



STUDY MANAGEMENT

Subject Management

Version 10.02

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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).

The screenshot displays the 'Study Application' form. At the top, it shows 'Study Number: NRP104.303' and 'PI: Investigator, Susan M., Ph.D.'. The form is divided into two main views: 'Section view of Application' (left sidebar) and 'Entire view of the Application' (main content area). The sidebar lists sections: 1.0 General Information, 2.0 Setup Department(s) Access, 3.0 Grant Key Personnel access to the study, and 4.0 Section 200. The main content area shows the '1.0 General Information' section with the following fields:

- * Please enter the full title of your study:** 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 (ADHD)
- * Please enter the Study Number you would like to use to reference the study:** NRP104.303
- Is this Study using Subject Management?** (This question is highlighted with a red box in the original image)
 - Yes
 - No

Additional buttons at the top right include 'Print Friendly', 'Convert to the New Form Version', 'Save and Continue to Next Section', and 'Back'.

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.

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

Study Status: **Open**

IRB Number: **GH-14-016**

Study Title: A Phase III, Randomized, Forced Dose Titration,

IRB Expiration Date: 03/03/2015

Submissions | Study Management | **Subject Management**

Protocol Items

Protocol Items

Study Application

Submissi

Study Co

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.

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

Study Summary 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

IRB Expiration Date: 03/03/2015

Save Changes

Study Summary Basic Information

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 (ADHD)

Status: Open

Study Number: NRP104.303

Use Subject Tracking: Yes No

Use Electronic Data Capture(EDC): Yes No

Animal Research: No

Study Classification: Study Classification 1

Federally Funded: Yes No

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.

Study Number: Adults with ADHD
 PI: Investigator, Susan M., Ph.D.

Subject Management

[Back](#)

Study Status: **Open** IRB Number : **GH-14-031** 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 (ADHD)

IRB Expiration Date: 09/29/2015

Filter Lists by Department: All



[Print Friendly](#)

Submissions **Study Management** **Subject Management**

Subject Tracking Scheduling

Displaying List By: **All Subject On Study Status** [Filter Results](#)

10 result(s) found...

| Edit | On Study Status | Last, First MI DOB - Survival Status | MRN | Participant Number | Department | Sex | Register Date | Off Study Date Off Study Reason |
|---|-----------------|---|---------|--------------------|------------|-----|---------------|------------------------------------|
|  | Screen Fail | Subject, Amy 05/20/1980 - | 4534234 | 101-4 | Oncology | F | | |
|  | Active | Subject, Donna 12/18/1975 - | 6543211 | 101-2 | Oncology | F | 10/03/2014 | |

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.

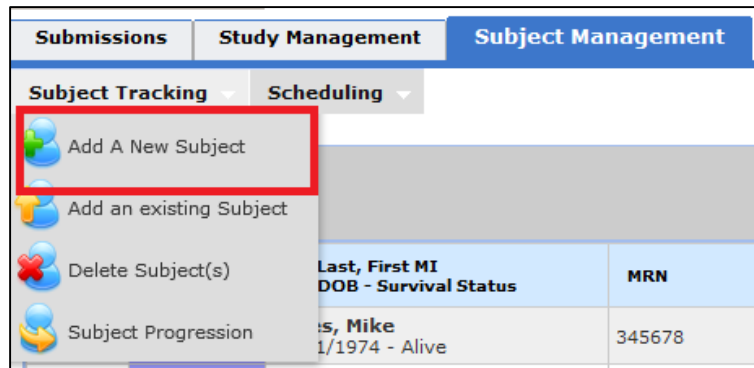
Register Date- If a registration date has been assigned to a subject, it will display here.

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.

Study Number: Adults with ADHD
PI: Investigator, Susan M., Ph.D.

Adults with ADHD - Add Subject Back

| | | |
|---------------------------------|-------------------------------|--|
| Study Status: Open | IRB Number : GH-14-031 | 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: 09/29/2015 | | Save Subject Information |

| | |
|--------------------------------|--|
| * Medical Record Number (MRN): | <input type="text"/> |
| Participant Number: | <input type="text"/> |
| * Last Name: | <input type="text"/> |
| First Name: | <input type="text"/> |
| Middle Initial: | <input type="text"/> |
| * Screening Date: | <input type="text"/> <input type="button" value="Calendar"/> |
| Screening Failure: | <input type="checkbox"/> |

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.

| Subject general | Subject study registration | Subject on study - NRP104.303 |
|--|--|--|
| <ul style="list-style-type: none"> <input type="radio"/> Subject Demographics <input type="radio"/> Physicians <input type="radio"/> Social history <input type="radio"/> Medication <input type="radio"/> Subject Contacts <input type="radio"/> Associated Departments <input type="radio"/> Insurance <input type="radio"/> Correspondence <input type="radio"/> Medical History <input type="radio"/> Allergies <input type="radio"/> General Documents | <ul style="list-style-type: none"> <input type="radio"/> Study screening <input type="radio"/> On study registration information | <ul style="list-style-type: none"> <input type="radio"/> Protocol Tracking and Project Management <input type="radio"/> Study Documents <input type="radio"/> Adverse events <input type="radio"/> Informed consent <input type="radio"/> Appointments <input type="radio"/> Calendar <input type="radio"/> Study drugs |

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.

Study Number: Adults with ADHD
PI: Investigator, Susan M., Ph.D.

Adults with ADHD - Add Subject

Study Status: Open **IRB Number :** GH-14-031 **Study Title :** A Phase III, Randomized, Double-Blind, Multi-Center, Pl Group, Forced Dose Titration, Safety and Efficacy Study

IRB Expiration Date: 09/29

| | |
|---------------------------------------|---|
| * Medical Record Number (MRN): | <input type="text" value="345678"/> |
| Participant Number: | <input type="text"/> |
| *Last Name: | <input type="text" value="Subject"/> |
| First Name: | <input type="text"/> |
| Middle Initial: | <input type="text"/> |
| * Screening Date: | <input type="text" value="10/22/2014"/> <input type="button" value="Calendar"/> |
| Screening Failure: | <input type="checkbox"/> |

Message from webpage

Duplicate Medical Record Number found!
Please resubmit the form with a new Medical Record Number or click OK to access the subject's medical record.

Do you want to open the subject's record?

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.

Study Number: Adults with ADHD (345678) Subject, Mike - Subject Management Back
 PI: Investigator, Susan M., Ph.D.

Study Status: **Open** IRB Number : **GH-14-031** 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 (ADHD)
 IRB Expiration Date: 09/29/2015

| Subject general | Subject study registration | Subject on study - Adults with ADHD |
|--|--|--|
| <ul style="list-style-type: none"> <input type="radio"/> Subject Demographics <input type="radio"/> Physicians <input type="radio"/> Social history <input type="radio"/> Medication <input type="radio"/> Subject Contacts <input type="radio"/> Associated Departments | <ul style="list-style-type: none"> <input type="radio"/> Insurance <input type="radio"/> Correspondence <input type="radio"/> Medical History <input type="radio"/> Allergies <input type="radio"/> General Documents | <ul style="list-style-type: none"> <input type="radio"/> Study screening <input type="radio"/> On study registration information <p>This subject has not been registered. Click On Study Registration to enroll the subject on this study.</p> |

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.

Study Number: Adults with ADHD (345678) (101-11) Subject, Mike - Subject Management Back
 PI: Investigator, Susan M., Ph.D.

Study Status: **Open** IRB Number : **GH-14-031** 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 (ADHD)
 IRB Expiration Date: 09/29/2015

| Subject general | Subject study registration | Subject on study - Adults with ADHD | | | | | | | | | | |
|--|--|--|--------------------|-------------------------|-------------|--------------------|----------------|------|-------------------------|--|-------|--------|
| <ul style="list-style-type: none"> <input type="radio"/> Subject Demographics <input type="radio"/> Physicians <input type="radio"/> Social history <input type="radio"/> Medication <input type="radio"/> Subject Contacts <input type="radio"/> Associated Departments | <ul style="list-style-type: none"> <input type="radio"/> Insurance <input type="radio"/> Correspondence <input type="radio"/> Medical History <input type="radio"/> Allergies <input type="radio"/> General Documents | <ul style="list-style-type: none"> <input type="radio"/> Study screening <input type="radio"/> On study registration information <ul style="list-style-type: none"> <input type="radio"/> Protocol Tracking and Project Management <input type="radio"/> Study Documents <input type="radio"/> Adverse events <input type="radio"/> Informed consent <input type="radio"/> Appointments <input type="radio"/> Calendar <input type="radio"/> Study drugs <p>Take Notice: This subject is registered on multiple studies:</p> <table border="1"> <thead> <tr> <th>Study Status</th> <th>IRB Number/Study Number</th> <th>Study Title</th> <th>Participant Number</th> <th>Subject Status</th> </tr> </thead> <tbody> <tr> <td>Open</td> <td>GH-14-016 NRP104.303</td> <td>A Phase III, Randomized, Double-Blind, Multi-Center, Placebo-Controlled, Parallel-</td> <td>101-3</td> <td>Active</td> </tr> </tbody> </table> | Study Status | IRB Number/Study Number | Study Title | Participant Number | Subject Status | Open | GH-14-016 NRP104.303 | A Phase III, Randomized, Double-Blind, Multi-Center, Placebo-Controlled, Parallel- | 101-3 | Active |
| Study Status | IRB Number/Study Number | Study Title | Participant Number | Subject Status | | | | | | | | |
| Open | GH-14-016 NRP104.303 | A Phase III, Randomized, Double-Blind, Multi-Center, Placebo-Controlled, Parallel- | 101-3 | Active | | | | | | | | |

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.

Study Number: Adults with ADHD
PI: Investigator, Susan M., Ph.D.
Adults with ADHD - Add Subject
Back

Study Status: **Open**

IRB Number : **GH-14-031**

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: 09/29/2015

Save Subject Information

* Medical Record Number (MRN):

Participant Number:

*Last Name:

First Name:

Middle Initial:

* Screening Date:

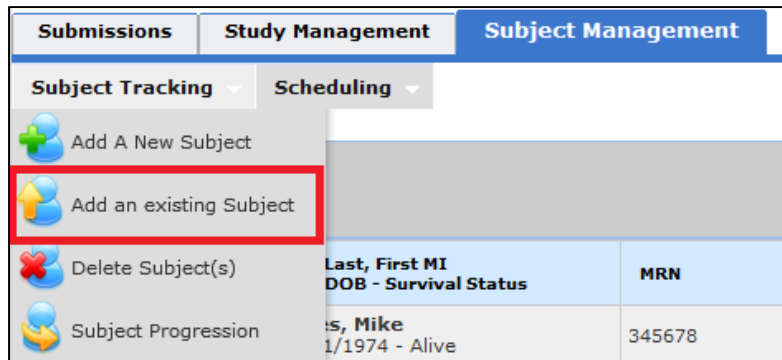
Screening Failure: * Screening failure will default Subject status: Yes No

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.

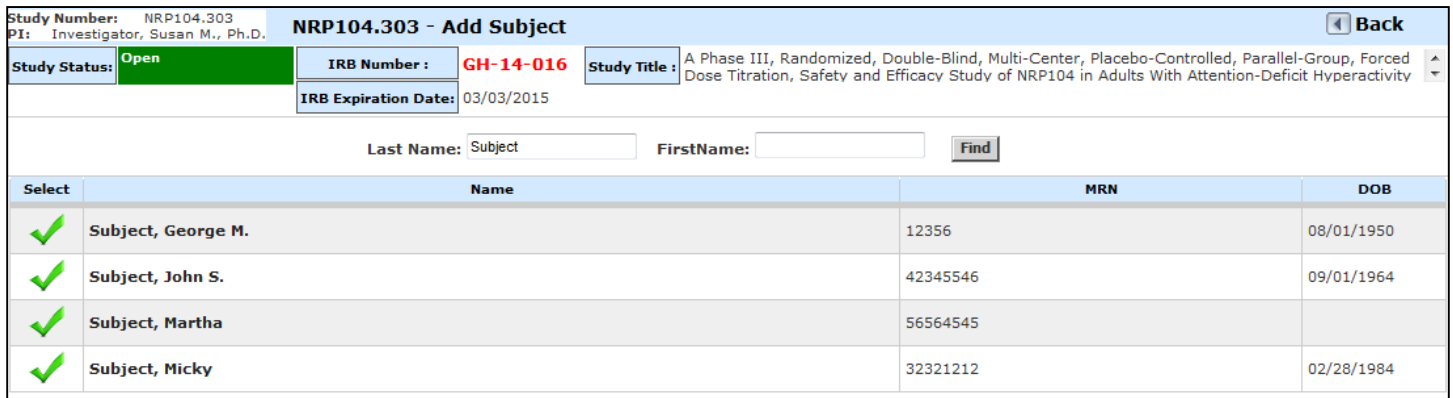
| Submissions | | Study Management | | Subject Management | |
|----------------------|-----------------|---|---------|--------------------|--|
| Subject Tracking | | Scheduling | | | |
| 3 result(s) found... | | | | | |
| Edit | On Study Status | Last, First MI DOB - Survival Status | MRN | Participant Number | |
| | Screen Fail | Subject, Amy 5/20/1980 - | 4534234 | 101-4 | |
| | Screen Fail | Subject, Melody Alive | 45234 | 101-5 | |

Add an Existing Subject

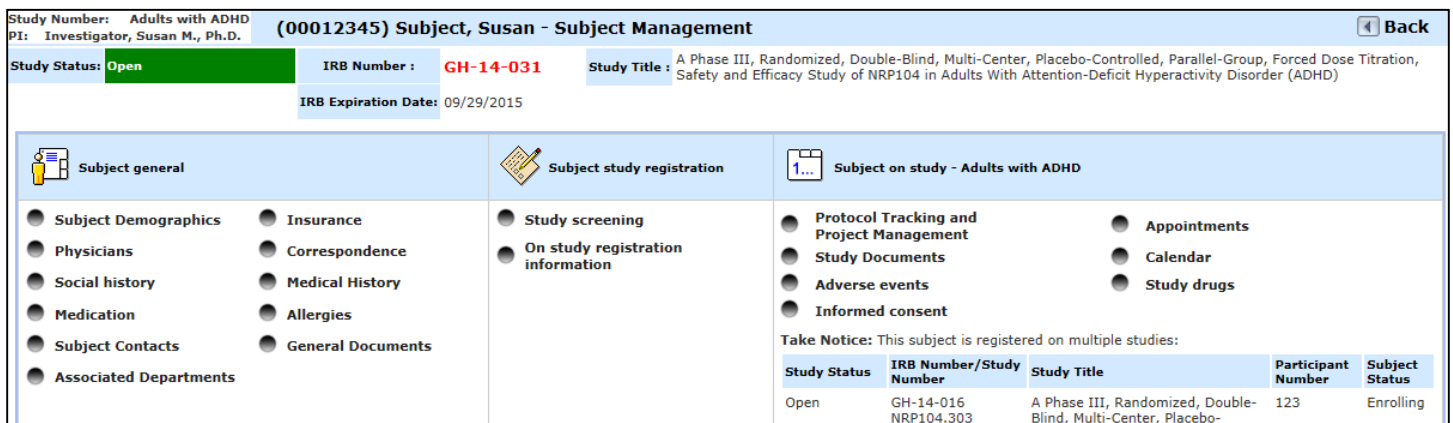
In addition to adding an existing subject from the method described above, you can choose to add an existing subject from the option provided in the **Subject Tracking** drop down list. This option may or may not be available depending on your system settings.



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.

The screenshot shows the 'Subject Management' tab selected. Under the 'Subject Tracking' dropdown menu, the 'Delete Subject(s)' option is highlighted with a red box. Other options include 'Add A New Subject', 'Add an existing Subject', and 'Subject Progression'. A table snippet shows columns for 'Last, First MI', 'DOB - Survival Status', and 'MRN' with a row for 'Jones, Mike' (DOB: 1/1974 - Alive, MRN: 345678).

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.

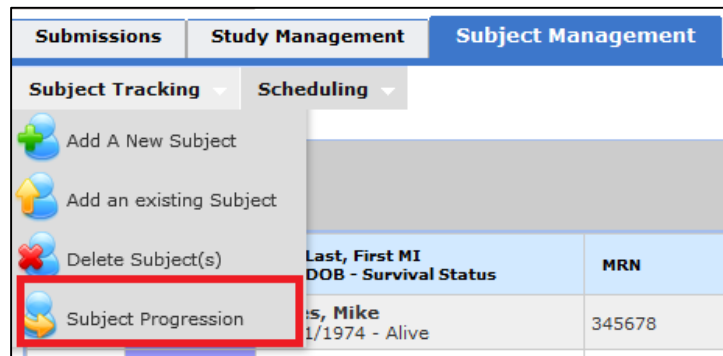
The screenshot shows the 'Study - Subject Deletion' page. At the top, it displays study details: Study Number: NRP104.303, PI: Investigator, Susan M., Ph.D., IRB Number: GH-14-016, IRB Expiration Date: 03/03/2015, and Study Title: A Phase III, Randomized, Double-Blind, Multi-Center, Placebo-Controlled, Parallel-Group, Forced Dose Titration, Safety and Efficacy Study of NRP104 in. A 'Back' button is in the top right. A 'Delete Selected Subject(s)' button with a red 'X' icon is also present. Below is a table of subjects:

| <input type="checkbox"/> | Study Status | (MRN) Name | Sex | Registration Date | Date of Birth | Survival Status | Off Study Details |
|-------------------------------------|--------------|----------------------------|-----|-------------------|---------------|-----------------|-------------------|
| <input checked="" type="checkbox"/> | Active | Jones, Mike(345678) | M | 09/02/2014 | 05/21/1974 | Alive | |
| <input type="checkbox"/> | Screen Fail | Subject, Martha(56564545) | F | | | | |
| <input type="checkbox"/> | Active | Subject, Micky(32321212) | M | | 02/28/1984 | | |
| <input type="checkbox"/> | Active | Subject, George M.(12356) | M | 04/10/2014 | 08/01/1950 | Alive | |
| <input type="checkbox"/> | Declined | Subject, John S.(42345546) | M | 04/07/2014 | 09/01/1964 | | 08/01/2014 |

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.

| Subject Progression | | | | | | | | | | | | | | |
|-----------------------------------|--------------------|------------------|----------------------|-----------------|---------|------------|---------|---------|---------|---------|---------|---------|---------|----------|
| Department: GH - 00232 - Oncology | | | Template: Template 1 | | | Arm: Arm 1 | | | Search | | | | | |
| (*) indicates completed visit. | | | | | | | | | | | | | | |
| Print Friendly | | | | | | | | | | | | | | |
| 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 | 123321123 | 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.

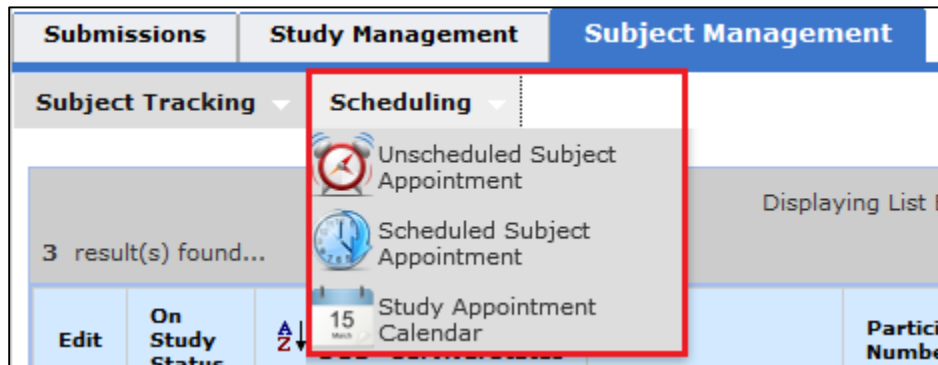
Visit column(s) – Will highlight each box for a completed visit. If a visit has not been completed the box will remain white. If a visit has been completed, it will highlight green and contain an asterisk in the column.

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.

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

Unscheduled Subject Appointments

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
 IRB Expiration Date: 03/03/2015

Filter By: Today (10/21/2014) 11/04/2014 Search...
 Visit Type: --none--

21 result(s) found... Legend Visits: Procedures:

| | 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.

| Study Number: NRP104.303 PI: Investigator, Susan M., Ph.D. Scheduled Subject 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 Attention-Deficit Hyperactivity | | | | |
| | IRB Expiration Date: 03/03/2015 | | | | | |
| Filter By: | Today (10/21/2014) ↔ 11/04/2014 | Search... | | | | |
| | Visit Type: --none-- | | | | | |
| | | | | | Legend | Visits: Procedures: |
| 1 result(s) found... | | | | | | 1 - 1 |
| | Visit Name | Visit Type | Subject | Appt. Date | Appt. Duration | Classification |
| | Visit 5 | Phone Screen | (4567765432) Subject, Jack | 10/21/2014 11:00 AM | 1 Hr | Visit |

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.

Study Appointment Calendar Back

Study Number: Adults with ADHD
 PI: Investigator, Susan M., Ph.D.

Study Status: **Open** IRB Number: **GH-14-031** 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: 09/29/2015

Month: Oct 2014 Go Week: Oct 19 - Oct 25 Go

October 2014

| Sun | Mon | Tue | Wed | Thu | Fri | Sat |
|--------------|-----|-----|------------------------|------------------------|------------------------|-----|
| (Week 40) | | | 01 | 02 | 03 | 04 |
| 05 (Week 41) | 06 | 07 | 08 08:00 AM-Visit 2 | 09 | 10 08:00 AM-Visit 6 | 11 |
| 12 (Week 42) | 13 | 14 | 15 | 16 | 17 | 18 |
| 19 (Week 43) | 20 | 21 | 22 08:00 AM-Visit 4 | 23 08:00 AM-Visit 4 | 24 08:00 AM-Visit 8 | 25 |
| 26 (Week 44) | 27 | 28 | 29 | 30 | 31 | |

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

Study Appointment Calendar Back

Study Number: Adults with ADHD
 PI: Investigator, Susan M., Ph.D.

Study Status: **Open** IRB Number: **GH-14-031** 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: 09/29/2015

Month: Oct 2014 Go **Week: Oct 19 - Oct 25 Go**

October 19 - 25, 2014 (Week 43)

| | Sun Oct 19 | Mon Oct 20 | Tue Oct 21 | Wed Oct 22 | Thu Oct 23 | Fri Oct 24 | Sat Oct 25 |
|--------------|---------------|---------------|---------------|------------------|------------------|------------------|---------------|
| 6:00 | | | | | | | |
| 7:00 | | | | | | | |
| 8:00 | | | | 08:00 AM-Visit 4 | 08:00 AM-Visit 4 | 08:00 AM-Visit 8 | |
| 9:00 | | | | | | | |
| 10:00 | | | | | | | |
| 11:00 | | | | | | | |

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

Study Appointment Calendar Back

Study Number: Adults with ADHD
 PI: Investigator, Susan M., Ph.D.

Study Status: **Open** IRB Number: **GH-14-031** 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: 09/29/2015

Month: Oct 2014 Go Week: Oct 19 - Oct 25 Go

Friday, October 24, 2014

| | |
|-------|----------------------|
| 6:00 | |
| 7:00 | |
| 8:00 | 08:00 AM- Visit 8 |
| 9:00 | |
| 10:00 | |
| 11:00 | |
| 12:00 | |

24

October 2014

| | | | | | | |
|-----|-----|-----|-----|-----|-----|-----|
| Sun | Mon | Tue | Wed | Thu | Fri | Sat |
| | | | 01 | 02 | 03 | 04 |
| 05 | 06 | 07 | 08 | 09 | 10 | 11 |
| 12 | 13 | 14 | 15 | 16 | 17 | 18 |
| 19 | 20 | 21 | 22 | 23 | 24 | 25 |
| 26 | 27 | 28 | 29 | 30 | 31 | |

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.

Study Appointment Calendar

Study Number: Adults with ADHD
 PI: Investigator, Susan M., Ph.D.

Study Status: **Open** IRB Number: **GH-14-031** Study Title: A Phase III, Randomized, Double-Blind, Multi-Ce
 Titration, Safety and Efficacy Study of NRP104 in

IRB Expiration Date: 09/29/2015

Month: Oct 2014 Go Week

Friday, October 24, 2014

| | |
|-------|----------------------|
| 8:00 | 08:00 AM- Visit 8 |
| 9:00 | |
| 10:00 | |
| 11:00 | |
| 12:00 | |

[X]

08:00 AM-60 minutes

Visit 8-

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.

Study Number: NRP104.303 **(4567765432) (101-9) Subject, Jack - Visit Details** Back

PI: Investigator, Susan M., Ph.D.

+ Add Stipend Request
 Schedule Visit
 Print Worksheet
 Save Changes

Visit Name: Visit 3 **Status:** Incomplete
Visit Type: Clinic Visit **Assessment Date:**
Description: **Comments:**
Target Date: 10/07/2014
Completion Window: 10/05/2014 - 10/09/2014

| Description | Open Form | Procedure | Canceled | Complete | Incomplete | No Show | Not Done |
|---------------------------------|-----------|---|-----------------------|-----------------------|----------------------------------|-----------------------|-----------------------|
| (Category not specified) | | | | | | | |
| | | Check-in | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| (Category not specified) | | | | | | | |
| | | Angiogram Of Heart (Coronary Angiogram) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | | Blood Draw | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> |

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.

The screenshot displays the 'Subject Management' page for a study titled 'Adults with ADHD'. The page includes a header with study details, a navigation menu, and a table of subjects.

Study Management Header:

- Study Number: Adults with ADHD
- PI: Investigator, Susan M., Ph.D.
- Study Status: **Open**
- IRB Number: **GH-14-031**
- IRB Expiration Date: 09/29/2015
- 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 (ADHD)

Navigation and Filter:

- Filter Lists by Department: All
- Print Friendly button
- Submissions | **Study Management** | Subject Management
- Subject Tracking | Scheduling

Subject List:

Displaying List By: All Subject On Study Status

10 result(s) found...

| Edit | On Study Status | Last, First MI DOB - Survival Status | MRN | Participant Number | Department | Sex | Register Date | Off Study Date Off Study Reason |
|------|--------------------|---|---------|--------------------|------------|-----|---------------|------------------------------------|
| | Screen Fail | Subject, Amy 05/20/1980 - | 4534234 | 101-4 | Oncology | F | | |
| | Active | Subject, Donna 12/18/1975 - | 6543211 | 101-2 | Oncology | F | 10/03/2014 | |

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.

| | | | | | | | | |
|--|--|--|-----------------|----------------------------|-------------------------------------|--|--|--|
| Study Number: Adults with ADHD (123654) (101-1) Subject, Mickey - Subject Management | | Back | | | | | | |
| PI: Investigator, Susan M., Ph.D. | | | | | | | | |
| Study Status: Open | IRB Number : GH-14-031 | 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 (ADHD) | | | | | | |
| IRB Expiration Date: 09/29/2015 | | | | | | | | |
| <table border="1"> <tr> <td> Subject general </td> <td> Subject study registration </td> <td> Subject on study - Adults with ADHD </td> </tr> <tr> <td> <input type="radio"/> Subject Demographics <input type="radio"/> Physicians <input type="radio"/> Social history <input type="radio"/> Medication <input type="radio"/> Subject Contacts <input type="radio"/> Associated Departments </td> <td> <input type="radio"/> Insurance <input type="radio"/> Correspondence <input type="radio"/> Medical History <input type="radio"/> Allergies <input type="radio"/> General Documents </td> <td> <input type="radio"/> Study screening <input type="radio"/> On study registration information <input type="radio"/> Protocol Tracking and Project Management <input type="radio"/> Study Documents <input type="radio"/> Adverse events <input type="radio"/> Informed consent <input type="radio"/> Appointments <input type="radio"/> Calendar <input type="radio"/> Study drugs </td> </tr> </table> | | | Subject general | Subject study registration | Subject on study - Adults with ADHD | <input type="radio"/> Subject Demographics <input type="radio"/> Physicians <input type="radio"/> Social history <input type="radio"/> Medication <input type="radio"/> Subject Contacts <input type="radio"/> Associated Departments | <input type="radio"/> Insurance <input type="radio"/> Correspondence <input type="radio"/> Medical History <input type="radio"/> Allergies <input type="radio"/> General Documents | <input type="radio"/> Study screening <input type="radio"/> On study registration information <input type="radio"/> Protocol Tracking and Project Management <input type="radio"/> Study Documents <input type="radio"/> Adverse events <input type="radio"/> Informed consent <input type="radio"/> Appointments <input type="radio"/> Calendar <input type="radio"/> Study drugs |
| Subject general | Subject study registration | Subject on study - Adults with ADHD | | | | | | |
| <input type="radio"/> Subject Demographics <input type="radio"/> Physicians <input type="radio"/> Social history <input type="radio"/> Medication <input type="radio"/> Subject Contacts <input type="radio"/> Associated Departments | <input type="radio"/> Insurance <input type="radio"/> Correspondence <input type="radio"/> Medical History <input type="radio"/> Allergies <input type="radio"/> General Documents | <input type="radio"/> Study screening <input type="radio"/> On study registration information <input type="radio"/> Protocol Tracking and Project Management <input type="radio"/> Study Documents <input type="radio"/> Adverse events <input type="radio"/> Informed consent <input type="radio"/> Appointments <input type="radio"/> Calendar <input type="radio"/> Study drugs | | | | | | |

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.

| | | |
|---|------------------------------------|--|
| Study Number: NRP104.303 (323212) (101-6) Subject, Micky - Demographics | | Back |
| PI: Investigator, Susan M., Ph.D. | | |
| 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 | | |
| Save Demographics | | |
| *Last Name: Subject | First Name: Micky | MI: <input type="text"/> |
| Title: Mr. | MRN: 32321212 | Date of Birth: <input type="text"/> |
| Marital Status: Single | Age: <input type="text"/> | Gender: <input checked="" type="radio"/> Male <input type="radio"/> Female |
| Race: African American | Religion: Christianity | Ethnicity: Black |
| Language: English | Diagnosis: Sarcoma | Stage: --none-- |
| Address: <input type="text"/> | Phone Number: <input type="text"/> | Phone Type: --none-- |
| E-mail: <input type="text"/> | Phone Number: <input type="text"/> | Phone Type: --none-- |

Checked indicates subject is interested in being recruited for new study

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.

Take Note: Subject has severe peanut allergies.

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

Subject Management: (32321212) (101-6) Subject, Micky - Subject Management

IRB Number: GH-14-016 Study Title: A Phase III, Randomized, Double-Blind, Multi-Center, Placebo-Controlled, Group, Forced Dose Titration, Safety and Efficacy Study of M...

IRB Expiration Date: 03/03/2015

Subject study registration: Subject on study - NRP104.303

Insurance: Study screening

Correspondence: On study registration information

Medical History

Allergies

General Documents

Message from webpage: Subject has severe peanut allergies.

OK

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.

Survival Status: --none--

Cause Of Death: --none--

Deceased Date: [Empty]

Cause of Death Explanation: [Empty]

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.

Survival Status: Deceased



Cause Of Death: --none--

Deceased Date: [Date]

Cause of Death Explanation: [Text]

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.

Filter Lists by Department:

| Submissions | Study Management | Subject Management |
|---|------------------|-----------------------------|
|  | Deceased | Subject, Rory - Deceased |
|  | Active | Subject, Rose - |

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.

Study Number: NRP104.303 (32321212) (101-6) Subject, Micky - Physicians Back

PI: Investigator, Susan M., Ph.D.

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

[+ Add a New Physician](#)

0 result(s) found...

| <input type="checkbox"/> | Edit | Name | Specialty | Type | Last Seen | Relationship |
|---|------|------|-----------|------|-----------|--------------|
| No Physicians have been assigned to this subject. | | | | | | |

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.





Study Number: NRP104.303 (32321212) (101-6) Subject, Micky - Physicians Back

PI: Investigator, Susan M., Ph.D.

Last Name: First Name:

Specialty: --none-- Department: --none-- Search

4 result(s) found...

| Select | Name | Title | Specialty | Facility | Type | Department |
|---|-----------------------------------|------------------------|--|------------------|-----------|---|
|  | Administrator | | Orthopedist | | Attending | GH - Department GH - Oncology GH - Cardiology |
|  | Dr. Investigator, Patrick, Ph.D | Principal Investigator | Neurosurgeon | GH | Attending | GH - Department GH - Oncology GH - Cardiology |
|  | Dr. Investigator, Susan M., Ph.D. | Principal Investigator | General Practitioner Cardiology Medical Oncology | General Hospital | Attending | GH - Oncology |
|  | Investigator, P | | | GH | Attending | |

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.

Study Number: NRP104.303 (32321212) (101-6) Subject, Micky - Physicians Back

PI: Investigator, Susan M., Ph.D. Save Physician

Patient-Doctor Relationship: Primary Physician

Date Last Seen: 09/02/2014

Comments:

Physician Information

| | |
|-----------------------------------|--|
| Last Name: Investigator | Email: sinvestigator@gh.com |
| First Name: Susan | Primary Number: (909) 555-2323 |
| Middle Name: M. | Cell Number: (909) 555-8956 |
| Job Title: Principal Investigator | Paber Number: (909) 555-2324 |
| Degree: Ph.D. | Fax Number: (909) 555-2325 |
| Employee id: 000006 | Mailing Address: 1234 Main Street Redlands, CA 92374 |

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.

Study Number: NRP104.303 (32321212) (101-6) Subject, Micky - Physicians Back

PI: Investigator, Susan M., Ph.D.

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

IRB Expiration Date: 03/03/2015

+ Add a New Physician
X Delete Selected Physician(s)

1 result(s) found...

| <input type="checkbox"/> | Edit | Name | Specialty | Type | Last Seen | Relationship |
|--------------------------|------|-----------------------------------|--|-----------|------------|-------------------|
| <input type="checkbox"/> | | Dr. Investigator, Susan M., Ph.D. | General Practitioner Cardiology Medical Oncology | Attending | 09/02/2014 | Primary Physician |

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.

Study Number: NRP104.303 (32321212) (101-6) Subject, Micky - Social History Back

PI: Investigator, Susan M., Ph.D.

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

IRB Expiration Date: 03/03/2015

+ Add a Social History

List of social history information associated with this subject.


0 result(s) found...

| <input type="checkbox"/> | Edit | Social History Group | Social History Detail | Start Date | End Date |
|--|------|----------------------|-----------------------|------------|----------|
| No social history information has been added for this subject. | | | | | |

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

Study Number: NRP104.303 (32321212) (101-6) Subject, Micky - Social History Back

PI: Investigator, Susan M., Ph.D.



Add social history information associated with this subject.

| | |
|-------------|--|
| *Group: | --none-- |
| *Detail: | Alcohol Use Exercise Illicit Drug Use Marital Status Tobacco Use |
| Start Date: | |
| End Date: | |
| Comments: | |

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

Add social history information associated with this subject.

| | |
|-------------|--|
| *Group: | Tobacco Use |
| *Detail: | --none-- <10 cigarettes/day >60 cigarettes/day 10-30 cigarettes/day 30-60 cigarettes/day none |
| Start Date: | |
| End Date: | |

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.

Study Number: NRP104.303 (32321212) (101-6) Subject, Micky - Social History Back

PI: Investigator, Susan M., Ph.D.

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 ▲

IRB Expiration Date: 03/03/2015

List of social history information associated with this subject.

1 result(s) found...

| <input type="checkbox"/> | Edit | Social History Group | Social History Detail | Start Date | End Date |
|--------------------------|---|----------------------|-----------------------|------------|----------|
| <input type="checkbox"/> |  | Tobacco Use | <10 cigarettes/day | 06/01/1998 | |

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.

Study Number: NRP104.303 (32321212) (101-6) Subject, Micky - Medication Back
 PI: Investigator, Susan M., Ph.D.

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
 IRB Expiration Date: 03/03/2015

Print Friendly Add a New Medication

List of medications associated with this subject.

0 result(s) found...

| <input type="checkbox"/> | Edit | Medication | Indication | Dosage | Regimen | Route | Start Date | End Date |
|---|------|------------|------------|--------|---------|-------|------------|----------|
| No medication information has been added to this subject. | | | | | | | | |

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.

Study Number: NRP104.303 (32321212) (101-6) Subject, Micky - Medication Back
 PI: Investigator, Susan M., Ph.D.

Save Medication

Add medication information associated with this subject.

Medication:

Other Medication:

Indication:

Dosage:

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.

Study Number: NRP104.303 (32321212) (101-6) Subject, Micky - Medication Back
 PI: Investigator, Susan M., Ph.D.

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
 IRB Expiration Date: 03/03/2015

Print Friendly Add a New Medication Delete Selected Medication(s)

List of medications associated with this subject.

1 result(s) found...

| <input type="checkbox"/> | Edit | Medication | Indication | Dosage | Regimen | Route | Start Date | End Date |
|--------------------------|------|---------------|------------|--------|-------------------|-----------|------------|----------|
| <input type="checkbox"/> | | Acetaminophen | | 500 mg | BID - Twice a day | PO - Oral | 09/11/2014 | |

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.

Study Number: NRP104.303
PI: Investigator, Susan M., Ph.D.
(32321212) (101-6) Subject, Micky - Contacts
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

IRB Expiration Date: 03/03/2015

+ Add a New Contact

Personal

Facility

List of personal contacts associated with this subject.

0 result(s) found...

| | Edit | Name | Relationship |
|--|------|------|--------------|
| No personal contacts associated with this subject. | | | |

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.

Personal

Facility

Add a personal contact associated with this study.

*** Name:**

Relationship:

Comments:

Primary Address:

Street:

City:

State: CA

Zip/Postal Code:

Secondary Address:

Street:

City:

State: CA

Zip/Postal Code:

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

Personal | **Facility**

Add a facility contact associated with this subject.

* **Name:**

Facility Contact:

Tests:

Local Contact:

Reports:

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.

Study Number: NRP104.303 (32321212) (101-6) Subject, Micky - Contacts Back

PI: Investigator, Susan M., Ph.D.

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

IRB Expiration Date: 03/03/2015

Personal | **Facility**

List of personal contacts associated with this subject.

1 result(s) found...

| <input type="checkbox"/> | Edit | Name | Relationship |
|--------------------------|------|-----------------------|--------------|
| <input type="checkbox"/> | | Personal Contact Name | Father |

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.

| | | | | |
|--|-------------------------------|---|--|------|
| Study Number: NRP104.303 | | (32321212) (101-6) Subject, Micky - Associated Departments | | Back |
| PI: Investigator, Susan M., Ph.D. | | | | |
| 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 | |
| IRB Expiration Date: 03/03/2015 | | Save Patient Departments | | |
| <input checked="" type="checkbox"/> Departments Associated With This Patient <input type="checkbox"/> Department <input checked="" type="checkbox"/> Oncology | | Departments Associated With This Study GH - 12345 - Department GH - 00232 - Oncology | | |

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.

| | | | | | | |
|-------------------------------------|-------------------------------|--|--|-------------------|-----------------|---------------|
| Study Number: NRP104.303 | | (32321212) (101-6) Subject, Micky - Insurance | | Back | | |
| PI: Investigator, Susan M., Ph.D. | | | | | | |
| 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 | | | |
| IRB Expiration Date: 03/03/2015 | | + Add a New Insurance | | | | |
| <input checked="" type="checkbox"/> | Edit | Insurance Name | Policy Number | Valid From | Valid To | Status |
| No insurances have been added. | | | | | | |

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.

| | | | | |
|-----------------------------------|-----------|--|-------------------|----------------|
| Study Number: NRP104.303 | | (32321212) (101-6) Subject, Micky - Insurance | | Back |
| PI: Investigator, Susan M., Ph.D. | | | | |
| | | | Cancel And Return | Save Insurance |
| Add/Edit Patient Insurance | | | | |
| *Select an insurance: | BlueCross | | | |
| Insurance Status: | Active | | | |
| Insurance is valid from: | | | | |
| Insurance is valid to: | | | | |
| Policy Number: | | | | |

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.

Study Number: NRP104.303 (32321212) (101-6) Subject, Micky - Insurance Back

PI: Investigator, Susan M., Ph.D.

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

IRB Expiration Date: 03/03/2015

+ Add a New Insurance
X Delete Selected Insurance(s)

| | Edit | Insurance Name | Policy Number | Valid From | Valid To | Status |
|--------------------------|------|----------------|---------------|------------|------------|--------|
| <input type="checkbox"/> | | BlueCross | R4543 | 01/01/2013 | 01/01/2014 | Active |

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.

Study Number: NRP104.303 (32321212) (101-6) Subject, Micky - Notes Back

PI: Investigator, Susan M., Ph.D.

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

IRB Expiration Date: 03/03/2015

+ Add a New Correspondence

List of correspondence associated with this subject.

0 result(s) found...

| | Edit/View | Last Edited By | Original Date | Modified Date | Correspondence |
|--|-----------|----------------|---------------|---------------|----------------|
| No notes have been added to this subjects notebook | | | | | |

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

Study Number: NRP104.303 (32321212) (101-6) Subject, Micky - Notes Back

Save correspondence

Edit a note associated with this subject.

Note:

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.

| | | | | | |
|--|---------------------------------|--|----------------------------------|------------------------|--|
| Study Number: NRP104.303 | | (32321212) (101-6) Subject, Micky - Notes | | Back | |
| PI: Investigator, Susan M., Ph.D. | | | | | |
| 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 | | | |
| | IRB Expiration Date: 03/03/2015 | | | | |
| | | + Add a New Correspondence | x Delete Selected Correspondence | | |
| List of correspondence associated with this subject. | | | | | |
| 1 result(s) found... | | | | | |
| <input type="checkbox"/> | Edit/View | Last Edited By | Original Date | Modified Date | Correspondence |
| <input type="checkbox"/> | | Coordinator, Mary Jane | 09/11/2014 04:17:20 PM | 09/11/2014 04:17:20 PM | Spoke with subject on the phone discussing test results. |

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.

| | | | | |
|---|---------------------------------|--|-----------------------|----------|
| Study Number: NRP104.303 | | (32321212) (101-6) Subject, Micky - Medical History | | Back |
| PI: Investigator, Susan M., Ph.D. | | | | |
| 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 | | |
| | IRB Expiration Date: 03/03/2015 | | | |
| | | Print Friendly | + Add Medical History | |
| List of medical history information associated with this subject. | | | | |
| 0 result(s) found... | | | | |
| <input type="checkbox"/> | Edit | Condition | Start Date | End Date |
| No medical history information has been added for this subject. | | | | |

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.

Study Number: NRP104.303 (32321212) (101-6) Subject, Micky - Medical History Back


PI: Investigator, Susan M., Ph.D.


 Save Medical History

Add medical history information associated with this subject.

Condition: Asthma

Other Condition:

Start Date: 09/01/1983 

End Date: 

Comments:




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.

Study Number: NRP104.303 (32321212) (101-6) Subject, Micky - Medical History Back

PI: Investigator, Susan M., Ph.D.


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 ▲▼

IRB Expiration Date: 03/03/2015

 Print Friendly  Add Medical History  Delete Selected Medical History

List of medical history information associated with this subject.

1 result(s) found...

| <input checked="" type="checkbox"/> | Edit | Condition | Start Date | End Date |
|-------------------------------------|---|-----------|------------|----------|
| <input type="checkbox"/> |  | Asthma | 09/01/1983 | |

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.

Study Number: NRP104.303 (32321212) (101-6) Subject, Micky - Allergies Back
 PI: Investigator, Susan M., Ph.D.

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
 IRB Expiration Date: 03/03/2015

Print Friendly Add a New Allergy

List of allergies associated with this subject.

0 result(s) found...

| <input checked="" type="checkbox"/> | Edit | Allergen | Reaction |
|---|------|----------|----------|
| No allergies have been added to this subject. | | | |

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.

Study Number: NRP104.303 (32321212) (101-6) Subject, Micky - Allergies Back
 PI: Investigator, Susan M., Ph.D.

Save Allergy

Add an allergy associated with this subject.

Allergen: FOOD - PEANUT

Other Allergen:

Reaction:

Comments:

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.

Study Number: NRP104.303 (32321212) (101-6) Subject, Micky - Allergies Back
 PI: Investigator, Susan M., Ph.D.

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
 IRB Expiration Date: 03/03/2015

Print Friendly Add a New Allergy Delete Selected Allergies

List of allergies associated with this subject.

1 result(s) found...

| <input checked="" type="checkbox"/> | Edit | Allergen | Reaction |
|-------------------------------------|------|---------------|----------------|
| <input type="checkbox"/> | | FOOD - PEANUT | Swelling, rash |

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.

Study Number: NRP104.303 (32321212) (101-6) Subject, Micky - Documents & Images Back
 PI: Investigator, Susan M., Ph.D.
 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
 IRB Expiration Date: 03/03/2015

Print Friendly + Add a New Document

Documents Images

List of documents associated with this subject.

Select A Category: All

0 result(s) found...

| <input type="checkbox"/> | Edit | File Type | Date Modified | Title | Category | Description |
|--|------|-----------|---------------|-------|----------|-------------|
| No documents associated with this subject. | | | | | | |

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

Documents Images

Add a document associated with this subject.

*Title: Subject Test Results

Category: Other

Description:

Upload Document: Upload ...

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.

Document Location: Browse...

Instruction: Uploading a document into iRIS™ requires locating the document on the computer. Once you have located the document click on the 'Save selected file' button. The buttons will become disabled. If the document is a large document the window will stay in place until the upload operation has completed.

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.

Study Number: NRP104.303 (32321212) (101-6) Subject, Micky - Documents & Images Back
 PI: Investigator, Susan M., Ph.D. Study Title: A Phase III, Randomized, Double-Blind, Multi-Center, Placebo-Controlled, Parallel-Group, Forced Dose Titration, Safety and Efficacy Study of

Study Status: **Open** IRB Number : **GH-14-016** IRB Expiration Date: 03/03/2015

Print Friendly Add a New Document Delete Selected Document(s)

Documents | Images

List of documents associated with this subject.

Select A Category: All

1 result(s) found...

| <input type="checkbox"/> | Edit | File Type | Date Modified | Title | Category | Description |
|--------------------------|------|-----------|---------------|----------------------|----------|-------------|
| <input type="checkbox"/> | | | 09/11/2014 | Subject Test Results | Other | |

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.

| Documents | | Images | | | | |
|---|------|--------|---------------|---------------|---------------|-------------|
| List of image documents associated with this subject. | | | | | | |
| 1 result(s) found... | | | | | | |
| <input type="checkbox"/> | Edit | Image | Patient Photo | Date Modified | Title | Description |
| <input type="checkbox"/> | | | Yes | 09/11/2014 | Patient Photo | |

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

| | | | | | | |
|-----------------------------------|-------------------------------|--|--------------|----------------------|----------------|--|
| Study Number: NRP104.303 | | (32321212) (101-6) Subject, Micky - Demographics | | Back | | |
| PI: Investigator, Susan M., Ph.D. | | | | | | |
| 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 | | | | |
| IRB Expiration Date: 03/03/2015 | | Save Demographics | | | | |
| | *Last Name | Subject | First Name | Micky | MI | |
| | Title | Mr. | MRN | 32321212 | Date of Birth | <input type="text"/> |
| | Marital Status | Single | Age | <input type="text"/> | Gender | <input checked="" type="radio"/> Male <input type="radio"/> Female |
| | Race | --none-- | Religion | --none-- | Ethnicity | --none-- |
| | Language | English | Diagnosis | Sarcoma | Stage | --none-- |
| | | | | | Place of Birth | <input type="text"/> |
| | | | Phone Number | <input type="text"/> | Phone Type | --non |

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 Number: NRP104.303 (32321212) (101-6) Subject, Micky - Subject Management Back
 PI: Investigator, Susan M., Ph.D.
 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

Subject general

- Subject Demographics
- Physicians
- Social history
- Medication
- Subject Contacts

Subject study registration

- Study screening information
- On study registration information

Subject on study - NRP104.303

- Protocol Tracking and Project Management
- Study Documents
- Adverse events
- Informed consent
- Appointments
- Calendar
- Study drugs

Take Notice: This subject is registered on multiple studies:

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.

Study Number: Adults with ADHD (989794) (101-7) Subject, Donna - Subject Screening Back
 PI: Investigator, Susan M., Ph.D.
 Study Status: **Open** IRB Number: **GH-14-031** 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 (ADHD)
 IRB Expiration Date: 09/29/2015

* Medical Record Number(MRN):
 Participant Number:
 *Last Name:
 First Name:
 Middle Initial:
 * Screening Date:
 Screening Failure:

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.

Study Number: NRP104.303 (989794) (101-7) Subject, Donna - Subject Screening Back
 PI: Investigator, Susan M., Ph.D.
 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
 IRB Expiration Date: 03/03/2015

List of screening records associated with this subject.

1 result(s) found...

| <input type="checkbox"/> | Edit | Screening Failure | Reason | Screening Date | Primary CRC | Secondary CRC |
|--------------------------|-------------------------------------|-------------------|--------|----------------|-------------|---------------|
| <input type="checkbox"/> | <input type="button" value="Edit"/> | No | | 09/04/2014 | | |

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.

| Submissions | | Study Management | | Subject Management | |
|----------------------|-----------------|--|----------|--------------------|--|
| Subject Tracking | | Scheduling | | | |
| 4 result(s) found... | | | | | |
| Edit | On Study Status | Last, First MI DOB - Survival Status | MRN | Partic Numbr | |
| | Active | Jones, Mike 05/21/1974 - Alive | 345678 | 101-3 | |
| | Active | Subject, George M. 08/01/1950 - Alive | 12356 | 101-1 | |
| | Expired | Subject, John S. 09/01/1964 - Alive | 42345546 | 101-2 | |
| | Screen Fail | Subject, Martha - | 56564545 | 101-4 | |

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.

Study Number: NRP104.303 (989794) (101-7) Subject, Donna - Subject Screening Back

PI: Investigator, Susan M., Ph.D. Save Screening

Edit the screening record for the select subject and study.

| | |
|--------------------|--------------------------|
| * Screening Date: | 09/04/2014 |
| Screening Failure: | <input type="checkbox"/> |
| Reason: | --none-- |
| Primary CRC: | --none-- |
| Secondary CRC: | --none-- |
| Comments: | |

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.

| INCLUSION CRITERIA | |
|--|---|
| Meets Criteria | Definition |
| <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Not Done <input type="radio"/> N/A | Must be 18-55 years of age, inclusive. |
| <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Not Done <input type="radio"/> N/A | Must be male or non-pregnant female. Females of childbearing potential (FOCP) must use contraception. |
| <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Not Done <input type="radio"/> N/A | Must have 12-lead ECGs defined by the following parameters: <ol style="list-style-type: none"> QT/QTcF interval < 450 msec for males and < 470 msec for females Resting heart rate is between 40 and 100 beats per minute P-R interval < 200 msec QRS interval <110 msec. |
| EXCLUSION CRITERIA | |
| Meets Criteria | Definition |
| <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Not Done <input type="radio"/> N/A | In the opinion of the investigator, the subject is significantly underweight [e.g., Body Mass Index (BMI) < 18.5] |

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.

Study Number: Adults with ADHD (123321123) (101-6) Subject, Jack - Study Registration Back

PI: Investigator, Susan M., Ph.D.

Study Status: **Open** IRB Number: **GH-14-031** 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 (ADHD)

IRB Expiration Date: 09/29/2015

Save Changes

*Subject Status: Active

Participant Number: 101-6 Enrolling Physician: --none--

Enrolling CRC: Coordinator, Mary Jane, R.N. *Following CRC: Coordinator, Mary Jane, R.N.

Registration Date: 09/03/2014

Treatment Start: Projected Treatment Completion: Treatment Completion:

Off Study Date: Off Study Reason: --none--

Comments:

Add a New Arm Delete Arm

| Arm Name | Protocol Start Date | Randomization Number | Randomization Start Date | Randomization By | Last Assessment Date |
|----------|---------------------|----------------------|--------------------------|------------------|----------------------|
|----------|---------------------|----------------------|--------------------------|------------------|----------------------|

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.

| On Study Status | Patient ID | Date |
|-----------------|------------|-------------------------|
| Enrolling | 16 | 2014-09-09 16:16:17.41 |
| Active | 16 | 2014-09-09 16:16:27.027 |
| Follow-up | 16 | 2014-09-12 15:16:23.317 |

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.

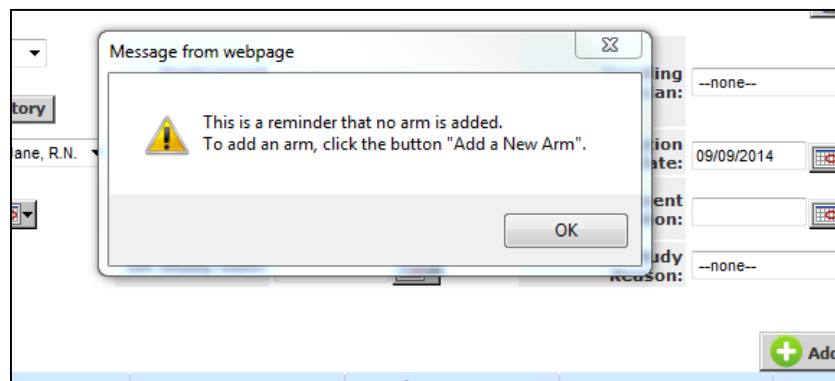
Treatment Completion- You can enter the actual Treatment Completion Date in this field. This date will be used to pull into certain reports.

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.


| Off Study Date: | | Off Study Reason: --none-- | | | |
|---|---------------------|----------------------------|--------------------------|------------------|----------------------|
| Comments: | | | | | |
| <input type="button" value="+ Add a New Arm"/> | | | | | |
| Arm Name | Protocol Start Date | Randomization Number | Randomization Start Date | Randomization By | Last Assessment Date |
| There are no arms associated with this patient. | | | | | |

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.

Study Number: NRP104.303 **(4567765432) (101-9) Subject, Jack - Arm Selection** Back

PI: Investigator, Susan M., Ph.D.



Select the study template: Template 7

Select the arm(s) you want to enroll this patient in:

Arm 1

Placebo

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.

| + Add a New Arm x Delete Arm | | | | | | |
|---|---------------------|---|----------------------|--------------------------|------------------|----------------------|
| | Arm Name | Protocol Start Date | Randomization Number | Randomization Start Date | Randomization By | Last Assessment Date |
| <input type="checkbox"/> | Template 7 -- Arm 1 | 09/12/2014 <small>Clear schedules?</small> | | | --none-- | |

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.

| + Add a New Arm x Delete Arm | | | | | | |
|---|---------------------|---------------------|----------------------|--------------------------|------------------|----------------------|
| | Arm Name | Protocol Start Date | Randomization Number | Randomization Start Date | Randomization By | Last Assessment Date |
| <input type="checkbox"/> | Template 7 -- Arm 1 | 09/11/2014 | | | --none-- | 09/12/2014 |

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.

Study Number: NRP104.303 (4567765432) (101-9) Subject, Jack - Subject Management Back
 PI: Investigator, Susan M., Ph.D.
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
IRB Expiration Date: 03/03/2015

| | | |
|---|--|--|
| Subject general | Subject study registration | Subject on study - NRP104.303 |
| <input type="radio"/> Subject Demographics <input type="radio"/> Physicians <input type="radio"/> Social history <input type="radio"/> Medication <input type="radio"/> Insurance <input type="radio"/> Correspondence <input type="radio"/> Medical History <input type="radio"/> Allergies | <input type="radio"/> Study screening <input type="radio"/> On study registration information | <input type="radio"/> Protocol Tracking and Project Management <input type="radio"/> Study Documents <input type="radio"/> Adverse events <input type="radio"/> Informed consent <input type="radio"/> Appointments <input type="radio"/> Calendar <input type="radio"/> Study drugs |

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**, **Completed 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.

Study Number: NRP104.303 (32321212) (101-6) Subject, Micky - Protocol Tracking Back
 PI: Investigator, Susan M., Ph.D.
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
IRB Expiration Date: 03/03/2015 Print Summary

Incomplete Visits | **Completed Visits** | **Pending Tasks**

Filter by arm: Template 8 -- Arm 1

5 result(s) found... 1 - 5

+ Add a New Visit

| Edit | Task | Sub Req. | Completion Window | Target Date | Sched | Schedule Date/ Appt. Duration |
|------|---------|----------|-------------------------|-------------|-------|--|
| | Visit 1 | No | 09/13/2014 - 09/17/2014 | 09/15/2014 | | 09/15/2014 03:00:00 PM / 60 Minutes |
| | Visit 2 | No | 09/20/2014 - 09/24/2014 | 09/22/2014 | | 09/22/2014 03:00:00 PM / 60 Minutes |
| | Visit 3 | No | 09/27/2014 - 10/01/2014 | 09/29/2014 | | |

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.

Study Number: NRP104.303
PI: Investigator, Susan M., Ph.D. **(32321212) (101-6) Subject, Micky - Schedule Appointment** [Back](#)

[Save Changes](#) [View Availability](#)

Study Number: NRP104.303
Task: Visit 3
Visit Type: Clinic Visit
Target Date: 09/29/2014
Completion Window: 09/27/2014 - 10/01/2014

Scheduled Date:
Scheduled Time: 08 : 00 AM PM **Duration:** 60 Minutes

| Personnel: | Appointment Personnel: |
|---|------------------------|
| Administrator Coordinator, Mary Jane Investigator, Patrick Investigator, Susan M.. Staff, Stacy | |

[Comments](#)

<< >>

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.

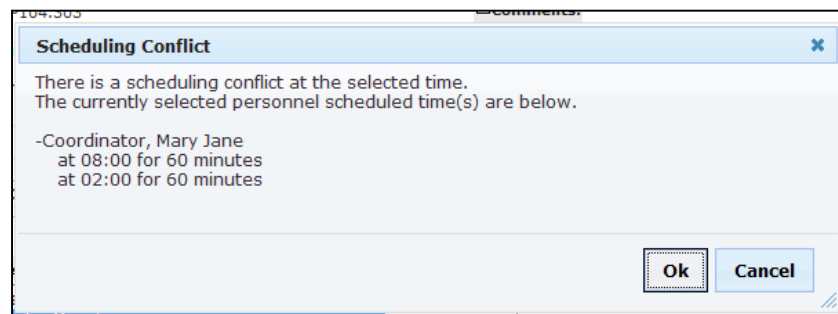
On this page, you can select a date in the **Scheduled Date** field and adjust the **Scheduled Time** by selecting the time in hours/minutes, AM or PM and then set the **Duration**. You can also add comments by clicking on the **Comments** link.

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.

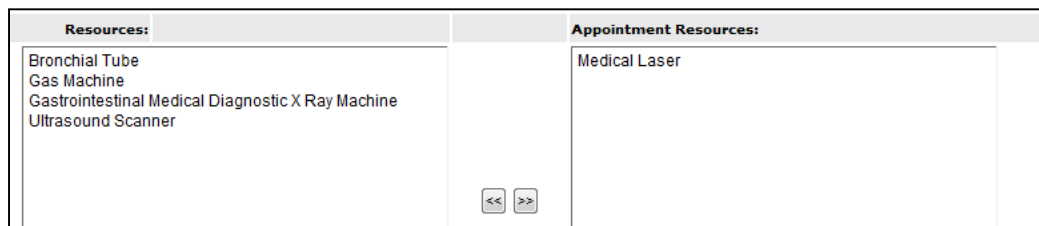
| Personnel: | Appointment Personnel: |
|--|------------------------|
| Administrator Investigator, Patrick Investigator, Susan M.. Staff, Stacy User, Aaron COL. | Coordinator, Mary Jane |

<< >>

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

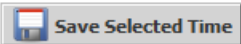
schedule a visit in any of the time blocks, even if a user is associated to another visit or has flagged a block of time as unavailable.

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.

Study Number: NRP104.303 (4567765432) (101-9) Subject, Jack - Schedule Appointment Back

PI: Investigator, Susan M., Ph.D.




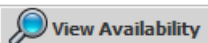
Priority by: Selected personnels Date: 09/30/2014 08 : 00 AM PM Duration: 60 Minutes

| Time | Administra... | Coordinato... | Staff, Stacy | Medical La... |
|-------|-------------------------------|---------------|--------------|---------------|
| 08:00 | 08:00-08:15 | * | | |
| | 08:15-08:30 | * | | |
| | 08:30-08:45 | * | | |
| | 08:45-09:00 | * | | |
| 09:00 | Time selector 9:00 - 10:00 | | | |
| 10:00 | 10:00-10:15 | | | |
| | 10:15-10:30 | | | |
| | 10:30-10:45 | | | |
| | 10:45-11:00 | | | |
| 11:00 | 11:00-11:15 | | | |
| | 11:15-11:30 | | | |
| | 11:30-11:45 | | | |
| | 11:45-12:00 | | | |
| 12:00 | 12:00-12:15 | | | |
| | 12:15-12:30 | | | |
| | 12:30-12:45 | | | |
| | 12:45-13:00 | | | |
| 13:00 | 13:00-13:15 | | | |

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.

Study Number: NRP104.303 (4567765432) (101-9) Subject, Jack - Schedule Appointment Back

PI: Investigator, Susan M., Ph.D.

Study Number: NRP104.303

Task: Visit 2

Visit Type: Clinic Visit

Target Date: 09/30/2014

Completion Window: 09/28/2014 - 10/02/2014

Scheduled Date: 09/30/2014

Scheduled Time: 09 : 00 AM PM Duration: 60 Minutes

Comments:

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.

| Incomplete Visits | | Completed Visits | | Pending Tasks | | |
|--|---------|------------------|-------------------------|---------------|-------|--|
| Filter by arm: Template 9 -- Arm 1 | | | | | | |
| 4 result(s) found... 1 - 4 | | | | | | |
| + Add a New Visit + Extend Template Visits | | | | | | |
| Edit | Task | Sub Req. | Completion Window | Target Date | Sched | Schedule Date/ Appt. Duration |
| | Visit 2 | No | 09/28/2014 - 10/02/2014 | 09/30/2014 | | 09/30/2014 09:00:00 AM / 60 Minutes |
| | Visit 3 | No | 10/05/2014 - 10/09/2014 | 10/07/2014 | | |
| | Visit 4 | No | 10/12/2014 - 10/16/2014 | 10/14/2014 | | |

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.

Study Number: NRP104.303 (4567765432) (101-9) Subject, Jack - Visit Details Back

PI: Investigator, Susan M., Ph.D.

+ Add Stipend Request
 Schedule Visit
 Print Worksheet
 Save Changes

Visit Name: Visit 2

Visit Type: Clinic Visit

Description:

Target Date: 09/30/2014

Completion Window: 09/28/2014 - 10/02/2014

Arm: Arm 1

Status: Incomplete

Assessment Date:

Comments:

| Description | Open Form | Procedure | Canceled | Complete | Incomplete | No Show | Not Done |
|---------------------------------|-----------|---|-----------------------|-----------------------|----------------------------------|-----------------------|-----------------------|
| (Category not specified) | | | | | | | |
| | | Check-in | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| (Category not specified) | | | | | | | |
| | | Angiogram Of Heart (Coronary Angiogram) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | | Blood Draw | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | | CAT Scan | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | | Fundoplication | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | | GFR/Global Family Rating | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Outpatient Procedure | | | | | | | |
| | | Acupuncture | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> |

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.

| Description | Open Form | Procedure | Canceled | Complete | Incomplete | No Show | Not Done |
|---|---|--------------------------------|-----------------------|-----------------------|----------------------------------|-----------------------|-----------------------|
| (Category not specified) | | | | | | | |
|  |  | Check-in | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Outpatient Procedure | | | | | | | |
|  |  | Acupuncture | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> |
|  | | Amniotic Fluid (Amniocentesis) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Blood Work | | | | | | | |
|  | | ANC- Absolute Neutrophil Count | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| (Category not specified) | | | | | | | |
|  | | Case Report Form | | | | | |

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

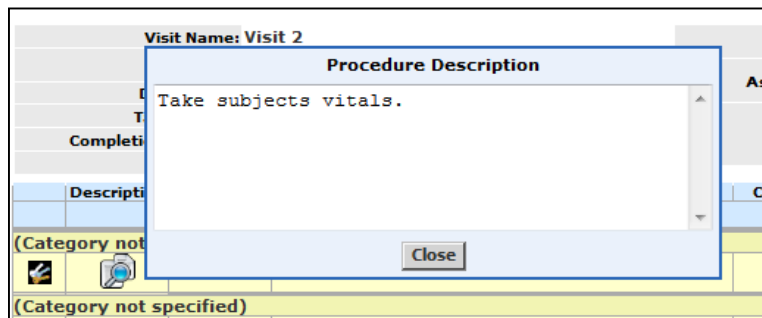
 - Clinical Procedure

 - 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.

Personnel Involved :

Administrator

Coordinator, Mary Jane, R.N.

Investigator, Susan M., Ph.D.

Investigator, Patrick, Ph.D

Staff, Stacy

Staff, Tim

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 Name: Visit 1 | | Status: Complete | |
| Visit Type: --none-- | | Assessment Date: 09/16/2014 | |
| Description: | | Comments: | |
| Target Date: 09/22/2014 | | | |
| Completion Window: 09/20/2014 - 09/23/2014 | | | |
| Arm: Placebo | | | |

| Description | Open Form | Procedure | Canceled | Complete | Incomplete | No Show | Not Done |
|---------------------------------|-----------|---|-----------------------|----------------------------------|-----------------------|-----------------------|-----------------------|
| (Category not specified) | | | | | | | |
| | | Call Coordinating Center | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| (Category not specified) | | | | | | | |
| | | Angiogram Of Heart (Coronary Angiogram) | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | | Fundoplication | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | | GFR/Global Family Rating | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

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.

| | |
|---|------------------------------------|
| Visit Name: Visit 2 | Status: Complete |
| Visit Type: Initial Vist | Assessment Date: 09/16/2014 |
| Description: | Comments: |
| Target Date: 09/29/2014 | |
| Completion Window: 09/27/2014 - 09/30/2014 | |
| Arm: Placebo | |

| Description | Open Form | Procedure | Canceled | Complete | Incomplete | No Show | Not Done |
|---------------------------------|-----------|---|-----------------------|----------------------------------|----------------------------------|-----------------------|-----------------------|
| (Category not specified) | | | | | | | |
| | | Angiogram Of Heart (Coronary Angiogram) | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | | Fundoplication | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | | GFR/Global Family Rating | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

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.

| | | | |
|--|--|-------------------------------|---|
| Study Number: NRP104.303 | (989794) (101-7) Subject, Donna - Protocol Tracking | | Back |
| PI: Investigator, Susan M., Ph.D. | 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 |
| | IRB Expiration Date: 03/03/2015 | | Print Summary |

| | | |
|--------------------------|-------------------------|----------------------|
| Incomplete Visits | Completed Visits | Pending Tasks |
|--------------------------|-------------------------|----------------------|

Filter by arm: Template 9 -- Placebo

| Edit | Task | Task Status | Assessment Date | Submission Date | Target Date | Schedule Date/ Appt. Duration |
|------|---------|-------------|-----------------|-----------------|-------------|-------------------------------|
| | Visit 2 | Complete | 09/16/2014 | | 09/29/2014 | |

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.

| | |
|---|------------------------------------|
| Visit Name: Visit 3 | Status: Complete |
| Visit Type: Initial Vist | Assessment Date: 09/16/2014 |
| Description: | Comments: |
| Target Date: 10/06/2014 | |
| Completion Window: 10/04/2014 - 10/07/2014 | |
| Arm: Placebo | |

| Description | Open Form | Procedure | Canceled | Complete | Incomplete | No Show | Not Done |
|---------------------------------|-----------|---|----------------------------------|----------------------------------|-----------------------|-----------------------|-----------------------|
| (Category not specified) | | | | | | | |
| | | Angiogram Of Heart (Coronary Angiogram) | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | | Fundoplication | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | | GFR/Global Family Rating | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

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.

| | |
|---|--|
| Visit Name: Visit 5 | Status: Canceled |
| Visit Type: Clinic Visit | Assessment Date: <input type="text"/> |
| Description: | Comments: |
| Target Date: 11/17/2014 | |
| Completion Window: 11/15/2014 - 11/18/2014 | |
| Arm: Placebo | |

| Description | Open Form | Procedure | Canceled | Complete | Incomplete | No Show | Not Done |
|---------------------------------|-----------|---|----------------------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| (Category not specified) | | | | | | | |
| | | Angiogram Of Heart (Coronary Angiogram) | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | | Fundoplication | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | | GFR/Global Family Rating | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

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.

| | |
|---|--|
| Visit Name: Visit 5 | Status: No Show |
| Visit Type: Clinic Visit | Assessment Date: <input type="text"/> |
| Description: | Comments: |
| Target Date: 11/17/2014 | |
| Completion Window: 11/15/2014 - 11/18/2014 | |
| Arm: Placebo | |

| Description | Open Form | Procedure | Canceled | Complete | Incomplete | No Show | Not Done |
|---------------------------------|-----------|---|-----------------------|-----------------------|-----------------------|----------------------------------|-----------------------|
| (Category not specified) | | | | | | | |
| | | Angiogram Of Heart (Coronary Angiogram) | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> |
| | | Fundoplication | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> |
| | | GFR/Global Family Rating | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> |

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.

Study Number: NRP104.303 (4567765432) (101-9) Subject, Jack - Protocol Tracking Back

PI: Investigator, Susan M., Ph.D.

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

IRB Expiration Date: 03/03/2015 Print Summary

Incomplete Visits **Completed Visits** **Pending Tasks**

Filter by arm: Template 7 -- Arm 1 A new template plan version has been published for this study. Click here to transfer this subject to the new version.

4 result(s) found... 1 - 4

+ Add a New Visit

| Edit | Task | Sub Req. | Completion Window | Target Date | Sched | Schedule Date/ Appt. Duration |
|------|---------|----------|-------------------------|-------------|-------|----------------------------------|
| | Visit 2 | No | 09/24/2014 - 09/28/2014 | 09/26/2014 | | |
| | Visit 3 | No | 10/01/2014 - 10/05/2014 | 10/03/2014 | | |
| | Visit 4 | No | 10/08/2014 - 10/10/2014 | 10/10/2014 | | |

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.

Study Number: NRP104.303 (4567765432) (101-9) Subject, Jack - Plan Template Transfer Back

PI: Investigator, Susan M., Ph.D.

Screen Instructions Perform Subject Transfer

Legend:
● Red: Complete/Closed
● Yellow: Cancel
● Green: Active/In Process

Current Arm Enrollments

Arm: Template 7 -- Arm 1

Please select the visits to cancel for this arm:

| Action | Task | State | Target |
|-------------------------------------|---------|------------|------------|
| <input checked="" type="checkbox"/> | Visit 1 | Complete | 09/19/2014 |
| <input type="checkbox"/> | Visit 2 | Incomplete | 09/26/2014 |
| <input type="checkbox"/> | Visit 3 | Incomplete | 10/03/2014 |
| <input type="checkbox"/> | Visit 4 | Incomplete | 10/10/2014 |
| <input type="checkbox"/> | Visit 5 | Incomplete | 10/17/2014 |

Available Transfer Arms

Protocol Start: Arm: Template 8 -- Arm 1

Please select the starting visit for the transfer arm:

| Action | Task |
|-----------------------|---------|
| <input type="radio"/> | Visit 1 |
| <input type="radio"/> | Visit 2 |
| <input type="radio"/> | Visit 3 |
| <input type="radio"/> | Visit 4 |
| <input type="radio"/> | Visit 5 |

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.

Current Arm Enrollments

Arm:

Please select the visits to cancel for this arm:

| <input type="checkbox"/> | Action | Task | State | Target |
|-------------------------------------|--------|---------|------------|------------|
| <input type="checkbox"/> | ▶ | Visit 1 | Complete | 09/19/2014 |
| <input checked="" type="checkbox"/> | ▶ | Visit 2 | Incomplete | 09/26/2014 |
| <input checked="" type="checkbox"/> | ▶ | Visit 3 | Incomplete | 10/03/2014 |
| <input checked="" type="checkbox"/> | ▶ | Visit 4 | Incomplete | 10/10/2014 |
| <input checked="" type="checkbox"/> | ▶ | Visit 5 | Incomplete | 10/17/2014 |

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.

Available Transfer Arms

Protocol Start: Arm:

Please select the starting visit for the transfer arm:

| <input type="radio"/> | Action | Task |
|----------------------------------|--------|---------|
| <input type="radio"/> | ▶ | Visit 1 |
| <input checked="" type="radio"/> | ▶ | Visit 2 |
| <input type="radio"/> | ▶ | Visit 3 |
| <input type="radio"/> | ▶ | Visit 4 |
| <input type="radio"/> | ▶ | Visit 5 |

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.

Incomplete Visits | **Completed Visits** | **Pending Tasks**

Filter by arm: Template 9 -- Arm 1

4 result(s) found... 1 - 4

+ Add a New Visit
+ Extend Template Visits

| Edit | Task | Sub Req. | Completion Window | Target Date | Sched | Schedule Date/ Appt. Duration |
|------|---------|----------|-------------------------|-------------|-------|----------------------------------|
| | Visit 2 | No | 09/28/2014 - 10/02/2014 | 09/30/2014 | | |
| | Visit 3 | No | 10/05/2014 - 10/09/2014 | 10/07/2014 | | |

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.

Incomplete Visits | **Completed Visits** | **Pending Tasks**

Filter by arm: Template 7 -- Arm 1

5 result(s) found... 1 - 5

| Edit | Task | Sub Req. | Task Status / Modified By | Assessment Date | Submission Date | Target Date | Completion Window |
|------|---------|----------|---|-----------------|-----------------|-------------|-------------------------|
| | Visit 1 | No | Complete / Coordinator, Mary Jane, R.N. | 09/15/2014 | | 09/19/2014 | 09/17/2014 - 09/21/2014 |
| | Visit 2 | No | Cancelled / Coordinator, Mary Jane, R.N. | | | 09/26/2014 | 09/24/2014 - 09/28/2014 |
| | | | Cancelled / | | | | |

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.

The screenshot shows the 'Add Visit' form for Study Number NRP104.303 (4567765432) (101-9) Subject, Jack. The form includes the following fields and controls:

- Study Information:** Study Number: NRP104.303, PI: Investigator, Susan M., Ph.D., (4567765432) (101-9) Subject, Jack - Add Visit. Buttons: Back, Print Worksheet, Save Changes.
- Visit Details:**
 - *Visit Name: [Text Field]
 - Target Date: [Date Picker]
 - Arm: Template 7 -- Arm 1 [Dropdown]
 - Visit Type: --none-- [Dropdown]
 - Visit Status: Incomplete [Dropdown]
 - Comments: [Text Area]
 - Visit Duration: [Text Field] --none-- [Dropdown]
 - Deviation Window: [Text Field] --none-- [Dropdown] Minus Plus
 - Schedulable: [Checkbox]
 - Description: [Text Area]
 - Assessment Date: [Date Picker]
 - Insert Before: --none-- [Dropdown]
- Actions:** Add Case Report Forms, Add Clinical Tasks, Add Administrative Tasks, Delete Tasks.
- Task List:**

| Procedure | Canceled | Complete | Incomplete | No Show | Not Done |
|-----------|----------|----------|------------|---------|----------|
| | | | | | |

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.

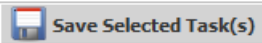
Insert Before – This drop down list will contain any other visit listed in the Incomplete Visits tab. Select the visit from this list to indicate where you want the visit you are creating to be placed. If this visit should be listed last, leave this option empty.

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.

Master List Of Clinical Tasks
◀ Back



Filter By: CPT Code


Procedure Name

Category Name


All

8 result(s) found... 1 - 8

| | CPT Code | Procedure Name | Category |
|--------------------------|----------|---|----------------------|
| <input type="checkbox"/> | | Amniotic Fluid (Amniocentesis) | Outpatient Procedure |
| <input type="checkbox"/> | | ANC- Absolute Neutrophil Count | Blood Work |
| <input type="checkbox"/> | | Angiogram Of Heart (Coronary Angiogram) | |
| <input type="checkbox"/> | | Blood Draw | |

 - 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.

Master List Of Administrative Tasks
◀ Back




Filter By: Task Name

All

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

| | Administrative Task Name |
|--------------------------|--------------------------|
| <input type="checkbox"/> | Call Coordinating Center |
| <input type="checkbox"/> | Check-in |

 - 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.

Master List Of Case Report Forms ◀ Back

Save Selected Task(s)

| <input checked="" type="checkbox"/> | Case Report Form Name |
|-------------------------------------|-----------------------|
| <input type="checkbox"/> | Case Report Form |

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.

| | | Add Case Report Forms | Add Clinical Tasks | Add Administrative Tasks | Delete Tasks | | |
|--------------------------|--|--------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|
| | | Procedure | Canceled | Complete | Incomplete | No Show | Not Done |
| <input type="checkbox"/> | | Case Report Form | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| <input type="checkbox"/> | | Amniotic Fluid (Amniocentesis) | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <input type="checkbox"/> | | Blood Draw | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <input type="checkbox"/> | | Check-in | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

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.

Incomplete Visits
Completed Visits
Pending Tasks

Filter by arm: Template 9 -- Placebo

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

Add a New Visit
 Delete Selected Visits

| | Edit | Task | Sub Req. | Completion Window | Target Date | Sched | Schedule Date/ Appt. Duration |
|--------------------------|------|---------|----------|-------------------------|-------------|-------|-------------------------------|
| <input type="checkbox"/> | | Visit 4 | No | 10/25/2014 - 10/28/2014 | 10/27/2014 | | |
| <input type="checkbox"/> | | Visit 6 | No | | 09/17/2014 | | |

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.

Study Number: NRP104.303 (32321212) (101-6) Subject, Micky - Study Documents & Images Back

PI: Investigator, Susan M., Ph.D.

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

IRB Expiration Date: 03/03/2015

Print Friendly Add a New Document

Documents Images

List of documents associated with this subject.

0 result(s) found...

| <input checked="" type="checkbox"/> | Edit | File Type | Date Modified | Title | Description |
|--|------|-----------|---------------|-------|-------------|
| No study documents associated with this subject. | | | | | |

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

Documents Images

Add a document associated with this subject.

*Title:

Description:

Upload Document:

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.

Document Location:

Instruction: Uploading a document into iRIS™ requires locating the document on the computer. Once you have located the document click on the 'Save selected file' button. The buttons will become disabled. If the document is a large document the window will stay in place until the upload operation has completed.

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.

Study Number: NRP104.303 (32321212) (101-6) Subject, Micky - Study Documents & Images Back
 PI: Investigator, Susan M., Ph.D. **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
IRB Expiration Date: 03/03/2015 Print Friendly Add a New Document Delete Selected Document(s)

Documents Images

List of documents associated with this subject.

1 result(s) found...

| <input type="checkbox"/> | Edit | File Type | Date Modified | Title | Description |
|--------------------------|------|-----------|---------------|----------------------|-------------|
| <input type="checkbox"/> | | | 09/17/2014 | Cancer site document | |

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.

Documents

Images

List of image documents associated with this subject.

1 result(s) found...

| | Edit | Image | Date Modified | Title | Description |
|--------------------------|------|-------|---------------|-------------|-------------|
| <input type="checkbox"/> | | | 09/17/2014 | Cancer site | |

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.

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

Adverse Event Initial Form

[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

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

0 result(s) found...

| | Show Rev | Show Follow-Up | Edit/View | Form Number | Ref Number | Sub. Rounds | Track Location | Process Submission | Submission Date | Created By | Date Created | Modified By | Date Modified |
|-------------------------------|----------|----------------|-----------|-------------|------------|-------------|----------------|--------------------|-----------------|------------|--------------|-------------|---------------|
| No records have been created. | | | | | | | | | | | | | |

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.

| Process Submission | Submission Date | Created By | Date Created | Modified By | |
|--------------------|-----------------|------------------------|------------------------|------------------------|------|
| ▶ Send | | Principal Investigator | 12/12/2012 04:43:27 PM | Principal Investigator | 12/1 |

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.

| Process Submission | Process Submission |
|--------------------|--------------------|
| ↶ Retract | ▶ Send |

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.

Study Number: NRP104.303
 PI: Investigator, Susan M., Ph.D. **Adverse Event Initial Form** Back

Print Friendly Refresh Constant Fields Save and Continue

Section view of the Form Entire view of the Form

1.0 General Hospital Adverse Event Report Form

1.0 General Hospital

Adverse Event Report Form

1.1 Principal Investigator:
 Susan M. Investigator, Ph.D.

1.2 RB #:
 GH-14-016

1.3 Title of project:
 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 (ADHD)

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.

1.5 * Report type:

New report

Follow-up report

If **Follow-up**, select the report that this is a follow-up to:

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

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.

Study Number: NRP104.303
 PI: Investigator, Susan M., Ph.D. **Adverse Event Initial Form** Back

Return back to the Form Save Selected Event

List of records associated with form: Adverse Event Initial Form.

1 result(s) found...

| | Version | Ref Number | Principal Investigator | IRB Number | Study Title | Report Type | Subject Age | Subject Initials | Date of Occurance | AE Category | AE Attribution | A.E. Grade | Created By | Date Created | Modified By | Date Modified |
|----------------------------------|------------------|------------|------------------------------|------------|--|-------------|-------------|------------------|-------------------|-------------|----------------|------------|-----------------------|------------------------|-----------------------|------------------------|
| <input checked="" type="radio"/> | GH-14-016-AE-1.0 | 000143 | Susan M. Investigator, Ph.D. | GH-14-016 | 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 (ADHD) | New report | 22 | AJ | 03/05/2014 | Pulmonary | Probable | 2 | Mary Jane Coordinator | 03/06/2014 03:45:10 PM | Mary Jane Coordinator | 03/06/2014 03:46:03 PM |

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.

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

Adverse Event Initial Form

Print Friendly Refresh Constant Fields

Section view of the Form

1.0 **General Hospital Adverse Event Report Form**

Entire view of the Form

New report
 Follow-up report

If **Follow-up**, select the report that this is a follow-up to:

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

Reference Number: 000143
Principal Investigator: Susan M. Investigator, Ph.D.
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 (ADHD)
Report Type: New report
Subject Age: 22
Subject Initials: AJ
Date of Occurrence: 03/05/2014
AE Category: Pulmonary
AE Attribution: Probable

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.

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

Adverse Event Initial Form

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

Copy Form Add a New Form Compare Two Versions Delete Selected Form(s)

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

1 result(s) found...

| | Show Rev | Show Follow-up | Edit/View | Apply to Multiple | Form Number | Ref Number | Sub. Rounds | Track Location | Process Submission | Submission Date | Principal Invest... | IRB Number | | | |
|--------------------------|----------|--------------------------------------|-----------|-------------------|-------------|-------------------------------------|-------------------------------------|----------------|--------------------|-----------------|------------------------|------------|------------|---------------------|-----------|
| <input type="checkbox"/> | | ✗ Click to close the follow-up event | | | | | <input checked="" type="checkbox"/> | AE-1.0 | 000143 | | Waiting for PI signoff | | 03/06/2014 | Susan M. Investi... | GH-14-016 |
| <input type="checkbox"/> | | | | | | <input checked="" type="checkbox"/> | AE-1.0 F1.0 | 000144 | | | | | | Susan M. Investi... | GH-14-016 |

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 (4567765432) (101-9) Subject, Jack - Consent version history Back
 PI: Investigator, Susan M., Ph.D.
 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...

| <input type="checkbox"/> | Edit | Title | Consented | Date Consented | View Patient Consent | View Study Consent | Reconsent Required | Version Date | Category | Version Number | IRB Approval Date | IRB Expiration Date |
|--------------------------|------|---------------------------|-----------|----------------|----------------------|--------------------|--------------------|--------------|--------------------|----------------|-------------------|---------------------|
| <input type="checkbox"/> | | Informed Consent / Assent | No | | | | No | 02/18/2014 | | 1.6 | 03/03/2014 | 03/03/2015 |
| <input type="checkbox"/> | | Informed Consent / HIPAA | No | | | | No | 04/01/2014 | | 1.0 | 03/03/2014 | 03/03/2015 |
| <input type="checkbox"/> | | Informed Consent | No | | | | Yes | 02/11/2014 | Consent Category 1 | 1.1 | 03/03/2014 | 03/03/2015 |
| <input type="checkbox"/> | | 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 (4567765432) (101-9) Subject, Jack - Consent version history Back
 PI: Investigator, Susan M., Ph.D.
 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...

| <input type="checkbox"/> | Edit | Title | Consented | Date Consented | View Patient Consent | View Study Consent | Reconsent Required | Version Date | Category | Version Number | IRB Approval Date | IRB Expiration Date |
|-------------------------------------|------|---------------------------|-----------|----------------|----------------------|--------------------|--------------------|--------------|----------|----------------|-------------------|---------------------|
| <input type="checkbox"/> | | Informed Consent / Assent | No | | | | No | 02/18/2014 | | 1.6 | 03/03/2014 | 03/03/2015 |
| <input checked="" type="checkbox"/> | | 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.

| <input type="checkbox"/> | Edit | Title | Consented | Date Consented | View Patient Consent | View Study Consent | Reconsent Required | Version Date | Category | Version Number | IRB Approval Date | IRB Expiration Date |
|--------------------------|------|---------------------------|-----------|----------------|----------------------|--------------------|--------------------|--------------|----------|----------------|-------------------|---------------------|
| <input type="checkbox"/> | | Informed Consent / Assent | No | | | | No | 02/18/2014 | | 1.6 | 03/03/2014 | 03/03/2015 |
| <input type="checkbox"/> | | 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.

| | | Title | Consented | Date Consented | View Patient Consent | View Study Consent | Reconsent Required | Version Date | Category | Version Number | IRB Approval Date | IRB Expiration Date |
|--------------------------|--|---------------------------|-----------|----------------|----------------------|--------------------|--------------------|--------------|--------------------|----------------|-------------------|---------------------|
| <input type="checkbox"/> | | Informed Consent / Assent | No | | | | No | 02/18/2014 | | 1.6 | 03/03/2014 | 03/03/2015 |
| <input type="checkbox"/> | | Informed Consent / HIPAA | No | | | | No | 04/01/2014 | | 1.0 | 03/03/2014 | 03/03/2015 |
| <input type="checkbox"/> | | Informed Consent | No | | | | Yes | 02/11/2014 | Consent Category 1 | 1.1 | 03/03/2014 | 03/03/2015 |
| <input type="checkbox"/> | | 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.

| | | |
|--|---|---|
| Study Number: NRP104.303 | (4567765432) (101-9) Subject, Jack - Consent version history | Back |
| PI: Investigator, Susan M., Ph.D. | |  |
| <input type="text" value="Edit an informed consent document for this subject."/> | | |
| Title: | Informed Consent | |
| Version Date: | 02/11/2014 | |
| Category: | Consent Category 1 | |
| Description: | | |
| Version Number: | 1 | |
| IRB Approval Date: | 03/03/2014 | |
| IRB Expiration Date: | 03/03/2015 | |
| Reconsent Required: | Yes | |
| Reconsent Reason: | | |
| Consented: <input type="radio"/> | Not Applicable: <input type="radio"/> | |
| Comment: | <input type="text"/> | |
| Upload Document: | <input type="button" value="Upload ..."/> | |

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.

| |
|---|
| Reconsent Required: YES |
| Reconsent Reason: |
| Consented: <input checked="" type="radio"/> Not Applicable: <input type="radio"/> |
| Date Consented: <input type="text"/>  |
| <input type="text"/> |

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.

Document Location:

Instruction: Uploading a document into iRIS™ requires locating the document on the computer. Once you have located the document click on the 'Save selected file' button. The buttons will become disabled. If the document is a large document the window will stay in place until the upload operation has completed.

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.

Reconsent Required: Yes

Reconsent Reason:

Consented: Not Applicable: reset

Date Consented: 09/03/2014

Comment:

Upload Document:

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...

| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
|--------------------------|--------------------------|---------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| | Edit | Title | Consented | Date Consented | View Patient Consent | View Study Consent | Reconsent Required | Version Date | Category | Version Number | IRB Approval Date | IRB Expiration Date | |
| <input type="checkbox"/> | <input type="checkbox"/> | Informed Consent / Assent | NA | | | | No | 02/18/2014 | | 1.6 | 03/03/2014 | 03/03/2015 | |
| <input type="checkbox"/> | <input type="checkbox"/> | Informed Consent / HIPAA | NA | | | | No | 04/01/2014 | | 1.0 | 03/03/2014 | 03/03/2015 | |
| <input type="checkbox"/> | <input type="checkbox"/> | 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.

The screenshot shows the 'Subject Management' page for subject Jack. A modal dialog box titled 'Message from webpage' is displayed in the center, containing a yellow warning triangle icon and the text 'Subject needs to reconsent.' with an 'OK' button below it. The background interface includes fields for Study Number (NRP104.303), PI (Investigator, Susan M., Ph.D.), IRB Number (GH-14-016), and Study Title. A sidebar on the left lists various subject information categories like Demographics, Insurance, and Medication. The main content area shows 'Subject on study - NRP104.303' with a list of management options.

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

The screenshot shows the 'Consent version history' page. It features a table with the following data:

| Checkmark | Edit | Title | Consented | Date Consented | View Patient Consent | View Study Consent | Reconsent Required | Version Date | Category | Version Number | IRB Approval Date | IRB Expiration Date |
|--------------------------|------|---------------------------|-----------|----------------|----------------------|--------------------|--------------------|--------------|--------------------|----------------|-------------------|---------------------|
| <input type="checkbox"/> | | Informed Consent | No | | | | Yes | 02/11/2014 | Consent Category 1 | 1.2 | 09/18/2014 | 03/03/2015 |
| <input type="checkbox"/> | | Informed Consent / Assent | NA | | | | No | 02/18/2014 | | 1.6 | 03/03/2014 | 03/03/2015 |
| <input type="checkbox"/> | | 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.

The screenshot shows the 'Consent version history' page with two records. The second record is highlighted in yellow:

| Checkmark | Edit | Title | Consented | Date Consented | View Patient Consent | View Study Consent | Reconsent Required | Version Date | Category | Version Number | IRB Approval Date | IRB Expiration Date |
|--------------------------|------|------------------|-----------|----------------|----------------------|--------------------|--------------------|--------------|--------------------|----------------|-------------------|---------------------|
| <input type="checkbox"/> | | Informed Consent | No | | | | Yes | 02/11/2014 | Consent Category 1 | 1.2 | 09/18/2014 | 03/03/2015 |
| <input type="checkbox"/> | | 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.

| | | Title | Consented | Date Consented | | | 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 (4567765432) (101-9) Subject, Jack - Appointments Back

PI: Investigator, Susan M., Ph.D.

| | | | |
|--|-------------------------------|---|--|
| 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: | |

| | Task Name | Classification | Target Date | Appt. Duration | |
|---------------------------------------|-----------|----------------|-------------|----------------|--|
| Unscheduled Tasks - NRP104.303 | | | | | |
| | Visit 3 | Visit | 10/07/2014 | 1 Hr | |
| | Visit 4 | Visit | 10/14/2014 | | |
| | Visit 5 | Visit | 10/21/2014 | | |

| | Task Name | Classification | Target Date | Appt. Duration | Task Status | Scheduled Date | Scheduled Time |
|-------------------------------------|-----------|----------------|-------------|----------------|-------------|----------------|---------------------|
| Scheduled Tasks - NRP104.303 | | | | | | | |
| | | 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.

Study Number: NRP104.303 (4567765432) (101-9) Subject, Jack - Subject Calendar Back

PI: Investigator, Susan M., Ph.D.

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

Month: Sep 2014 Week: Sep 14 - Sep 20

◀ October 2014 ▶

| (Week 40) | | | 01 | 02 | 03 | 04 |
|--------------|----|------------------------------|----|----|----|----|
| 05 (Week 41) | 06 | 07 JS 08:00 AM-Visit 3 | 08 | 09 | 10 | 11 |
| 12 (Week 42) | 13 | 14 JS 10:00 AM-Visit 4 | 15 | 16 | 17 | 18 |
| 19 (Week 43) | 20 | 21 JS 02:00 PM-Visit 5 | 22 | 23 | 24 | 25 |
| 26 (Week 44) | 27 | 28 | 29 | 30 | 31 | |

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 Number: NRP104.303 (4567765432) (101-9) Subject, Jack - Visit Details Back

PI: Investigator, Susan M., Ph.D.

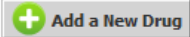
Visit Name: Visit 3
 Visit Type: Clinic Visit
 Description:
 Target Date: 10/07/2014
 Completion Window: 10/05/2014 - 10/09/2014
 Arm:

Status: Incomplete
 Assessment Date:
 Comments:

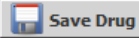
| Description | Open Form | Procedure | Canceled | Complete | Incomplete | No Show | Not Done |
|---------------------------------|-----------|---|-----------------------|-----------------------|----------------------------------|-----------------------|-----------------------|
| (Category not specified) | | | | | | | |
| | | Check-in | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| (Category not specified) | | | | | | | |
| | | Angiogram Of Heart (Coronary Angiogram) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | | Blood Draw | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | | CAT Scan | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | | Fundoplication | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | | GFR/Global Family Rating | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> |

Study Drugs


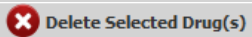

This area allows you to list any study drugs the subject is using. When you first access this area, the page will not display any records for the subject. You can associate a study drug record to the subject by clicking on the **Add New Drug** button.

| | | | | |
|---|---------------------------------|--|--|--------|
| Study Number: NRP104.303 | | (4567765432) (101-9) Subject, Jack - Study Drug/Biologic/Chemical agent | | ◀ Back |
| PI: Investigator, Susan M., Ph.D. | | | | |
| 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 | | | |
|  | | | | |
| List of drugs associated with this subject. | | | | |
| 0 result(s) found... | | | | |
| <input checked="" type="checkbox"/> | Edit | Study Drug/Biologic/Chemical agent | Drug Supplier | |
| No drugs have been added for this subject. | | | | |

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

| | | | | |
|---|------------------------|--|--|--------|
| Study Number: NRP104.303 | | (4567765432) (101-9) Subject, Jack - Study Drug/Biologic/Chemical agent | | ◀ Back |
| PI: Investigator, Susan M., Ph.D. | | | | |
|  | | | | |
| Add a note associated with this subject. | | | | |
| | *Study Drug: | <input type="text"/> | | |
| | *Drug Supplier: | <input type="text"/> | | |

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.

| | | | | |
|---|---|--|--|--------|
| Study Number: NRP104.303 | | (4567765432) (101-9) Subject, Jack - Study Drug/Biologic/Chemical agent | | ◀ Back |
| PI: Investigator, Susan M., Ph.D. | | | | |
| 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 | | | |
|   | | | | |
| List of drugs associated with this subject. | | | | |
| 1 result(s) found... | | | | |
| <input checked="" type="checkbox"/> | Edit | Study Drug/Biologic/Chemical agent | Drug Supplier | |
| <input type="checkbox"/> |  | Acetaminophen | Bayer | |