

# UPR MSC IRB Manuals for Investigators

UPR MEDICAL SCIENCES CAMPUS



# INITIATING A NEW PROTOCOL

**STREAMLYNE™**  
Research

Currently signed in as admin

Main Menu System Admin Identity Maintenance

Refresh Filter

Apply Default NONE

**Action List**

- Pre-Award
- Negotiations
- Post-Award
- IRB**
  - IACUC
  - Conflict of Interest
  - Settings

- IRB Actions**
  - IRB Protocol **+ Create new**
  - IRB Committee **+ Create new**
- IRB Lookups**
  - Protocol Submissions
  - Pending Protocols
  - Protocols Pending PI Action
  - Protocol Online Review
  - IRB Committee Schedules

	Action	ID	Title	Route Status	Delegator	Date Created	Group Request	Actions	Log
Show	FYI	948	Proposal 69 is submitted	FINAL		07:32 AM 03/25/2015		NONE	
Show	COM	156	Proposal No: 122; PI: Pediatrics Professor; Sponsor: National Institutes of Health; Due Date: null	SAVED		03:29 PM 10/20/2015			
Show	FYI	192	Proposal 172 is submitted	FINAL		08:56 AM 04/26/2016		NONE	
	APP	220	COI Demo	ENROUTE		04:08 AM 12/20/2016	IRBAdmin		
	COM	261	- tes	SAVED		09:45 AM 06/16/2020			
	COM	26178	Quick Proposal	SAVED		10:08 AM 06/16/2020			
	COM	26183	IRB Protocol	SAVED		11:06 AM 06/16/2020			
	APP	26232	IRB Protocol	ENROUTE		02:57 PM 06/16/2020	IRBAdmin		
Show	FYI	26241	Streamlyne Research Notification	FINAL		03:55 PM 06/16/2020		NONE	
Show	FYI	26247	Streamlyne Research Notification	FINAL		03:56 PM 06/16/2020		NONE	

26 items found, displaying 1 to 10.

« < 1 2 3 > »

# UPDATING THE PROTOCOL TAB



Currently signed in as admin

## Initial IRB Protocol Document

☆ Bookmark this document

Document Number : 26792  
Initiator:Last Updated : admin  
Protocol # :

Document Status : Pending/In Progress  
Submission Status :  
Expiration Date :

### Protocol

- Personnel
- Questionnaire
- Custom Data
- Special Review
- Notes & Attachments
- Protocol Actions
- Permissions
- Streams



#### Document Overview

\* Description :

Explanation :

Organization Document Number :

#### Required Fields for Saving Document

##### Required Fields for Saving Document

\* Protocol Type :

\* Principal Investigator :

Internal User Name Search

External Address Book Search

To locate the PI enter their UPR e-mail

\* Title :

\* Lead Unit :

Complete these 3 requires fields.

Status & Dates

Additional Information

Organizations

Funding Sources

Participant Types

# EXTERNAL IRB ACCEPTED PROTOCOL (IF APPLICABLE)



Currently signed in as admin

Main Menu System Admin Identity Maintenance

Bookmarks

## Initial IRB Protocol Document

Bookmark this document

Document Number : 26793  
Initiator: Last Updated : admin  
Protocol # :

Document Status : Pending/In Progress  
Submission Status :  
Expiration Date :

### Protocol

- Personnel
- Questionnaire
- Custom Data
- Special Review
- Notes & Attachments
- Protocol Actions
- Permissions
- Streams



Document Overview

Required Fields for Saving Document

Status & Dates

Additional Information

#### Area of Research

add:	Code/Description (select)	Actions
1	000001:All Research Areas	Delete

#### Additional Information

FDA IND or IDE # :

Reference ID1:

Reference ID2:

Summary/Keywords :

#### Other Identifiers

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

\* Indicates required field

Select External IRB and enter the name.



# FUNDING SOURCES



Currently signed in as admin

## Initial IRB Protocol Document

Document Number : 26794  
Initiator: Last Updated : admin  
Protocol # :

Document Status : Pending/In Progress  
Submission Status :  
Expiration Date :

☆ Bookmark this document

### Protocol

- Personnel
- Questionnaire
- Custom Data
- Special Review
- Notes & Attachments
- Protocol Actions
- Permissions
- Streams



Document Overview

Required Fields for Saving Document

Status & Dates

Additional Information

Organizations

Funding Sources

Funding Sources

* Funding Type	* Funding Number	* Source	Title	Actions
Add: select	<input type="text"/>	<input type="text"/>		<input type="button" value="Add"/>

Participant Types

Participant Types

* Type	* Count	Actions
Add: select	<input type="text"/>	<input type="button" value="Add"/>

Total Participants: 0

Save Close

Link your IRB Protocol to your proposal.



\* Indicates required field

# PARTICIPANT TYPES



Currently signed in as admin

Main Menu System Admin Identity Maintenance

Bookmarks

Initial IRB Protocol Document

Document Number : 26794  
Initiator: Last Updated : admin  
Protocol # :

Document Status : Pending/In Progress  
Submission Status :  
Expiration Date :

☆ Bookmark this document

## Protocol

- Personnel
- Questionnaire
- Custom Data
- Special Review
- Notes & Attachments
- Protocol Actions
- Permissions
- Streams



Document Overview

Required Fields for Saving Document

Status & Dates

Additional Information

Organizations

Funding Sources

Funding Sources

* Funding Type	* Funding Number	* Source	Title	Actions
Add: select	<input type="text"/>	<input type="text"/>		<input type="button" value="Add"/>

Participant Types

Participant Types

* Type	* Count	Actions
Add: select	<input type="text"/>	<input type="button" value="Add"/>

Total Participants: 0

You must complete this section for your protocol to submit.



Save Close

# UPDATING THE PERSONNEL TAB



Currently signed in as admin

## Initial IRB Protocol Document

Document Number : 26794  
Initiator: Last Updated : admin  
Protocol # :

Document Status : Pending/In Progress  
Submission Status :  
Expiration Date :

☆ Bookmark this document

### Protocol

### Personnel

### Questionnaire

### Special Review

### Notes & Attachments

### Protocol Actions

### Permissions

### Streams



\* Indicates required field

### Protocol Personnel

Protocol Personnel

Internal User Name  
 External Address Book ID



Add other employees like Co-I or Study Personnel.

* Person	Unit	* Protocol Role
Add:		select

Add Clear

### SHARON M SANTIAGO PAGA Principal Investigator

SHARON M SANTIAGO PAGAN

Hide Person Details

Protocol Role : Principal Investigator Update View  
Affiliation Type : select

Show Training

Show Contact Information

# UPDATING THE QUESTIONNAIRE TAB



Currently signed in as admin

Main Menu System Admin Identity Maintenance

Bookmarks

Initial IRB Protocol Document

Document Number : 26794  
Initiator: Last Updated : admin  
Protocol # :

Document Status : Pending/In Progress  
Submission Status :  
Expiration Date :

☆ Bookmark this document

Protocol

Personnel

Questionnaire

Special Review

Notes & Attachments

Protocol Actions

Permissions

Streams



\* Indicates required field

New IRB Protocol (Incomplete)

Questions **Print**

Please select the category that best describes your submission:

More Information...

select

Answer the questions and add notes and attachments accordingly.

IRB Screening Questionnaire (Optional) (Incomplete)

Save

Reload

Close

Contact the IRB Coordinator at [oppih.rcm@upr.edu](mailto:oppih.rcm@upr.edu) or visit the IRB webpage <https://irbcm.rcm.upr.edu/> if you have any questions.



# UPDATING THE SPECIAL REVIEW TAB (FOR PROTOCOLS)



Currently signed in as admin

Main Menu System Admin Identity Maintenance

Bookmarks

Initial IRB Protocol Document

Document Number : 26794  
Initiator:Last Updated : admin  
Protocol # :

Document Status : Pending/In Progress  
Submission Status :  
Expiration Date :

☆ Bookmark this document

- Protocol
- Personnel
- Questionnaire
- Special Review**
- Notes & Attachments
- Protocol Actions
- Permissions
- Streams



## Special Review

Special Review

\* Indicates required field

	* Type	* Approval Status	Protocol Number	Application Date	Approval Date	Expiration Date	Exemption #	Actions
Add:	<input type="text" value="select"/>	<input type="text" value="select"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	E1 E2 E3	<input type="button" value="Add"/> <input type="button" value="Reset"/>
Comments :	<input type="text"/>							<input type="button" value="Pin"/>

Save Reload Close

Add other special reviews (NOT HUMAN SUBJECTS) linked to your IRB protocol like biosafety, IACUC, foreign travel, etc.

# UPDATING THE PERMISSIONS TAB



Currently signed in as admin

Main Menu System Admin Identity Maintenance

Bookmarks

Initial IRB Protocol Document

Document Number : 26794  
Initiator:Last Updated : admin  
Protocol # :

Document Status : Pending/In Progress  
Submission Status :  
Expiration Date :

☆ Bookmark this document

- Protocol
- Personnel
- Questionnaire
- Special Review
- Notes & Attachments
- Protocol Actions
- Permissions**
- Streams



Assigned Roles

Users

Users

	* User Name	Full Name	Unit #	Unit Name	Role	Actions
Add:	<input type="text"/>				unassigned	<input type="button" value="Add"/>
1	mariela.maisonet@upr.edu	MARIELA MAISONET ALEJANDRO	00000002	Chancellor's Office	Aggregator	<input type="button" value="Edit Role"/> <input type="button" value="Delete"/>
2	souhail.malave@upr.edu	SOUHAIL M MALAVE RIVERA	00001242	Social Sciences, Department of	Aggregator PI	<input type="button" value="Edit Role"/>



Enter the users e-mail, press search to add them and assign a role.

Save Reload Close

# UPDATING THE NOTES & ATTACHMENTS TAB



Currently signed in as admin

Main Menu System Admin Identity Maintenance

Bookmarks

Initial IRB Protocol Document

Document Number : 26794  
Initiator: Last Updated : admin  
Protocol # :

Document Status : Pending/In Progress  
Submission Status :  
Expiration Date :

☆ Bookmark this document

- Protocol
- Personnel
- Questionnaire
- Special Review
- Notes & Attachments**
- Protocol Actions
- Permissions
- Streams



\* Indicates required field

Protocol Attachments (0)

Add Protocol Attachment

\* Attachment Type : select

\* Status : select

Contact Name :

Phone :

\* Description :

Email :

Comments :

\* File Name :  No file chosen

Repeat the process for every attachment.

# PROTOCOL ACTIONS TAB



Currently signed in as admin

Main Menu System Admin Identity Maintenance

Bookmarks

Initial IRB Protocol Document

Document Number : 26794  
Initiator:Last Updated : admin  
Protocol # :

Document Status : Pending/In Progress  
Submission Status :  
Expiration Date :

☆ Bookmark this document

- Protocol
- Personnel
- Questionnaire
- Special Review
- Notes & Attachments
- Protocol Actions**
- Permissions
- Streams



\* Indicates required field

- Request an Action
- Print
- Summary & History
- Copy to New Document
- Route Log

### Data Validation

Data Validation

You can activate a Validation check to determine any errors or incomplete information. The following Validations types will be determined:

- errors that prevent submission into routing
- warnings that serve as alerts to possible data issues but will not prevent submission into routing

Turn On Validation to ensure no errors in the protocol.



Turn Off Validation

### Validation Errors

Hide

New IRB Protocol (1)

Mandatory Questionnaire not complete.

Fix

# PROTOCOL ACTIONS TAB



Currently signed in as admin

Main Menu System Admin Identity Maintenance

Bookmarks

Initial IRB Protocol Document

Document Number : 26794  
Initiator:Last Updated : admin  
Protocol # :

Document Status : Pending/In Progress  
Submission Status :  
Expiration Date :

☆ Bookmark this document

- Protocol
- Personnel
- Questionnaire
- Special Review
- Notes & Attachments
- Protocol Actions**
- Permissions
- Streams



\* Indicates required field

## Request an Action

Available Actions

Visit the IRB webpage <https://irbcm.rcm.upr.edu/> if you have any questions regarding levels of Submission Type.

Hide

Submit for Review

\* Submission Type : Initial Protocol Submission

\* Submission Review Type : Expedited

Type Qualifier : select \*Optional

Committee : select

Schedule Date : select

\*Checklist (Expedited)

- Category 1: Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that signi...
- Category 2: Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week ...
- Category 3: Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates ...
- Category 4: Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must ...
- Category 5: Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be e...
- Category 6: Collection of data from voice, video, digital, or image recordings made for research purposes.

# REVIEWING THE STREAMS TAB



Currently signed in as admin

## IRB Protocol Document

☆ Bookmark this document

Document Number : 9348  
Initiator:Last Updated : irbadmin : 12:47 PM 03/18/2015  
Protocol # : 1412000265  
Document Status : Withdrawn  
Submission Status : Withdrawn  
Expiration Date :

- Protocol
- Personnel
- Questionnaire
- Custom Data
- Special Review
- Notes & Attachments
- Protocol Actions
- Permissions
- Streams**



Document was successfully reloaded.

### Streams

Streams

View:

Proposal > Award

Award > Proposal

Refresh



Institutional Proposal 00000041

Institutional Proposal 00000041

Click to view details.



Open Proposal

Open Proposal Notes

Proposal No.  
00000041

KD 3

Title

Status  
Pending

Proposal Type: New

Sponsor Proposal No:

Account:

Activity Type: Research

NSF Code:

Notice of Opp:

Sponsor: 000340 National Institutes of Health

Prime Sponsor:

Initial Period

Total Period

Requested Start Date: 07/01/2015

07/01/2015

Requested End Date: 06/30/2016

06/30/2018

Total Direct Cost: \$16,749.66

\$216,749.66

Total F&A Cost: \$8,039.84

\$58,039.84

Total All Cost: \$24,789.50

\$274,789.50

Investigators

Units

Pediatrics Professor (Principal Investigator)

105030 : Pediatrics (Lead Unit)

Cost Sharing	<input checked="" type="checkbox"/>
Unrecovered F&A	<input type="checkbox"/>
Special Review	<input checked="" type="checkbox"/>

# HOW TO APPROVE PROTOCOLS



Currently signed in as admin

Main Menu System Admin Identity Maintenance

Bookmarks

Initial IRB Protocol Document

Document Number : 26794  
Initiator:Last Updated : admin  
Protocol # :

Document Status : Pending/In Progress  
Submission Status :  
Expiration Date :

☆ Bookmark this document

**Protocol** [collapse/expand icons]

- Personnel
- Questionnaire
- Special Review
- Notes & Attachments
- Protocol Actions**
- Permissions
- Streams

- > Request an Action
- > Print
- > Summary & History
- > Copy to New Document
- > Route Log
- > Data Validation
- > Ad Hoc Recipients

Send Notification Send AdHoc Save Reload **Approve** Disapprove Close Recall

Co-I or Supervisor will have to approve the protocol or vice versa. Click the Questionnaire Tab and Protocol Actions to Review.



# HOW TO SEARCH FOR PENDING ACTIONS



Currently signed in as admin

Main Menu System Admin Identity Maintenance

Bookmarks

Initial IRB Protocol Document

Bookmark this document

- Protocol
- Personnel
- Questionnaire
- Special Review
- Notes & Attachments
- Protocol Actions**
- Permissions
- Streams

- Request an Action
- Print
- Summary & History
- Copy to New Document
- Route Log**
- Data Validation
- Ad Hoc Recipients

### Route Log

ID: 4731

Title	2202000359; ABIGAIL QUINONES CHANZA		
Type	IRB Protocol	Created	01:26 PM 02/09/2022
Initiator	QUINONES CHANZA, ABIGAIL	Last Modified	01:27 PM 02/09/2022
Route Status	SAVED	Last Approved	
Node(s)	Initiated	Finalized	

#### Actions Taken

Action	Taken By	For Delegator	Time/Date	Annotation
SAVED	QUINONES CHANZA, ABIGAIL		01:26 PM 02/09/2022	

#### Pending Action Requests

Action	Requested Of	Time/Date	Annotation
<a href="#">show</a> IN ACTION LIST COMPLETE	QUINONES CHANZA, ABIGAIL	01:26 PM 02/09/2022	

#### Future Action Requests

Action	Requested Of	Time/Date	Annotation
<a href="#">show</a> PENDING APPROVE	QUINONES CHANZA, ABIGAIL	09:15 AM 04/26/2022	KC-PROTOCOL PI
<a href="#">show</a> PENDING APPROVE	(Multiple - expand to see details)	09:15 AM 04/26/2022	KC-UNT IRB Administrator Y 000001

“In Action List Approve” = means the protocol is on that person(s) Streamlyne Action List and waiting for them to review & approve it.



# HOW TO RESPOND TO A REVISION REQUEST



Currently signed in as admin

Main Menu System Admin Identity Maintenance

Bookmarks

Initial IRB Protocol Document

Document Number : 26794  
Initiator:Last Updated : admin  
Protocol # :

Document Status : Pending/In Progress  
Submission Status :  
Expiration Date :

Bookmark this document

The screenshot shows the Streamlyne interface with a sidebar menu on the left and a main content area on the right. The sidebar menu includes items like Protocol, Personnel, Questionnaire, Special Review, Notes & Attachments, Protocol Actions (highlighted), Permissions, and Streams. The main content area shows a similar menu with 'Request an Action' highlighted. A red box highlights 'Request an Action' in the sidebar, and a red arrow points to the 'Request an Action' dropdown in the main content area. The dropdown menu shows 'Available Actions' with three options: 'Submit for Review', 'Delete Protocol, Amendment, or Renewal', and 'Unavailable Actions'. A red arrow points to the 'Show' button next to 'Submit for Review'.

You can review with the link sent by email or through here.

# HOW TO LOCATE YOUR IRB APPROVAL LETTER



Currently signed in as admin

Main Menu System Admin Identity Maintenance

Bookmarks

Initial IRB Protocol Document

Document Number : 26794  
Initiator:Last Updated : admin  
Protocol # :

Document Status : Pending/In Progress  
Submission Status :  
Expiration Date :

Bookmark this document

The screenshot shows the 'Protocol Actions' menu on the left. The 'Summary & History' option is highlighted with a red box. A red arrow points from this box to the expanded 'Summary & History' sub-menu on the right. In the sub-menu, the 'Summary & History' section is expanded, and a red arrow points to the 'Show' button next to the 'Summary' item.

You can view with the link sent by email or through here.

Description	Date	Action Date
<input type="radio"/> Expedited Approval	05/02/2022 01:39 PM	05/02/2022
<input type="radio"/> <a href="#">Show</a>	Correspondences (1)	

Description	Date Created	Final	Actions
Expedited Approval Letter	04/26/2022 10:53 AM	Yes (04/26/2022 10:54 AM )	<a href="#">View</a>