Study Assistant

-Submissions Tab-

Version 8.02

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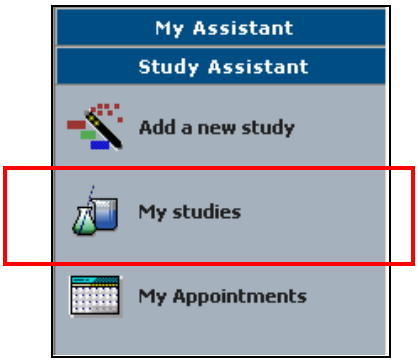
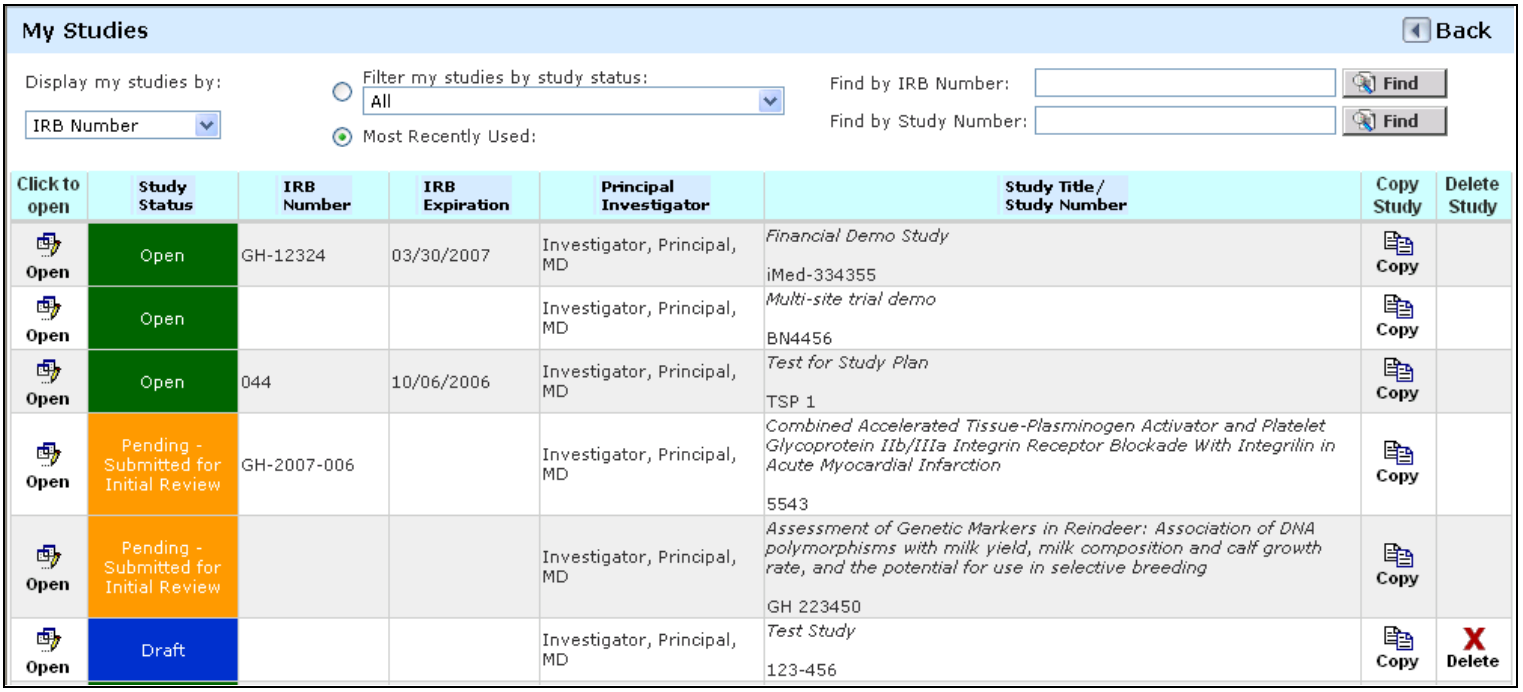
To access or view a Study Submission you must first locate the study. To do so, click the **My Studies** link in Study Assistant.

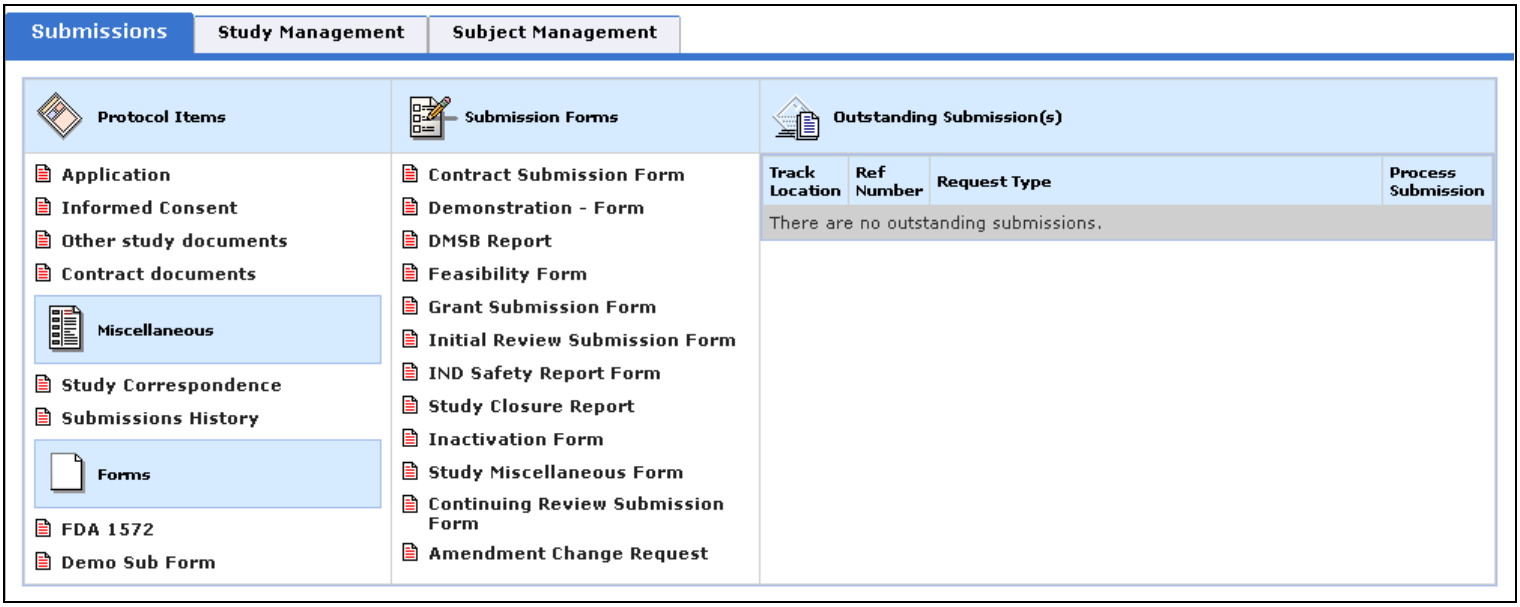




Click to open	Study Status	IRB Number	IRB Expiration	Principal Investigator	Study Title / Study Number	Copy Study	Delete Study
Open	Open	GH-12324	03/30/2007	Investigator, Principal, MD	*Financial Demo Study* iMed-334355	Copy	
Open	Open			Investigator, Principal, MD	*Multi-site trial demo* BN4456	Copy	
Open	Open	044	10/06/2006	Investigator, Principal, MD	*Test for Study Plan* TSP 1	Copy	
Open	Pending - Submitted for Initial Review	GH-2007-006		Investigator, Principal, MD	*Combined Accelerated Tissue-Plasminogen Activator and Platelet Glycoprotein IIb/IIIa Integrin Receptor Blockade With Integrilin in Acute Myocardial Infarction* 5543	Copy	
Open	Pending - Submitted for Initial Review			Investigator, Principal, MD	*Assessment of Genetic Markers in Reindeer: Association of DNA polymorphisms with milk yield, milk composition and calf growth rate, and the potential for use in selective breeding* GH 223450	Copy	
Open	Draft			Investigator, Principal, MD	*Test Study* 123-456	Copy	X Delete

Click on the **Open** icon associated with the Study Title that you wish to access. This will take you to the main **Submission** screen depending on the status of the study.

If the study is still in Draft status and you open the study it will open to the study application. Also, depending on your specific study, study submissions may or not contain the same content as the example used in all the screen shots in this manual.



The Submissions tab is where all submission forms, study documents and consent forms are stored for the study. You may track completed or on-going submissions, send an e-mail concerning the study, upload any document and complete and submit a form to the IRB.

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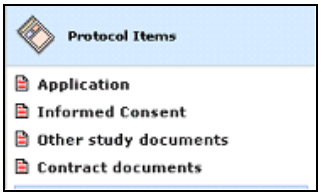
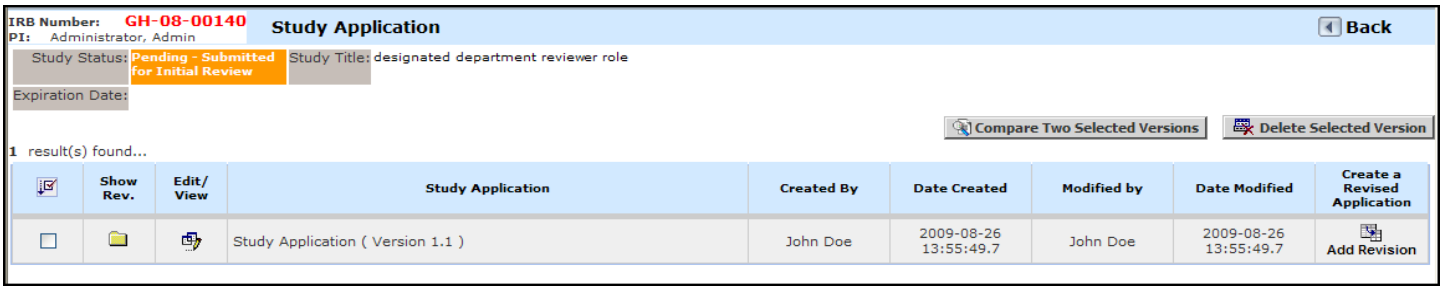
Protocol Items

This is the area of the Submissions tab where a user is able to access the **Application**, **Informed Consent**, **Other study documents,** and **Contract documents** (depending on the configuration of the software).



Application

After you have completed the **Add a new Study** feature, the application that was completed during this process will appear here. This data (Study Title, KSP, Multi-site study, etc.) will be shared throughout the database to automatically pre-populate all correlating data points. The four columns Created By, Date Created, Modified By, and Date Modified can be turned on and off.



*If there is more than one version of the application, a yellow folder would display in the Show Rev. column. To view the previous versions click on the folder.

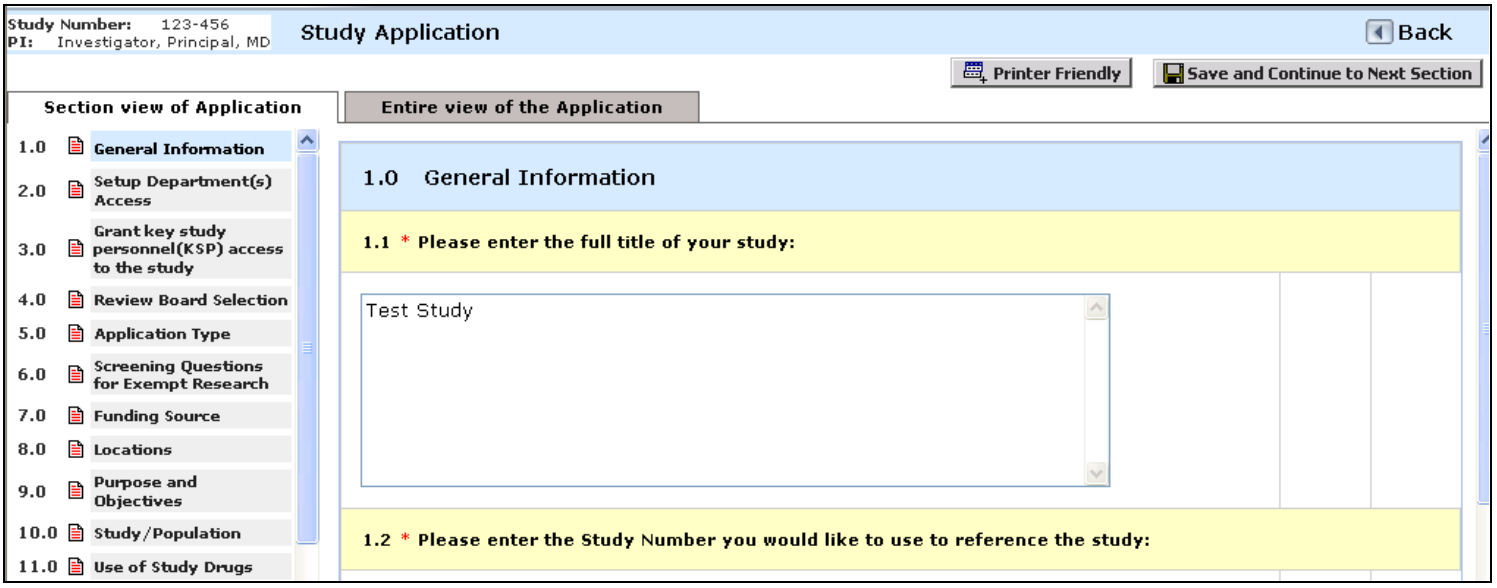
Click on the icon in the **Edit/ View** column to edit or view the application. If the application has been submitted to the IRB, you will not be able to edit the form; you will only be able to view it.

Once the application form is completed, click on the **Revision** icon in the right side of the table to create a revision of the application form.

You can view the application one of two ways:

Section view of the Application – Allows you to go to any specific section of the application by clicking on the navigation panel listed along the left side of your screen. Use this view to edit the application (if it has not been submitted to the IRB).

Entire view of the Application – Allows you to see the entire application at one time. You would select this tab most often when you want to review your work or print the application. **Note: You cannot edit the application when in this view. To edit the application, you must be in the Section view of the Application.**



To print the application form use the **Print Friendly** button and select the format to print the form in.

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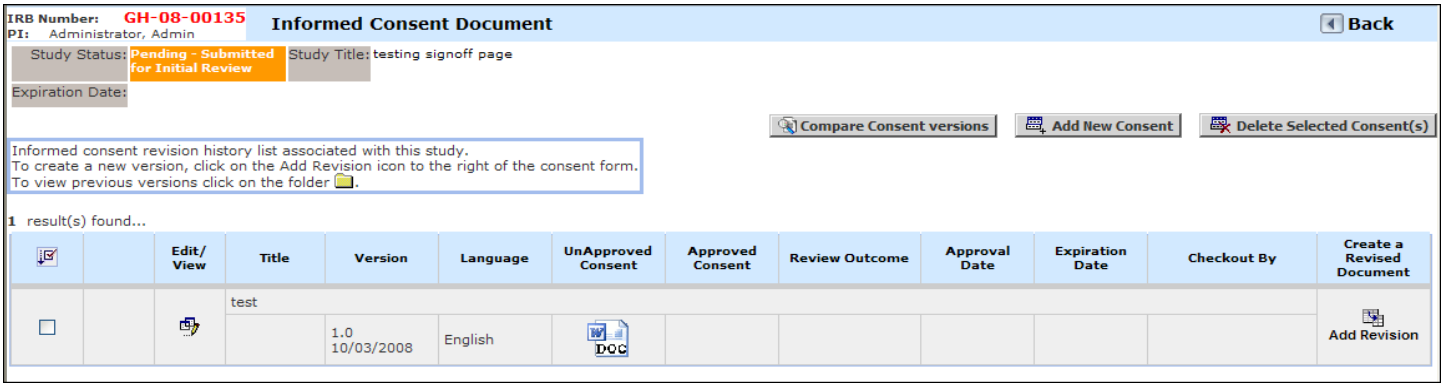
Informed Consent

You can add/ edit an Informed Consent document and attach it to your study by clicking on the **Informed Consent** link. The screen will list any Informed Consents that have been attached to the study. In this screen you have the ability to compare consent versions, add a new consent, delete an existing consent, or edit an existing consent.



The columns in the table will display specifics about the consent form.

Edit/View- Click the icon in this column to access the consent form. From here you can view the document and make any changes (if it has not been submitted to the IRB).

Title- The title of the consent form will display here.

Version- The current version and version date will display. (If there are multiple versions a folder icon will appear. Click on the folder to access previous versions of the form.)

Language- The selected language of the form will display here.

Unapproved Consent- When a new consent is attached to a study it will display in Word format in the Unapproved Consent column. You can click on the icon to edit/ view the document. Once the submission has been approved you can no longer edit that version.

Approved Consent- Once a consent form has been approved by the IRB the form will change to PDF format and move to the Approved Consent column. You can click on the icon to view the document.

Review Outcome- This will display the outcome of the consent form (i.e. approved, approved with changes or denied).

Approval Date- The date the consent form was approved.

Expiration Date- The date the consent form will expire.

Checkout By- If a user has checked out the consent form for editing purposes the name of that user will display here.

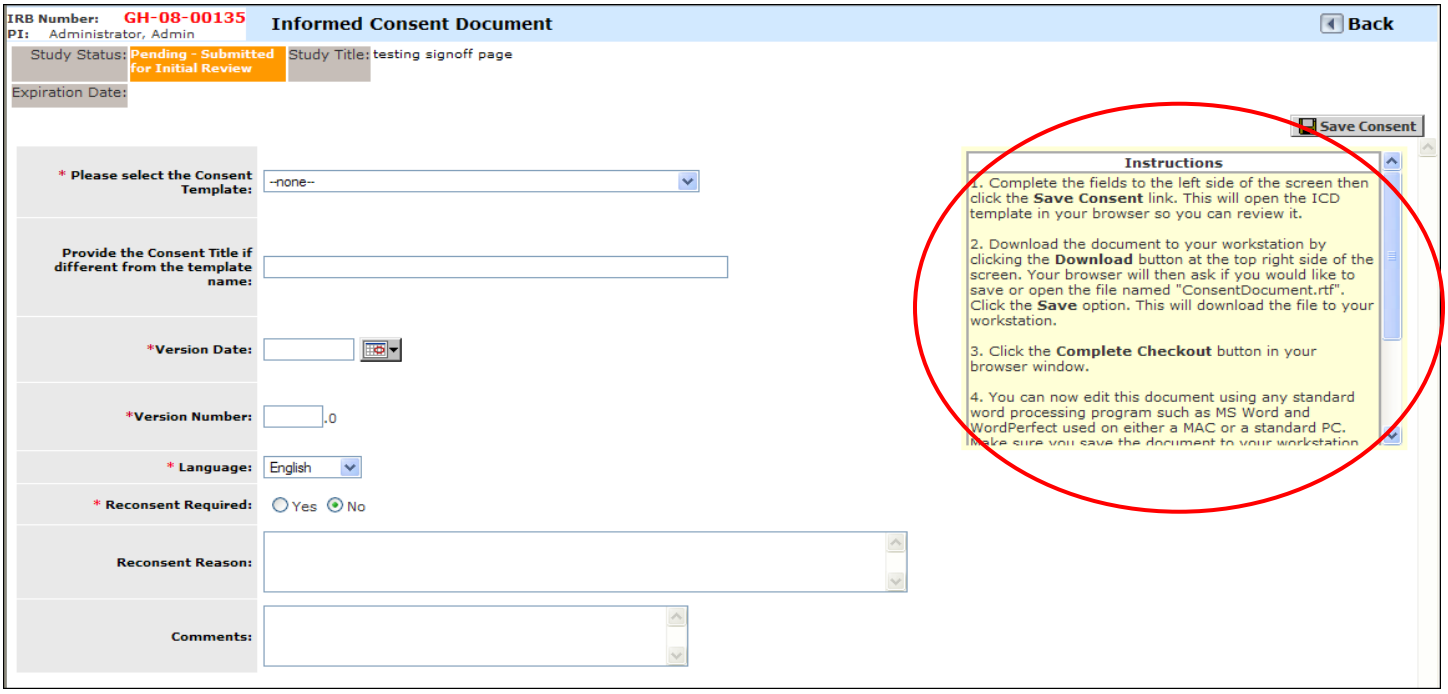
Create a Revised Document- Click the icon to create a revised document. This is mainly used if the consent form has been sent back by the IRB for revision or if the current form is close to expiration.

To add a new consent, click the **Add New Consent** button.

You will be presented with two (or three depending on the configuration of your system) options:

OPTION 1 – Add an informed consent from the list of Informed Consent Template Documents.

Selecting the first option will open the screen shown below. Follow the instructions to complete the addition of the Informed Consent.

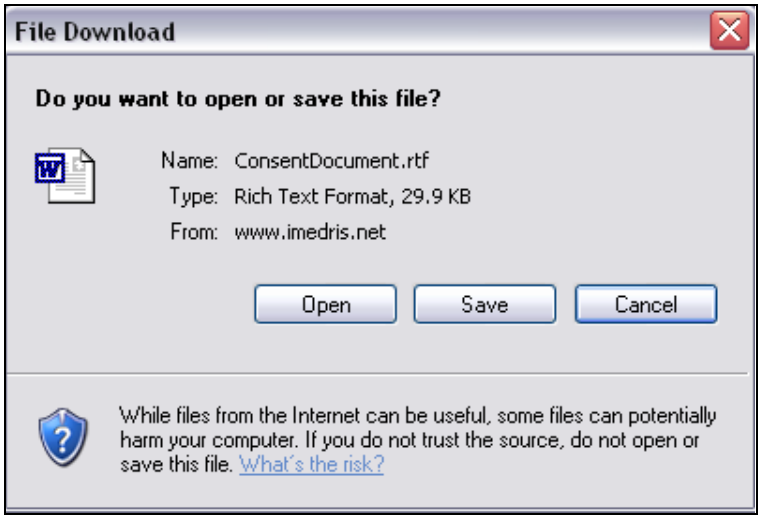


(**Note**: *required field)

- Select the **Consent Template** from the drop down menu (these templates are configured in Review Board Administration).
- Provide a **Title** for the document that is unique for you (e.g. Informed Consent – XYZ Study). **If you do not provide a title here, the document will be called by the name of the template** (e.g. Informed Consent Template).
- Select a **Version Date** from the calendar.
- Type a **Version Number**. Typically the first version would be 1.0
- Select the appropriate **Language** (English, Spanish, etc.).
- Select Yes or No for **Reconsent required.**
- Use the **Reconsent Reason** area to provide details.
- Add any necessary comments to the **Comments** field.

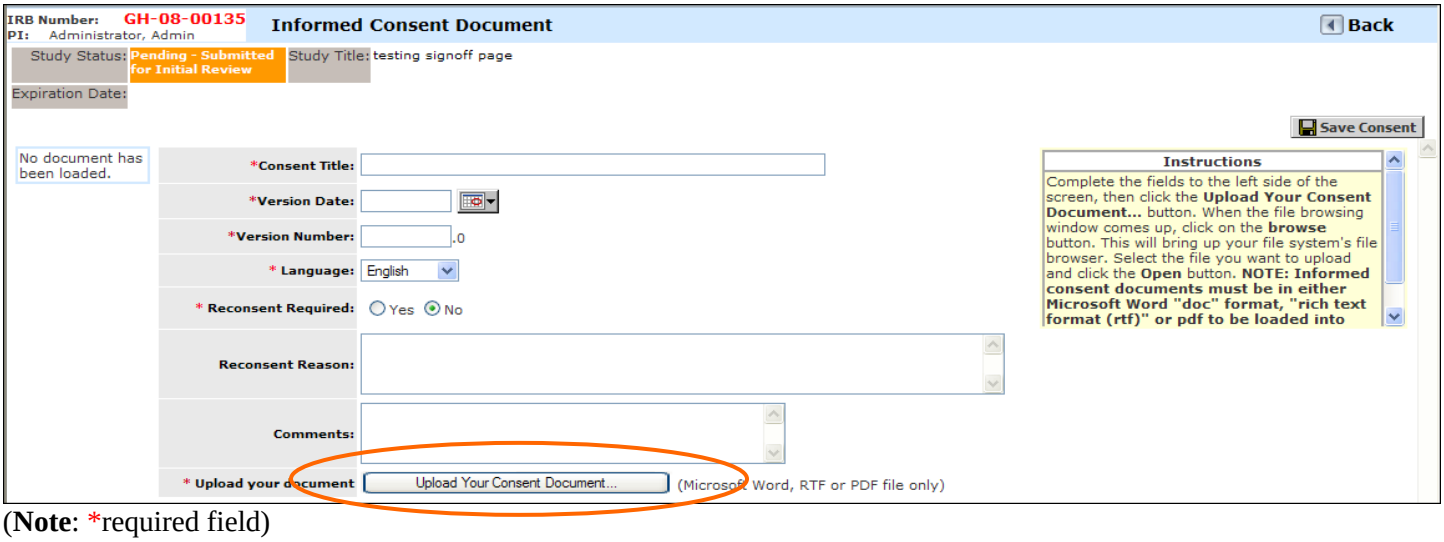
Once you click the **Save** button the file will download to your computer. Consent files are in .RTF file format which is editable by standard word processors such as **Microsoft Word**™ and **Word Perfect**™. When you have completed your modifications to the consent document open the consent record and check it back into iRIS.

Once you click the **Save** button at the top of your screen, you will be prompted to either **Open** or **Save** this file. **Note:** Always save the file to your computer. If you click **Open** the file is saved to your temporary folder and any edits you make will not be saved permanently.



OPTION 2 – Add an informed consent from an existing electronic document you already have.

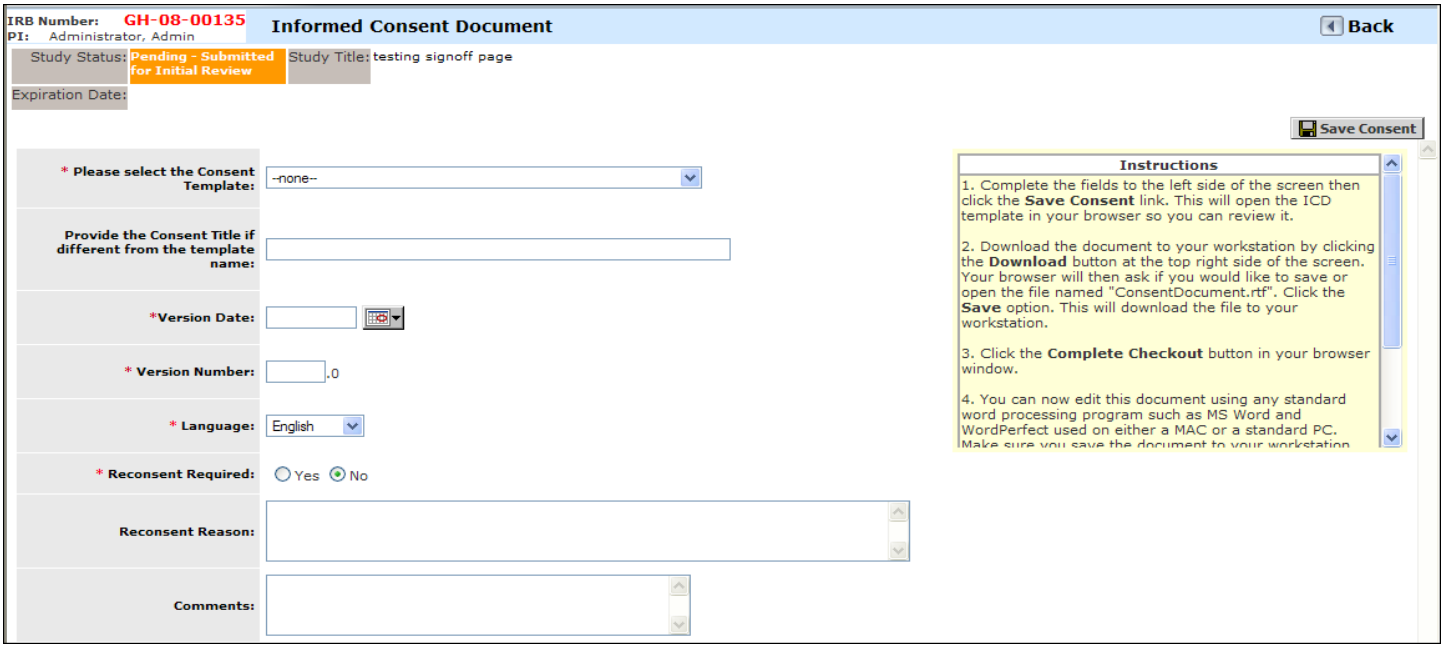
This option is generally for studies being done at facilities that have or require their own unique informed consent.



(**Note**: *required field)

- Enter a unique **Consent Title** for your document.
- Select a **Version Date** from the calendar.
- Type a **Version Number**. Typically the first version would be 1.0
- Select the **Language** (English, Spanish, etc.).
- Select Yes or No for **Reconsent required.**
- Use the **Reconsent Reason** area to provide details.
- Add any additional **Comments** if applicable.
- Click on the **Upload your Consent Document** button to select the document from your computer or network directory.
- Click the **Save Consent** button.

OPTION 3 (this option may or may not appear depending on the configuration of your system) – Add an informed consent from the list of Informed Consent Builder Templates.



(**Note**: *required field)

- Select the **Consent Template** from the drop down menu (these templates are configured in Review Board Administration).
- Provide a **Title** for the document that is unique for you (e.g. Informed Consent – XYZ Study). **If you do not provide a title here, the document will be called by the name of the template** (e.g. Informed Consent Template).
- Select a **Version Date** from the calendar.
- Type a **Version Number**. Typically the first version would be 1.0
- Select the appropriate **Language** (English, Spanish, etc.).
- Select Yes or No for **Reconsent required.**
- Use the **Reconsent Reason** area to provide details.
- Add any necessary comments to the **Comments** field.

Once you click the **Save** button the consent template will appear in your screen. To edit the file, click the **Download** button on the top left of the screen. The file will download to your computer. **Note:** Always save the file to your computer. If you click **Open** the file is saved to your temporary folder and any edits you make will not be saved permanently. Consent files are in .RTF file format which is editable by standard word processors such as **Microsoft Word**™ and **Word Perfect**™. When you have completed your modifications to the consent document open the consent record and check it back into iRIS.

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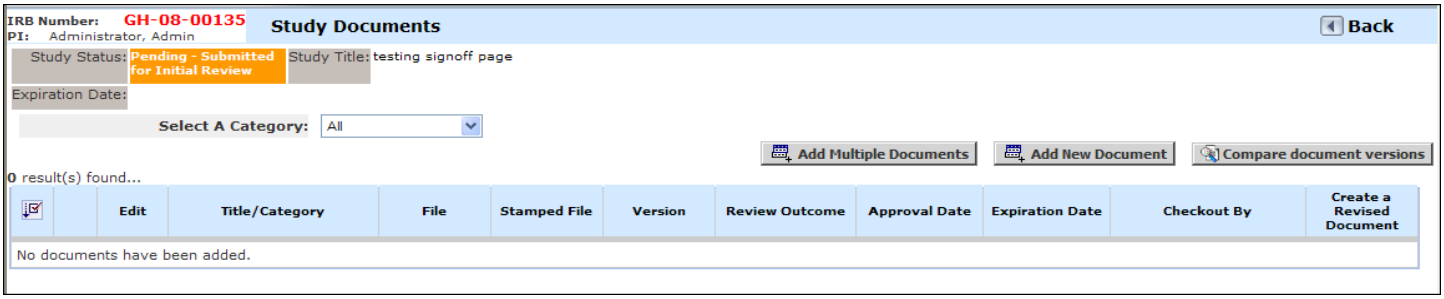
Other Study Documents

This section is used for uploading various study documents such as protocols, investigator brochures, questionnaires, surveys, etc. In other words, all the documents that are not an IRB Application, Informed Consent or specific review board form can be considered Study Documents. All study documents must be created/ edited and saved outside of iRIS (on your computer) before they can be uploaded into iRIS.
Once you click on the **Other Study Documents** link you will be brought to a screen similar to the one shown below.



The columns in the table will display specifics about the study document.

Edit- Click the icon in this column to access the study document. From here you can edit/ view the document.

Title/Category- The title and category of the study document will display here.

File- Any unapproved document will display under this column until it has been approved by the review board.

Stamped File- Once a document has been approved by the review board it will display under this column.

Version- The current version number will display. (If there are multiple versions a folder icon will appear. Click on the folder to access previous versions of the document.)

Review Outcome- This will display the outcome of the study document (i.e. approved, approved with changes, or denied).

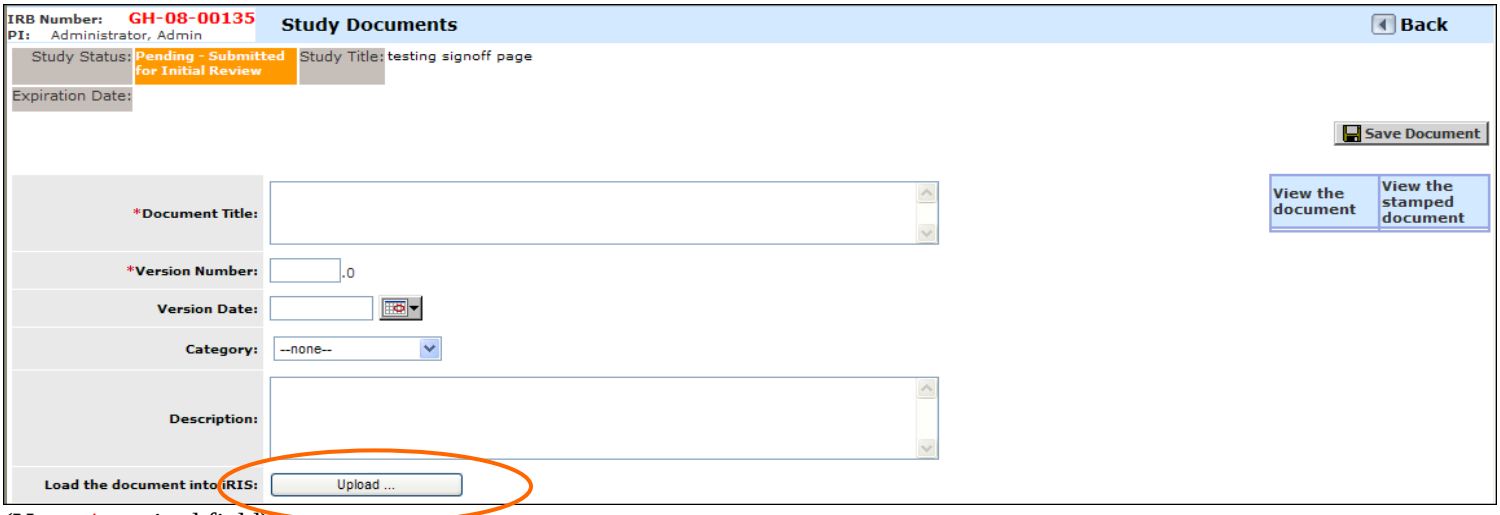
Approval Date- The date the document was approved by the review board.

Expiration Date- The date the document will expire by the review board.

Checkout By- If a user has checked out a document the name of that user will display here.

Create a Revised Document- Click the icon to create a revised document. This is mainly used if the document has been sent back by the IRB for revision or if the current form is close to expiration.

To create a new document in iRIS, click the **Add New Document** button.



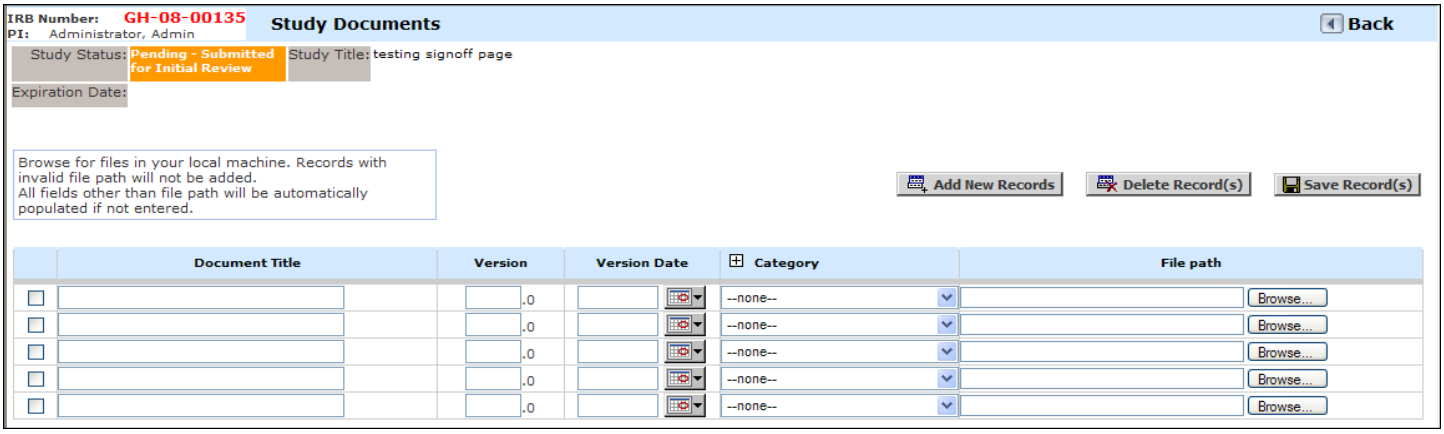
(**Note**: *required field)

- Enter the **Title** of the document.
- Type a **Version Number**. Typically the first version would be 1.0

- Select a **Version Date** from the calendar.
- The **Category** drop down list will show the available categories to associate to the document.
- Use the **Description** text field to add any additional information.
- Click on the **Upload** button to select the document from your computer or network directory.
- When a document is uploaded, an icon will appear under the **View the Document** heading. This icon can be clicked to view the uploaded document.
- When a document is approved by the review board, then an icon will appear under the **View the Stamped Document** column. This icon can be clicked the view the approved study document.

Once you have finished uploading the document into iRIS click the **Save Document** button in the upper right hand corner. This will save and attach the document to the study.

Multiple study documents can be added on at the same time by clicking the **Add Multiple Documents** button.



As described earlier, simply enter in the document title, version, version date, category, and choose the file from your computer. Up to five documents can be added at a time here. When the desired number of documents have been added, click the **Save Records** button. All the records will be saved.

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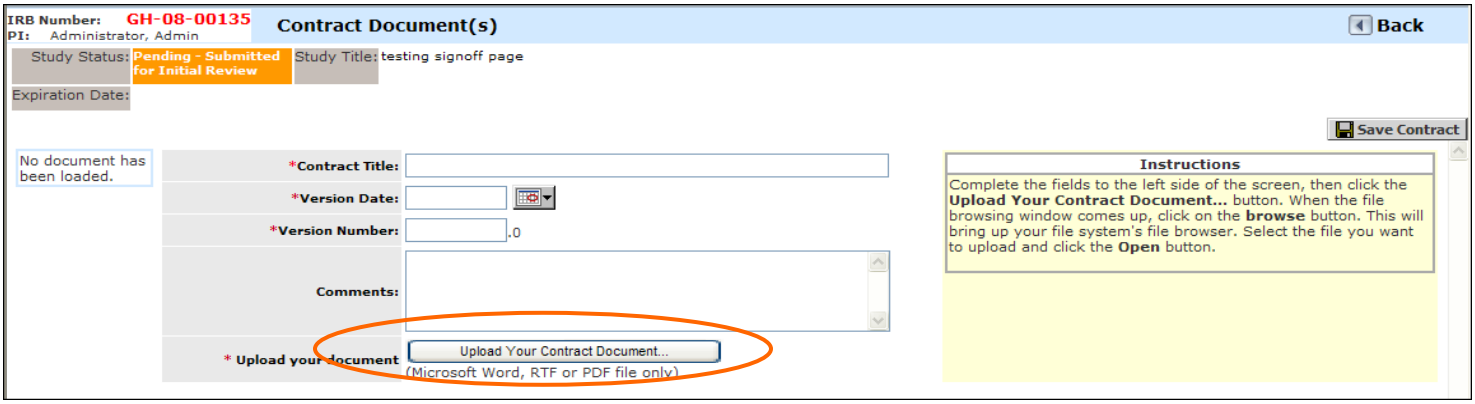
Contract Document

This section is used for uploading a **Contract Document** to a study. All **Contract Documents** must be created/ edited and saved outside of iRIS (on your computer) before they can be uploaded into iRIS.

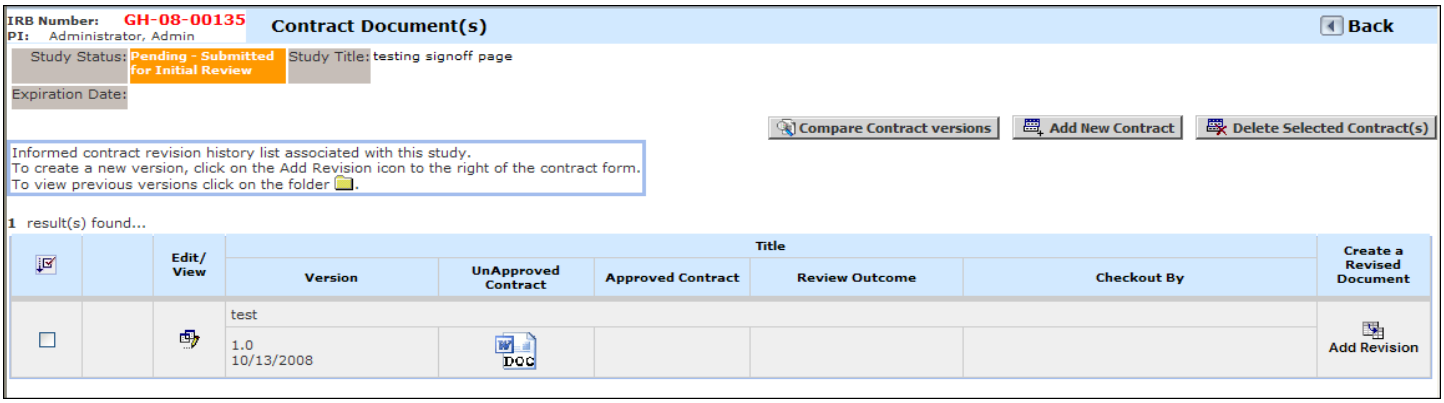


(**Note**: *required field)

- Enter the **Title** of the contract.
- Select a **Version Date** from the calendar.

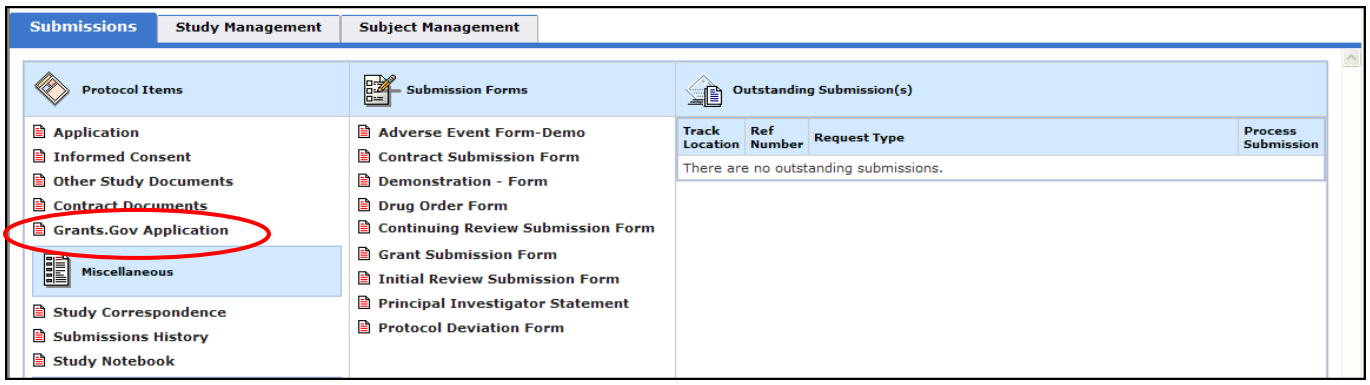
- Type a **Version Number**. Typically the first version would be 1.0
- Add any additional **Comments** if applicable.
- Click on the **Upload** button to select the contract from your computer or network directory.

Once you have finished uploading the contract into iRIS click the **Save Contract** button in the upper right hand corner. This will save and attach the contract to the study.



Grant.Gov Application Package

If the Grant feature of iRIS has been purchased by your institution, then there is an additional feature within Study Management (controlled by the Role Access Matrix in System Administration) that allows an existing study to be linked to a Grant Application.



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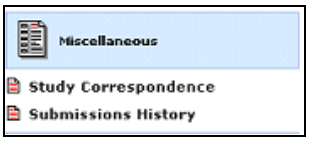
Miscellaneous

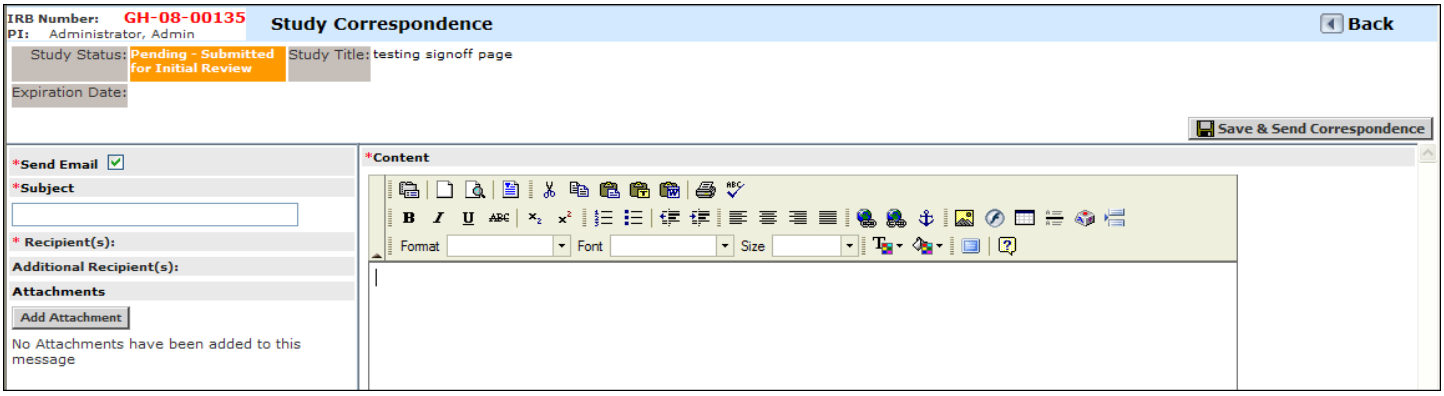
This is the area of the Submissions tab where a user is able to access the **Study Correspondence** and **Submissions History**.



Study Correspondence

This section is used for any correspondence between study personnel and the IRB related to the study.

To generate correspondence click on the **Add a New Correspondence** button. A user will be brought to a screen similar to the one shown below.

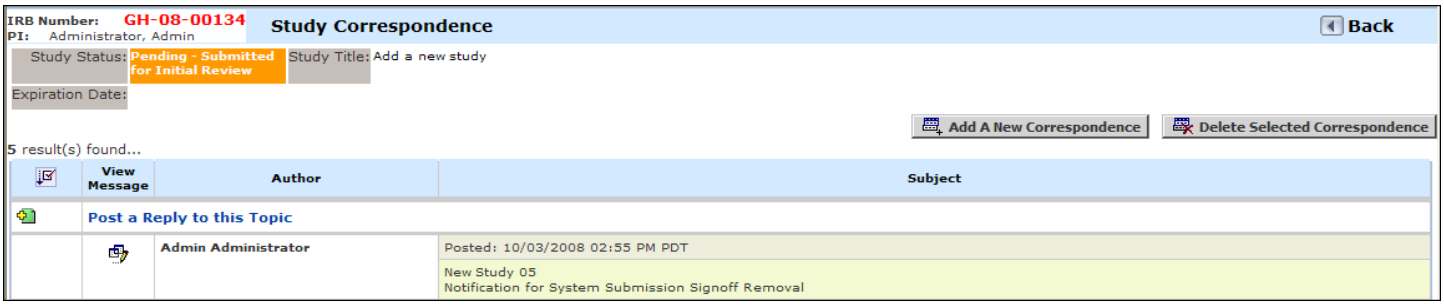


(**Note**: *required field)

- Select the checkbox if you want an **Email** notification sent to the recipient(s). This checkbox is selected by default. If you do not want the correspondence to send as an email (i.e. because someone does not have an iRIS user account), make sure the checkbox is not selected.
- Enter a **Subject** for the correspondence.
- Assign **Recipients** to the correspondence.
- Add any **Additional Recipients** you would like a copy of the correspondence sent to.
- Add any **Attachments** you would like to include with the correspondence.
- Enter the **Content** in the text editor.

Once you have completed the correspondence click the **Save and Send Correspondence** button. If the Send Email checkbox is selected, an email will send to the recipients and will also be posted in their Unopened Correspondence. If the Send Email is not selected, the recipients will only have the correspondence in their Unopened Correspondence.

When correspondence has been added to this screen, others can post a reply by clicking the icon next to the **Post a Reply to this Topic**.



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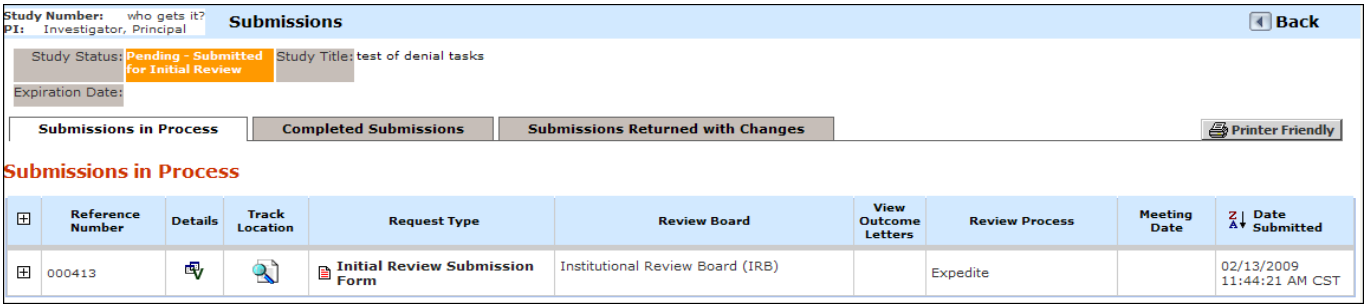
Submissions History

This section can be viewed two ways:

Submissions in Process- This tab displays all of the submissions in process. From here a user can track the location of the submission, view the reference number, details of the submission, request type, review board, outcome letters, review process, meeting dates, and the date submitted.

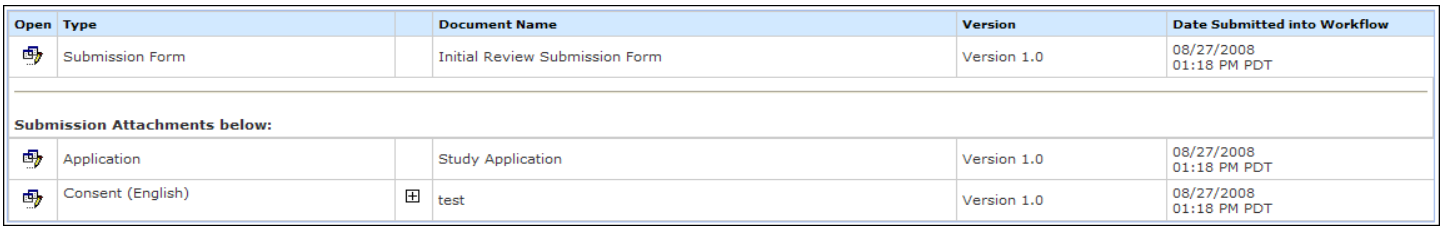


Completed Submissions- This tab displays all the completed submissions. From here a user can track the location of the submission, view the reference number, details of the submission, request type, review board, view outcome letters, review process, meeting dates, and the date submitted.

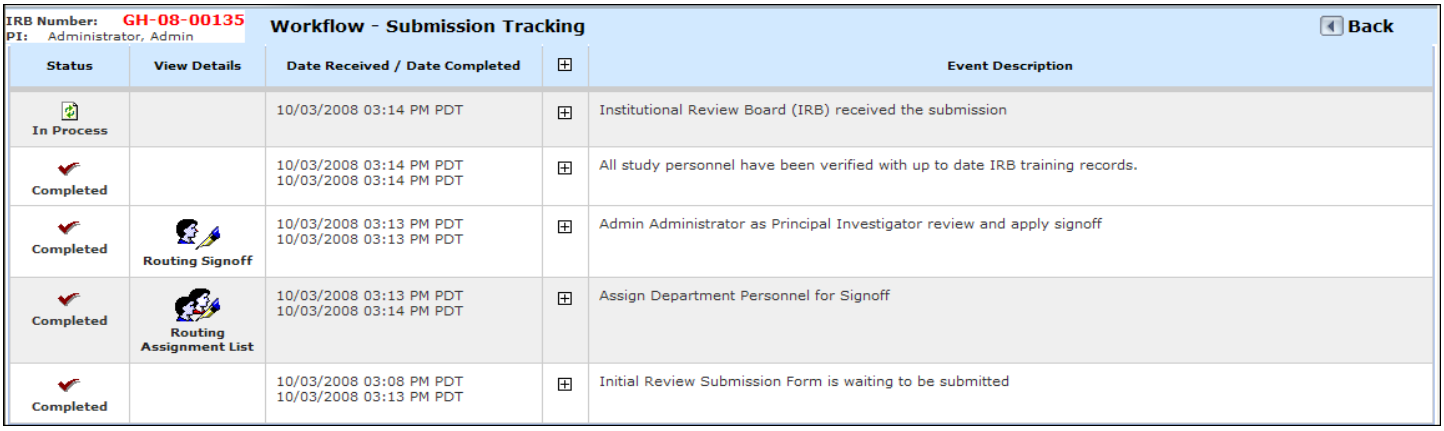
Submissions Returned with Changes - There is a third tab that lists the Submissions that have been returned for corrections for that protocol.

Within all three tabs an icon appears under the Details, Track Location, and Request Type columns.

Details – Click this icon to view the forms and attachments within the submission and details about each one.



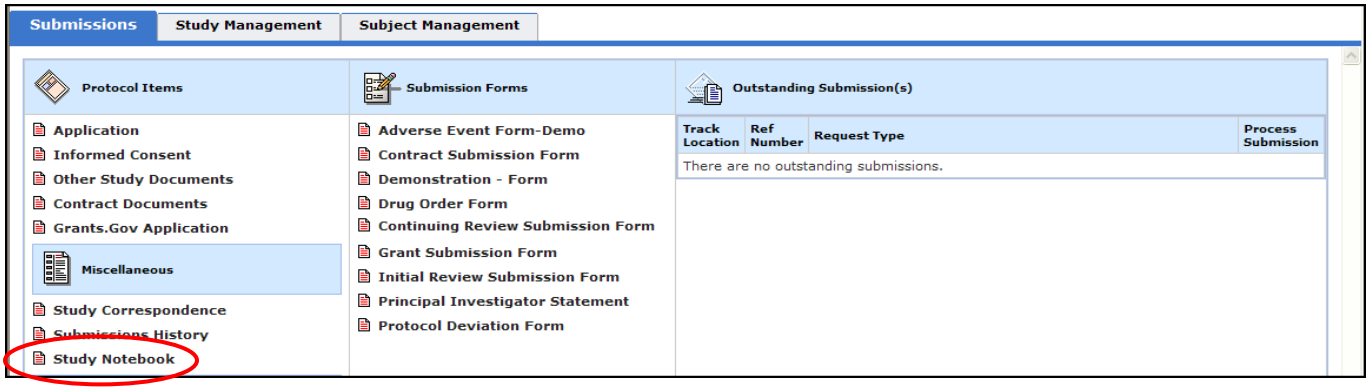
Track Location- Click on this icon to view a step by step break down of the submission process.



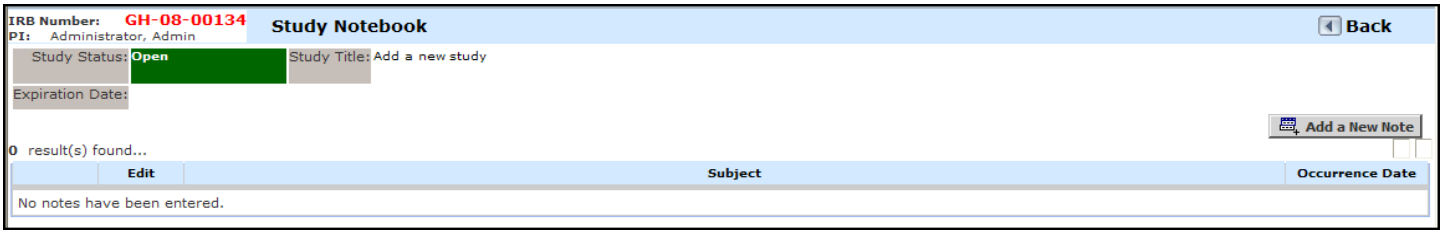
Request Type- Click on this icon to view the submission form.

Study Notebook

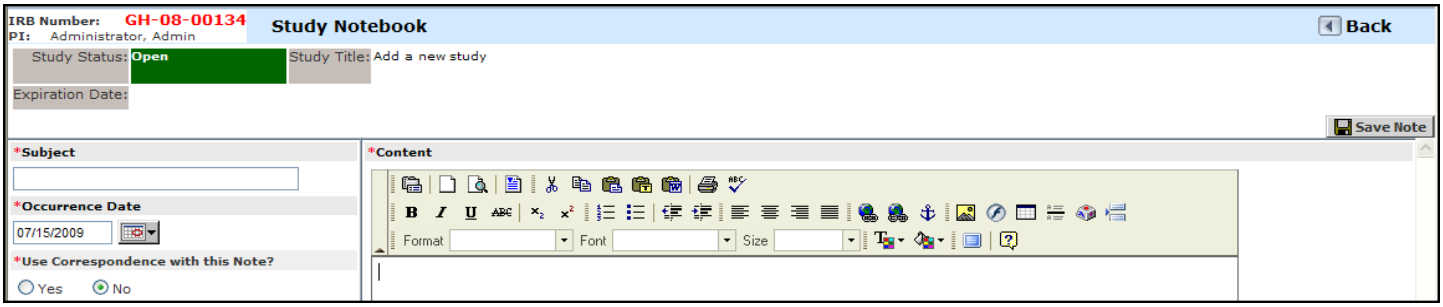
The Notebook feature is available in Study Management under the Miscellaneous group of links found in the Submission tab:



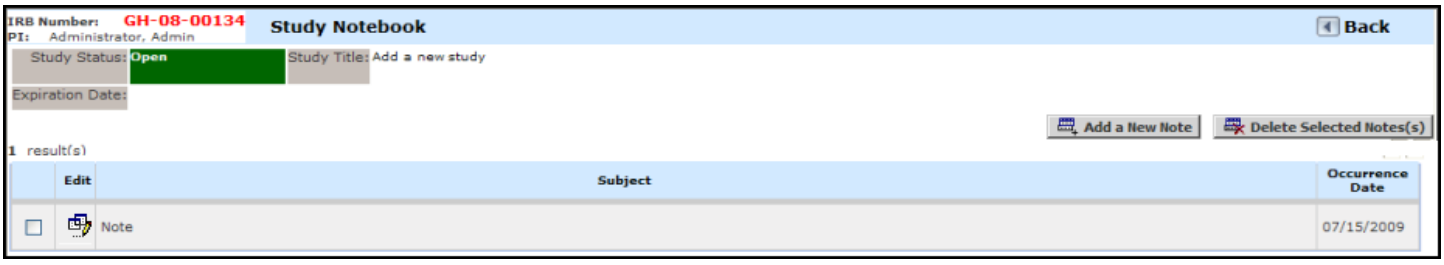
The study notebook can be used to record notes about the study. These notes can either be sent within a correspondence email, or simply stored as a note.



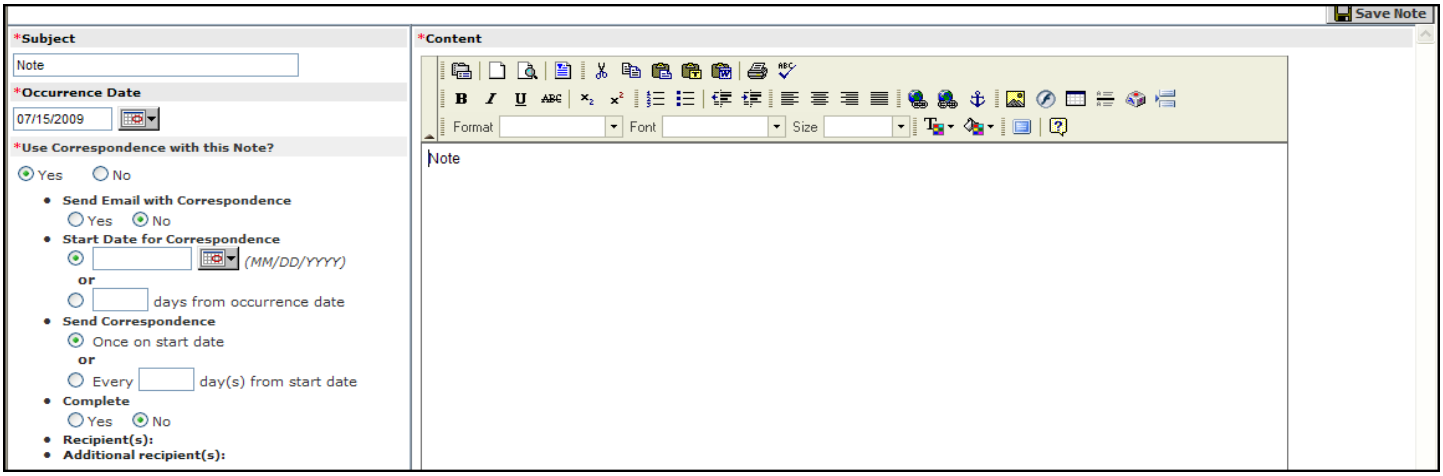
To add a note, click the **Add a New Note** button. This will bring you to a screen similar to the one shown below:



Specify the Subject of the note, the occurrence date, and the Content. If this is simply a note, then do not choose **Yes** to use correspondence with this note. Rather, simply save the note. To edit the note click the **Edit** icon. To delete a note, select the checkbox next to the desired note and click the **Delete Selected Note(s)** button.



However, to use the note within a correspondence and/or send it via an email, then select **Yes** to the **Use Correspondence with this Note?**



Notice a number of options allow you to configure the correspondence setup of the note. An email can be sent with the correspondence. Specify the start date of the correspondence or the number of days that the correspondence will be posted from the occurrence date specified above. The correspondence can be sent once on the start date, or every 'x' number of days from the start date. Mark the Note as Complete in order to post the correspondence and mark the recipients and additional recipients of the correspondence (and email if one is being sent).

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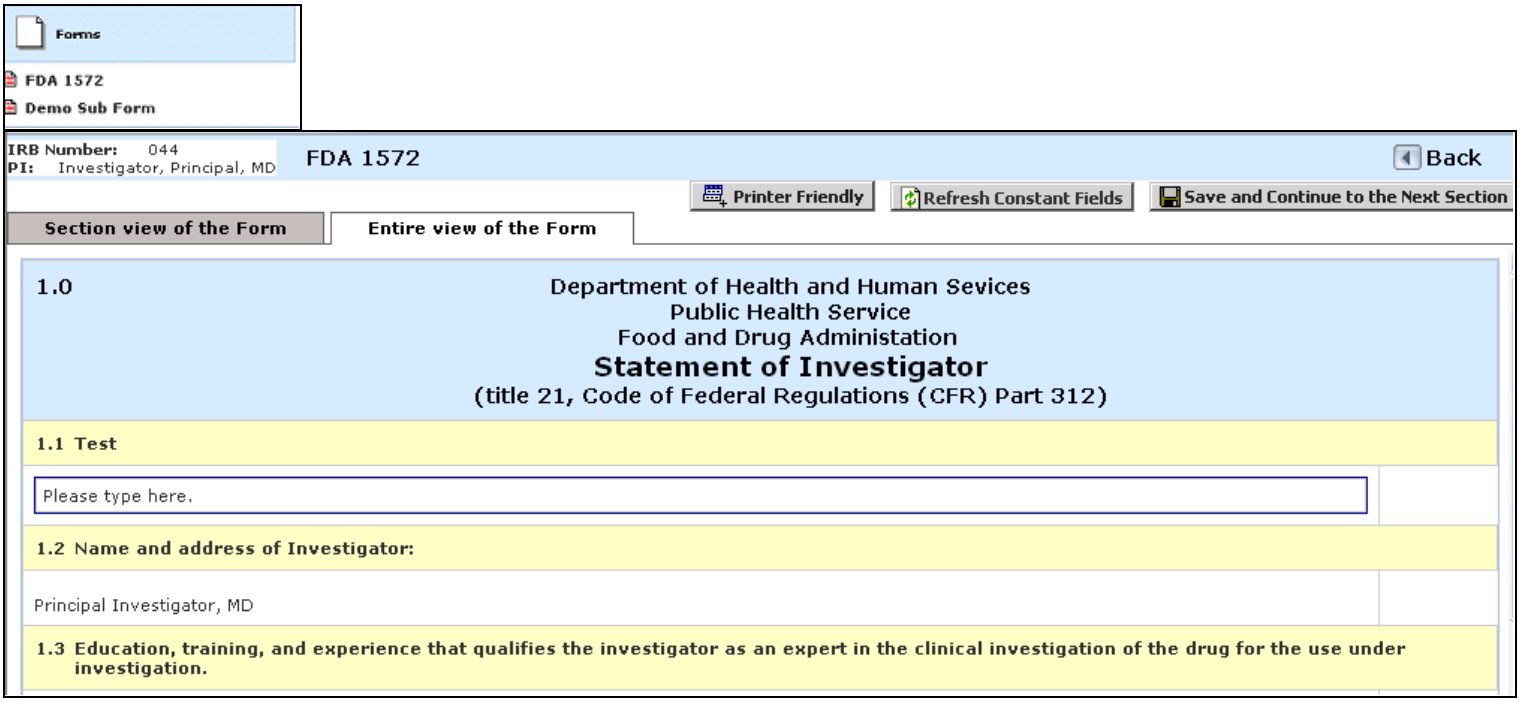
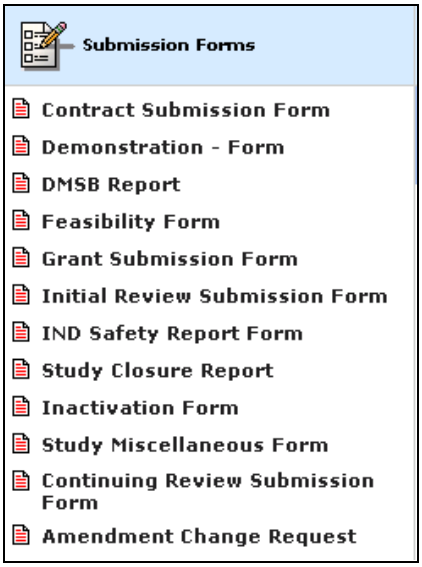
Forms

This lists any review board or Submission Forms available for the study. These forms are typically filled out while completing the parent form but can be accessed here as well. Click on a link to open a particular form. The screenshots below are examples of what your forms may look like. However, these forms are designed within the Forms Designer according to your institutions needs.



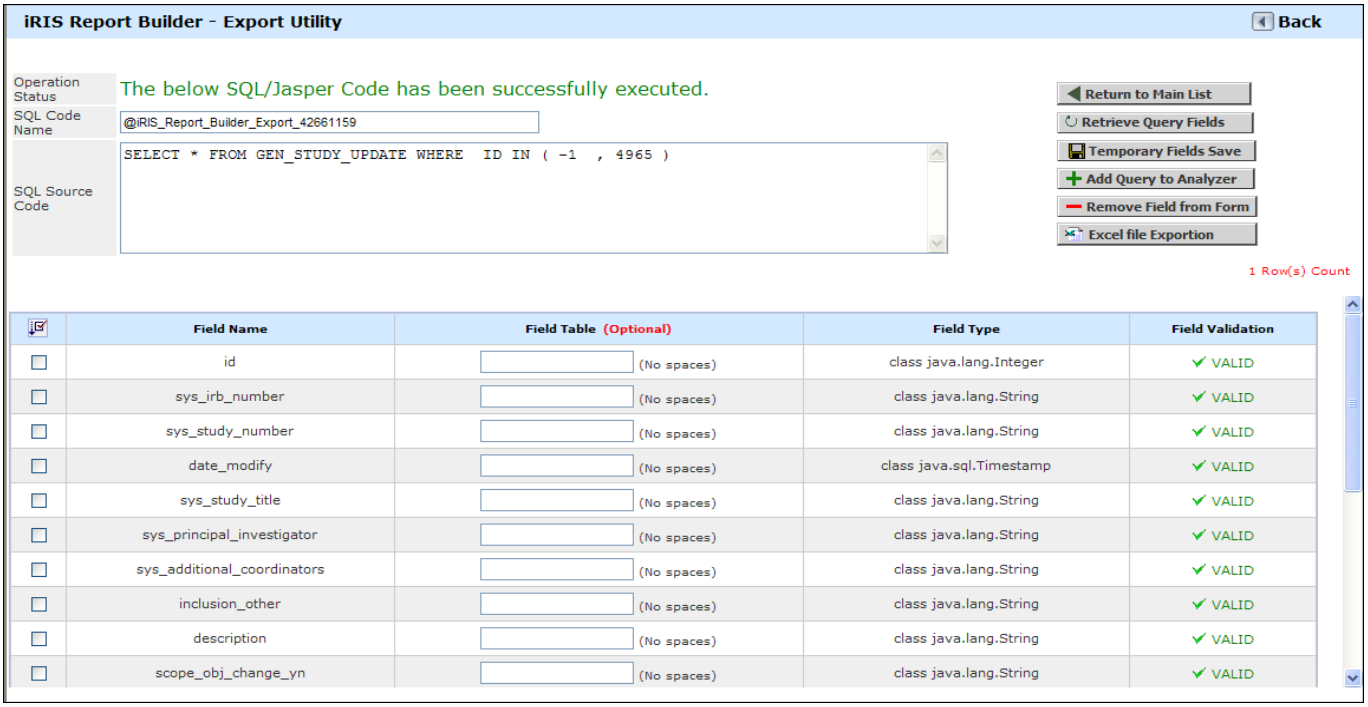
Submission Forms

This is the area of the Submissions tab where a user can access submission forms. The names and types of forms that display in this area are configured by your institution. Some examples of a form that might appear in this section would be: Continuing Review Submission Form, Initial Review Submission Form or a Contract Submission Form. A user would complete and submit these forms as needed/ required by the review board.

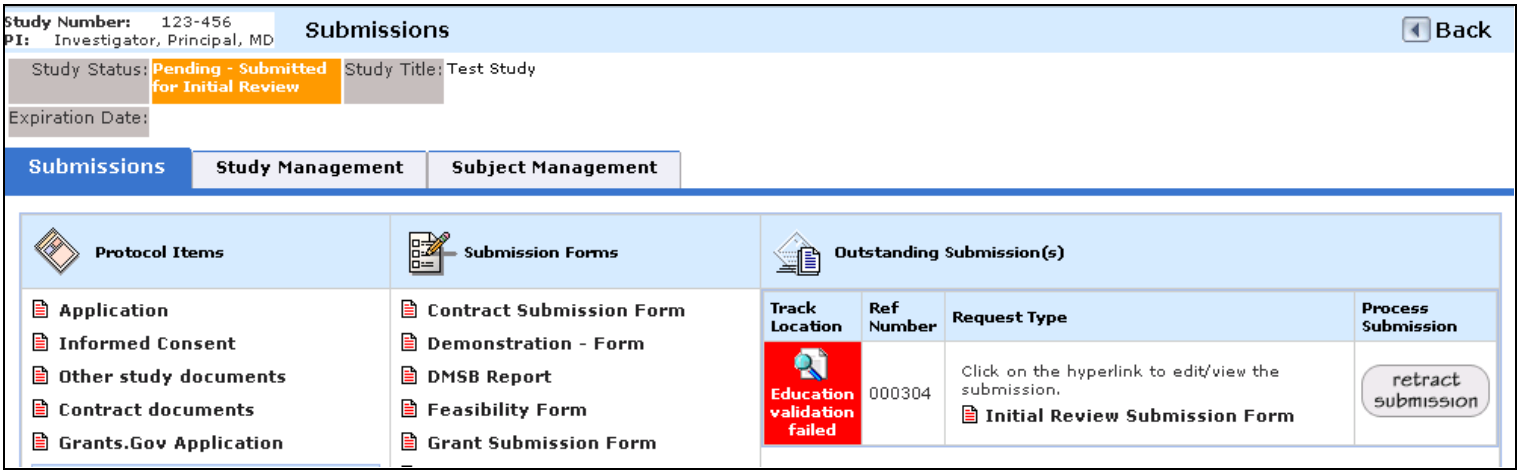


When viewing the list of forms for any particular type of form within study management, there is a button called Export to Excel. When a form is selected and this option is selected, the user will be given the option of simply downloading the form to an excel sheet or of customizing their excel sheet by excluding certain unneeded columns. When the form is downloaded to an excel sheet, then the excel sheet will consist of a simple excel sheet where the first row designates every data value within each column using the Column Names assigned to each data value in Form's Designer. Then the next row contains any input from the user within the form corresponding to each data value.

If the user chooses to customize the excel sheet, then they will actually be brought to the iRIS Report Builder Export Utility Screen. The basics you need to know to customize your report is simply to know the Column Names of the fields that you don't want to include in your report; check the box next to those names and click Remove Field from Form. If needed fields are removed and need to be restored, click Retrieve Query Fields. When the excel sheet is customized as desired, click the Excel File Exportion button.



Once a submission form has been completed and is ready to be submitted to the review board it will appear in the Outstanding Submission(s) section of the Submissions tab. (See below)



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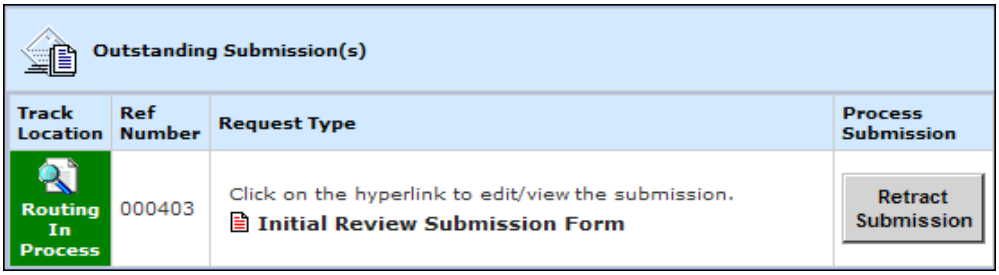
Outstanding Submission(s)

This is the area of the Submissions tab where a user can view any **Outstanding Submissions**. Within Outstanding Submissions a user is able to the Track Location, view the Reference Number, Request Type, and Process the Submission.



Track Location- This column displays information on the current routing status of the submission. If the background color for this column is green, the routing is processing without errors. If the background is red, the routing has been stopped. This is usually due to lack of necessary education and/ or training. Click on the Track Location icon to open the submission tracking page. This screen will give you a step-by-step break down of the submission to date.

Ref Number- A number automatically assigned to each submission once it has been submitted. This reference number will carry over to the review board as well.

Request Type- Lists the type of submission that is outstanding. Click on the link to open and view the form.

Process Submission- This will display a button that will read: **Send Submission** if the submission is ready to be sent or **Retract Submission** if the submission has been sent to a review board and needs to be retracted for changes. Once a submission is processed on the review board you will no longer be able to retract it.

Once a user clicks on the Track Location icon they will be brought to a Submission Tracking screen similar to the one shown in the screenshot below. The columns in the table will display specifics about the submission tracking.

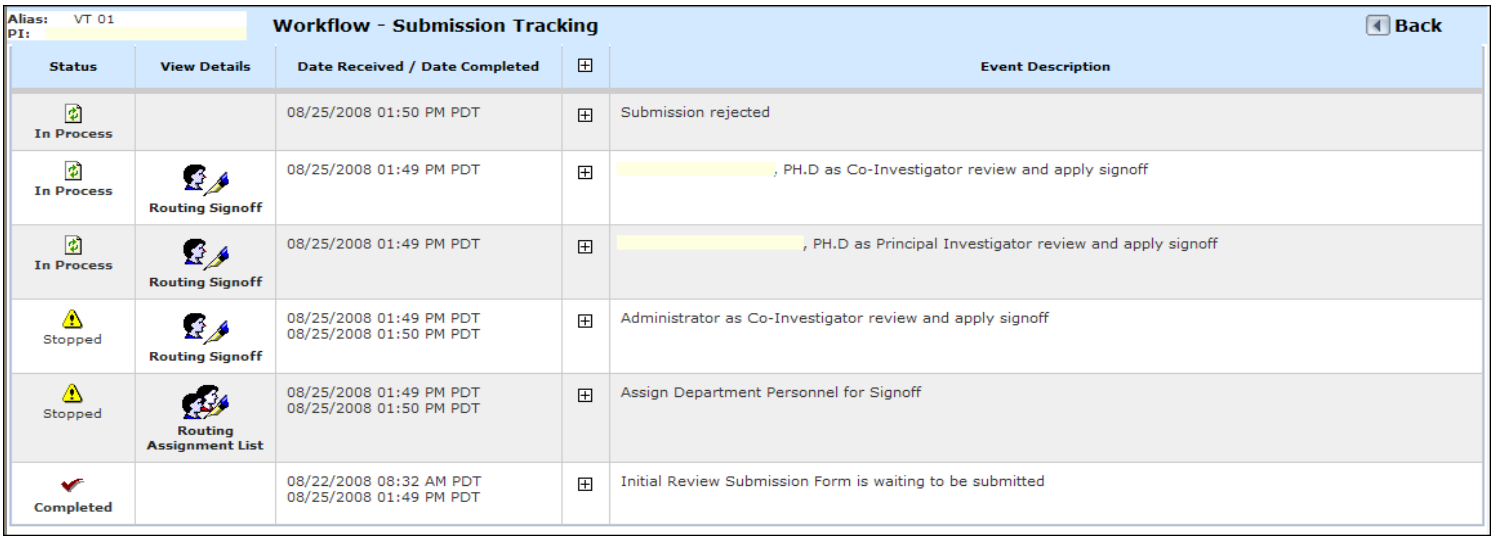
Status- Displays the status of each process the submission has been through (i.e. Stopped, Completed and In Process) with the most recent process near the top.

View Details- Displays any pending and completed signoffs. A user can click on the icon in this column to view the signatures and any comments that may be attached with them.

Date Received- The date each submission process started.

Date Completed- The date each process was completed.

Event Description- Gives a detailed description of each process of the submission. Click on the + icon to view the specific details about the event.



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