iMedRIS
Integrated Medical Research Information Systems

# The Basics of Study Management
# For Study Coordinators

**Version 8.02**

Included:

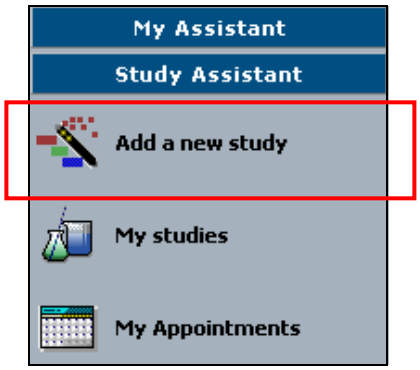
1. Add a New Study
   a. Application
   b. Initial Review Transition
   c. Notifying PI to Signoff
2. Managing A Study
3. Adding a Continuing Review form
4. Adding an Adverse Event form
5. Review Response Form

# Chapter 1: Adding a new Study

## *A. Application*

The basics of Adding a Study begin first of all with completing the Study Application. If you are using Study Management with the IRB Assistant to create a study within the iRIS System, you must first complete the Study Application. If you are using Study Management alone, you may still fill out the application but will not be able to submit it to the Review Board.

To begin, click Add a Study under Study Assistant.




This brings you to the first of three "Study Shell screens." After the first three initial screens of this application have been completed, a new study will be created in the system. You can exit the application at any time. Some of the fields in the study application are required. In order to Save and Continue to the next section of the application, data must be entered into these required fields. Note that you may return to the application and edit these fields any time before submitting to the review board. After an application has been submitted it can be viewed but cannot be edited.

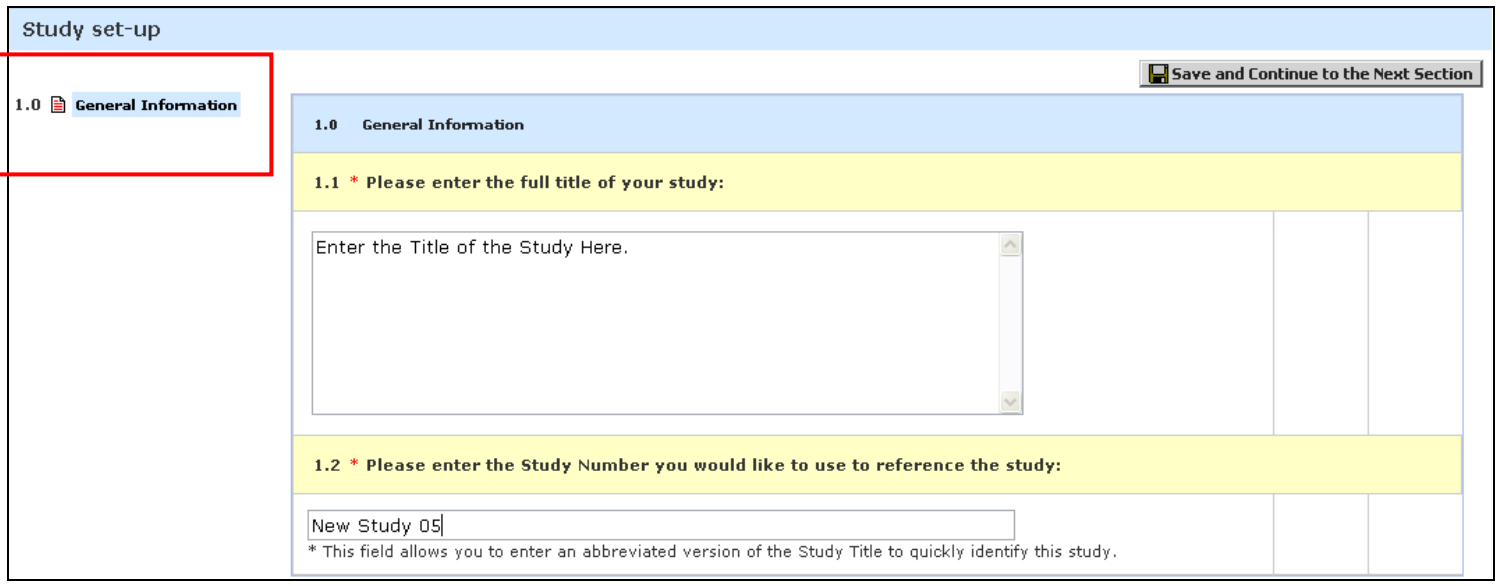
## 1.0 General Information

The first of the Study Shell screens is the General Information screen. This screen regards specifications of basic information like the Study Title, Study Number, etc. of the Study.

When constructing the Application it is important to remember that if you desire to return to the previous section, DO NOT hit the Back button on your Internet Browser; to navigate to the previous section, click on the link for that section in the Navigation pane.

Some of the sections will contain help files . Click on the icon to open a window that will list available information about a question.

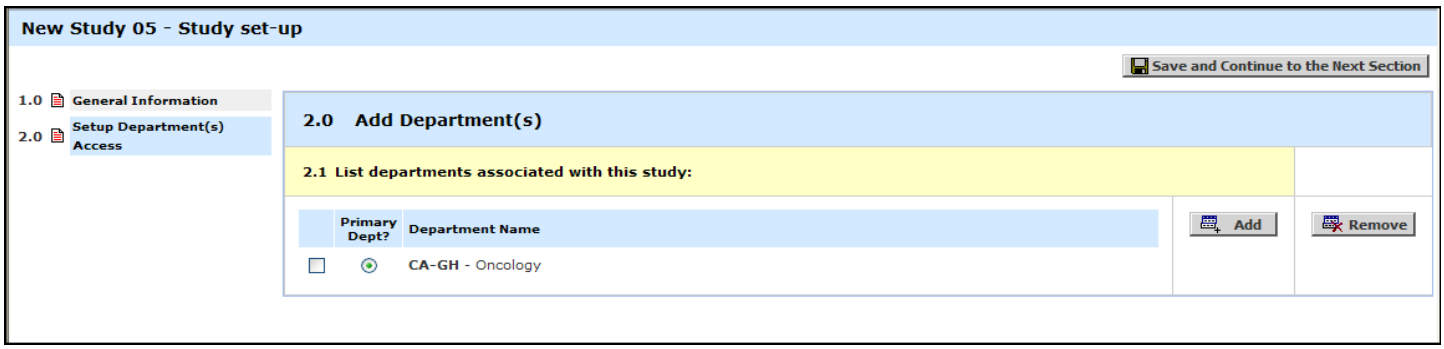
On the left side of the screen, a Navigation pane builds as you build the application. Click on the link of a section at any time to move to that section. The section you are in will appear blue, while the other sections will appear gray.




Click **Save and Continue to the Next Section** button in the upper right corner of the screen after the Study Title and Study Number have been added to this section.

## 2.0 Add Department(s)

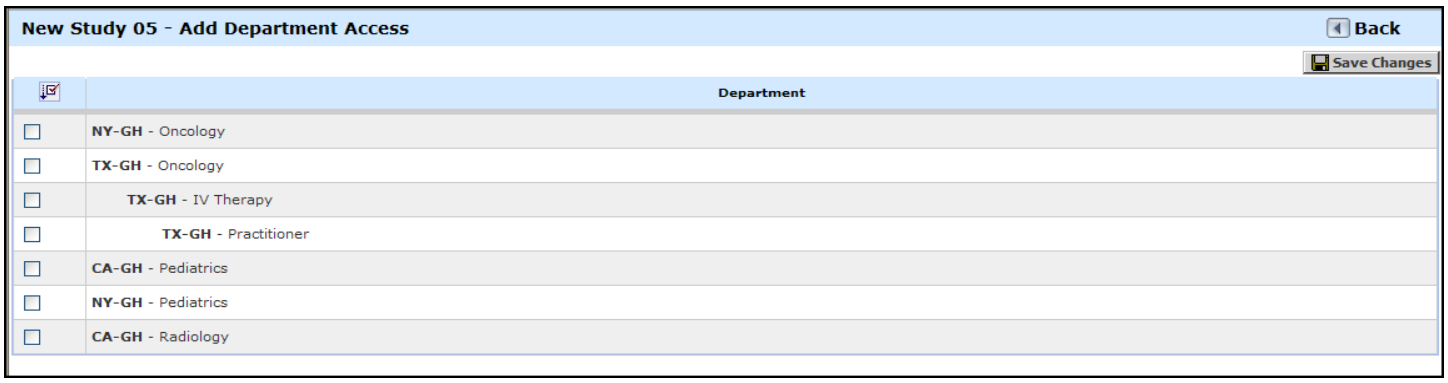
The second of the Study Shell Screens involves the setting up of departments that will have access to this study. You want to select any department the study is involved with and note that study will be linked to the department for report purposes. It is important to associate the correct departments to the study, for the reporting purposes Department Administrators will be able to pull data from the study into certain reports based on the Department(s) associated to the study..



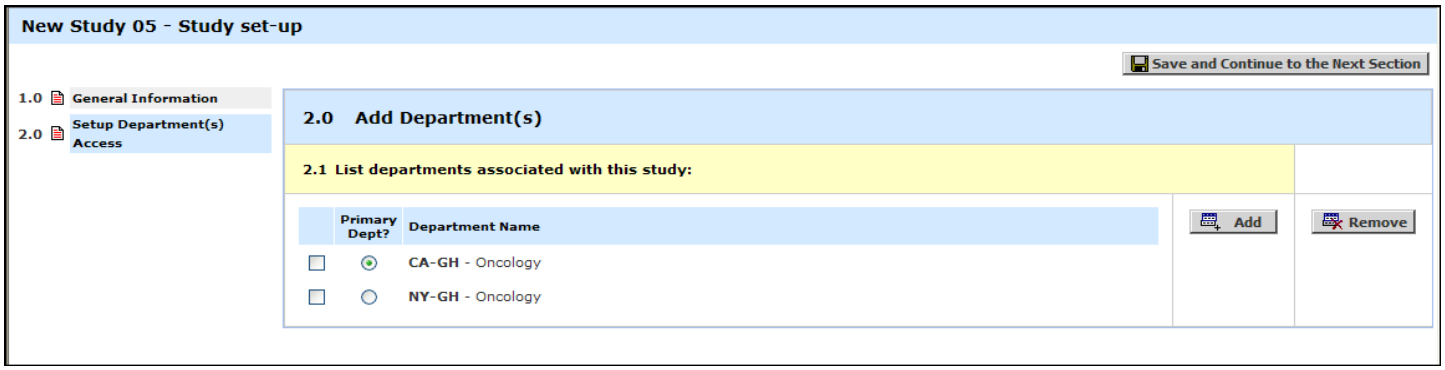

To associate another department to this study, click the Add button.

The departments will display in a list with the child/sub departments indented under their corresponding parent departments. Choose a department (s) and click the check box next to the desired department (s) and click the **Save Changes** button when you are ready to add the selected departments to the study.

There is the ability to select/deselect all departments by clicking the  icon at the top of the checkboxes column.



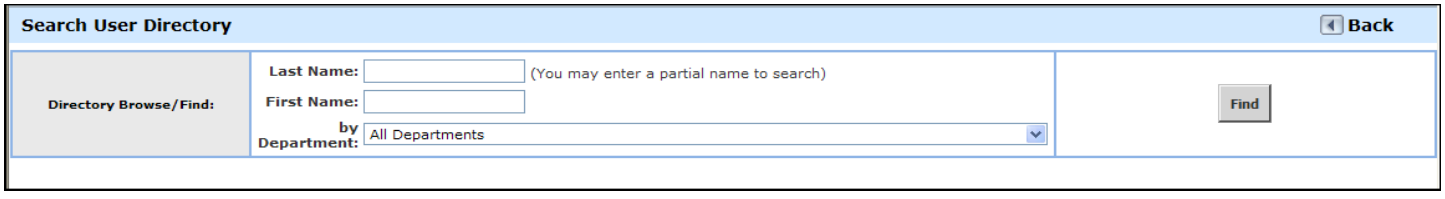

The added department(s) will now show in the table. To remove a department, click the **checkbox** next to the appropriate department then click the **Remove** button. You can change the default department, if necessary. To do this, click the radio button for the department under the Primary Dept. column. Only one primary department can be selected at one time.



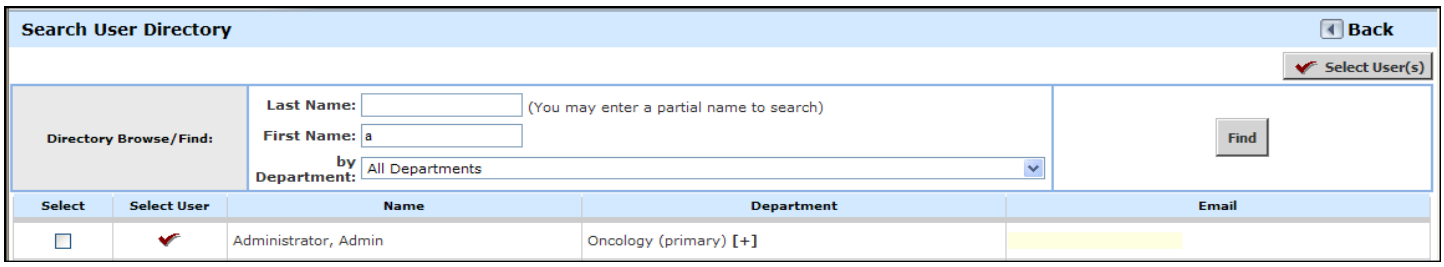

After adding the necessary departments, click the Save and Continue to the Next Section button.

## 3.0 Assign key study (KSP) access to the study

The third of the Study Shell Screens involves assigning Key Study Personnel to the study. To add any user to any role, click the **Add** button next to the corresponding role. This allows you to search the user directory by First name, Last name, or department. Enter all or part of the criteria you know and click the **Find** button.




To select a user to add, click the **Select User** icon  . This selects the user and brings you back to section 3.0 of the application. To select more than one user, check the boxes next to the corresponding users and click the **Select User(s)** button.




**If Key Study Personnel are assigned here they will not be able to access the protocol. *A user must have a role on the study in this section in order to access the study in iRIS.*

After all of the necessary KSP's have been associated to the study, click the **Save and Continue to the Next Section** button.

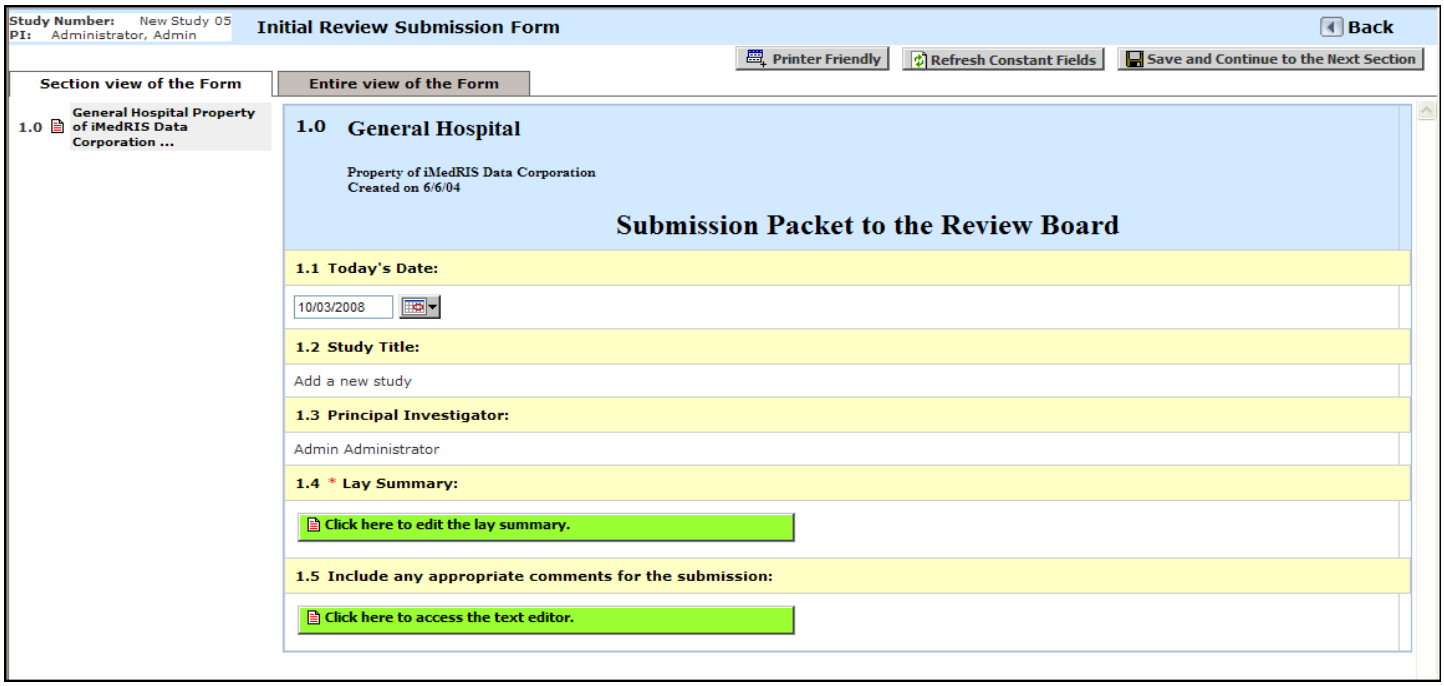
## Custom Application Sections

The sections in the application following the initial three sections are customized based on the needs of your Study application.

When you complete a section, click the **Save and Continue to Next Section** button. If a required field is left blank and you try to save and continue you will get an error message alerting you to the missing field. Correct the missing field to save and continue.

## *B. Initial Review Transition*

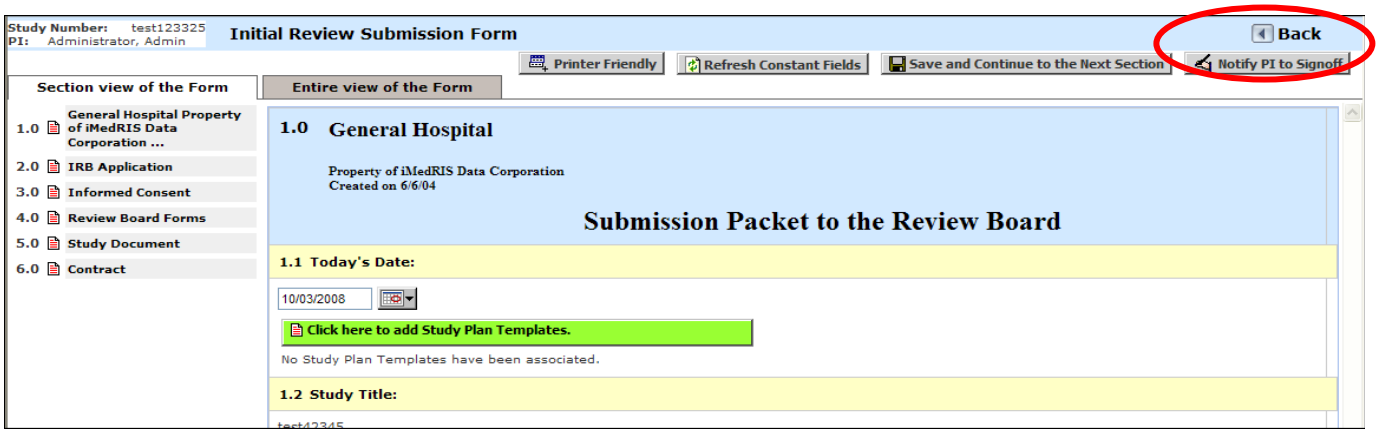
Once you have completed the Application form, you will automatically be transitioned into the Initial Review Submission form. This form serves as a packet to attach all of the necessary documents associated to the study (i.e. Study Application, Informed Consent or HIPAA forms) into an electronic submission packet to be sent to the Review Board.



In the screenshot above is an example of an Initial Review Submission form. This form can be closed and accessed later in Study Management if the necessary documents have not been collected yet to complete the submission.

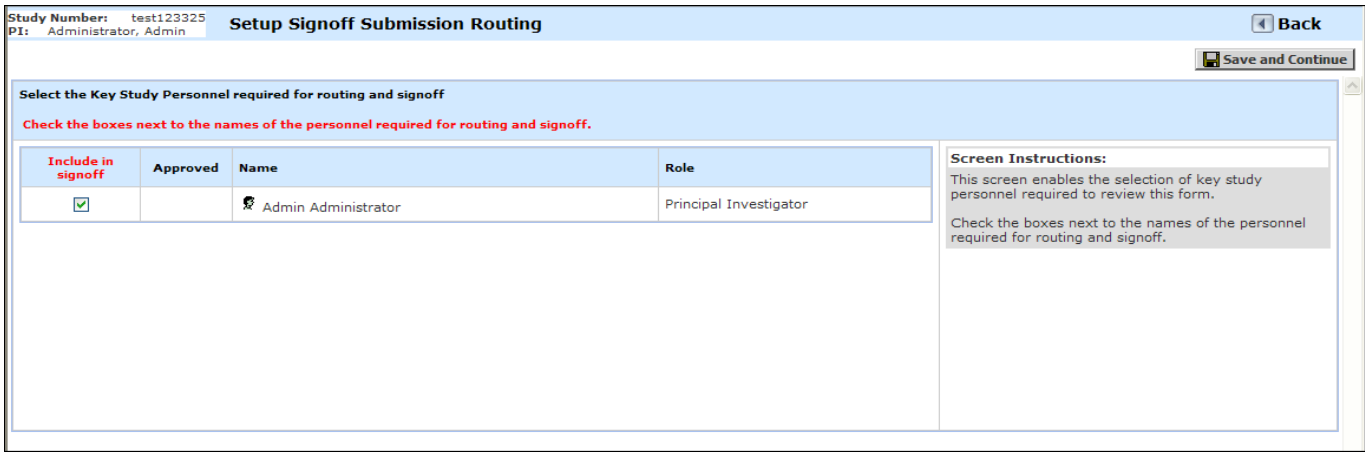
## *C. Notifying the PI to Signoff*

Once the Initial Review Submission Packet is complete and the required documents are attached the form is ready to send to the Review Board. At this point, the Study Coordinator will have the option of Notifying the PI to Signoff. The **Notify PI to Signoff** button will appear when the Initial Review Packet is completed and open.

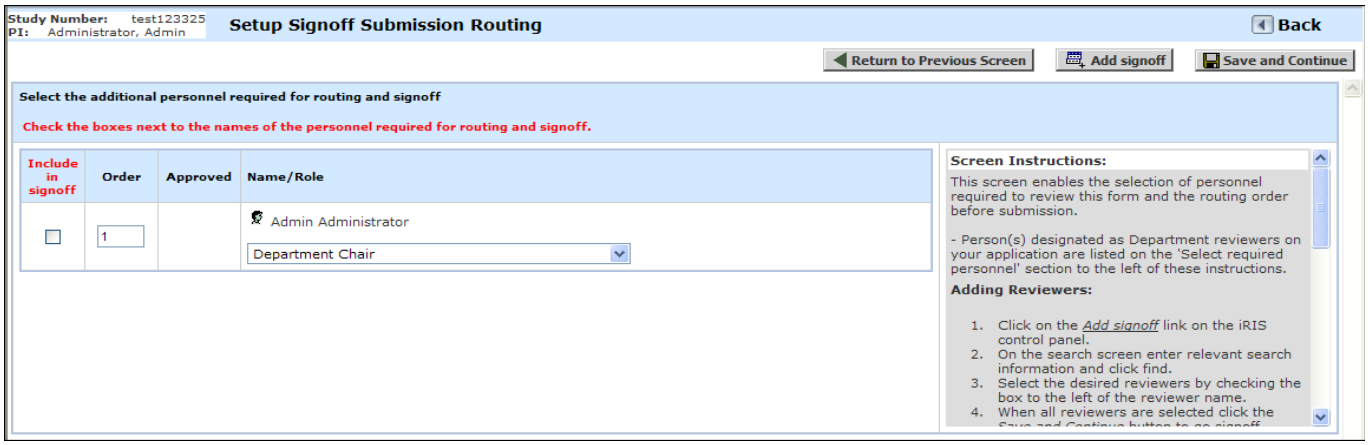



Clicking this button will bring the user to the Signoff Routing Setup screen. It is highly recommended that the Study Coordinator click the **Refresh Constant Fields** button to refresh the constant fields in the form (like the Study Title or PI listing), just to ensure that the latest information about the study is included in the form before the PI signs off.

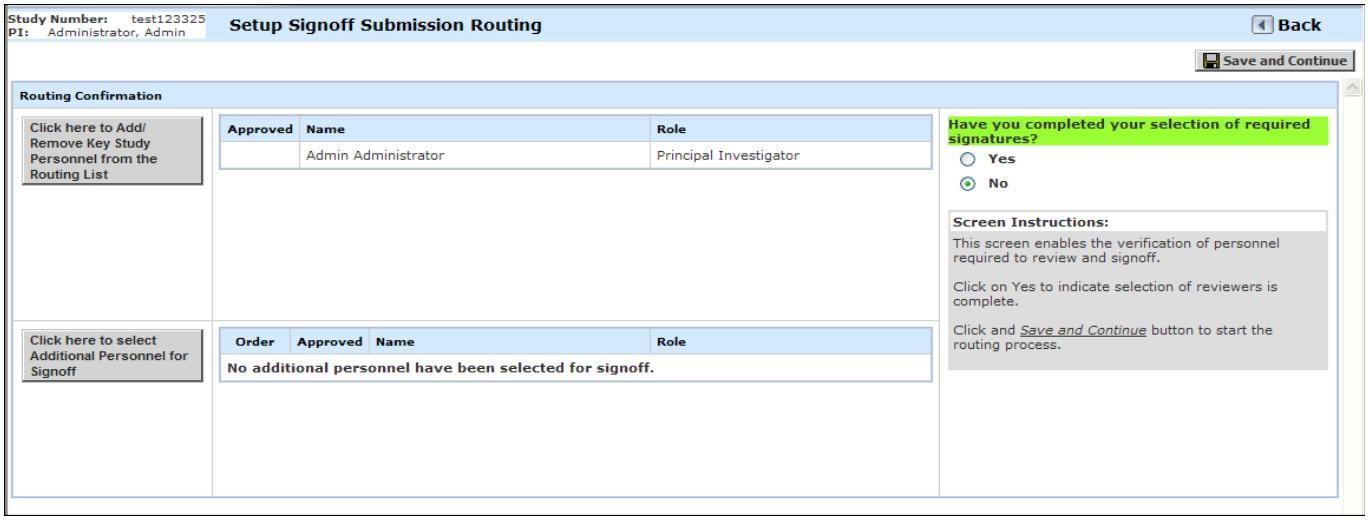
Here the Study Coordinator basically sets up two sections of the submission routing list: KSP routing and Additional Personnel. The screenshot below displays the setup of the first section. Every member of the KSP will be listed here, and can be checked to include in the Signoff List. Click Save and Continue.



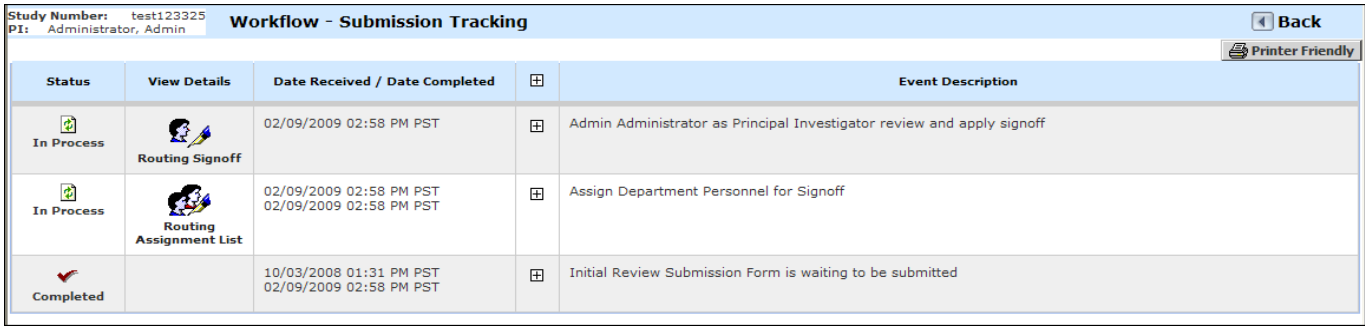

This brings you to the Additional Personnel list. User's can be added here by clicking Add Signoff and searching the User directory. Click Save and Continue.




This brings you to the summary screen of the Routing List which displays a summary of the users assigned to signoff on the Submission in each section. This is also where you need to finalize the list of users necessary for signoff. To do this click Yes to the "Have you completed your selection of required signatures?" question. This will send a notification to the PI to notify them that the Initial Review submission form is ready to be signed and submitted.

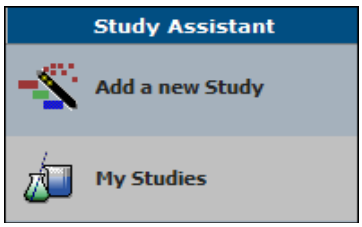



When the list is finalized, you will be taken to the workflow tracking screen displaying that the PI has been notified to review and apply signoff.

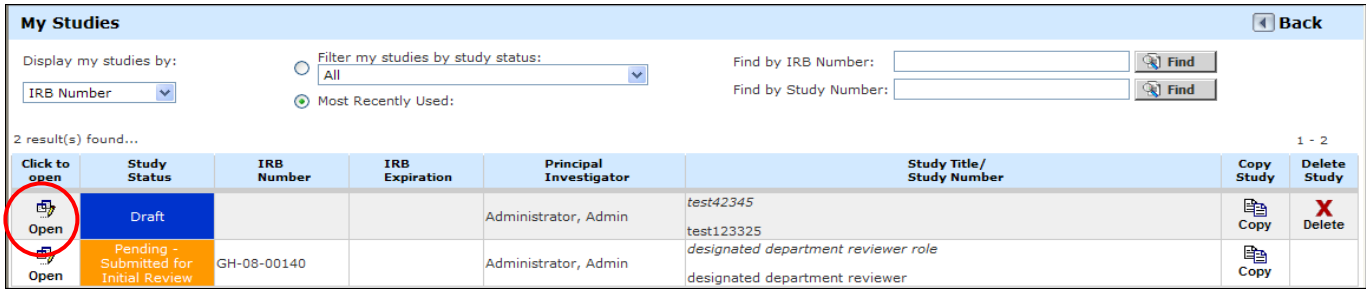


# Chapter 2: Managing Studies

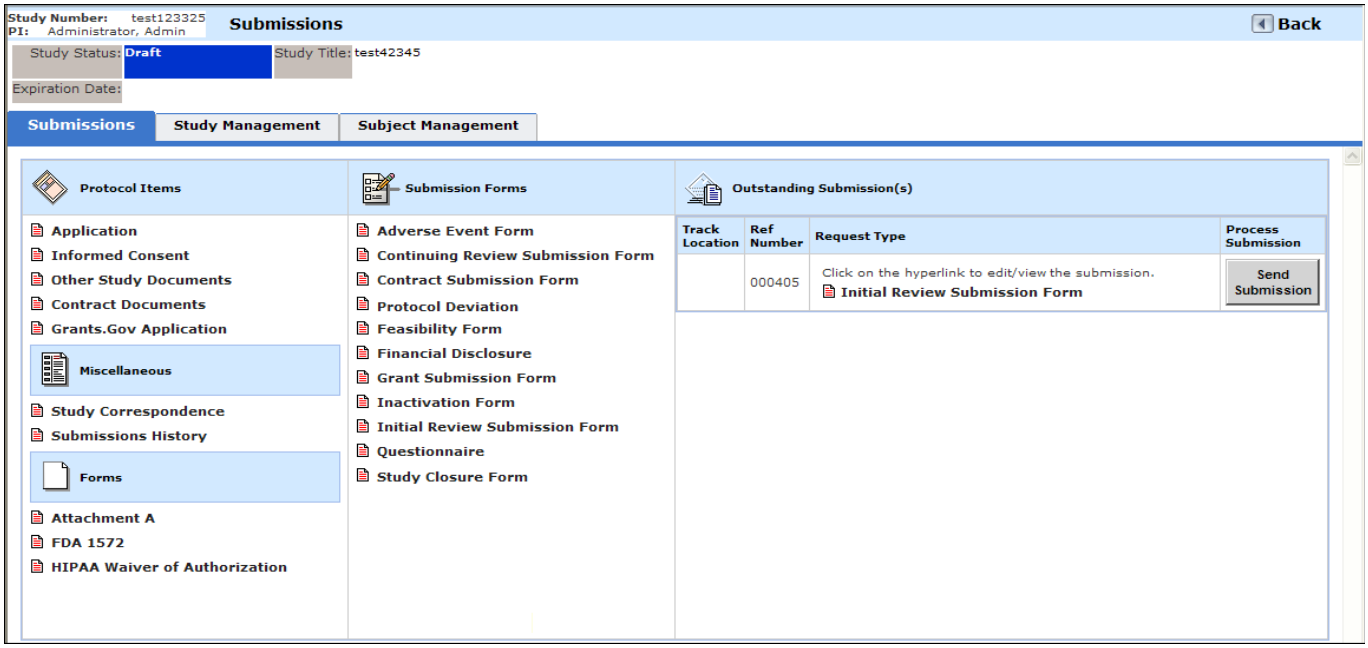
To locate your study, open the My Studies List found under your Study Assistant




This lists all of the studies you have a role on along with basic information about each study. Use the filters to narrow the list to the study you need to open.




Once you've located the Study in the list, click the Open icon. This will bring you to the Submissions tab of the Study. This view mainly lists the important forms that the Study may need to fill out. The Protocol Items are the documents and forms directly related to the Study (Study Application, Consent forms, etc.) The Forms and Submission Forms are the forms available to Study Management that are necessary for proper study management. The Miscellaneous section contains access to a list Study Correspondence and a list of the History of Submissions the Study has made.



The Outstanding Submissions section lists any submissions that are either ready to be submitted, or that have been submitted and are waiting for the Review Board to process them.

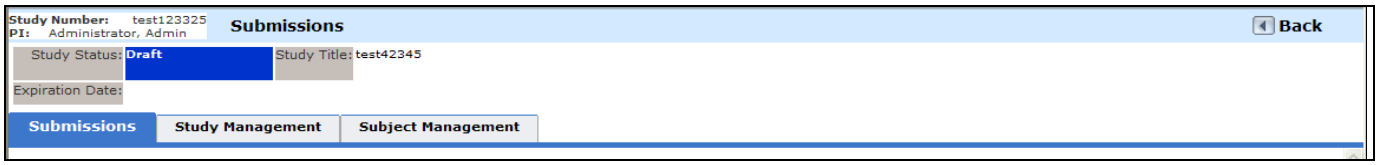
**Track Location** – If your submission has been sent, this column will serve as a link that allows you to view the tracked location of the submission.

**Ref Number** which is an internal number assigned to the form when it is created.

**Request Type** – This area details the kind of submission that is in the queue. Here the Initial Review Submission Form is ready for submission. You may click on the link to open the submission to edit before you submit the form.

**Process Submission** – This area has a button that will change depending on the status of the submission. If it has not been submitted yet the button will read **Send Submission**. If the form has been submitted but has not been reviewed by the review board the button will read **Retract Submission**. Once the submission has been reviewed it will disappear from this list altogether.

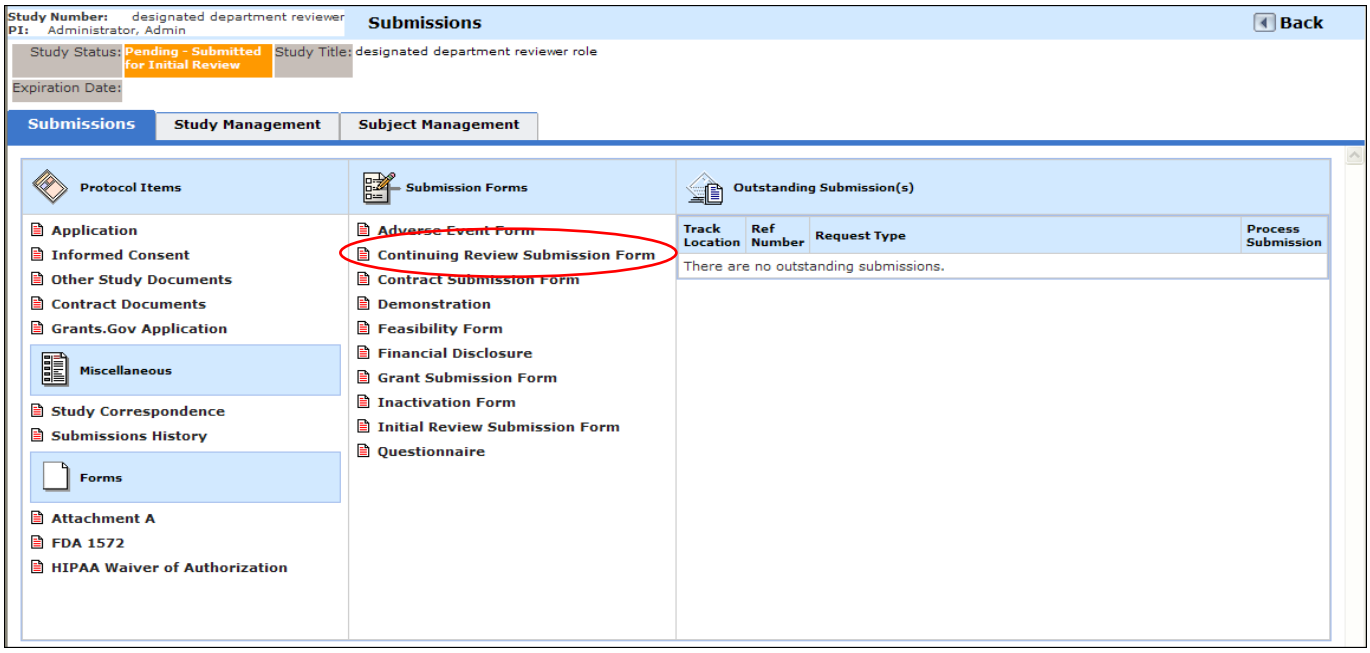
Notice that beside the Submissions tab there is a Study Management tab and Subject Management tab that can also be used to manage the study effectively.



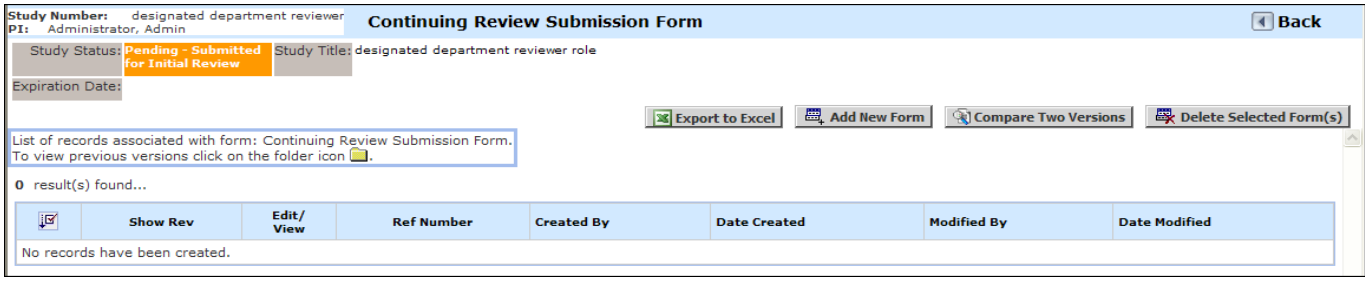

Within the Study Management tab, various study details can be specified, like Sponsors, Drugs, Devices Lists, Financial Information, and other Miscellaneous Information. The Subject Management tab (most likely used by nurses and clinicians) allows for the management of each subject on the study.

# Chapter 3: Adding a Continuing Review Form

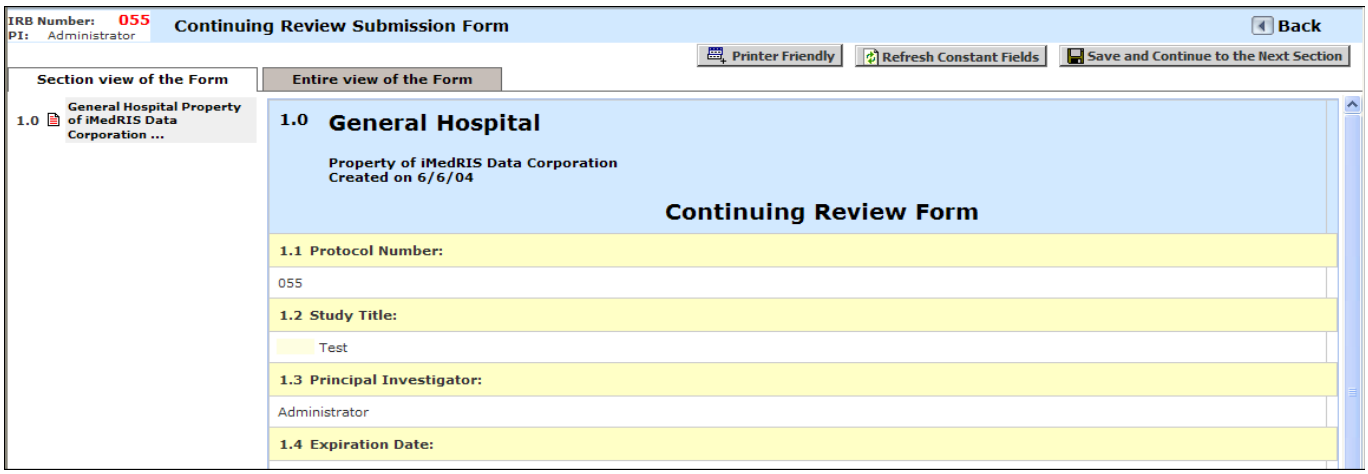
In iRIS, there are Continuing Review Notifications that can be configured to be sent out to the PI and Study Contact a certain number of days before the Continuing Review Due Date or the Expiration date (depending on the settings in the Review Board). To add a Continuing Review form, click the Continuing Review form link in the Submissions tab of the Study:



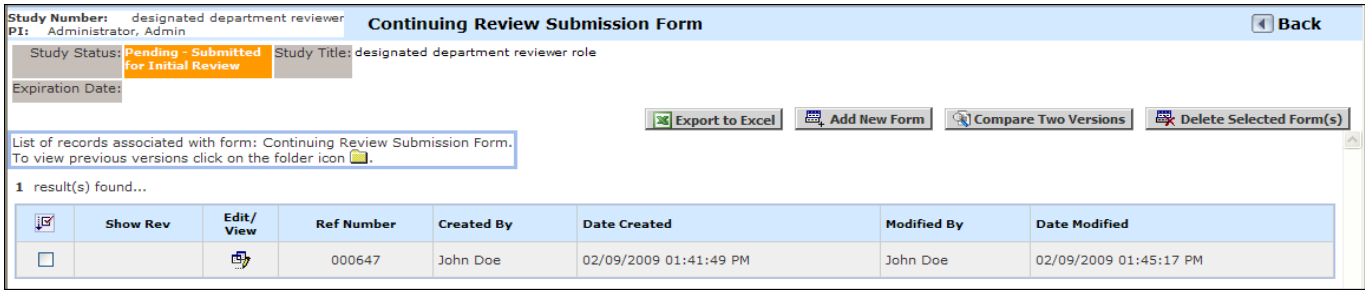

This will bring you to the list of Continuing Review forms:



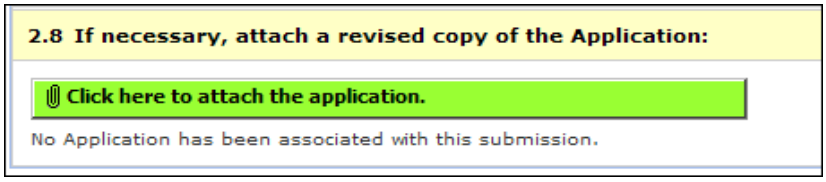

Click **Add New Form** to start a new Continuing Review form. Similar to the Application form, click Save and Continue to navigate to the next section as you fill out the form. The navigation pane on the left side of the form will build as you build the form section by section.



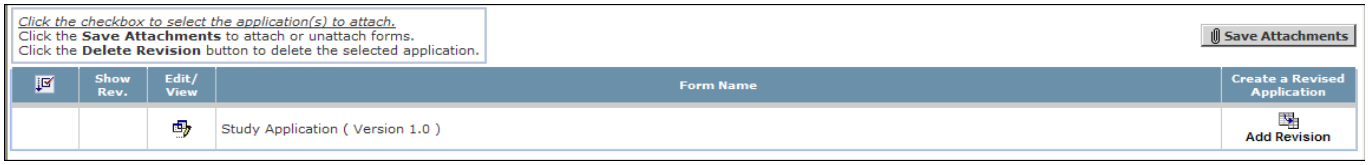

Once you've added a new form and clicked the Save and Continue button at least once, the record of the form being created will appear in the list of Continuing Review forms. The form can be edited as long it has not been submitted. Once a form has been submitted, it cannot be edited or deleted.



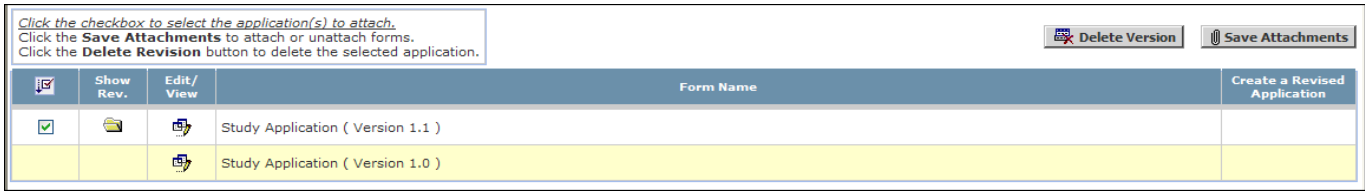

It may be necessary to attach a revised copy of the study application to the Continuing Review form. If this is needed, then a field will most likely be available in the Continuing Review form similar to the one shown below.



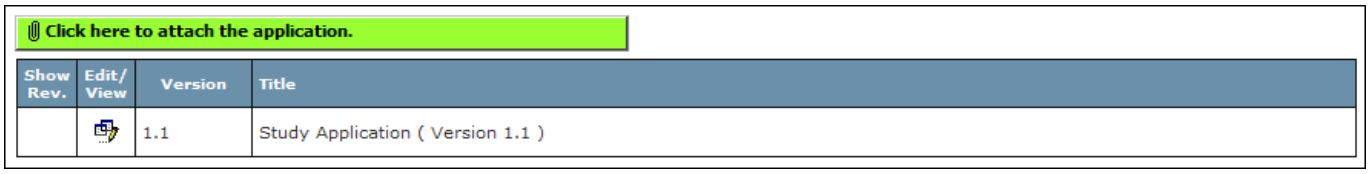

Clicking this button will bring you to the listing of the application.




Since the application has been submitted already, an **Add Revision** icon will be available. Click this icon to create a revised application.

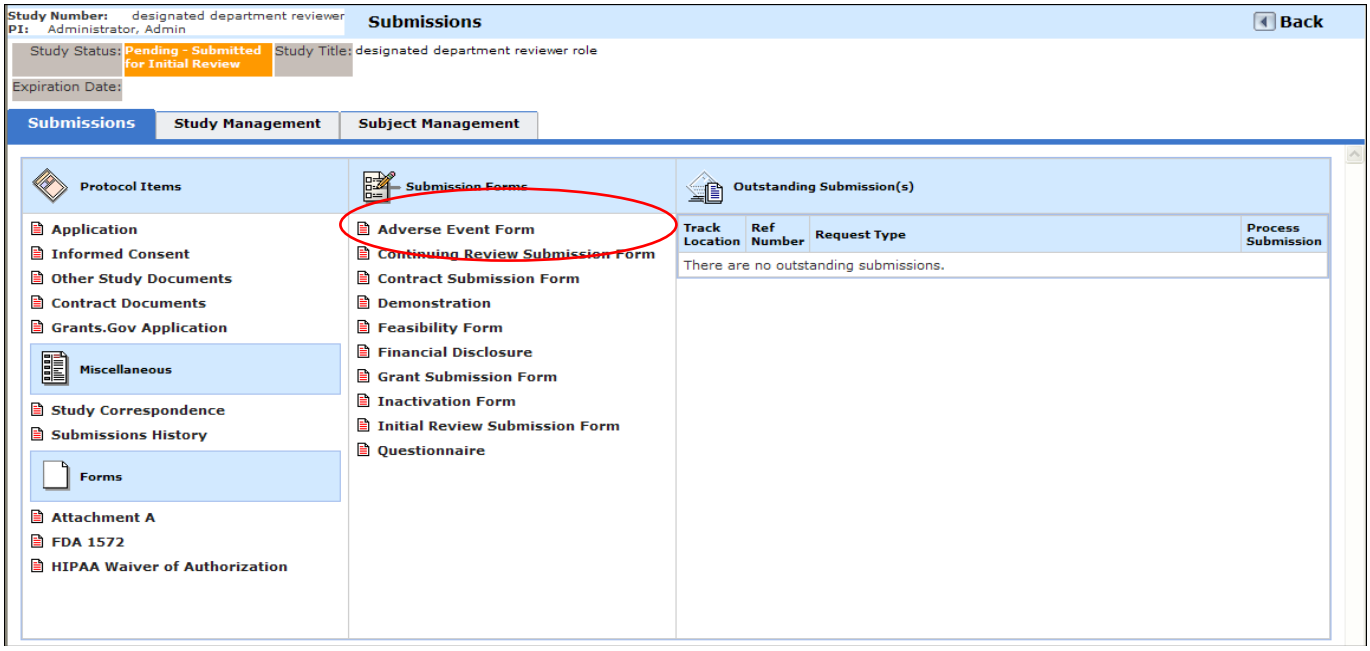



Once you have created a revision, a folder will display as shown above in the listing of the Study Application. The latest version will be 1.1. This will have a checkbox next to it, allowing you to save this version as an attachment to your Continuing Review Form. To do so, make sure the box is checked and click **Save Attachments.** This will attach the application to the form as displayed in the Continuing Review Form below:

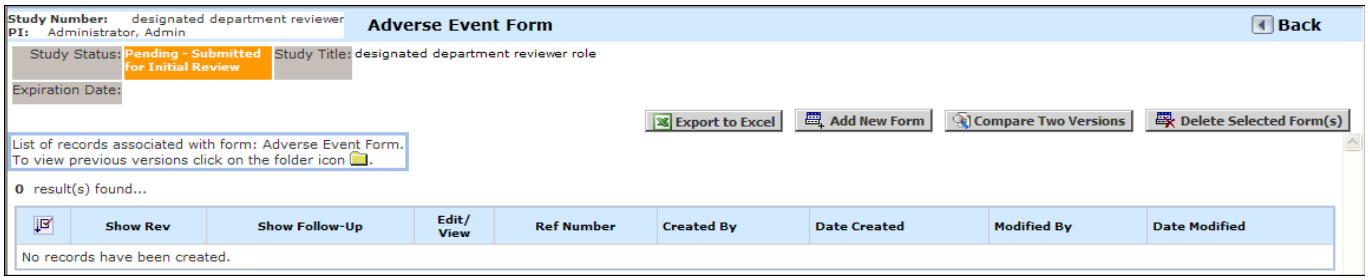


# Chapter 4: Adding an Adverse Event Form

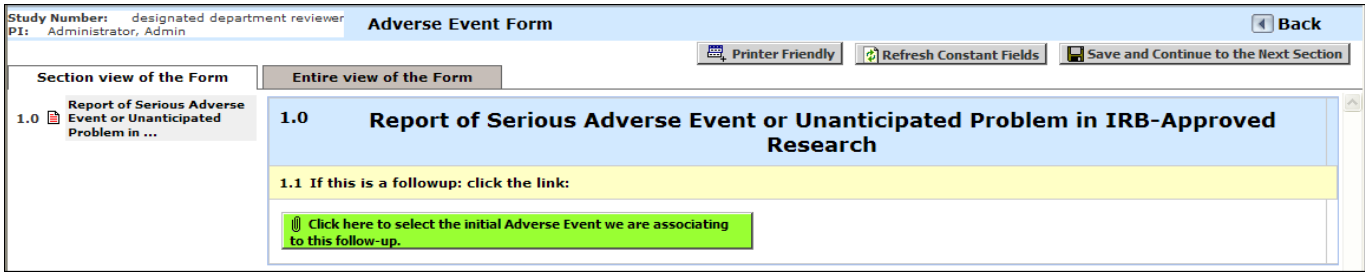
To add an Adverse Event form, click the Adverse Event form link in the Submissions tab of the Study:



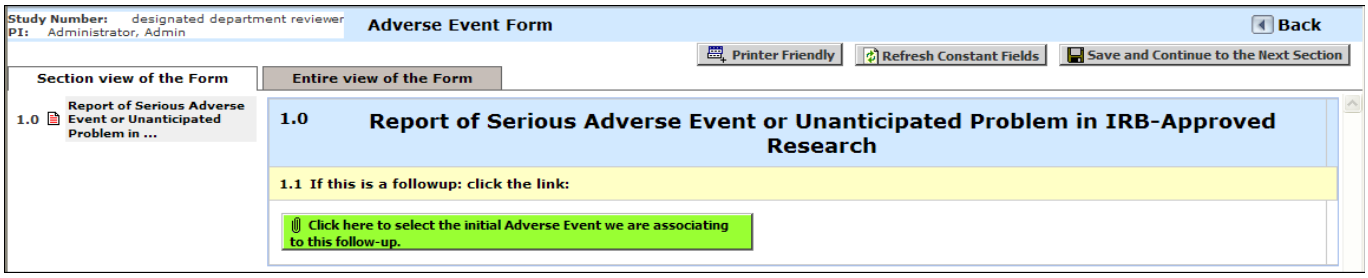

This will bring you to the list of Adverse Event forms:




Click **Add New Form** to start a new Adverse Event form. Similar to the Application form, click Save and Continue to navigate to the next section as you fill out the form. The navigation pane on the left side of the form will build as you build the form section by section.

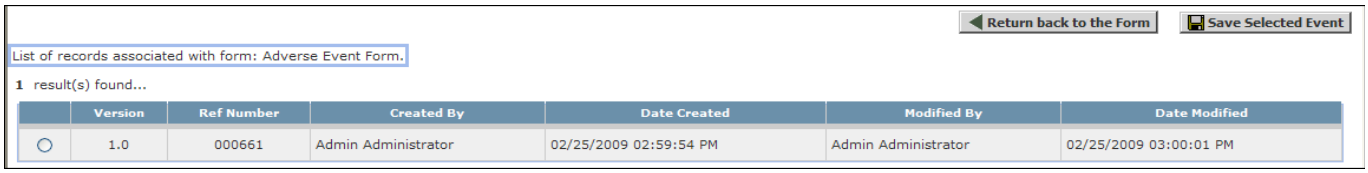



Once you've added a new form and clicked the Save and Continue button at least once, the record of the form being created will appear in the list of Adverse Event forms. The form can be edited as long it has not been submitted. Once a form has been submitted, it cannot be edited or deleted.

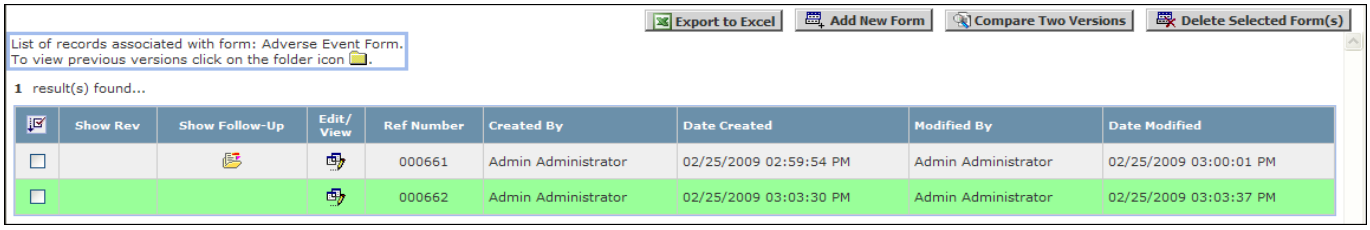



After an Adverse Event has been reported, a follow-up form can be added, as well, to refine the management of such events. To create a follow-up to an initial Adverse Event form, simply Add a New Form. Within the new Adverse Event form, there will most likely be a button allowing you to select the initial Adverse Event form to associate to the follow-up:


When you click this button, you will be brought to a list of existing initial Adverse Event forms. Be sure to note the reference number associated with the initial Adverse Event form to make sure you associate this follow-up to the correct form.

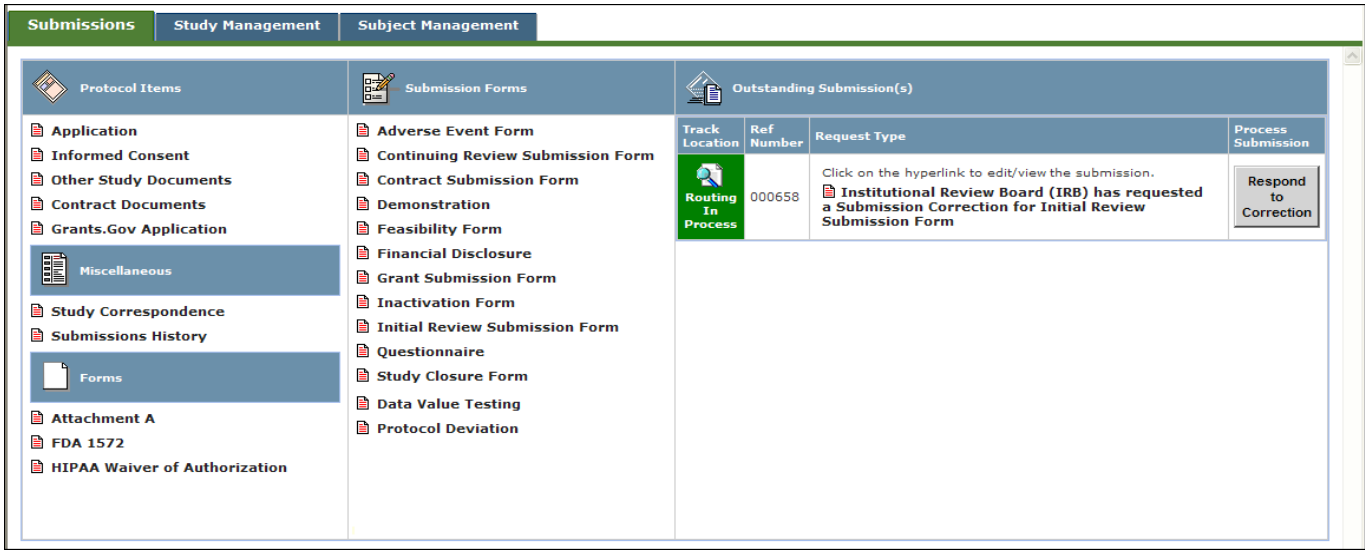



Once you've made a selection, click the Save Selected Event button. This follow-up form will now appear in the list of Adverse Event forms list as shown below:

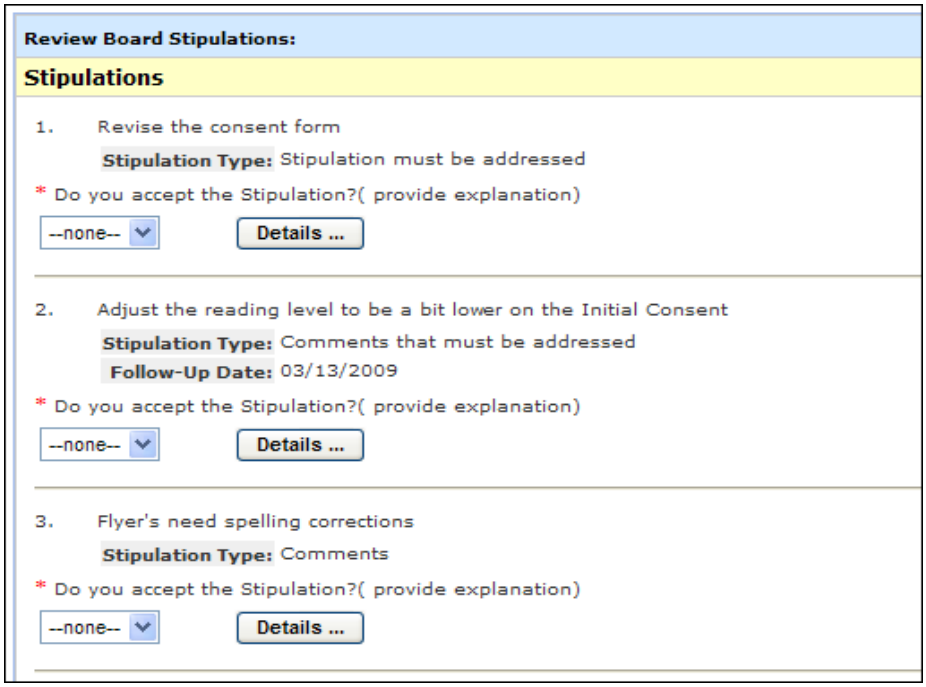


# Chapter 5: Review Response Form

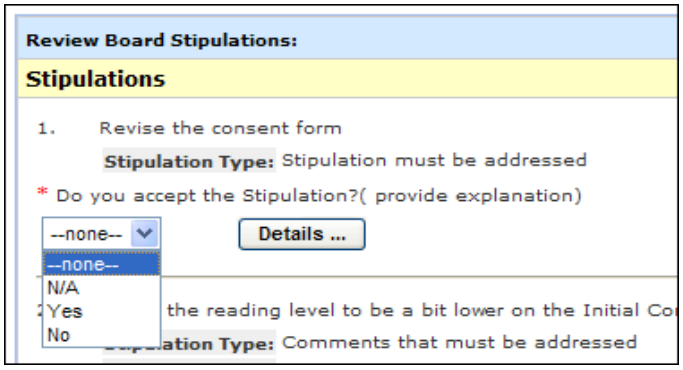
After an initial review is sent to the review board, the review board may return the submission along with several changes requested. When the board has returned a submission back to the study with changes requested, an entry will display in the Outstanding Submissions queue with a link to the return response form.



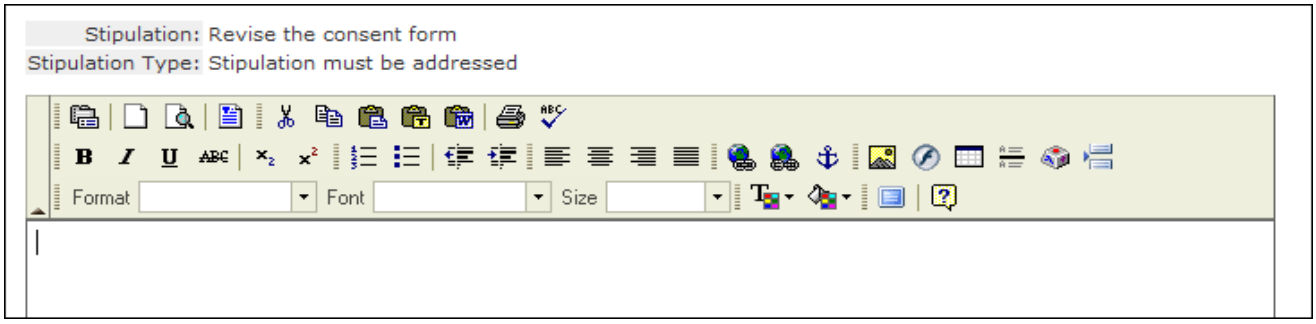

Within this form is most likely a section containing the stipulations the review board has specified for the submission.



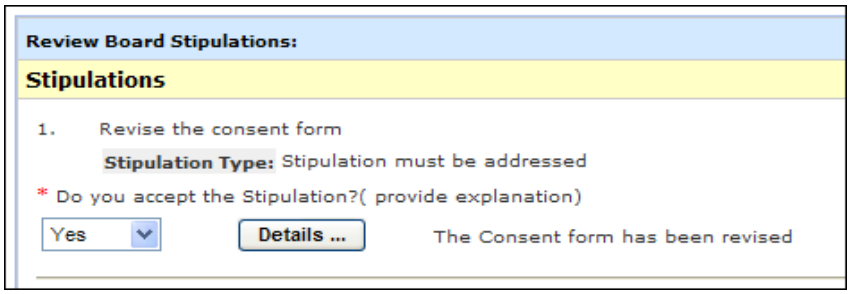
The text of the stipulation and the type of each stipulation will display. Each stipulation can be addressed by selecting the status of its acceptance from the drop down list.




Details for why the stipulation was or was not accepted can also be defined by clicking the **Details** button.




This will bring you to a text editor with the stipulation and stipulation type displayed above. Enter any necessary information and click **OK**.




The rest of the form can be filled out and submitted similarly to the AE, CR, and Initial Review Submission form.