Protocol Tracking and Management System (PTMS)

National Human Genome Research Institute

Reference Guide > Principal Investigator

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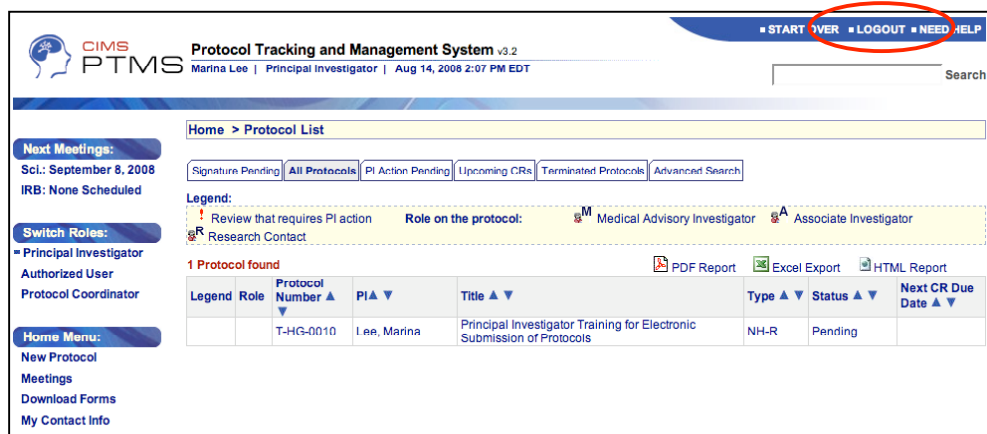## Logging into the System

Enter the URL:
https://ptms.nhgri.nih.gov/.

Enter your username and password (Note: Use the same username and password used to access the NIH network).
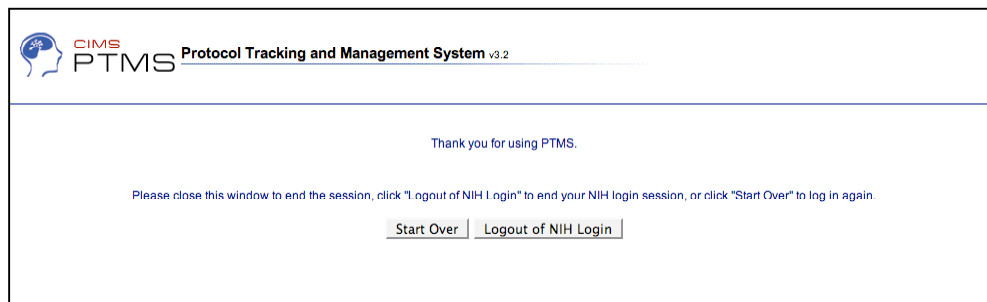
Click **[Log In].**

Logging out of the System

Click **[LOGOUT]** in the top right corner of the screen.

To return to PTMS, click **[Start Over].**
To exit PTMS, click **[Close Window].**

PTMS: Layout & Navigation

After logging in, users are automatically presented with a list of their protocols.

- The user's name and current role are displayed at the top of the page, and the path to the current location is displayed directly beneath. ("Home > Protocol List" at the bottom of the first circled area above). By default, users with multiple system roles will first be displayed as Principal Investigators.
- User roles are displayed in the left column. Switch roles by clicking any that are displayed.
- Users may add a new protocol, display meetings, download forms or view their contact information by following the appropriate links beneath "Home Menu:".
- To return to the PTMS homepage at any time, click **[Home]** in the path circled above.

Click tabs along the top of the grid to view protocol actions.

Protocols with the action icon ( ) require user activity.

Arrange protocols by using the sorting icons ( ).

Access protocols by clicking the Protocol Number or Title.

Creating your first Protocol

From the home menu, click **[New Protocol]** located at the bottom left of the screen.

Fill out the 1195 form completely.

After completing the form click **[Save 1195]**. A temporary protocol number will automatically be assigned.

Click on the protocol number to go to the protocol status page.

The Protocol Menu and Status Page

The PTMS Protocol Menu and Status Page, the hub of PTMS activity.

To access the protocol menu and status page, select **[Home]** to return to the homepage. A list of available protocols will be displayed.

Click any protocol number to access the protocol menu and status page.

From the status page you may review protocol information and changes as well as accrual and review summaries. You may also add amendments, SAEs, violations and terminations, all of which will be discussed in later sections.

In addition to these abilities, the protocol menu and status page displays the status of the initial review and all continuing reviews, amendments, SAEs, and terminations entered in the system.

Finally, the Protocol Information screen, discussed in a later section, is accessed via the Protocol Menu and Status Page by following the **[Protocol Information]** link.

In the following sections, we will review many of the tasks users are able to perform using the Protocol Menu and Status page.

From the protocol menu and status page, click **[Add Amendment]**.

Fill out all fields in the Add Amendment screen and click **[Save]** when finished.

After saving the amendment, you may delete it by selecting **[Delete Amendment]**.

You may also choose to add attachments by following the **[Amendment Attachments]** link.

To add an attachment, click the attachment icon ( ). Find the document on your computer, enter a description and click **[Save]**. (More detailed instructions can be found in the Attachments section.)

PTMS now displays the attachment beside the "download", "change" and "delete" icons ( ).

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Adding an SAE

From the protocol menu and status screen select **[Add SAE]**.

Fill out the form in the Add Serious Adverse Event screen, making sure to fill out all required fields. When you have finished, click **[Save]**.

After entering the SAE, you may edit, delete or print it by clicking the appropriate buttons.

Attachments are added by clicking **[SAE Attachments]** and following the instructions for uploading found in the previous section. A more detailed explanation of the attachment process is found in the Attachments section.

From the protocol menu and status screen click **[Add Violation]**.

Fill out the Add Protocol Violation, making sure to complete all required fields.

Click **[Save]** when you have finished.

After entering the SAE, you may choose to edit or delete it by following the appropriate links.

You may attach documents to the protocol violation by selecting **[PV Attachments]** and following the attachment procedures already described.

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Adding a Termination

From the protocol menu and status screen click **[Add Termination]**.

Fill out the form. When you have finished click **[Save 1195-1]**.

You may now edit or Print the 1195-1 by following the appropriate links.

A variety of documents may be attached to protocols such as Consent Forms, Radiation Safety Docs and Tech Transfer Notes, among others. Begin the attachment process by going to the Protocol Menu and Status page of the protocol you wish to attach a document to.

From the status menu, select the IR, CR, SAE, etc. you wish to attach to, by clicking on the review name. In this example, we are adding attachments to an IR.
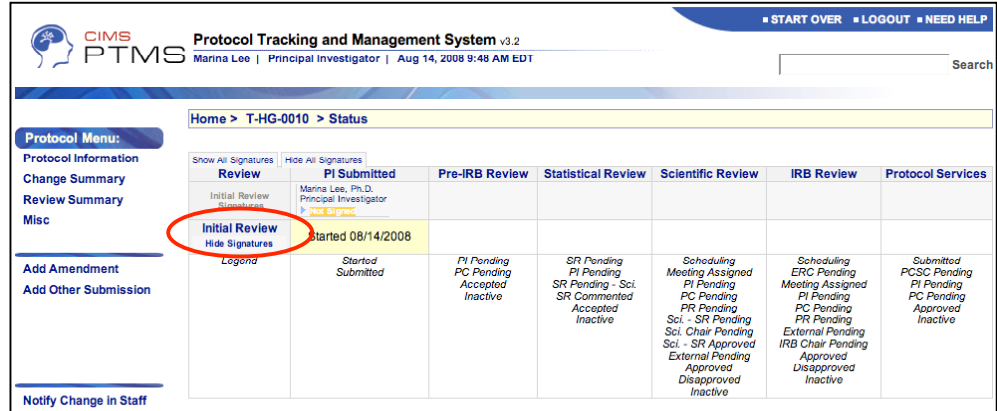
In the following screen, select **[IR Attachments]** from the Review Menu. The Initial Review Attachments screen

(Note the 'Attachments' link changes names based on review you are working with. If files to an SAE, it will be called working with a CR, it will be Regardless of the name, the the same.)
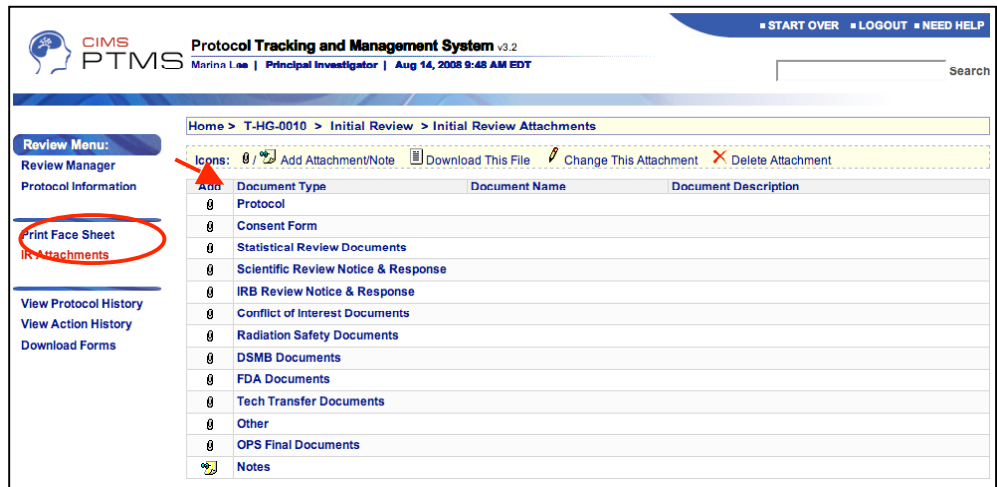
To attach a document, click the attach icon ( ) beside the like to attach.

Enter a description of the document, locate it on your computer by clicking **[Browse]** and then click **[Save]**. The file is now attached.
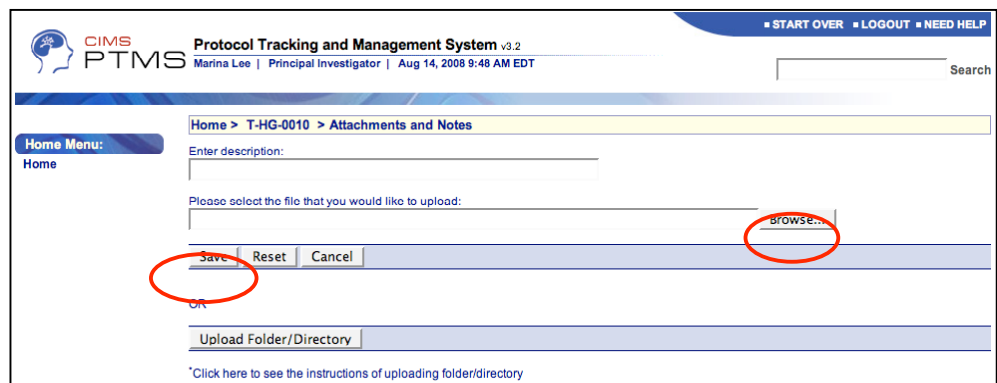
To upload multiple documents from one Folder/Directory click **[Upload Folder/Directory]**. A window will pop up (requires Java). **[Browse]** to select folder then click **[Upload]**.

Note: You may only attach files to an IR, CR, SAE, etc. that has not been submitted or returned to you. After submission, attachments may be viewed by clicking the view icon ( ) but they may not be added or deleted.

Another important hub of PTMS activity is the Review Menu and Review Manager, from which users are able to submit reviews, view comments and view meeting minutes and stipulations.

Review	PI Submitted	Pre-IRB Review	Statistical Review	Scientific Review	IRB Review	Protocol Services
Termination Review	Submitted 11/03/2005	Accepted 11/03/2005	N/A	Disapproved 11/04/2005		
Protocol Violation A	Submitted 11/03/2005	Accepted 11/03/2005	N/A	N/A	Disapproved 11/03/2005	N/A
Serious Adverse Event C	Started 11/16/2005		N/A	N/A		N/A
Serious Adverse Event B	Started 11/15/2005		N/A	N/A	Meeting Assigned 11/16/2005	N/A
Serious Adverse Event A	Submitted 1/03/2005	Accepted 11/03/2005	N/A	N/A	Scheduling 11/04/2005	N/A
Continuing Review 00	Started 11/14/2005		N/A			
Initial Review	Submitted 10/26/2005	Accepted 10/26/2005	Accepted 10/27/2005	Approved 10/27/2005	Approved 11/01/2005	Approved 11/01/2005

From the Protocol Menu and Status Screen select the review you would like to work with (i.e., Initial Review, Continuing Review, Amendment, etc) and click on it.

The Review Menu and Review Manager screen appears.

To submit a review, amendment, termination, etc., simply click **[Submit]** and follow the instructions.

You may also add PI notes by selecting **[Edit PI Notes]**.

To view comments, select **[View Reviewer Comments]**. This selection will be displayed only if comments have been entered in the system.

View meeting minutes and stipulations by clicking **[View Minutes/Stipulations]**.

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Viewing Protocol History, Action History & Changes
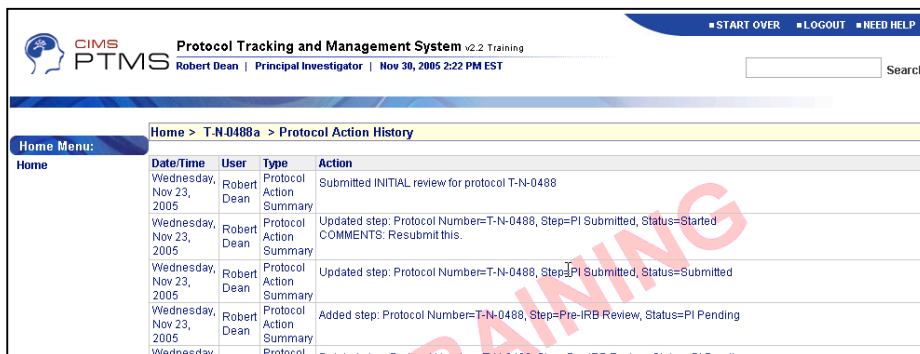
Begin by going to the Review Menu and Manager screen.

To view the protocol's history, select **[View Protocol History]**. A complete list of changes made to the protocol will be displayed.

You may print the protocol history by scrolling to the bottom and clicking **[Print]**.

To review the protocol's action history, click **[View Action History]**. A list of all actions taken on the protocol will be displayed.

Print the history following the same procedures used to print the protocol history, listed above.

The Protocol Information Menu

The Protocol Info Menu allows users to perform routine tasks on protocols.

The Protocol Information Menu (or Protocol Info Menu as it is affectionately known to users) is another area crucial to working with protocols in PTMS. From it, users are able to view, edit and print 1195 data, as well as add DSMB information, Special Exemptions, Conditions and Technology Transfers.

The Protocol Info Menu is accessed from the Protocol Menu and Status Page; simply click **[Protocol Information]** beneath 'Protocol Menu' and you will be taken directly to the page.

In the following sections we will review some of the tasks users may perform using the Protocol Info menu.

Note that all actions described below can only be taken on protocols that have not been submitted or that have been returned. Users cannot edit protocols or make changes to the DSMB information, conditions or special exemptions after a record has been submitted.

Editing, Viewing & Printing Protocols

Whenever users access the Protocol Information Menu, the 1195 data is automatically displayed for viewing.

To edit an 1195, select **[Edit Protocol Information]**.

Make any changes necessary to the 1195 using the same procedures learned in Creating your First Protocol.

Click **[Save 1195]** when you have finished.

To print a protocol, click **[Print 1195 Form]** in the Protocol Info Menu screen.

A PDF file will be displayed. Depending on what version of Adobe Acrobat you are using, you will need to either select "File > Print" or simply click the print icon in the new window.

After printing, close the window to return to PTMS.

From the Protocol Info Menu, click **[DSMB]**. The DSMB screen appears.

DSMB information is changed by following the **[Edit DSMB Information]** button and meetings are added using **[Add Meeting]**.

If you choose to edit the DSMB information, you must first decide if it is required. If so, a variety of fields will be displayed requiring user input. Add Chairs and Meetings be clicking the select icon ( ) or **[Add]** buttons, respectively. Information may be removed by clicking the remove icon ( ).

If you choose to add a meeting, enter the meeting date and any other information.
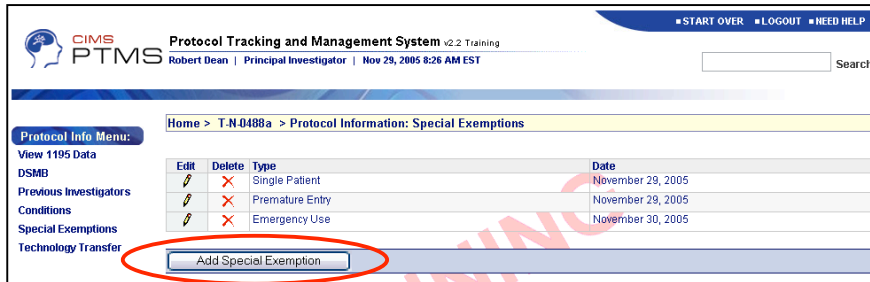
When you have finished, click **[Save DSMB]** and the information will be saved.

Special Exemptions & Conditions

Begin by going to the Protocol Information screen.

Click **[Special Exemptions]** under 'Protocol Info Menu'.

A list of special exemptions within the selected protocol, if any, appears. To add an exemption click **[Add Special Exemption]**.

Enter the requested information and click **[Save]**.

Special exemptions may be edited or deleted by selecting the appropriate icons (circled to the left). Note that edit and delete icons appear only if a special exemption exists.

To add conditions, click **[Conditions]** in the Protocol Info menu. A list of already added conditions will be displayed.
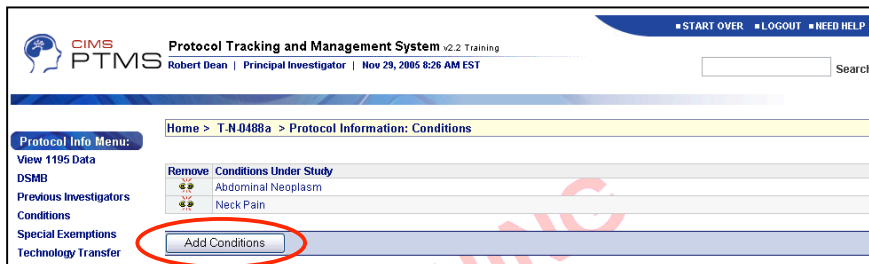
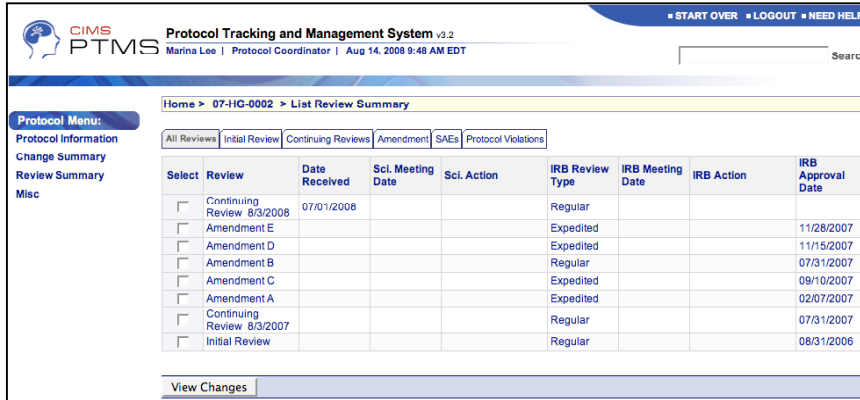To add a new condition, click **[Add Conditions]**.
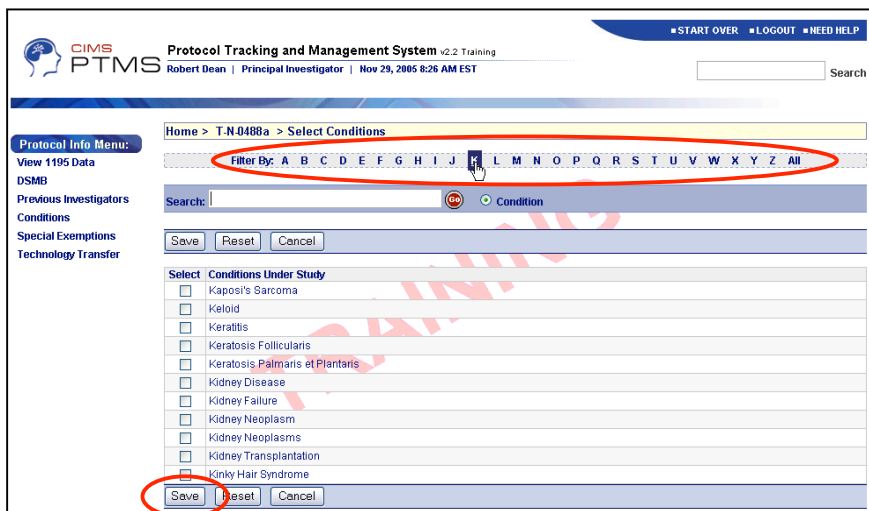
Conditions may be filtered by choosing a letter at the top of the screen, or users may search for conditions by entering a name and clicking **[Go]**.

After locating a condition, check the box beside it and click **[Save]**.

Conditions are removed with the remove icon ( ).

Review Summary, Accrual Summary & Protocol Info Changes

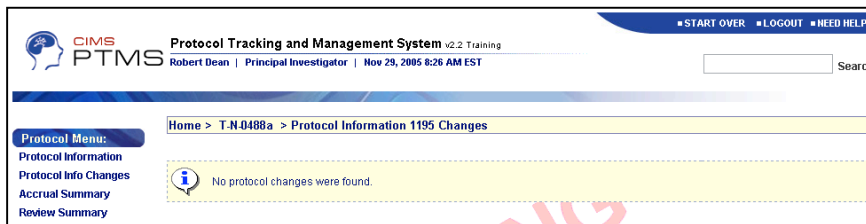Begin by going to the Protocol Menu and Status Page.

To view a summary of the protocol, select **[Review Summary]** from the menu. A list of all reviews created, the date they were received and all IRB/SRC actions taken will be displayed.

To view changes made to the 1195 since the initial review, select applicable continuing review and click **[View Changes]** button. A list of changes will be displayed.

The PTMS Advanced Search feature.

From the home page, click the **[Advanced Search]** tab.

Type in one or more criteria to search for and click [Search].

A list of protocols matching your criteria will be displayed. Access protocols by clicking their numbers.

Note that you may also search by entering a single criterion in the search field located in the top right corner of the screen and clicking **[Search]**. All protocols matching the specified criterion will be displayed.

Submitting a CR is a relatively straightforward exercise in PTMS. After an Initial Review has been approved by Protocol Services, a Continuing Review for the following year will automatically be displayed in the Protocol Menu and Status Screen.

Beginning a Continuing Review.

To begin a Continuing Review, click on its name in the Protocol Menu and Status Screen, then click **[Start]** as demonstrated above.

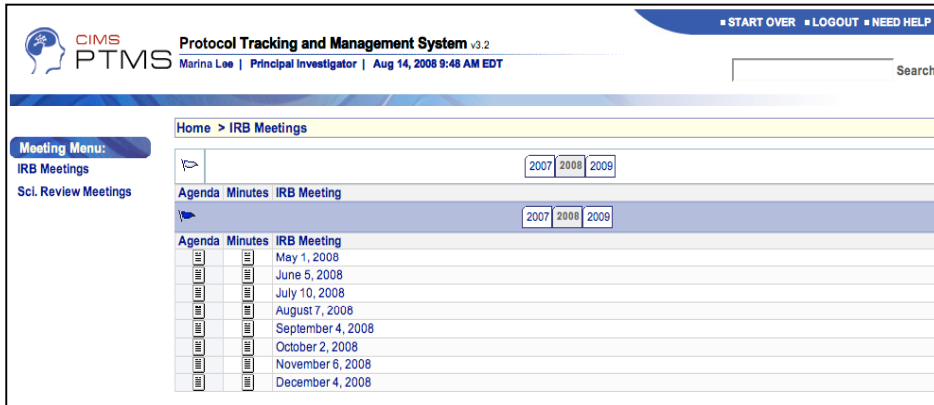Users may attach documents for the CR by selecting **[CR Attachments]**.

To edit or print the review, first click **[Protocol Information]** then click **[1195-1 Form]** in the Protocol Info Menu.

Next, select **[Edit 1195-1 Information]** or **[Print 1195-1 Form]** depending on your needs.

After making all necessary changes to a CR, submit it using the submission procedures learned in The Review Menu & Manager section.

Viewing Meetings & Printing Agendas & Minutes

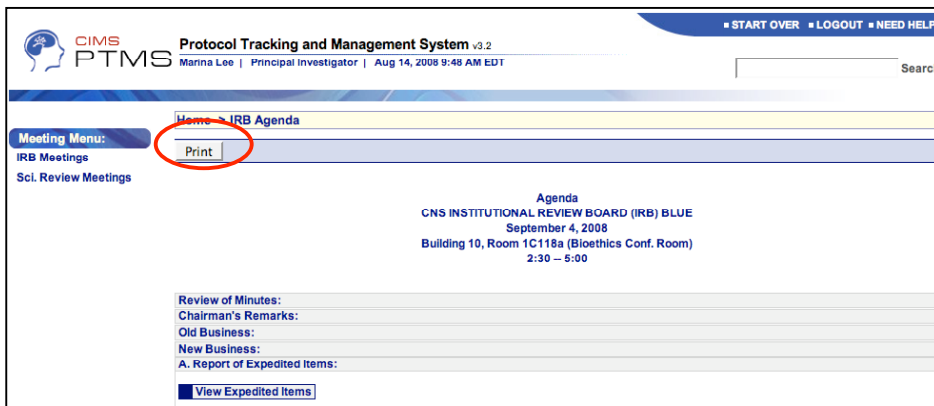Begin by selecting **[Meetings]** from the Home Menu on the main PTMS page.

Choose IRB or Scientific Review meetings by following the appropriate links beneath the Meeting Menu.

A schedule of meetings both present and past is now displayed.

View meeting agendas or minutes by clicking the notepad icon ( ).

Agendas and minutes are printed by first viewing them and then selecting **[Print]** at the top of the screen.

Users may also view protocol attachments by clicking **[View Attachments]** beside the different protocol numbers.

Viewing and editing your PTMS contact information begins in the main menu. Select **[My Contact Info]** beneath the Home Menu and the screen above will appear.

Make any necessary changes and click **[Save]**.