HARRISHEALTH SYSTEM

ePROTOCOL

enabling paperless research compliance

Protocol Management System (PMS)

Investigator User Guide

Harris Health System Administrative Approval

November 2013

Table of Contents

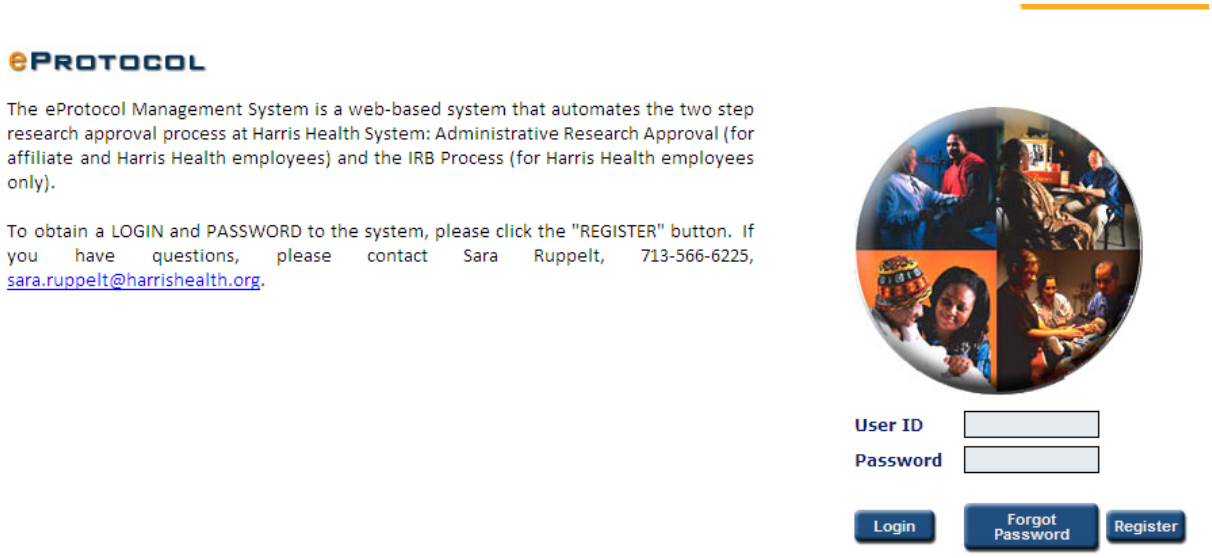
1. Introduction

This document explains the steps to perform various functions of Investigator in eProtocol, a web-based protocol management system developed by Key Solutions Inc.

2. Starting eProtocol

The eProtocol application can be accessed from any computer system with a relatively current version of a web browser -- including Internet Explorer, Firefox and Safari.

The system can be accessed at https://harrishealth.keyusa.net. The first page displayed is the login window of the eProtocol Application.



1. Enter your User ID and Password. First time users can click **Register** to obtain a login and password.
2. Click **Login**, or press **Enter**. Investigator **Home** page is displayed.

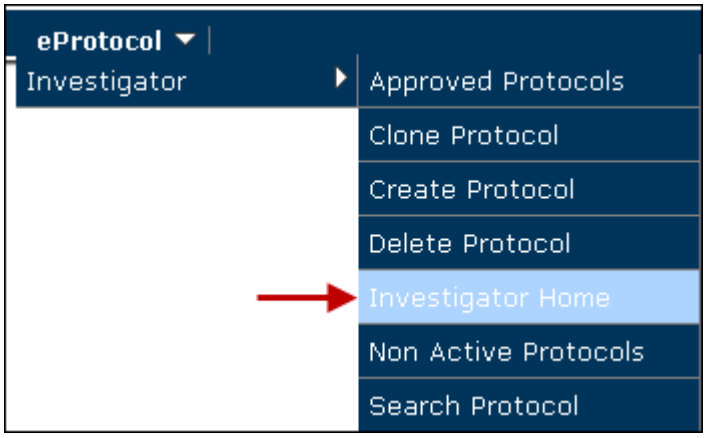
Note: *If the User ID and/or Password are incorrect, a message stating "Login Failed. Invalid User ID or Password" will be* displayed.

3. Investigator Home Page

The functions of an Investigator are to create and submit protocols to the Harris Health System Office of Research & Sponsored Programs for administrative review and approval. After initial protocol approval, investigators can create Amendment, Continuing Review and Final Report forms.

Home page is the starting point for Investigators to perform various key functions. On **Home** page, details of all ongoing protocols within your purview are displayed. The protocols created by you and the protocols in which you are a member are automatically displayed on the **Home** page after their creation.

You are automatically directed to the **Home** page after login. You can go to the **Home** page at any stage by clicking on **Investigator** on the top menu or by clicking on **Investigator Home** displayed after pointing the cursor to **Investigator**.



Protocols are categorized and displayed in the following sections:

Protocols (In Preparation/Submitted)

In this list, protocol forms which are in preparation, submitted to ADMIN REV and/or undergoing ADMIN REV are displayed. The protocol forms are categorized based on their Form Type – New, Amendment, Continuing Review, Final Report, etc.

Approved Protocols

In this list, the protocols approved by the Harris Health System Office of Research & Sponsored Programs are displayed.

Non-Active Protocols

In this list, the protocols not approved/ closed/ expired are displayed

Note: Click **Show/Hide** button to view/hide the protocols list of the form type.

Definition of Form Types

Different Protocol Form Types in '(In Preparation/Submitted)' list of protocols are explained below.

1. **New**: This is the first document prepared for a protocol. When a protocol is created for the first time, it is considered a New form.
2. **Amendment**: After a protocol form is approved, if there are any revisions to the protocol, an Amendment form should be submitted.
3. **Continuing Review**: For an approved protocol, a renewal or Continuing Review form should be submitted before its expiration.
4. **Final Report**: At the conclusion of the research, a Final Report form should be submitted. This is the final document submitted for a protocol. *Please note that protocols should remain active with Harris Health until closed with the IRB.*

Important Note:

New, Amendment and Continuing Review forms are considered as the main protocol documents. Only one of these forms can exist for a protocol at any point of time. For example, if you've submitted an

Amendment, you cannot create a Continuing Review form until the Amendment is processed by Harris Health.
The protocol information present in a New form is carried forward to the other two types of forms. Only one Final Report can be created for a protocol, as this is the document submitted for protocol closure.

Explanation of Columns in the Tables

Protocol ID: a unique Harris Health System ID assigned to a protocol when it is created, is displayed in this column. This Protocol ID stays with the protocol throughout its life cycle - all the way to archival.

Principal Investigator: The name of the Principal Investigator of the protocol is displayed in this column.

Protocol Event: the event happening for the protocol form is displayed in the column. Different Protocol Events are explained below.

a. **Yet to Submit to ADMIN REV**: Protocol form has not yet been submitted to Harris Health; it can be seen in view/edit mode.
b. **Submitted to ADMIN REV**: Protocol form has been submitted to Harris Health for review.
c. **Comments Received (Cycle 1)**: The protocol form submitted for review has received the first cycle (cycle 1) of comments from the Manager of the Office of Research & Sponsored Programs.
d. **Responses Sent (Cycle 1)**: The Investigator has responded to the comments received from the Manager - informing them of how s/he has acted on the comments made on the protocol form or in fulfilling the changes they wanted to see.
e. **Resubmit the Protocol**: Protocol form is returned for resubmission asking for changes to be made.
f. **Resubmitted to ADMIN REV**: Protocol form returned by the Harris Health is resubmitted after making required changes.

Status/Comments: the current status of the protocol form submission is displayed in the column. Different protocol statuses are explained below.

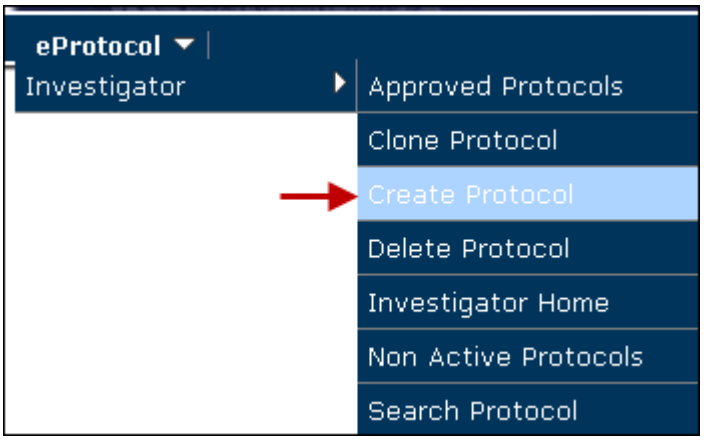
a. **New:** The protocol is newly created and yet to be submitted for ADMIN REV.
b. **Submitted:** The protocol is submitted for ADMIN REV.
c. **In Progress:** The protocol is undergoing review.
d. **Returned:** The protocol is returned for resubmission asking changes to be made.
e. **Resubmitted**: The protocol returned is resubmitted after making required changes.

4. Investigator Functions

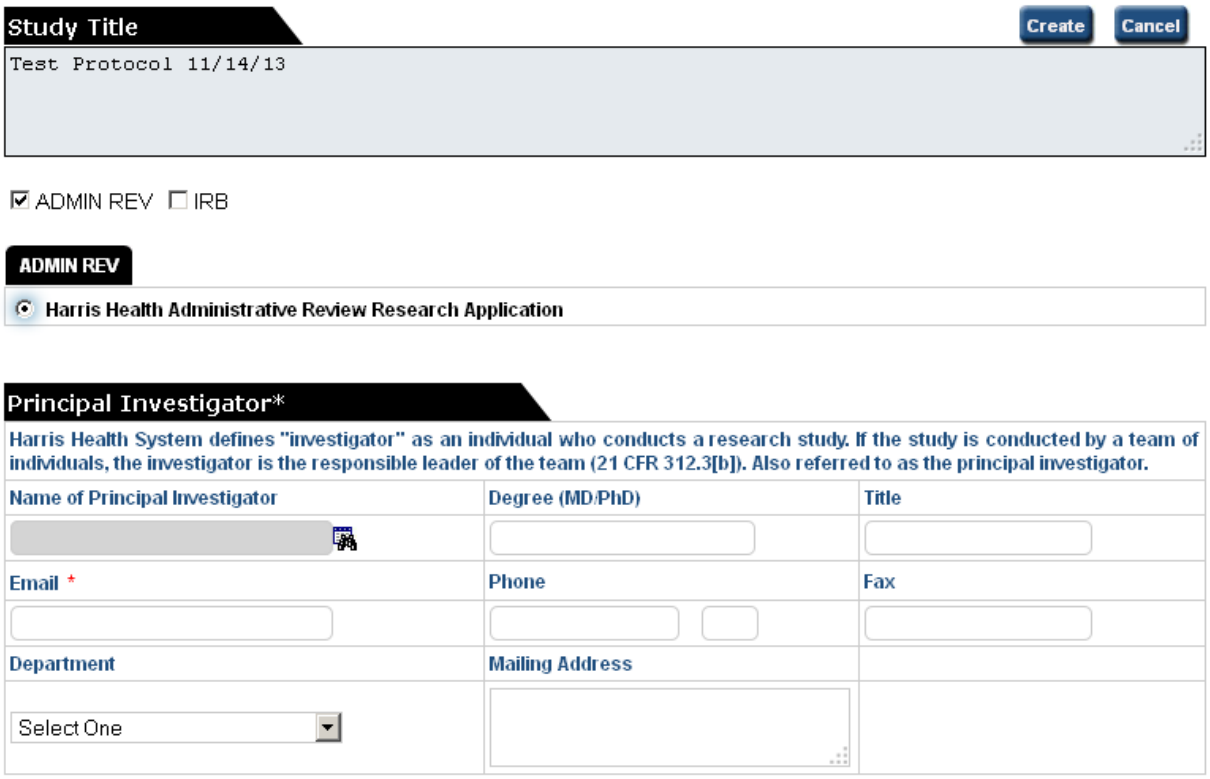
4.1. Create Protocol

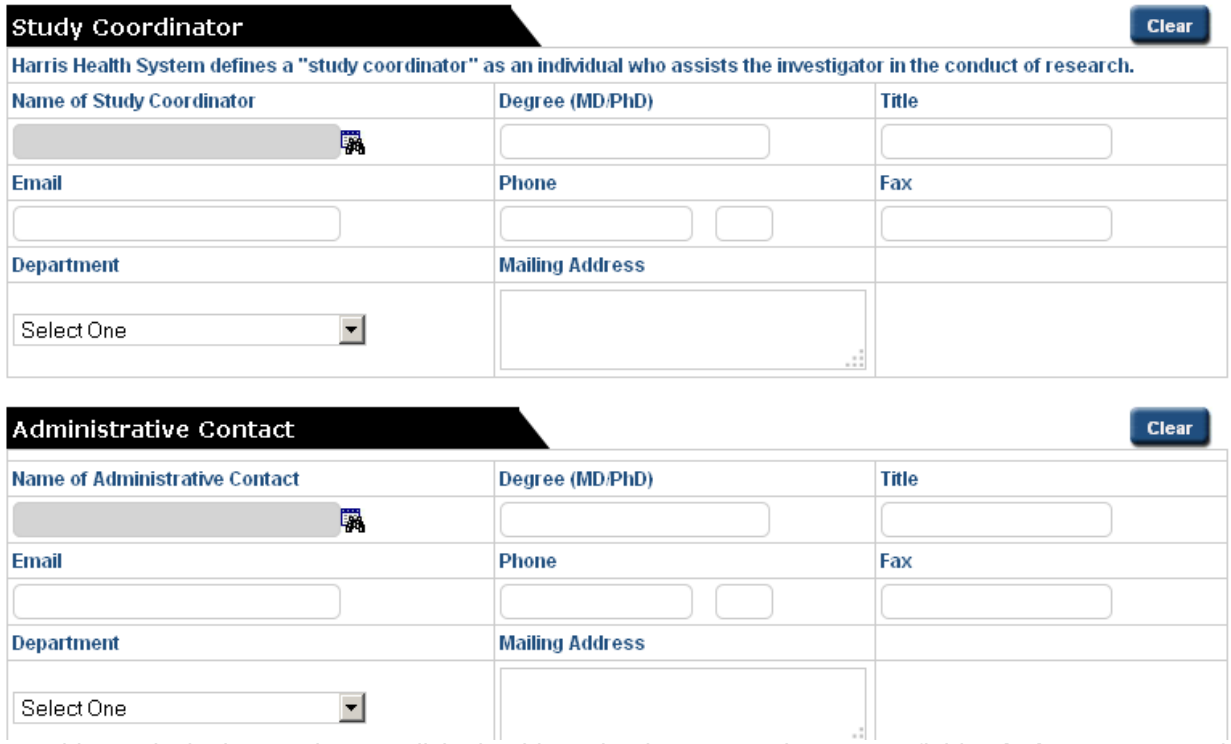
To conduct research within Harris Health System, you need to complete an application and submit it for Administrative Review (ADMIN REV) by the Harris Health System Office of Research & Sponsored Programs.

Point to **Investigator** on top menu and click **Create Protocol**. **Create Protocol** page is displayed. You can also click on **Create Protocol** button on the **Home** page and navigate to **Create Protocol** page.

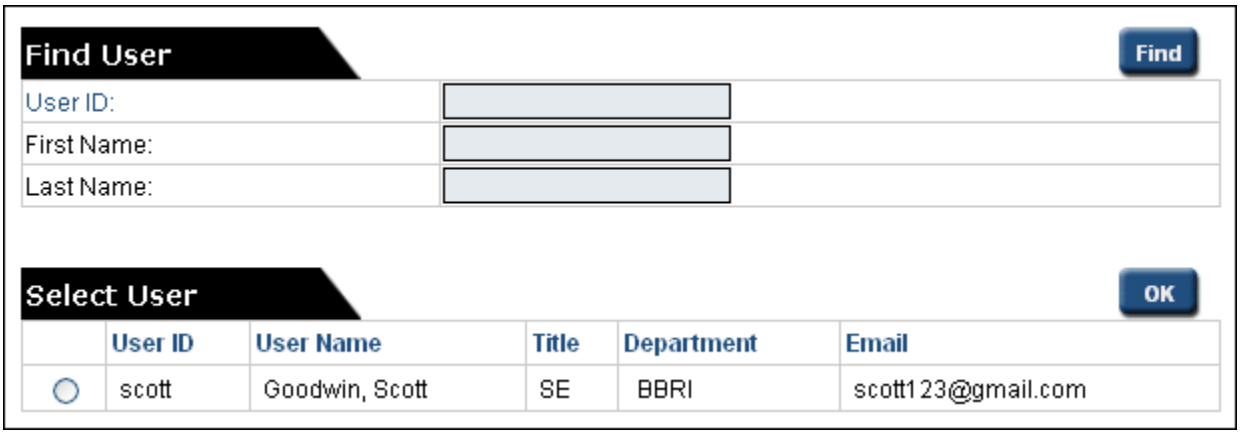


Enter the title of your research study in **Study Title** textbox. Be sure ADMIN REV is selected and choose HCHD Administrative Review Research Application. The personnel information will display below.



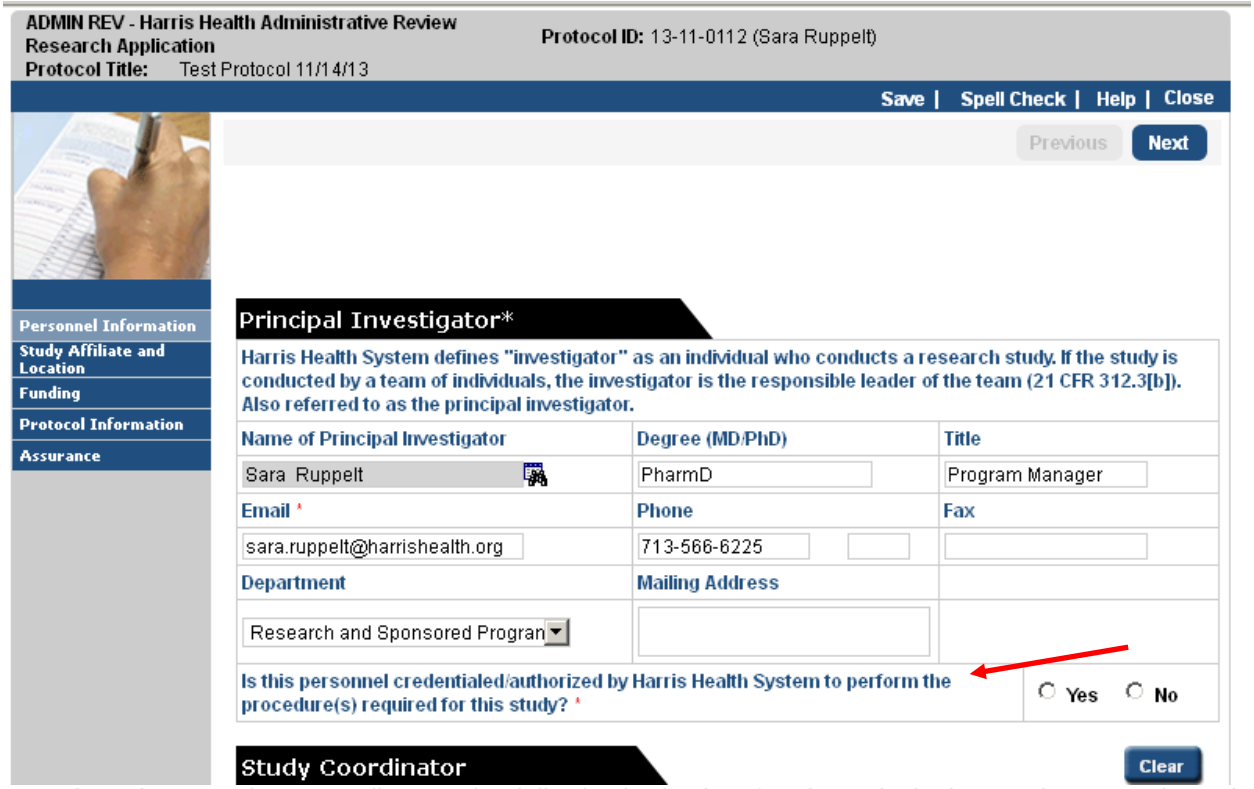


To add a Principal Investigator, click the binocular icon near the **Name** field. **Find User** popup is displayed.



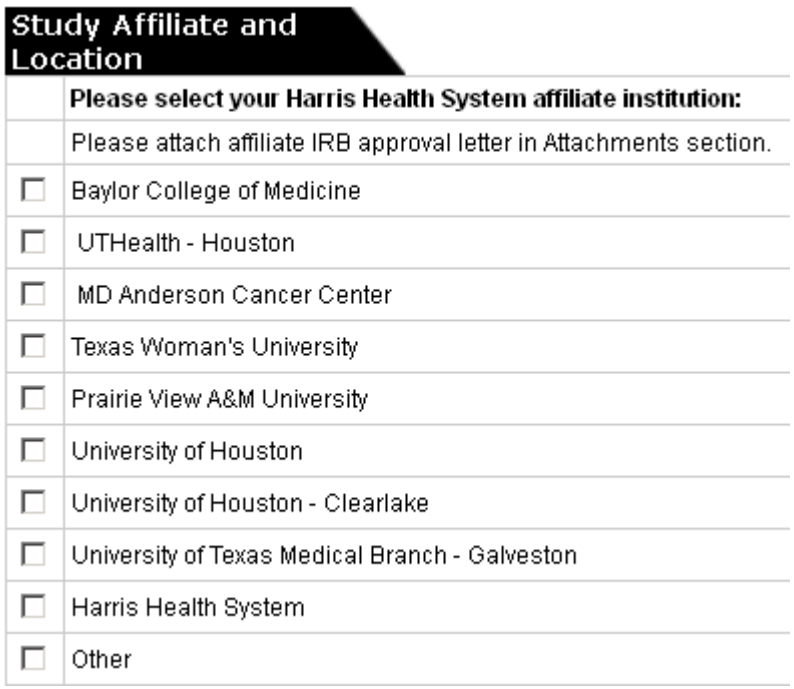
Search the user, select and click OK. Selected user's name and other details are displayed in the role section. Only users who have registered for an eProtocol account are searchable in the system. If you are unable to locate a particular user, please contact the user or the Harris Health System Office of Research & Sponsored Programs to verify registration.

Add other users to the protocol following the steps above. Only the Principal Investigator field is mandatory. Study Coordinator and Administrative Contact fields can remain empty. Click **Create**. The Harris Health application opens in a new window. **If you have pop-up blocker software installed on your computer, you must configure the pop-up blocker software to allow pop-ups within eProtocol.**



Complete the question regarding credentialing/authorization for the Principal Investigator and Study Coordinator. Questions regarding the authorization process should be directed to Tam Perkins at Tamineshia.perkins@harrishealth.org or 713.566.6914.

Navigate through the application using the **Next** button or the menu on the left-hand side.



Choose your affiliate institution from the list provided. Do not check “Harris Health System” unless you are a Harris Health employee.

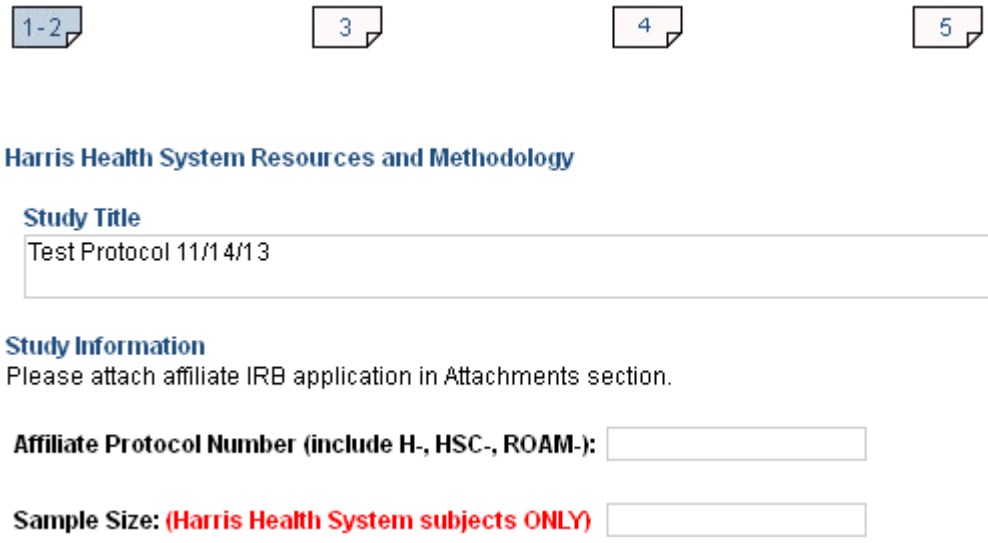
Choose all study locations and enter the specific unit or clinic if prompted. Click **Next**.

	STUDY LOCATION (we strongly recommend that you discuss this study with applicable Unit/Health Center representatives) (Check all that apply)
☐	Ben Taub General Hospital Unit/Specific Clinic(s)
☐	Lyndon B. Johnson General Hospital Unit/Specific Clinic(s)
☐	Quentin Mease Hospital Unit/Specific Clinic(s)
☐	Thomas Street Health Center
☐	Acres Home Health Center
☐	Aldine Health Center
☐	Baytown Health Center
☐	Casa De Amigos Health Center
☐	Gulfgate Health Center
☐	MLK Health Center
☐	Northwest Health Center
☐	Vallbona Health Center (formerly People's Health Center)
☐	Settegast Health Center
☐	E.A. Squatty Lyons Health Center
☐	Strawberry Health Center
☐	School Based Clinics Unit/Specific Clinic(s)

If the research protocol is not funded, check **None** at the top of the page. If the protocol is funded, click **Add** under the appropriate category, chose the name of the appropriate funding agency from the drop down box and click **Save**. Please note that if the funding agency is not listed, there is an "Other" option in the list under each category. Click **Next**.

The Protocol Information portion of the application is comprised of 5 sections; Resources and Methodology, Recruiting and Advertising, Informed Consent and Attachments. You can navigate through these sections by clicking **Next** or clicking the numbers across the top.

The Study Title will populate from the information added at protocol creation. Enter the affiliate protocol number and the sample size of Harris Health participants only.



Section 1 and 2 inquire about the use of Harris Health resources for **research-specific** services. Please note that it is important these questions be answered correctly as this information is used for the Harris Health financial agreement.

1. Harris Health System Resources

Will this study involve the use of any research-specific resources or services from Harris Health System? ☑ Yes ☐ No

Indicate which of the following services will be used for research-specific procedures only. Select all that apply.

- ☑ Pharmacy Services
- ☐ Pathology/Laboratory Services
  - ☐ a. Data Report Search
  - ☐ b. Block/Slide/Sample Retrieval
  - ☐ c. Stain/Test or Procedure
  - ☐ d. Other
- ☐ Nursing Service
- ☐ Radiology Service
- ☐ Electronic extraction of data by Information Technology (IT). Contact the Office of Research at research@harrishealth.org or 713.566.6914 for an IT Research Report Request (attach the completed form in the Attachments section).
- ☐ Nuclear Medicine Service
- ☐ Health Information Management (Chart Review)
- ☐ Other (specify):

2. Methodology

☐ **Please check here if the protocol does not involve patient care or clinical interventions (e.g. medical record review, employee survey research).**

a) Specify which procedures and/or diagnostic tests are considered routine clinical care.

All laboratory assessments and imaging procedures are considered standard of care.

b) Specify the research-specific procedures and/or diagnostic tests (not routine clinical care) that would be provided by Harris Health System and if applicable, reimbursed by the study sponsor. If none, please indicate.

Dispensing of study drug will be done by the Investigational Drug Service.

Click **Next**.

Some investigators utilize Harris Health for recruitment purposes only and interested patients are asked to visit a non-Harris Health location for the informed consent process and all research interventions. If this is the case, answer "Yes" to the first question.

If recruitment flyers will be posted within a Harris Health facility, please upload the document(s) in the Attachments section (Section 5). Harris Health will stamp the flyers once the application is approved. Please note that only flyers to be posted must be stamped. Study brochures provided to potential participants do not require the Harris Health stamp of approval.

3. Recruiting and Advertising

Are you requesting access to Harris Health facilities for recruitment purposes ONLY? Patients will be required to undergo all research interventions at an off-site, non-Harris Health location. ○ Yes ◉ No

Will you use recruitment flyers to be posted in a Harris Health System facility? ○ Yes ◉ No

In the Attachments section, please upload a copy of all recruitment flyers that will be posted within Harris Health System.

Section 4 is related to the process of informed consent. The Harris Health injury disclaimer MUST be included in all English and fully translated Spanish consent documents. The application will be returned if the disclaimer is not present.

4. Informed Consent

The following injury disclaimer must be included in all English and Spanish consent documents.

"In the event of injury resulting from this research, (your institution) and/or the Harris Health System (name of Harris Health facility or facilities) are not able to offer financial compensation nor to absorb the costs of medical treatment. However, necessary facilities, emergency treatment and professional services will be available to you, just as they are to the general community."

a) Will informed consent be obtained from participants in this study? ☑ Yes ☐ No

b) Will Spanish-speaking only participants be included in this study? ☑ Yes ☐ No

If no, please provide a scientific rationale for excluding this population.

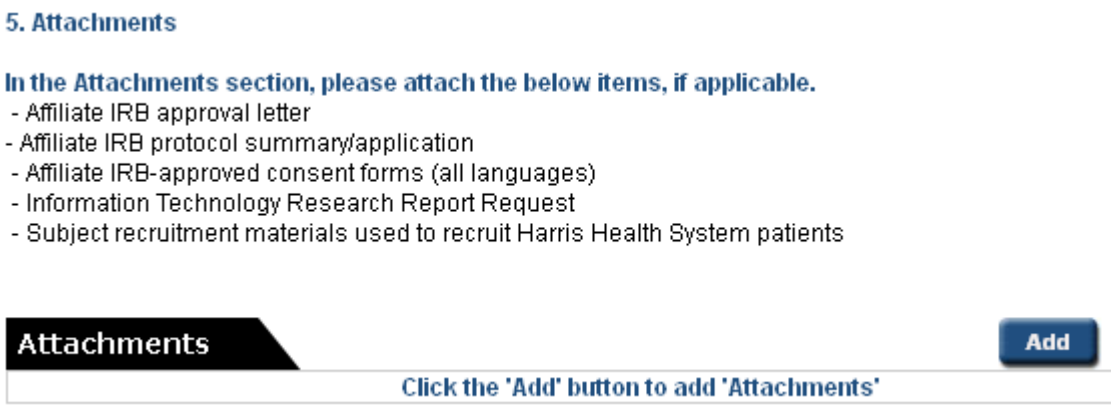
Are foreign language consent forms, other than Spanish, being used for this study (e.g. Arabic, Chinese, Vietnamese)? ○ Yes ◉ No

In the Attachments section, please upload all IRB-approved informed consent documents.

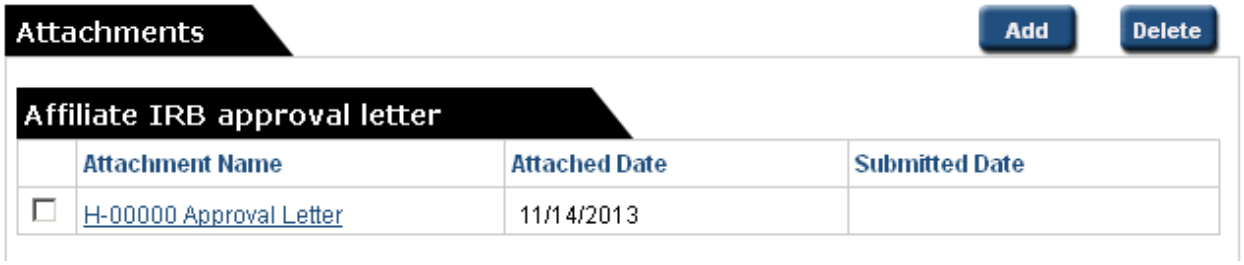
For studies enrolling Spanish-speaking only participants, please ensure a translated full Spanish consent document is uploaded in the Attachments section. If the Spanish consent document is pending approval by the affiliate IRB, Harris Health will grant a 3-month approval, at which time submission of the translated document is required for continued approval.

******Spanish consent documents submitted following the initial approval must be submitted via a Continuing Review form, not an Amendment form.******

Please ensure all required documents are uploaded in the Attachments section. Applications will be returned if required documents are missing. Click **Add**, select the appropriate Type from the drop down list, browse for the applicable file and click **Save**.



The saved document(s) will appear in the Attachments section. You can choose to add additional documents or delete documents that have been uploaded. Please note that an application cannot be submitted without at least one attachment in Section 5.



Once all required documents have been uploaded, click **Next** to proceed to the Assurance page.

Check the box at the bottom of the page, indicating that the Principal Investigator has read and agrees to abide by the assurances listed.

Assurance

The Principal Investigator of this study provides the following assurances:

The eProtocol application submitted for this study is complete and accurate.

The PI acknowledges responsibility for the conduct of this project as described in the Harris Health System Administrative Review application.

The PI has evaluated the protocol and determined that s/he has sufficient resources to conduct the study as submitted and necessary to protect subjects who enroll in the study.

All co- or sub-investigators, study coordinators, and other research personnel to whom the PI delegates study-related responsibilities will receive thorough training in human subjects protections as well as in the specific details of study procedures.

The PI will not begin the study until s/he has received notification of final Harris Health System Administrative approval.

The PI acknowledges his/her responsibility for the accuracy of all documents submitted to the Harris Health System Office of Research on his/her behalf.

The PI will comply with all Harris Health System Office of Research requests regarding the status of the study.

The PI will seek and obtain Harris Health System Administrative approval for all study modifications.

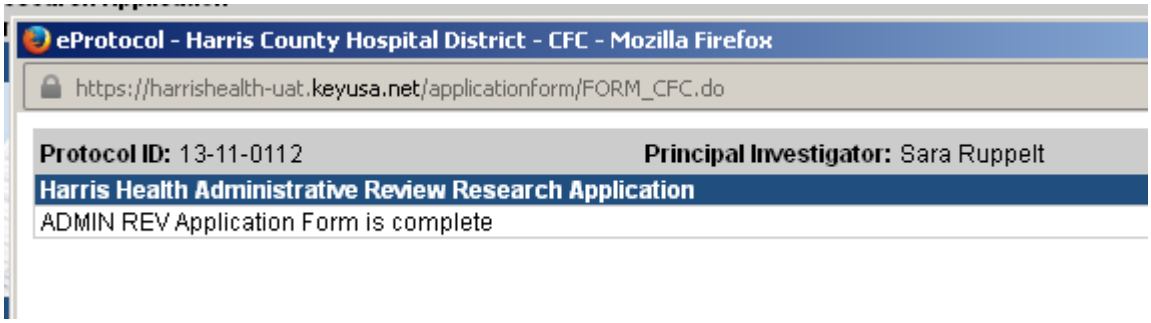
The PI will promptly report any unexpected or otherwise significant adverse events or unanticipated problems or incidents that may occur in the course of this study.

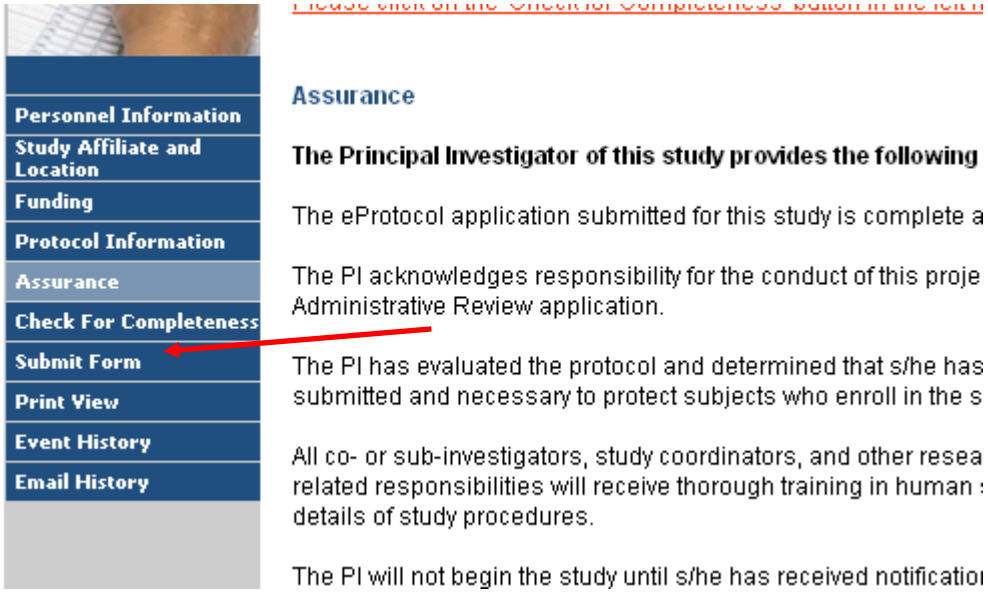
The PI will notify the Harris Health System Office of Research when his/her research has been completed or terminated.

☑ **The Principal Investigator has read and agrees to abide by the above obligations.**

Please click on the 'Check for Completeness' button in the left navigation to check if your application is complete.

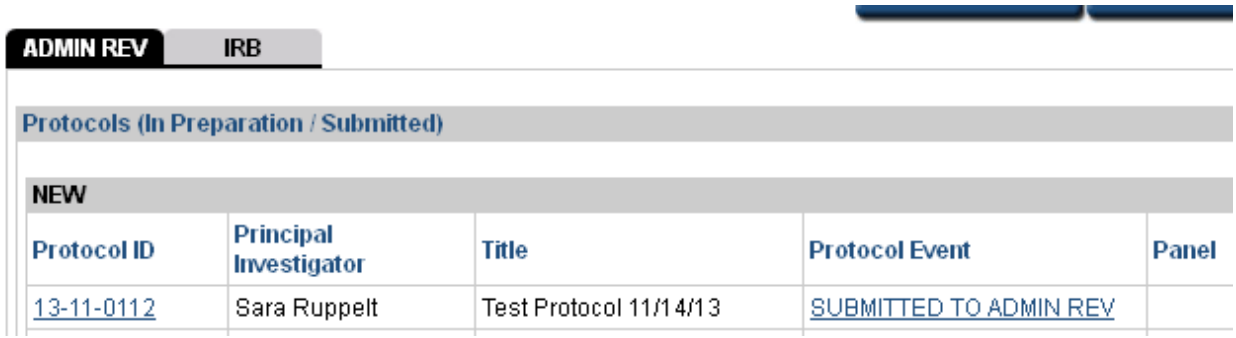
Click **Check for Completeness** in the left navigation to finalize the application. A pop-up box will appear indicating any sections of the application that are incomplete.





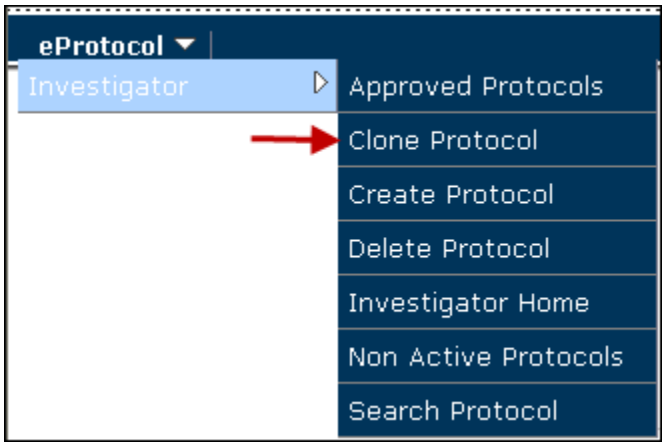
Once the application is complete, click **Submit Form** in the left navigation. Confirmation pop-up is displayed; click **Yes**. An email will be sent to the Office of Research & Sponsored Programs, as well as all personnel listed on the application, confirming submission.

Protocol ID is assigned to the newly created protocol for identification. You can find the protocol added for ADMIN REV on the **Investigator Home** page with the appropriate event indicated.

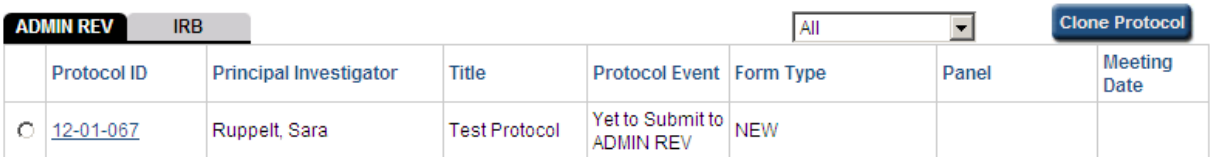


4.2. Clone Protocol

Instead of creating a new protocol, you can clone an existing protocol, if there are little or no modifications. Point to **Investigator** on top menu and click **Clone Protocol**. **Clone Protocol** page is displayed.



Select a protocol and click **Clone Protocol**. Confirmation popup is displayed. Click **Yes**. New protocol is created and added to the **Home** page. New protocol created is opened in a new window.

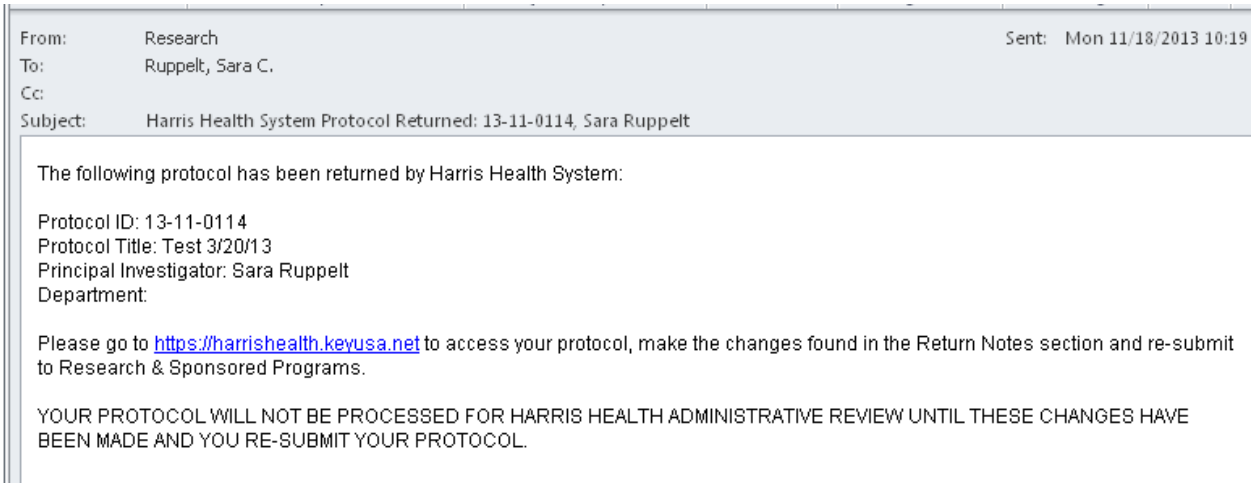


Note:

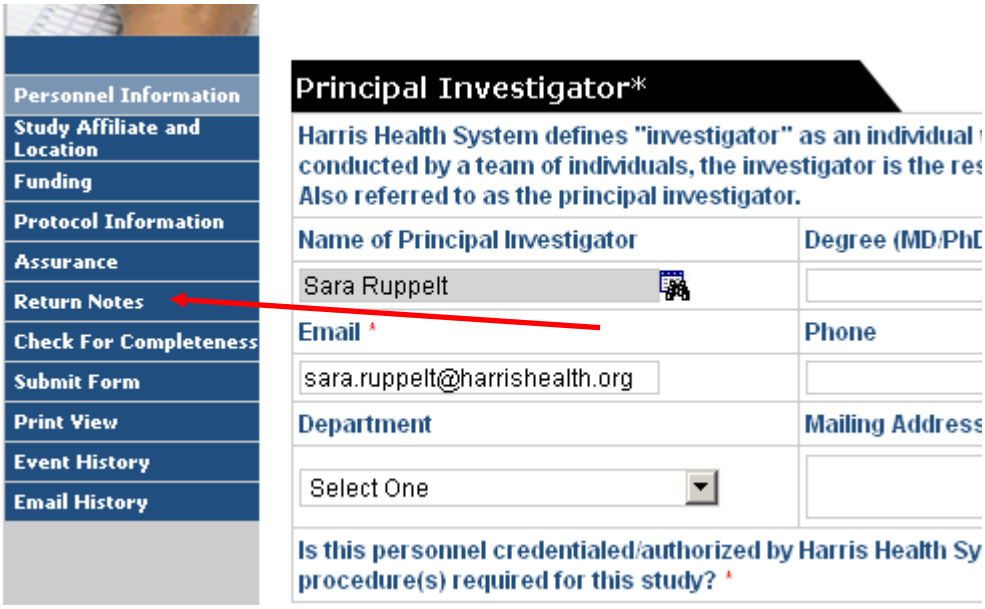
- Click the **Protocol ID** to view/edit the protocol.
- Click **Column Heads** to sort the protocols in ascending/descending order.

4.3. Returned Protocols

If the Office of Research & Sponsored Programs determines the application is incomplete, it will be returned. An email will be received, notifying research personnel of the returned application. The returned application will appear on the Investigator **Home** page with **Protocol Event** Resubmit the Protocol.



To access the Return Notes, click on the **Protocol ID** to open the application and click **Return Notes.**



Information regarding the reason for the returned application will display. Please note that you cannot respond to a Return Note. If you have questions about the information entered, contact Research & Sponsored Programs.

Once the requested changes have been made, resubmit the application using the **Submit Form** menu option in the left navigation.

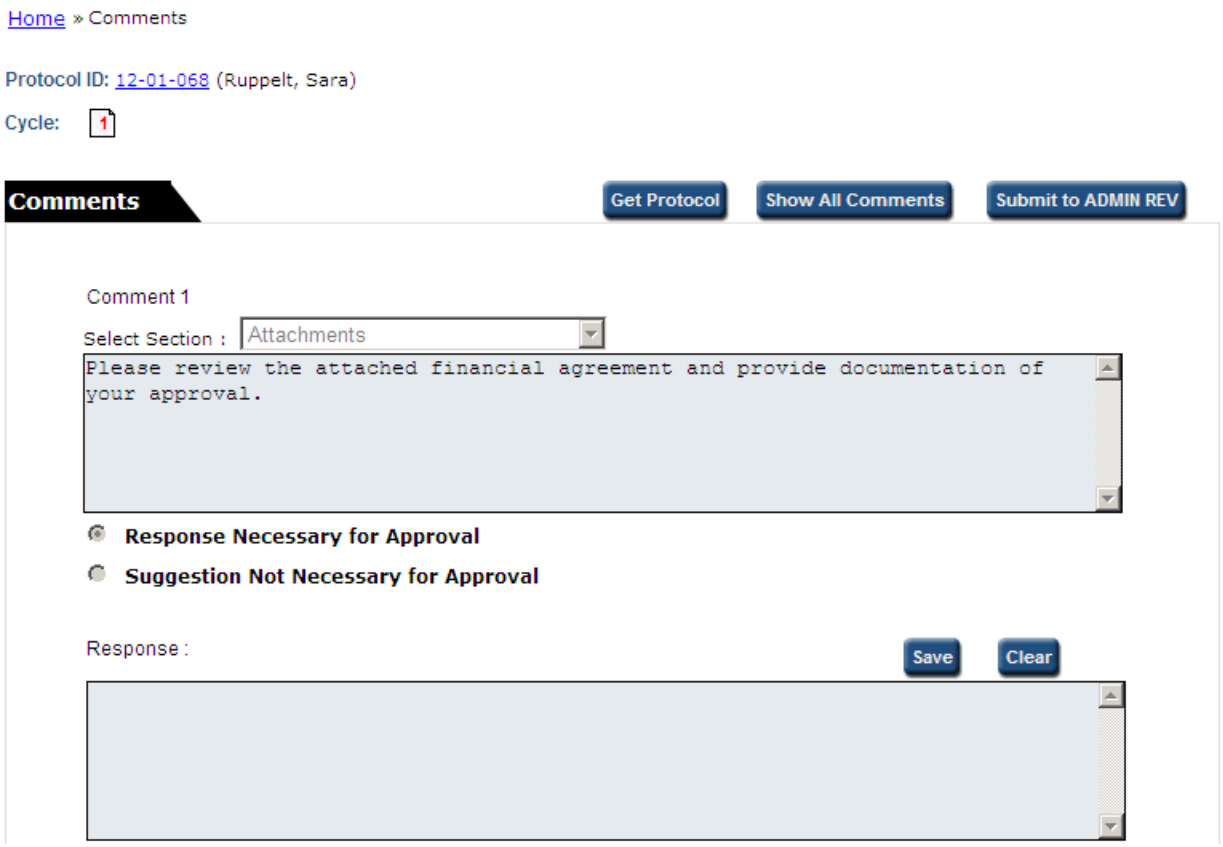
4.4. Responding to Comments and Approving the Financial Agreement

When the Office of Research & Sponsored Programs reviews the application, clarifications or additional information may be needed. In such cases, the Comments function is used, as unlike the Return Notes function, this allows for dialogue between research personnel and the Office of Research & Sponsored Programs.

Follow these steps to write and send responses to comments. **This process will also be used to document the investigator's approval of the financial agreement.**

Navigate to **Home** page.

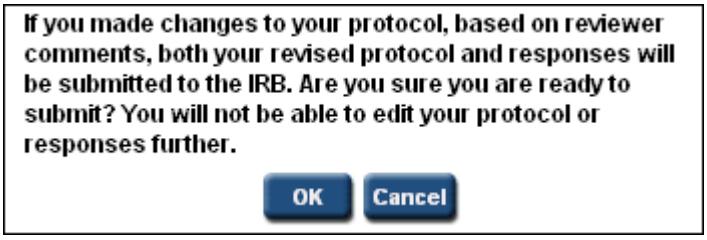
When you receive comments from the Office of Research & Sponsored Programs, the event of the protocol form changes to 'Comments Received (Cycle 1)'. To view and respond to comments, click the event. You are directed to **Comments** page, where you can view the comments and the sections commented on.



To review the financial agreement, click **Get Protocol** and the protocol will open. Click on **Protocol Information** and navigate to the **Attachments** section (section #5).

Open the attached financial agreement and review. Once reviewed, close the protocol and you will be returned to the **Comments** page. In the **Response** textbox, enter your response (e.g. "Financial agreement reviewed and approved") and click **Save**.

Documentation of approval of the financial agreement by the Principal Investigator is required. Document your approval in the **Response** section and click **Submit to Admin Rev**. Confirmation popup is displayed.



Click **OK**. Your responses are sent to the Office of Research & Sponsored Programs.

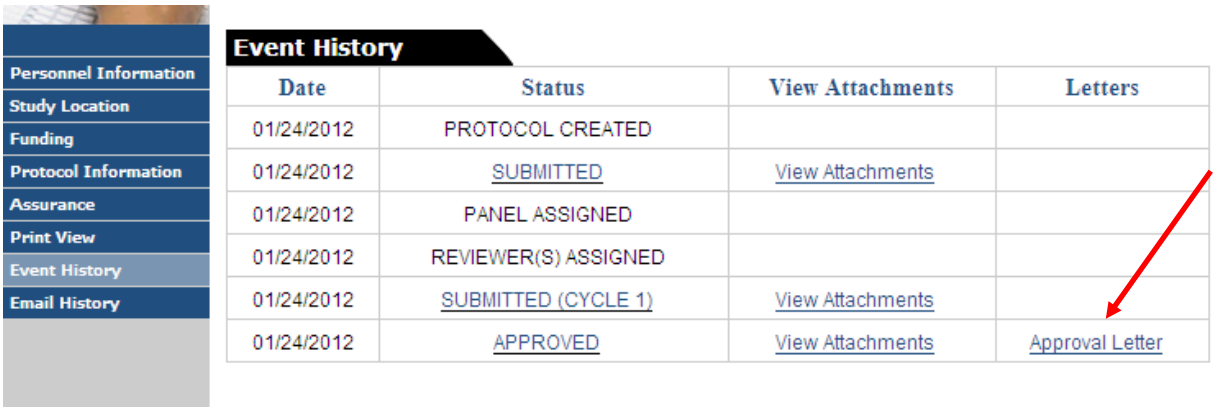
Note:

- Click **Get Protocol** button to view/edit the protocol. You can edit the protocol details only if the Office of Research & Sponsored Programs has given you edit permissions to the protocol.
- If you receive additional comments from the Office of Research & Sponsored Programs after you send the first cycle of responses, they are displayed as new cycles (e.g. cycle 2, cycle 3, etc.) on the **Home** page.
- Click **Cycle Number** to view the respective Comments/Responses. Present cycle number is shown in red color.

4.5. Accessing the Approval Letter and Harris Health Stamped Documents

Once the protocol has been approved by the Office of Research & Sponsored Programs, the protocol will be listed under the **Approved Protocols** section on the Investigator **Home** page.

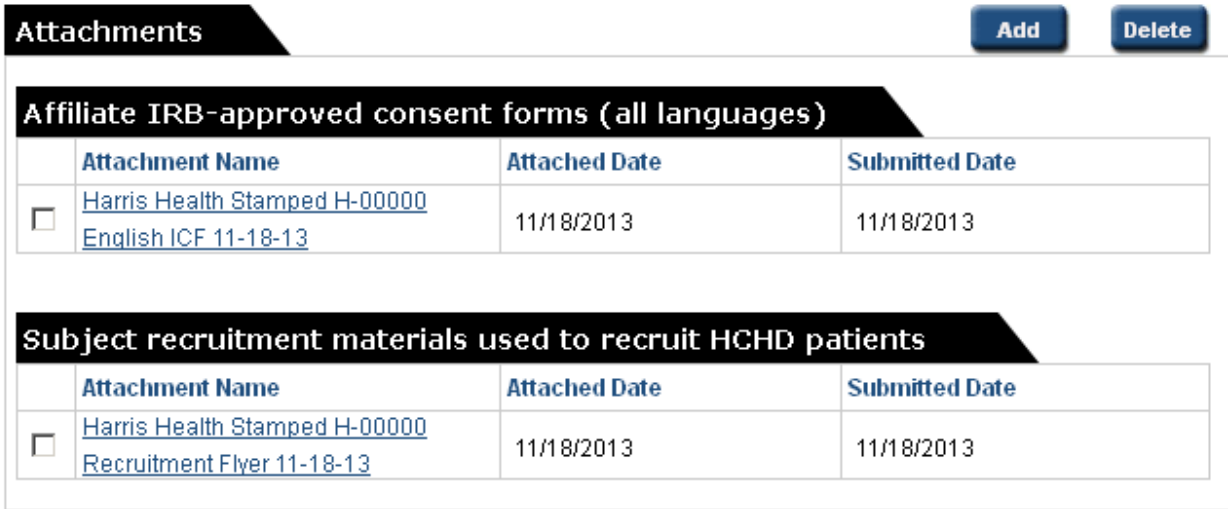
To access the approval letter, click on **Protocol ID** and **Open in View Mode**. Go to **Event History** and click on **Approval Letter** in the **Letters** column.



Harris Health stamped consent documents and recruitment flyers are uploaded in the Attachments section of the approved application. From the Investigator **Home** page, click on **Protocol ID** and **Open in View Mode**. Navigate to the Attachments section (section 5) of **Protocol Information.**

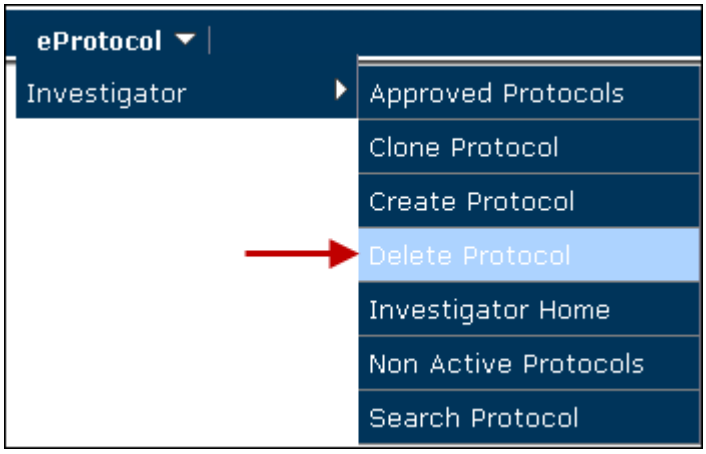
5. Attachments

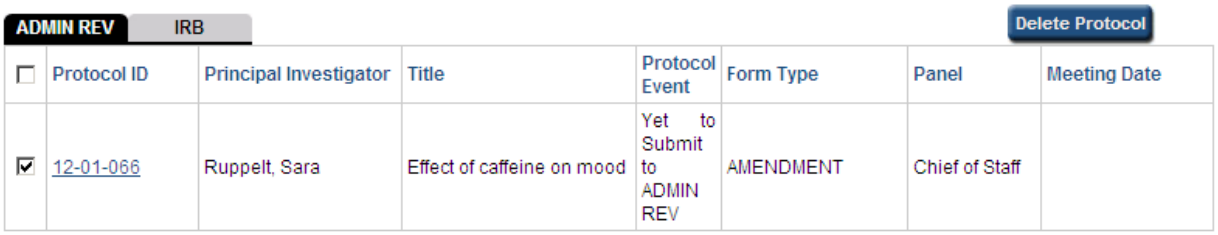
In the Attachments section, please attach the below items, if applicable.
- Affiliate IRB approval letter
- Affiliate IRB application
- Affiliate IRB-approved consent forms (all languages)
- Information Technology Research Report Request
- Subject recruitment materials used to recruit Harris Health System patients



4.6. Delete Protocol Form

You can delete a protocol form before it is submitted to the Office of Research & Sponsored Programs. Point to **Investigator** on top menu and click **Delete Protocol**. **Delete Protocol** page is displayed.

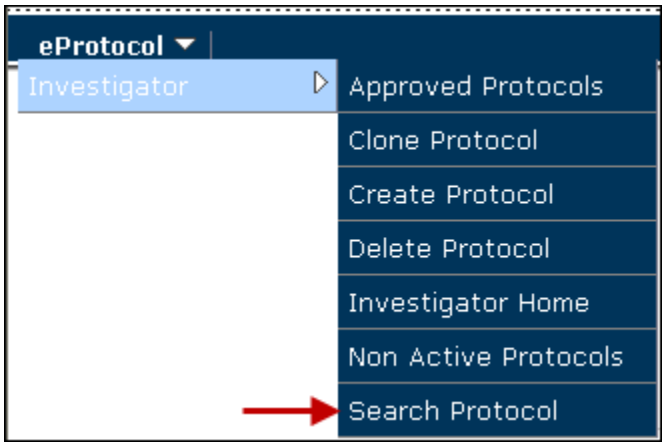




A list of protocols that have not been submitted is displayed. Select the protocol(s) you want to delete and click **Delete Protocol**. Confirmation popup is displayed. Click **Yes**. Please note that only forms not yet submitted can be deleted. If you would like to delete a submitted form, contact the Office of Research & Sponsored Programs and the form can be returned for deletion.

4.7. Search Protocol

You can search for protocols under your purview using the search protocol feature. Point to **Investigator** and click **Search Protocol**. **Search Protocol** page is displayed.

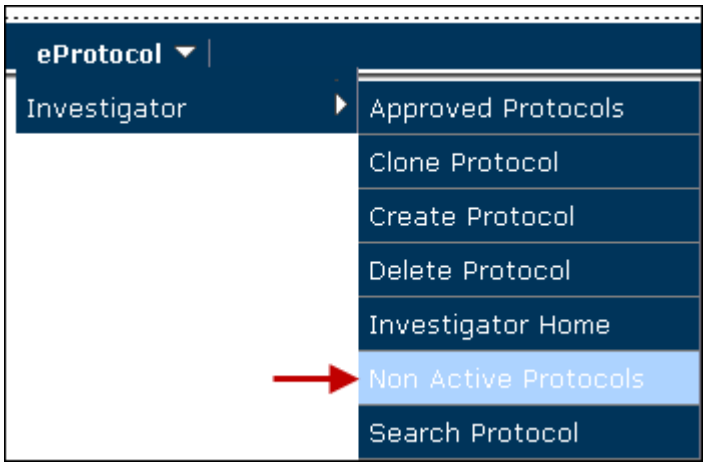


Enter your search criteria in one or more fields and click **Search**. Search results are displayed with all the related documents of the specified search criteria.

You can also save the search results. To save the search results, click **Save**. **Search Criteria** textbox is displayed. Enter a name for your search result and click **Save**. Search results are saved with the given name. You can refer to these search results any time later by selecting the name given (to the search result) from **Selected Search Criteria** dropdown.

4.8. Non Active Protocols

The protocols that are inactive and can no longer be conducted are displayed in **Non Active Protocols** list. Point to **Investigator** on top menu and click **Non Active Protocols**. **Non Active Protocols** page is displayed.



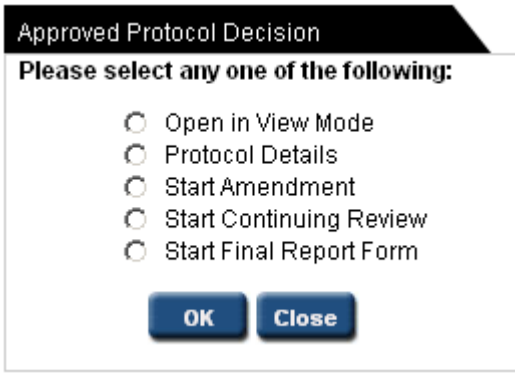
You can also find the list of inactive protocols on your dashboard in **Non Active Protocols** section.

The list of protocol statuses which are considered as non-active and their meanings are given below.

Closed – The protocol is closed by the Office of Research & Sponsored Programs.
Not Approved – The protocol is not approved by the Office of Research & Sponsored Programs.
Expired– The protocol is expired after the expiration date.

In general, the non-active protocols are read-only and no edits can be done.

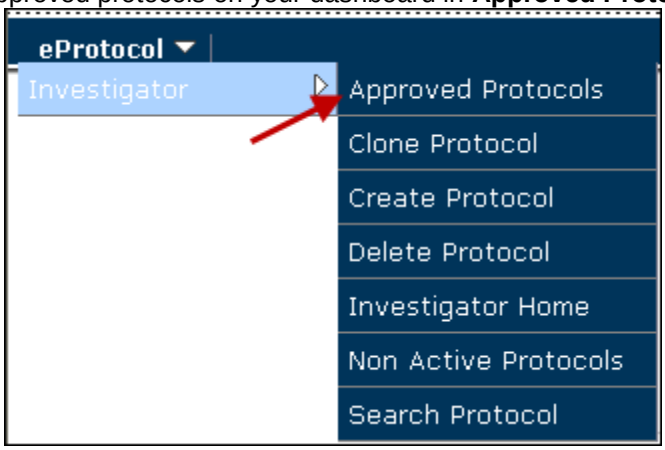
You can create a Continuing Review or Amendment form for an expired protocol. Click on **Protocol ID**. **Non Active Protocol Decision** popup is displayed as shown below.



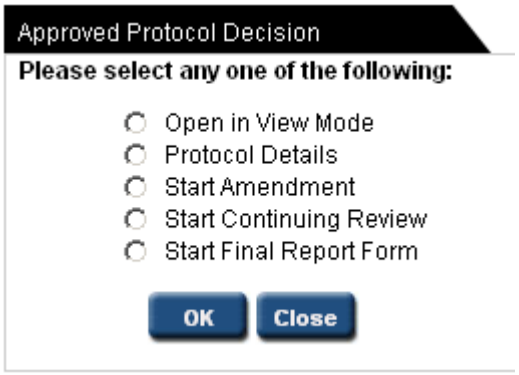
Select the form option and click Create. The form is created and displayed on your dashboard. The protocol will remain in non-active state (i.e. expired state until the form created is approved by the Office of Research & Sponsored Programs). Once the form is approved, the protocol becomes active and appears in Approved Protocols list. The expired protocol disappears from the Non Active Protocols section.

4.9. Creation and Submission of Additional Forms for an Approved Protocol

For an approved protocol you can create different associated forms such as an Amendment, Continuing Review, and Final Report form. Point to **Investigator** on top menu and click **Approved Protocols**. You can also find the list of approved protocols on your dashboard in **Approved Protocols** section.

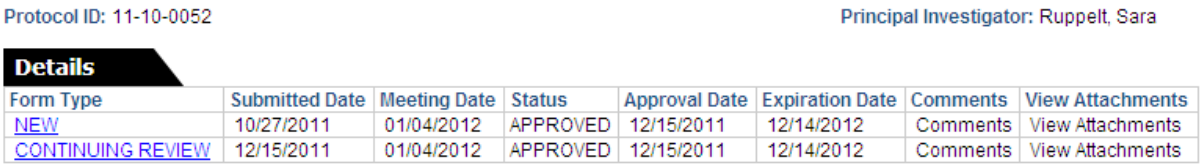


Click **Protocol ID**. **Approved Protocol Decision** popup is displayed with various options



Select the appropriate option and click **OK**. The selected form is created and displayed in a new window.

To view the details of different forms created for the protocol, select **Protocol Details** and click **OK**. You are directed to **Details** page where you can view the complete form history of the protocol.



Form Type	Submitted Date	Meeting Date	Status	Approval Date	Expiration Date	Comments	View Attachments
NEW	10/27/2011	01/04/2012	APPROVED	12/15/2011	12/14/2012	Comments	View Attachments
CONTINUING REVIEW	12/15/2011	01/04/2012	APPROVED	12/15/2011	12/14/2012	Comments	View Attachments

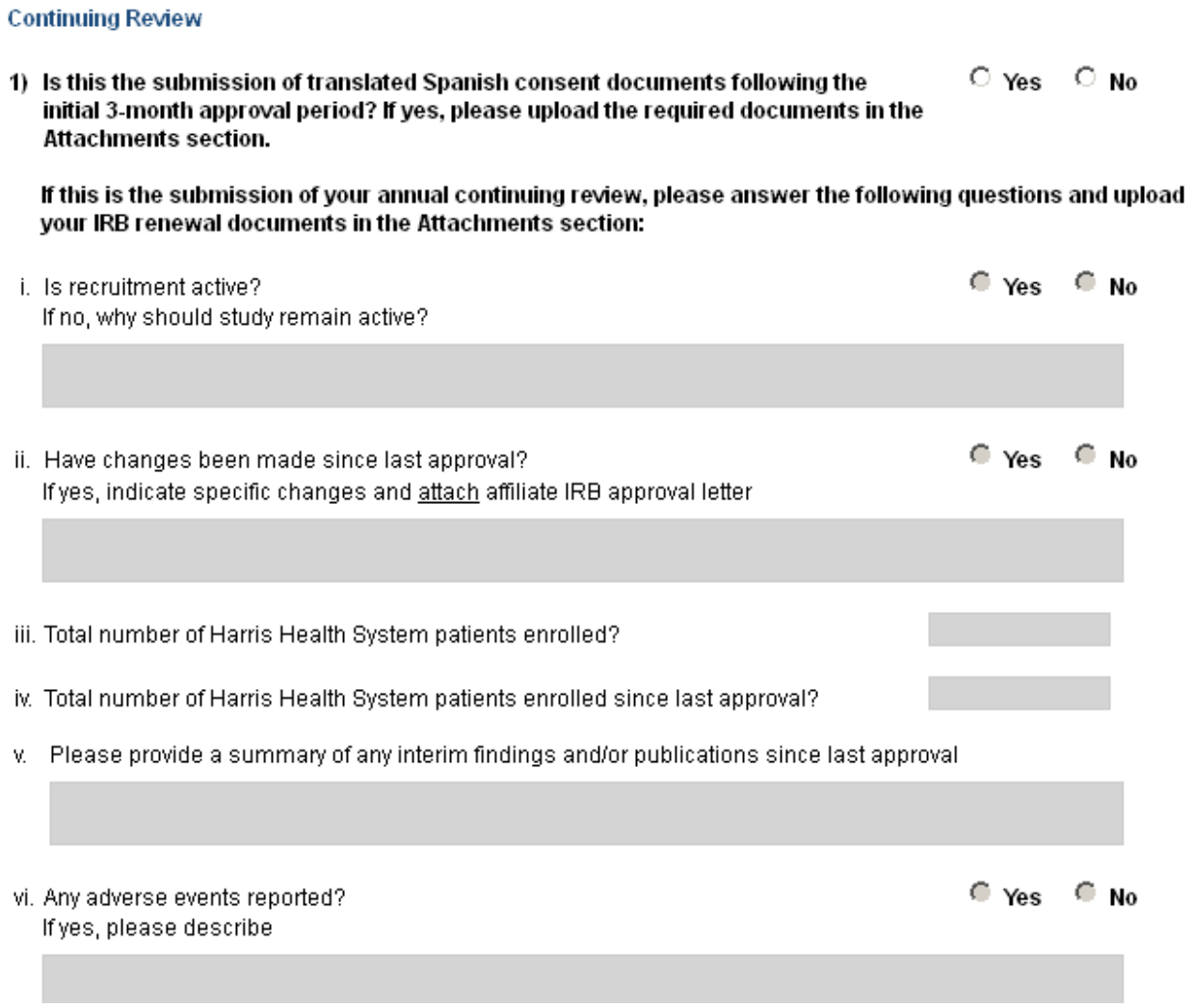
4.9.1. Amendment Form

If you select **Start Amendment**, you are directed to **Amendment** page. Complete the form, upload all relevant IRB documents (e.g. updated consent documents, protocol summary…) and click **Submit Form**.

When an Amendment form is created for a new protocol, you cannot create this form again until the previously created form is approved or deleted.

4.9.2. Continuing Review Form

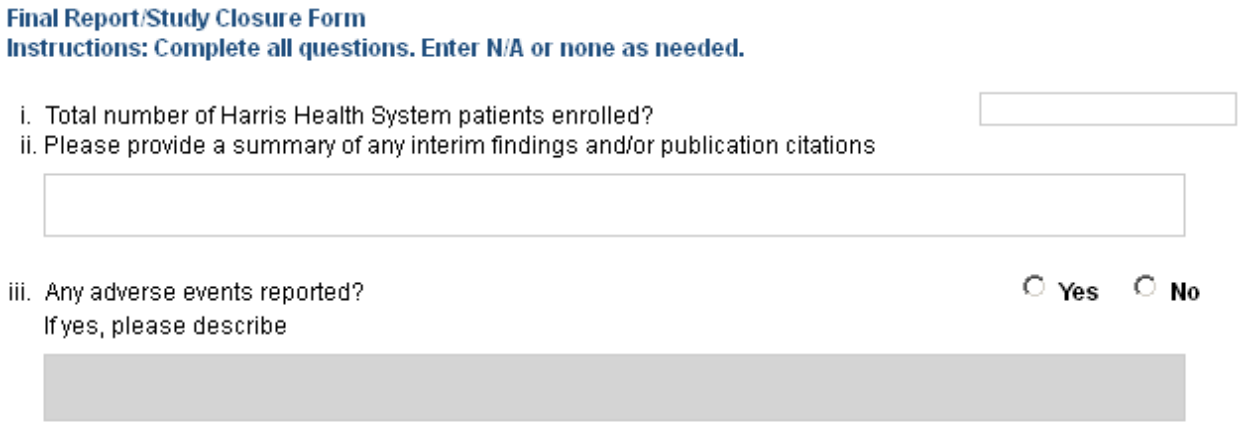
If you select **Start Continuing Review**, you are directed to **Continuing Review** page. Complete the form, upload all relevant IRB documents (e.g. updated consent documents, renewal letter, protocol summary…) and click **Submit Form**.



When a Continuing Review form is created for a new protocol, you cannot create this form again until the previously created form is approved or deleted.

4.9.3. Final Report Form

If you select **Start Final Report Form**, you are directed to **Final Report** page. Complete the form and click **Submit Form**. Please note that Attachments cannot be uploaded when completing a Final Report form. All information must be entered into the form itself.



When a Final Report form is created, options to create all other forms are removed in **Approved Protocol Decision** popup. When the form is approved, the protocol will be made inactive and moves to **Non-Active Protocols** list.

4.9.4. Serious Adverse Events (SAEs) / Unanticipated Problems (UPs)

All SAEs and UPs that involve Harris Health participants must be reported to the Office of Research & Sponsored Programs following submission to the IRB. At this time, SAEs and UPs are not reported via eProtocol. Reports should be emailed securely to research@harrishealth.org. Please attach IRB documentation of the report details.

5. Additional Resources & Contact Information

Visit the Harris Health Office of Research & Sponsored Programs website for additional information:
https://www.harrishealth.org/en/about-us/research/pages/default.aspx

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