STUDY MANAGEMENT

Subject Management

Version 10.02

Contents

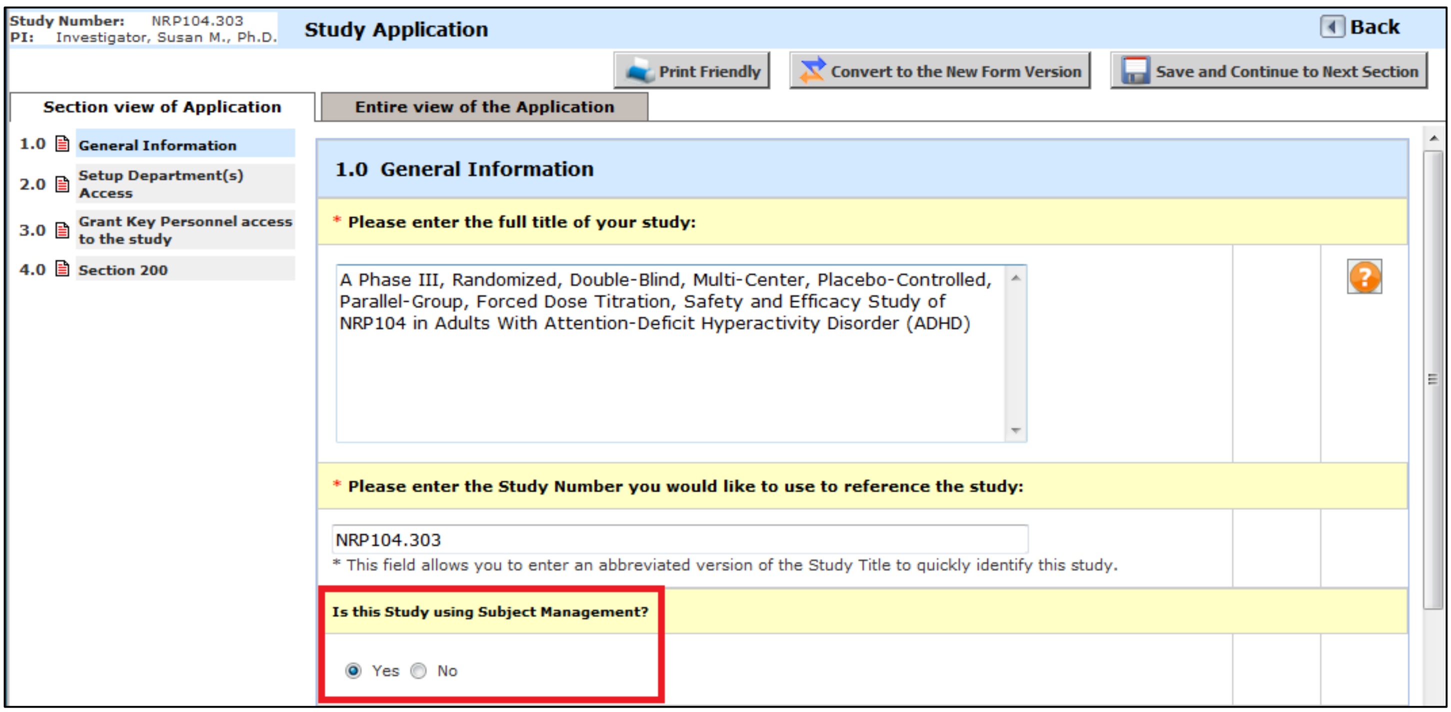
Subject Management Manual

Introduction

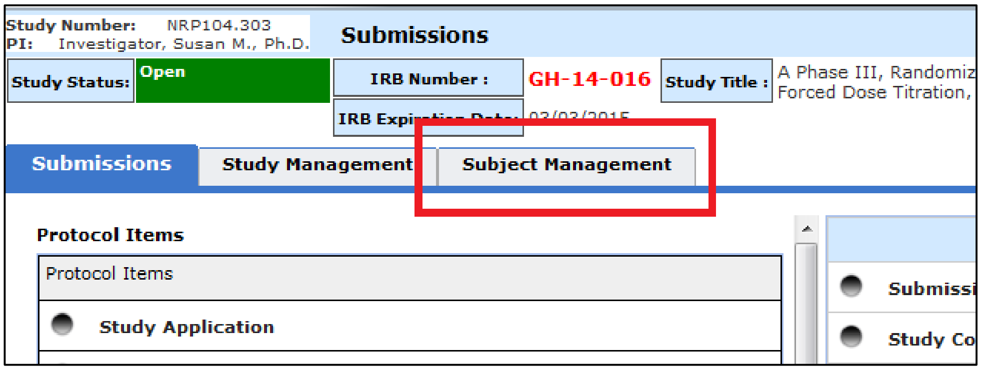
The Subject Management module within Study Assistant allows a research team to register subjects on to a study, enroll the subject on custom study plans and track the subject activity as the subject begins treatment. This manual will guide you through adding a subject to a study, flagging the screening process, registering the subject onto a study plan, updating subject demographic information and accessing existing subjects on the study. It will also cover reviewing protocol specific tasks, such as completing a visit, submitting an Adverse Event form related to the subject and accessing the subject's Informed Consent. This manual also reviews the subject progression and study visit schedule calendars.

Enabling Subject Management for a Study

Subject Management is accessible within a study record that has been flagged as using Subject Management. When a study record is first created in iRIS, the user filling out the Study Application will be asked if the study is using Subject Management (this question is only available if your system has Subject Management enabled).

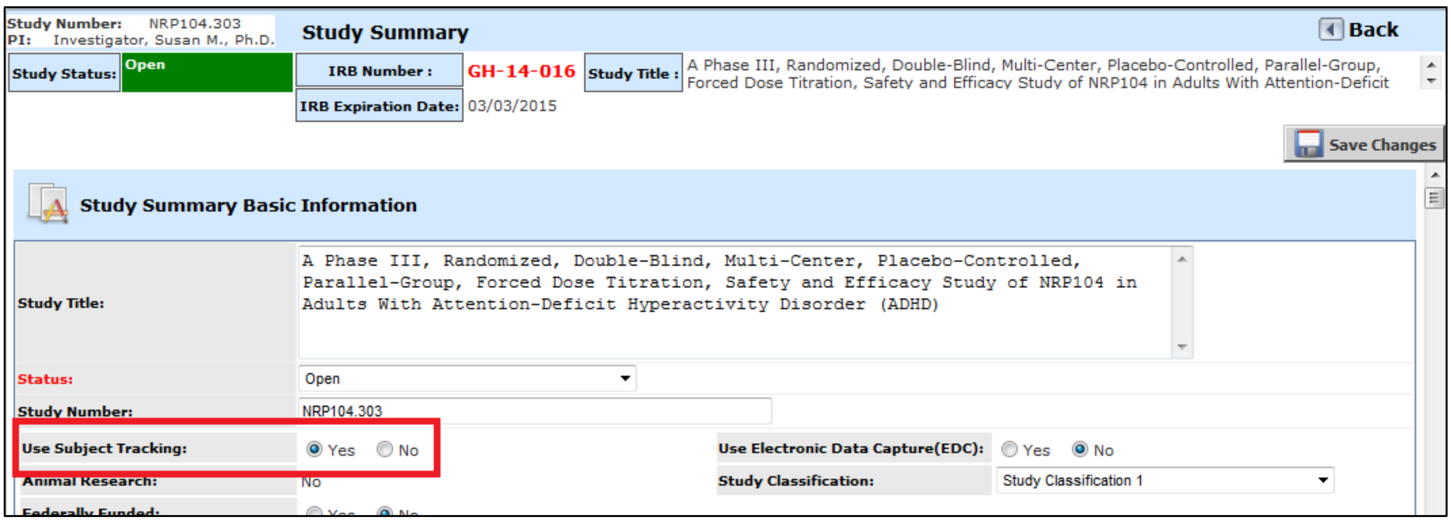


When the Subject Management flag is set to "Yes" within the Study Application, the Subject Management tab will be available within the study, as shown in the screenshot below.



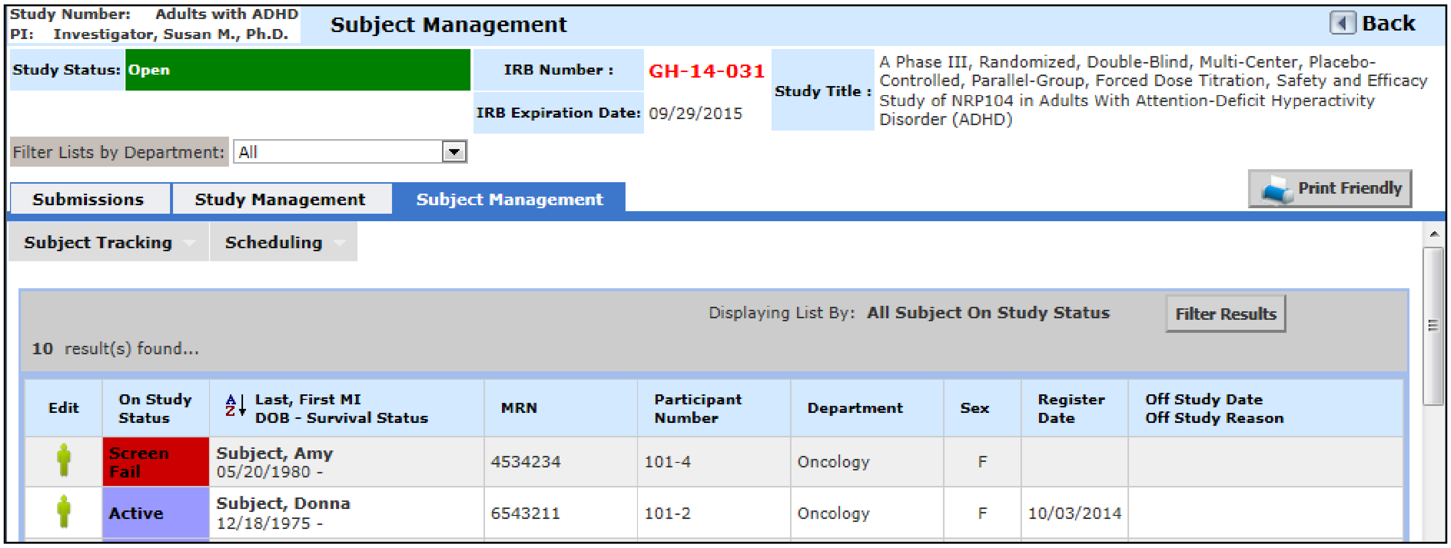
If this question was not initially set to include Subject Management within the study, the value can be changed later by contacting the review board of record. The RB Coordinator can then set the information in the Study Profile.

Note: The IRB will have the ability to allow Subject Management and set the number of approved subjects; however, the IRB does not have access to subject information.



Accessing Subject Management

The Subject Management tab can be accessed at any time once the study record is created and the Subject Management flag is set to “Yes”. Your role must also have access rights to Subject Management and the pages within. In order to add subjects to the study and access existing subjects, the IRB must first approve the study. Otherwise, you will not be able to access the records in this area.



The columns listed on this page are as follows:

Edit- You can click on this icon to open the subject record. From here a user can view and/or make changes to the subject's demographic information and study-specific information. This includes subject on study information and visit-specific information.

On Study Status- Displays the current on-study status of the subject (e.g. Active, Inactive, Complete, etc.)

Last, First, MI, DOB- Survival Status - Displays the last name, first name, middle initial, DOB, and Survival Status (e.g. Alive, Deceased) of the subject.

MRN- If assigned to a subject, the medical record number (MRN) will display here.

Participant Number- If assigned to a subject, the participant number will display here.

Department- This field will display the department that has been associated with the subject.

Sex- Lists the gender of the subject.

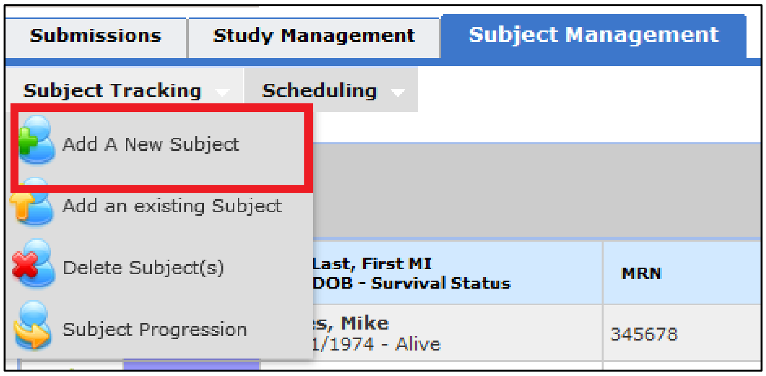
Register Date- If a registration date has been assigned to a subject, it will display here.

Off Study Date/ Off Study Reason- If a subject is no longer participating in the study, the date and reason for leaving will display here.

Depending on the current status of the study, you may or may not be able to modify Subject Records. If the Edit column reads View, the current Study Status does not allow Subject Management modifications. If you open a Subject Record, you will be able to view information about the subject, but you will not be able to change information.

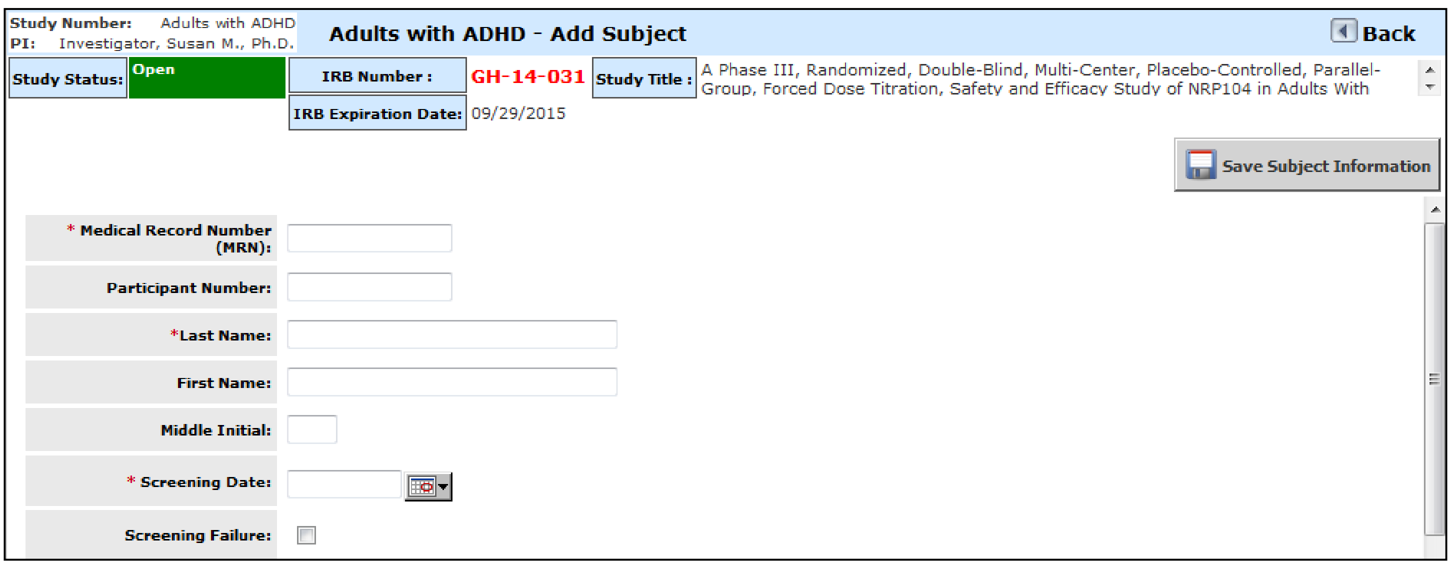
Subject Tracking

At the top of the Subject Management page, a menu bar allows you to access different areas of Subject Management. From this area you can add a subject, delete a subject and view subject progression on the study. You can also view schedule information.

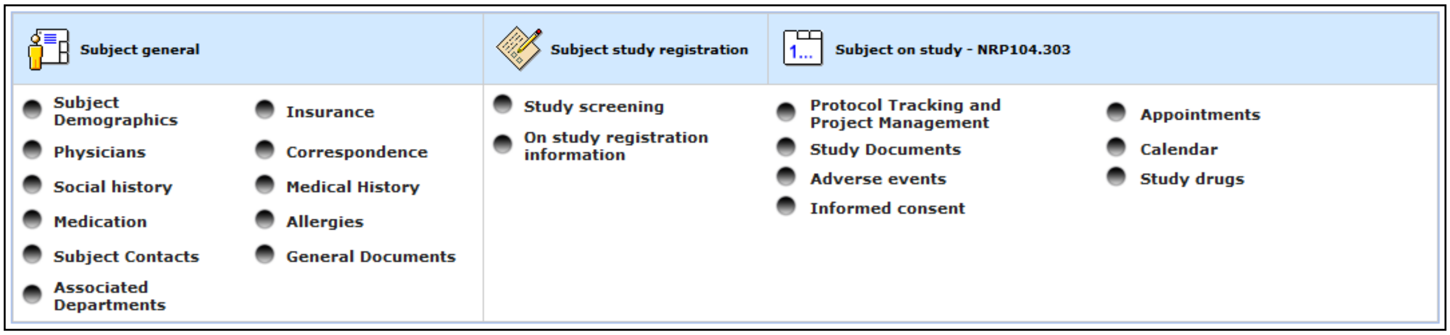


Add a New Subject

To add a subject to the study, mouse over the **Subject Tracking** menu, then click the **Add a New Subject** button. A new page opens, allowing you to input basic subject information. Your screen may or may not have the same fields as shown below, depending on your system setup. Any field marked with a * is a required field and must be completed before saving the page.

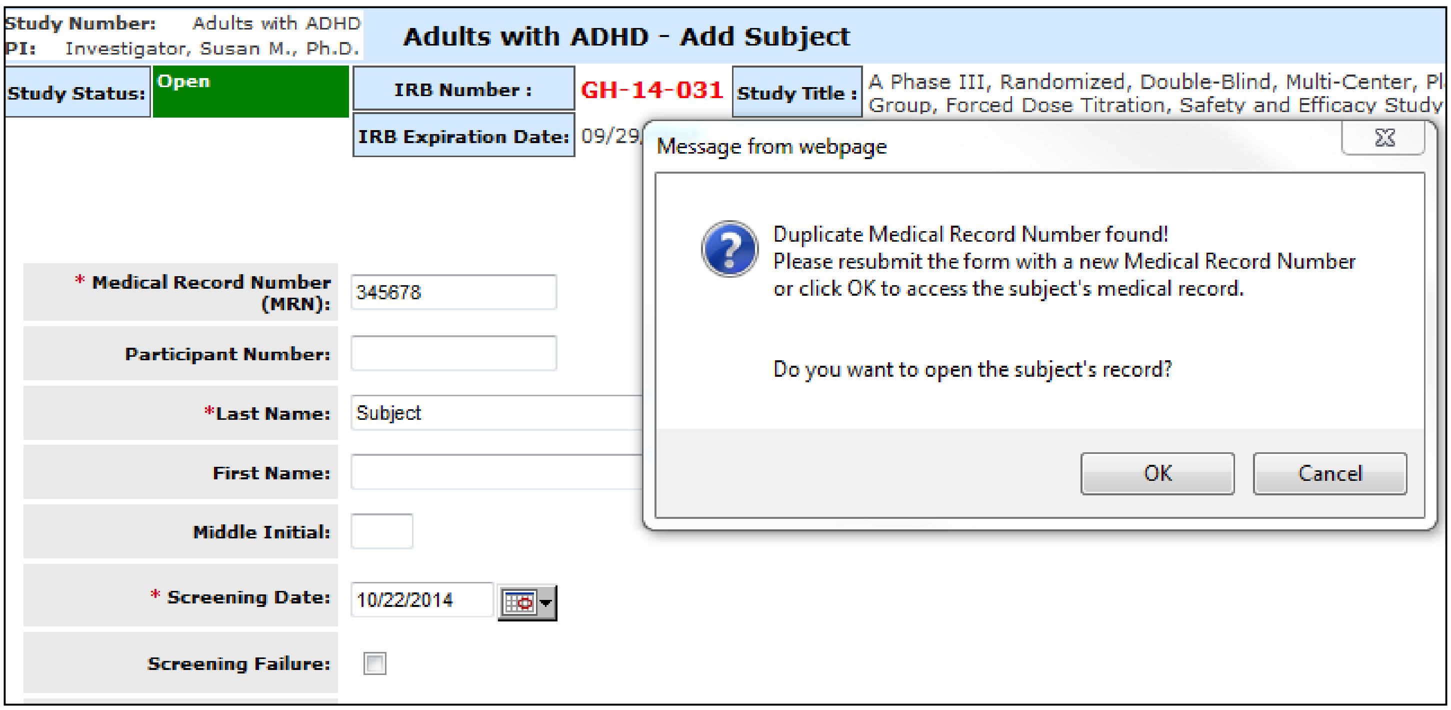


After saving the Subject Information, you will be directed to the Subject Information page, as shown in the screenshot below. From here you can access **Subject General**, **Subject Study Registration** and **Subject on Study** – all areas specific to this subject.

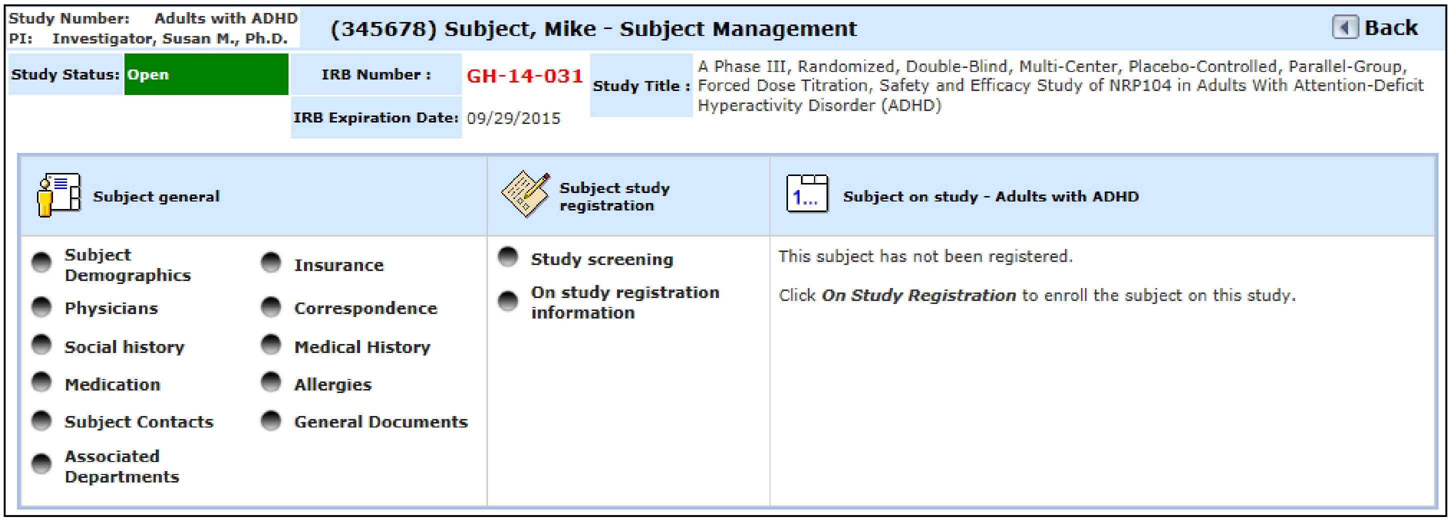


Adding an Existing Subject

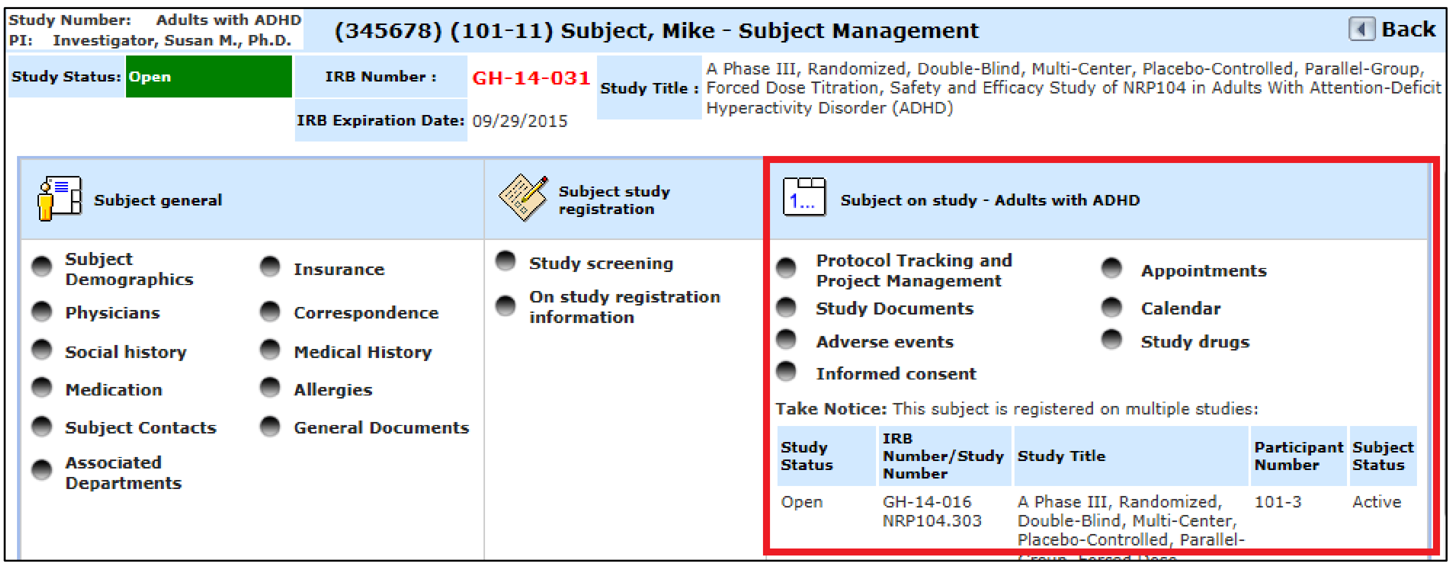
If you enter an MRN for a subject record that already existing in iRIS, the system will prompt you that the subject already exists. When this happens, you can choose to reenter the MRN if the MRN originally entered was incorrect, by selecting the **Cancel** button in the popup. Or, you can access the current record for the existing subject by clicking on the **OK** button.



Clicking **OK** will cause the system to open the existing subject information within your current study. You can then go on to register the existing subject to your study by accessing the **On Study Registration Information** link. For more information on registering a subject on to a study, see the On Study Registration section.

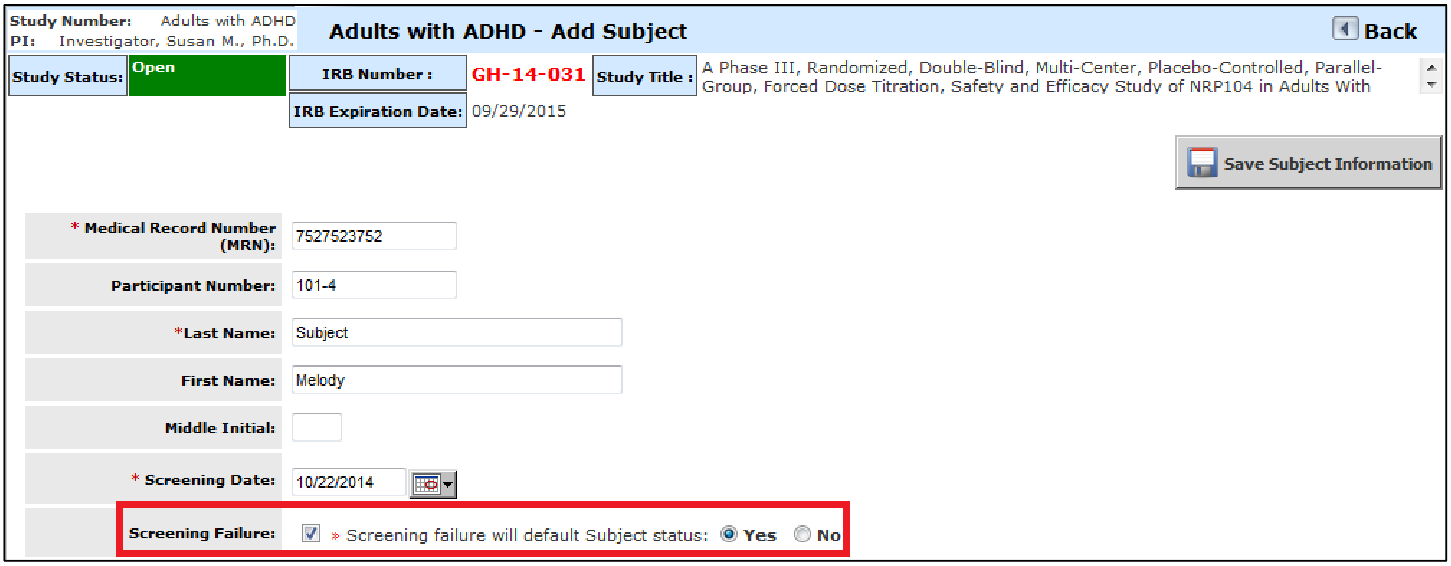


Once the existing subject is successfully registered onto your study, the **Subject on Study** column will update, as shown in the screenshot below. You can now enter study-specific information to the subject. Also listed is any other study on which the subject is registered.

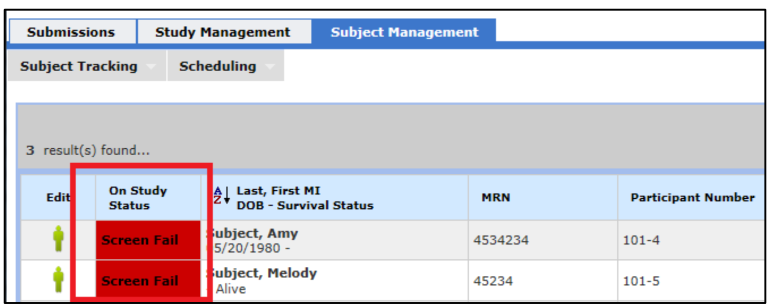


Screening Failure

When a subject you are adding to the study has failed screening, check the **Screening Failure** option on the Add Subject page. When you indicate a subject has failed screening, the system will ask if you need to default the subject to the failed screening status.

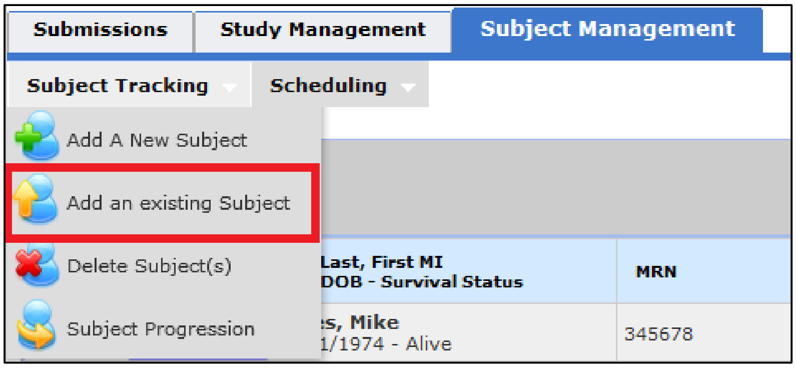


When you indicate "Yes," the status of the subject will default to the pre-configured Screen Fail subject status, similar to the status assigned in the screenshot below.

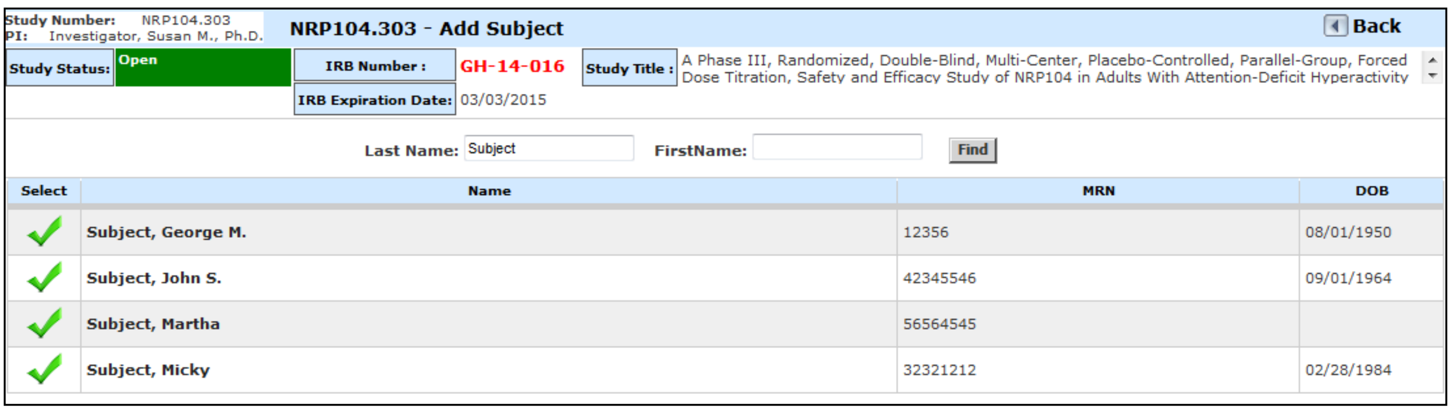


Add an Existing Subject

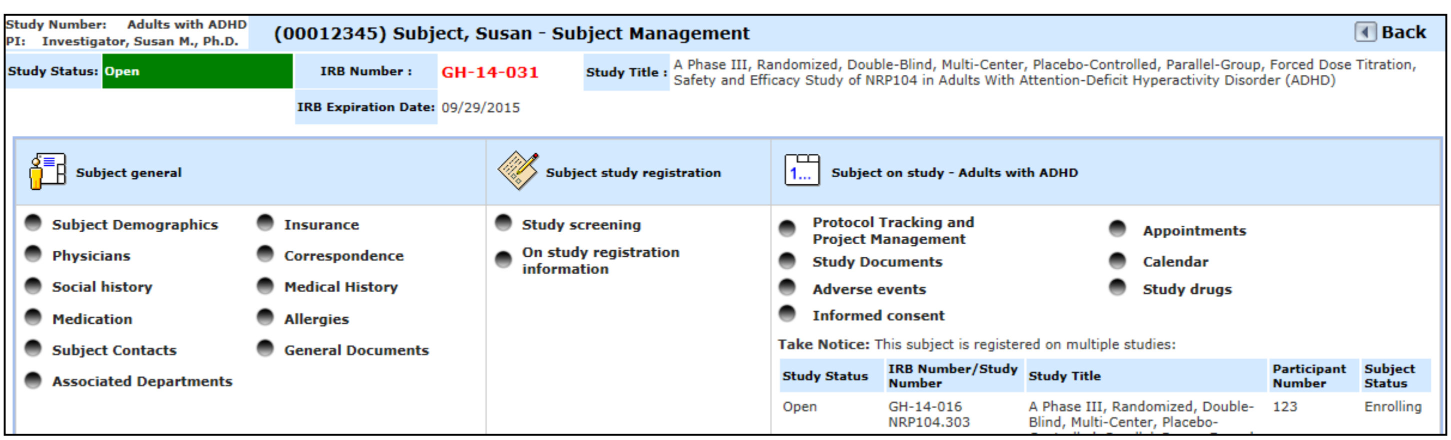
In addition to adding an existing subject from the method described above, you can choose to add an existing subject from the option provided in the **Subject Tracking** drop down list. This option may or may not be available depending on your system settings.



Choosing to add an existing subject using the menu item will allow you to look up the subject by Last Name and First Name. Results will populate on the page. Select the subject you would like to add to the study.

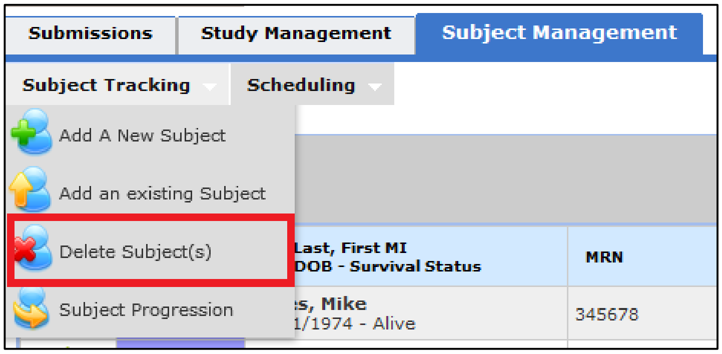


You can then go on to register the existing subject to your study by accessing the **On Study Registration Information** link. For more information on registering a subject on to a study, see On Study Registration section. Once the existing subject is successfully registered onto your study, the **Subject on Study** column will update, as shown in the screenshot below. You can now enter study-specific information to the subject. Also listed is any other study on which the subject is registered.

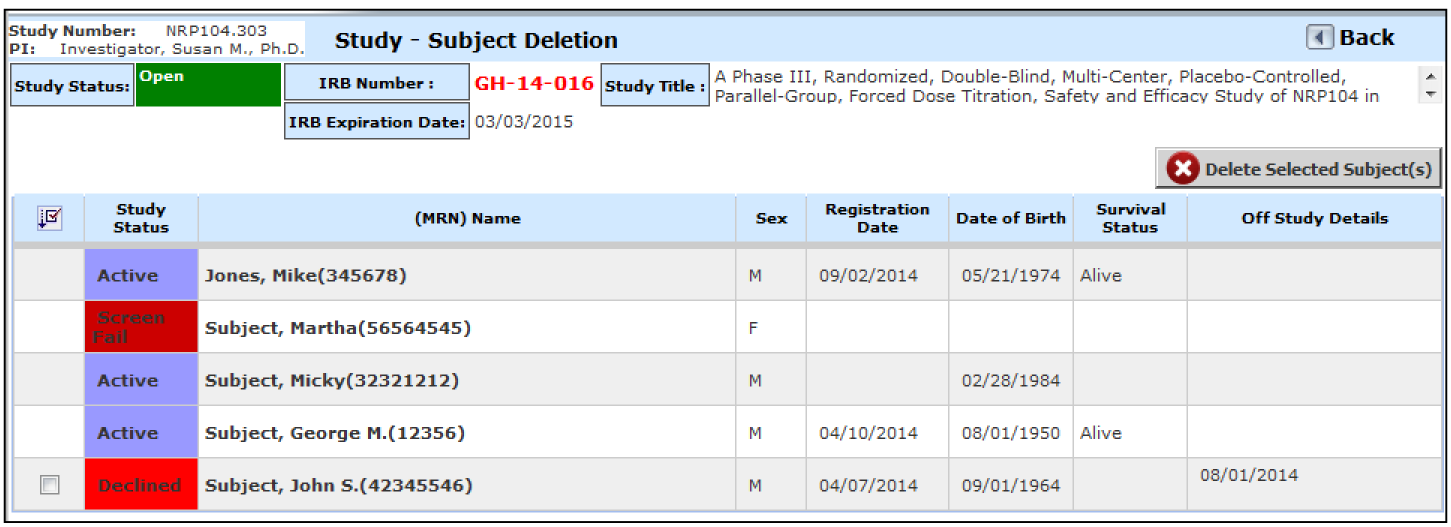


Delete Subject(s)

In some cases, you may need to delete a subject from a study. This should only be done for subject records that do not need to be listed on the study. Once you delete a subject from a study, any study-related information will not be retained with the subject record. Any completed visits, tasks, consents, and study-related documents will be disassociated from the subject record.



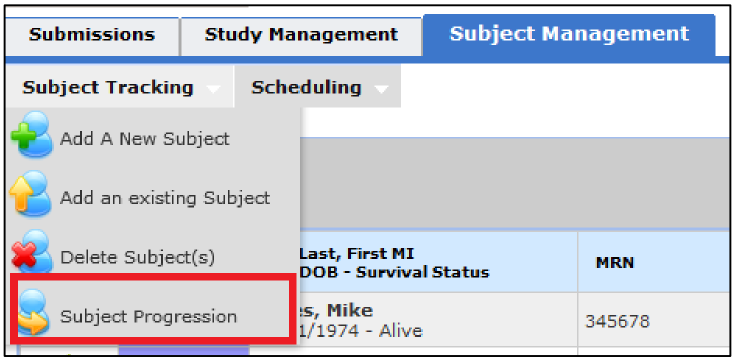
Clicking the **Delete Subject(s)** link within the Subject Tracking menu will open a page listing all the subjects on the study. Depending on their individual status you may or may not be able to delete them from the study. After clicking on the checkbox to select the subject(s) you wish to delete, click the **Delete Selected Subject(s)** button in the upper right hand corner. This will remove the selected subjects from the study.



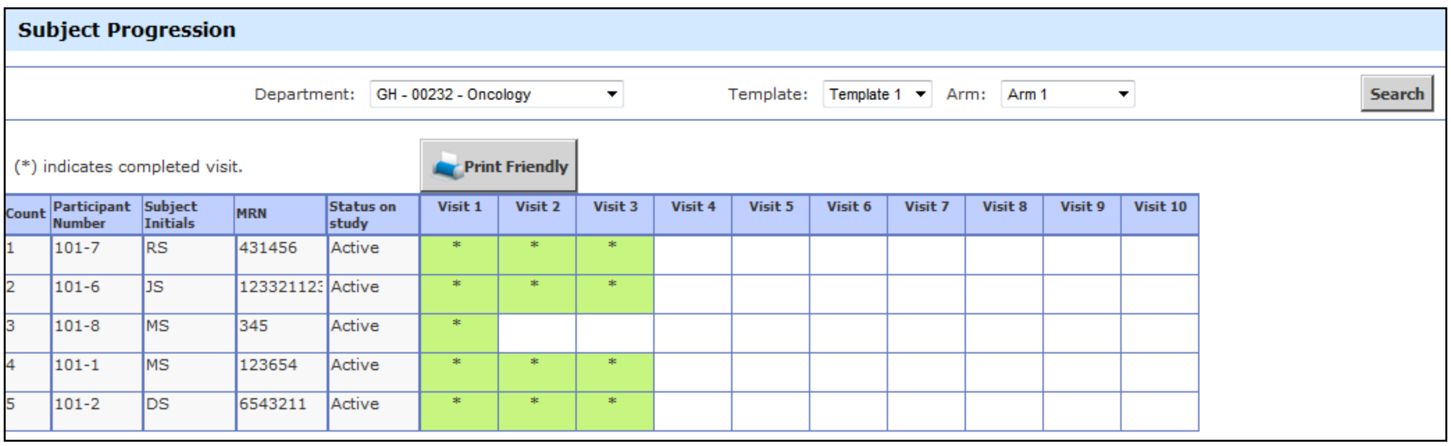
In order for a subject on the study to be deleted from the study, that subject record must be in a certain Study Status. The screenshot above displays five subject records, but only one has a checkbox, allowing that subject to be deleted from the study. This is because the "Declined" Study Status is the only status that allows subjects to be deleted. The Study Status is configurable, so the status that allows deletion may be labeled differently.

Subject Progression

Another item available in the **Subject Tracking** drop down list is the **Subject Progression** area. This area will allow you to view subject progression on the study, as related to the study plan visits that have been completed.



When you click this link, a new page will open, displaying in the progression information. This page can be filtered by **Department, Template,** and **Arm**. The columns in the table display details about the subject progression.



Count	Participant Number	Subject Initials	MRN	Status on study	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Visit 10
1	101-7	RS	431456	Active	*	*	*							
2	101-6	JS	12332112	Active	*	*	*							
3	101-8	MS	345	Active	*									
4	101-1	MS	123654	Active	*	*	*							
5	101-2	DS	6543211	Active	*	*	*							

Count – Displays the subject record number.

Participant Number – Displays the participant number associated with the subject.

Subject Initials – Displays the subject initials.

MRN – Displays the subject by MRN if one has been assigned.

Status on study – Displays the status of the study subject.

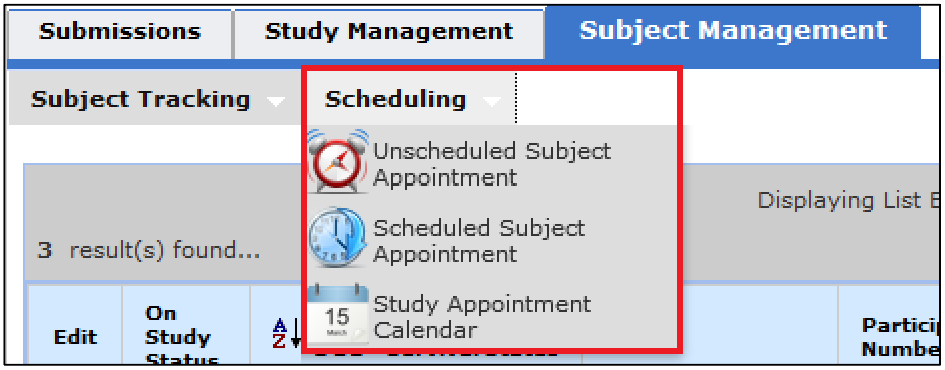
Visit column(s) – Will highlight each box for a completed visit. If a visit has not been completed the box will remain white. If a visit has been completed, it will highlight green and contain an asterisk in the column.

This page can be printed by clicking on the **Print Friendly** button.

Scheduling

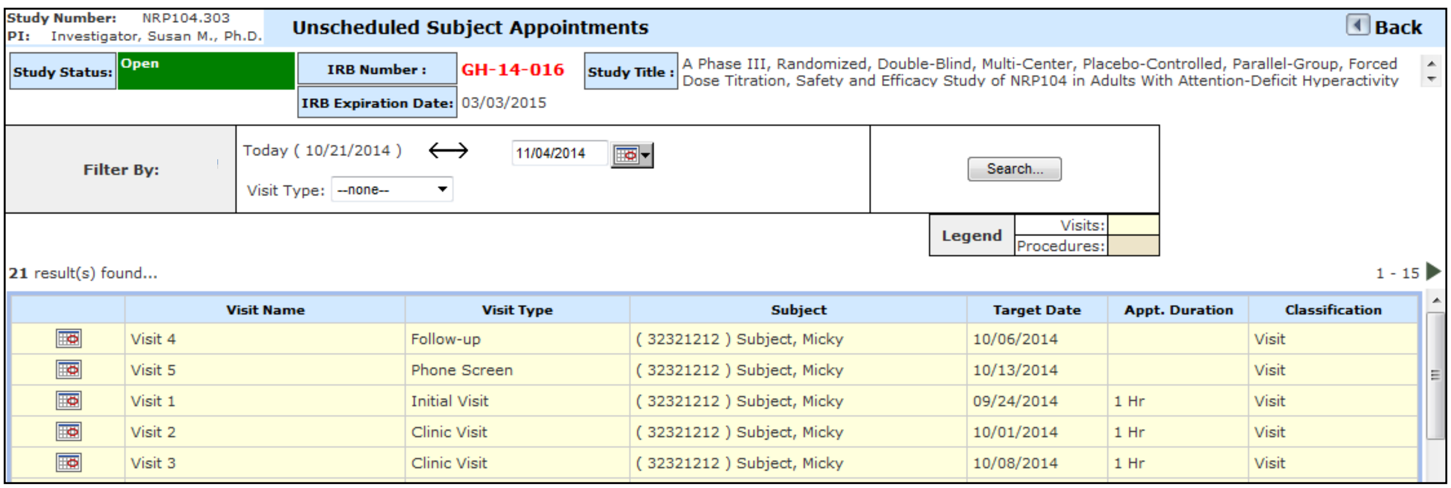
The **Scheduling** area will allow you to view and schedule any unscheduled subject visits, view already scheduled visits, and access the study appointment calendar, which will provide you with a calendar view of all subjects with scheduled visits. This area allows you to manage visits for the study as a whole, as it is related to all subjects on the study. You can also manage visits on an individual subject level by editing that subject's record on the study.

Scheduling will allow a user to manage scheduled and unscheduled visits without accessing the subject's record on the study. This is often granted to a user who should be able to schedule visits, but not have the ability to complete visits in the system.



Unscheduled Subject Appointments

The **Unscheduled Subject Appointments** area will list out all subjects that have unscheduled visits within a certain date range. From this area, you can schedule visits.



	Visit Name	Visit Type	Subject	Target Date	Appt. Duration	Classification
	Visit 4	Follow-up	(32321212) Subject, Micky	10/06/2014		Visit
	Visit 5	Phone Screen	(32321212) Subject, Micky	10/13/2014		Visit
	Visit 1	Initial Visit	(32321212) Subject, Micky	09/24/2014	1 Hr	Visit
	Visit 2	Clinic Visit	(32321212) Subject, Micky	10/01/2014	1 Hr	Visit
	Visit 3	Clinic Visit	(32321212) Subject, Micky	10/08/2014	1 Hr	Visit

The columns in the table will display details about the unscheduled subject appointments.

Calendar icon - Clicking on the icon will allow you to schedule the visit. See Schedule Visit section for more information on scheduling visits.

Visit Name - This is the name selected when the visit was initially set-up.

Visit Type - If a visit type has been associated with a visit, it displays here.

Subject - The name of the subject and MRN, if assigned, displays here.

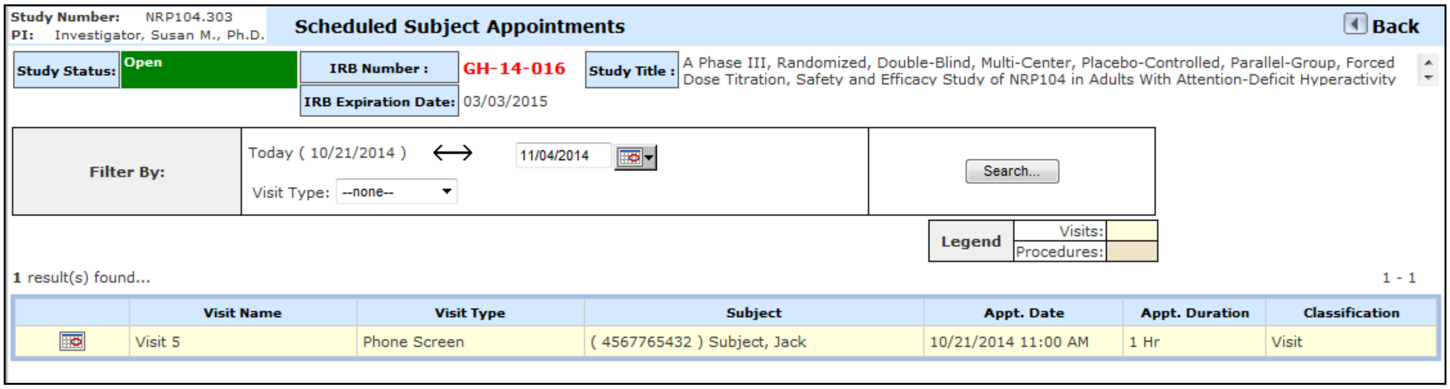
Target Date - Displays the original target date set for the visit.

Appointment Duration - Displays the length of time for the visit.

Classification - Displays the visit classification (e.g., Visit, Clinical, etc.).

Scheduled Subject Appointment

The **Scheduled Subject Appointments** area lists out all subjects that have scheduled visits within a certain date range. From this area, you can change the scheduled visit information, if needed.



The columns in the table will display details about the scheduled subject appointments.

Calendar icon- Clicking on the icon will allow you to change the scheduled visit. See Schedule Visit section below for more information on scheduling visits.

Visit Name- This will be the name selected when the visit was initially set-up.

Visit Type- If a visit type has been associated with an appointment, it displays here.

Subject - The name of the patient and MRN, if assigned, displays here.

Appointment Date- Displays the scheduled date of the appointment.

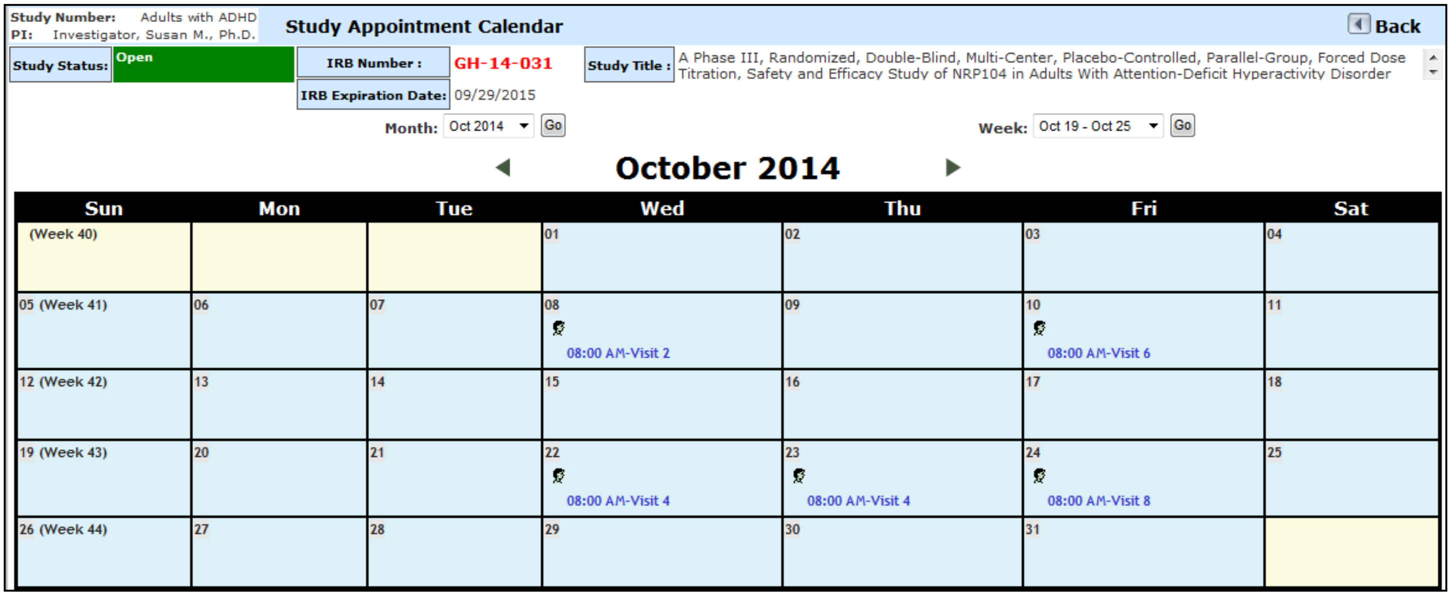
Appointment Duration- Displays the length of time for the appointment.

Classification- Displays the visit classification (e.g. Visit, Clinical, etc.).

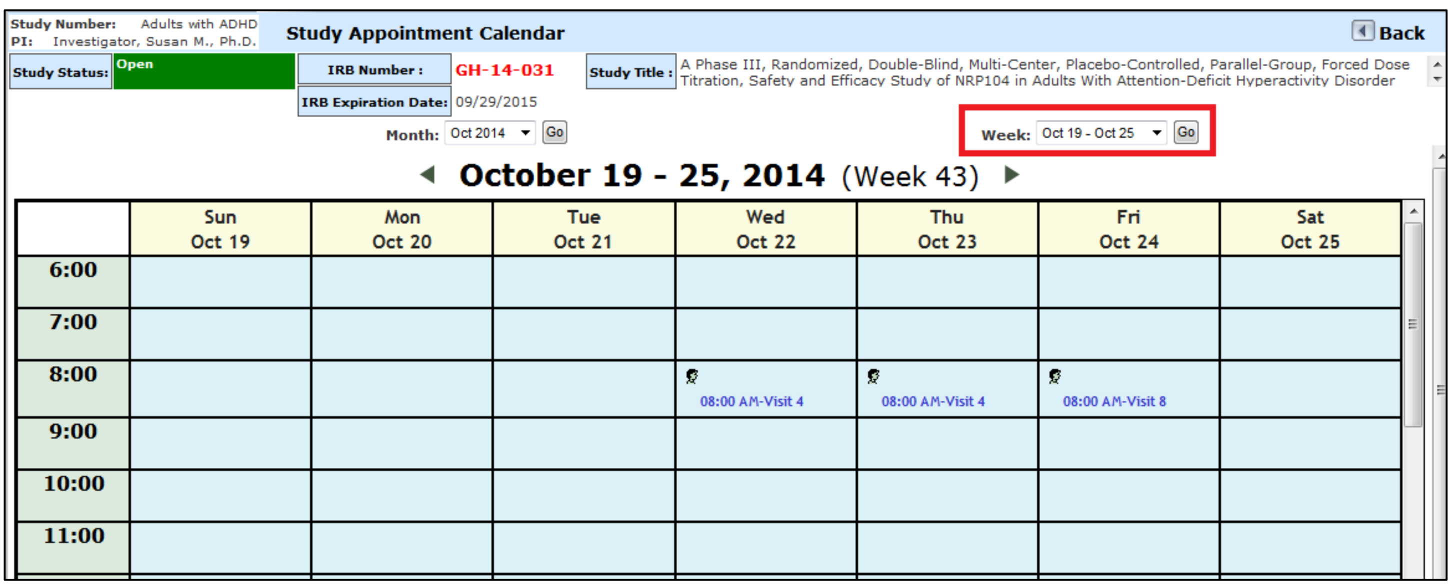
Study Appointment Calendar

The **Study Appointment Calendar** is a link to a calendar view of all subject scheduled visits. From this area, all scheduled visits will display in a month calendar, with the current month displayed by default, as shown in the screenshot below.

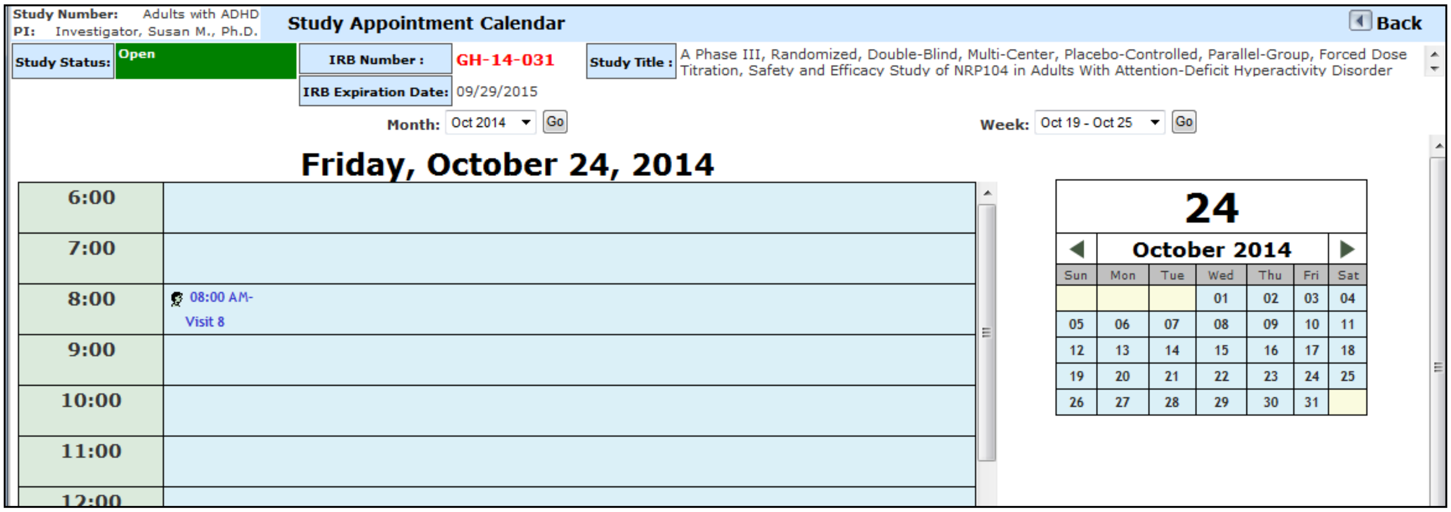
You can navigate to a different month by clicking on the green arrow icons next to the month name, or choose the month from the dropdown list provided above the calendar.



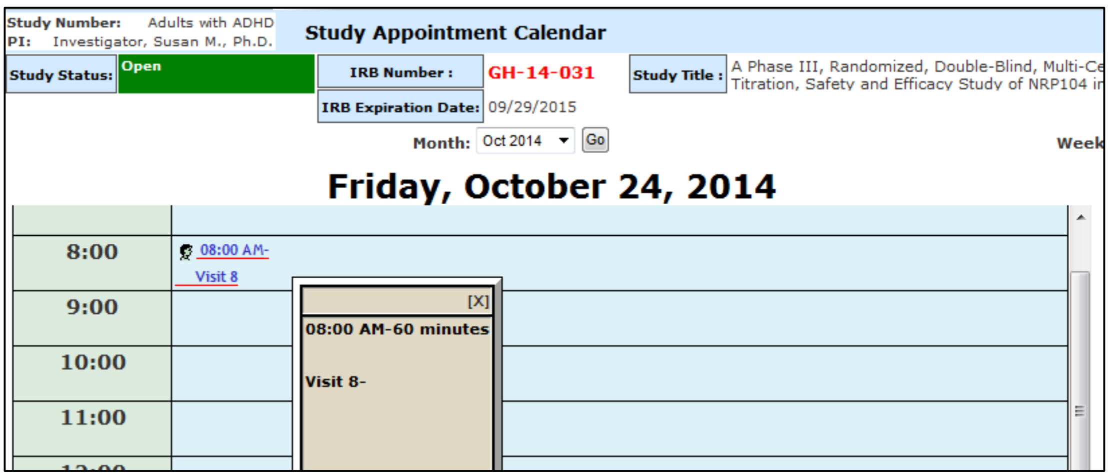
You can also change the view to a weekly (shown below) by selecting a week from the **Week** drop down list.



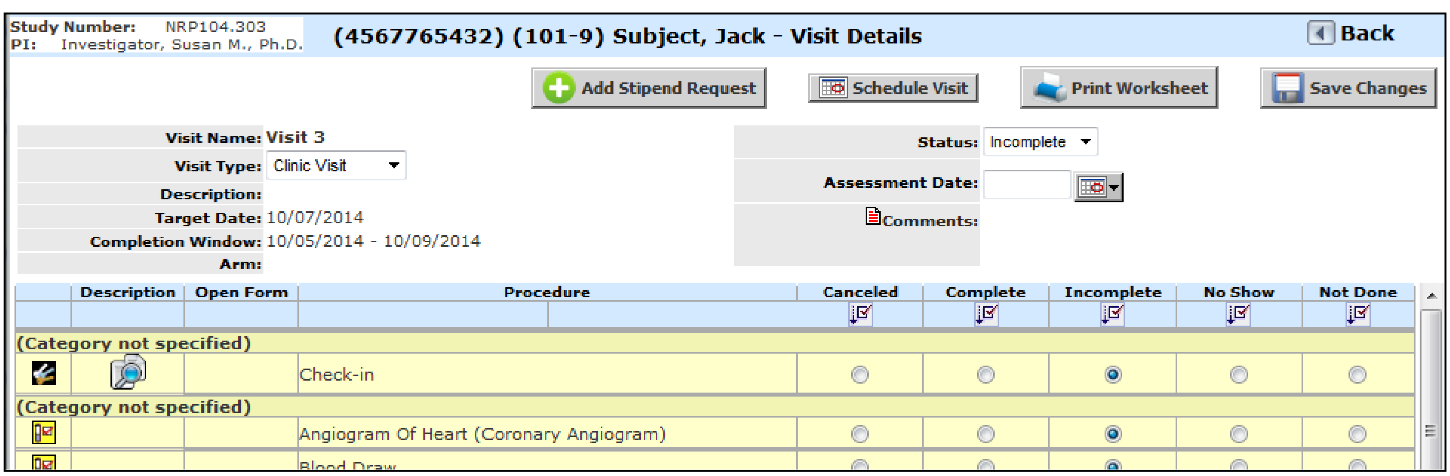
You can also switch to a daily view by clicking on a specific day within the calendar.



For any visit that has been scheduled, it will populate on the specific day with the scheduled time and visit name displayed. If you mouse over a visit, a small popup will display listing further details related to the visit.



If your role has the correct access, you can also click on the visit link to open the Visit Details page, as shown in the screenshot below. More information on completing a visit can be viewed in the Completing a Visit section of this manual.

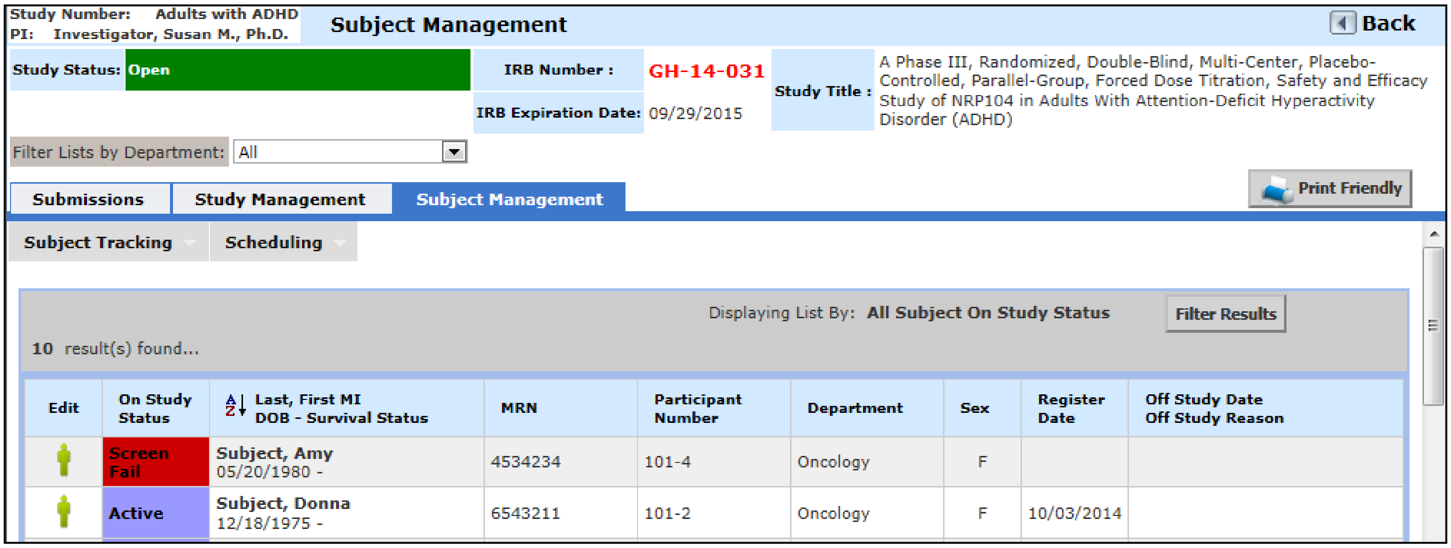


Managing Subject Records

Once a subject record has been added to a study, it can be accessed through the Subject Management tab. Within the Subject record, general subject information can be entered and updated, the subject can be registered onto a Study Plan Arm, visits can be scheduled and completed, the consent record can be updated and general subject on study records can be maintained.

When accessing the Subject Management tab, any subject added to the study will be listed (depending on your access and system settings, you may or may not see all subjects added to the study).

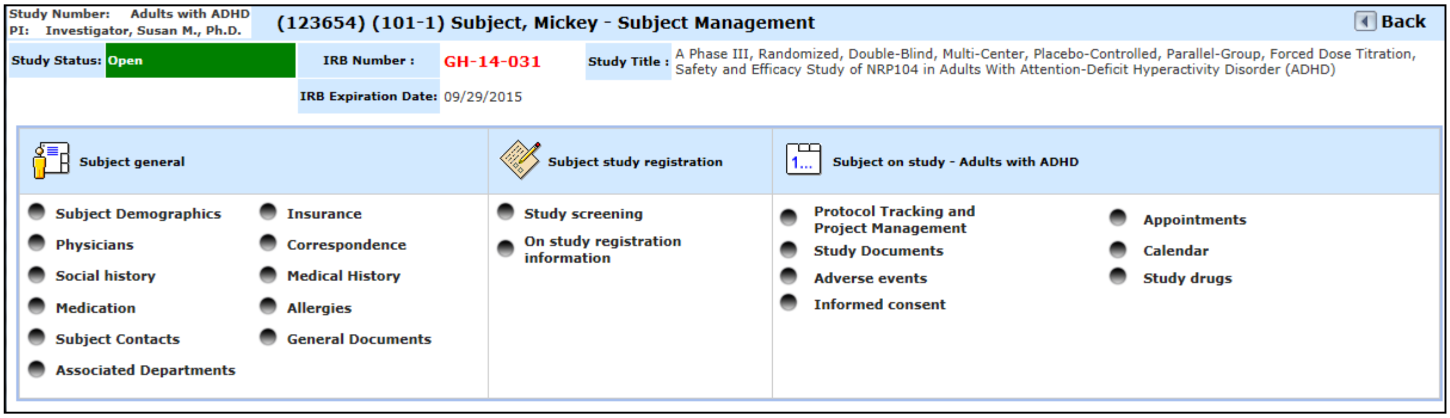
Click on the icon in the **Edit** column to access the subject record.



A new page will open that contains links to various subject and subject on study areas of Subject Management. At the top of the page is the Subject Management header that provides details related to the study and the subject record being accessed. This information will remain on the page as you navigate through the different links on this page.

The Subject Management page is broken up into three parts and may or may not contain the same links, based on your system's configuration. This manual discusses the standard options available within Subject Management. Your system may have more or less access depending on the configuration.

The first part, **Subject General**, contains links to basic, general subject information. The second part, **Subject Study Registration**, contains access to subject on study screening and registration. And the third part, **Subject on Study** contains links to study related activities for your subject, including protocol tracking, adverse events and informed consents. Each section is described in detail below.

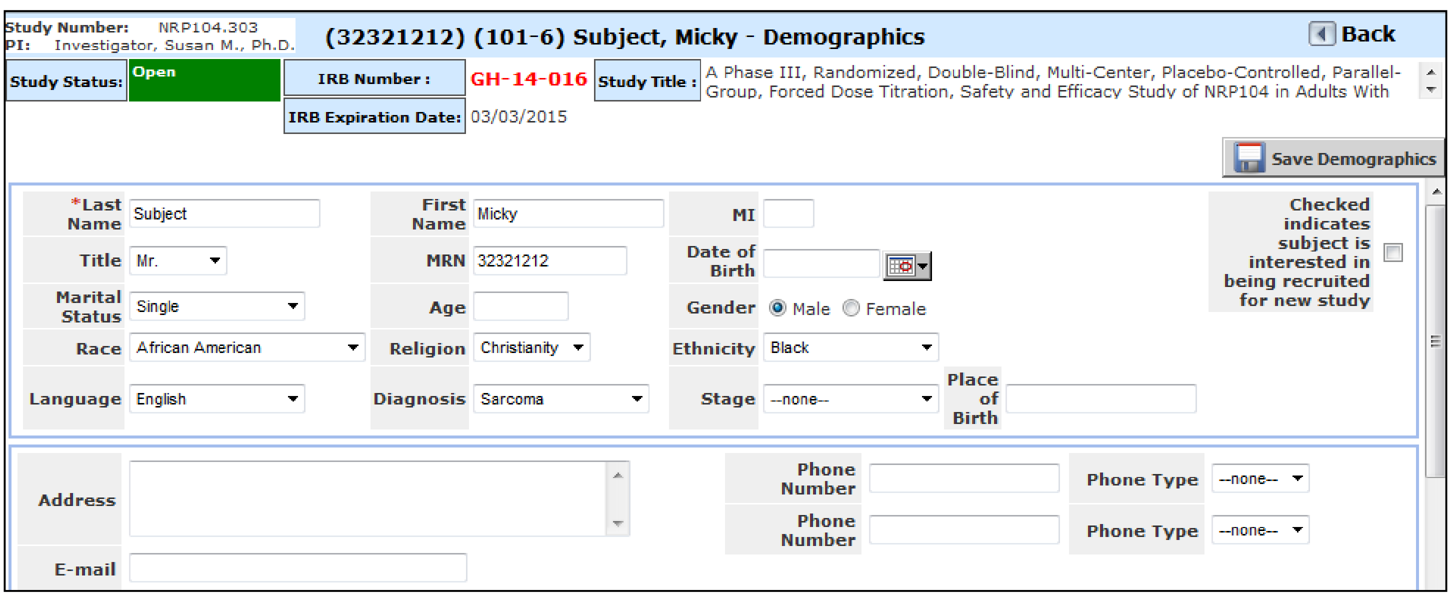


Subject General

Subject General contains links to the subject's general information, including demographic information, physicians, contacts, medical history, insurance on file, allergies, etc. This information is not specific to the study, rather specific to the subject. If this subject is registered on multiple studies, the information added to this area is shared and accessible by all the studies that have this subject registered. If you update the Insurance information within one study record, the other study that the subject is registered on will also have that information.

Subject Demographics

Subject Demographics contains basic subject information, such as name, MRN, DOB, language, contact information and survival information. Depending on your system setup, you may or may not have the same fields available as shown in the screenshot below.



Basic Subject Information

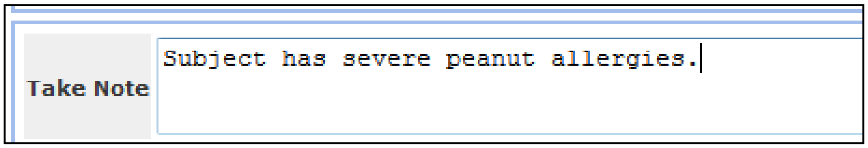
At the top of the page you can identify basic subject information, such as Last Name, First Name, Middle Initial, MRN, Date of Birth, and Language, among other fields, depending on your system setup. And field noted with a red * is a required field and you will not be able to save this page without entering the information. Other fields are available to be used as needed.

Contact information

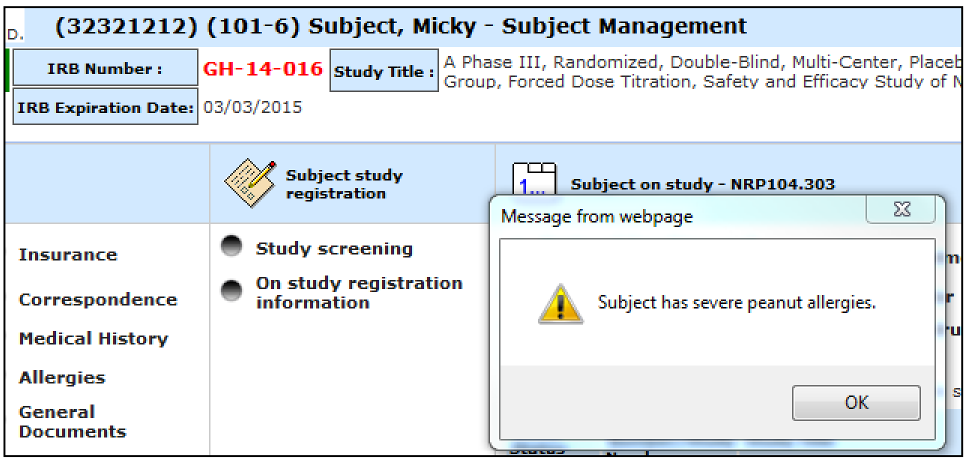
Below the basic subject information you can enter the Address, E-mail and Phone Numbers for the subject.

Take Note

A Take Note field is available to post important messages related to the subject.

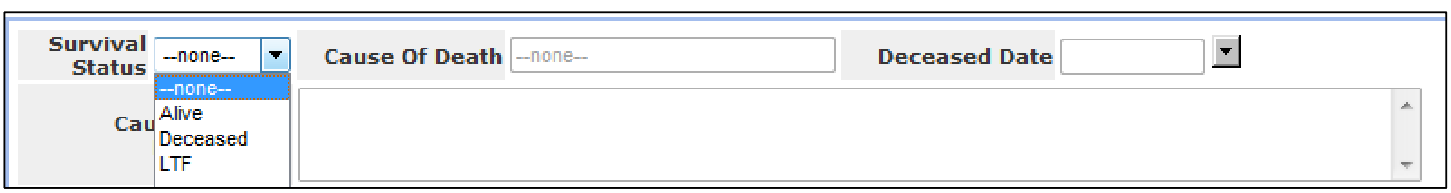


Anytime the subject record is accessed, the message from the Take Note will display in a popup, as shown in the screenshot below.

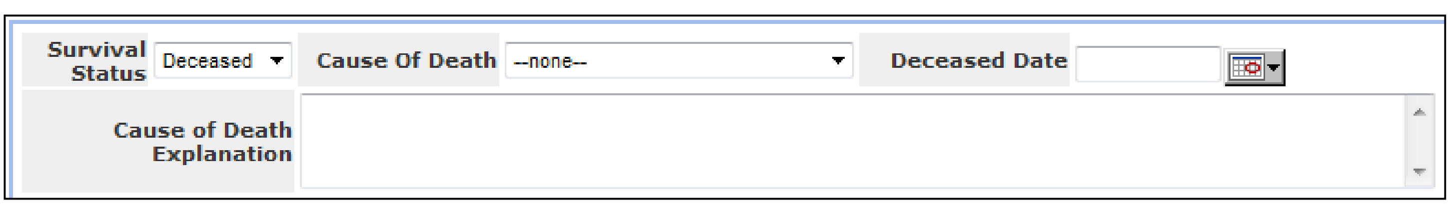


Survival Status

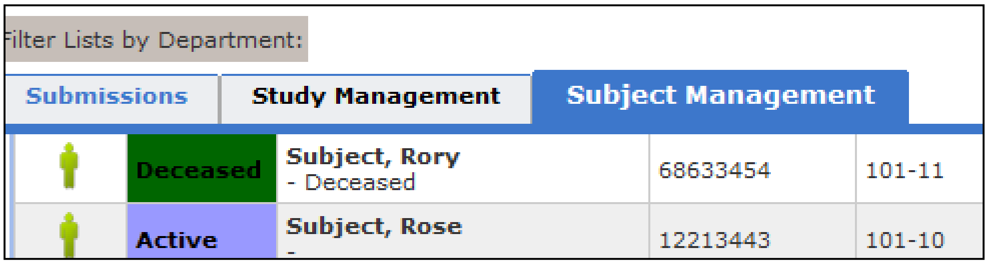
The Survival Status portion of this page allows you to track the current status of the subject. You can set the status of the subject any time.



If the subject is flagged as Deceased, the **Cause of Death** and **Deceased Date** fields become available and are required before you can save the page.

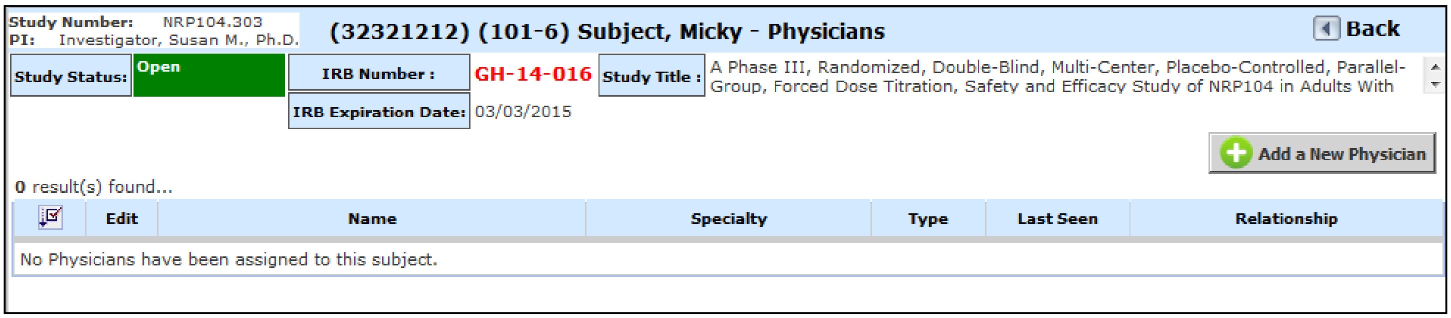


Also, once the subject is flagged as Deceased and the Subject Demographics page is saved, the Subject Status may change to reflect that the subject is deceased, depending on the setup of the Subject Status list in your system.



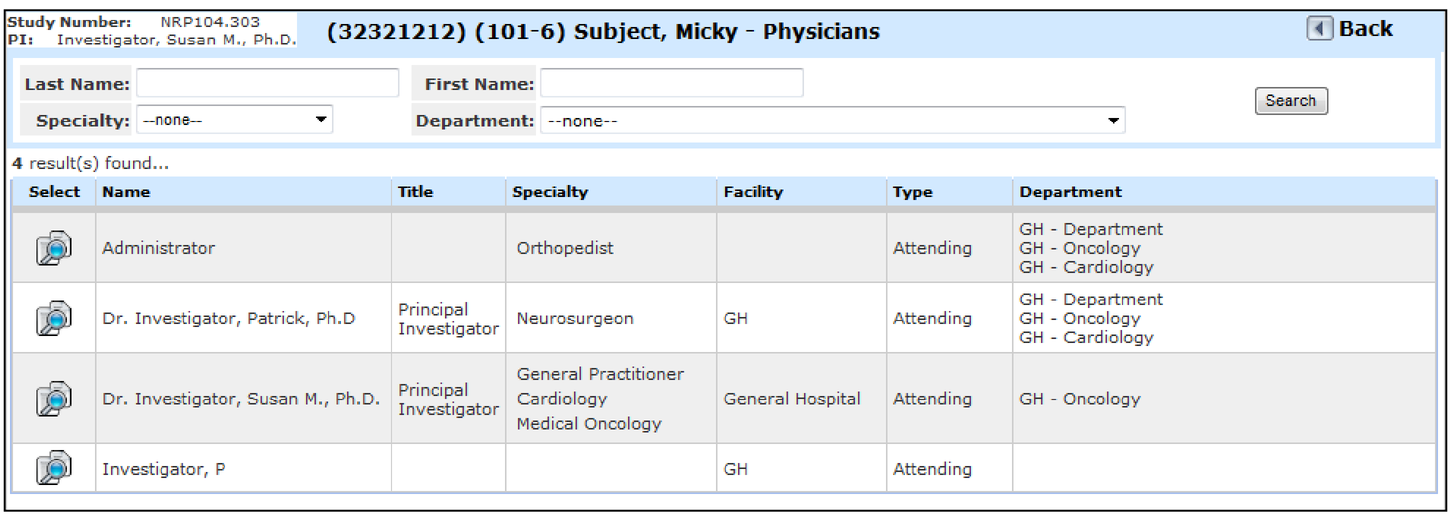
Physicians

This area allows you to list the subject's physicians. When you first access this area, the page will not display any physicians for the subject. You can associate a physician to the subject by clicking on the **Add a New Physician** button.

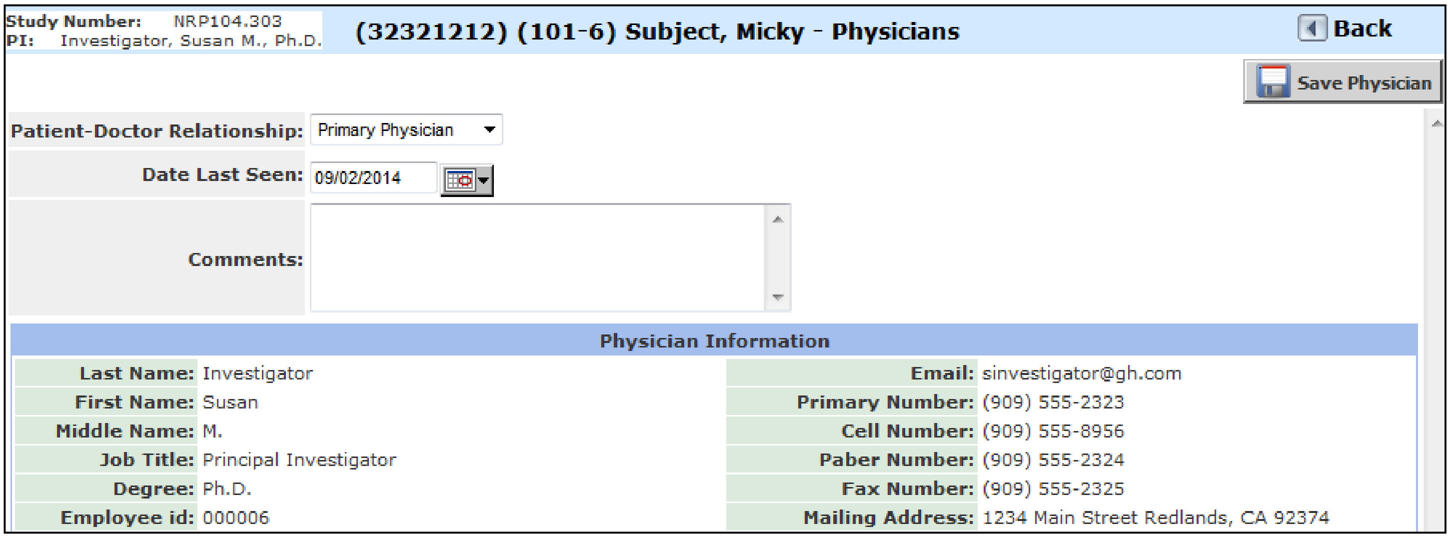


A page listing the available Physicians will open. Physician records are added to this page through System Administration -> List Configuration and Maintenance –> Site List Setup –> Physicians, or they can be added through the User Accounts area by flagging a user as a Physician. You can use the search tools at the top of the page to narrow down your results.

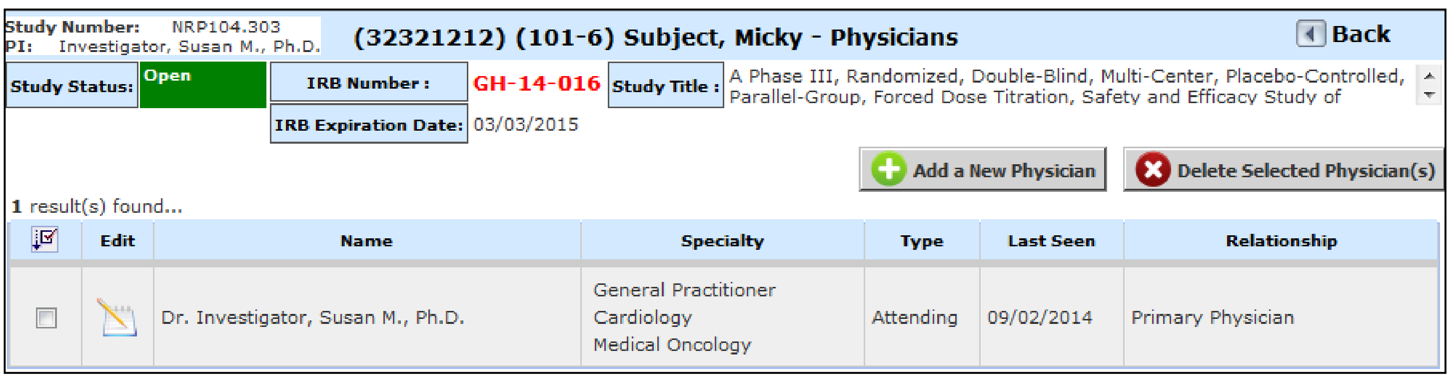
When you locate the physician you need to add, click the icon in the **Select** column.



You will then need to specify the **Patient-Doctor Relationship** by selecting a value from the dropdown list. You can also enter the **Date Last Seen** and any **Comments**. Click the **Save Physician** button.

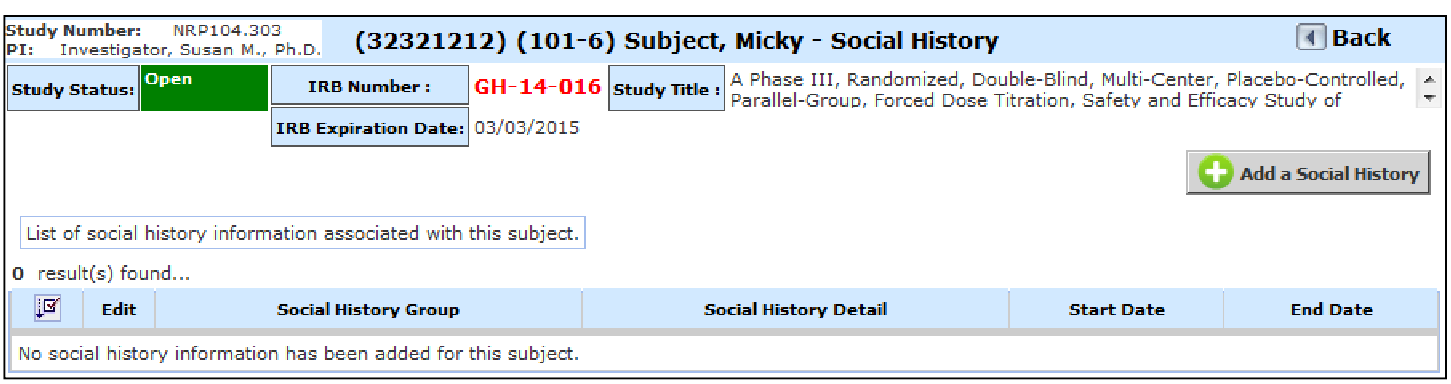


The Physician will be associated to the subject. You can modify the details for the physician by clicking on the icon in the **Edit** column and delete the physician from the subject record by selecting the checkbox next to the Physician name and clicking on the **Delete Selected Physician(s)** button. Additional Physicians can be associated to the subject by clicking on the **Add a New Physician** button.

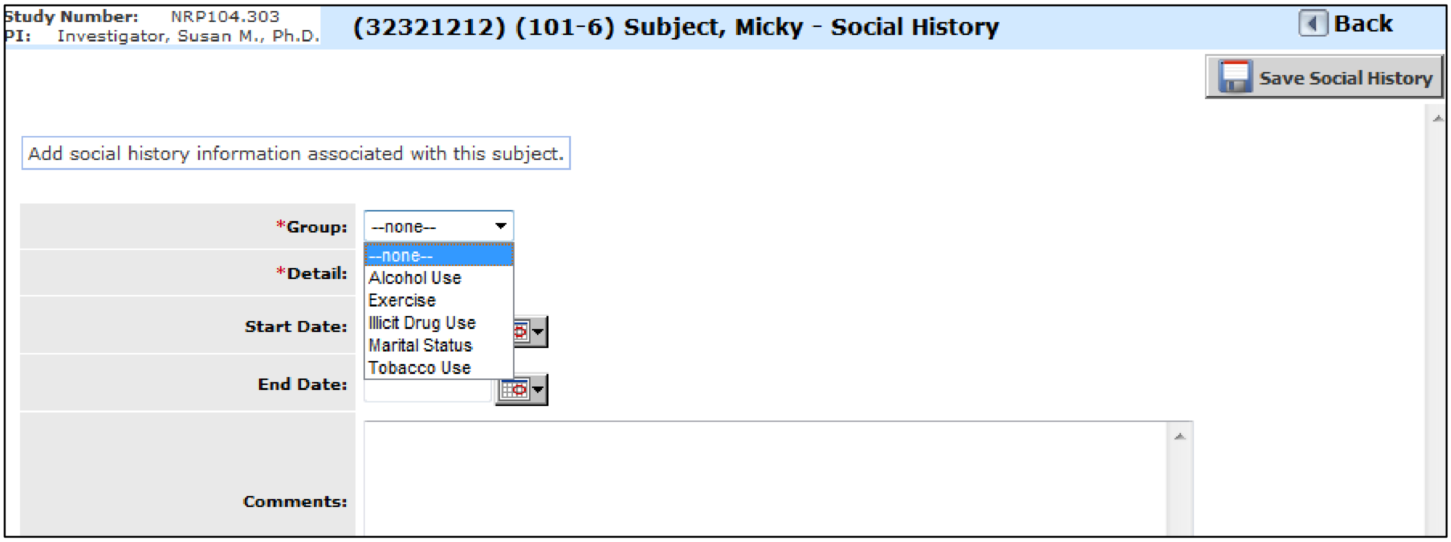


Social History

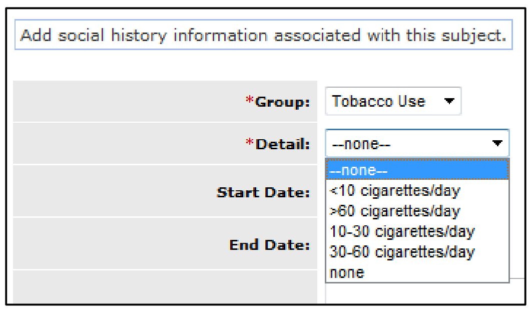
This area allows you to list the social history for the subject. When you first access this area, the page will not display any records for the subject. You can associate a social history record to the subject by clicking on the **Add a Social History** button.



From the page that opens, you can select a social history item from the **Group** dropdown list.

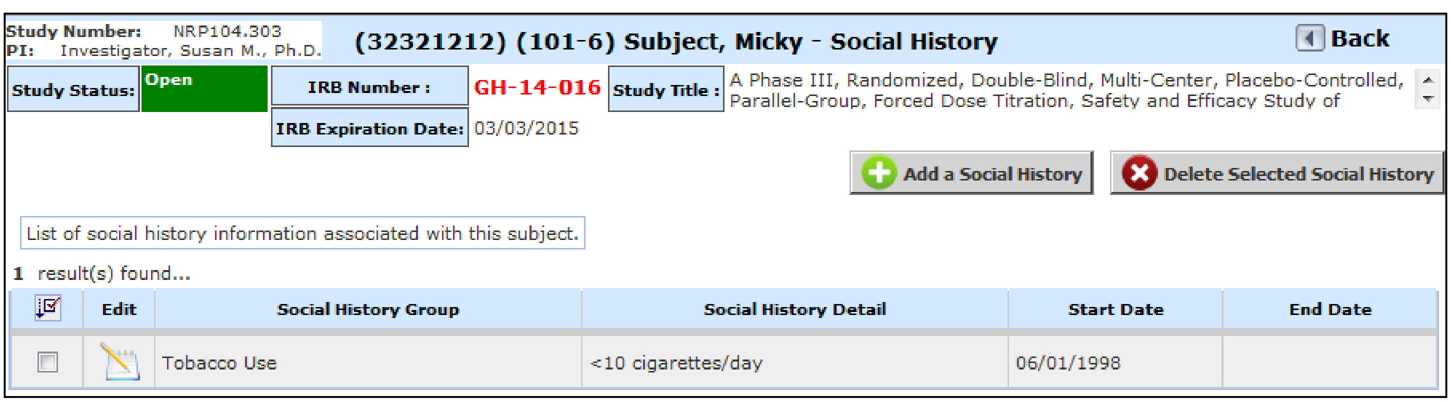


Once you select a group, the **Detail** dropdown list will update with items specific to the chosen Group.



After selecting the Group and Detail, you can then enter a **Start Date**, and **End Date** (if applicable), and any **Comments** related to the Social History record. Click the **Save Social History** button when you are done.

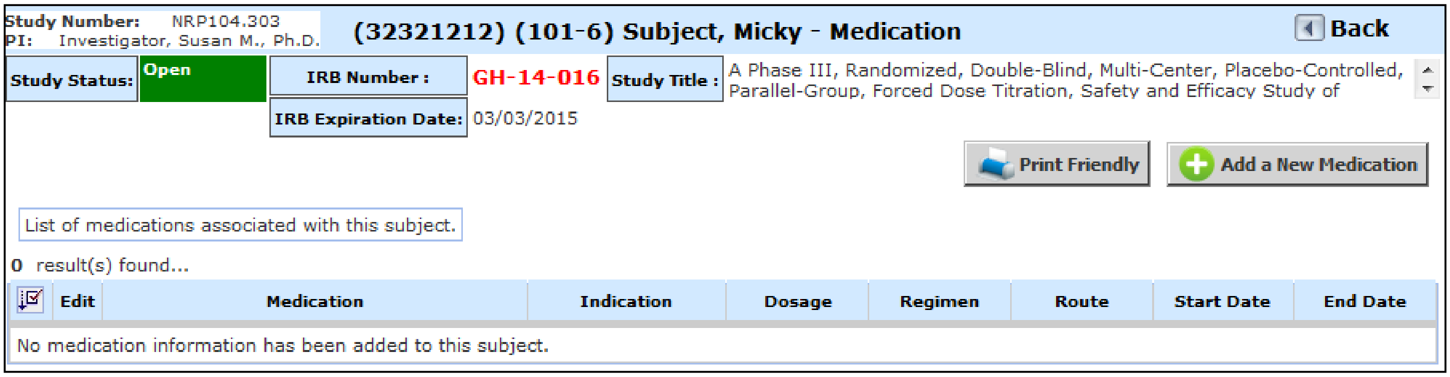
The Social History will be associated to the subject. You can modify the details for the Social History record by clicking on the icon in the **Edit** column and delete the record by selecting the checkbox next to the Social History and clicking on the **Delete Selected Social History** button. Additional records can be associated to the subject by clicking on the **Add a Social History** button.



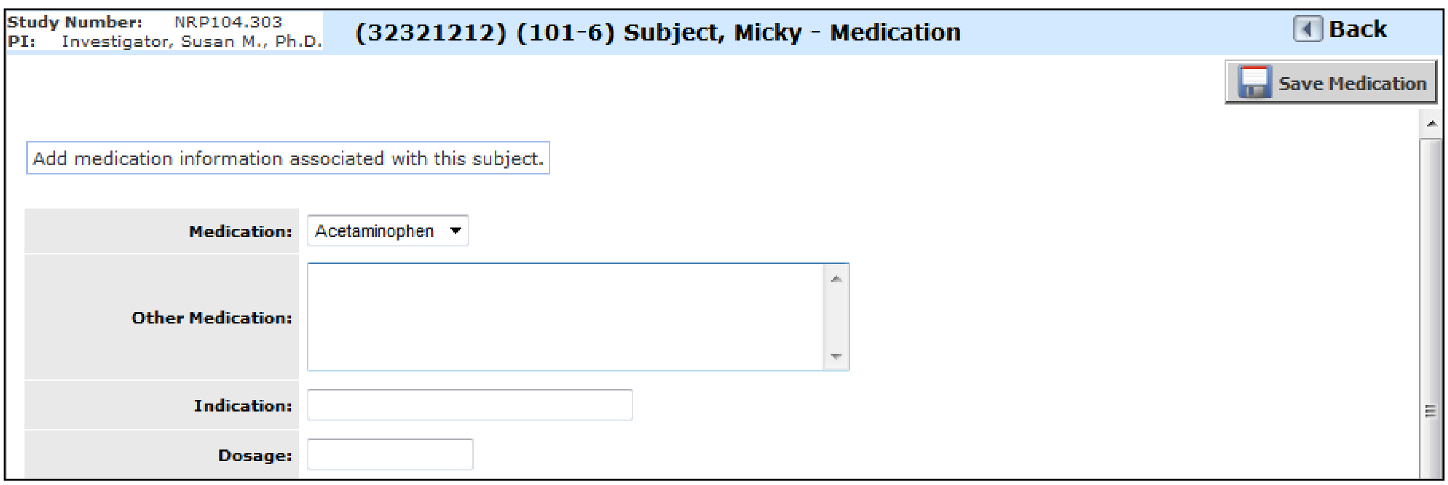
The information defined in the Group and Detail dropdown list are configured in System Administration – List Configuration and Maintenance – Site List Setup – Social History.

Medication

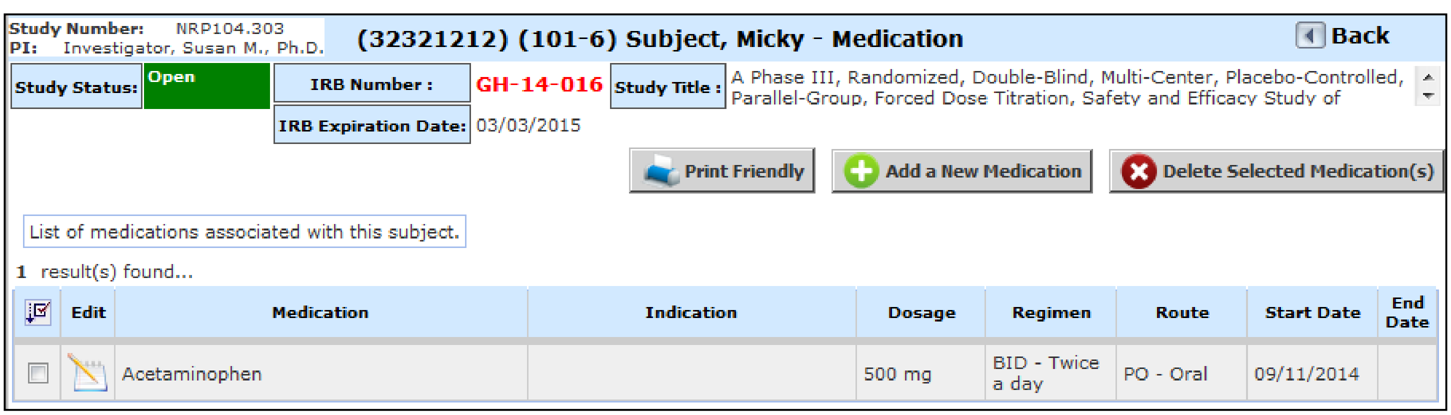
This area allows you to list the medications for the subject. When you first access this area, the page will not display any records for the subject. You can associate a medication record to the subject by clicking on the **Add a New Medication** button.



From the page that opens, you can select a Medication from the **Medication** dropdown list. You can also specify additional details, including, Dosage, Route, Regime, Start Date, and End Date (if applicable). Click the **Save Medication** button when you are done.



The Medication record will be associated to the subject. You can modify the details for the Medication record by clicking on the icon in the **Edit** column and delete the record by selecting the checkbox next to the Medication and clicking on the **Delete Selected Medication(s)** button. Additional records can be associated to the subject by clicking on the **Add a New Medication** button.

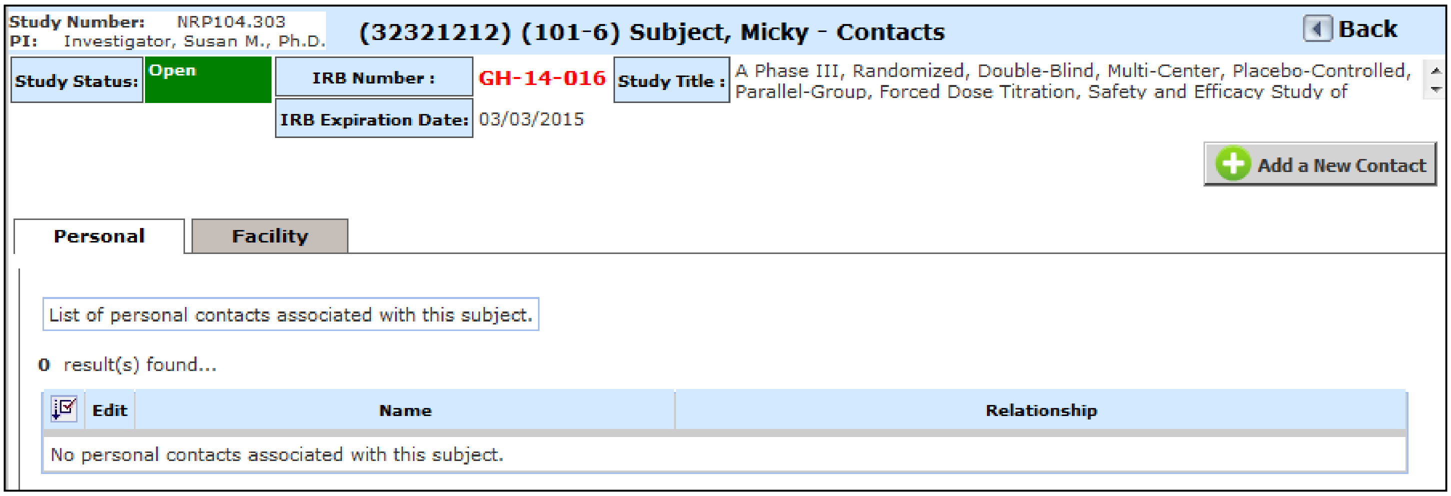


The information defined in the Medication, Regime, and Route dropdown list are configured in System Administration – List Configuration and Maintenance – Site List Setup – Medication; Medication Regime; Medication Route.

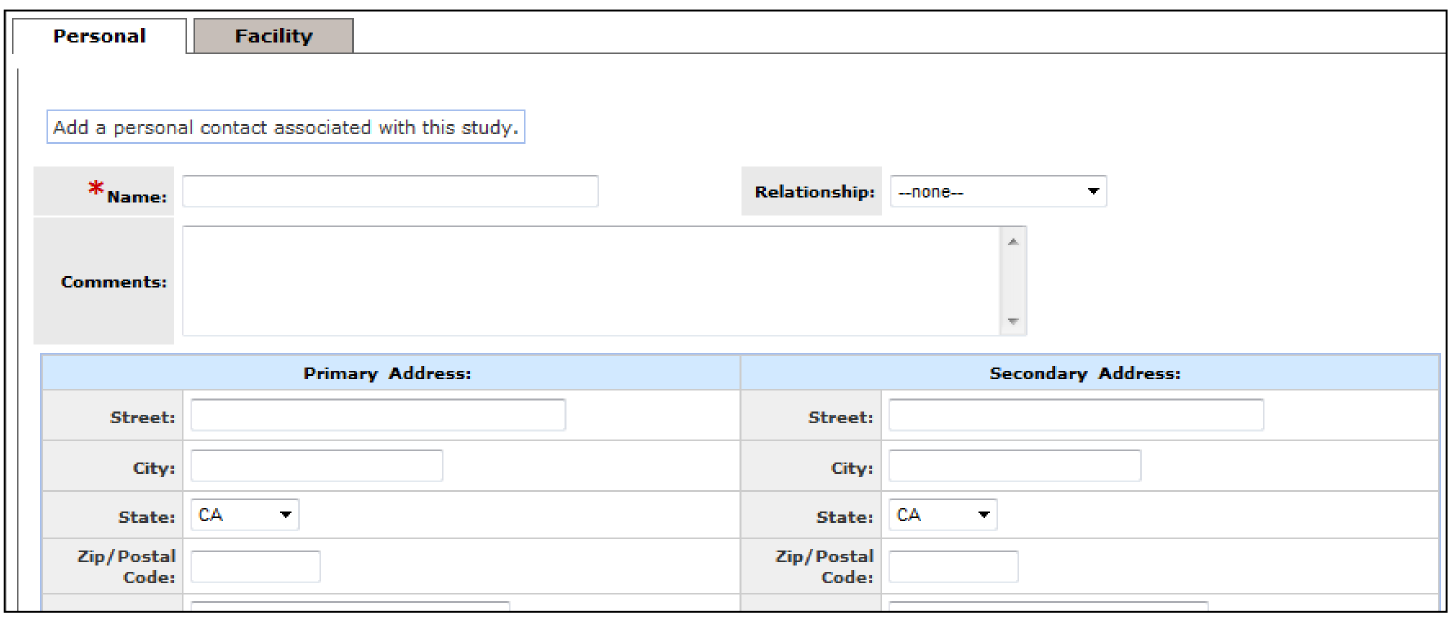
Subject Contacts

This area allows you to list the contacts for the subject. When you first access this area, the page will not display any records for the subject. Two types of contacts can be added, **Personal** and **Facility**. You can flip between the two types of contacts by clicking on their corresponding tabs at the top of the page.

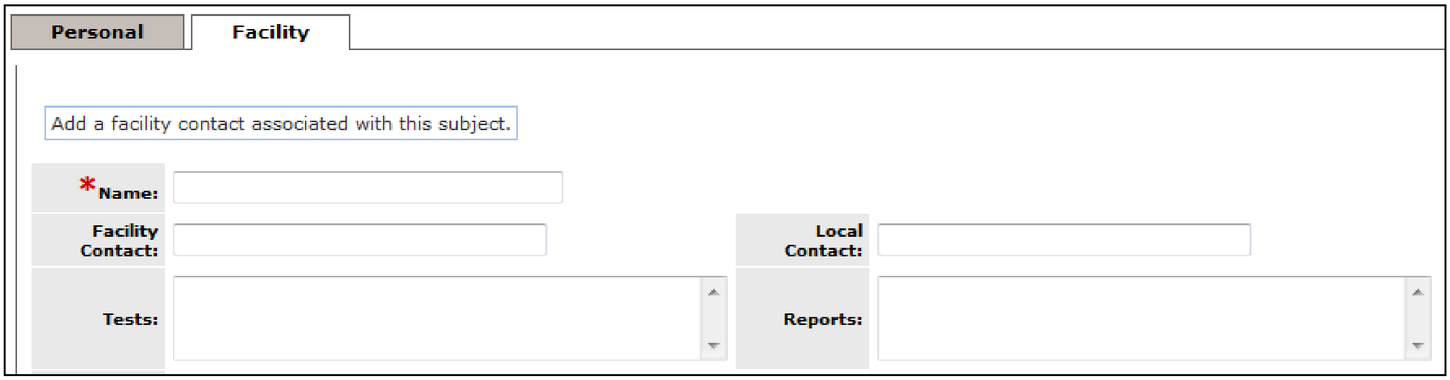
To add a contact, click the **Add a New Contact** button in the corresponding tab.



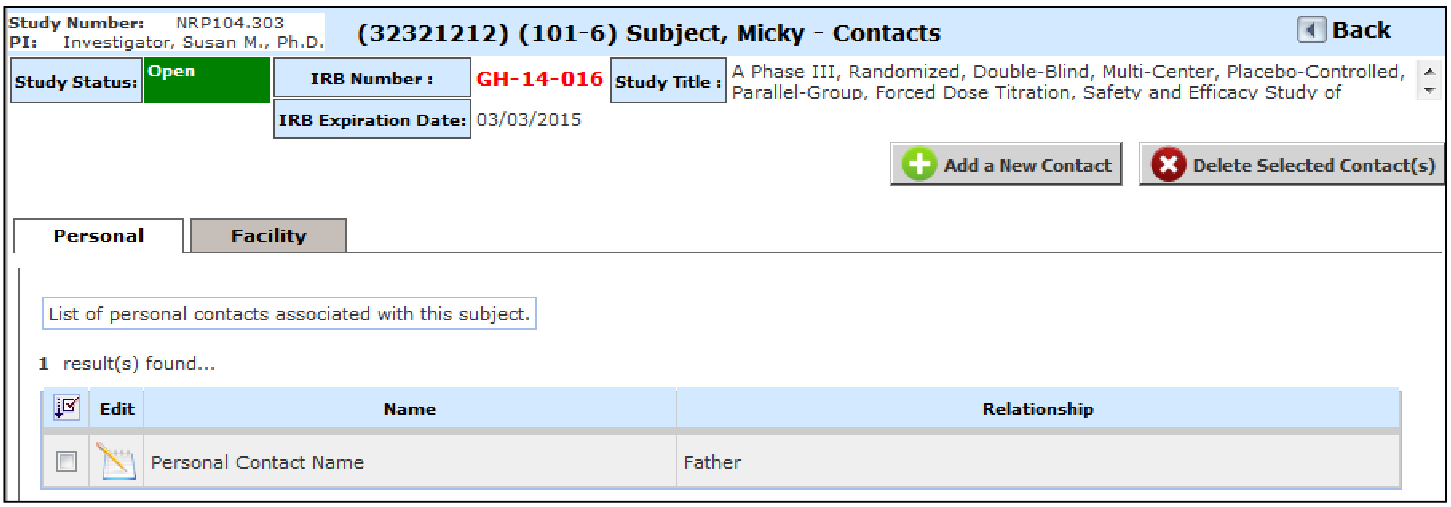
When adding a Personal Contact, enter the **Name**, choose a **Relationship** from the drop down list and enter any of the other information presented on this page.



When adding a Facility Contact, enter the **Name** and enter any of the other information presented on this page. Click the **Save Contact** button.



The contact record will be added to the appropriate tab. You can modify the details for the contact by clicking on the icon in the **Edit** column and delete the record by selecting the checkbox next to the Contact and clicking on the **Delete Selected Contact(s)** button. Additional records can be associated to the subject by clicking on the **Add a New Contact** button.



The information defined in the Personnel Contact Relationship dropdown list are configured in System Administration –> List Configuration and Maintenance – > Site List Setup – > Contact Relationship.

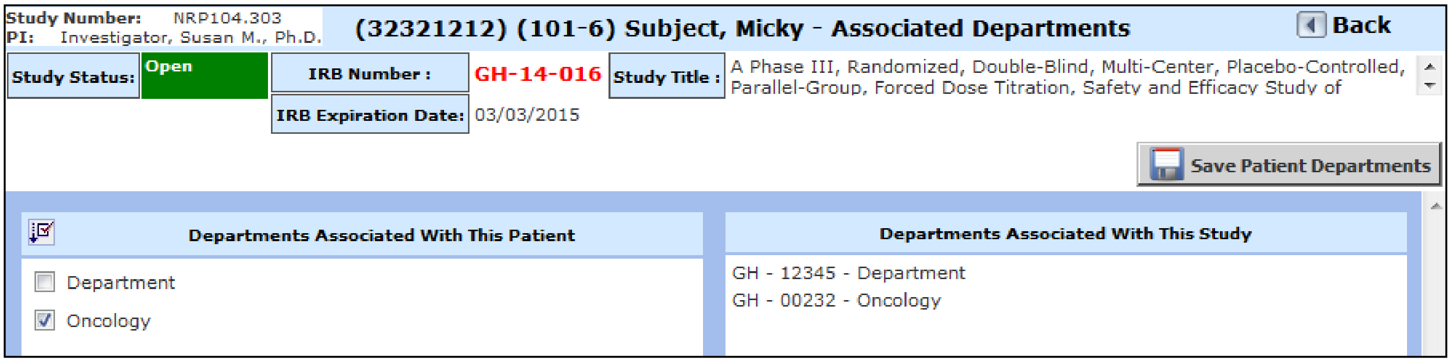
Associated Departments

This area lists the departments associated with the subject and study. The left side of the screen displays the department(s) associated to the subject. The right side of the screen displays the departments associated with the study for reference.

The departments available to associate to the subject may be restricted to departments associated to the study, based on your system setup.

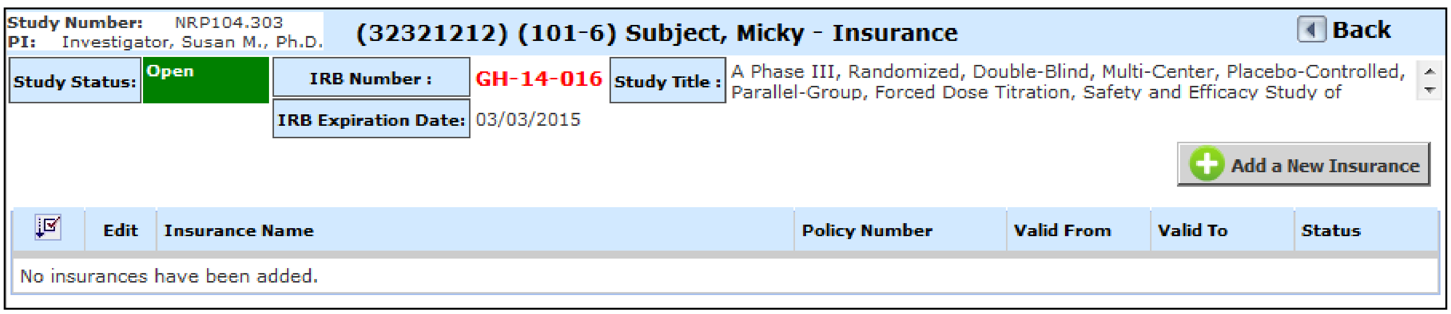
Departments are assigned to a subject when the subject is added to the study, either based on a selection from a drop down list, or if the property "system.use_dept_for_subject" = "Yes," the Primary Department on the study will be automatically assigned.

This page allows you to view the current subject departments and add additional departments as needed. To associate a new department to a subject, click the checkbox next to the Department on the right and then click the **Save Patient Department** button.

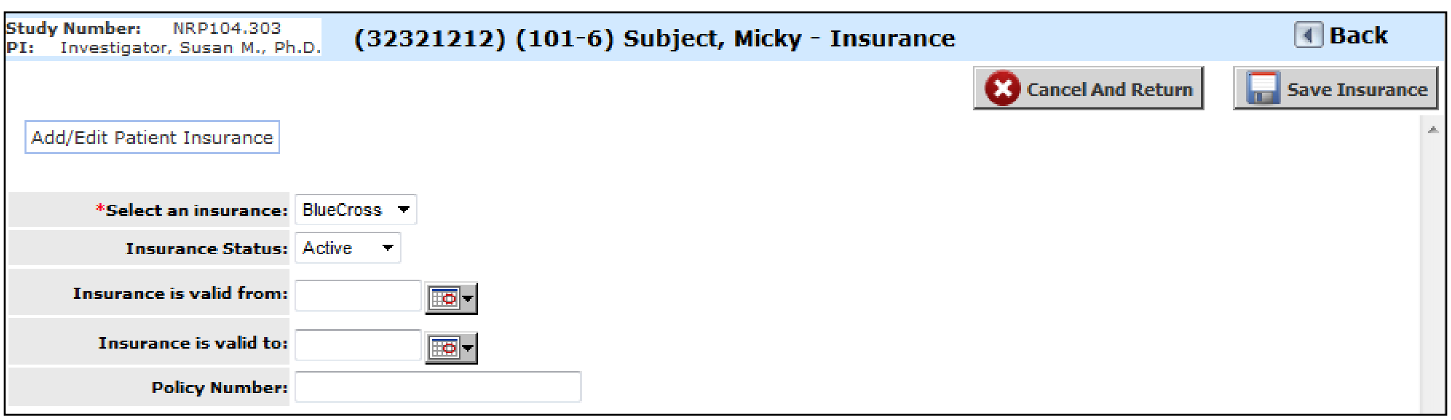


Insurance

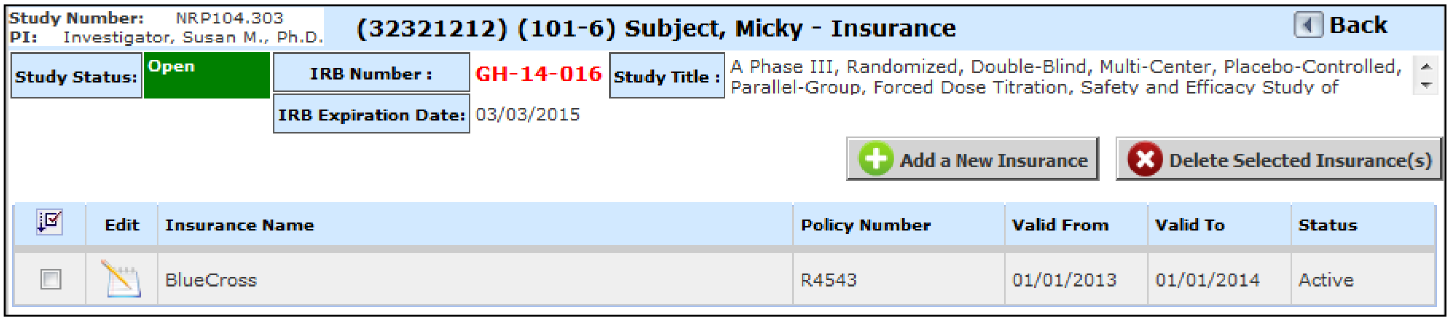
This area allows you to list the insurance records for the subject. When you first access this area, the page will not display any records for the subject. You can associate an insurance record to the subject by clicking on the **Add a New Insurance** button.



From the page that opens, you can select an insurance company from the **Insurance** dropdown list. You can also specify additional details, including, Insurance Status, Valid Dates and Policy Number. Click the **Save Insurance** button when you are done.



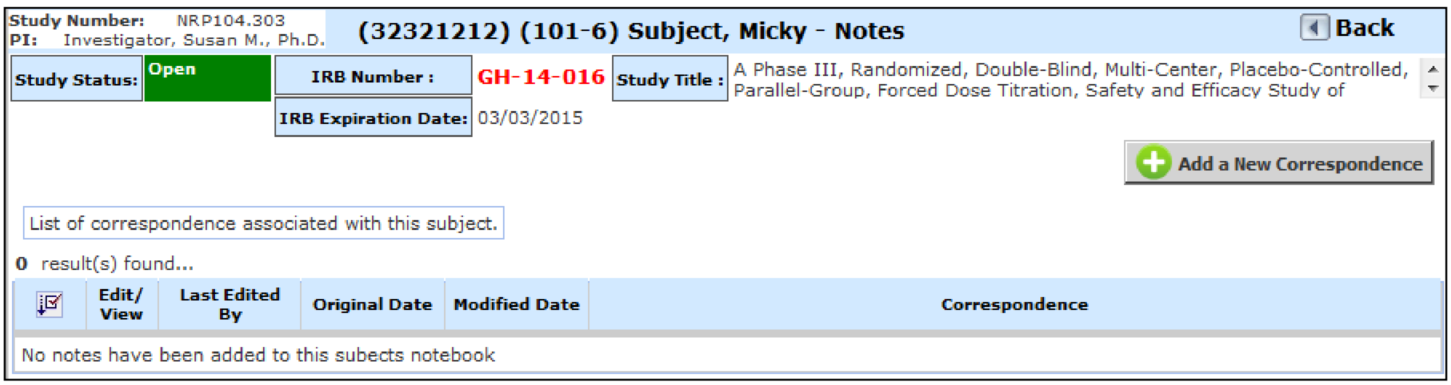
The Insurance record will be associated to the subject. You can modify the details for the Insurance record by clicking on the icon in the **Edit** column and delete the record by selecting the checkbox next to the Insurance and clicking on the **Delete Selected Insurance(s)** button. Additional records can be associated to the subject by clicking on the **Add a New Insurance** button.



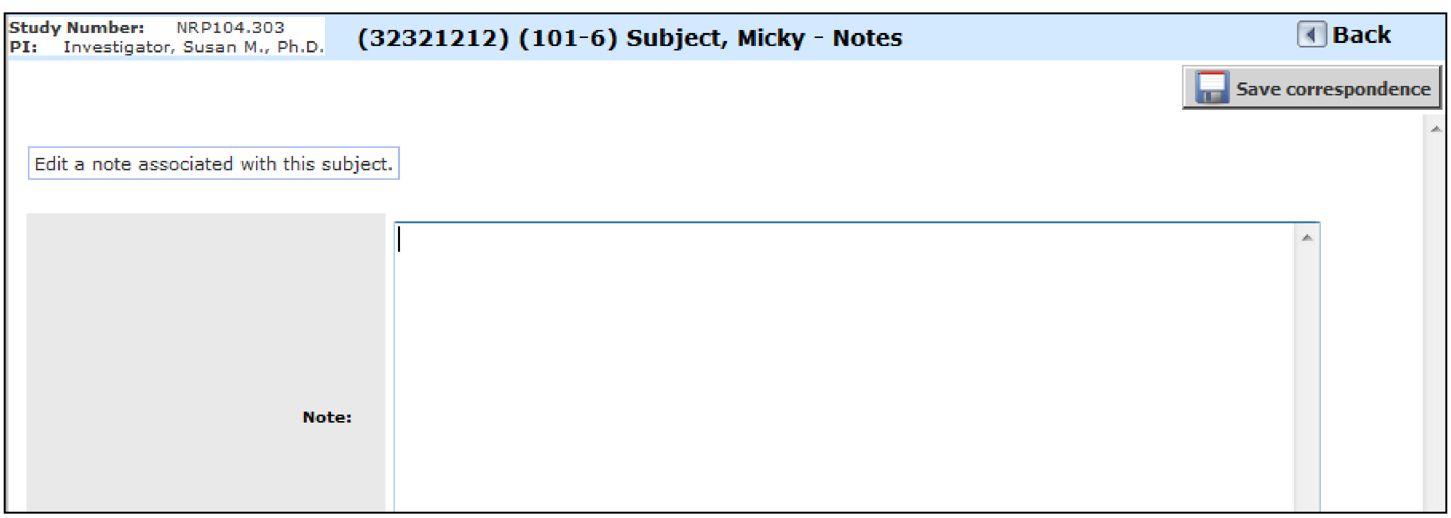
The information defined in the Insurance dropdown list is configured in System Administration –> List Configuration and Maintenance –> Site List Setup –> Define Insurance Companies.

Correspondence

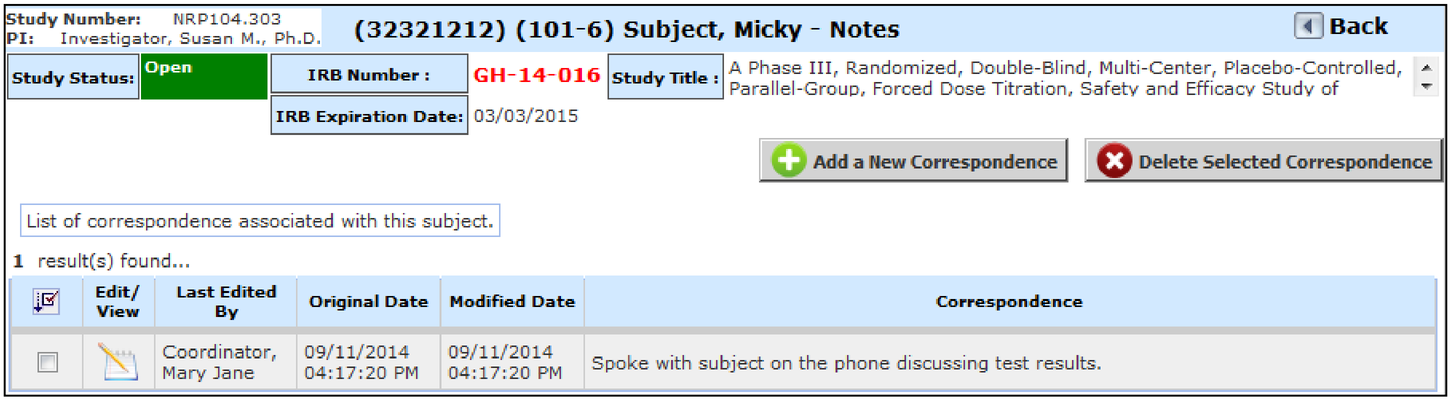
This area allows you to list the correspondence records for the subject. When you first access this area, the page will not display any records for the subject. You can associate a correspondence record to the subject by clicking on the **Add a New Correspondence** button.



From the page that opens, you can type in the correspondence **Note**. Click the **Save correspondence** button when you are finished.

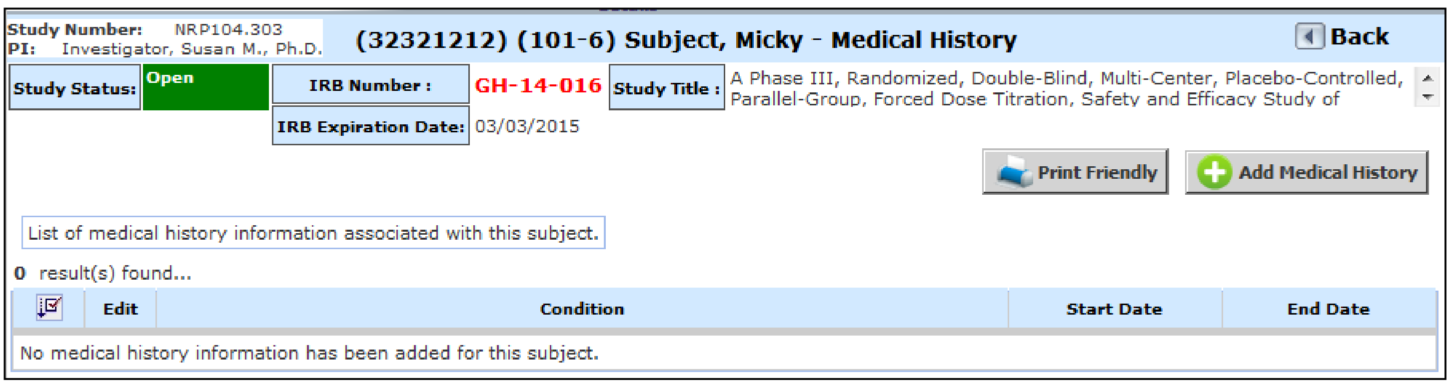


The Correspondence record will be associated to the subject. You can modify the details for the Correspondence record by clicking on the icon in the **Edit** column and delete the record by selecting the checkbox next to the Correspondence and clicking on the **Delete Selected Correspondence** button. Additional records can be associated to the subject by clicking on the **Add a New Correspondence** button. Correspondence can be updated and information in the **Last Edited By** and **Modified Date** will update with the latest information.

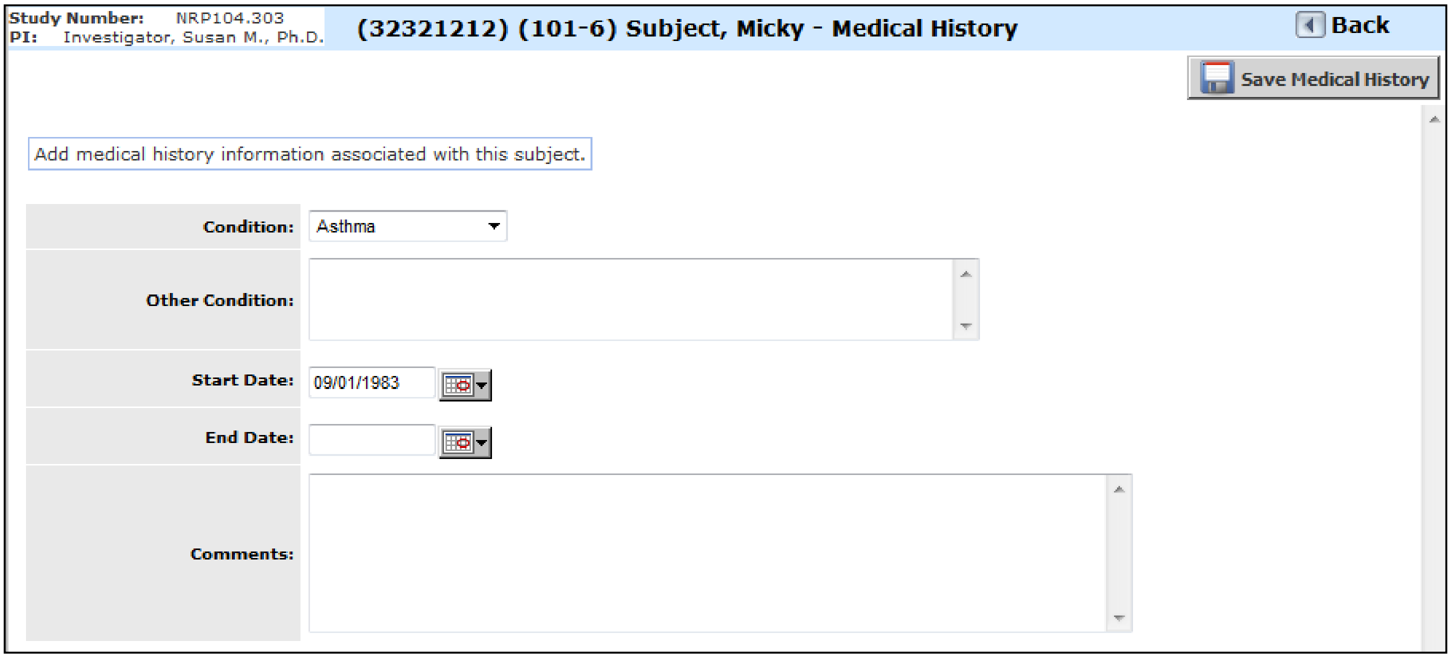


Medical History

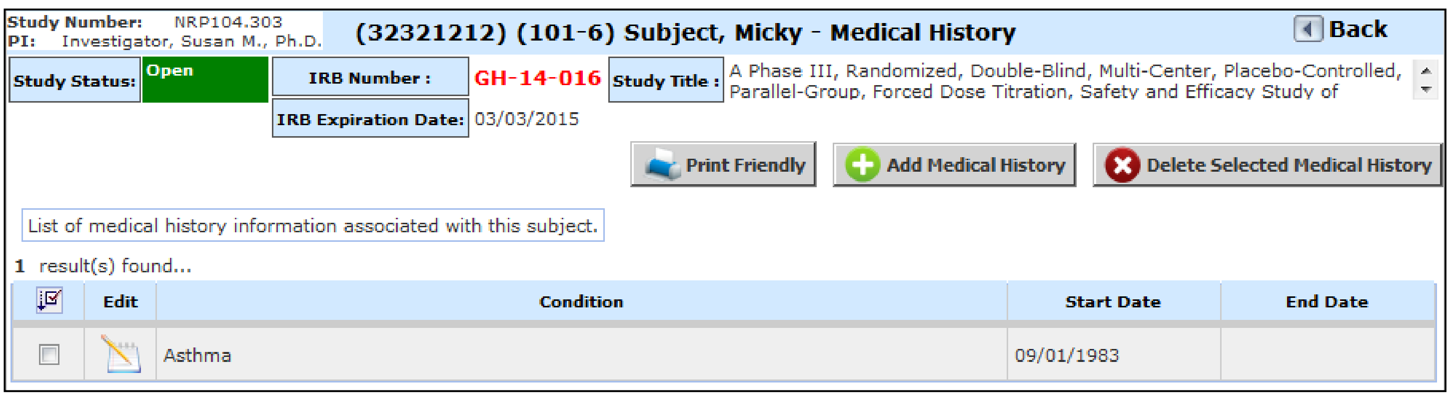
This area allows you to list Medical History for the subject. When you first access this area, the page will not display any records for the subject. You can associate Medical History to the subject by clicking on the **Add Medical History** button.



From the page that opens, you can select a **Condition** from the dropdown list. You can also specify additional details, including, Start Date, End Date and Comments. Click the **Save Medical History** button when you are finished.



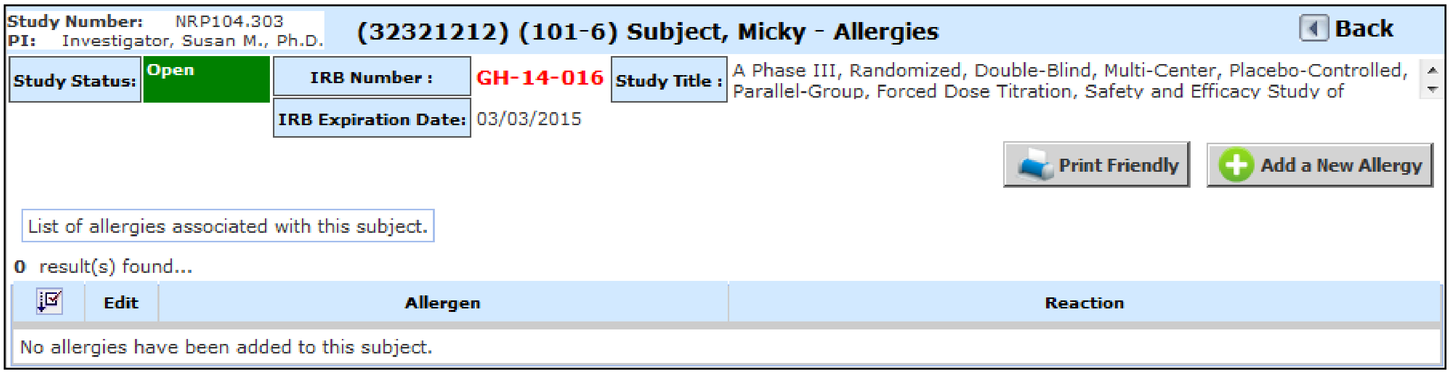
The Medical History record will be associated to the subject. You can modify the details for the record by clicking on the icon in the **Edit** column and delete the record by selecting the checkbox next to the Medical History and clicking on the **Delete Selected Medical History** button. Additional records can be associated to the subject by clicking on the **Add Medical History** button.



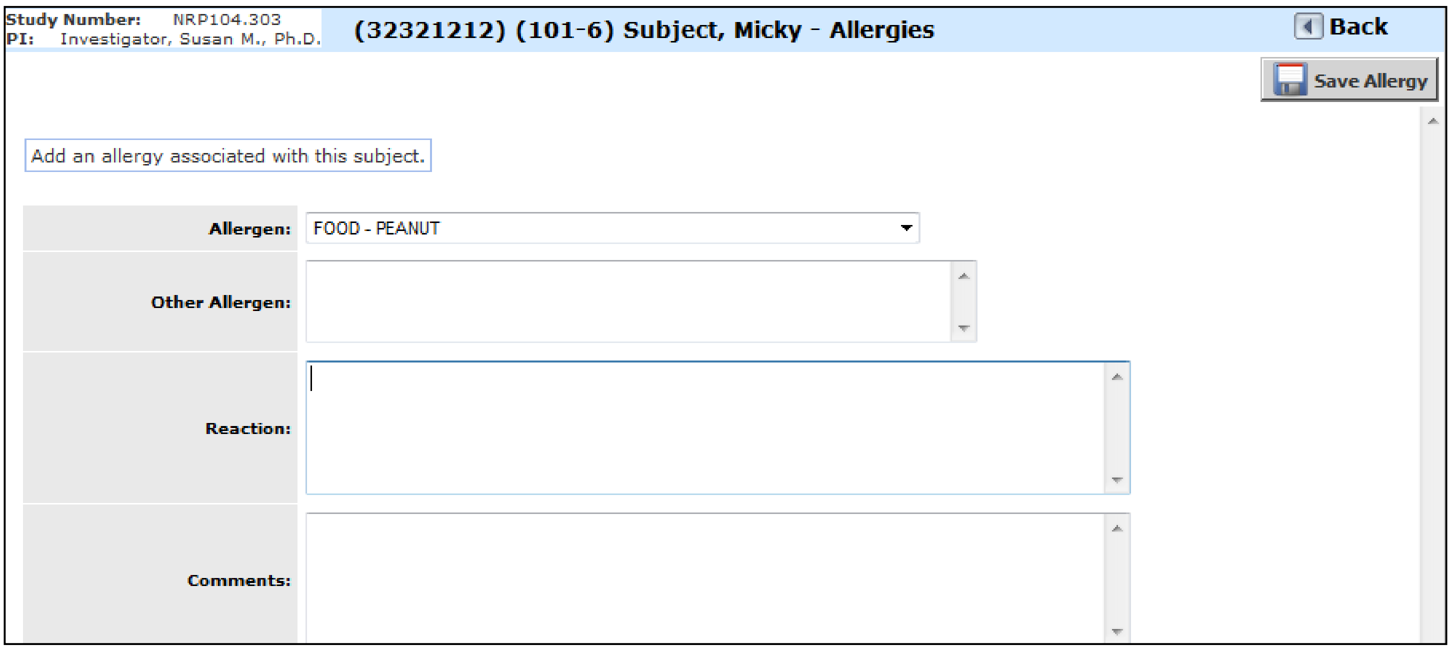
The information defined in the Condition dropdown list are configured in System Administration –> List Configuration and Maintenance –> Site List Setup –> Medication.

Allergies

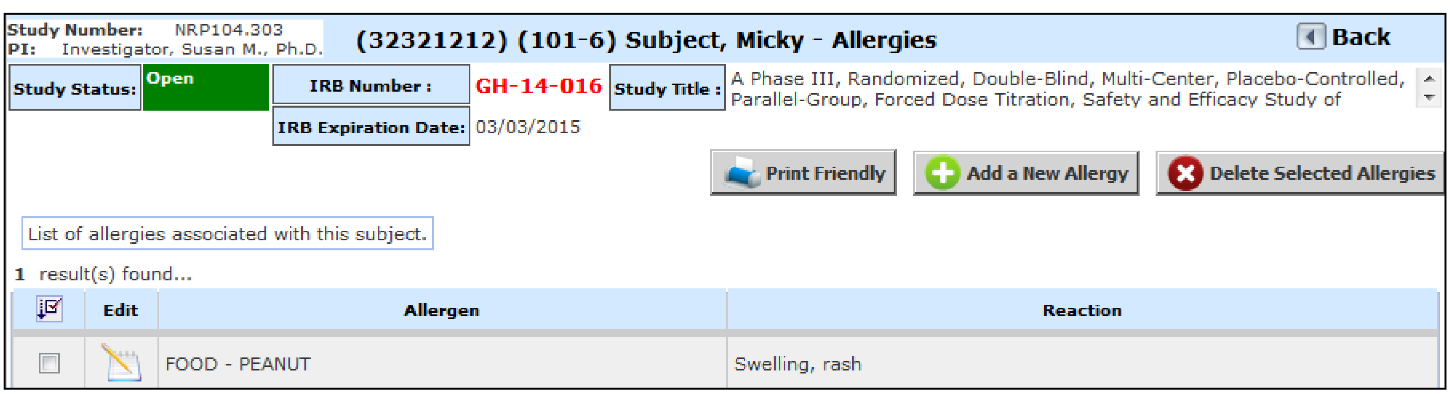
This area allows you to list Allergies for the subject. When you first access this area, the page will not display any records for the subject. You can associate an allergy to the subject by clicking on the **Add a New Allergy** button.



From the page that opens, you can select an **Allergen** from the dropdown list. You can also specify additional details, including Reaction and Comments. Click the **Save Allergy** button when you are finished.



The Allergy record will be associated to the subject. You can modify the details for the record by clicking on the icon in the **Edit** column and delete the record by selecting the checkbox next to the Allergy and clicking on the **Delete Selected Allergies** button. Additional records can be associated to the subject by clicking on the **Add a New Allergy** button.

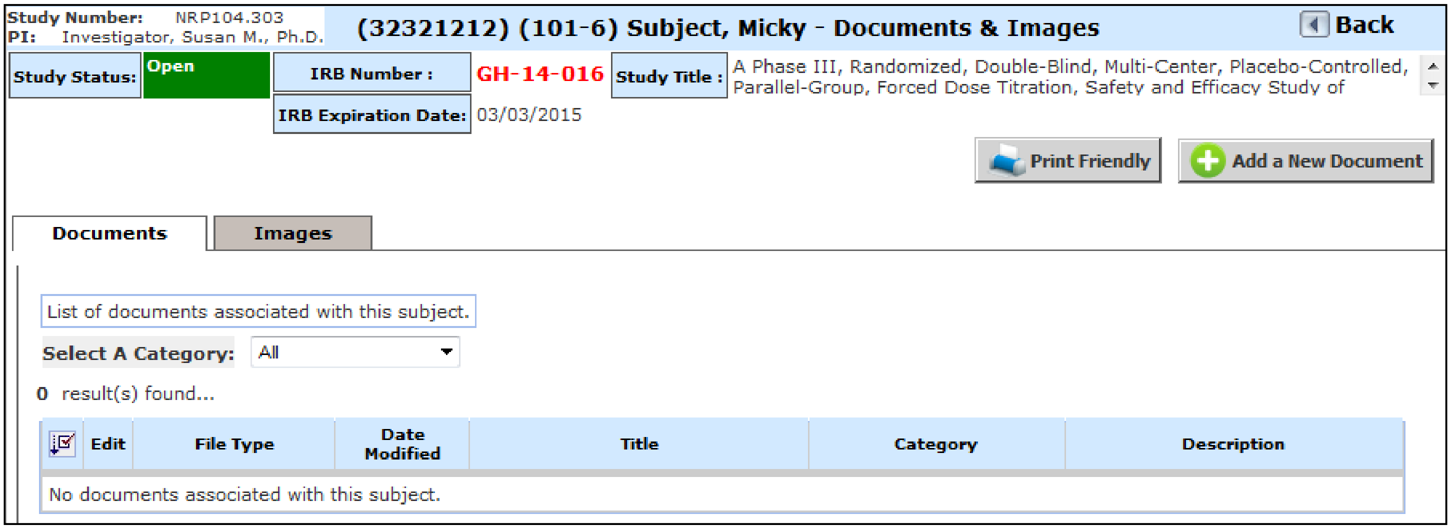


The information defined in the Allergen dropdown list are configured in System Administration –> List Configuration and Maintenance –> Site List Setup –> Allergen.

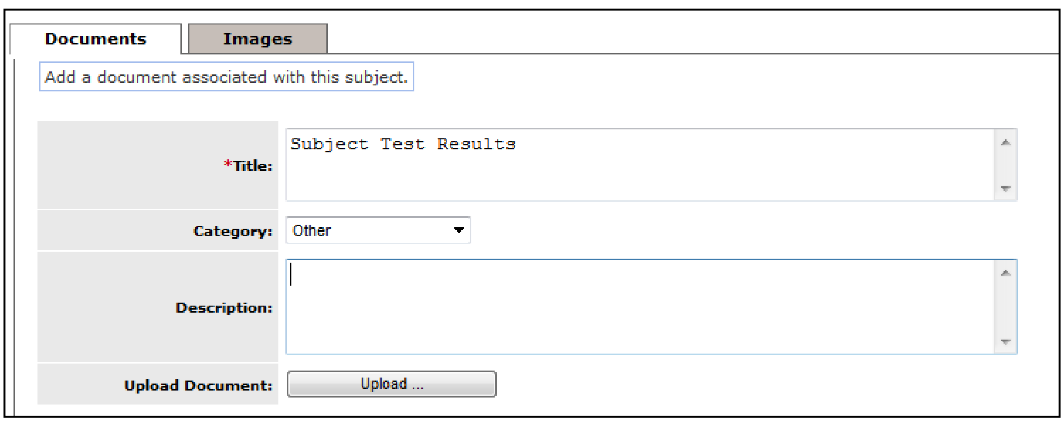
General Documents

This section is where a user can associate any general documents and/ or images to the subject record. This page is broken up into two tabs, **Documents** and **Images**. Each tab allows you to upload a document for the subject.

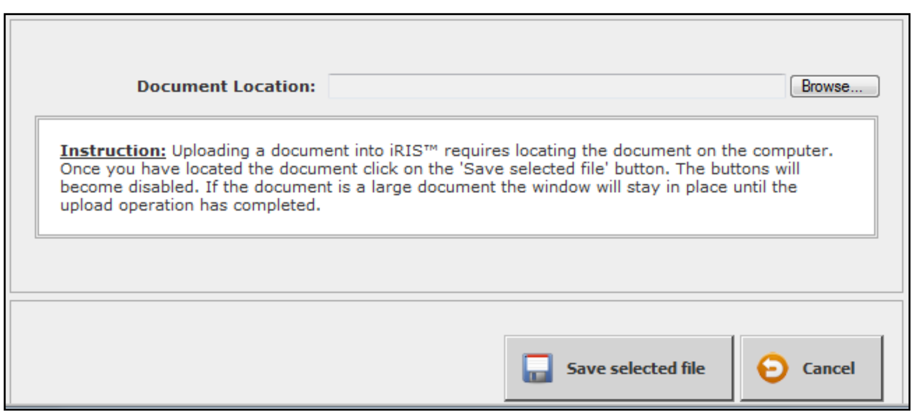
To add a document, verify you have the **Documents** tab selected and click the **Add a New Document** button.



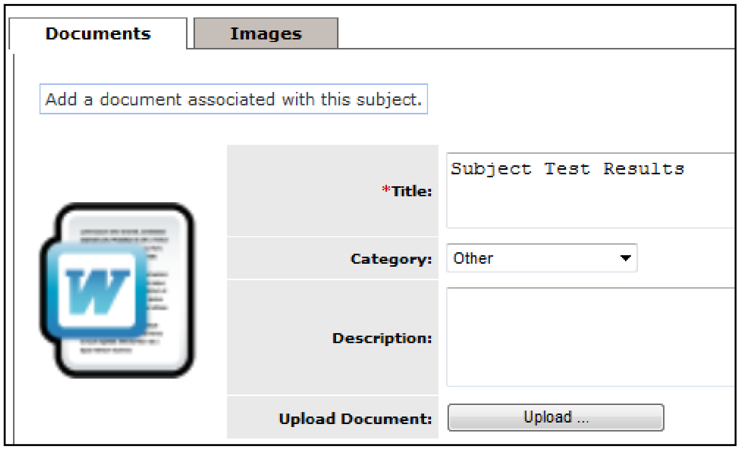
Enter the **Title** and associate a **Category** and **Description**, if applicable. Then click the **Upload** button.



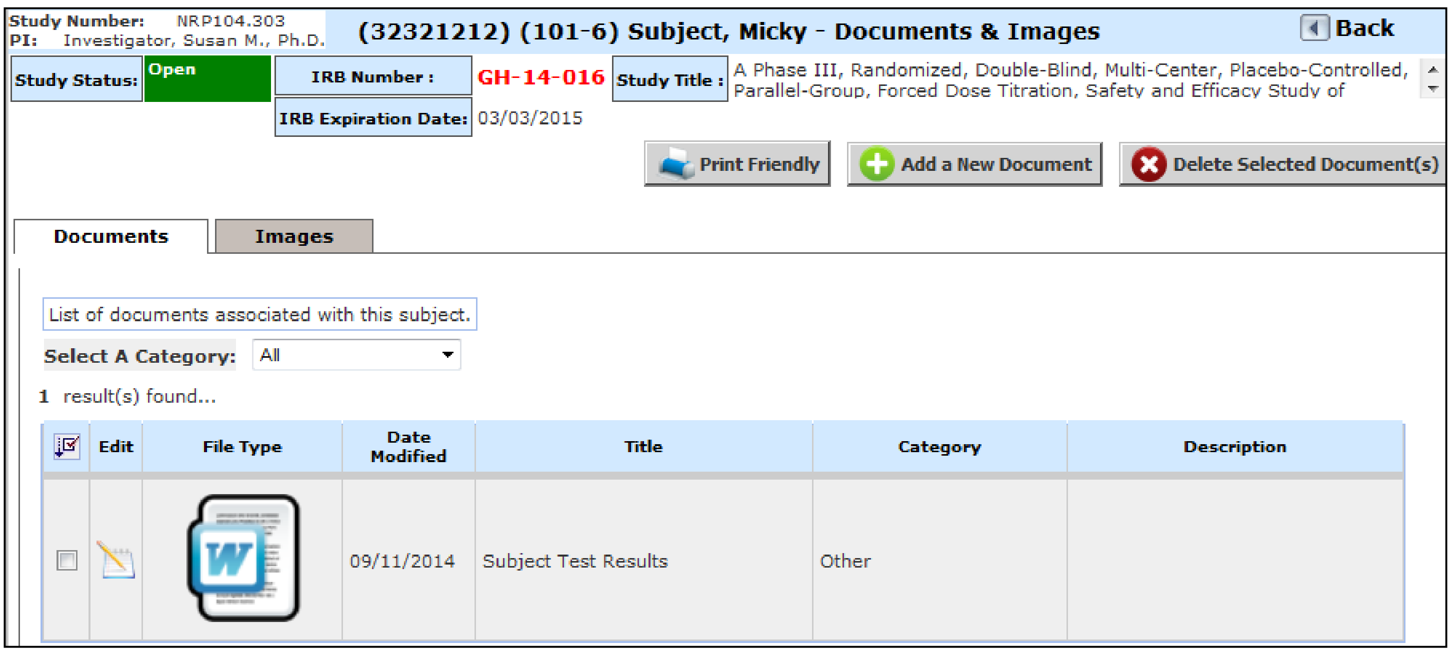
A popup window opens allowing you to **Browse** your computer for the document. Once you select the document, click the **Save selected file** button. Click the **Cancel** button to return to the Documents page without uploading a document.



A Microsoft Word icon populates next to the document information when you successfully upload a document. Be sure to click the **Save Document** button to complete the upload.



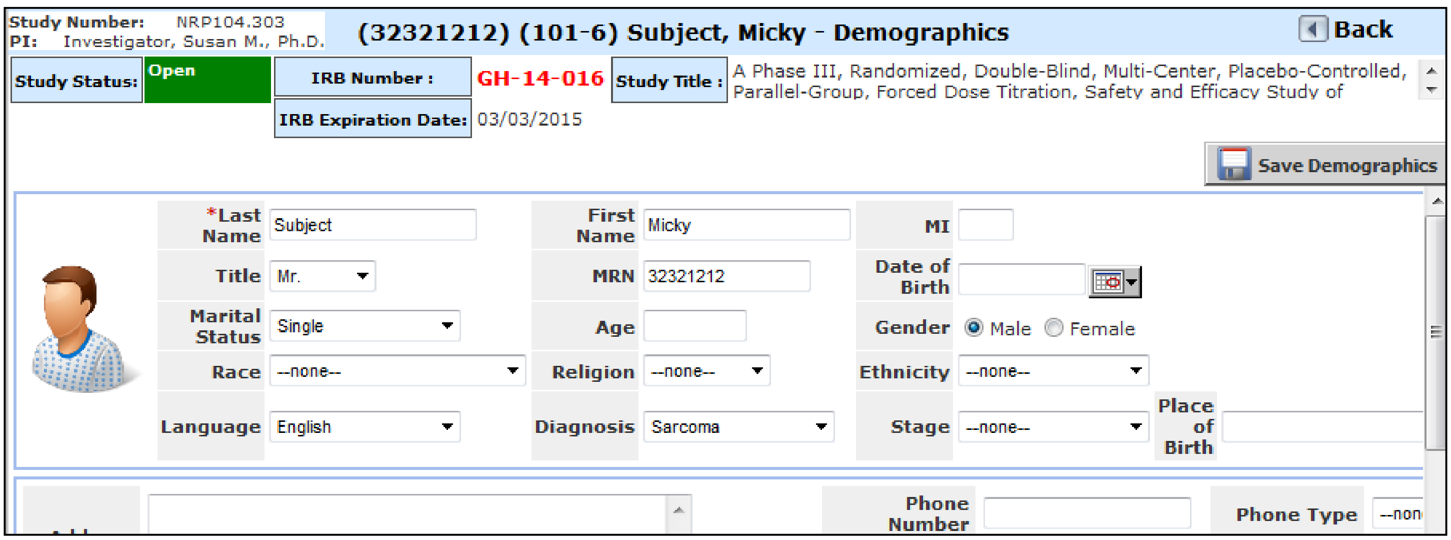
Any document record added displays within the Documents tab.



To add an image, verify the Images tab is selected and click the **Add a New Document** button. You can then enter the **Title**, **Description** and indicate if the image being uploaded is a **Patient Photo**. Click the **Upload** button.

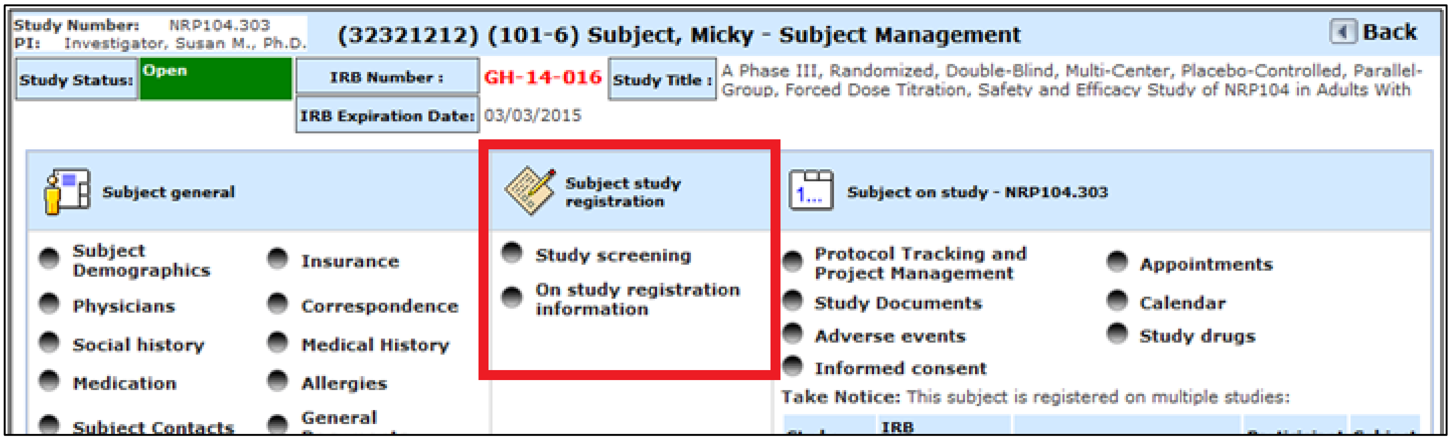
Repeat the same process for adding a document. Be sure to click the **Save Document** button to complete the upload. Any images uploaded will populate in the Images tab.

If you indicate that the image uploaded is a Patient Photo, the image will display within Subject Demographics, similar to the screenshot below.



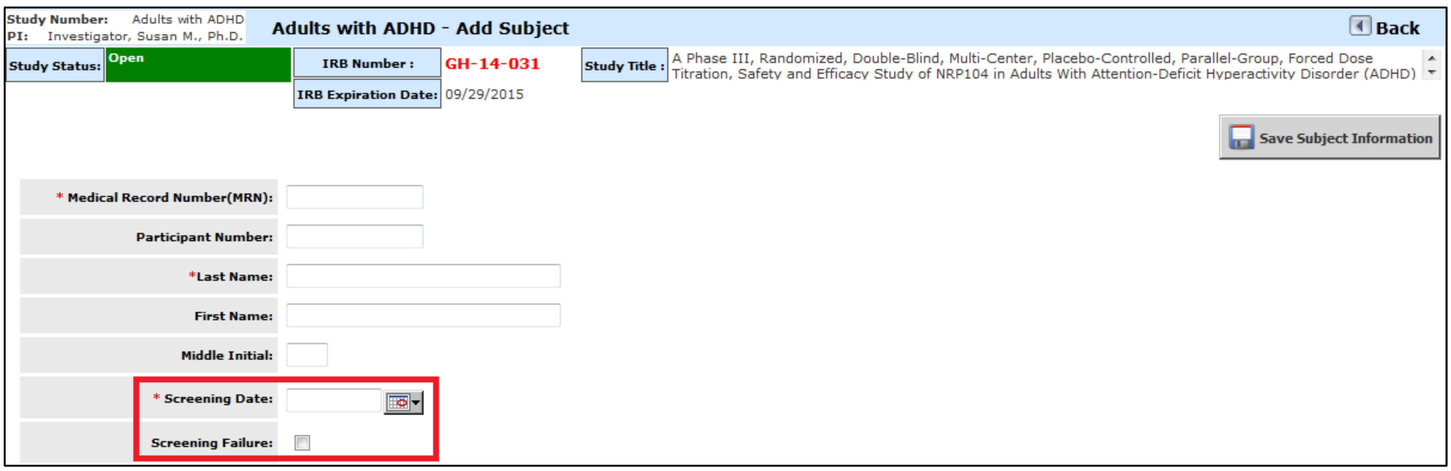
Subject Study Registration

The links within Subject Study Registration allow researchers to manage the screening and registration information related to the subject on study. Screen fails can be tracked, the current subject status can be managed and the subject can be enrolled onto an arm from within these screens.



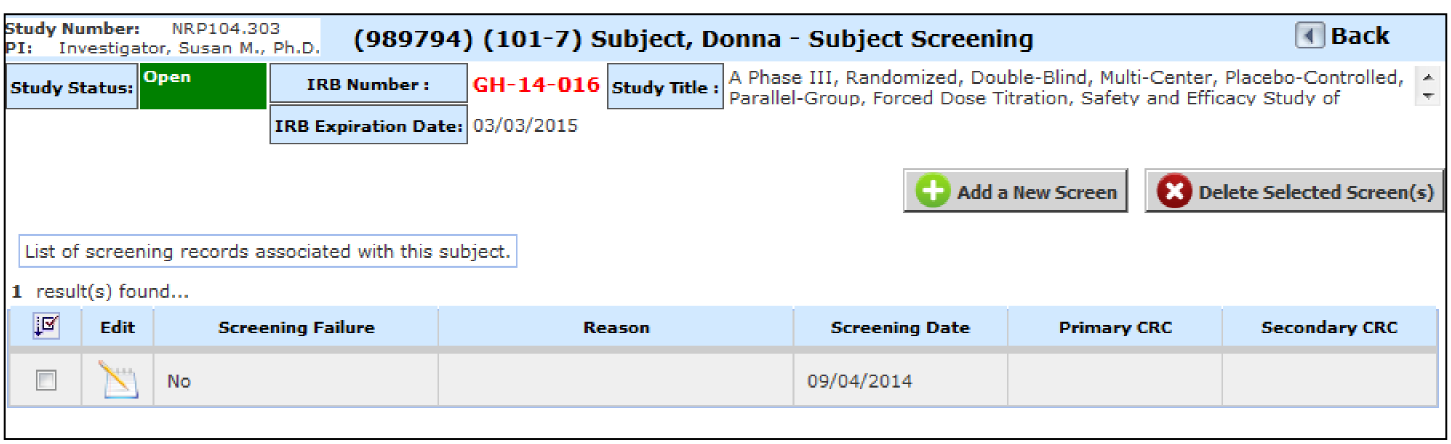
Study Screening

When subjects are added to a study, the system will create a screening record for that subject. At the time you add a subject to the study, you are able to indicate whether or not the screen was a fail.



The **Screening Date** and **Screening Failure** information entered when adding the subject to the study populate within Study Screening, as shown in the screenshot below. You can provide additional details for the screening record from this page, as well as add new screening records.

To edit the existing record, click the icon in the **Edit** column. To add a new record, click the **Add a New Screen** button.

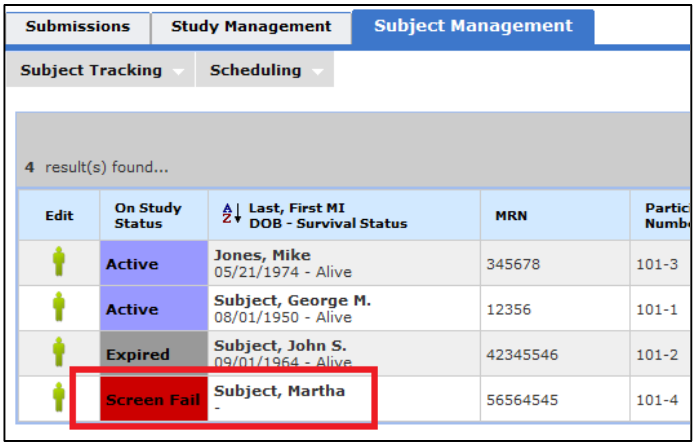


Whether you are editing or adding a record, a page similar to the one in the screenshot below will open. The fields are described below.

Screening Date – This required field is the date the screening for the subject took place. This date will be pre-populated with the Screening Date provided when adding the subject to the study if you are editing the existing record.

Screening Failure – When a subject has failed screening, check the **Screening Failure** option. When you indicate a subject has failed screening, the system will ask if you need to default the subject to the failed screening status.

When you indicate "Yes," the status of the subject will default to the pre-configured Screen Fail subject status, similar to the status assigned in the screenshot below.

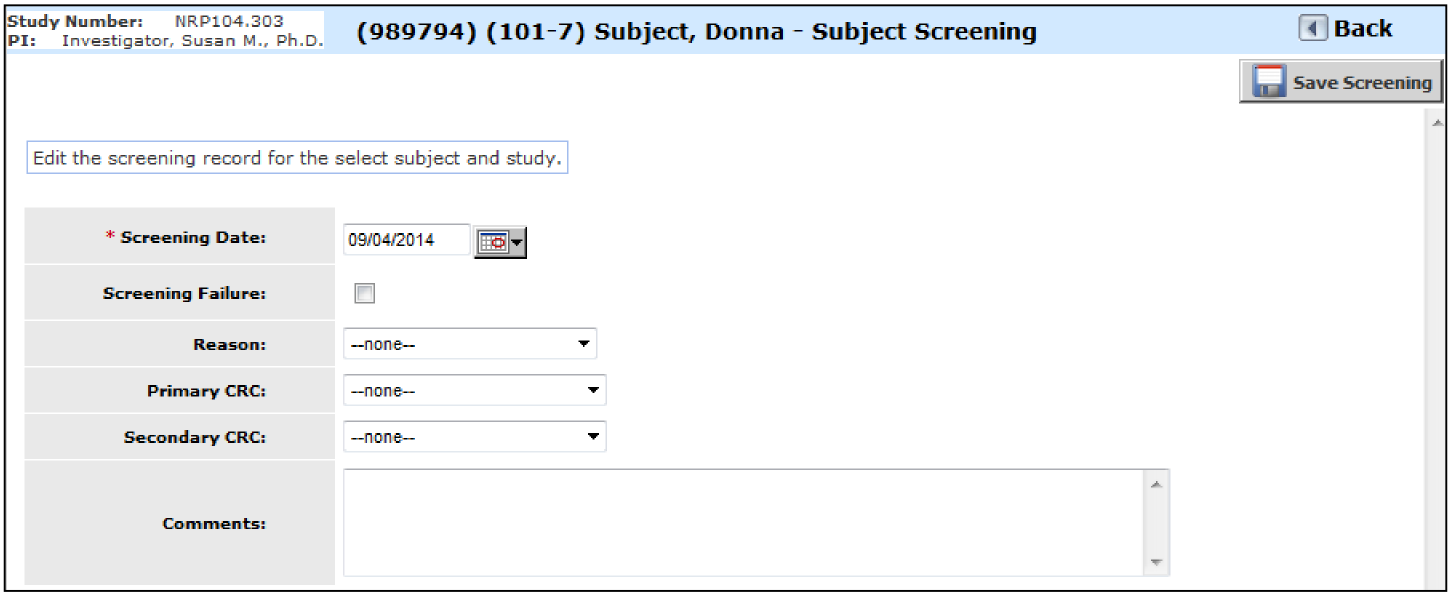


Reason – This is a configurable list of screen fail reasons. When you flag a subject as failed screening, you can also choose the reason from this list. The configuration list is located in System Administration –> List Configuration and Maintenance –> Site List Setup –> Screening Reason.

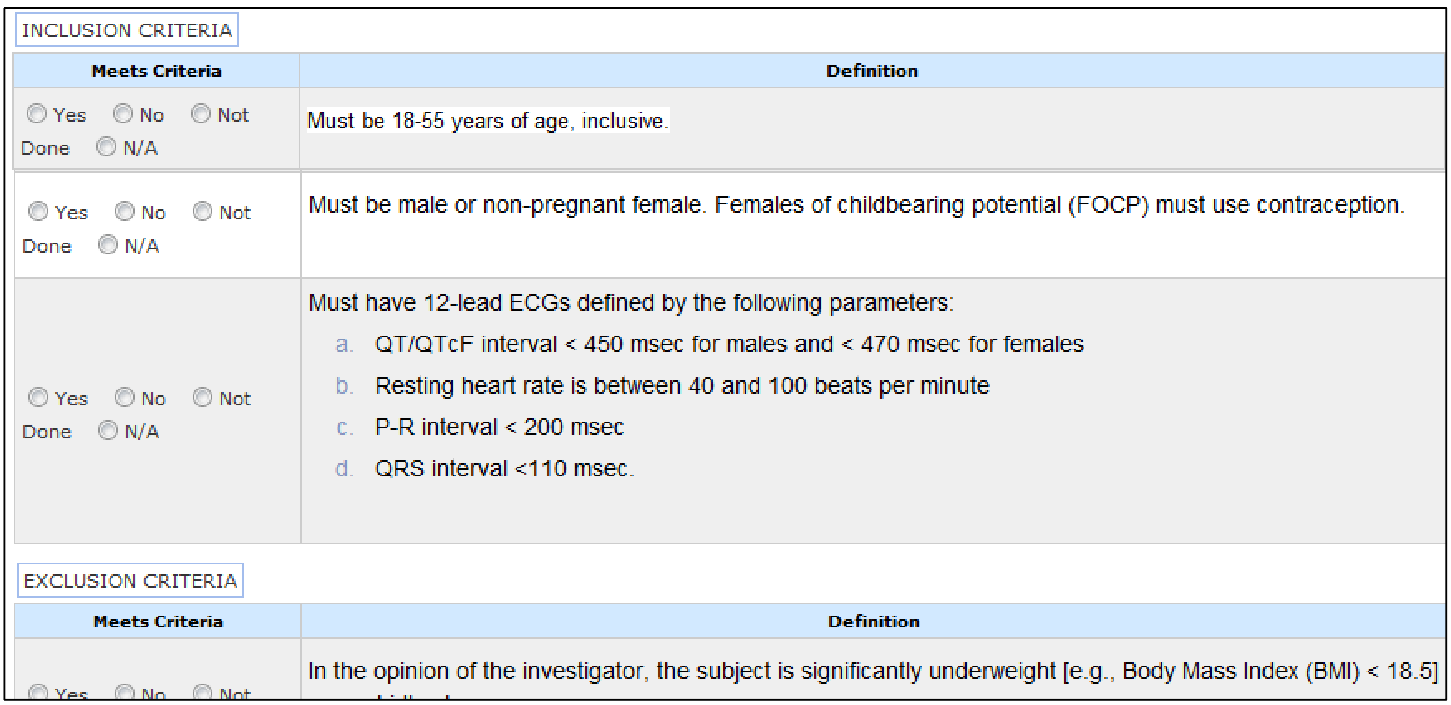
Primary CRC – This dropdown list contains a list of personnel listed on the study for selection as Primary CRC for the screening record.

Secondary CRC – This dropdown list contains a list of personnel listed on the study for selection as Secondary CRC for the screening record.

Comments – You can add any supporting comments to the field provided here.



Below the screening information, you may have listed the study's IRB approved Inclusion and Exclusion Criteria. You can indicate whether or not the subject met the criteria by selecting either "Yes," "No," "Not Done," or "N/A" from the options provided.

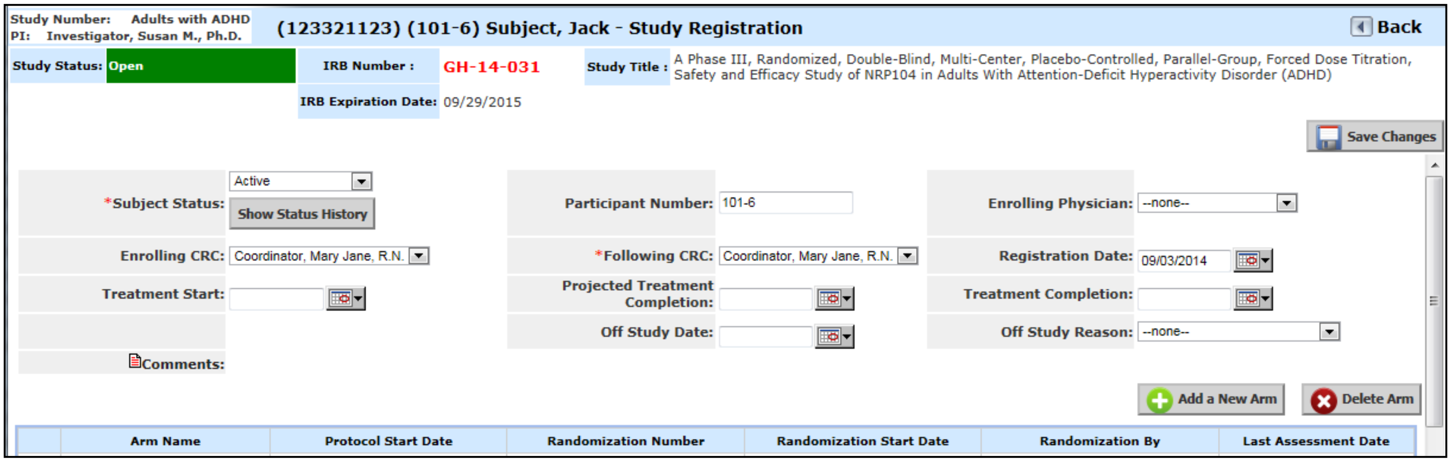


On Study Registration Information

On Study Registration Information contains elements related to the subject's current on study status. This is also the area where you can add the subject to a Study Plan Arm. The fields shown in the screenshot below may or may not be the same fields you have in your system, depending on your system settings.

This page lists the current information related to the subject and is meant to be updated as information related to the subject on study changes. When you first add a subject to the study, you would update this page to reflect the current Subject Status, enter the Enrolling Physician, Enrolling CRC, Following CRC and supply any necessary dates (Registration

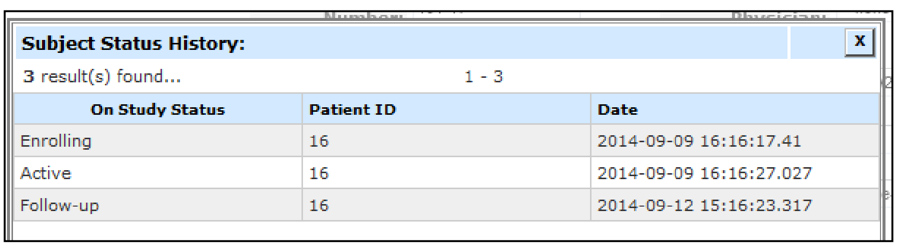
Date, Treatment Start and Projected Treatment Completion, for example). Then, later, when the subject has completed or is off the study, this page would be updated again to reflect that information. The data captured here will be used in certain Subject related reports.



Some of the fields listed on this page are as follows:

Subject Status- This is a required field. Select the Status of the Study Subject from the drop-down menu. The status of the subject should be pre-populated from when the subject was added to the study. This status should be changed as the subject progresses through various stages of the study.

> **Show Status History** – The system will keep an audit of the different subject status associated to the subject. At any time, you can click this button to display the audit for the status. A small window will open within the browser displaying the On Study Status field, the Patient ID, and the Date the status was applied to the subject.



Participant Number – This is the number used within the study to identify the subject. This is different from the MRN, where the MRN is shared between studies the on which the subject is enrolled. The Participant Number is unique to each study on which the subject is enrolled.

Enrolling Physician – You can associate a Physician to the subject here. The Enrolling Physician will display in certain reports. This list is supplied from the current list of Physicians within System Administration –> List Configuration and Maintenance –> Site List Setup –> Physician List.

Enrolling CRC- You can associate an Enrolling CRC to the subject here. The Enrolling CRC will display in certain reports. This list is supplied from the current list of users on the study.

Following CRC- You can associate a Following CRC to the subject here. The Following CRC will display in certain reports and will also receive tasks related to the subject (Visit Tasks). This list is supplied from the current list of users on the study.

Registration Date- You can enter the Registration Date in this field. This date will be used to pull into certain reports.

Treatment Start- You can enter the Treatment Start Date in this field. This date will be used to pull into certain reports.

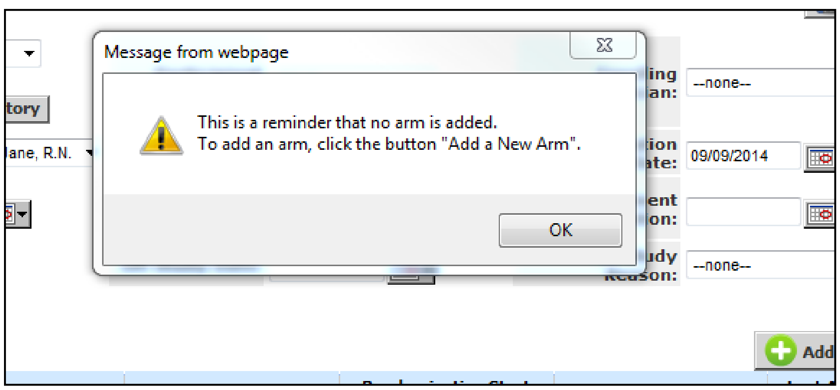
Projected Treatment Completion- You can enter the Projected Treatment Completion Date in this field. This date will be used to pull into certain reports.

Treatment Completion- You can enter the actual Treatment Completion Date in this field. This date will be used to pull into certain reports.

Off Study Date- You can enter the Off Study Date in this field. This date will be used to pull into certain reports.

Off Study Reason- When indicating the subject is off study, you can choose an Off Study Reason from this drop down list. This list is a configurable list within System Administration –> List Configuration and Maintenance –> Site List Setup –> Off Study Reasons.

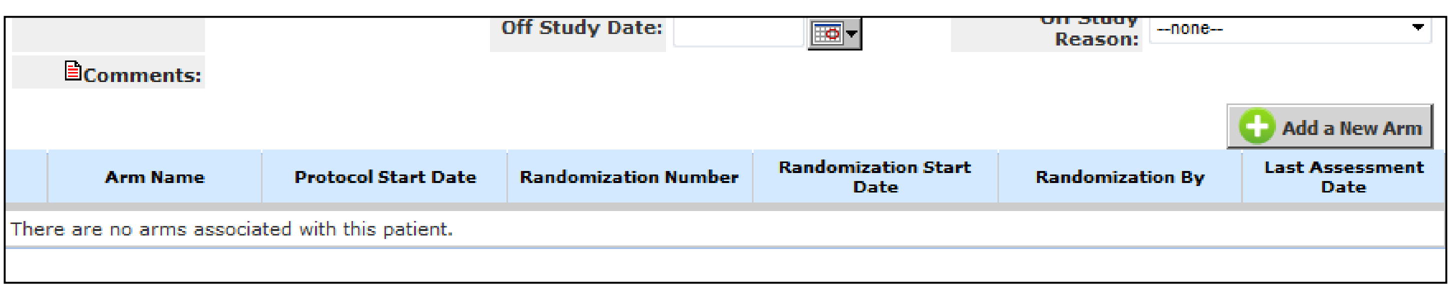
Comments- Comments related to the registration information can be added by clicking on this link.
When you are finished entering the necessary information on this page, be sure to click the **Save Changes** button. When you save the page without adding an arm to the subject, the system will provide a reminder message that the subject has not been enrolled on an arm.



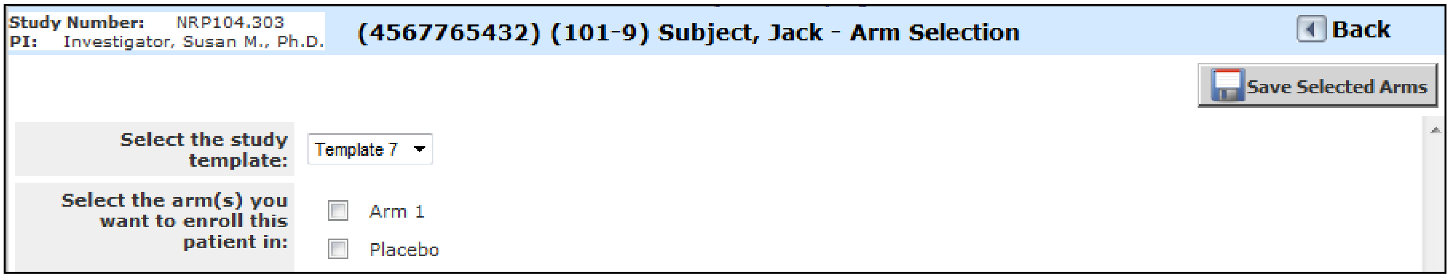
Adding an arm to the subject is not required, so it is not necessary to complete the steps below until you are ready to start the Study Plan Arm for the subject.

Add New Arm

Below the current registration information for the subject is the Study Plan Arm table. If the subject is currently associated to an arm, a record will populate in the table. To add the subject to an arm, click the **Add a New Arm** button.

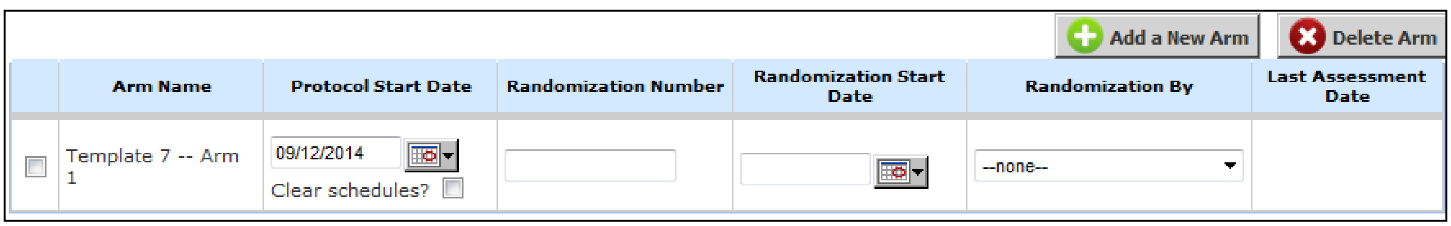


A new page will open. Select a study plan from the drop down list. Only one study plan template will ever be available here, as only one template can be published and available at a time. Study Plans are created and published within Study Management. See the Subject Management –> Study Plans and Timelines Manuals for more information. The template used in this example is titled “Template 7”. Once the template is selected from the dropdown list, the Arm(s) associated to the Study Plan will populate on the page. Select the arm(s) to associate to the subject then click the **Save Selected Arms** button.



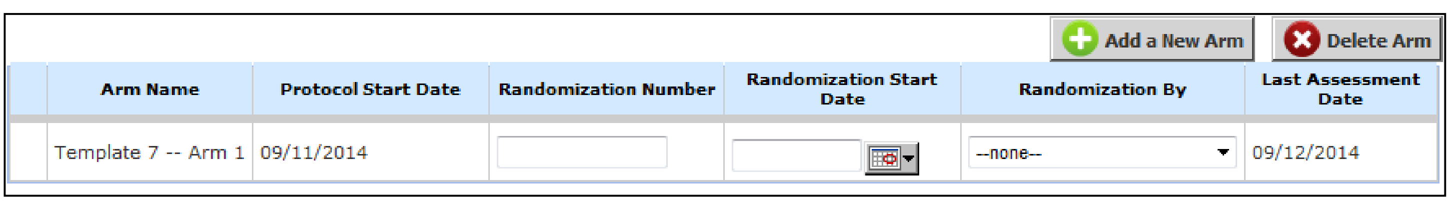
You will be returned to the Study Registration page and a record for each arm you added the subject to will populate on the page. In order to drive the Timeline associated to the Study Plan Arm, you will need to supply a **Protocol Start Date**. When you enter a date, the option “Clear Schedules?” will populate. This is only applicable if you are changing an already set Protocol Start Date and visits associated to the study plan have been scheduled within Protocol Tracking. Choose this option if you would like to unscheduled visits that have been scheduled according to the previous Protocol Start Date.

The Randomization information is not required and may not display on this page, depending on your system configuration. The last column in the table, **Last Assessment Date,** will populate with a date once the subject has completed a visit within Protocol Tracking and Project Management.



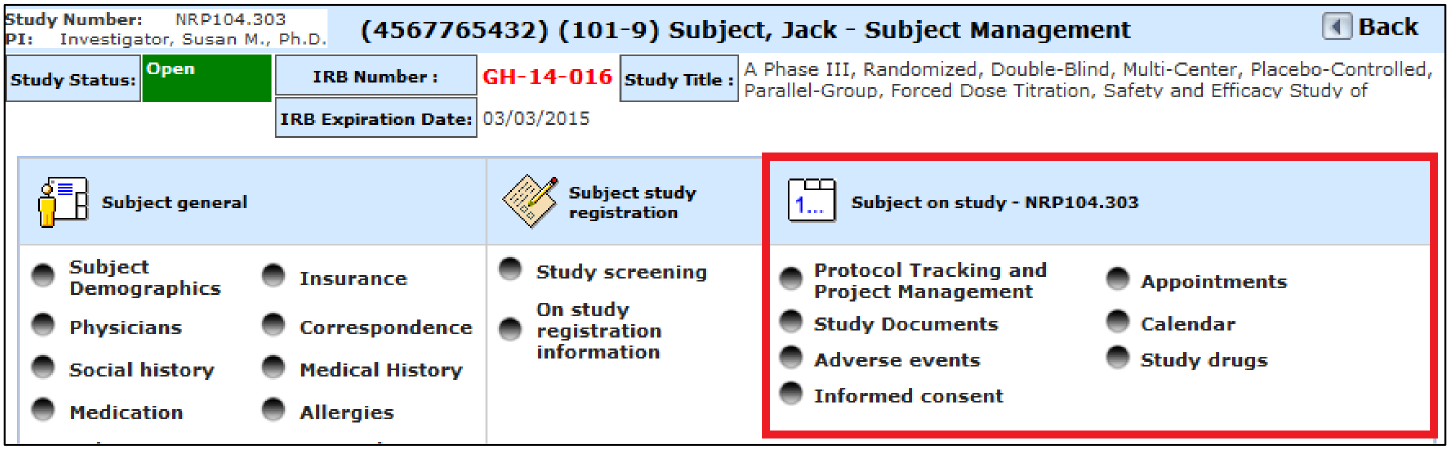
You may delete the arm from this page by selecting the checkbox next to the arm and clicking on the **Delete Arm** button.

Any Arms that have completed visits associated cannot be deleted from this page. If a visit has been completed for the arm, the delete option will not be available, the Protocol Start Date will lock down, (Randomization information can be changed at any time) and the Last Assessment Date will populate with the date of the last completed visit.



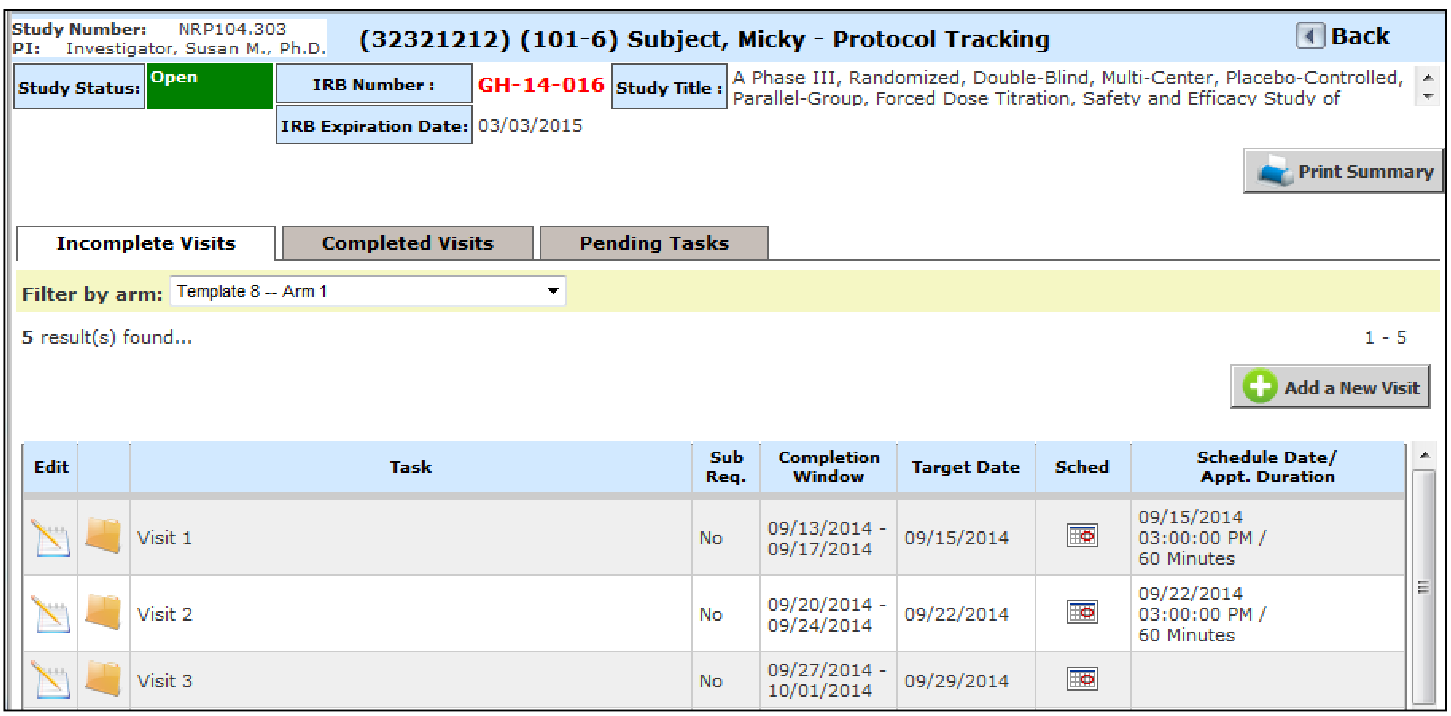
Subject on Study

The Subject on Study area contains links to various study-related screens for the subject. From here, you can view the visits for a subject (these visits are populated based on the Study Plan Arms assigned in On Study Registration, as discussed above), schedule and complete visits, submit Adverse Event forms to the review board, access study documents and record the consent information. The information in this area is specific to the subject on this study only, meaning if the subject is enrolled on another study, only information related to the study being accessed will be viewable within these screens.



Protocol Tracking and Project Management

Protocol Tracking and Project Management contains the management of the Study Plan Arm visits. Once a subject is enrolled on an arm, the visits that are associated to that arm will populate in this area. The page is broken up into three parts: **Incomplete Visits**, **Complete Visits**, and **Pending Tasks**. All visits come over as Incomplete and from this area can be scheduled, completed or cancelled. Once a visit is completed, it will move from the **Incomplete Visits** tab and move to the **Completed Visits** tab. The **Pending Tasks** tab will populate with visits that have any incomplete items within the visit but the visit has been marked as complete. More on this will be discussed below.



Within all three tabs the following information is available, unless otherwise noted. At the top of the page is a filter dropdown list, allowing you to switch the view of visits to a different arm. Other arm options are only available in this drop down list if the subject is actively enrolled on more than one arm through On Study Registration Information.

Visits that are not included in the Study Plan Arm can be added to the Incomplete Visits tab as needed. To add a visit, click the **Add a New Visit** button. This is described in more detail below.

Each visit is listed in the corresponding tab, depending on the visit status and in order based on the Study Plan they are associated to. The columns on this page are described below.

Columns in Incomplete Visits tab:

Edit – To complete a visit, click the icon in this column. More is discussed about completion of visits below.

Folder – Clicking on this folder will expand a list of Procedures and Case Report Forms associated to the visit.

Task – This column displays the name of the visit.

Sub Req. – Will display if a submission of a Case Report Form is required in order for this visit to be flagged as Complete.

Completion Window – The dates that populate in this column are based on the Protocol Start Date supplied in On Study Registration Information and the information created in Study Plan Timeline. This window sets the time plus or minus for scheduling a visit.

Target Date – This date populates based on the Protocol Start Date supplied in On Study Registration Information and the information created in Study Plan Timeline.

Sched – Click this icon to schedule the visit for the subject. This column will only appear if the Study Plan Timeline indicates that scheduling will be used for this visit.

Schedule Date / Appt. Duration – Once a visit has been scheduled, the date scheduled and amount of time for the visit will populate in this column.

Columns in Completed Visits tab and Pending Tasks tab

Edit – To modify a visit or to mark a pending task as complete, click the icon in this column. More is discussed about completion of visits below.

Folder – Clicking on this folder will expand a list of Procedures and Case Report Forms associated to the visit.

Task – This column displays the name of the visit.

Sub Req. – Will display if a submission of a Case Report Form is required in order for this visit to be flagged as Complete.

Task Status/ Modified By – This column displays in the Completed Visits and Pending Tasks tab and will display the status of the overall visit and which user last modified the visit details.

Assessment Date – This column displays the Assessment Date provided at the time of visit completion. This may or may not contain a date, depending on the **Task Status**. If a visit was flagged as “Not Done,” “No Show,” or “Canceled” an Assessment Date is typically not assigned.

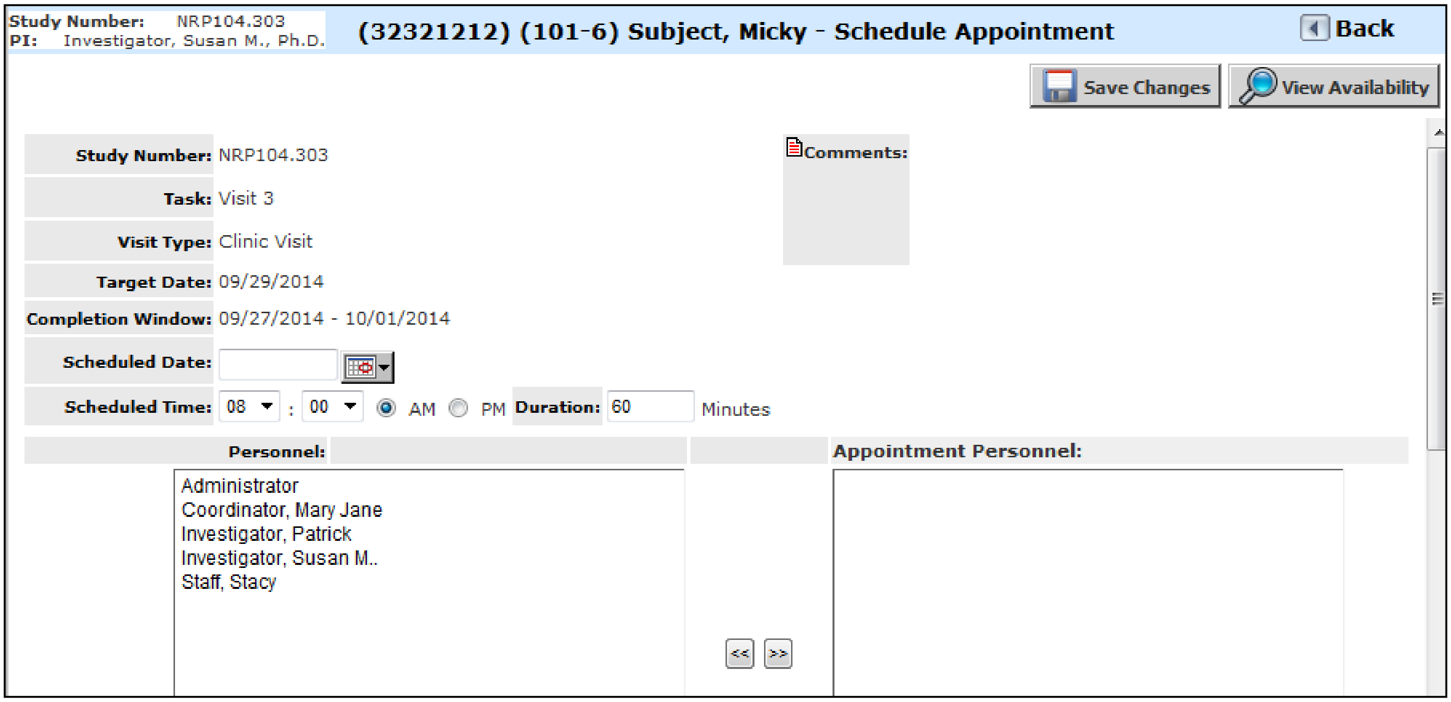
Submission Date – If the visit had been flagged in Study Plan Timeline as a Submission Required (see the Sub Req. column), this column would populate with the date the Case Report Form was flagged as submitted. This is a date input field given within Visit Details.

Target Date – This date populates based on the Protocol Start Date supplied in On Study Registration Information and the information created in Study Plan Timeline.

Completion Window – The dates that populate in this column are based on the Protocol Start Date supplied in On Study Registration Information and the information created in Study Plan Timeline. This window sets the time plus or minus for scheduling a visit.

Scheduling Visits

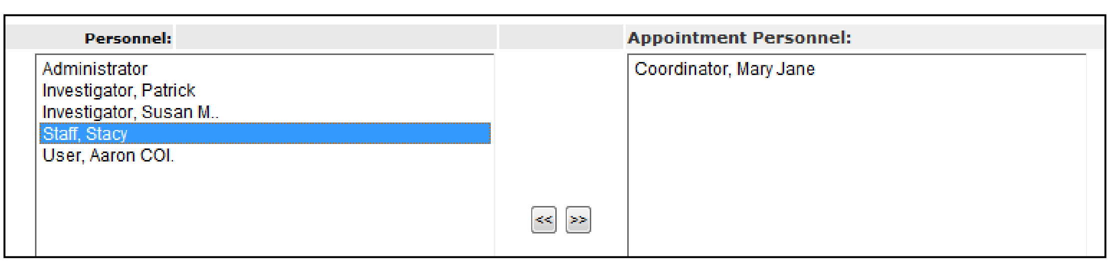
You can schedule a visit within Protocol Tracking and Project Management. Within the Incomplete Visits tab is a **Sched** column that contains a calendar icon. You can click this icon to open the visit schedule page. Visits can also be scheduled through the Appointments link within Subject on Study.



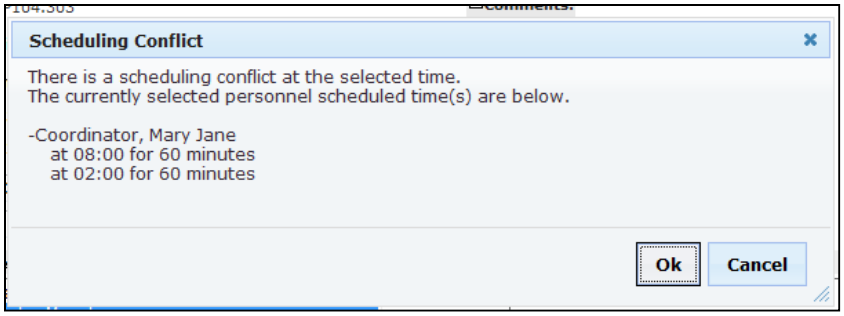
When you click the icon in the **Sched** column, a Schedule Appointment page will open. This page will list the visit details: Study Number, Task (Visit Name), Visit Type, Target Date and Completion Window.

On this page, you can select a date in the **Scheduled Date** field and adjust the **Scheduled Time** by selecting the time in hours/minutes, AM or PM and then set the **Duration**. You can also add comments by clicking on the **Comments** link.

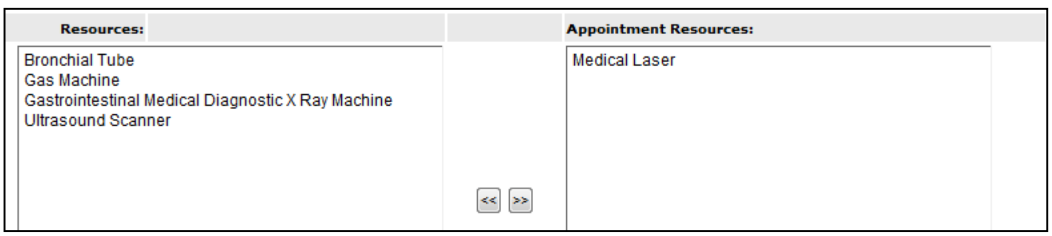
You may also associate study personnel to the visit using the **Personnel** and **Appointment Personnel** areas. Within the **Personnel** table are all personnel on the study. You can click on the personnel who should be associated to the appointment, then click the Right Arrow to add them to the **Appointment Personnel** table. If you added a user by mistake, click their name in the **Appointment Personnel** table and click the Left Arrow to return them to the **Personnel** table.



If the user being added to the appointment already has scheduled appointments on the same day, the system will provide a Scheduling Conflict appointment, similar to the screenshot below. This will provide the user and the other appointment times and lengths for the day you are attempting to schedule this visit for. At this point you can click the **Cancel** button to discontinue adding the user to the appointment or to proceed, click the **OK** button.



Below the appointment area, you may associate department resources to the visit using the **Resources** and **Appointment Resources** areas. Within the **Resources** table is a list of all available resources within the subject department on the study. You can click on the resource needed at the appointment then click the Right Arrow to add it to the **Appointment Resources** table. If you added a resource by mistake, click the name in the **Appointment Resources** table and click the Left Arrow to return it to the **Resources** table.



Before saving the scheduled visit, you can check the availability of the personnel you associated to the visit by clicking on the **View Availability** button at the top of the page.

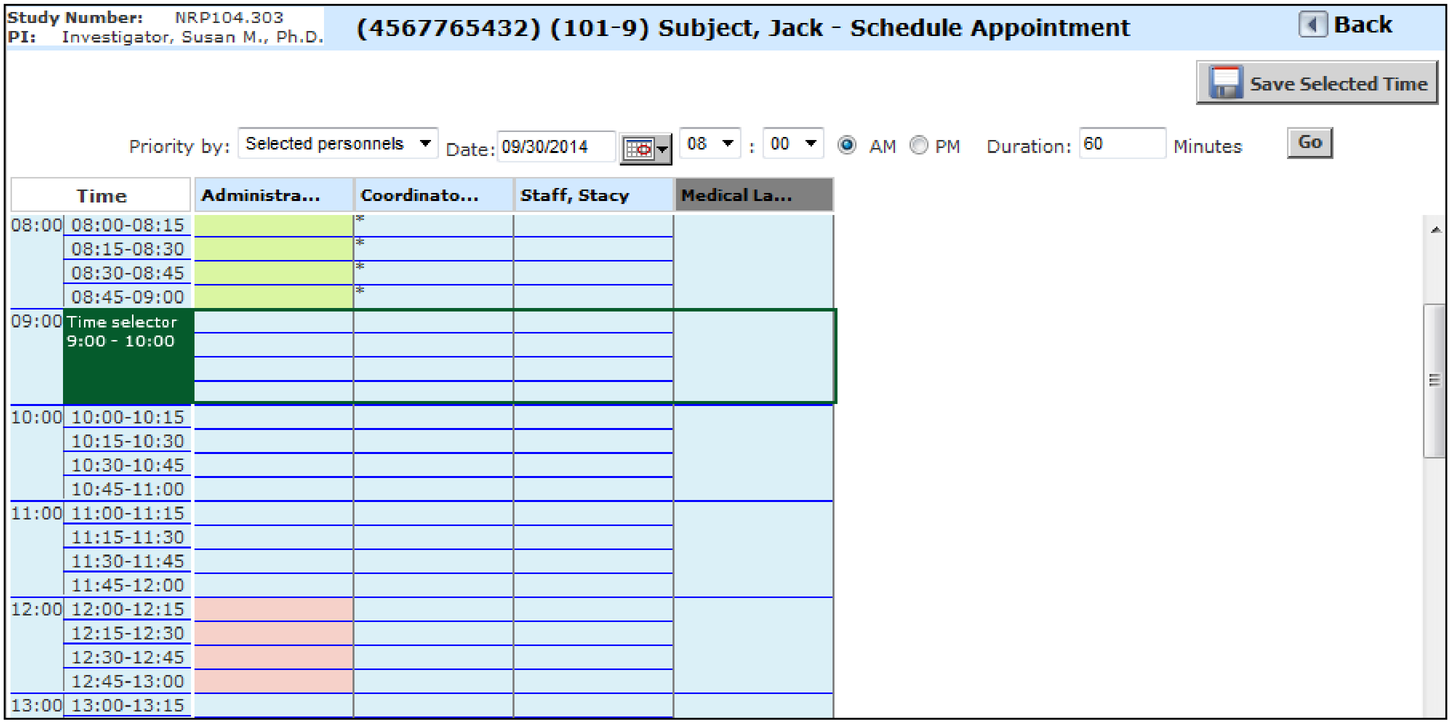
Doing this opens a page that lists all the Appointment Personnel and Appointment Resources and displays any blocks of time any of the personnel or resources are unavailable that day. The screenshot below displays three users added to the Appointment Personnel table and one resource added to the Appointment Resources table. The visit scheduled date is 9/30/2014 at 8:00 AM. That information is displayed at the top of the page, but can be changed by selecting a new date from the **Date** field or a new time from the time fields.

The page displays blocks of time for the selected date, in 15-minute increments. A Time Selector appears on the page that highlights blocks of time based on the **Duration** set for this visit. The visit in this example is set for 60 minutes, so the Time Selector covers one hour of time. The Time Selector also incorporates all the personnel and resources because all four of these must be available at the same block of time in order to schedule the visit. You can drag the Time Selector to different blocks of time until a free block is located (or you can adjust the time at the top of the page and the Time Selector will adjust appropriately after clicking the **Go** button).

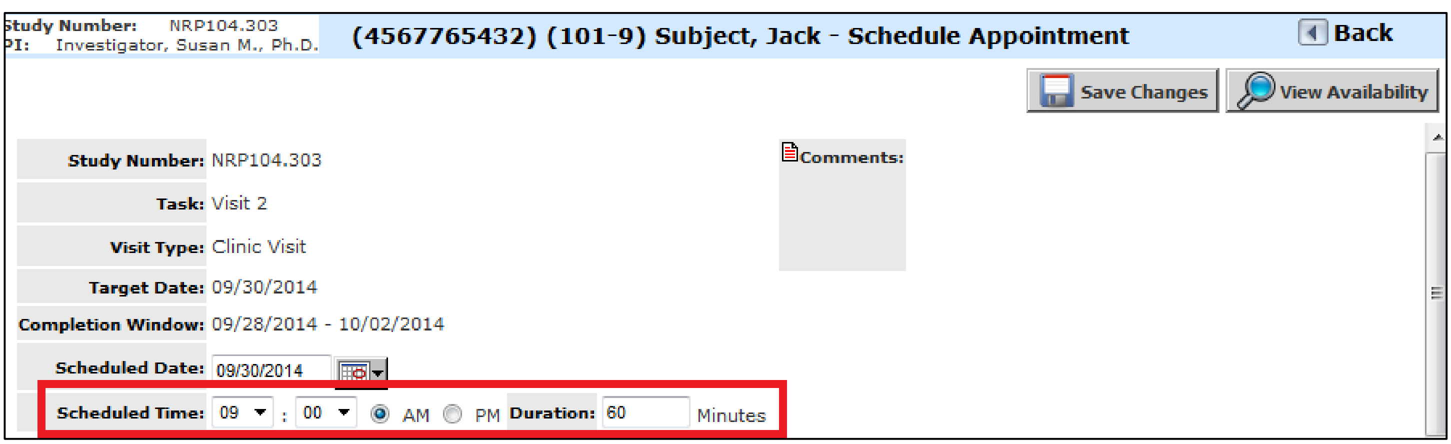
Some areas within the blocks of time will be shaded green, red, or will contain an asterisk. A green highlight in a block of time means specifically that that user is available at that time. A red highlight means that a user has specifically set that time as unavailable. Any blocks of time with an asterisk means that the user is associated to a different scheduled visit within that block. Using these three indicators, you can select the best time to schedule the appointment. You may schedule a visit in any of the time blocks, even if a user is associated to another visit or has flagged a block of time as unavailable.

A user becomes “Unavailable” with the red highlight by creating a Personnel Appointment within Study Assistant –> Department Schedule –> Personnel Scheduling. See the My Appointments / Department Schedule Manual for more information.

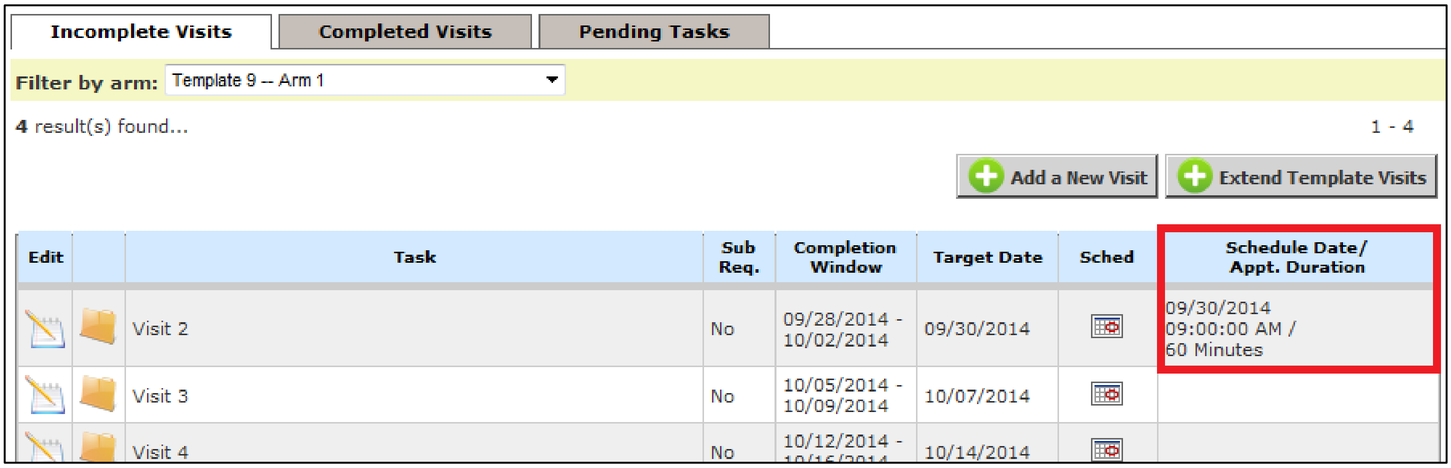
Once you select a time that works for all personnel and resources, click the **Save Selected Time** button.



You will return to the Schedule Appointment page and any update in the time to schedule the visit will be updated in the **Scheduled Time** area. Click the **Save Changes** button to save and schedule this visit.



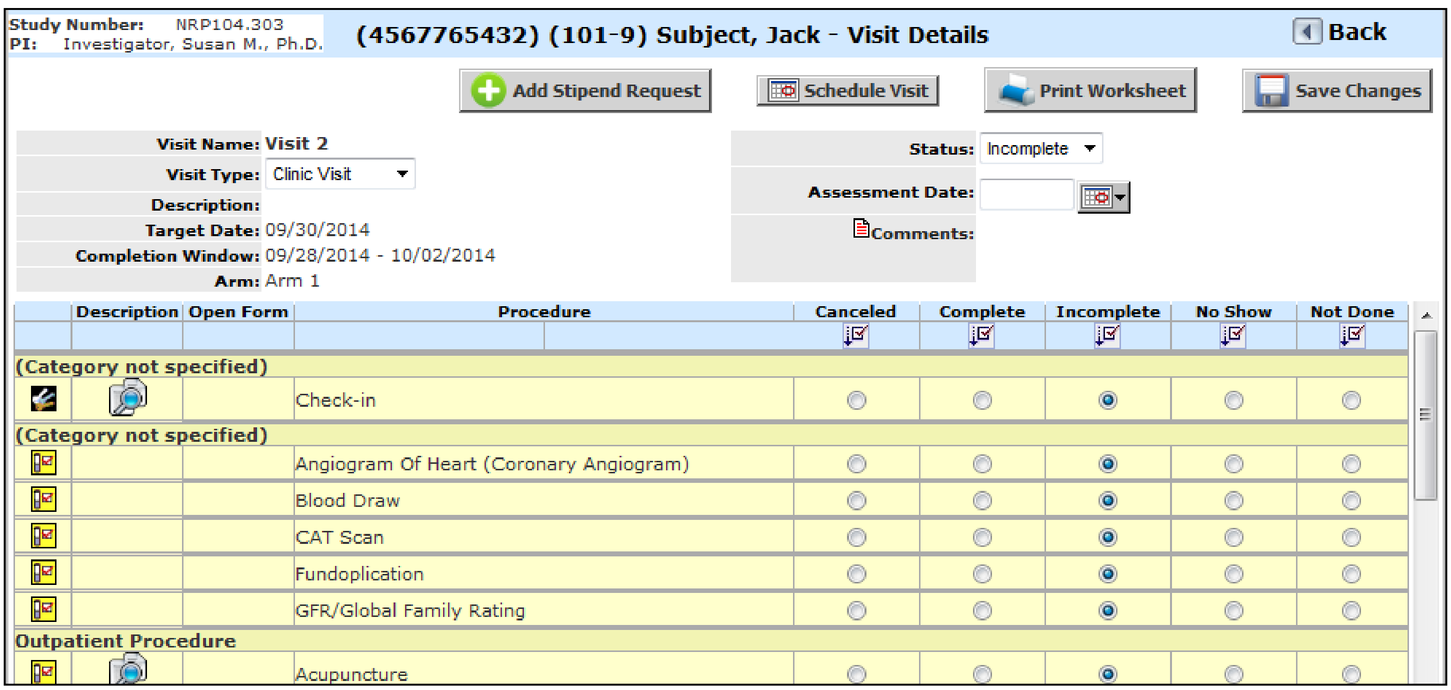
When the visit has been scheduled, the date, time and duration will populate in the **Schedule Date / Appt Duration** column in the Incomplete Visits tab. This information will also be viewable in the Appointments calendar, within a selected personnel’s My Calendar in Study Assistant and in the subject’s Department Calendar in Study Assistant –> Department Schedule.



Completing a Visit

When a subject has completed a visit, you can navigate to the Incomplete Visits tab and status the visit and its related procedures as complete. Select the icon in the **Edit** column to open the Visit Details page.

At the top of the page are several buttons for different functionality. You can request a stipend, schedule the visit, print the page or save the page using the buttons. For more information on scheduling the visit, see the Scheduling a Visit section of this manual. You can open a PDF view of this page by clicking on the **Print Worksheet** button. You will be provided the option of including or excluding the subject name from the PDF.

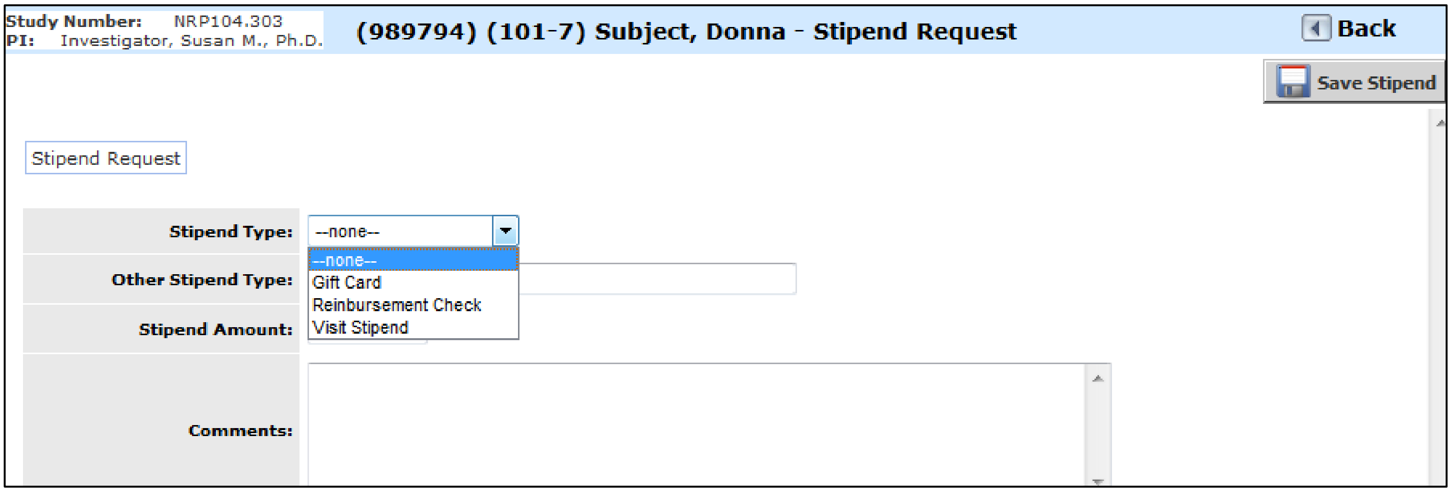


Stipend Requests

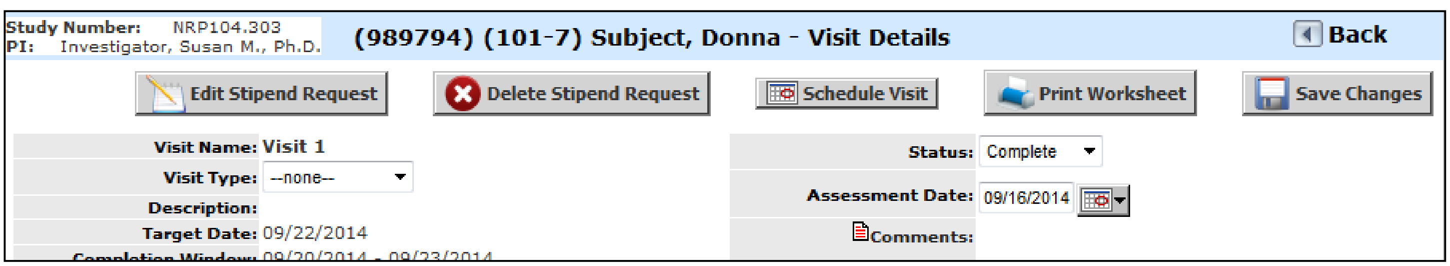
This option is only available within the Visit if the system property "system.use_stipend_request" is set to "Yes." The property is located in System Administration –> System Configuration –> Subject Protocol Tracking. Stipend Requests are also only applicable if your system is using Subject Management with Financial Tracking.

Allowing users to request stipends at the time of visit completion will allow a record to be transferred to the Finance Assistant, flagging the request from the study. Once the record is received by Finance, they will either approve or reject the request which in turn will update the study's General Ledger. More information related to the General Ledger is available in the Finance Assistant Manual.

Clicking on the **Add Stipend Request** will open a page similar to the screenshot below. Choose the **Stipend Type** from the drop down list. This is a configurable list within System Administration – >List Configuration and Maintenance –> Site List Setup – >Stipend Type. If the Stipend Type you are requesting is not in this list, you can enter the information in the **Other Stipend Type** field. Then enter an amount in the **Stipend Amount** field and if necessary add **Comments**. Click **Save Stipend** when you are finished and the request will be sent to the Finance Assistant.

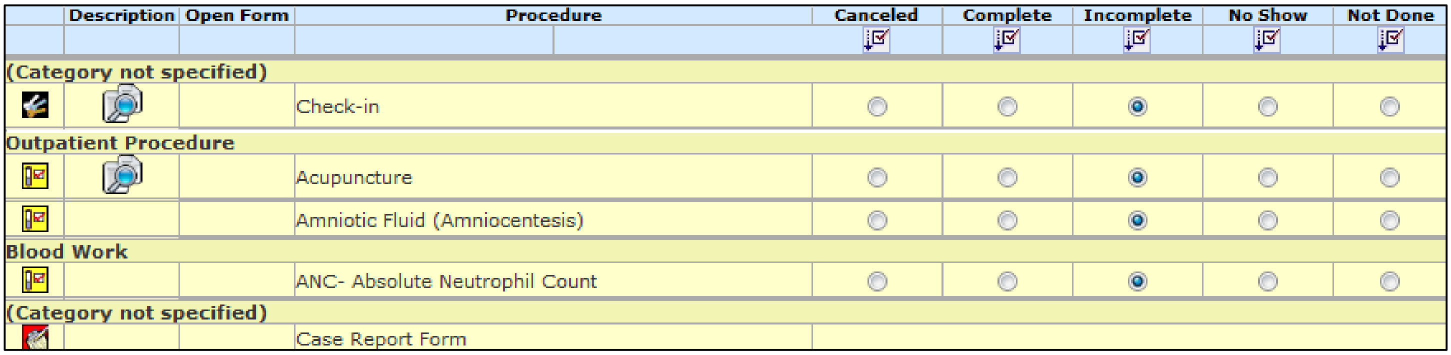


Back within Visit Details, the **Add Stipend Request** button is replaced by an **Edit Stipend Request** button and a **Delete Stipend Request** button. You can modify your request by clicking the **Edit Stipend Request** button and you can withdraw your request by clicking the **Delete Stipend Request** button.



The Visit Name, Visit Type, Description, Target Date, Completion Window and Arm fields all populate from Construct Study Plan and Study Plan Timeline. Status, Assessment Date and Comments are all fields you can use when completing the visit.

Below the visit details, a list will populate of all the procedures and case report forms that need to be completed for this visit. This information comes from Construct Study Plan.



There are three types of items that can be included in this list. They are associated to a category icon.

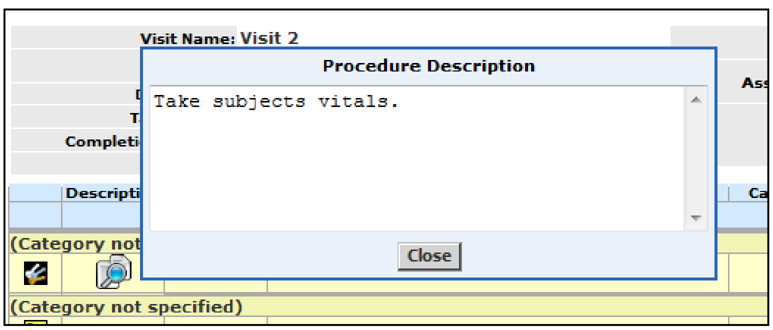
- Clinical Procedure

- Administrative Task

- Case Report Form

The other columns in this table are as follows:

Description – If a description has been provided for the procedure, an icon will populate in this column. Clicking on the icon will open the Description in a small window. Click the **Close** button to close the window.



Open Form – The column will populate with an icon next to a Case Report Form, but only if the Case Report Form is associated to a system form. This is only available with the CRF addition to your system.

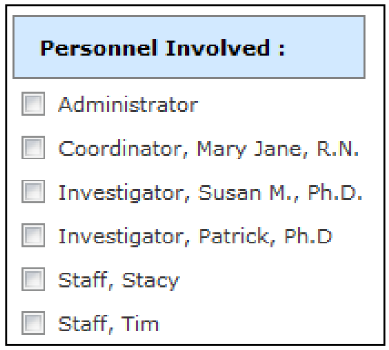
Procedure – This column will display the name of the Procedure, Task or Case Report Form

Status Selections – When completing a visit, you must status the procedures individually by selecting the appropriate status. Each is described below.

> **Canceled** – If a procedure is cancelled, it can be set in the “Canceled” status.
>
> **Complete** – This status indicates the procedure was completed. Any budget information related to this procedure will be accounted for when a procedure is marked as “Complete.”
>
> **Incomplete** – All procedures default to “Incomplete.”
>
> **No Show** – This status indicates the subject did not show for the visit and/or selected procedure.

Not Done – This status is used to indicate that a certain procedure was not done during the visit. This is used for optional procedures that may or may not be completed during a visit.

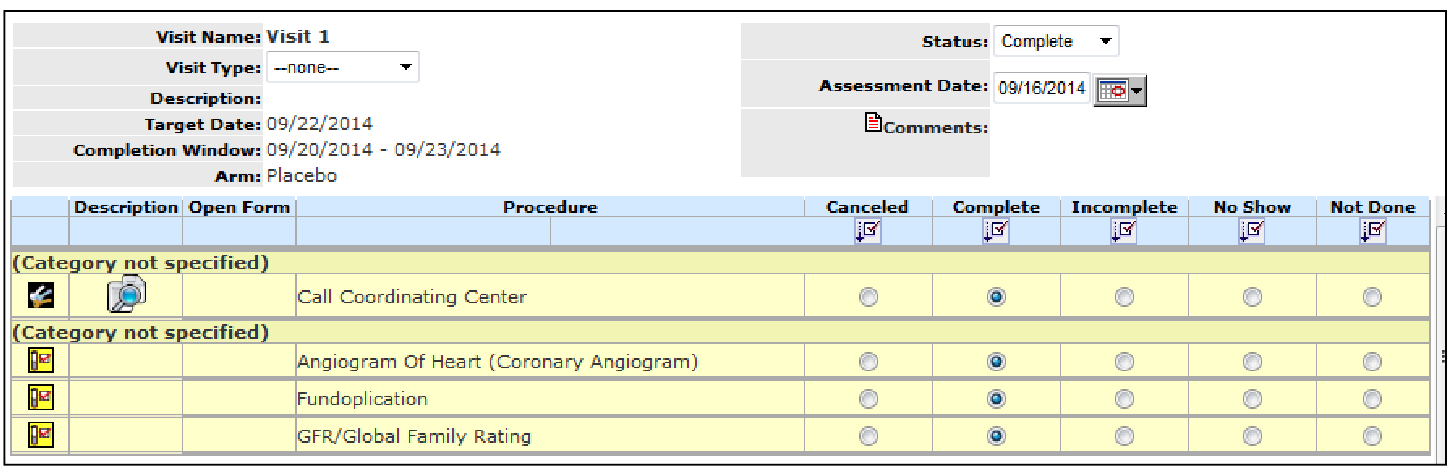
Below the associated procedures is a table where you can indicate the personnel involved with the visit. Select the checkbox next to the names of the personnel present at the visit.



When a visit is completed, select the appropriate **Status** from the dropdown list. The options available here are the same statuses that can be applied to each individual procedure on the visit. Completing a visit is different than completing a procedure on the visit – both visit and visit procedures must have a status. A visit can be completed, with four of the five procedures on the visit marked “Complete” and one “Not Done” because that procedure was unnecessary. In certain cases, a visit may be completed, but a procedure listed on the visit needed to be scheduled to a different time, so it would be left as “Incomplete.” Each case is listed below.

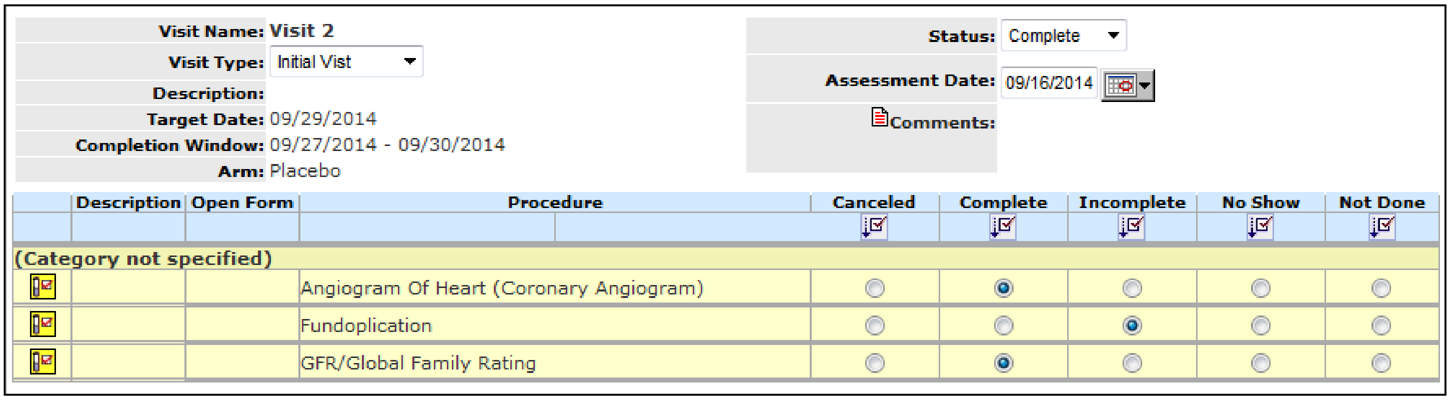
Visit Complete / Tasks Complete

When a visit is complete and all associated tasks are completed, select the “Complete” option from the **Status** drop down list and flag all procedures listed on the page as “Completed.” You will also need to supply the actual **Assessment Date**, this is the date the visit actually took place and could be different from the Target Date and Scheduled Date.

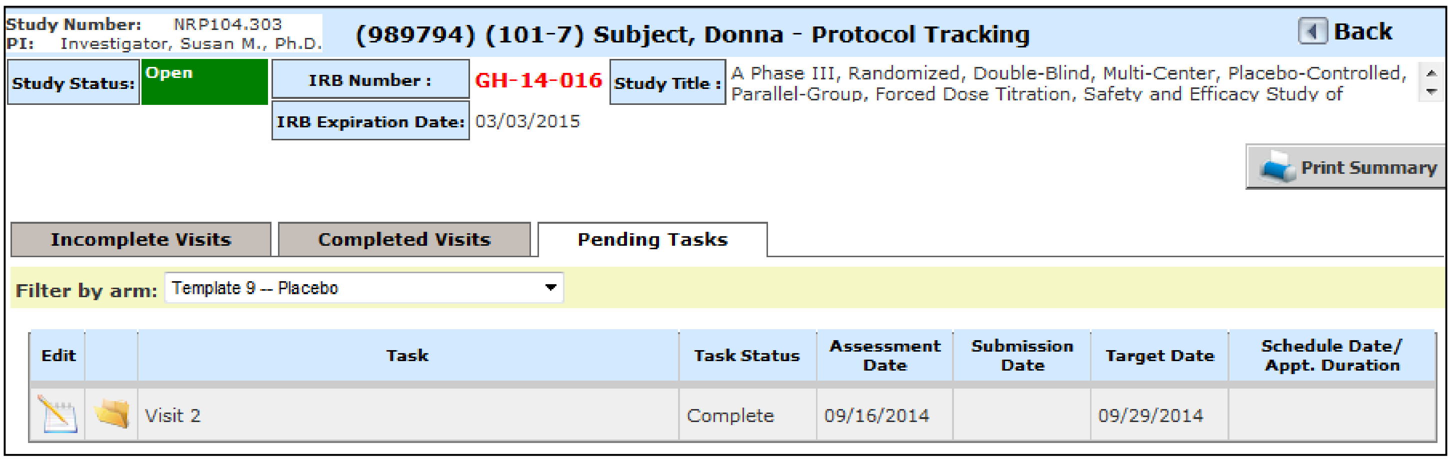


Visit Complete / Tasks Left Undone, to be finished later

When a visit is complete but some of the tasks associated were not completed during the visit and need to be completed later, select the “Complete” option from the **Status** drop down list and flag all complete procedures listed on the page as “Completed.” Then, mark the incomplete tasks as “Incomplete.” You will also need to supply the actual **Assessment Date**, this is the date the visit actually took place and could be different from the Target Date and Scheduled Date.

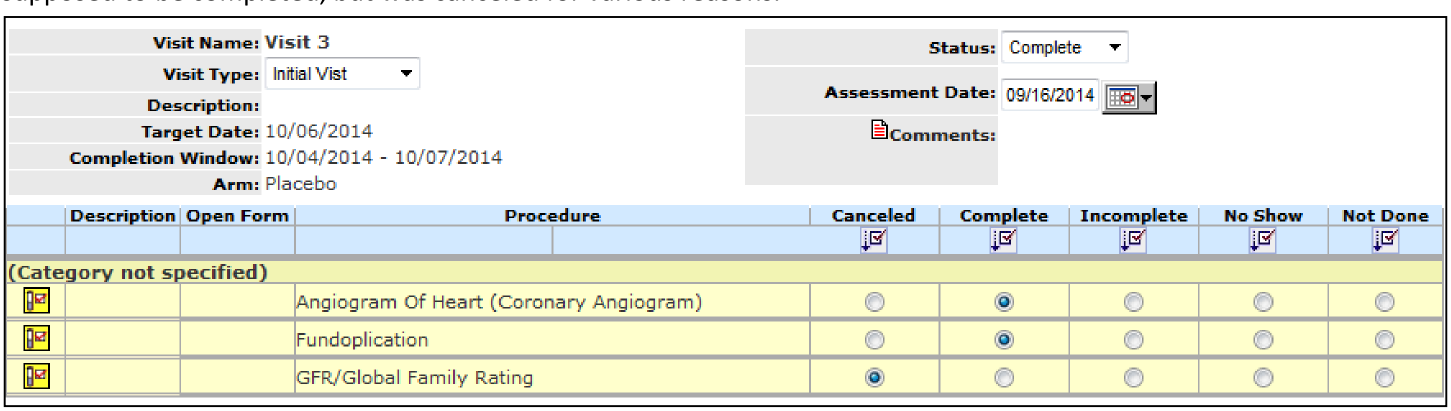


When you save a visit that is complete, but with incomplete tasks, a record will populate in the **Pending Tasks** tab. This record will remain here until the remaining procedures on this visit are flagged with a completed status.



Visit Complete / Tasks Cancelled or Not Done

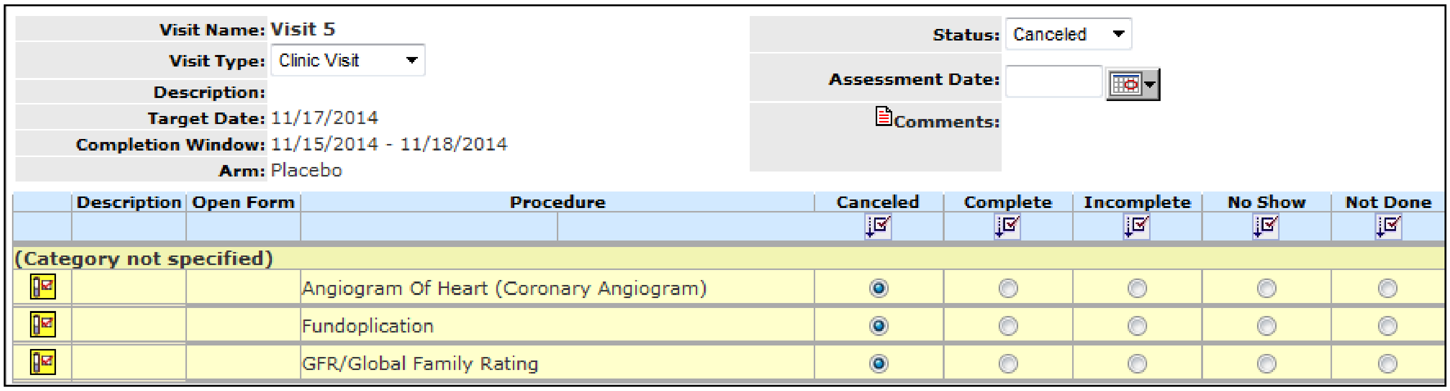
When a visit is complete but some of the tasks associated were cancelled, select the “Complete” option from the **Status** drop down list and flag all complete procedures listed on the page as “Completed.” Then, mark the cancelled items as “Cancelled.” You will also need to supply the actual **Assessment Date**. This is the date the visit actually took place and could be different from the Target Date and Scheduled Date. You can set the task to either “Canceled” or “Not Done.” “Not Done” indicates that the task was optional or not done during the visit. “Canceled” indicates that the task was supposed to be completed, but was canceled for various reasons.



When a visit is completed but some of the tasks are not flagged as “Complete,” those items will not be accounted for in the budgeted items.

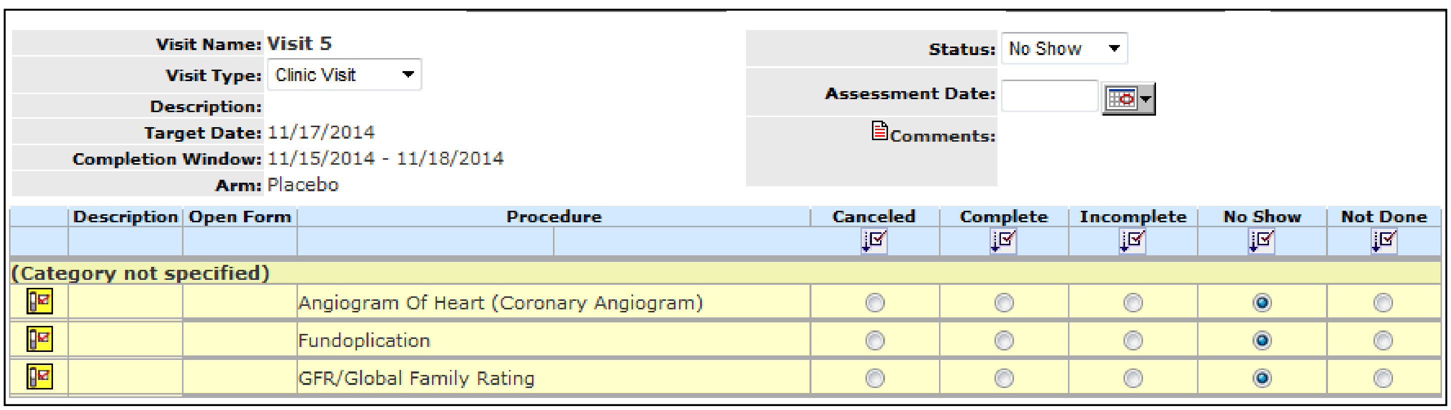
Visit Canceled / Tasks Canceled

If a visit is cancelled, and none of the tasks were completed, select the “Canceled” **Status** from the drop down list and flag the tasks as “Canceled.” There is no need to set an **Assessment Date** for a visit that was never completed.



Subject No Show

If a subject did not come to the visit, and none of the tasks were completed, select the “No Show” **Status** from the drop down list and flag the tasks as “No Show.” There is no need to set an **Assessment Date** for a visit that was never completed.

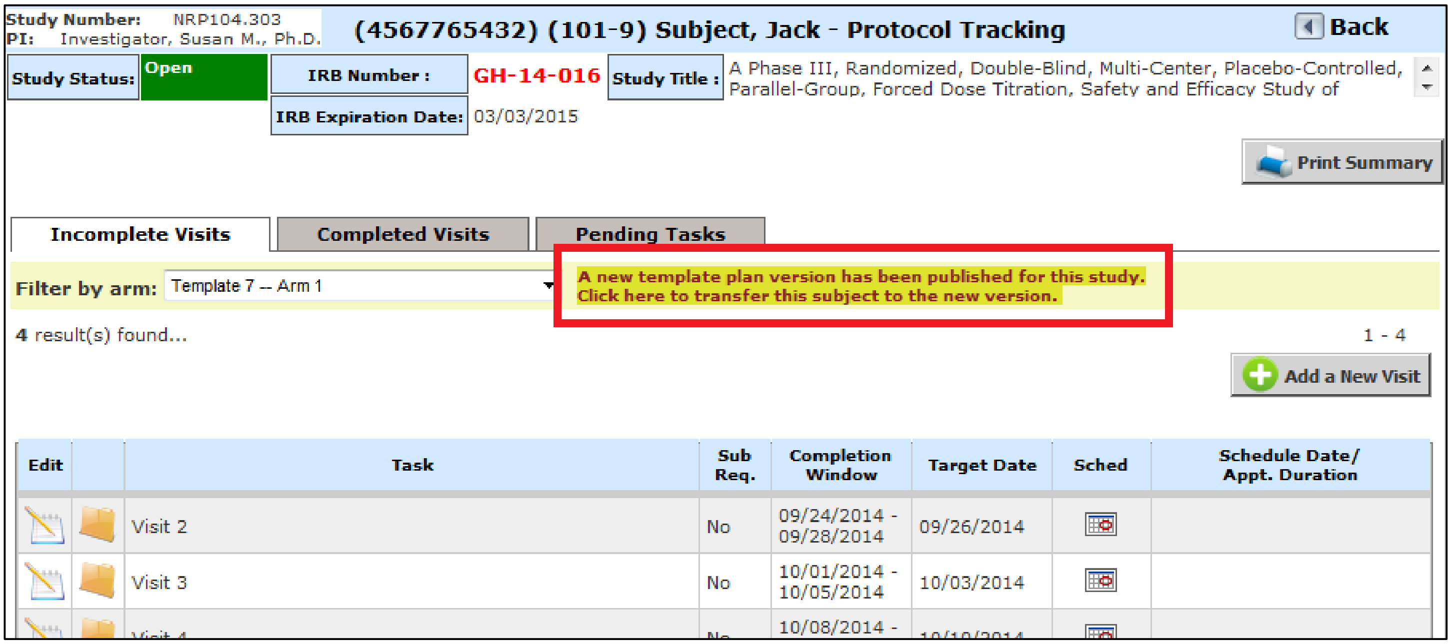


After selecting the appropriate **Status**, entering the **Assessment Date** and **Comments**, if applicable and setting the appropriate task **Status** for each task listed within the visit, click the **Save Changes** button.

Transfer to a New Study Plan

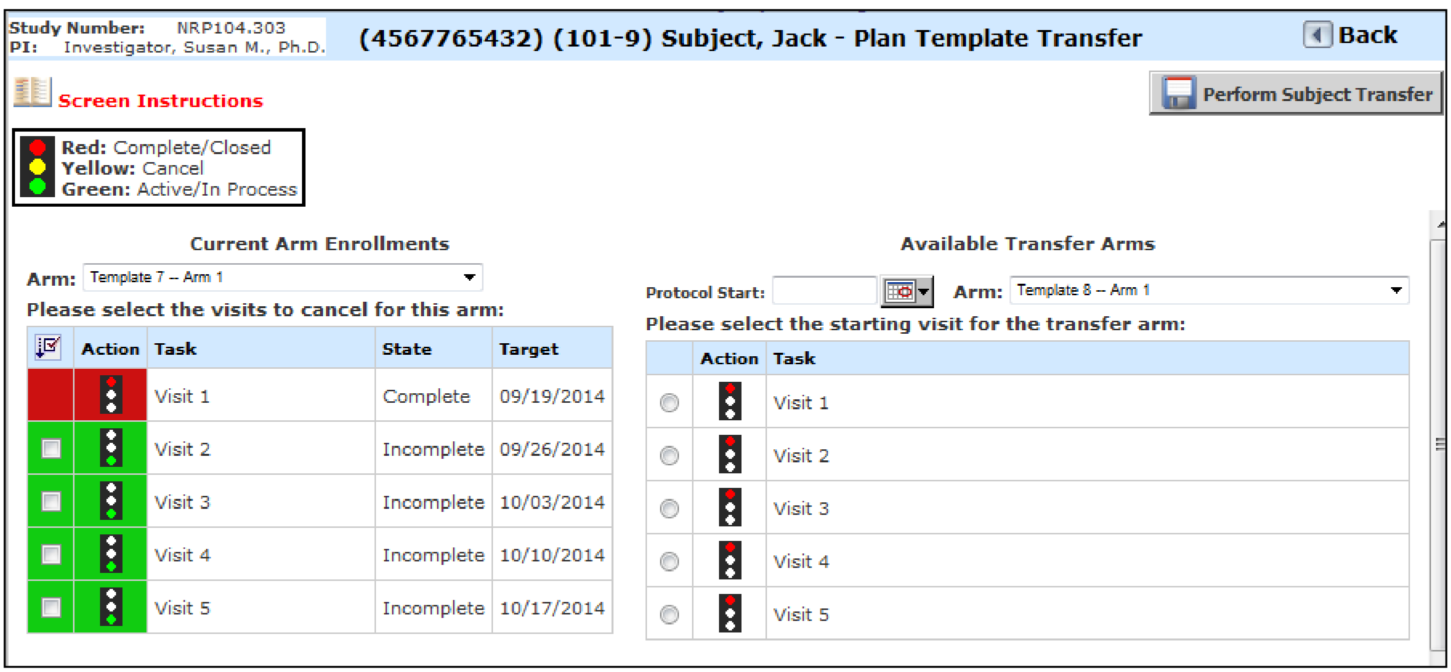
If there is a new Study Plan published within Construct Study Plan, a message will display within the tabs alerting you that the plan is published and you may choose to transfer the subject from the current Study Plan Arm to the new published Study Plan Arm.

To transfer to the new arm, click the message.



A new page will open. From this screen, the old arm information will display on the left side of the page and the new arm information displays on the right.

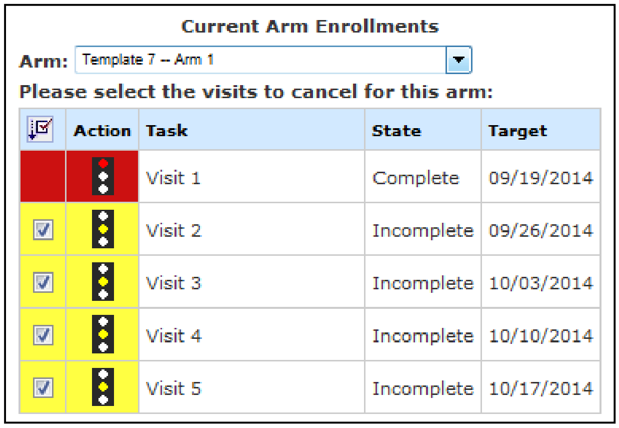
Choosing to transfer subjects to the new arm using this method allows you to maintain previously completed visits without disturbing the Study Plan Timeline already put in place for this subject.



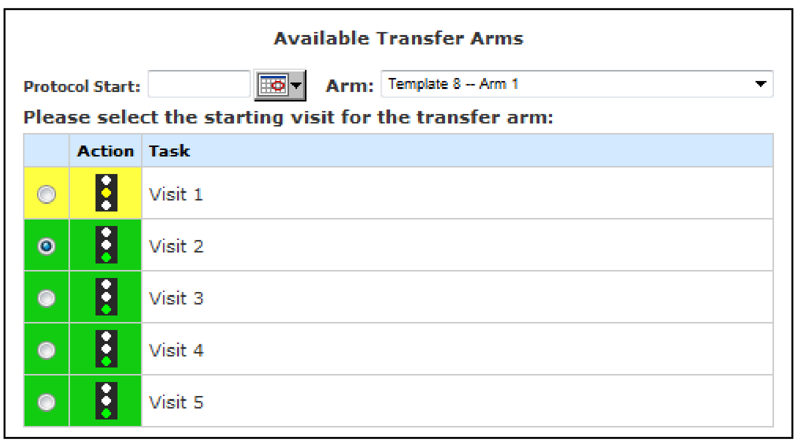
Steps for transferring a subject to a new arm:

1. On the left of the screen in **Current Arm Enrollments**, using the arm drop down box of the current subject enrollments, select the arm you would like to transfer the subject from. This dropdown list only populates with arms on which the subject is currently enrolled.
2. On the right of the screen in **Available Transfer Arms**, using the arm drop down box of the available transfer arms, select the arm you to which you would like the subject to be transferred.

3. Next to the transfer arm drop down box, enter the protocol start date for the subject in this new arm.
4. In **Current Arm Enrollments**, select the checkbox next to the visit records you would like the system to automatically cancel. You can use the icon in the column header if selecting all visits to be canceled. As the records are selected, the background color of the visit record becomes yellow to clearly show the records selected. The Action column also displays the corresponding action the system will perform on that record. Records that are not checked will remain active in the current arm enrollment. And any visit that has already been completed cannot be included in the cancel. These types of visits will be in the “Complete” State, the Action displays red, and you cannot select this record.



5. In **Available Transfer Arms**, select the radio button next to the visit you would like the subject to begin on the new arm. When selected, the system modifies the background color of all visit records from the selection forward, displaying green, meaning the selected visit and the visits moving forward will be placed in the Incomplete Visits tab.

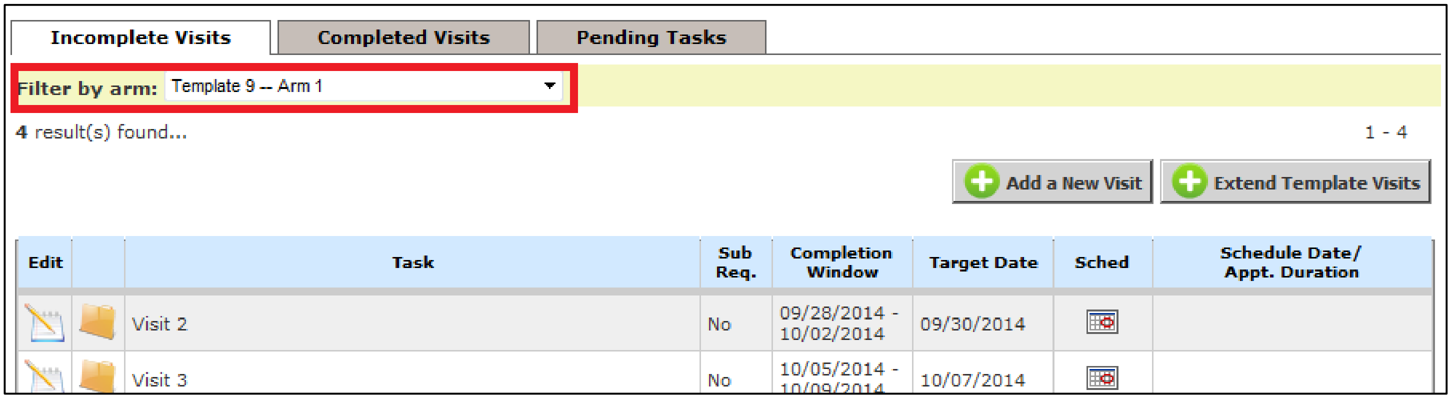


6. After all selections have been made, click on the **Perform Subject Transfer** button to complete the process.

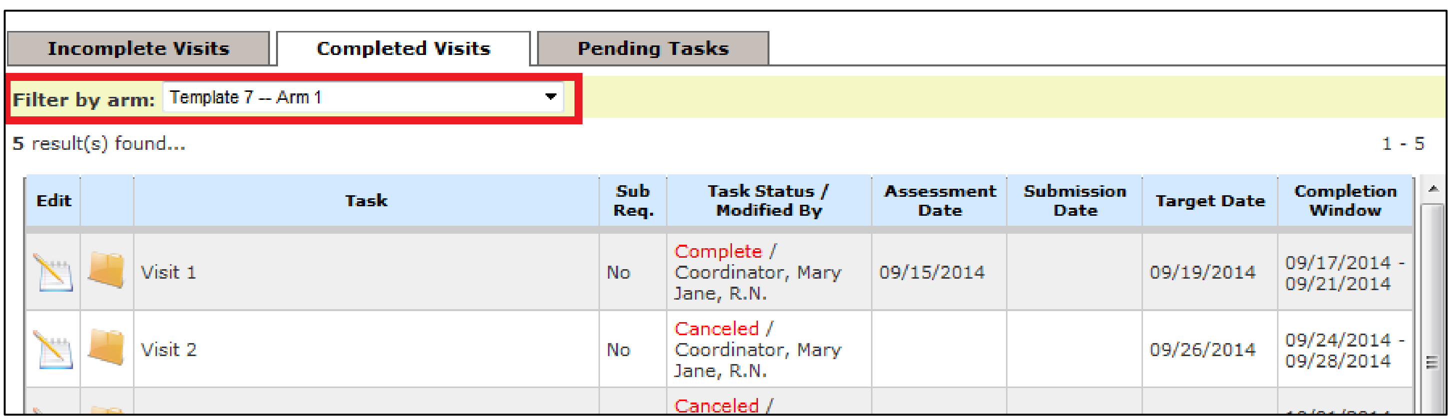
In the example used here, there are five visits associated to the old arm. Visit 1 has already been completed for the subject, therefore cannot be included in the transfer. The remaining four visits are chosen for cancellation. There are also five visits associated to the new arm. Visit 2 has been selected as the visit to begin the transfer, so the following three visits (Visits 3-5) are highlighted green along with Visit 2. Visit 1 displays yellow, meaning it will not be placed in the Incomplete Visits tab.

It is important that you provide a Protocol Start date when transferring the subject to a new arm so that the new Study Plan Timeline also carries forward.

Once the transfer is complete, you will be returned to the Incomplete Visits tab. The new arm and the visits chosen to include in the transfer will be displayed on this page. The Completion Window and Target Date will base off of the new Protocol Start Date provided.

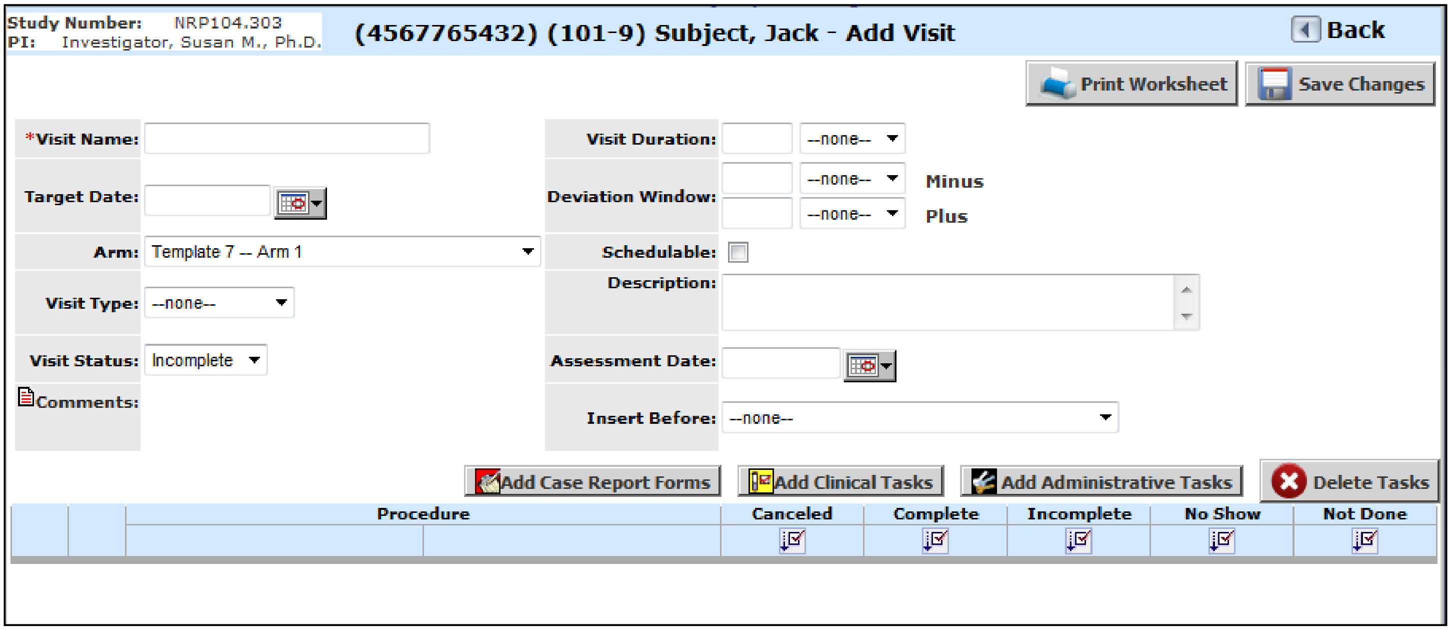


If you navigate to the Completed Visits tab, you can flip to the previous arm by selecting it from the **Filter by Arm** dropdown list. The visits associated to this arm display. Any visits that had been completed prior to the transfer will continue to display their completion information (see Visit 1 in the screenshot below) and visits that were chosen for cancellation through the transfer will display as "Cancelled" (see Visit 2 in the screenshot below). The subject will not continue on the new arm.



Adding a Visit

In certain cases, you may need to add a visit that is outside of the Study Plan. Within the Incomplete Visits tab is an **Add a New Visit** button. When you click this button, an Add Visit page will open. This page contains the same details available when completing a visit; however, the fields are all editable allowing you to create the elements of the visit.



Visit Name – This is the only required field on the page. This is the name that will populate in the Task column within Incomplete Visits.

Target Date – If applicable, enter the target completion date for this visit.

Arm - You can associate this visit to a Study Plan arm by selecting from the drop down list. You cannot add a visit without an arm association.

Visit Type – Select the Visit Type from the drop down. This list is defined in System Administration –> List Configuration and Maintenance –> Site List Setup – >Visit Type.

Visit Status – Initially, a visit you create will be in the "Incomplete" status, but if you are adding a visit and completing it at the same time, you may change this option to reflect the current visit status.

Comments – Add any comments related to the visit by selecting this link.

Visit Duration – You can enter the length of time for this visit.

Deviation Window – Add the amount of time, plus or minus, to deviate from the Target Date.

Schedulable – If you would like to have the ability to schedule this visit, click this option.

Description – Add a visit description, if applicable.

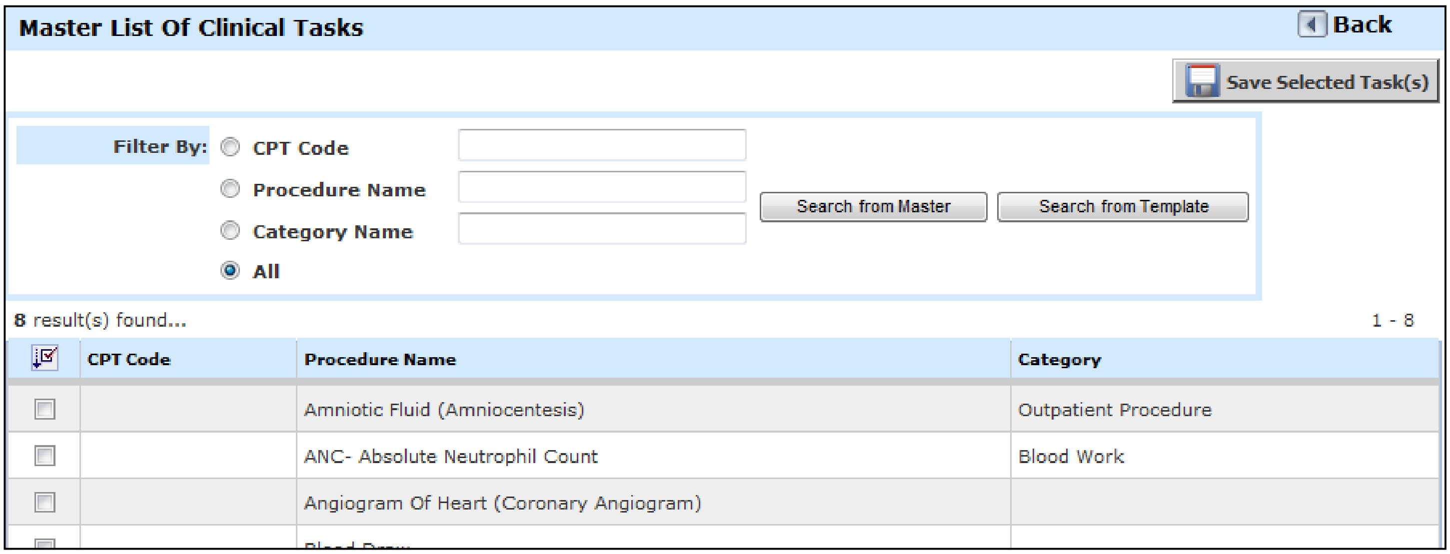
Assessment Date – If you are completing the visit at the time you are creating the visit, enter the actual completion date here.

Insert Before – This drop down list will contain any other visit listed in the Incomplete Visits tab. Select the visit from this list to indicate where you want the visit you are creating to be placed. If this visit should be listed last, leave this option empty.

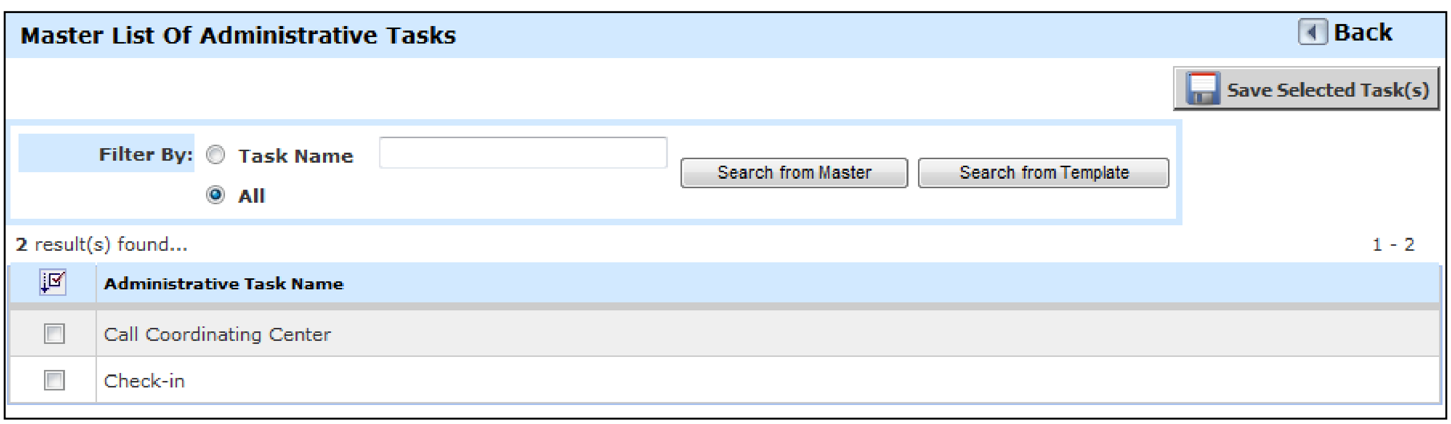
Below the visit details will populate a list of all the procedures and case report forms that need to be completed for this visit. When you initially add a visit, no procedures will be listed in this table.

There are three types of items that can be added to the visit. They are associated to a category icon. Select the appropriate button at the top of the Procedures table to add each procedure.

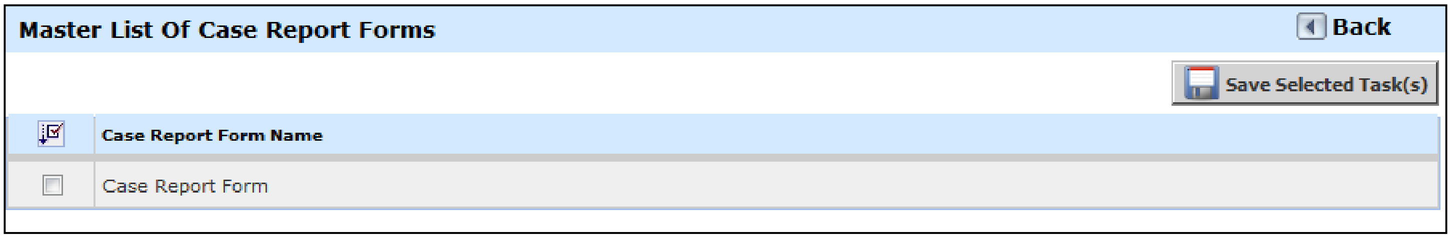
- Clinical Procedure – When you choose to add a Clinical Procedure, a list of all Clinical Procedures associated in the selected Study Plan will be selectable. Choose the appropriate Procedures, then click the **Save Selected Task(s)** button.



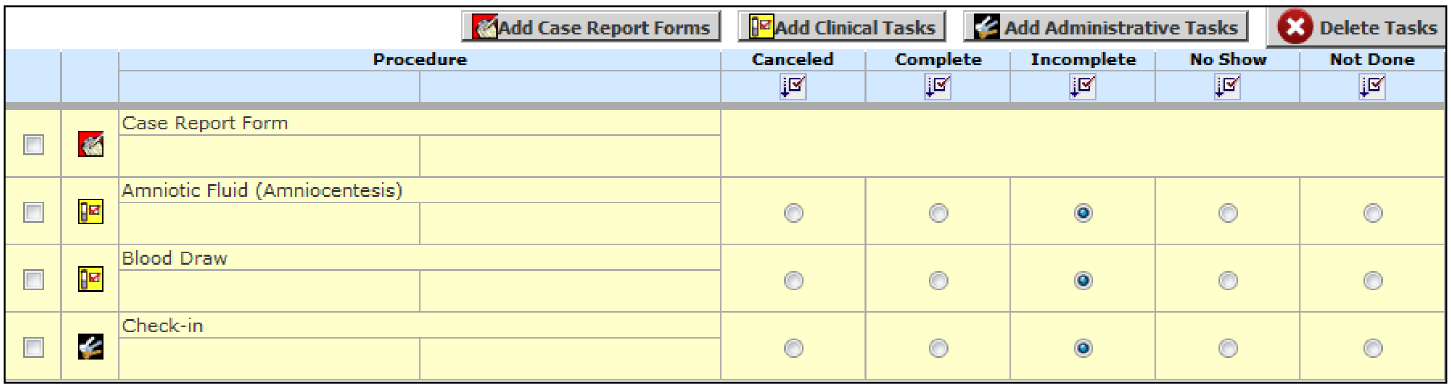
- Administrative Task - When you choose to add an Administrative Task, a list of all Administrative Tasks associated in the selected Study Plan become selectable. Choose the appropriate Tasks, then click the **Save Selected Task(s)** button.



- Case Report Form – When you choose to add a Case Report Form, a list of CRFs associated in the selected Study Plan become selectable. Choose the appropriate CRF and then click the **Save Selected Task(s)** button.

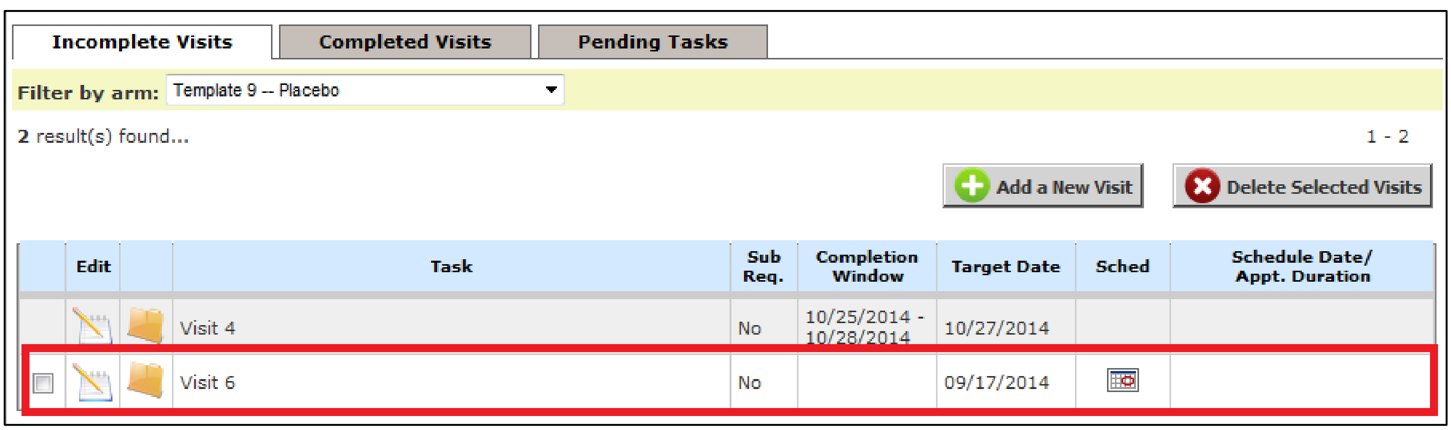


Any items added will display in the table. You can remove procedures from the list by selecting the checkbox next to the Procedure and clicking the **Delete Tasks** button.



The other columns in this table are described in Completing a Visit.

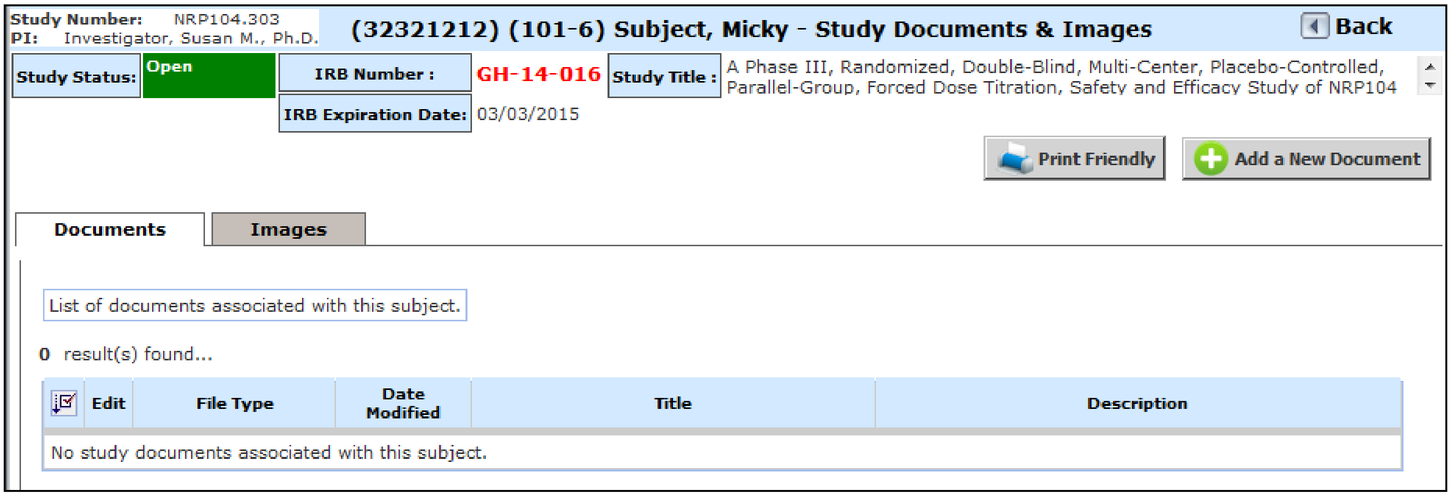
When you are finished defining the details of your visit, click the **Save Changes** button. The visit will then be listed in the Incomplete Visits tab, unless you indicated it was completed. Only visits that have been added outside of the Study Plan can be deleted from the list. Click the checkbox next to the visit, and then click the **Delete Selected Visits** button to delete the added visit.



Study Documents

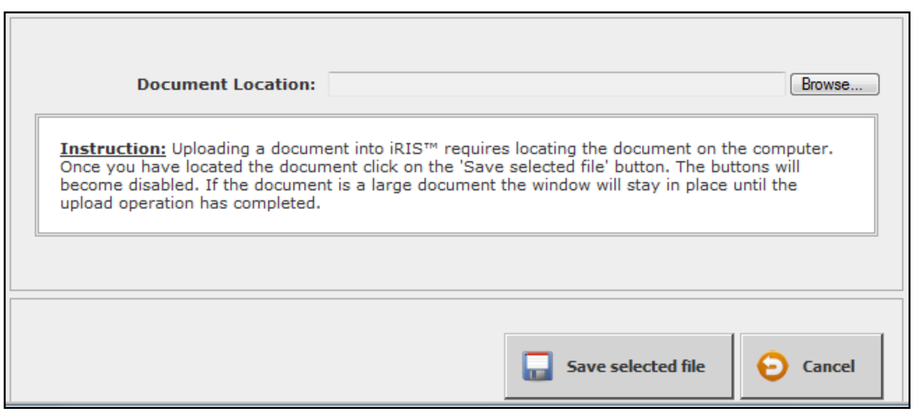
Study Documents allow you to associate any documents and/or images to the subject record *on the study*. Study Documents differ from General Documents in that any document uploaded to Study Documents is related to the subject on the study and will not be accessible to other studies that have the same subject enrolled. General Documents are accessible to the subject, so wherever the subject is enrolled, that study will have access to those documents. This page is broken up into two tabs, **Documents** and **Images**. Each tab allows you to upload a document for the subject.

To add a document, verify you have the **Documents** tab selected and click the **Add a New Document** button.

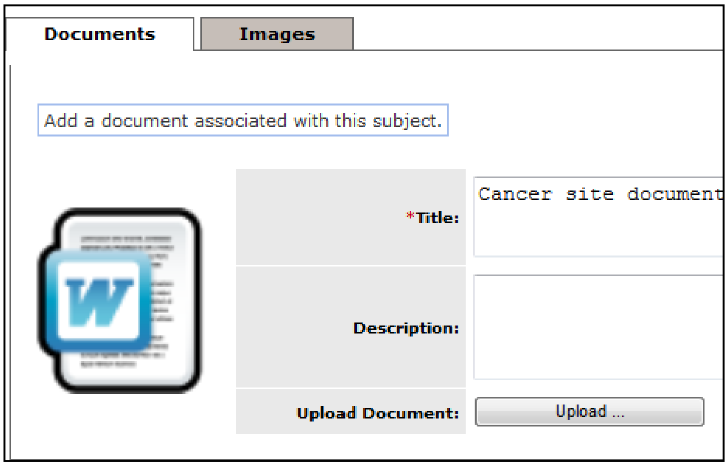


Enter the **Title** and **Description**, if applicable. Then click the **Upload** button.

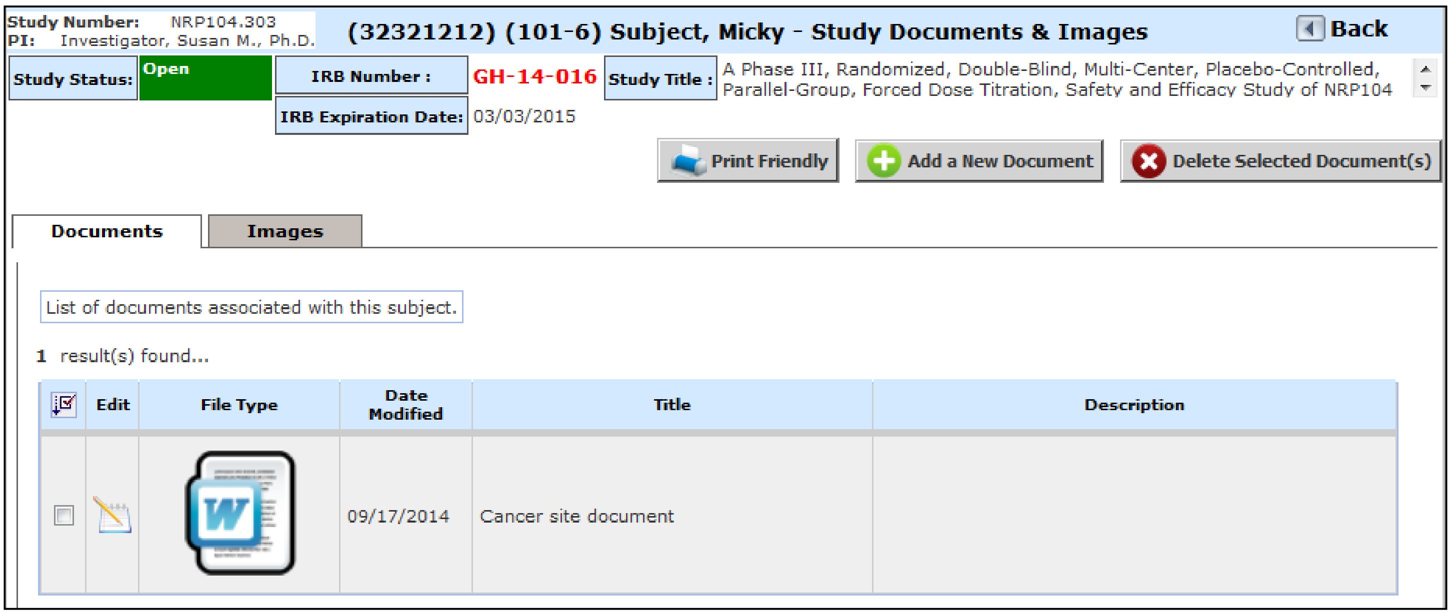
A popup window will open allowing you to **Browse** your computer for the document. Once you select the document, click the **Save selected file** button. Click the **Cancel** button to return to the Documents page without uploading a document.



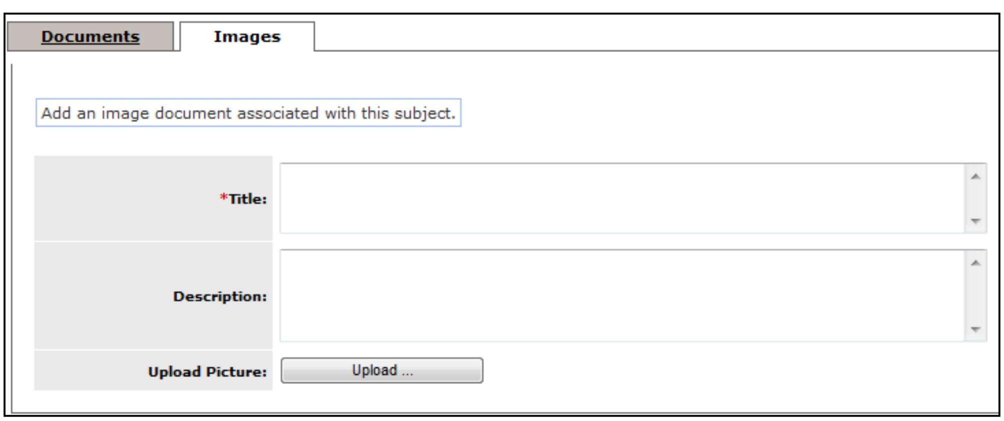
A Microsoft Word icon will populate next to the document information when you successfully upload a document. Be sure to click the **Save Document** button to complete the upload.



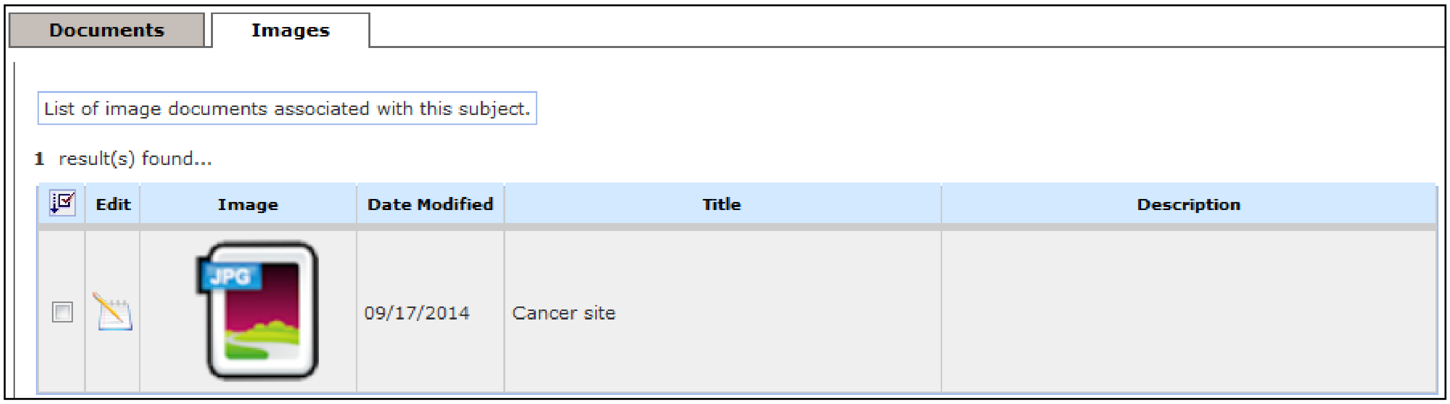
Any document record added will display within the Documents tab.



To add an image, verify the Images tab is selected and click the **Add a New Document** button. You can then enter the **Title**, and **Description**. Click the **Upload** button.



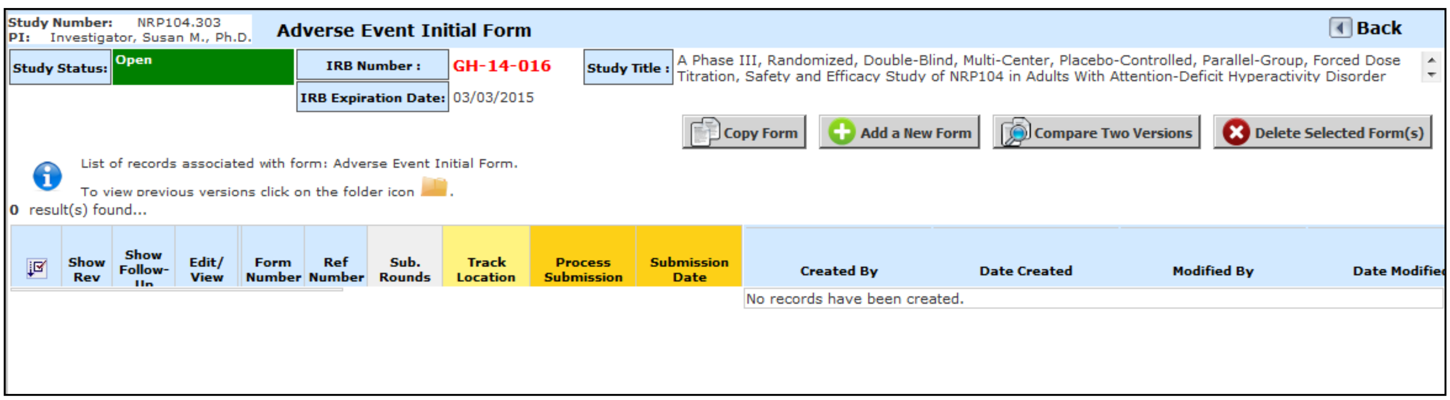
Repeat the same process for adding a document. Be sure to click the **Save Document** button to complete the upload. Any images uploaded will populate in the Images tab.



Adverse Events

In the case that a subject has an Adverse Event that needs to be reported, you can either access the Adverse Event form through the Submissions tab within the study, or you can navigate to the subject record and access the Adverse Event link within Subject on Study. Creating the form through Subject on Study automatically associates the Adverse Event to the subject and will keep a log within Adverse Events both in Subject on Study and within the Adverse Event forms for the study within the Submissions tab.

When you initially access the page through Subject on Study, the page displays any previously created Adverse Events for the subject. If no form has been created, the page will not list any records.



The columns in the table will display specifics about the adverse event form.

Show Rev- If a revision has been created a folder icon will appear here. Selecting this icon provides the user with a display of the previous versions of the specific form. (Note: you are able to compare a new version with a previous version, by using the **Compare Two Versions** button at the top of the screen).

Show Follow-Up- If a follow up form has been created an icon will appear here.

Edit/View- Click on the icon in this column to access the adverse event form. From here a user can view the adverse event form information and make any necessary changes.

Form Number – This column populates with the Adverse Event form number (the initial form created for the study will be 1.0, and any follow up forms associated will number 1.1, 1.2, etc.).

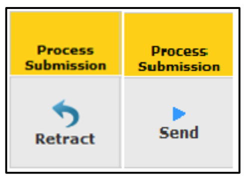
Ref Number – Each form submission within iRIS is associated with its own unique reference number, the correlating number displays here.

Submission Rounds – This icon will allow the user to view a pop-up window of the submission rounds associated with the particular submission of the form.

Track location – If a form has been submitted, this column will populate with the current status of the form. You can click on the text to view detailed information about the steps the form has taken since it was submitted, see screen shot below.

Process Submission – This column will populate with two buttons or will display empty, based on where the submission is, in relation to completion or having been submitted.

If the form has been filled out but not yet submitted into the workflow, a **Send** button will populate in the column, allowing you to send the form without opening it. If the form has been submitted into the workflow but has not been processed by the review board, a **Retract** button will populate in the column, allowing you to pull the form back to make any corrections. Otherwise this column will be blank.



Submission Date – Displays the date the form was submitted into the workflow.

Created By – Displays the name of the user who created the form record.

Date Created – Displays the date and time the form record was created.

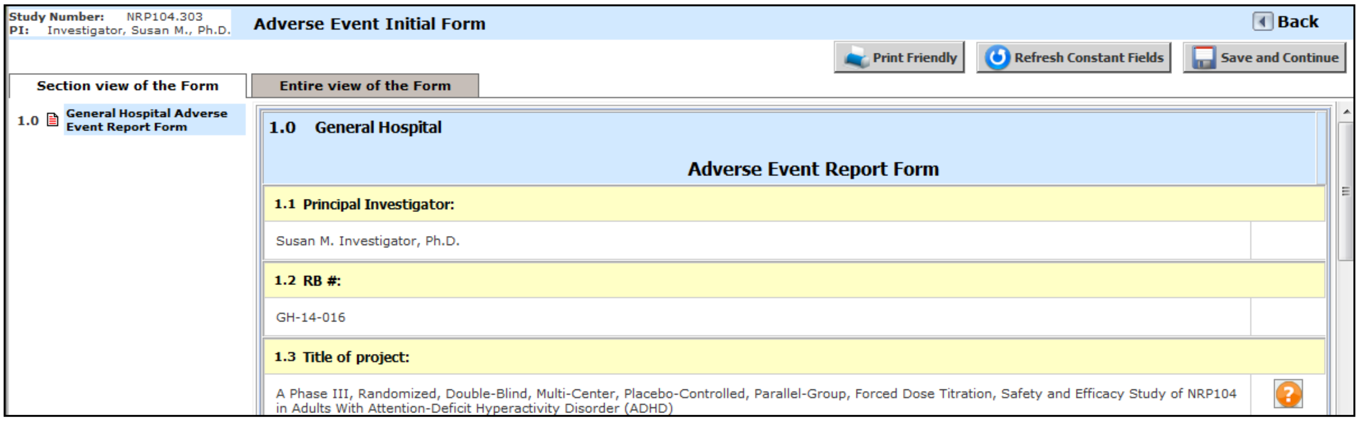
Modified By – Displays the name of the user who last modified the form record.

Date Modified - Displays the date and time the form record was last modified.

To create a new Adverse Event, click the **Add a New Form** button.

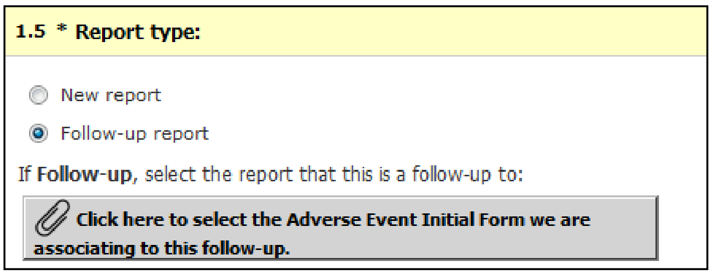
This opens the form as it has been defined in the Forms Designer.

You can fill out the form using the **Save and Continue** button at the top right of the page to navigate through the sections.

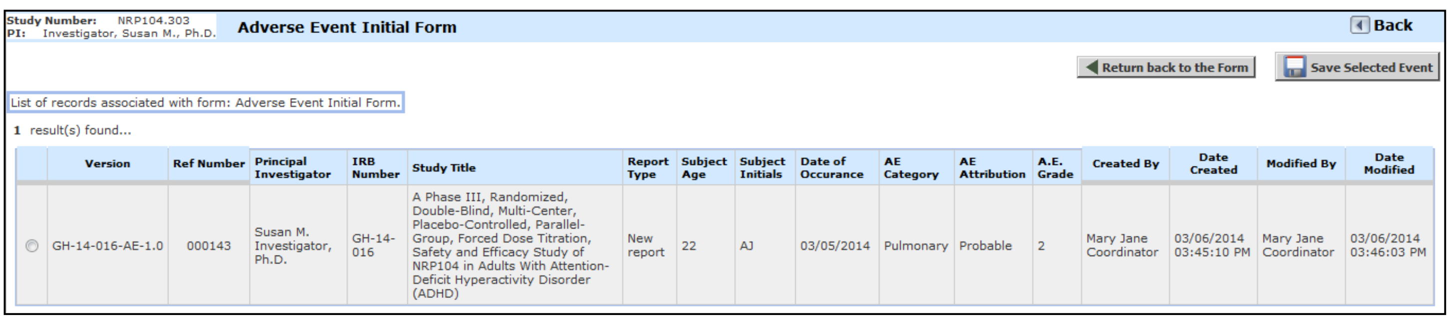


Within this form you may be asked to indicate if the Adverse Event is an initial or follow up. If this is an initial report, you can select New Report and continue to complete the form, as seen in the image below.

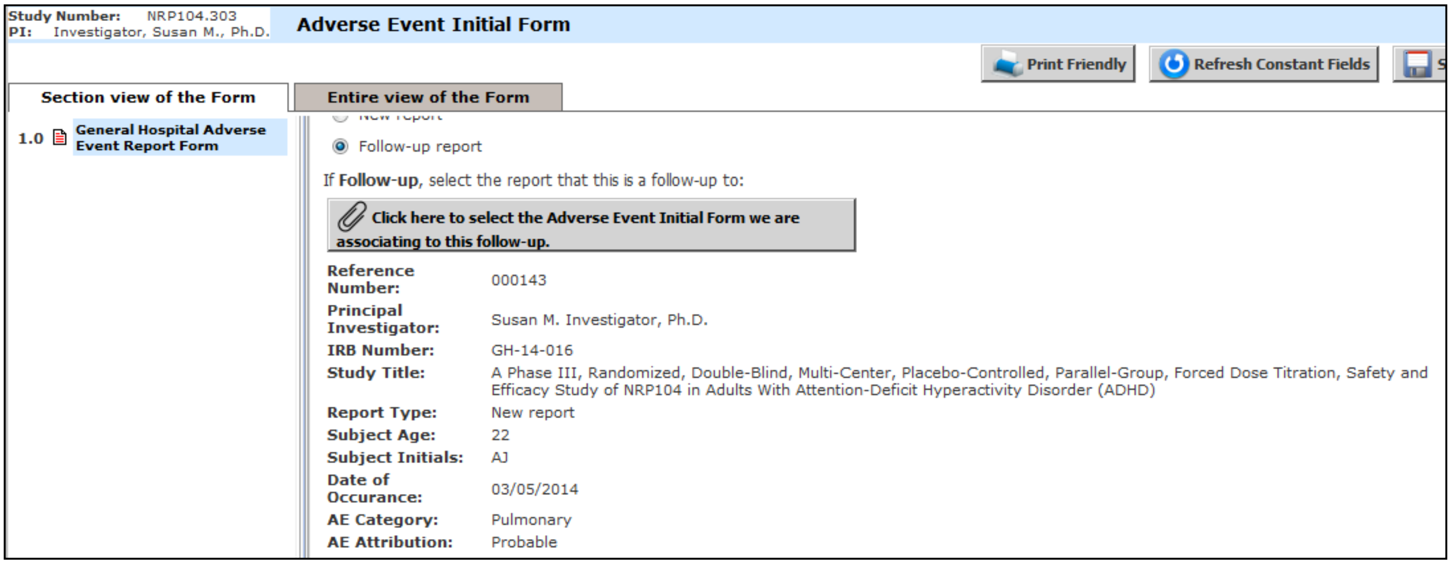
If this is a follow-up report, select **Follow-up Report** and then click the link in the image below to associate a previous Adverse Event form.



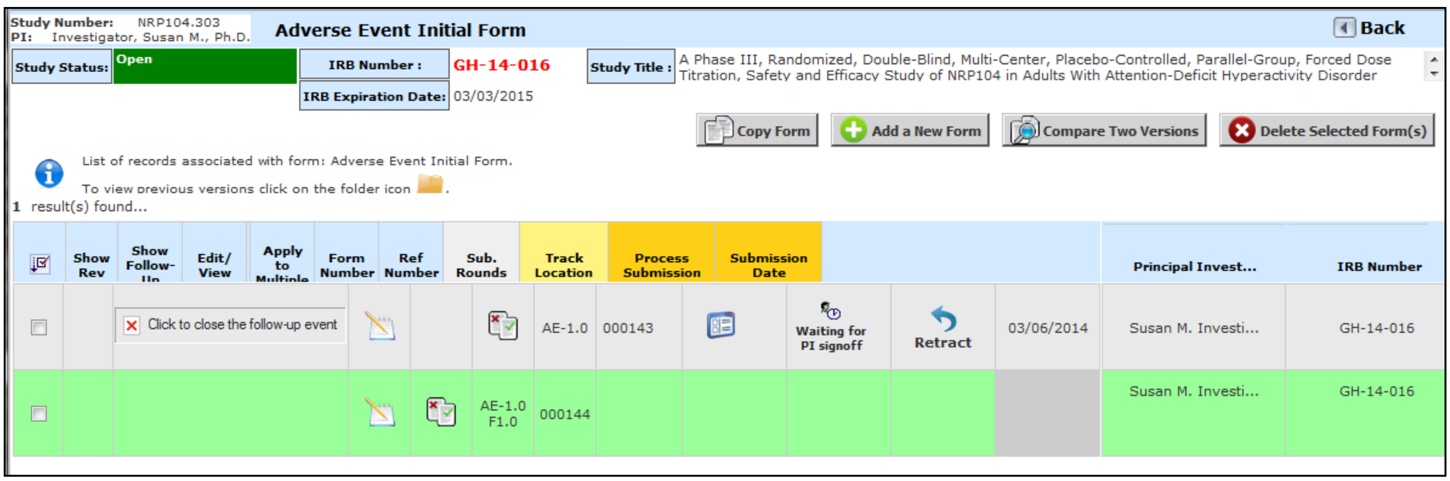
A list of previously completed Adverse Events for the study will populate in a new page. You can select the Adverse Event to which you are sending a follow up, and then click the **Save Selected Event** button.



Information related to the initial report will populate in a table below the data value. The rest of the Adverse Event form will populate based on the information completed in the Initial Report. You can save the form, verify the information is correct and change items as needed.



Any Adverse Event that you create as a Follow-up Report will become associated to the Initial Report in the list of Adverse Event forms. You can expand the folder in the **Show Follow-up** column to view and Follow-up reports.

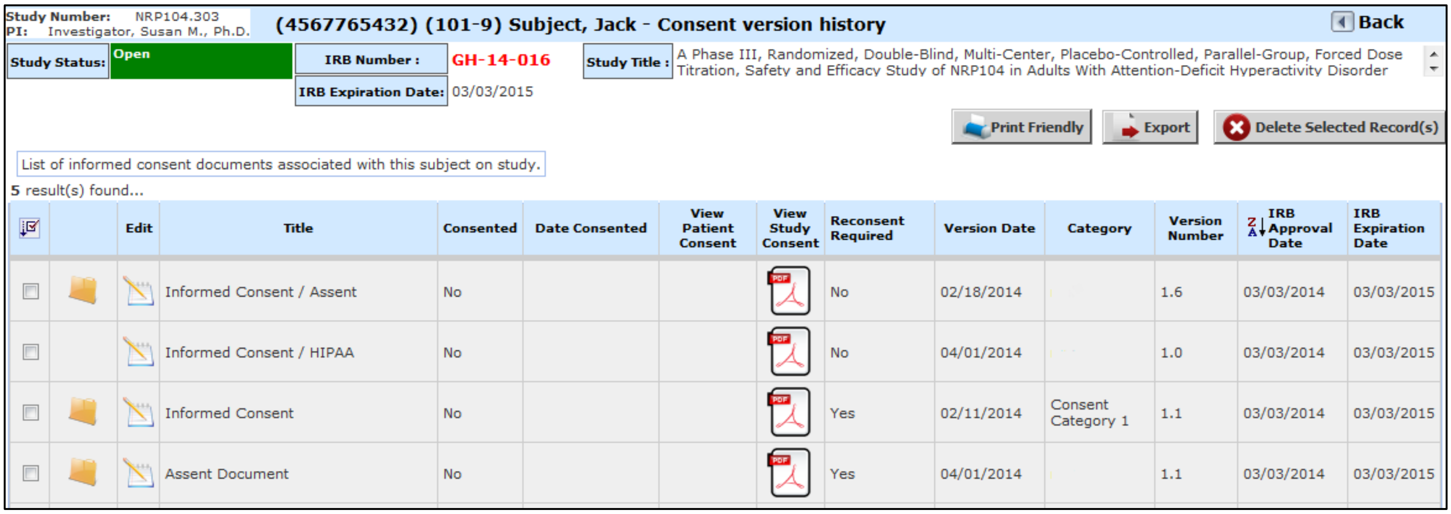


Once the Adverse Event form is completed, you will be prompted to submit and signoff on the form. See the Study Assistant –> Study Submissions Manual for information on submitting a form.

Informed Consent

The link to Informed Consents within Subject on Study will contain a list of the available Informed Consents associated to the study. From here you can download a copy of the IRB approved version of the consent, print it, consent the patient, then scan it back to the system and keep a record on file that the subject was consented.

This page will list any consent forms uploaded to the study.



Study Number: NRP104.303
PI: Investigator, Susan M., Ph.D.

(4567765432) (101-9) Subject, Jack - Consent version history

Back

Study Status: Open | IRB Number : GH-14-016 | Study Title : A Phase III, Randomized, Double-Blind, Multi-Center, Placebo-Controlled, Parallel-Group, Forced Dose Titration, Safety and Efficacy Study of NRP104 in Adults With Attention-Deficit Hyperactivity Disorder

IRB Expiration Date: 03/03/2015

Print Friendly | Export | Delete Selected Record(s)

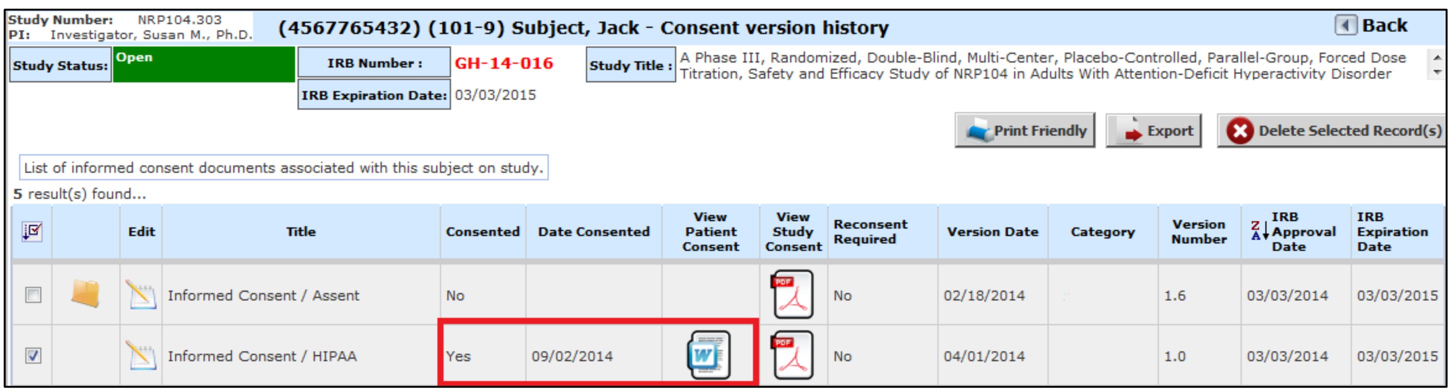
List of informed consent documents associated with this subject on study.

5 result(s) found...

		Edit	Title	Consented	Date Consented	View Patient Consent	View Study Consent	Reconsent Required	Version Date	Category	Version Number	IRB Approval Date	IRB Expiration Date
			Informed Consent / Assent	No				No	02/18/2014		1.6	03/03/2014	03/03/2015
			Informed Consent / HIPAA	No				No	04/01/2014		1.0	03/03/2014	03/03/2015
			Informed Consent	No				Yes	02/11/2014	Consent Category 1	1.1	03/03/2014	03/03/2015
			Assent Document	No				Yes	04/01/2014		1.1	03/03/2014	03/03/2015

The columns on this page are as follows:

Delete – You can delete a consent record, but only as it pertains to the subject record. For example, you indicated that a subject was consented for a record, and saved the record, then uploaded the signed consent, but applied it to the incorrect consent form. You can delete the subject related consent by clicking the checkbox next to the consent and then clicking the **Delete Selected Record(s)** button.



Study Number: NRP104.303
PI: Investigator, Susan M., Ph.D.

(4567765432) (101-9) Subject, Jack - Consent version history

Back

Study Status: Open | IRB Number : GH-14-016 | Study Title : A Phase III, Randomized, Double-Blind, Multi-Center, Placebo-Controlled, Parallel-Group, Forced Dose Titration, Safety and Efficacy Study of NRP104 in Adults With Attention-Deficit Hyperactivity Disorder

IRB Expiration Date: 03/03/2015

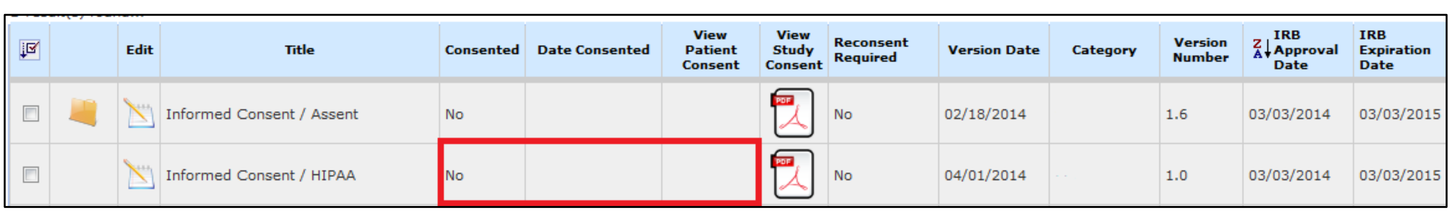
Print Friendly | Export | Delete Selected Record(s)

List of informed consent documents associated with this subject on study.

5 result(s) found...

		Edit	Title	Consented	Date Consented	View Patient Consent	View Study Consent	Reconsent Required	Version Date	Category	Version Number	IRB Approval Date	IRB Expiration Date
			Informed Consent / Assent	No				No	02/18/2014		1.6	03/03/2014	03/03/2015
			Informed Consent / HIPAA	Yes	09/02/2014			No	04/01/2014		1.0	03/03/2014	03/03/2015

When you delete, only the subject information is removed. You cannot delete any consent form record added to the study from this area.



		Edit	Title	Consented	Date Consented	View Patient Consent	View Study Consent	Reconsent Required	Version Date	Category	Version Number	IRB Approval Date	IRB Expiration Date
			Informed Consent / Assent	No				No	02/18/2014		1.6	03/03/2014	03/03/2015
			Informed Consent / HIPAA	No				No	04/01/2014		1.0	03/03/2014	03/03/2015

- If any of the consent records have more than one version, a folder icon will populate in this column. You can click the folder to expand the list and preview previous versions of the consent.

		Edit	Title	Consented	Date Consented	View Patient Consent	View Study Consent	Reconsent Required	Version Date	Category	Version Number	IRB Approval Date	IRB Expiration Date
			Informed Consent / Assent	No				No	02/18/2014		1.6	03/03/2014	03/03/2015
			Informed Consent / HIPAA	No				No	04/01/2014		1.0	03/03/2014	03/03/2015
			Informed Consent	No				Yes	02/11/2014	Consent Category 1	1.1	03/03/2014	03/03/2015
			Informed Consent	No				No	02/11/2014	Consent Category 1	1.0		

Edit-Clicking the icon in this column allows you to view the consent form details and flag the subject as consented with this record.

Title- Displays the title of the informed consent form.

Consented- This column will either indicate "No" (subject has not been consented with this version of the consent form) or "Yes" (subject has been consented with this version of the consent form).

Date Consented- The date the subject was consented.

View Patient Consent- If a subject consent form has been uploaded the record can be viewed here.

View Study Consent - This column will only populate with the IRB approved PDF copy of the consent form. You can click on this link to open the approved version of the consent form and then print it out and use it when consenting the subject.

Re-consent Required - This column will indicate if a re-consent is required when a new version of this consent is approved by the IRB.

Version Date - This column displays the version date of the consent form document.

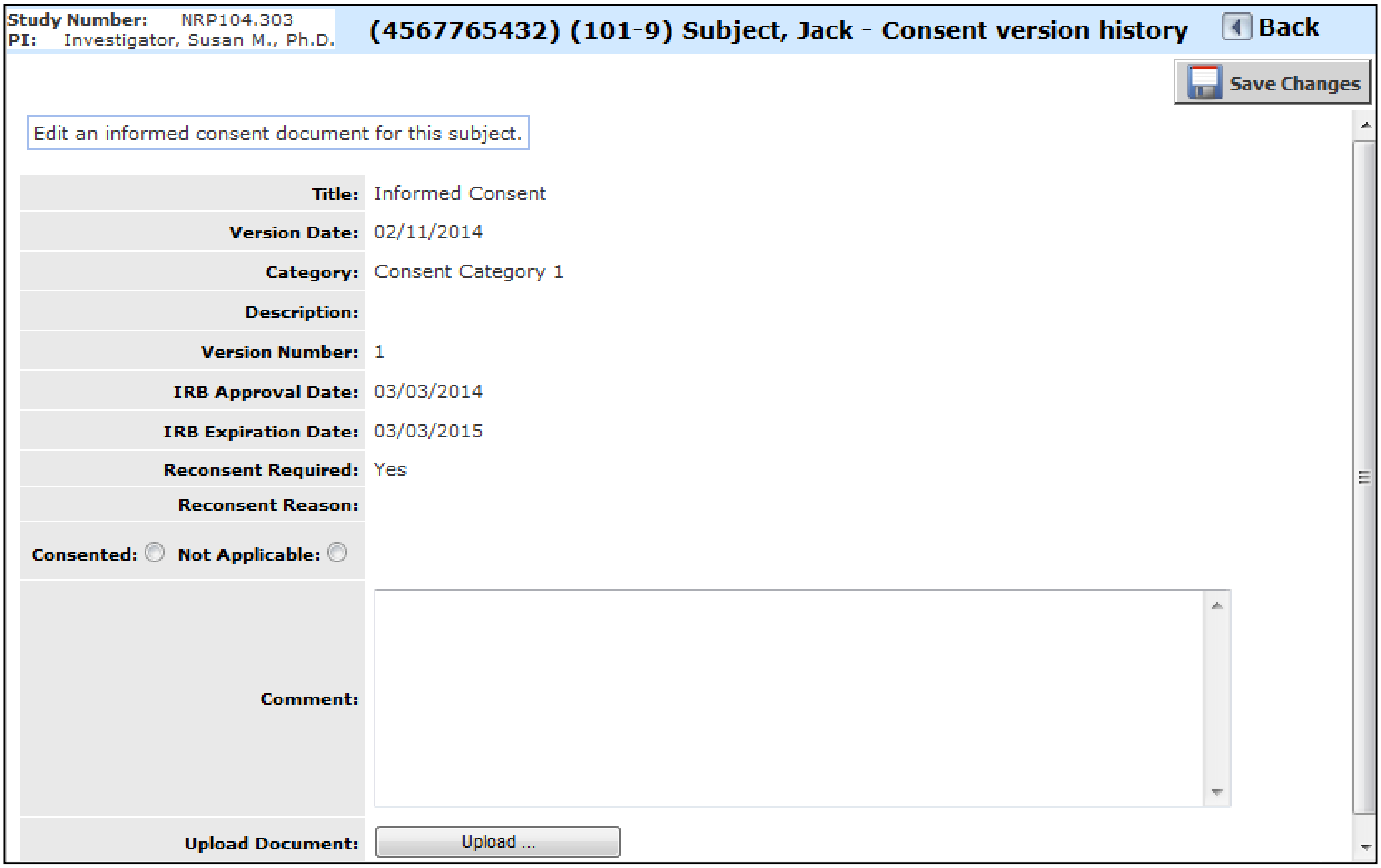
Version Number - This column displays the current version number.

IRB Approval Date - The date the IRB approved the consent form.

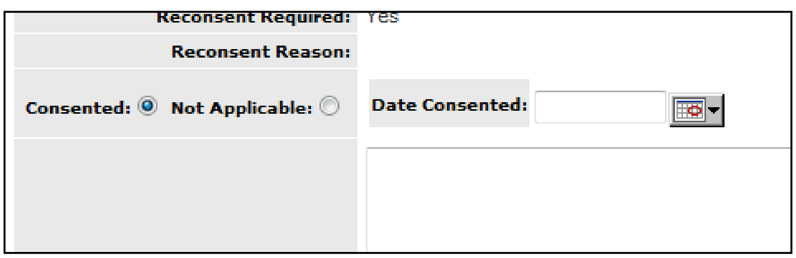
IRB Expiration Date - The date the IRB has set for the consent to expire.

To indicate that a subject has been consented, you can navigate to this page, locate the appropriate consent record and click the **Edit** icon.

A page similar to the one below will open. This page contains consent details such as Title, Version Information, Category, Description, IRB Approval Information and Reconsent Information.

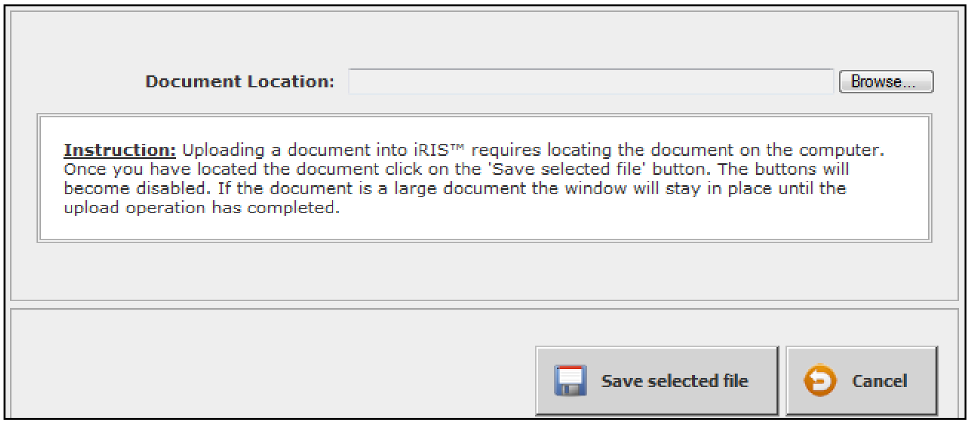


Below this is an option to select **Consented** or **Not Applicable**. To indicate that a subject has been consented, select the **Consented** option. A **Date Consented** field will populate on the page, allowing you to input the date the subject was consented. If a subject does not need to be consented for a specific consent record, you can choose the **Not Applicable** option and also select a **Not Applicable Reason**. The Not Applicable Reason drop down list is a configuration list available within System Administration –> List Configuration and Maintenance.

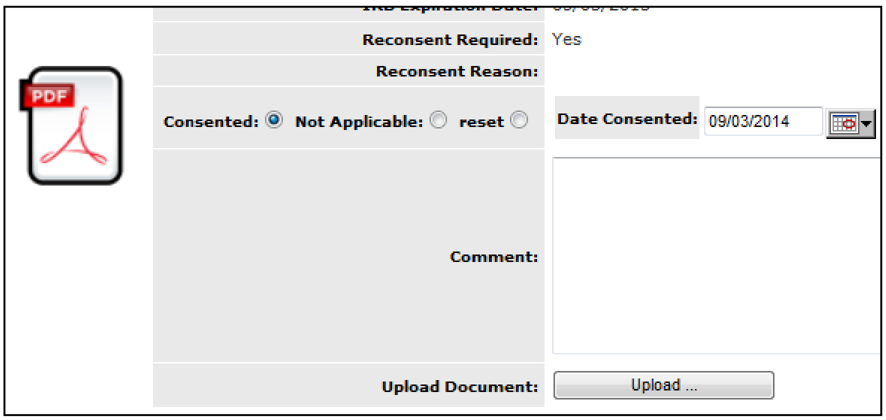


You can also add any appropriate comments to the **Comment** field. You can also upload a copy of the signed subject consent by clicking on the **Upload** button.

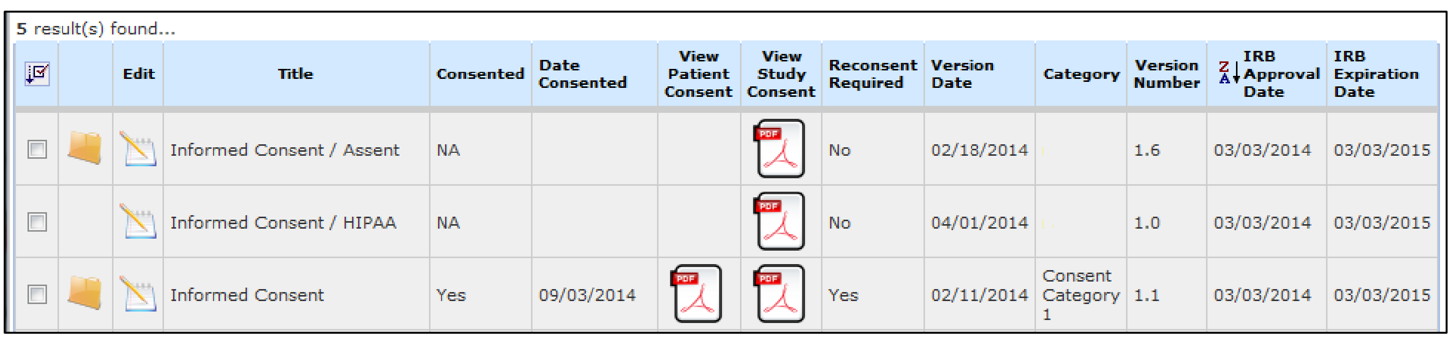
A popup window will open allowing you to **Browse** your computer for the document. Once you select the document, click the **Save selected file** button. Click the **Cancel** button to return to the consent page without uploading a document.



A document icon will populate next to the document information when you successfully upload a document. Be sure to click the **Save Changes** button to complete the upload.



Any consent you upload will populate in the **View Patient Consent** column. You can access this consent at any time by clicking on the document icon in this column. Also note that the **Consented** and **Date Consented** columns populate with information added for the consent record.

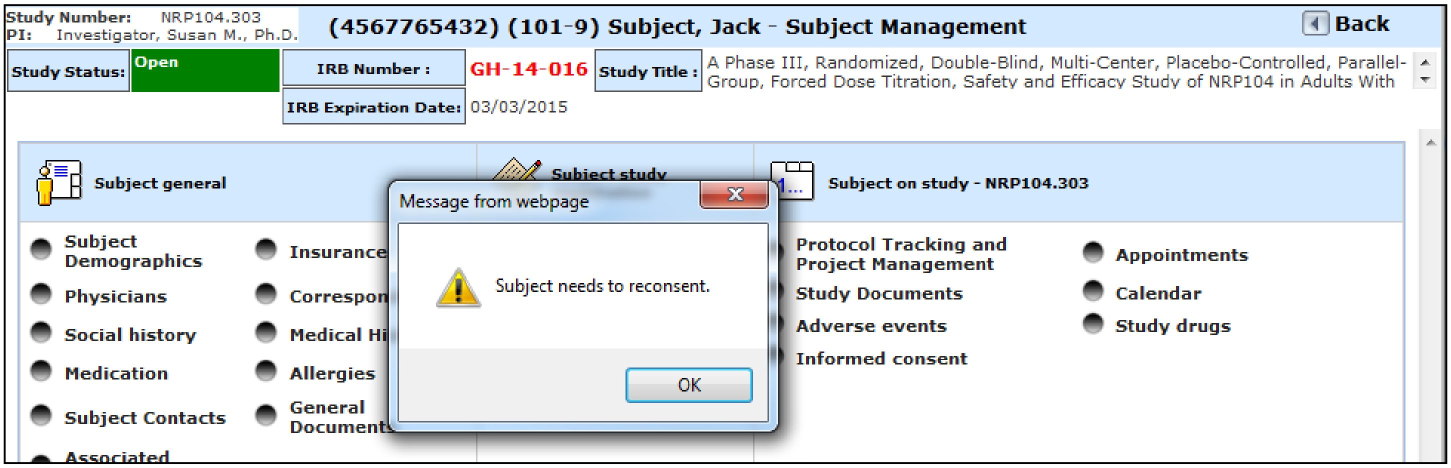

5 result(s) found...

		Edit	Title	Consented	Date Consented	View Patient Consent	View Study Consent	Reconsent Required	Version Date	Category	Version Number	IRB Approval Date	IRB Expiration Date
			Informed Consent / Assent	NA				No	02/18/2014		1.6	03/03/2014	03/03/2015
			Informed Consent / HIPAA	NA				No	04/01/2014		1.0	03/03/2014	03/03/2015
			Informed Consent	Yes	09/03/2014			Yes	02/11/2014	Consent Category 1	1.1	03/03/2014	03/03/2015

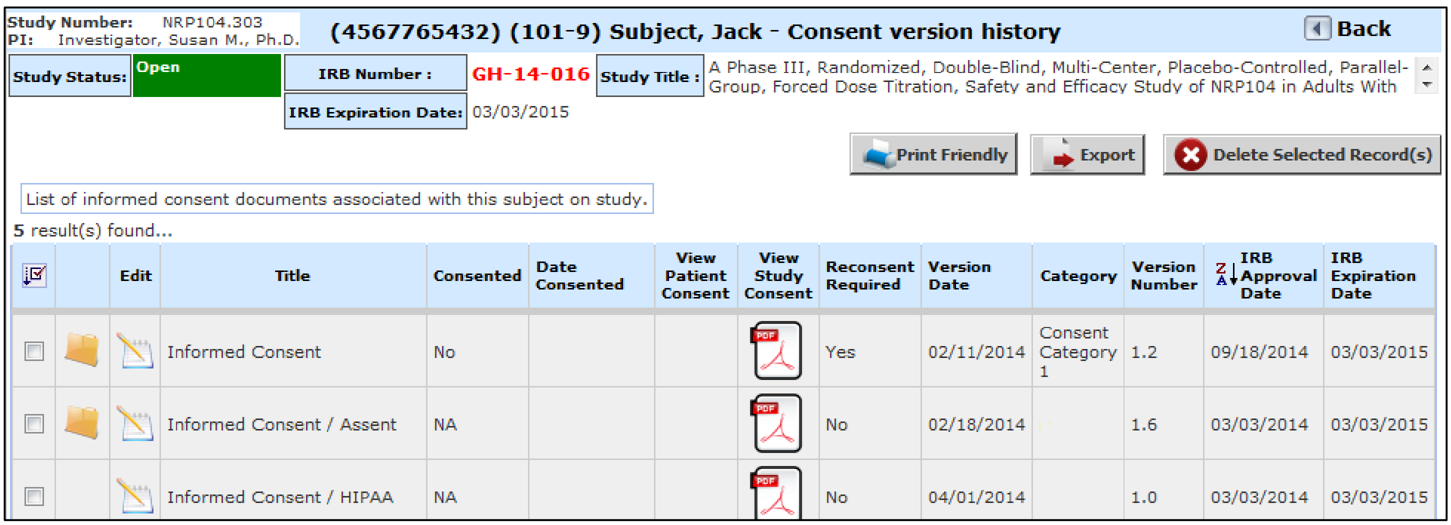
Reconsenting a Subject

If a new version of a consent form flagged as "Reconsent Required" is approved by the IRB and the subject has been consented on the old version, the system will display a message the next time you access that subject record.

*Note: The subject must also be in a Subject Status that has the operation "Reminder to reconsent the subject" set.

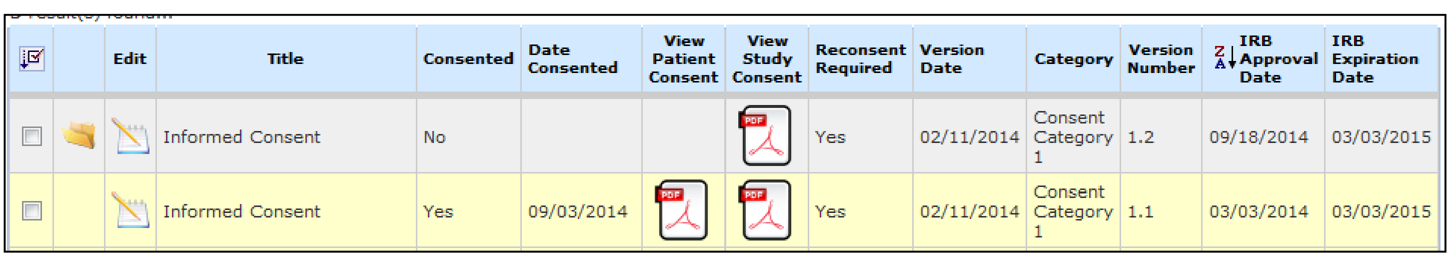


When you access Informed Consent, the consent form needing reconsent will populate at the top of the list of consents.



		Edit	Title	Consented	Date Consented	View Patient Consent	View Study Consent	Reconsent Required	Version Date	Category	Version Number	IRB Approval Date	IRB Expiration Date
			Informed Consent	No				Yes	02/11/2014	Consent Category 1	1.2	09/18/2014	03/03/2015
			Informed Consent / Assent	NA				No	02/18/2014		1.6	03/03/2014	03/03/2015
			Informed Consent / HIPAA	NA				No	04/01/2014		1.0	03/03/2014	03/03/2015

This is a newer version of the previously consented record, and clicking on the yellow folder can access the older record. You can follow the steps listed above when initially setting the consent information for any consent requiring a reconsent.



		Edit	Title	Consented	Date Consented	View Patient Consent	View Study Consent	Reconsent Required	Version Date	Category	Version Number	IRB Approval Date	IRB Expiration Date
			Informed Consent	No				Yes	02/11/2014	Consent Category 1	1.2	09/18/2014	03/03/2015
			Informed Consent	Yes	09/03/2014			Yes	02/11/2014	Consent Category 1	1.1	03/03/2014	03/03/2015

Once you indicate the subject was consented on the new version that information will display within the Informed Consent page, similar to the screenshot displayed below.

		Edit	Title	Consented	Date Consented	View Patient Consent	View Study Consent	Reconsent Required	Version Date	Category	Version Number	IRB Approval Date	IRB Expiration Date
			Informed Consent	Yes	09/18/2014			Yes	02/11/2014	Consent Category 1	1.2	09/18/2014	03/03/2015
			Informed Consent / Assent	NA				No	02/18/2014		1.6	03/03/2014	03/03/2015

Appointments

The Appointments area contains a list of all the Scheduled and Unscheduled visits for the subject. From this area, you can schedule visits and also cancel the scheduled visit. This area is useful for scheduling visits or canceling visits. Often, this area is granted to a study user who will perform scheduling tasks but will not need to access the details of the visit, so they do not have access to the Protocol Tracking and Project Management area.

A visit can be scheduled by clicking the icon in either the **Unscheduled Tasks** area, or within the **Scheduled Tasks** area to change the currently scheduled visit to another date and/or time.

Visits can also be canceled from this area by clicking on the icon. As soon as this icon is clicked, the visit will be flagged as “Canceled” within Protocol Tracking and Project Management.

Study Number: NRP104.303
PI: Investigator, Susan M., Ph.D.

(4567765432) (101-9) Subject, Jack - Appointments Back

Study Status: Open **IRB Number :** GH-14-016 **Study Title :** A Phase III, Randomized, Double-Blind, Multi-Center, Placebo-Controlled, Parallel-Group, Forced Dose Titration, Safety and Efficacy Study of NRP104 in Adults With

IRB Expiration Date: 03/03/2015

Legend Visits: Procedures:

Unscheduled Tasks - NRP104.303

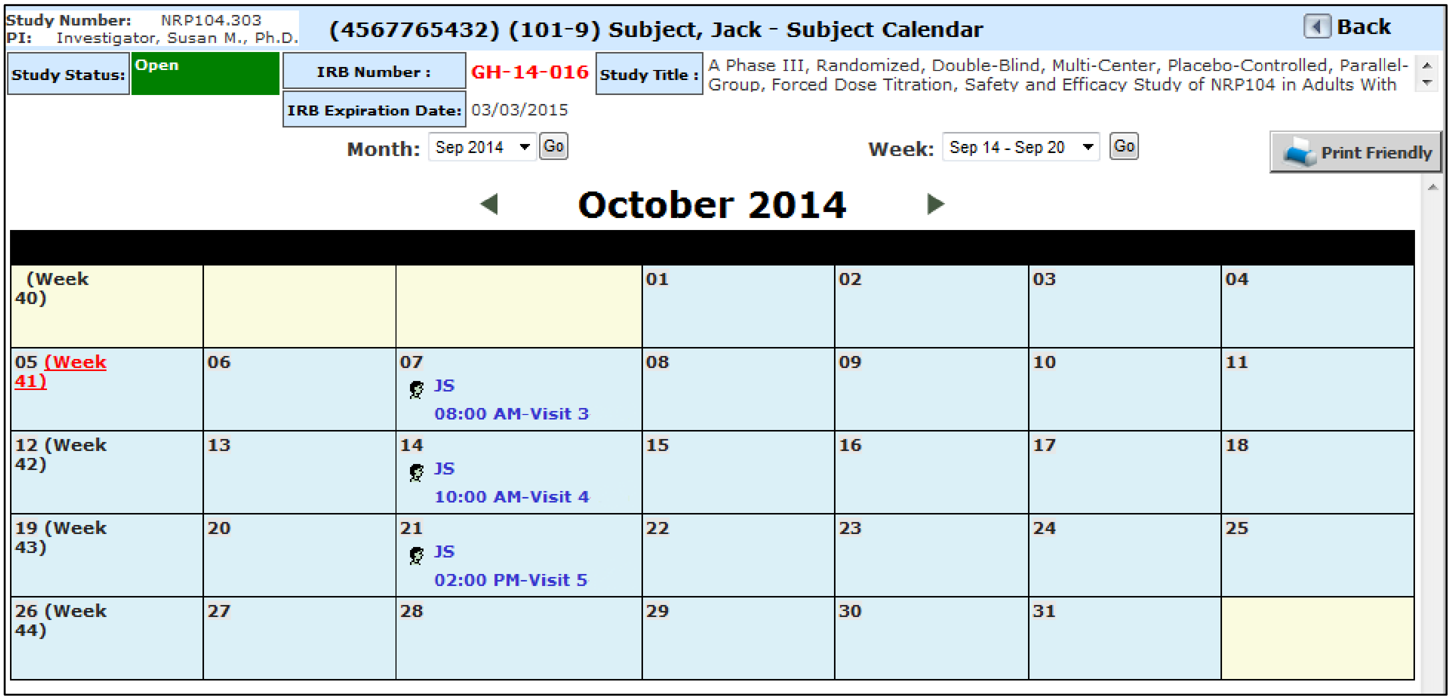
	Task Name	Classification	Target Date	Appt. Duration
	Visit 3	Visit	10/07/2014	1 Hr
	Visit 4	Visit	10/14/2014	
	Visit 5	Visit	10/21/2014	

Scheduled Tasks - NRP104.303

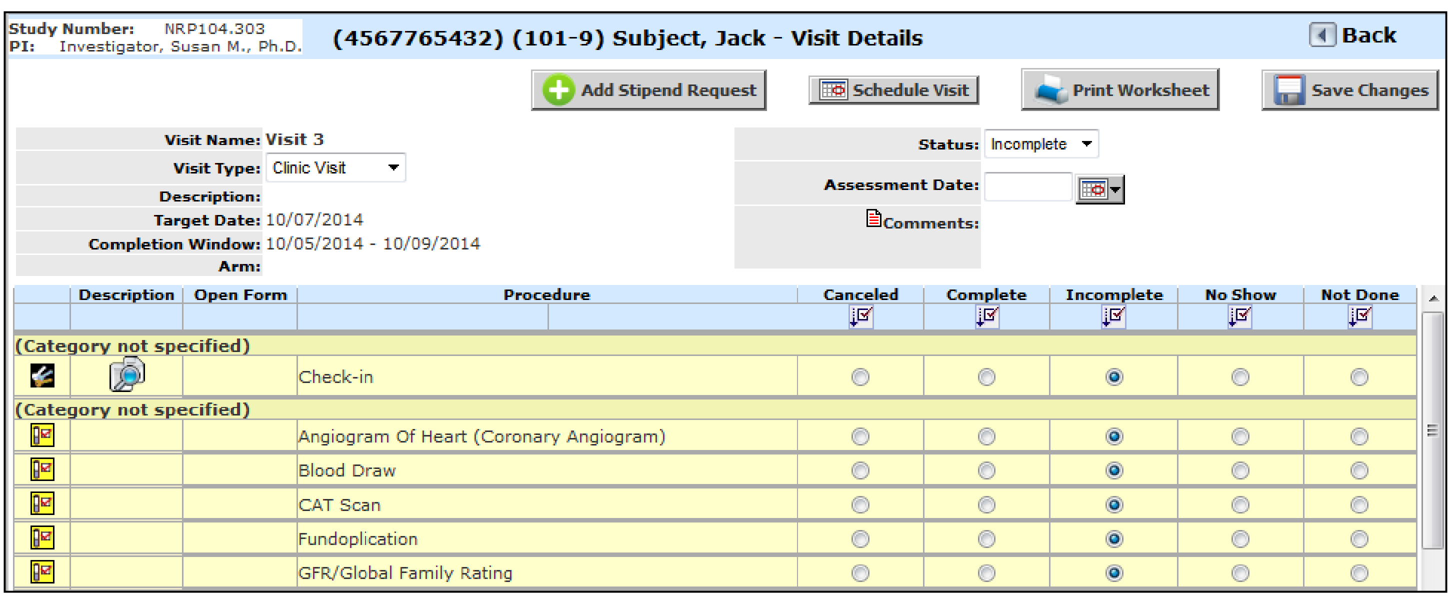
		Task Name	Classification	Target Date	Appt. Duration	Task Status	Scheduled Date	Scheduled Time
		Visit 1	Visit	09/19/2014	1 Hr	Complete	09/19/2014	08:00 AM
		Visit 2	Visit	09/30/2014	1 Hr	Incomplete	09/30/2014	09:00 AM

Calendar

The Calendar link within Subject on Study contains the same functionality as the Study Appointment Calendar, but will only display scheduled visits related to the subject. See the Study Appointment Calendar section of this manual for more information on the functionality of this page.

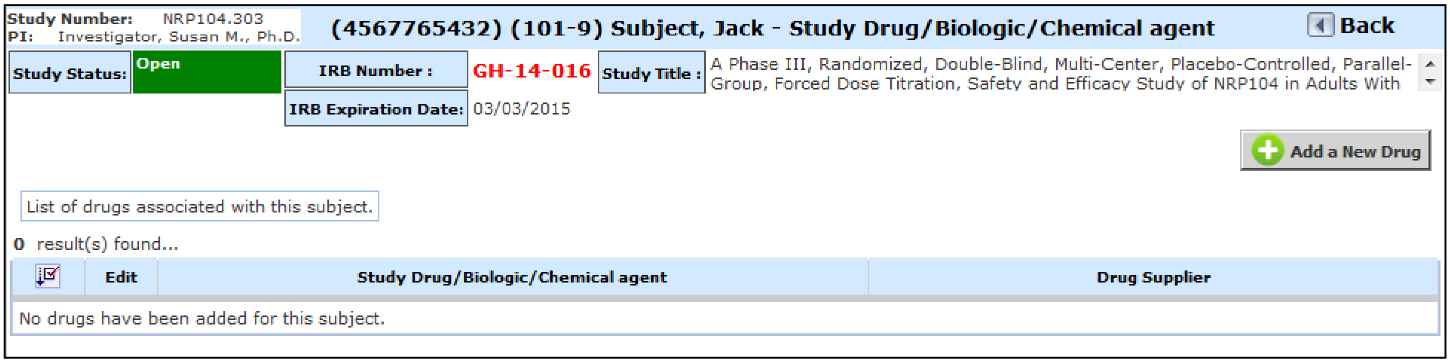


If you click on a visit link, you will be directed to the Visit Details page where you can then status the visit. See the Completing a Visit section of this manual for more information about the functionality on this page.

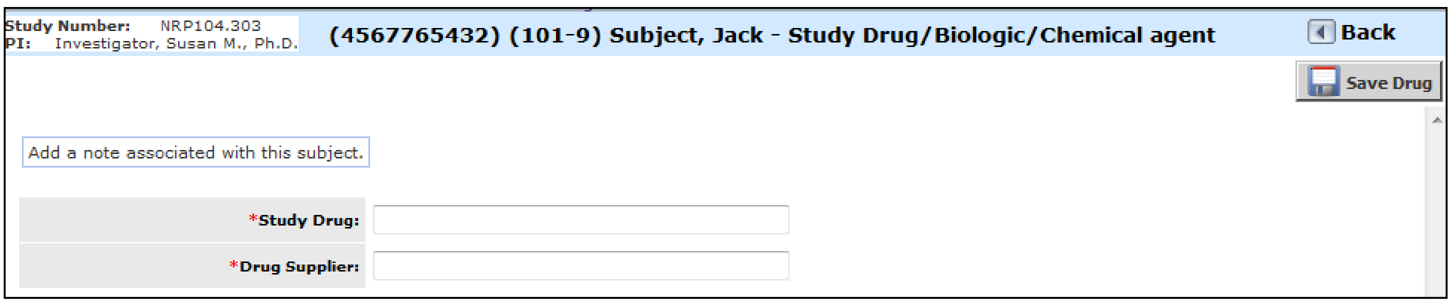


Study Drugs

This area allows you to list any study drugs the subject is using. When you first access this area, the page will not display any records for the subject. You can associate a study drug record to the subject by clicking on the **Add New Drug** button.



From the page that opens, you enter the **Study Drug** and **Drug Supplier** then click the **Save Drug** button.



The Study Drug will be associated to the subject. You can modify the details for the Study Drug record by clicking on the icon in the **Edit** column and delete the record by selecting the checkbox next to the Study Drug and clicking on the **Delete Selected Drug(s)** button. Additional records can be associated to the subject by clicking on the **Add a New Drug** button.