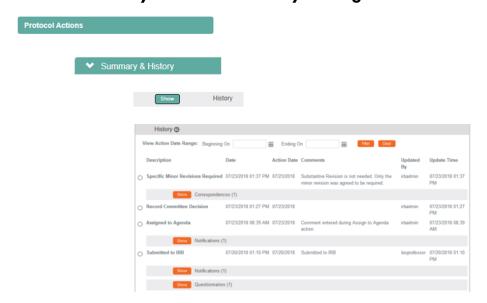
# **Viewing Official Correspondence**

To access official correspondence generated from protocol actions, follow these steps:

1. Navigate to:

**Protocol Actions > Summary and History > History.** 

In this section, you will find a chronological list of actions taken on the protocol. Some of these actions will generate official letters, which can be downloaded directly from this section by clicking the "View" button.



# **Creating and Submitting an Amendment**

This section allows you to initiate an amendment to an existing protocol.

1. Navigation:

Go to Main Menu > IRB > IRB Actions > Amend or Renew IRB Protocol.

This will display a list of your existing protocols.

2. Select Protocol:

Locate the protocol you wish to amend and click the "Perform Action" button.



3. Request Action:

After selecting the protocol, proceed to Request an Action > Create Amendment.

#### 4. Summary Section:

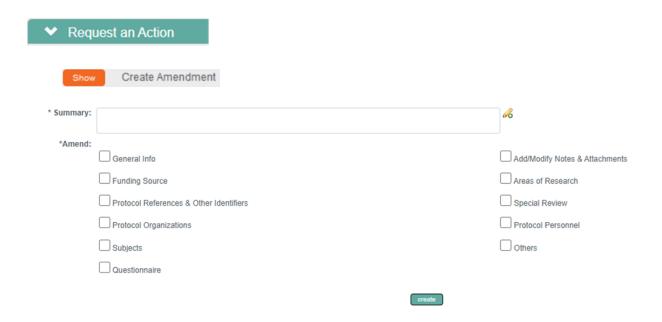
In the Summary field, provide a brief description of the amendment's purpose and content.

Note: If the study is not new, be sure to include the current amendment number in the summary.

#### 5. Editable Sections:

Select the specific sections of the protocol that need to be made editable for the amendment.

Important: If you do not select the sections to edit, they will remain in Viewer Mode and cannot be modified. After making your selections, click on the "create" button.

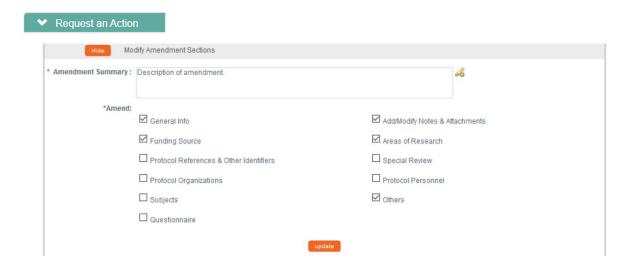


#### 6. Amendment Questionnaire:

The system will automatically generate an Amendment Questionnaire, which is required to complete the amendment process.

# **Modifying Amendment Sections**

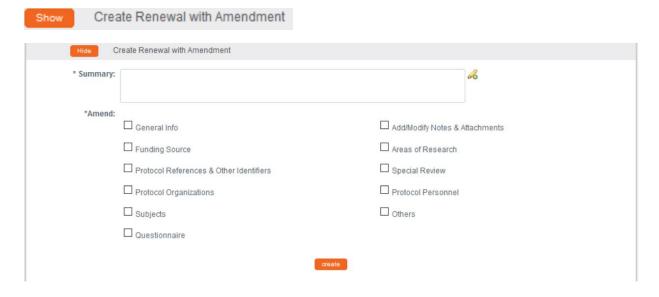
In this section, you can select additional parts of the protocol that were not included in the initial amendment request. This allows you to make further modifications as needed. After making your selections, click the "Update" button to enable editing for the selected sections.



# **Creating a Renewal with Amendment**

In this section, follow the same instructions outlined on page 29-30 to create an amendment.

Note: If the study is not new, be sure to include both the current amendment and renewal numbers in the summary field.



# **Renewal without Amendment**

You will only need to enter a summary paragraph describing the renewal.

Then, click the "Create" button.

Note: If the study is not new, be sure to include the current renewal number in the summary field.

Once initiated, a Renewal Questionnaire will be generated, which is mandatory to complete.



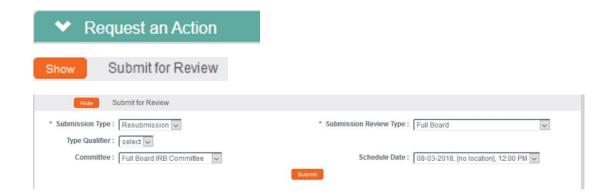
# **Resubmitting a Protocol**

After completing any required modifications, amendments, or renewals, the protocol must be resubmitted for IRB review.

#### Steps:

- 1. In the Submission Type section, select the appropriate option from the drop-down menu:
  - Amendment,
  - Continuing Review,
  - Resubmission
- 2. In the Committee section select IRB committee
- 3. In the Submission Review Type select:
  - a. Full Board
  - b. Expedited
  - c. Exempt
- 4. In the Schedule Date selecting the next IRB committee meeting

Protocol Actions



# Communicating with the IRB Administrator/Committee

To notify the IRB regarding specific matters, please follow the steps below:

1. Navigate to:

Protocol Actions > Request an Action > Notify IRB

- 2. Select the appropriate submission type qualifier from the dropdown menu:
  - Safety Letters
  - Protocol Deviation
  - Adverse Events
  - Unanticipated Problems
  - DSMB Report
  - Contingent/Conditional Approval / Deferred Approval / Non-Approval
  - Protocol-Related COI Reported
  - Self-report for Noncompliance
  - Other
- 3. Committee Selection:

Choose IRB Committee from the available options.

4. Submission Review Type:

Leave the review type as FYI (For Your Information).

5. Comments Section:

Provide a brief and clear description of the nature of your submission.

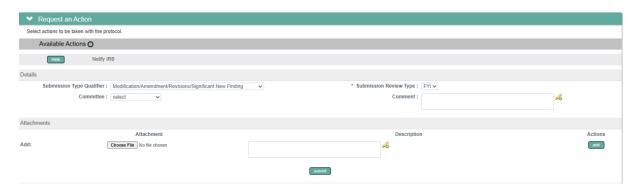
6. Documentation Attachment:

Upload all supporting documents related to your IRB notification (e.g., safety letters, protocol deviations, adverse events).

After uploading each file, click the "Add" button to ensure it is properly attached.

Once all documents have been uploaded and added, click the "Submit" button to finalize the process.

This action will generate an FYI notification in the Action List for the IRB Administrator and Committee.



#### Other Available Actions:

Request to close- PI (Principal Investigator) is requesting to close the study.

Typical Reason: Study completed or no longer active.

Request for suspension- Temporarily halt study activities.

#### **Typical Reasons:**

- Noncompliance
- Serious adverse events
- Unfavorable risk-benefit ratio
- Request for Termination- Permanently end the study.

#### **Typical Reasons:**

- Safety or ethical concerns
- Noncompliance
- Lack of funding
- Request to close enrollment- Stop enrolling new participants.

Typical Reason: PI determines enrollment is complete or no longer needed.

Request to Re- open enrollment- Resume participant enrollment.

#### **Typical Reasons:**

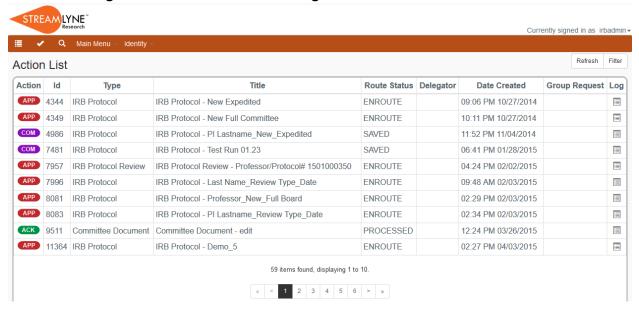
- Noncompliance
- Serious adverse events
- Unfavorable risk-benefit ratio
- Request for Data analysis only- Transition study to data analysis.
  - Typical Reason: No further recruitment or data collection planned.

# For Departmental Reviewers and Approvers

#### Reviewing and Approving protocols in workflow

1. Access your Action List

This list displays all documents requiring approval, specifically those assigned to the PI or other designated administrators.



2. Identify Documents for Approval

Look for documents marked with the Approval symbol in the Action column.



3. Open the Document

Click on the Document ID hyperlink to open the protocol.

4. Review of the Protocol

Carefully review all sections and information provided in the protocol.

5. Approve the Document

Once the review is complete and no issues are found, go to Protocol Actions and click the Approve button.

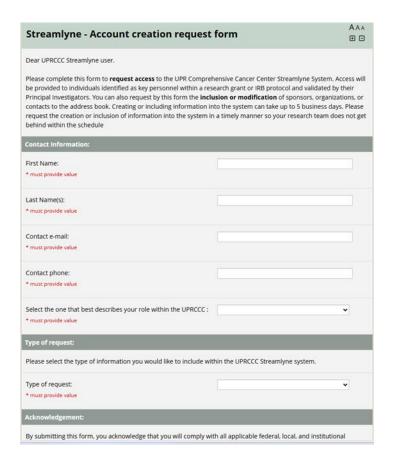
This will route the protocol to the next user in the workflow.



# If You Need to Add Personnel, Organizations, or Sponsors to the Streamlyne Platform

To request access or updates within the Streamlyne system, follow these steps:

- 1. Visit https://www.cccupr.org.
- 2. Navigate to the section titled "Centro de Investigación y Desarrollo" and click on the Streamlyne icon.
  - 3. Click on the link labeled "Creación de cuenta de Streamlyne.".
  - 4. You will be directed to a form where you can:
    - Request access for a new individual to use the system
    - Include or modify a sponsor record
    - Include or modify an organization
    - Create or update a contact in the address book (note: this does not grant system access)



After submitting the form, please allow up to five business days for your account or requested update to be processed. Once completed, a system administrator will contact you.

# **Need Help?**

If you have any questions or concerns, please contact the IRB Office/Shared Resources personnel:

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