STUDY ASSISTANT

Study Management

Version 10.03

Contents

Study Management

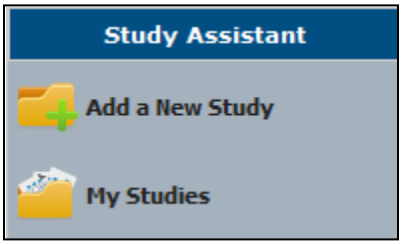
Introduction

Within the study record, the study is broken up into sections, Submissions, Study Management, and, if using the Subject Management module, Subject Management. These tabs allow you to access different portions of the study so you can maintain study information in the system. The Study Management tab allows you to access study details like review board information and current study personnel. You can also access and manage sponsors and subrecipients, view study drugs and devices, and enrollment criteria. If your system is using Subject Management with Finance, this area will also contain links to create Study Plans and Timelines, Budgets, Milestones, and Invoices. See the appropriate Finance Assistant manual.

This manual will guide you through different options you may have available within the Study Management tab. The main purpose of the Study Management tab is to house study details.

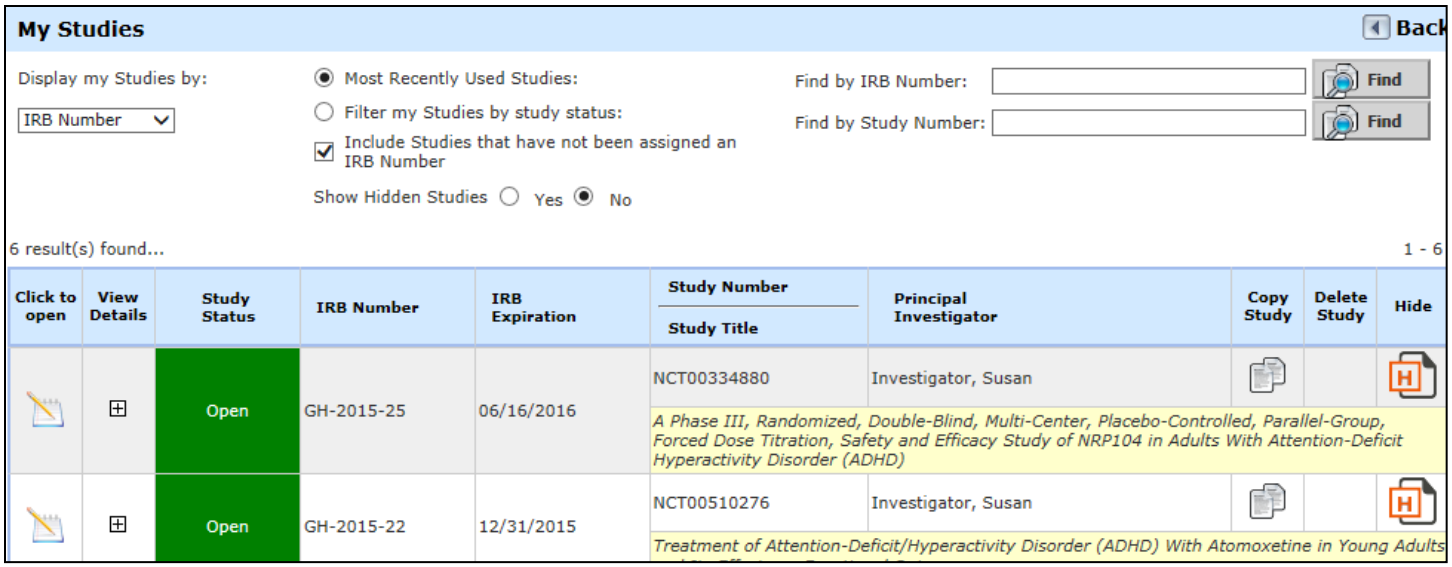
Accessing a Study

To locate your study, open the My Studies menu item found under Study Assistant.

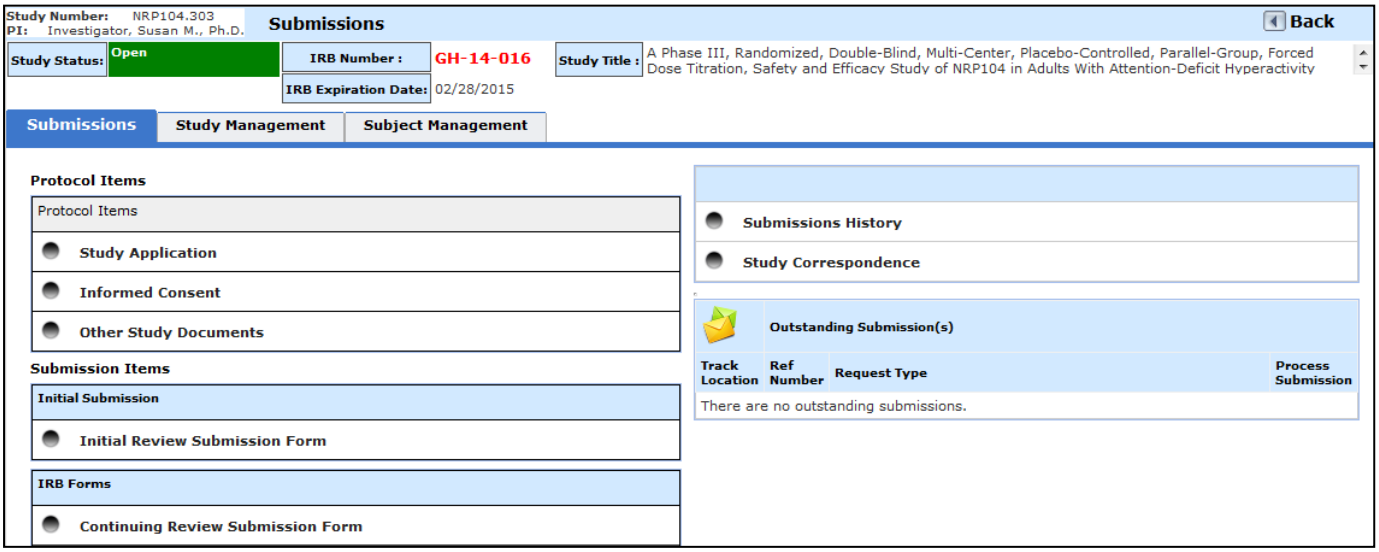


The page that opens will display the studies on which you have a role along with basic information about each study. Use the filters to narrow the list to the study you need to open. iRIS will default this screen to show the most recently used study at the top of the list. You can use the search criteria at the top of the page to locate the study you are looking for.

Once you have located the study in the list, click the Open icon.

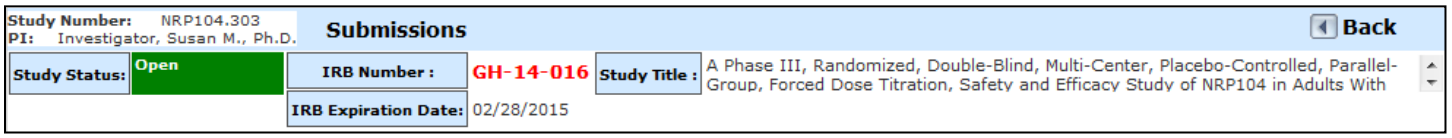


When you open a study the page will open to the Submissions tab. This tab contains links to various forms that can be created, completed, and submitted throughout the lifetime of the study. The top of the page lists a header with study-specific details. The left portion of the page contains links to the Study Application, Informed Consent, Other Study Documents, and any form you may need to create and submit for review. The right side of the page contains a link to Submission History which will list out all forms submitted for review on the study. Also listed is a link to Study Correspondence and Outstanding Submissions. For more information on these tabs see the Study Submissions manual.



The Header

When you are within the study record, at the top of the page will always display the study header. The header contains current information related to the study you are viewing.



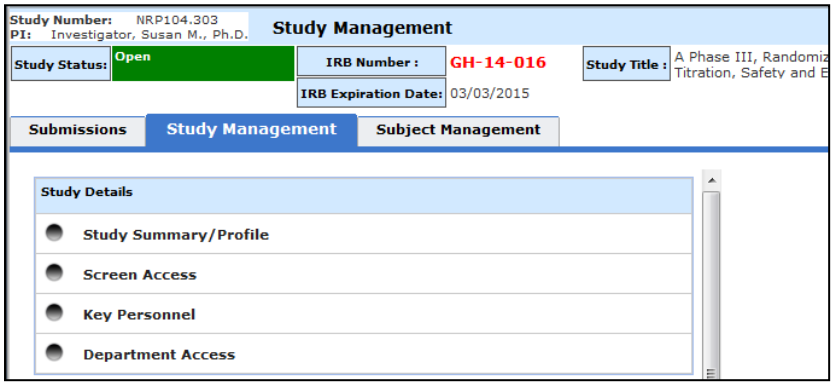
Displayed at the top left of the header is the **Study Number** and **PI**.

Below this is listed the current **Study Status**, the **IRB Number**, **Study Title** and the **IRB Expiration Date**, depending on whether or not a date has been provided by the IRB.

The information in the header will update as it is changed.

Study Management

The Study Management tab is located at the top of the study screen next to the Submissions tab. Study Management contains links to different Study details including personnel on the study, sponsors and subrecipients, budgets, and departments. Most of this detail is defined in the Study Application when you create the Study in iRIS. The information entered in the application in specific data values will be stored in corresponding fields in Study Management. Note: see the Add a New Study manual for more details. At any time you can access this information by linking to the appropriate field in Study Management.



Study Details

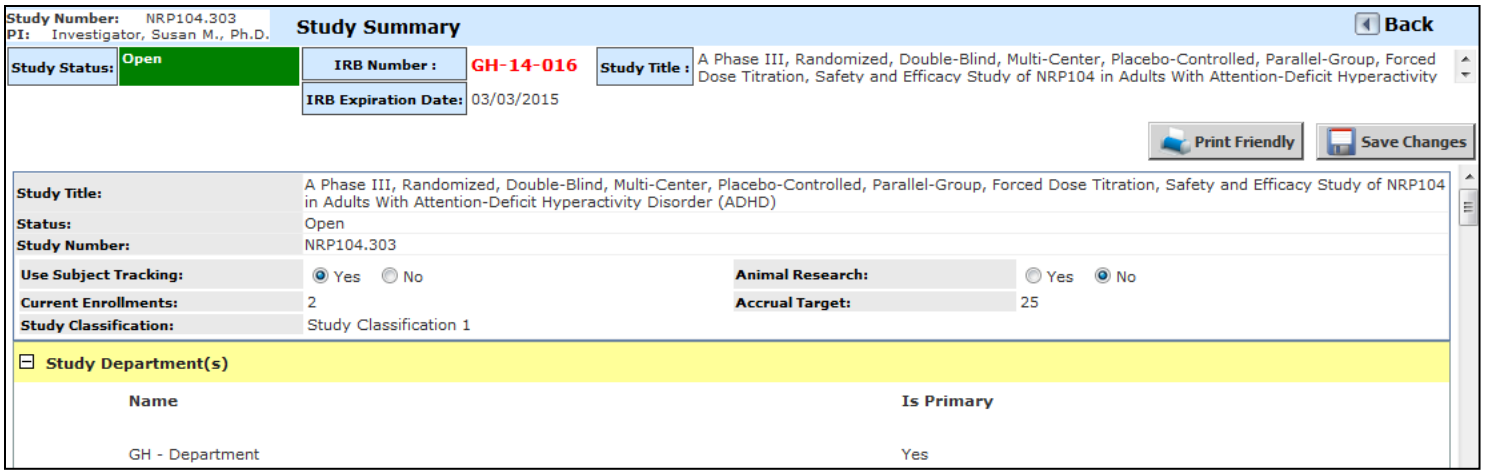
The first section in Study Management contains links to different Study core fields – study summary information as set by the review board, personnel screen access, personnel on the study, and departments on the study.

Study Summary/Profile

The Study Summary will display the current status information related to the study. Anytime the review board updates these fields, that information will update here. This page is broken up into several parts. The first part displays basic study information and may appear differently in your system, depending on system settings. Always displayed are the Study Title, Status, and Study Number. The Status field is the current Study Status.

Below lists different groups that can be expanded and collapsed by clicking on the ⊟ or ⊞.

You can also open a view of this page so you can print it for your records by clicking on the **Print Friendly** button.

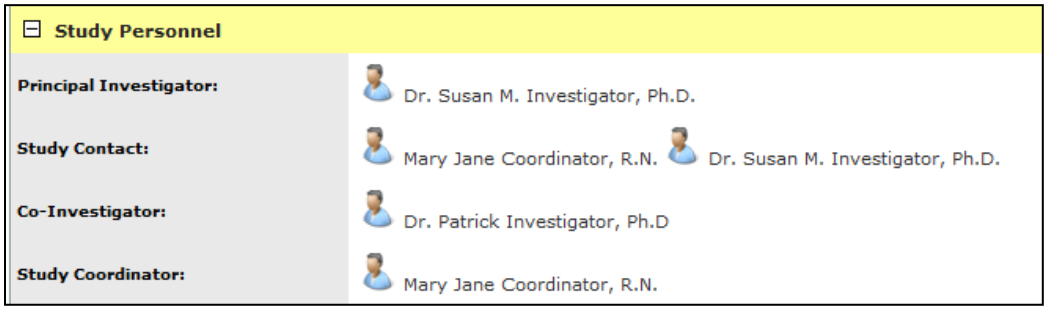


Study Departments

The first group on this page will list current departments associated to the Study (as defined in section 3.0 of the Study Application).

Study Personnel

Study Personnel displays the names and roles of the current Study Personnel that are associated with the study (as defined in section 2.0 of the Study Application). A user's profile can be viewed by clicking on the icon next to their name, as seen in the image below.

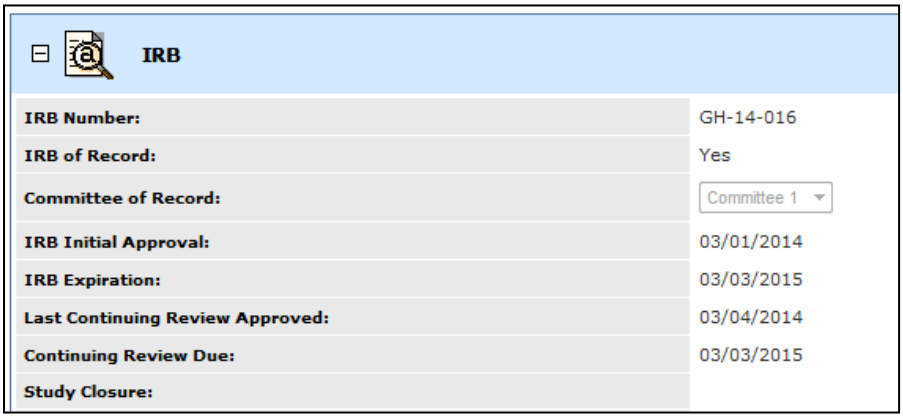


The users detail page will list contact information as defined in their user account, training records defined under the Education History group and any Medical Licenses and CV's uploaded. Click the **Back** button on the top right of the screen to return to the Study Dashboard.

Review Boards

Listed within the Study Summary is any review board information related to this study. Any review board that has reviewed this study will be grouped on this page with a list of review board attributes for the study. Whenever the review board updates this information, this page will reflect those changes. From this group, the study can obtain information regarding approval dates, expiration dates, risk assigned to the study, closure information, and subject approval information. Depending on system settings, and which review board is associated to the study, the information that displays on this page may differ.

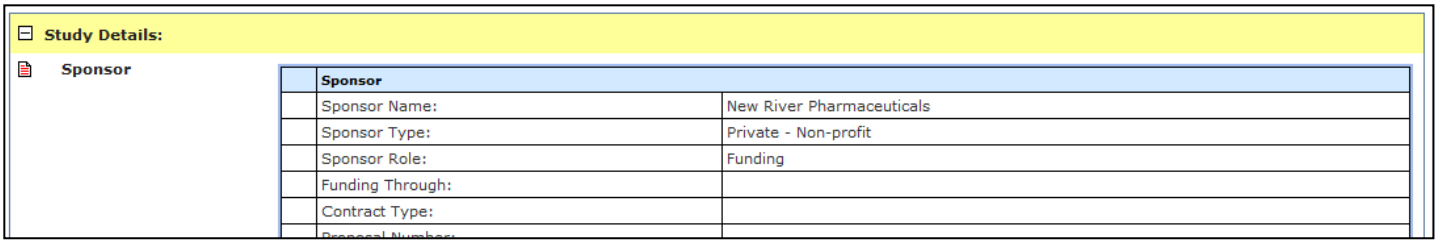
If more than one review board is associated to the study, each review board would be listed separately in different groups. In the study used in this example, only one review board, IRB, has been assigned to this study and the current IRB information displays on this page, as seen in the image below.



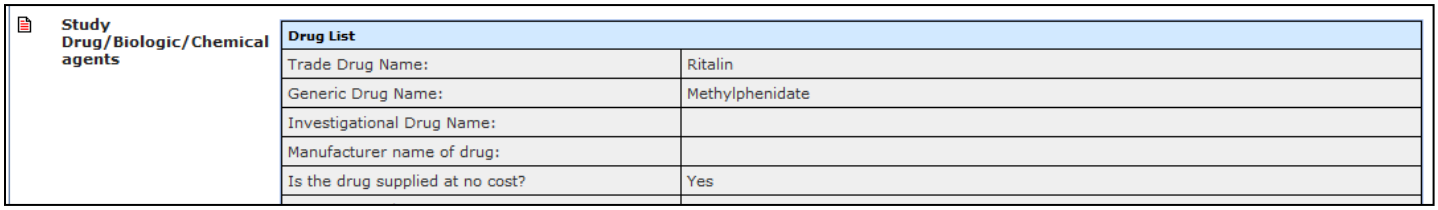
Study Details

This area of the Study Summary will provide a summary of other items in the study record like Sponsors, Drugs, Devices, and Enrollment Criteria. If information has been associated to the study in any of these groups, they will display in this area along with the details for those items.

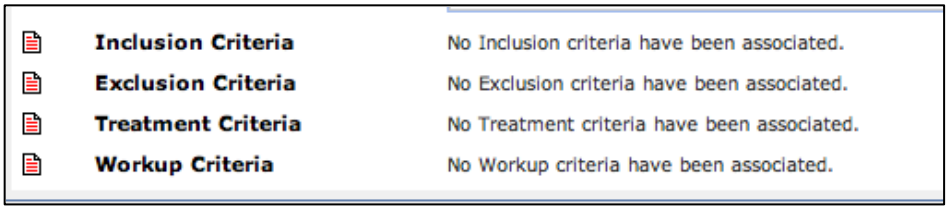
Sponsors on the study will display. You can click on the link **Sponsor** to obtain additional information.



Study Drugs and Devices will also display, listing the detail for each item on the study. You can click on the link for either **Study Drug/Biologic/Chemical** agents or **Study Devices** for additional details.



The Study Profile also displays any Inclusion or Exclusion Criteria added to the study with clickable links for additional details.



When you are finished viewing the Study Profile, click the **Back** button to return to the Study Management tab.

Screen Access

Screen Access gives the ability to custom access to screens within the study to certain users on the study. By default, if a user is assigned a role on the study, they will have access to the study as specified in the Study Role Access within System Administration (see the System Administration – System Setup manual for more information). Each role on the study could have different access to the study depending on their access level.

You can further detail what screens within a study a user has access to with the Screen Access as shown in the image below.

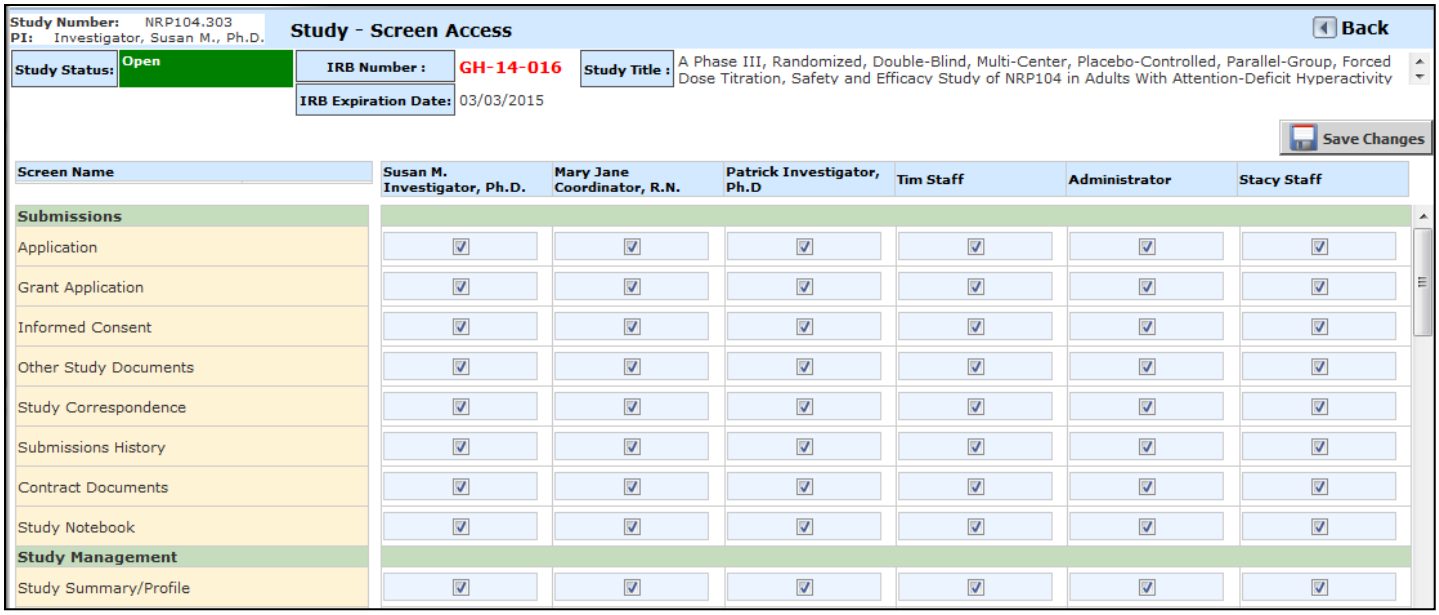
This page will list available screens on the left side. The top of the page displays a list of users on the study. Within each user column are checkboxes that represent whether or not a user can access the screen to the left.

If the checkbox is selected, that means the user has full access to that page in the system. They can view and update on the page.

Depending on the number of users on the study, there may be vertical and horizontal scroll bars at the bottom and right of the screen so you can navigate to the other roles and screens available on the page.

If you need to restrict or allow a certain user on the study access to certain screens, this is where you set the appropriate access.

After making the necessary changes to this screen, click the **Save Changes** button and then the **Back** button to return to the main Study Management screen

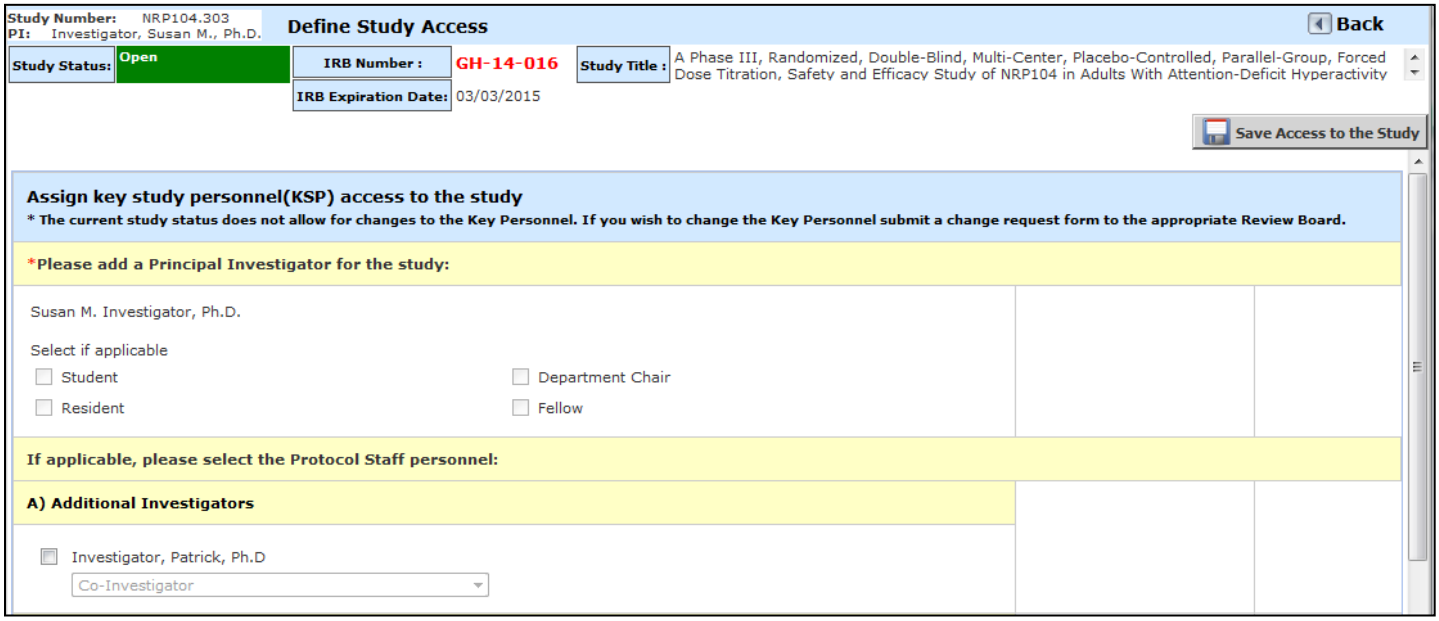


Key Personnel

This link will open a screen similar to the one found in Section 3.0 of the Study Application. This page lists the current personnel on the study. Users need to have access to a study in order to be able to open/ view that study. The study will not show up in the **My Studies** link on their home page if they have not been added as Study Personnel.

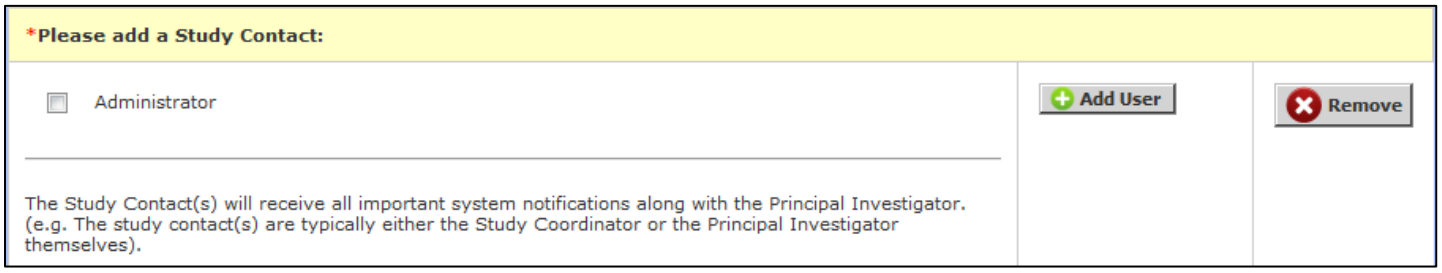
Your system may or may not display all the roles shown below, depending on how your system is configured.

Depending on the Study Status, this page may be locked and means that your study is in a state where any changes to personnel need to be submitted to the review board for approval. See the Submissions manual for information on submitting change requests for approval.

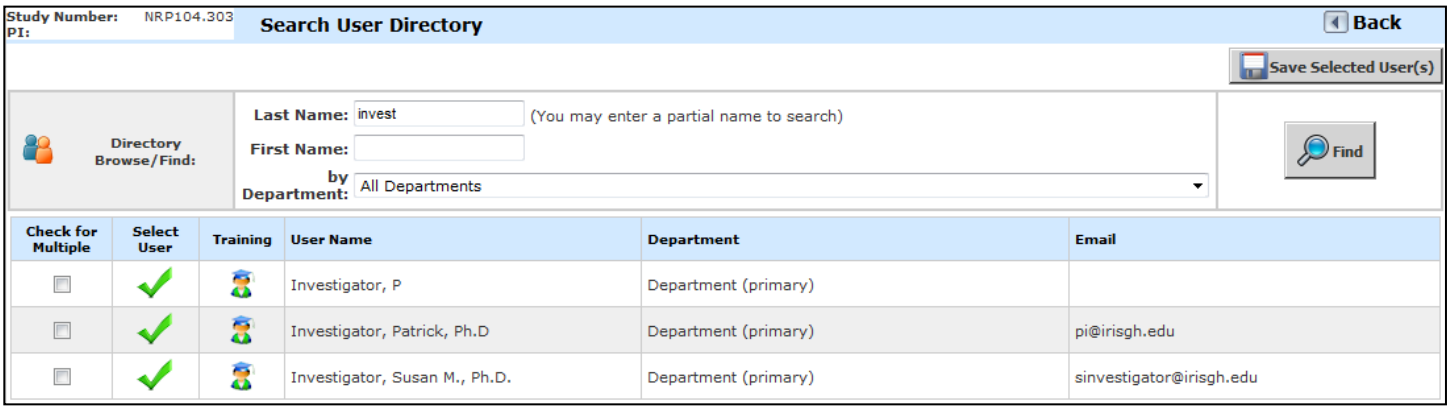


If the Study Status allows for Personnel changes, the page will not be locked and you will be able to add and remove users from the Study.

To add any user to any role, click the **Add User** button next to the corresponding role, as seen in the image below.



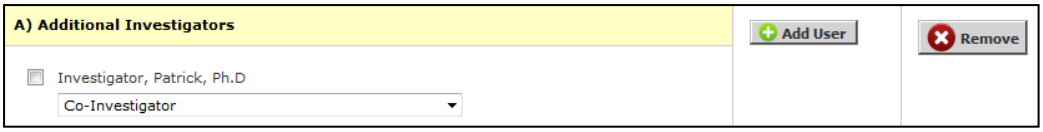
This allows you to search the user directory by First name, Last Name, or Department. Enter all or part of the criteria and click the **Find** button. To select a user to add, click the **Select User** icon. This selects the user and brings you back to Define Study Access. To select more than one user, check the boxes in the **Check for Multiple** column next to the corresponding users and click the **Select User(s)** button.



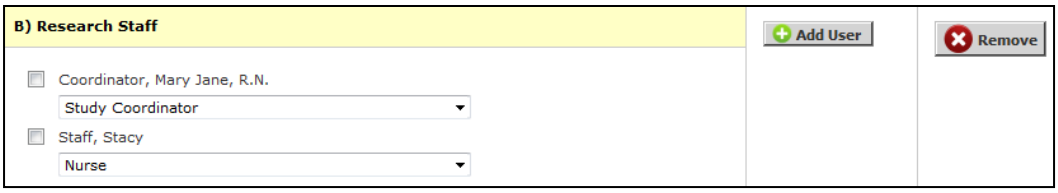
You may or may not see the same role options as presented in this document, depending on your system configuration. Some of the roles available in this section include the following:

Principal Investigator – All study records must have a Principal Investigator. You can only have one Principal Investigator listed in the first section. If additional PIs are needed on the study, you may add them in the Additional Investigator's section, if available.

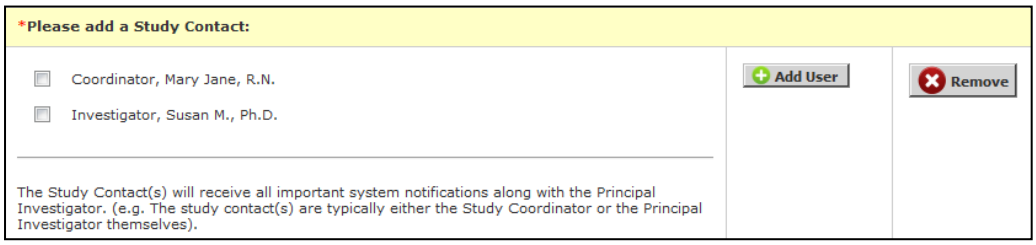
Additional Investigators – Any investigator roles for the study, aside from the Principal Investigator, can be listed here. You may have any number of Additional Investigator's and after you add a user to this group, you will be able to specify which role they have.



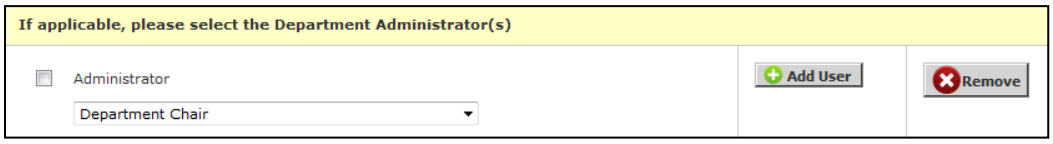
Research Staff – This section is for any non-investigator users you need to list on the study. You may have any number of research support staff listed here and after you add a user to this group, you will be able to specify their role.



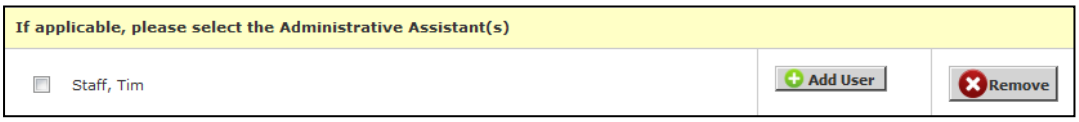
Study Contact – The user you add as the Principal Investigator will default to the Study Contact. You may add additional Study Contacts as needed. A Study Contact is a user on the study who will receive study related notifications from the system such as Continuing Review notifications, Submission Correction notifications, Review Response notifications, etc. The Study Contact usually has another role on the study, such as a Research Coordinator or PI. Since the Study Contact is a role solely used for notification purposes, you can add users to this role without review board approval.



Department Administrator – You can add a user to Designated Department Approvals if you need to route submissions to a department reviewer before the review board will accept your submission. You can have any number of users listed here. When you submit a form that requires department approval, you will be able to select any user added here to include in the approval process. Because Designated Department Approvals are not study roles, you can add users to this role without review board approval.



Administrative Assistants – If you would like to allow an administrative assistant access to the study for data entry purposes, you can add them here. You can have any number of users listed. These users typically have limited access to the study and will not be considered KSP in the education check and will not be included in the submission signoff process. This role is not considered KSP so you can add users to this role without review board approval.



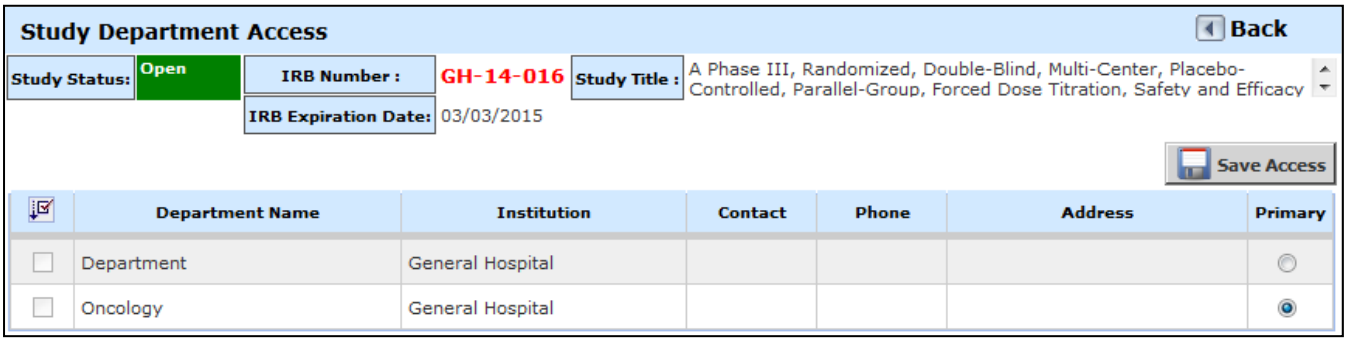
You can remove any user from the study by clicking the checkbox next to their name, and then clicking the **Remove** button in that same group. If you need to remove the PI, you will have to select a new user to take the PI's place because a study record cannot be created without this information. However, if the study is in a status that requires review board approval, you will need to request the removal of the user by submitting a form to the review board. Any personnel change requested will not take place until the review board approves the request.

After all of the necessary users have been associated to the study, click the **Save Access to the Study** button and then **Back** to return to the main Study Management screen.

Department Access

The Department Access link will open a screen similar to the one found in Section 2.0 of the Study Application and will list the current departments associated to the study.

From this area, you will be able to indicate the study's primary department by selecting the appropriate radio button in the **Primary** column. If any changes to the page are made, click the **Save Access** button before exiting and the **Back** button to return to the main Study Management screen.

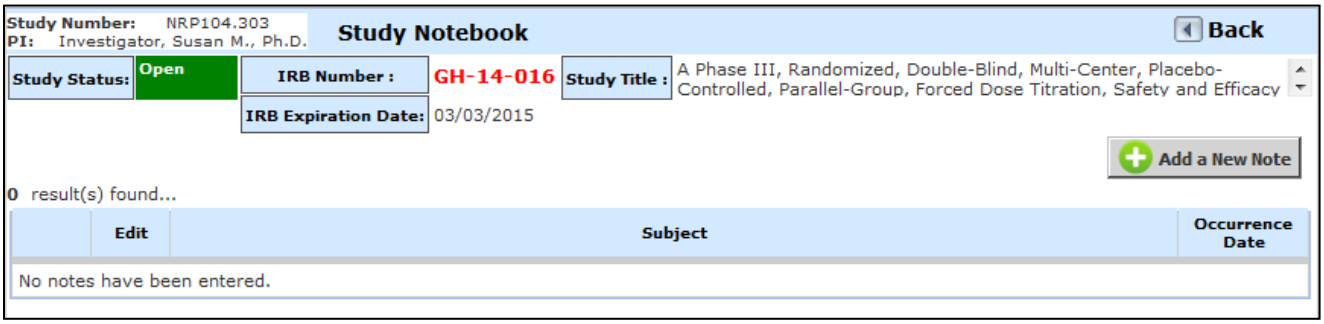


If you need to request changes to the departments on the study, you need to submit a form to the review board with the Study Application attached showing the changes in section 2.0. Requested changes in the department will not reflect on this screen until the review board approves the change.

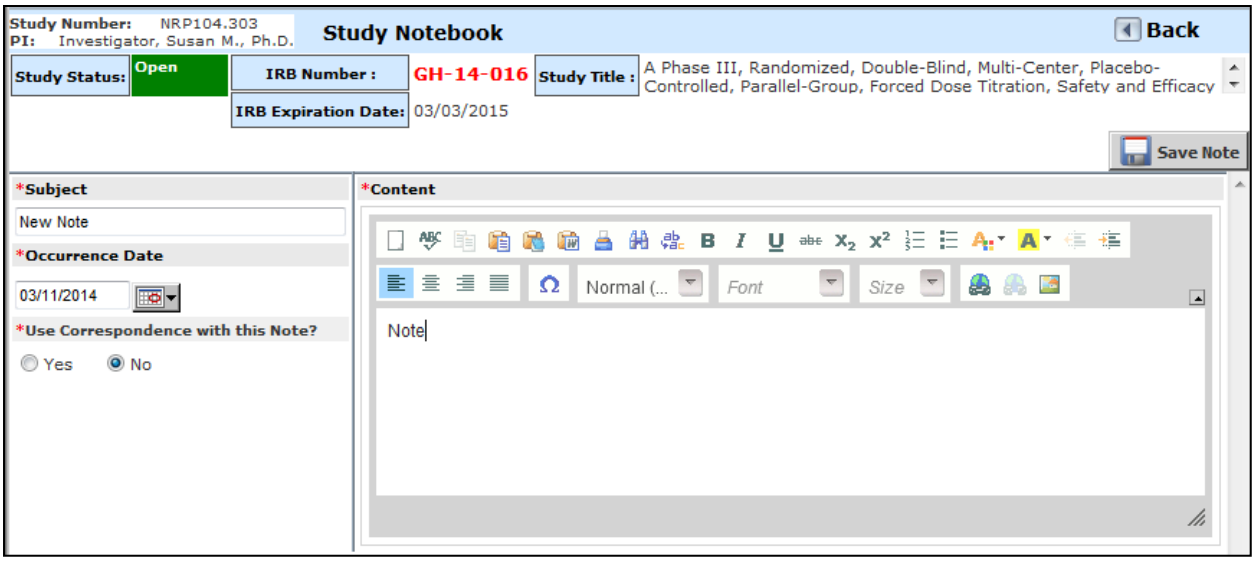
Study Tasks – Study Notebook

Study Notebook is a tool you can use to collect documentation for the study. You can use the notebook to keep an internal study log, or you can generate correspondence using the notebook.

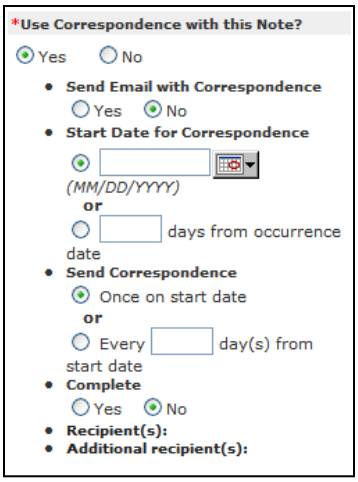
When you initially view the Study Notebook page, there will be no records listed. Click the **Add a New Note** button to create a new note.



A new page will open. You must enter a **Subject**, **Occurrence Date** and **Content** for the note. If you choose not to select **the Use Correspondence with this Note,** click the **Save Note button** to add the note to Study Notebook ledger. Anyone with access to Study Notebook can see your note.



You can also specify to send a correspondence with the note if you need to email the note to another user. Indicate **Yes** to **Use Correspondence with this Note?**



This will present a list of options about how you want to send the correspondence. Each item is described below.

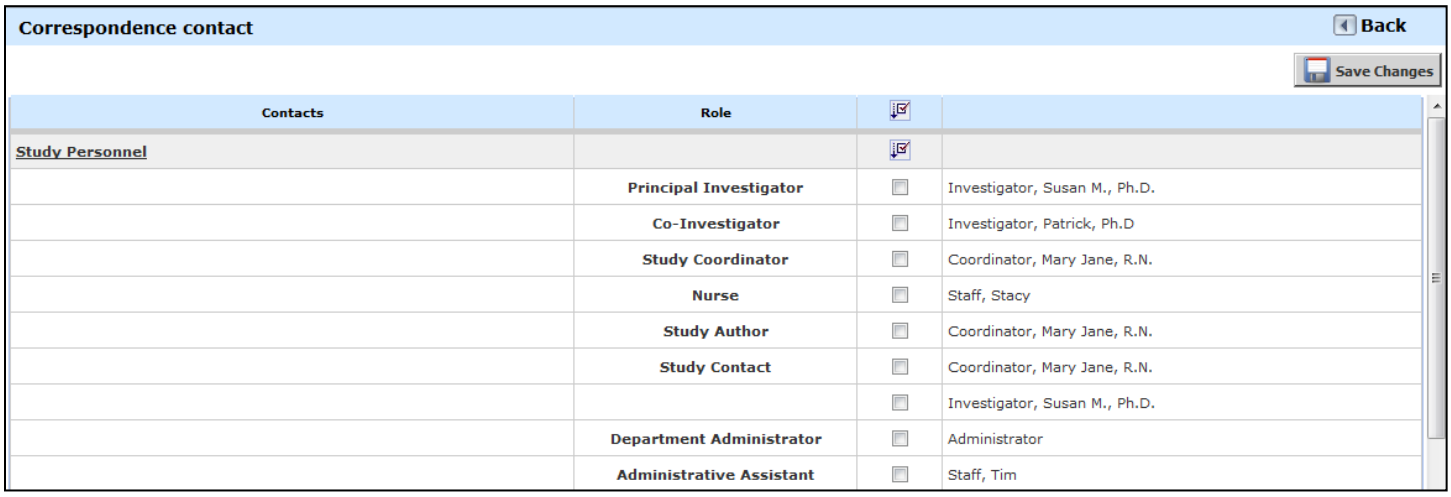
Send Email with Correspondence – You must indicate “Yes” or “No”. “Yes” means that an email will be generated with this note and sent to the recipients. If you indicate “No”, the recipients will receive a Correspondence within iRIS on their homepage only.

Start Date for Correspondence – This is the date when you want the correspondence to generate. You can choose a calendar date or specify a number of days after the occurrence date (date you saved the note to the study).

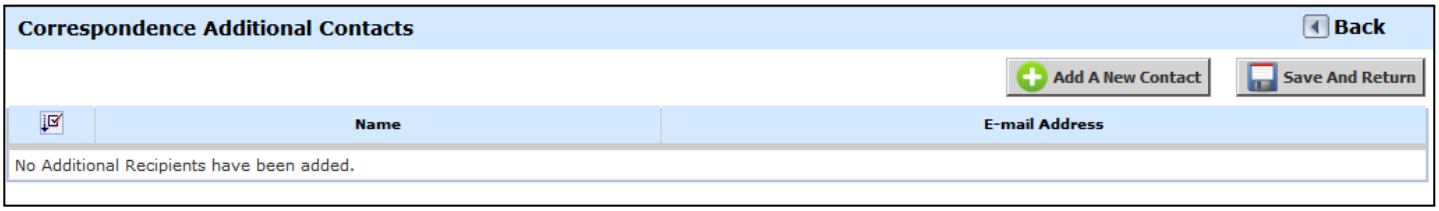
Send Correspondence – Choose how often to send the correspondence. Once on the start date or indicate a certain number of days after the start date that you wish the correspondence to be sent.

Complete – The default selection is “No”, meaning when you save the note, the system will not look at the criteria to send the note as a correspondence. Only when you indicate “Yes” and save the note will the system then send the correspondence based on the criteria set.

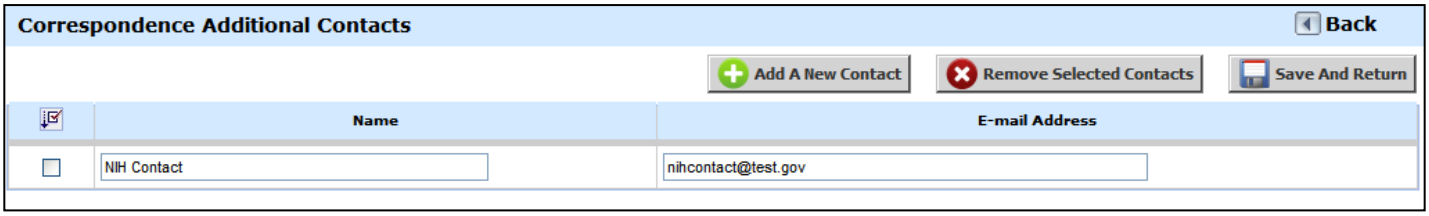
Recipients – This is a clickable link that will open a page listing all current Study Personnel, as seen in the image below. If the Study Application has been submitted, board members of the review board overseeing your study will be listed as well. After you select who will receive the correspondence, click the **Save Changes** button.



Additional Recipients – This is a clickable link. If you would like to include a recipient who does not have an account in iRIS, you can choose to add additional recipients to the Correspondence. When you click on this link, a new page will open. Click on the **Add a New Contact** button.

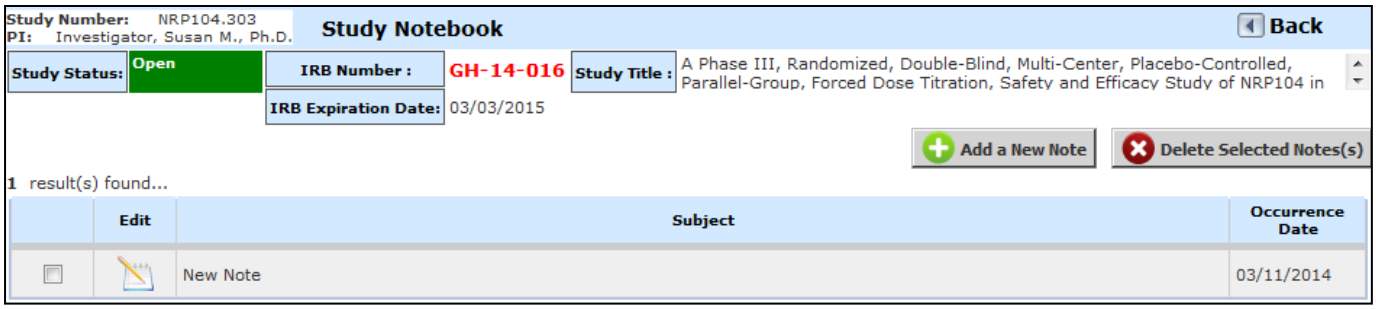


From here you can add the recipient's name and email address. You can choose to add any number of additional recipients, or remove them if you added them in error (you will need to click the checkbox next to the recipient then click the **Remove Selected Contacts** button). When you are finished entering in the names and email addresses of your additional recipients, click the **Save and Return** button, as seen in the image below.

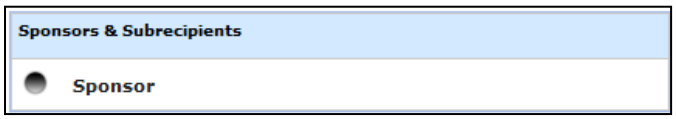


This will return you to your note. When you are finished entering the details click the **Save Note** button.

Your note will post in the Study Notebook. At any time you can view this note or generate additional notes for the Study. Click the **Back** button to return to the main Study Management screen.



Sponsors & Subrecipients



Sponsor

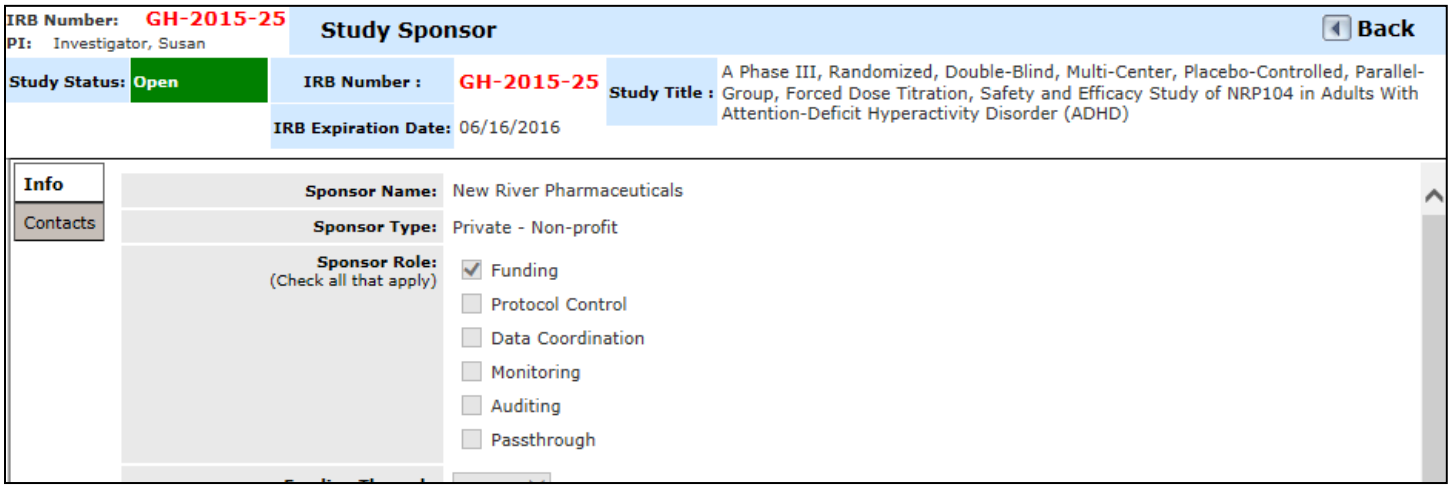
The Study Sponsor page contains any Sponsors added to the study through the Study Application. From this area you view details for current Sponsors. The page will list current Sponsors on the study and is split in to two groups, Approved Sponsor and Pending Approval. If you need to modify, add, or remove a sponsor from a study you will need to submit an Amendment form to the review board.

Sponsors populate in the **Approved Sponsor** section when the review board approves a submission to which the sponsor is associated. Once a sponsor becomes approved, any modifications to that sponsor need to be submitted to the review board for approval. Therefore, you cannot make any changes to the records listed here.

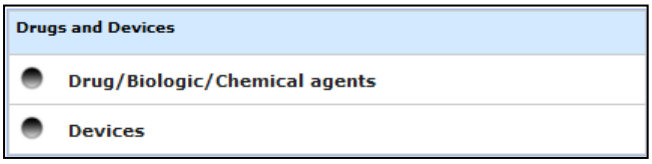
Sponsors populate in the **Pending Approval** section whenever a modification to an existing sponsor is requested or whenever a new sponsor is in the process of being approved by the review board.

You can view sponsor details by clicking on the icon in the **Open** column.

This will open a new page listing read only details, as seen in the image below.



Drugs and Devices



Drug/Biologic/Chemical Agents

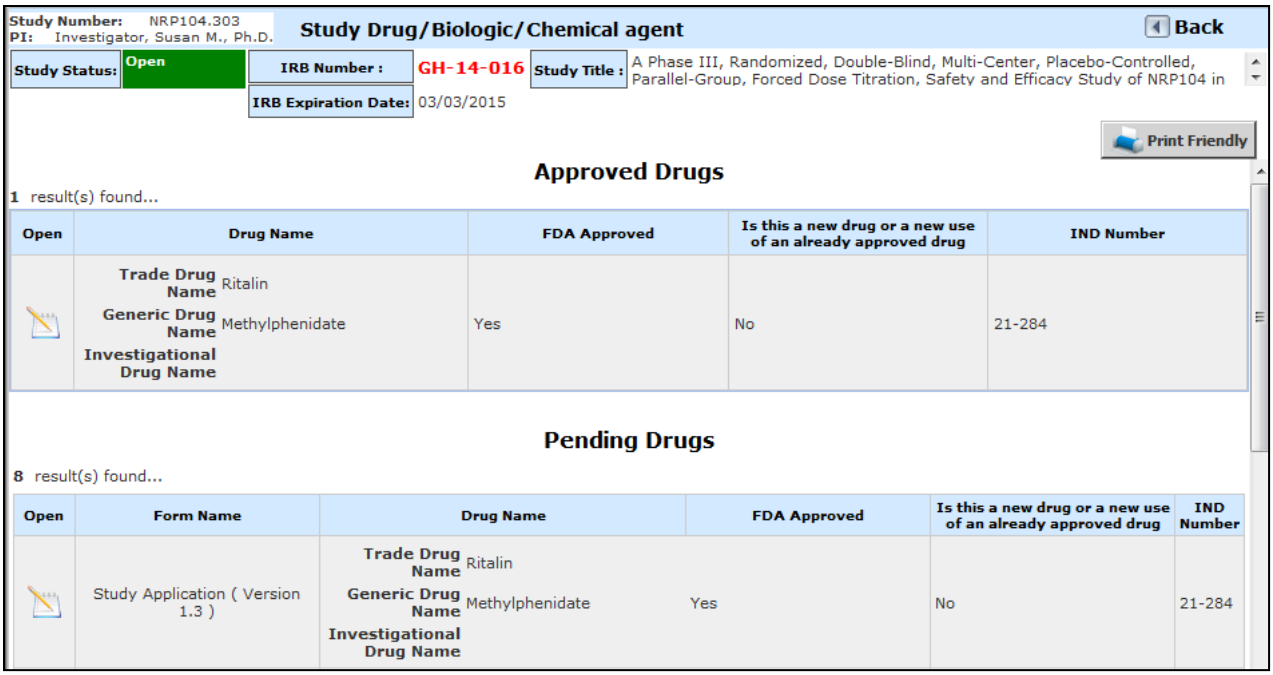
Click on the link to be directed to a page that will display any Study Drug that has been added to the Study Application. This page is broken up in to two parts, Approved Drugs and Pending Drugs, as seen in the image below.

Drugs populate in the **Approved Drugs** section when the review board approves a submission to which the drug is associated. Once a drug becomes approved, any modifications to that drug need to be submitted to the review board for approval. Therefore, you cannot make any changes to the records listed here.

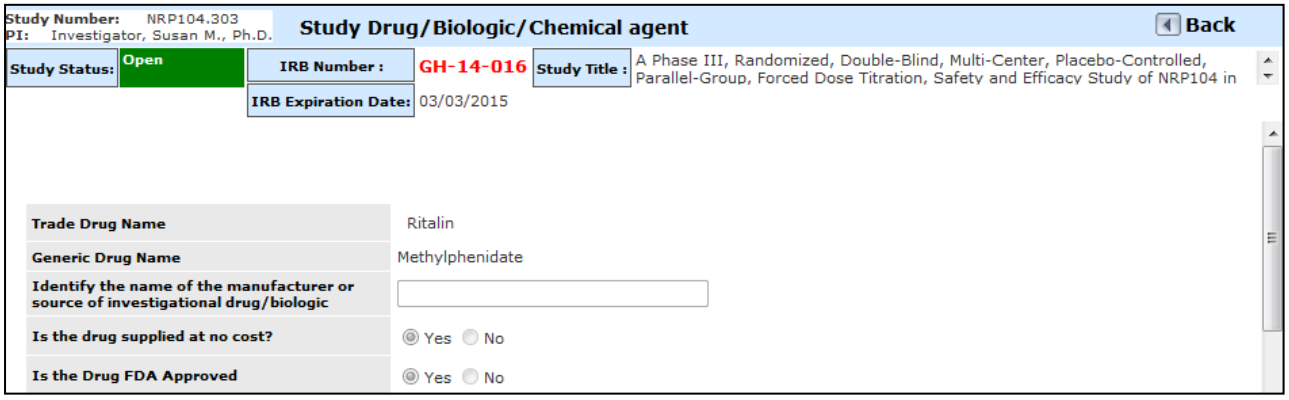
Drugs populate in the **Pending Drugs** section whenever a modification to an existing drug is requested or whenever a new drug is in the process of being approved by the review board.

You can view this page in a printer friendly format by clicking the **Printer Friendly** button on the top right of the page.

You can view drug details by clicking on the icon in the **Open** column.



This will open a new page listing read only details, as seen in the image below.



Devices

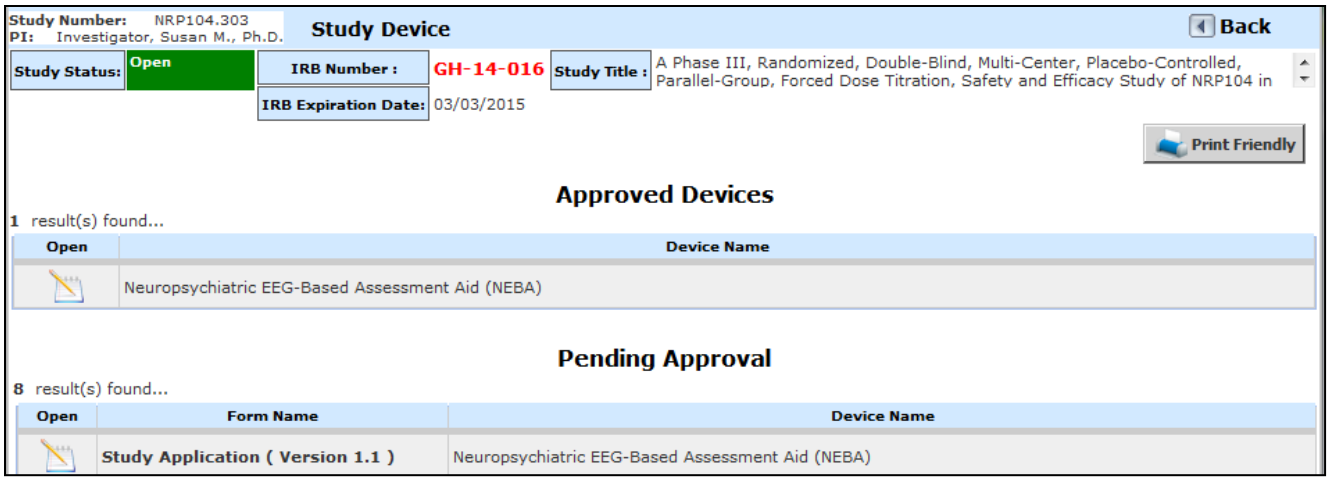
Click this link to view any Device that has been added to the Study Application. This page is broken up in to two parts, Approved Devices and Pending Approval, as seen in the image below.

Devices populate in the **Approved Devices** section when the review board approves a submission to which the device is associated. Once a device is approved, any modifications to that device on the study need to be submitted to the review board for approval. Therefore, you cannot make any changes to the records listed here.

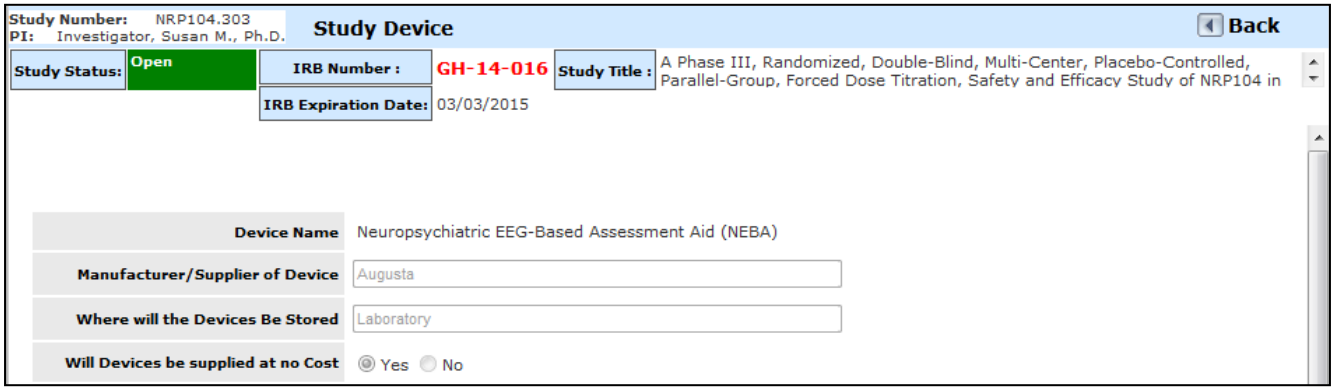
Devices populate in the **Pending Approval** section whenever a modification to an existing device is requested or whenever a new device is in the process of being approved by the review board.

You can view this page in a printer friendly format by clicking the **Printer Friendly** button on the top right of the page.

You can view device details by clicking on the icon in the **Open** column.

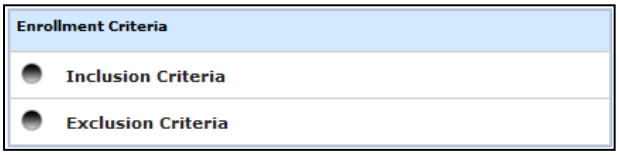


This will open a new page listing read only details.



Click the Back button to return to the main Study Management screen.

Enrollment Criteria



Inclusion Criteria and Exclusion Criteria

If you are using Inclusion / Exclusion Criteria in your Study Application the information entered there will be housed within this link, as shown in the image below. The following steps are used for both Inclusion and Exclusion Criteria.

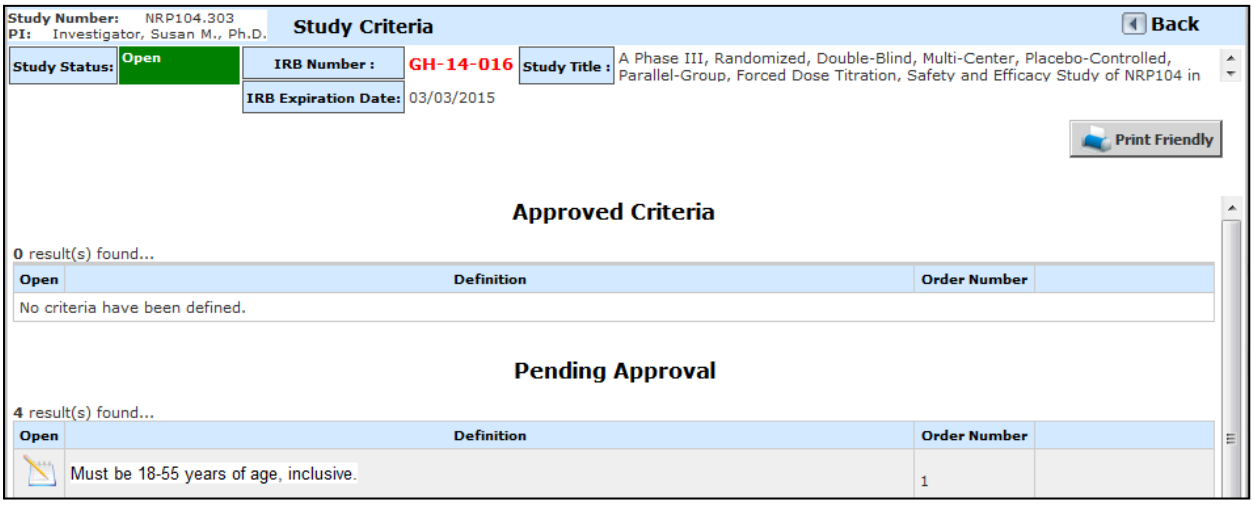
This page is broken up in to two parts, Approved Criteria and Pending Approval.

Inclusion or Exclusion Criteria populates in the **Approved Criteria** section when the review board approves a submission to which the criteria is associated. Once the criteria are approved, any modifications need to be submitted to the review board for approval. Therefore you cannot make any changes to the records listed here.

Criteria will populate in the **Pending Approval** section whenever a modification to an existing criteria record is requested or whenever new criteria are in the process of being approved by the review board.

You can view this page in a printer friendly format by clicking the **Printer Friendly** button on the top right of the page.

You can view device details by clicking on the icon in the **Open** column, as seen in the image below.



This will open a new page listing read only details.