



The Basics of Study Management For Study Coordinators

Version 8.02

Included:

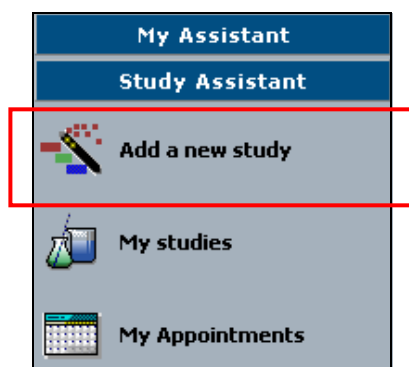
1. Add a New Study
 - a. Application
 - b. Initial Review Transition
 - c. Notifying PI to Signoff
2. Managing A Study
3. Adding a Continuing Review form
4. Adding an Adverse Event form
5. Review Response Form

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.

Study set-up

1.0 General Information

1.0 General Information

1.1 * Please enter the full title of your study:

Enter the Title of the Study Here.

1.2 * Please enter the Study Number you would like to use to reference the study:

New Study 05

* This field allows you to enter an abbreviated version of the Study Title to quickly identify this study.

Save and Continue to the Next Section

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..

New Study 05 - Study set-up

1.0 General Information

2.0 Setup Department(s) Access

2.0 Add Department(s)

2.1 List departments associated with this study:

| Primary Dept? | Department Name | | |
|-------------------------------------|------------------|--|--|
| <input checked="" type="checkbox"/> | CA-GH - Oncology | | |

Add Remove

Save and Continue to the Next Section

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.

| New Study 05 - Add Department Access | | Back |
|--------------------------------------|----------------------|------|
| Save Changes | | |
| <input type="checkbox"/> | Department | |
| <input type="checkbox"/> | NY-GH - Oncology | |
| <input type="checkbox"/> | TX-GH - Oncology | |
| <input type="checkbox"/> | TX-GH - IV Therapy | |
| <input type="checkbox"/> | TX-GH - Practitioner | |
| <input type="checkbox"/> | CA-GH - Pediatrics | |
| <input type="checkbox"/> | NY-GH - Pediatrics | |
| <input type="checkbox"/> | CA-GH - Radiology | |

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.


| New Study 05 - Study set-up | | Save and Continue to the Next Section | | | | | | | | | | | | |
|---|---|---------------------------------------|---------------|-----------------|-----|--------|---|------------------|--|--|--|------------------|--|--|
| <ul style="list-style-type: none"> 1.0 General Information 2.0 Setup Department(s) Access | <h3>2.0 Add Department(s)</h3> <p>2.1 List departments associated with this study:</p> <table border="1"> <thead> <tr> <th>Primary Dept?</th> <th>Department Name</th> <th style="text-align: center;">Add</th> <th style="text-align: center;">Remove</th> </tr> </thead> <tbody> <tr> <td><input type="checkbox"/> <input checked="" type="radio"/></td> <td>CA-GH - Oncology</td> <td></td> <td></td> </tr> <tr> <td><input type="checkbox"/> <input type="radio"/></td> <td>NY-GH - Oncology</td> <td></td> <td></td> </tr> </tbody> </table> | | Primary Dept? | Department Name | Add | Remove | <input type="checkbox"/> <input checked="" type="radio"/> | CA-GH - Oncology | | | <input type="checkbox"/> <input type="radio"/> | NY-GH - Oncology | | |
| Primary Dept? | Department Name | Add | Remove | | | | | | | | | | | |
| <input type="checkbox"/> <input checked="" type="radio"/> | CA-GH - Oncology | | | | | | | | | | | | | |
| <input type="checkbox"/> <input type="radio"/> | NY-GH - Oncology | | | | | | | | | | | | | |

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.

| Search User Directory | | Back |
|------------------------|---|------|
| Directory Browse/Find: | Last Name: <input type="text"/> (You may enter a partial name to search) First Name: <input type="text"/> by Department: <input type="text"/> All Departments | Find |

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.

| Search User Directory | | | | |
|--------------------------|-------------------------------------|--|------------------------|-------|
| Directory Browse/Find: | | Last Name: <input type="text"/> (You may enter a partial name to search) | | |
| | | First Name: <input type="text"/> a | | |
| | | by Department: All Departments | Find | |
| Select | Select User | Name | Department | Email |
| <input type="checkbox"/> | <input checked="" type="checkbox"/> | Administrator, Admin | Oncology (primary) [+] | |

****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.

| Study Number: New Study 05 | | Initial Review Submission Form | |
|---|--|---------------------------------------|-------------------------|
| PI: Administrator, Admin | | Back | |
| | | Printer Friendly | Refresh Constant Fields |
| | | Save and Continue to the Next Section | |
| Section view of the Form | Entire view of the Form | | |
| 1.0 General Hospital Property of iMedRIS Data Corporation ... | <p>1.0 General Hospital</p> <p>Property of iMedRIS Data Corporation Created on 6/6/04</p> <p>Submission Packet to the Review Board</p> <p>1.1 Today's Date: 10/03/2008</p> <p>1.2 Study Title: Add a new study</p> <p>1.3 Principal Investigator: Admin Administrator</p> <p>1.4 * Lay Summary: Click here to edit the lay summary.</p> <p>1.5 Include any appropriate comments for the submission: Click here to access the text editor.</p> | | |

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.

The screenshot shows the 'Initial Review Submission Form' for Study Number test123325. The interface includes a navigation menu on the left with sections like 'General Hospital Property of iMedRIS Data Corporation ...', 'IRB Application', 'Informed Consent', 'Review Board Forms', 'Study Document', and 'Contract'. The main content area is titled '1.0 General Hospital' and contains a 'Submission Packet to the Review Board' section. Below this, there are fields for '1.1 Today's Date' (set to 10/03/2008) and '1.2 Study Title'. A green button labeled 'Click here to add Study Plan Templates.' is visible. In the top right corner, the 'Notify PI to Signoff' button is highlighted with a red circle.

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.

The screenshot shows the 'Setup Signoff Submission Routing' screen for Study Number test123325. The instruction is to 'Select the Key Study Personnel required for routing and signoff' and to 'Check the boxes next to the names of the personnel required for routing and signoff.'. A table lists personnel with columns for 'Include in signoff', 'Approved', 'Name', and 'Role'. One entry is shown: 'Admin Administrator' with the role 'Principal Investigator'. The 'Include in signoff' checkbox is checked. A 'Screen Instructions' box on the right explains the purpose of the screen.

| Include in signoff | Approved | Name | Role |
|-------------------------------------|----------|---------------------|------------------------|
| <input checked="" type="checkbox"/> | | Admin Administrator | Principal Investigator |

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.

Study Number: test123325
PI: Administrator, Admin

Setup Signoff Submission Routing

Back

Return to Previous Screen Add signoff Save and Continue

Select the additional personnel required for routing and signoff

Check the boxes next to the names of the personnel required for routing and signoff.

| Include in signoff | Order | Approved | Name/Role |
|--------------------------|-------|----------|---|
| <input type="checkbox"/> | 1 | | Admin Administrator Department Chair |

Screen Instructions:

This screen enables the selection of personnel required to review this form and the routing order before submission.

- Person(s) designated as Department reviewers on your application are listed on the 'Select required personnel' section to the left of these instructions.

Adding Reviewers:

1. Click on the *Add signoff* link on the iRIS control panel.
2. On the search screen enter relevant search information and click find.
3. Select the desired reviewers by checking the box to the left of the reviewer name.
4. When all reviewers are selected click the *Save and Continue* button to go signoff.

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.

Study Number: test123325
PI: Administrator, Admin

Setup Signoff Submission Routing

Back

Save and Continue

Routing Confirmation

Click here to Add/Remove Key Study Personnel from the Routing List

| Approved | Name | Role |
|----------|---------------------|------------------------|
| | Admin Administrator | Principal Investigator |

Click here to select Additional Personnel for Signoff

| Order | Approved | Name | Role |
|---|----------|------|------|
| No additional personnel have been selected for signoff. | | | |

Have you completed your selection of required signatures?

Yes

No

Screen Instructions:

This screen enables the verification of personnel required to review and signoff.

Click on Yes to indicate selection of reviewers is complete.

Click and *Save and Continue* button to start the routing process.

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.

Study Number: test123325
PI: Administrator, Admin

Workflow - Submission Tracking

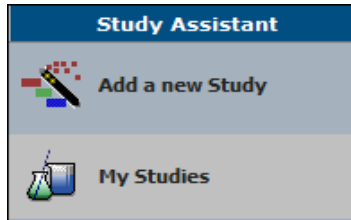
Back

Printer Friendly

| Status | View Details | Date Received / Date Completed | Event Description |
|------------|-------------------------|--|--|
| In Process | Routing Signoff | 02/09/2009 02:58 PM PST | Admin Administrator as Principal Investigator review and apply signoff |
| In Process | Routing Assignment List | 02/09/2009 02:58 PM PST 02/09/2009 02:58 PM PST | Assign Department Personnel for Signoff |
| Completed | | 10/03/2008 01:31 PM PST 02/09/2009 02:58 PM PST | Initial Review Submission Form is waiting to be submitted |

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.

My Studies Back

Display my studies by: Filter my studies by study status: All Most Recently Used: Find by IRB Number: Find Find by Study Number: Find

2 result(s) found... 1 - 2

| Click to open | Study Status | IRB Number | IRB Expiration | Principal Investigator | Study Title/ Study Number | Copy Study | Delete Study |
|---------------|--|-------------|----------------|------------------------|---|------------|--------------|
| Open | Draft | | | Administrator, Admin | test42345 | Copy | Delete |
| Open | Pending - Submitted for Initial Review | GH-08-00140 | | Administrator, Admin | test123325 designated department reviewer role designated department reviewer | Copy | |

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.

Study Number: test123325 **Submissions** Back
PI: Administrator, Admin
 Study Status: **Draft** Study Title: test42345
 Expiration Date:

Submissions | Study Management | Subject Management

| Protocol Items | Submission Forms | Outstanding Submission(s) | | | | | | | | | | |
|--|--|---|--------------------|------------|--------------|--------------------|--|--------|---|-----------------|--|--|
| <ul style="list-style-type: none"> Application Informed Consent Other Study Documents Contract Documents Grants.Gov Application Miscellaneous Study Correspondence Submissions History Forms Attachment A FDA 1572 HIPAA Waiver of Authorization | <ul style="list-style-type: none"> Adverse Event Form Continuing Review Submission Form Contract Submission Form Protocol Deviation Feasibility Form Financial Disclosure Grant Submission Form Inactivation Form Initial Review Submission Form Questionnaire Study Closure Form | <table border="1"> <thead> <tr> <th>Track Location</th> <th>Ref Number</th> <th>Request Type</th> <th>Process Submission</th> </tr> </thead> <tbody> <tr> <td></td> <td>000405</td> <td>Click on the hyperlink to edit/view the submission. Initial Review Submission Form</td> <td> Send Submission</td> </tr> </tbody> </table> | Track Location | Ref Number | Request Type | Process Submission | | 000405 | Click on the hyperlink to edit/view the submission. Initial Review Submission Form | Send Submission | | |
| Track Location | Ref Number | Request Type | Process Submission | | | | | | | | | |
| | 000405 | Click on the hyperlink to edit/view the submission. Initial Review Submission Form | Send Submission | | | | | | | | | |

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.

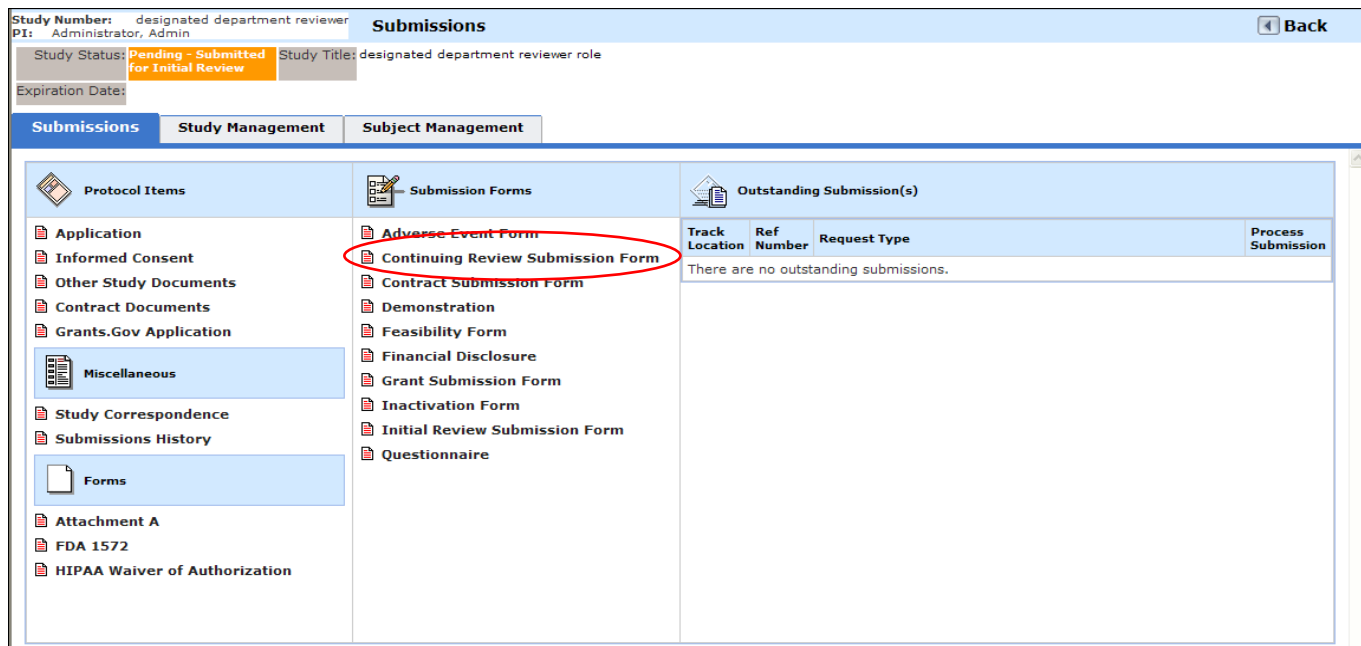
Notice that beside the Submissions tab there is a Study Management tab and Subject Management tab that can also be used to manage the study effectively.

The screenshot displays a web application interface for managing submissions. At the top, there is a header area with the title 'Submissions' and a 'Back' button. Below the header, there are several fields: 'Study Number: test123325', 'PI: Administrator, Admin', 'Study Status: Draft', and 'Study Title: test42345'. There is also an 'Expiration Date:' field. At the bottom of the interface, there are three tabs: 'Submissions', 'Study Management', and 'Subject Management'. The 'Submissions' tab is currently selected.

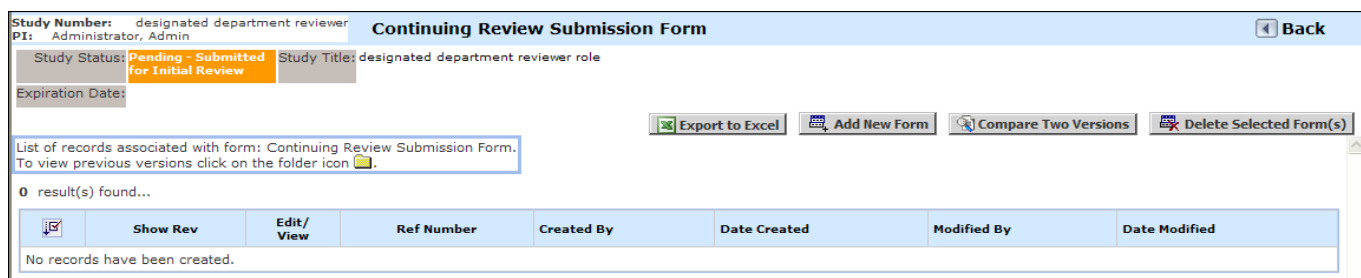
Within the Study Management tab, various study details can be specified, like Sponsors, Drugs, Devices Lists, Financial Information, and other Miscellaneous Information. The Subject Management tab (most likely used by nurses and clinicians) allows for the management of each subject on the study.

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.

IRB Number: **055** Continuing Review Submission Form Back
 PI: Administrator Printer Friendly Refresh Constant Fields Save and Continue to the Next Section

Section view of the Form Entire view of the Form

1.0 General Hospital Property of iMedRIS Data Corporation ...

1.0 General Hospital
 Property of iMedRIS Data Corporation
 Created on 6/6/04

Continuing Review Form

1.1 Protocol Number:
055

1.2 Study Title:
Test

1.3 Principal Investigator:
Administrator

1.4 Expiration Date:

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.

Study Number: designated department reviewer Continuing Review Submission Form Back
 PI: Administrator, Admin

Study Status: Pending - Submitted for Initial Review Study Title: designated department reviewer role
 Expiration Date:

Export to Excel Add New Form Compare Two Versions Delete Selected Form(s)

List of records associated with form: Continuing Review Submission Form. To view previous versions click on the folder icon.

1 result(s) found...

| <input type="checkbox"/> | Show Rev | Edit/View | Ref Number | Created By | Date Created | Modified By | Date Modified |
|--------------------------|----------|-----------|------------|------------|------------------------|-------------|------------------------|
| <input type="checkbox"/> | | | 000647 | John Doe | 02/09/2009 01:41:49 PM | John Doe | 02/09/2009 01:45:17 PM |

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.

2.8 If necessary, attach a revised copy of the Application:

[Click here to attach the application.](#)

No Application has been associated with this submission.



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





Click the checkbox to select the application(s) to attach. Click the **Save Attachments** to attach or unattach forms. Click the **Delete Revision** button to delete the selected application. Save Attachments

| <input type="checkbox"/> | Show Rev. | Edit/View | Form Name | Create a Revised Application |
|--------------------------|-----------|-----------|-----------------------------------|------------------------------|
| <input type="checkbox"/> | | | Study Application (Version 1.0) | Add Revision |


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


Click the checkbox to select the application(s) to attach.
 Click the **Save Attachments** to attach or unattach forms.
 Click the **Delete Revision** button to delete the selected application.

|  | Show Rev. | Edit/View | Form Name | Create a Revised Application |
|---|---|---|-----------------------------------|------------------------------|
| <input checked="" type="checkbox"/> |  |  | Study Application (Version 1.1) | |
| | |  | Study Application (Version 1.0) | |

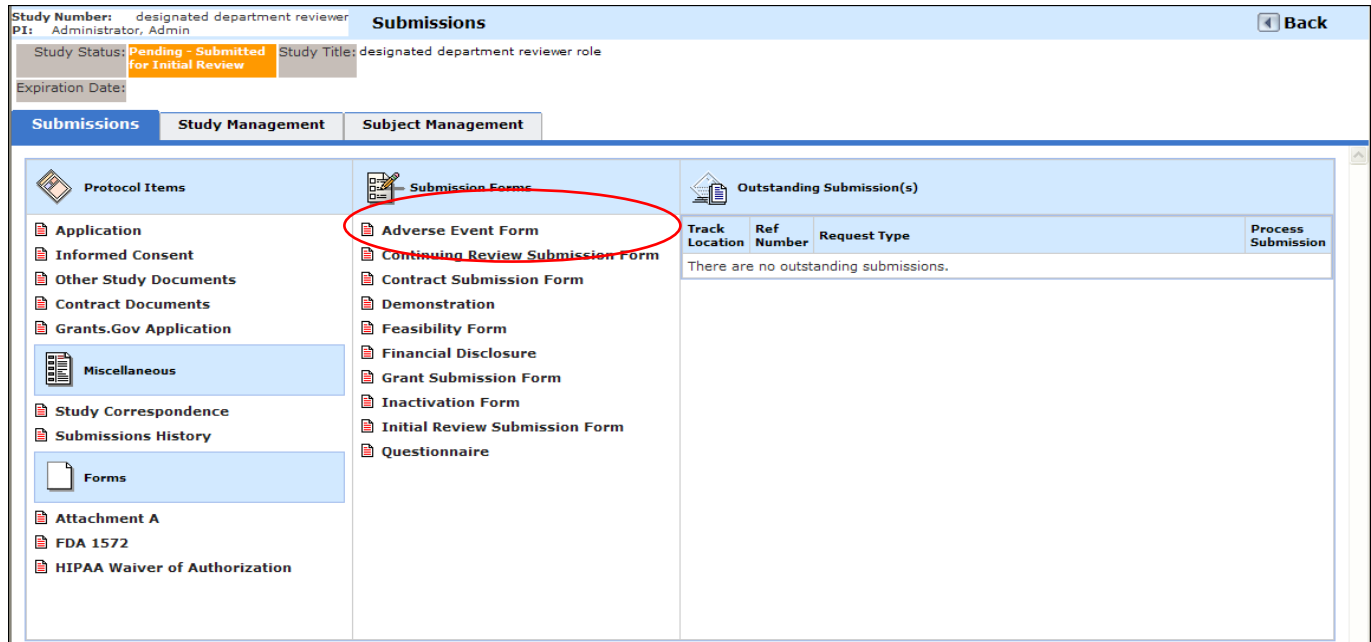
Once you have created a revision, a folder will display as shown above in the listing of the Study Application. The latest version will be 1.1. This will have a checkbox next to it, allowing you to save this version as an attachment to your Continuing Review Form. To do so, make sure the box is checked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

 [Click here to attach the application.](#)

| Show Rev. | Edit/View | Version | Title |
|-----------|---|---------|-----------------------------------|
| |  | 1.1 | Study Application (Version 1.1) |

Chapter 4: Adding an Adverse Event Form

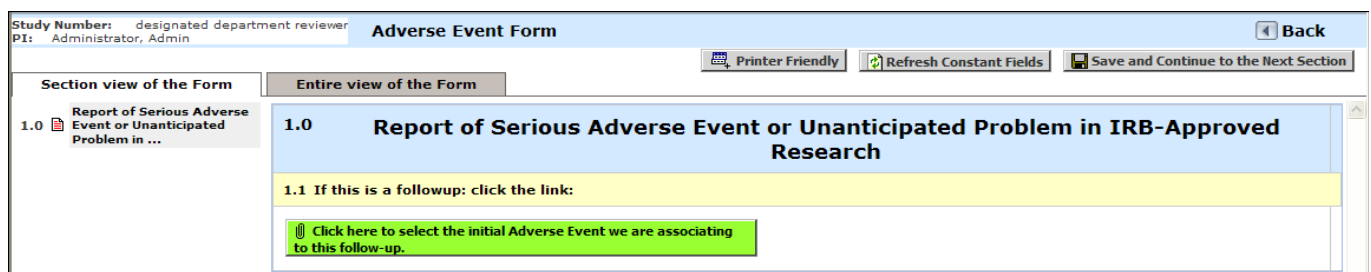
To add an Adverse Event form, click the Adverse Event form link in the Submissions tab of the Study:



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 as it has not been submitted. Once a form has been submitted, it cannot be edited or deleted.

Study Number: designated department reviewer
 PI: Administrator, Admin

Adverse Event Form Back

Printer Friendly Refresh Constant Fields Save and Continue to the Next Section

Section view of the Form

1.0 Report of Serious Adverse Event or Unanticipated Problem in ...

Entire view of the Form

1.0 Report of Serious Adverse Event or Unanticipated Problem in IRB-Approved Research

1.1 If this is a followup: click the link:

[Click here to select the initial Adverse Event we are associating to this follow-up.](#)

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:

[Click here to select the initial Adverse Event we are associating to this 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.

Return back to the Form Save Selected Event

List of records associated with form: Adverse Event Form.

1 result(s) found...

| Version | Ref Number | Created By | Date Created | Modified By | Date Modified |
|---------|------------|------------|---------------------|------------------------|---|
| ○ | 1.0 | 000661 | Admin Administrator | 02/25/2009 02:59:54 PM | Admin Administrator 02/25/2009 03:00:01 PM |

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:

Export to Excel Add New Form Compare Two Versions Delete Selected Form(s)

List of records associated with form: Adverse Event Form.
 To view previous versions click on the folder icon

1 result(s) found...

| | Show Rev | Show Follow-Up | Edit/View | Ref Number | Created By | Date Created | Modified By | Date Modified |
|--------------------------|----------|----------------|-----------|------------|---------------------|------------------------|---------------------|------------------------|
| <input type="checkbox"/> | | | | 000661 | Admin Administrator | 02/25/2009 02:59:54 PM | Admin Administrator | 02/25/2009 03:00:01 PM |
| <input type="checkbox"/> | | | | 000662 | Admin Administrator | 02/25/2009 03:03:30 PM | Admin Administrator | 02/25/2009 03:03:37 PM |

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.

| Track Location | Ref Number | Request Type | Process Submission |
|--------------------|------------|--|-----------------------|
| Routing In Process | 000658 | Click on the hyperlink to edit/view the submission. Institutional Review Board (IRB) has requested a Submission Correction for Initial Review Submission Form | Respond to Correction |

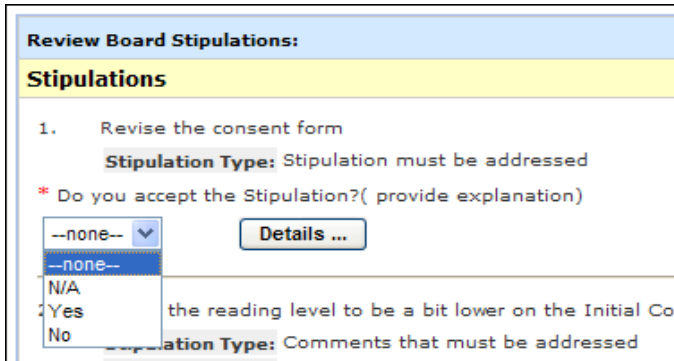
Within this form is most likely a section containing the stipulations the review board has specified for the submission.

Review Board Stipulations:

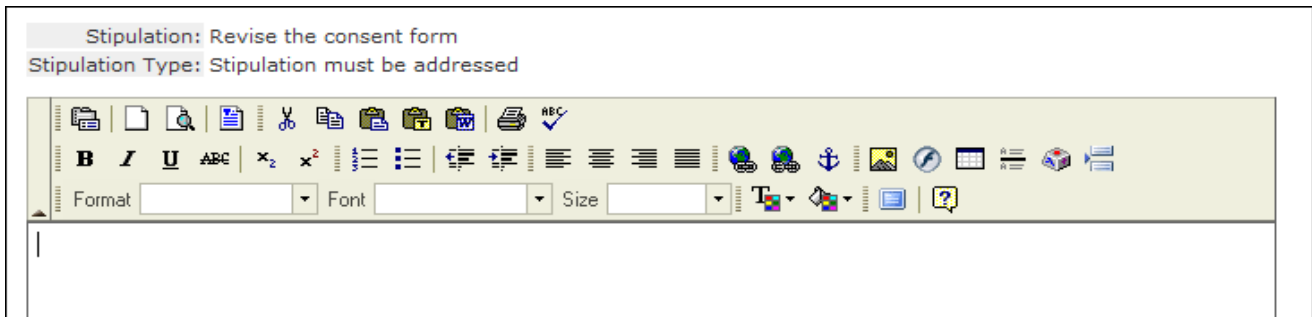
Stipulations

- Revise the consent form
Stipulation Type: Stipulation must be addressed
 * Do you accept the Stipulation?(provide explanation)
- Adjust the reading level to be a bit lower on the Initial Consent
Stipulation Type: Comments that must be addressed
Follow-Up Date: 03/13/2009
 * Do you accept the Stipulation?(provide explanation)
- Flyer's need spelling corrections
Stipulation Type: Comments
 * Do you accept the Stipulation?(provide explanation)

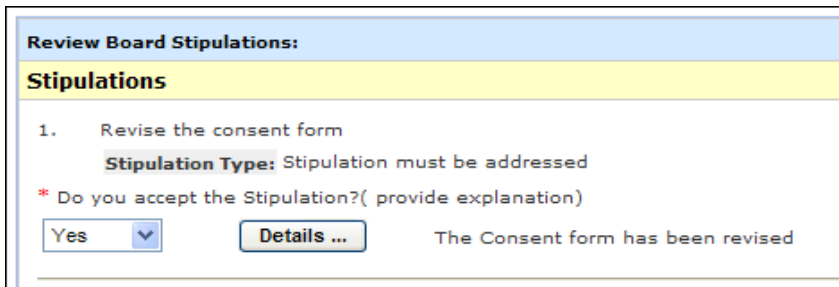
The text of the stipulation and the type of each stipulation will display. Each stipulation can be addressed by selecting the status of its acceptance from the drop down list.



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.