

# Protocol Tracking and Management System (PTMS)



National Human  
Genome Research  
Institute

**Reference Guide > Principal Investigator**

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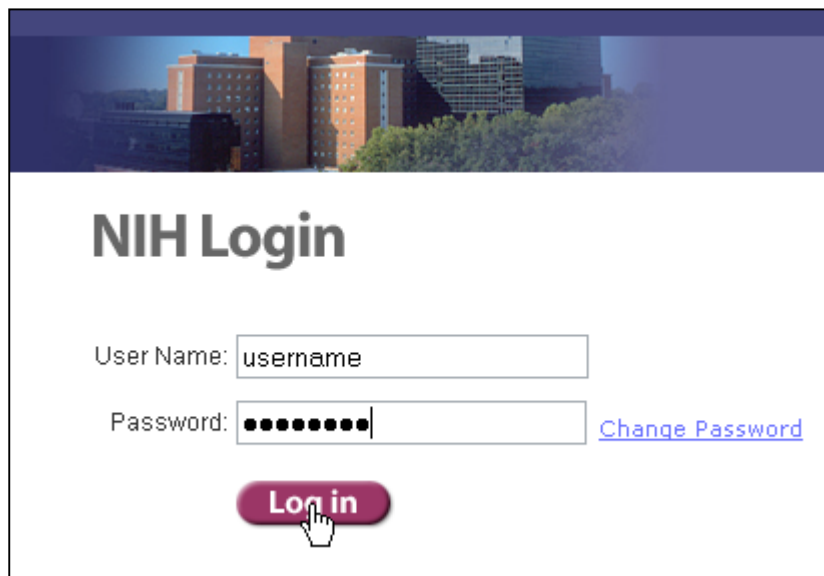
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# Introduction to PTMS

## Logging into the System



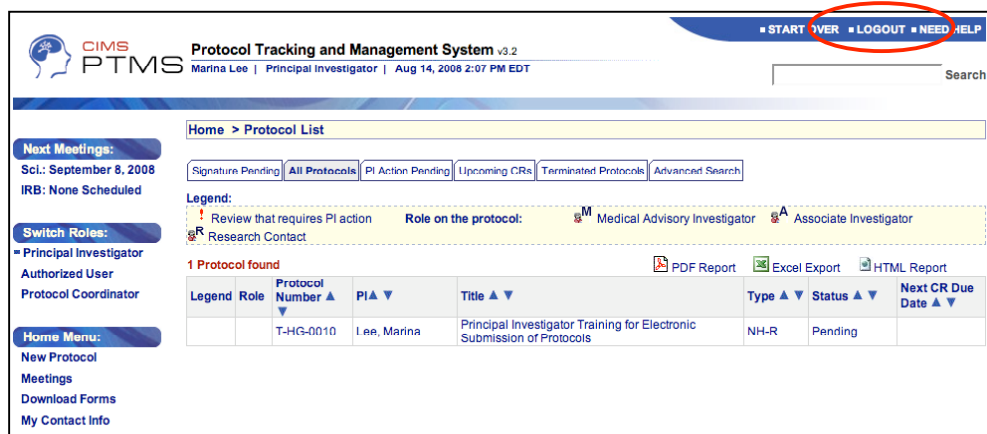
Enter the URL:

<https://ptms.nhgri.nih.gov/>.

Enter your username and password (Note: Use the same username and password used to access the NIH network).

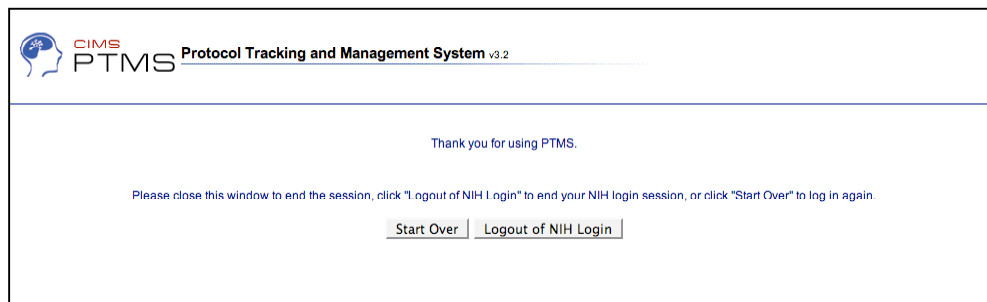
Click **[Log In]**.

## Logging out of the System



Legend	Role	Protocol Number ▲	PI ▲ ▼	Title ▲ ▼	Type ▲ ▼	Status ▲ ▼	Next CR Due Date ▲ ▼
		T-HG-0010	Lee, Marina	Principal Investigator Training for Electronic Submission of Protocols	NH-R	Pending	

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



Thank you for using PTMS.

Please close this window to end the session, click "Logout of NIH Login" to end your NIH login session, or click "Start Over" to log in again.

[Start Over](#) [Logout of NIH Login](#)

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.

Legend	Role	Protocol Number ▲	PI ▲ ▼	Title ▲ ▼	Type ▲ ▼	Status ▲ ▼	Next CR Due Date ▲ ▼
		T-HG-0010	Lee, Marina	Principal Investigator Training for Electronic Submission of Protocols	NH-R	Pending	

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

The screenshot shows the 'Edit 1195 Data' page in the PTMS. At the top, there is a navigation bar with 'Home > Edit 1195 Data'. Below this is a 'Home Menu' with a 'Save 1195' button circled in red, along with 'Reset' and 'Cancel' buttons. The main form area contains the following fields:

Protocol Number	T-HG-0010	Temporary Protocol #	T-HG-0010
Protocol Type *	NH-R	Status	Pending
Institute *	NHGRI	Branch *	CT
Principal Investigator	Lee, Marina Ph.D., NHGRI, 50/5305, leemarina@mail.nih.gov, 301-402-4271		
Title *	Principal Investigator Training for Electronic Submission of Protocols		
Short Title	PI-ESP	Accrual Ceiling	50
Proposed Start Date *	8/14/2008 (mm/dd/yyyy)	Proposed End Date *	8/14/2009 (mm/dd/yyyy)
Keywords	Remove Edit Keyword Add		

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.

The screenshot shows the 'Status' page for protocol T-HG-0010. The breadcrumb trail is 'Home > T-HG-0010 > Status'. The 'Protocol Menu' is visible at the bottom left.

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

# The Protocol Menu and Status Page

Protocol Tracking and Management System v3.2  
Marina Lee | Protocol Coordinator | Aug 14, 2008 9:16 AM EDT

Home > 08-HG-0059 > Status

Protocol Menu:  
 Protocol Information  
 Change Summary  
 Review Summary  
 Misc  
 Add Amendment  
 Add SAE  
 Add Violation  
 Add Termination  
 Backfill  
 Add Other Submission

Review	PI Submitted	Pre-IRB Review	Statistical Review	Scientific Review	IRB Review	Protocol Services
Amend Review tC Signatures	Julia A. Segre, Ph.D. Principal Investigator Not Signed					
Amendment tC	Started 06/17/2008					
Continuing Review 10/31/2008			N/A			
Expedited Amendment B					Approved 01/24/2008	Approved 01/29/2008
Expedited Amendment A					Approved 01/24/2008	Approved 01/28/2008
Initial Review					Approved 01/14/2008	Approved 01/22/2008
Legend	Started Submitted	PI Pending PC Pending Accepted Inactive	SR Pending PI Pending SR Pending - Sci. SR Commented Accepted Inactive	Scheduling Meeting Assigned PI Pending PC Pending PR Pending Sci. - SR Pending Sci. - SR Approved External Pending Approved Disapproved Inactive	Scheduling ERC Pending Meeting Assigned PI Pending PC Pending PR Pending External Pending IRB Chair Pending Approved Disapproved Inactive	Submitted PCSC Pending PI Pending PC Pending Approved Inactive

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.

# Adding an Amendment

The screenshot shows the 'Add Amendment' page in the PTMS. The breadcrumb trail is 'Home > T.N-0488a > Add Amendment'. There are radio buttons for 'Expedited Amendment?' (No is selected) and 'Have any of the Consents changed since the last review?' (No is selected). A large text area for 'Description:' is present. At the bottom, the 'Save', 'Reset', and 'Cancel' buttons are visible, with the 'Save' button circled in red.

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

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

The screenshot shows the 'View Amendment' page. The breadcrumb trail is 'Home > T.N-0488a > Amendment > View Amendment'. In the 'Review Menu' on the left, 'Amendment Attachments' is circled in red. In the main content area, the 'Delete Amendment' button is circled in red.

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.

The screenshot shows the 'Amendment Attachments' page. The breadcrumb trail is 'Home > T.N-0488a > Amendment > Amendment Attachments'. At the top, there are icons for 'Add Attachment/Note', 'Download This File', 'Change This Attachment', and 'Delete Attachment'. Below is a table of attachments:

Add	Document Type	Document Name	Document Description
	Amendment Memorandum		
	Protocol		
	Consent Form		
	Radiation Safety Doc		
	FDA Documentation		
	Tech Transfer Notes		
	Other		
	NonElectronic Documents		
	Notes		

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 ( ).

# Adding an SAE

The screenshot shows the 'Add Serious Adverse Event' form in the PTMS. At the top, there is a navigation bar with 'Home > T-N-0488a > Add Serious Adverse Event'. Below this, there are three buttons: 'Save SAE', 'Reset', and 'Cancel'. The 'Save SAE' button is circled in red. The form contains the following information:

- Protocol Number:** T-N-0488a
- Principal Investigator:** Robert Dean, Institute: NINDS, Office: 301-594-8391, Fax: deanra@ninds.nih.gov, Email: deanra@ninds.nih.gov
- Title:** Training Email Test 11.22.05

Below the protocol information, there are several form fields and options:

- SAE Details:** Top | Bottom
- Date of serious adverse event:** \* (mm/dd/yyyy)
- Location of serious adverse event:**
- Was this an unexpected adverse event?**  Yes  No
- Brief description of subject(s):**  Male  Female

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]**.

The screenshot shows the 'View Serious Adverse Event' screen in the PTMS. At the top, there is a navigation bar with 'Home > T-N-0488a > SAE > View Serious Adverse Event'. Below this, there are three buttons: 'Edit SAE', 'Delete SAE', and 'Print SAE Form'. These three buttons are circled in red. The form contains the following information:

- Protocol Number:** T-N-0488a
- Principal Investigator:** Robert Dean, Institute: NINDS, Office: 301-594-8391, Fax: deanra@ninds.nih.gov, Email: deanra@ninds.nih.gov
- Title:** Training Email Test 11.22.05

Below the protocol information, there are several form fields and options:

- SAE Details:** Top | Bottom
- Date of serious adverse event:** 11/28/2005

On the left side, there is a 'Review Menu' with several links. A red arrow points to the 'SAE Attachments' link.

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.



# Adding a Violation

The screenshot shows the 'Add Protocol Violation' form in the PTMS interface. The form includes fields for 'Violation Type' (radio buttons for Violation and Deviation), 'Violation Date' (with a calendar icon), and 'Description'. Below these fields are three buttons: 'Save', 'Reset', and 'Cancel'. The 'Save' button is circled in red. A calendar pop-up is open, showing the date 28/11/2005. The breadcrumb trail is 'Home > T-N-0488a > Add Protocol Violation'. The top navigation bar includes 'START OVER', 'LOGOUT', and 'NEED HELP' links. The user information at the top indicates 'Robert Dean | Principal Investigator | Nov 28, 2005 1:32 PM EST'.

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.

The screenshot shows the 'View Protocol Violation' page in the PTMS interface. The breadcrumb trail is 'Home > T-N-0488a > Protocol Violation > View Protocol Violation'. The left sidebar contains a 'Review Menu' with links: 'Review Manager', 'Protocol Information', 'Protocol Changes', 'Print Face Sheet', 'View Violation', 'PV Attachments', 'View Protocol History', 'View Action History', and 'Download Forms'. The 'PV Attachments' link is highlighted with a red arrow. The main content area shows the violation details: 'Violation Type' (radio buttons for Violation and Deviation), 'Violation Date' (11/29/2005), and 'Description'. The 'Edit' and 'Delete Protocol Violation' buttons are circled in red. The top navigation bar includes 'START OVER', 'LOGOUT', and 'NEED HELP' links. The user information at the top indicates 'Robert Dean | Principal Investigator | Nov 28, 2005 1:32 PM EST'.

# Adding a Termination

Protocol Tracking and Management System v2.2 Training  
Robert Dean | Principal Investigator | Nov 28, 2005 1:32 PM EST

Home > T-N-0488a > Add Termination

Save 1195-1 | Reset | Cancel

Protocol Number: T-N-0488a  
Principal Investigator: Dean Robert, NINDS/OCD, deanra@ninds.nih.gov, 301-594-8391  
Title: Training Email Test 11.22.05

Action Requested:  Terminate - Protocol discontinued  
Have there been any amendments since the last review?  Yes  No

Misc Narrative:

Save 1195-1 | Reset | Cancel

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.

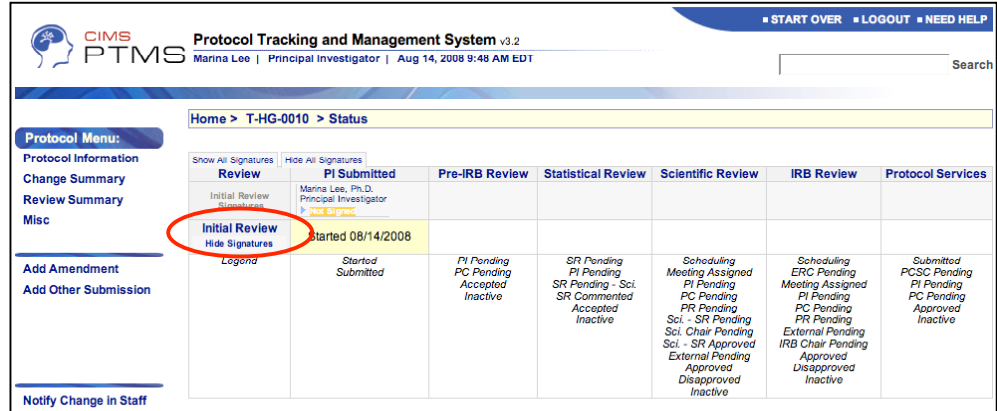
Misc Narrative:

Save 1195-1 | Reset | Cancel

# Attachments

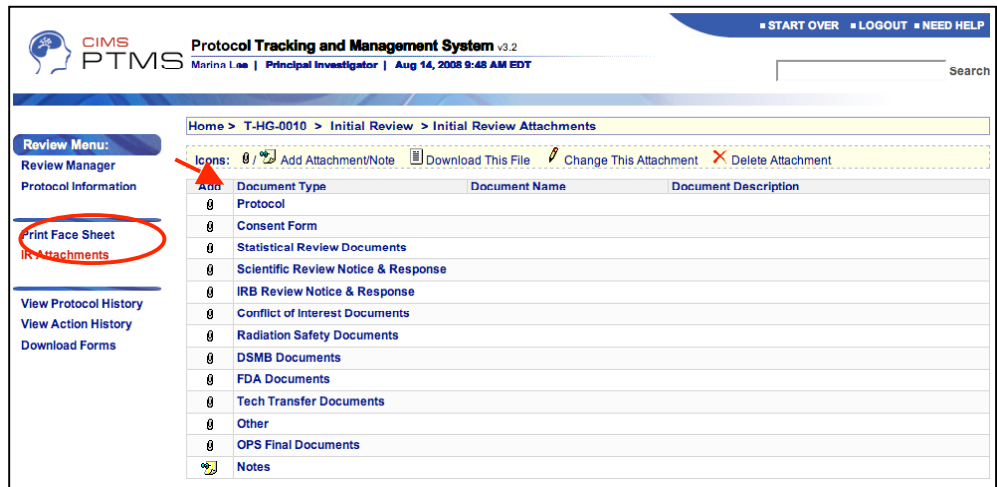
A variety of documents may be attached to protocols such as Consent Forms, Radiation Safety Docs and Tech Transfer Notes, among others. Begin the attachment process by going to the Protocol Menu and Status page of the protocol you wish to attach a document to.

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.



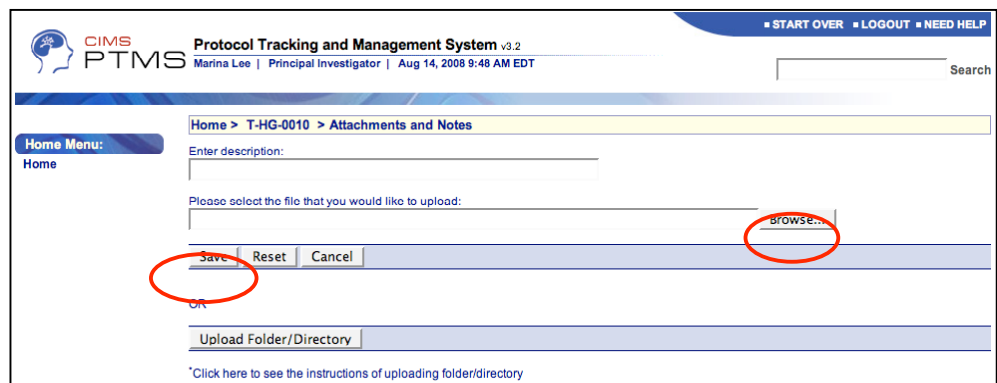
In the following screen, select **[IR Attachments]** from the Review Menu. The Initial Review Attachments screen

(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.

# The Review Menu & Manager/Submitting Forms/Viewing Comments

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 11/03/2005	Accepted 11/03/2005	N/A	N/A	Scheduling 11/04/2005	N/A
Continuing Review	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.

Protocol Tracking and Management System v2.2 Training  
Robert Dean | Principal Investigator | Nov 30, 2005 2:22 PM EST

Home > T-N-0490 > Initial Review > Review Manager

Review Menu:  
Review Manager  
Protocol Information  
Print Face Sheet  
IR Attachments  
View Protocol History  
View Action History  
Download Forms

PI Submitted: State: started, 11/03/2005  
**Submit**

Pre-IRB Review: State: N/A

Statistical Review: State: N/A

Scientific Review: State: N/A

IRB Review: State: N/A

Protocol Services: State: N/A

Review Notes (for Principal Investigator and Authorized Users):  
**Edit PI Notes**

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]**.

Protocol Tracking and Management System v2.2 Training  
Robert Dean | Principal Investigator | Nov 30, 2005 2:22 PM EST

Home > T-N-0488a > Initial Review > Review Manager

Review Menu:  
Review Manager  
Protocol Information  
Print Face Sheet  
IR Attachments  
View Protocol History  
View Action History  
Download Forms

PI Submitted: State: Submitted, 11/23/2005

Pre-IRB Review: State: Accepted, 11/23/2005  
**View Reviewer Comments**

Statistical Review: State: Accepted, 11/23/2005

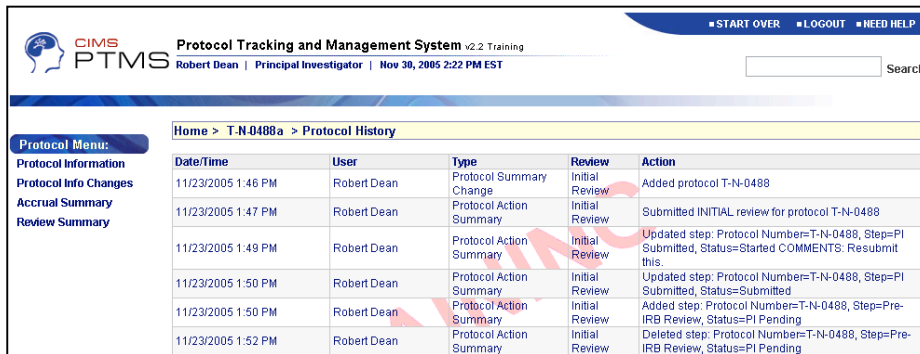
Statistical Reviewer Comments	Date/Time	User	Action	Comments
	11/23/2005	Robert Dean	Comment -- PI Response Required	Respond to this comment.
	11/23/2005	Robert Dean	Comment -- No PI Response	I never saw any comments.
	11/23/2005	Robert Dean	Comment -- No PI Response	Comment.

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]**.

# Viewing Protocol History, Action History & Changes

Begin by going to the Review Menu and Manager screen.

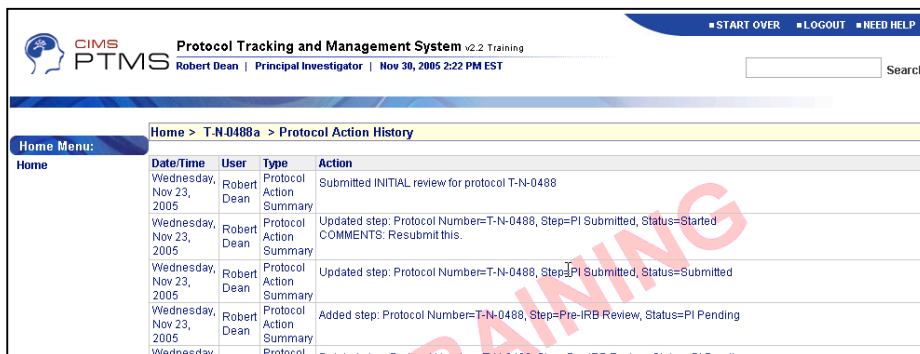


The screenshot shows the PTMS interface with the 'Protocol History' page selected. The breadcrumb trail is 'Home > T-N-0488a > Protocol History'. The left sidebar contains a 'Protocol Menu' with options: Protocol Information, Protocol Info Changes, Accrual Summary, and Review Summary. The main table lists the following actions:

Date/Time	User	Type	Review	Action
11/23/2005 1:46 PM	Robert Dean	Protocol Summary Change	Initial Review	Added protocol T-N-0488
11/23/2005 1:47 PM	Robert Dean	Protocol Action Summary	Initial Review	Submitted INITIAL review for protocol T-N-0488
11/23/2005 1:49 PM	Robert Dean	Protocol Action Summary	Initial Review	Updated step: Protocol Number=T-N-0488, Step=PI Submitted, Status=Started COMMENTS: Resubmit this.
11/23/2005 1:50 PM	Robert Dean	Protocol Action Summary	Initial Review	Updated step: Protocol Number=T-N-0488, Step=PI Submitted, Status=Submitted
11/23/2005 1:50 PM	Robert Dean	Protocol Action Summary	Initial Review	Added step: Protocol Number=T-N-0488, Step=Pre-IRB Review, Status=PI Pending
11/23/2005 1:52 PM	Robert Dean	Protocol Action Summary	Initial Review	Deleted step: Protocol Number=T-N-0488, Step=Pre-IRB Review, Status=PI Pending

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]**.



The screenshot shows the PTMS interface with the 'Protocol Action History' page selected. The breadcrumb trail is 'Home > T-N-0488a > Protocol Action History'. The left sidebar contains a 'Home Menu' with the option: Home. The main table lists the following actions:

Date/Time	User	Type	Action
Wednesday, Nov 23, 2005	Robert Dean	Protocol Action Summary	Submitted INITIAL review for protocol T-N-0488
Wednesday, Nov 23, 2005	Robert Dean	Protocol Action Summary	Updated step: Protocol Number=T-N-0488, Step=PI Submitted, Status=Started COMMENTS: Resubmit this.
Wednesday, Nov 23, 2005	Robert Dean	Protocol Action Summary	Updated step: Protocol Number=T-N-0488, Step=PI Submitted, Status=Submitted
Wednesday, Nov 23, 2005	Robert Dean	Protocol Action Summary	Added step: Protocol Number=T-N-0488, Step=Pre-IRB Review, Status=PI Pending
Wednesday, Nov 23, 2005	Robert Dean	Protocol Action Summary	Deleted step: Protocol Number=T-N-0488, Step=Pre-IRB Review, Status=PI Pending

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 screenshot displays the PTMS interface. At the top, it shows the CIMS PTMS logo, the system name 'Protocol Tracking and Management System v3.2', and user information for Marina Lee, Principal Investigator, dated Aug 14, 2008 2:07 PM EDT. Navigation links include 'START OVER', 'LOGOUT', and 'NEED HELP'. A search bar is present on the right.

The main content area shows a breadcrumb trail: Home > T-HG-0010 > Initial Review > Protocol Information: 1195 Data. Below this are three tabs: 'Edit Protocol Information' (selected), 'Print 1195 Form', and 'Launch ProtoType'.

On the left, a 'Protocol Info Menu' is visible with options: 'View 1195 Data', 'DSMB', 'Special Exemptions', 'Technology Transfer', 'Initial Review', 'Review Manager', and 'Switch to Current'.

The main data area contains the following information:

- Protocol Number: T-HG-0010
- Protocol Type: NH-R
- Institute: NHGRI
- Principal Investigator: Lee, Marina Ph.D., NHGRI, 50/5305, leemarina@mail.nih.gov, 301-402-4271
- Title: Principal Investigator Training for Electronic Submission of Protocols
- Short Title: PI-ESP
- Proposed Start Date: 8/14/2008
- Keywords:
- Temporary Protocol #: T-HG-0010
- Status: Pending
- Branch: GT
- Accrual Ceiling: 50
- Proposed End Date: 8/14/2009

Below the main data, there is a question: 'If a Phase 3 Clinical Trial, is analysis for sex, racial/ethnic subgroups required according to the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research?' with radio buttons for 'Yes', 'No', and 'N/A'.

A 'Contacts' section is also present, with a table listing roles and contact information:

	Name	Institute/Branch	Contact Info
Accountable Investigator *	ptms, pc M.D., Ph.D.	NHGRI/OD	
Medical Advisory Investigator	Krasnewich, Donna M.D.	NHGRI/MG	301-402-8255, dkras@mail.nih.gov
Research Contact			
Administrative Contact			
Lead Associate Investigator			

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.

CLINICAL RESEARCH PROTOCOL <b>INITIAL REVIEW APPLICATION</b>	PRINCIPAL INVESTIGATOR (Name of NIH Employee, Institute/Branch, Address, Telephone and email): <b>Marina Lee, Ph.D., NHGRI, 301-402-4271, 50/5305, leemarina@mail.nih.gov</b>
PROTOCOL TITLE: <b>Principal Investigator Training for Electronic Submission of Protocols</b>	
ABBREVIATED TITLE (30 characters or less): <b>PI-ESP</b>	
PROPOSED START DATE: <b>8/14/2008</b>	END DATE: <b>8/14/2009</b> TOTAL SUBJECTS TO BE ACCRUED (Attach target table for Phase 3-4): <b>50</b>
<p>MULTI-SITE COLLABORATION:</p> <p>Is this a multi-site collaboration? <input type="checkbox"/> Yes (complete this section) <input type="checkbox"/> No</p> <p>Will subjects participate on the protocol at the NIH CC? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Will subjects participate on the protocol at other sites? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If yes, are the sites <input type="checkbox"/> Domestic <input type="checkbox"/> Foreign <input type="checkbox"/> Both</p> <p>Is NIH the coordinating site?</p> <p><input type="checkbox"/> Yes. For each participating site, provide: Institution name, address, investigator(s), indicate if subjects will be recruited and if they are, include a contact name on attached sheet/protocol face sheet.</p> <p><input type="checkbox"/> No. Coordinating Site is _____</p> <p>REQUESTED ACCRUAL EXCLUSION (Check all that apply):</p> <p><input checked="" type="checkbox"/> None <input type="checkbox"/> Asian</p> <p><input type="checkbox"/> Male <input type="checkbox"/> Black or African American</p> <p><input type="checkbox"/> Female <input type="checkbox"/> White</p> <p><input type="checkbox"/> Children &lt;10 <input type="checkbox"/> Hispanic or Latino</p> <p><input type="checkbox"/> American Indian/ Alaskan Native <input type="checkbox"/> Native Hawaiian or Pacific Islander</p> <p>SUBJECT ACCRUAL CHARACTERISTICS:</p> <p>Minimum Age Permitted _____</p> <p>Maximum Age Permitted _____</p> <p>Pediatric <input type="checkbox"/> None <input type="checkbox"/> &lt;2 Yr. <input type="checkbox"/> 2-6 Yrs. <input type="checkbox"/> 7-17 Yrs.</p> <p>Protocol involves healthy volunteers? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Are Healthy Volunteers NIH Employees? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Does the protocol permit self referral? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Will the protocol involve adults unable to give informed consent? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>IONIZING RADIATION USE (X-rays, e.g., CT; radioisotopes, e.g. PET; etc.) check all that apply</p> <p><input type="checkbox"/> None <input type="checkbox"/> Medically indicated <input type="checkbox"/> Research indicated*</p> <p>*Complete NIH-88-23a, and attach to this application. Send a copy of entire protocol and NIH 88 23a to Chair, Radiation Safety for concurrent review).</p> <p>INVESTIGATIONAL NEW DRUG/DEVICE: <input checked="" type="checkbox"/> None <input type="checkbox"/> IND <input type="checkbox"/> IDE</p> <p>*If reporting more than one IND/IDE, list on attached sheet</p> <p>FDA No. _____</p> <p>IND/IDE Name: _____</p> <p>Sponsor: _____</p> <p>Who is the manufacturer of the above entity: _____</p> <p>Does the protocol involve a Tech Transfer Agreement? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Does the protocol involve a drug/device/product that may lead to you or the NIH receiving payment and/or royalties?</p> <p><input type="checkbox"/> Yes (Append a statement of disclosure)</p> <p><input type="checkbox"/> No</p> <p>Has the NIH IRP COI Guide been distributed to NIH Investigators?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Has the NIH IRP COI Guide been distributed to Non-NIH Investigators?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A</p> <p>CONFLICTS OF INTEREST REVIEW:</p> <p>Date submitted to IC DEC: _____ Date cleared by IC DEC: _____</p> <p>Is an Extramural Investigator an ADJUNCT PRINCIPAL INVESTIGATOR? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>

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.

# Recording DSMB Information

Protocol Tracking and Management System v2.2 Training  
Robert Dean | Principal Investigator | Nov 29, 2005 8:26 AM EST

Home > T.N.0488a > Protocol Information: Data Safety Monitoring Board

**Protocol Info Menu:**  
View 1195 Data  
DSMB  
Previous Investigators  
Conditions  
Special Exemptions  
Technology Transfer

**DSMB**

Required	Yes
Initiated By	Investigator
DSMB Chair	Name: Wang, Gladys Contact Info: 301-402-1921 / wangg@ninds.nih.gov
DSMB Members	Name: Contact Info
Meeting Schedule	Monthly

**Edit DSMB Information**

**DSMB Meetings**

Edit	Delete	Meeting Date	Meeting Minutes	Accrued Patients	Notes
		11/30/2005			

**Add Meeting**

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]**.

Protocol Tracking and Management System v2.2 Training  
Robert Dean | Principal Investigator | Nov 29, 2005 8:26 AM EST

Home > T.N.0488a > Edit DSMB Information

**Protocol Info Menu:**  
View 1195 Data  
DSMB  
Previous Investigators  
Conditions  
Special Exemptions  
Technology Transfer

**DSMB**

Required	<input checked="" type="radio"/> Yes <input type="radio"/> No
Initiated By	<input checked="" type="radio"/> Investigator <input type="radio"/> Sponsor
DSMB Chair	Remove  Select  Name: wang1_wang1 Contact Info
DSMB Members	Remove  Add  Name: Contact Info
Meeting Schedule	Monthly

**Save** **Cancel** **Reset**

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 ()

Protocol Tracking and Management System v2.2 Training  
Robert Dean | Principal Investigator | Nov 29, 2005 8:26 AM EST

Home > T.N.0488a > Add DSMB Record

**Protocol Info Menu:**  
View 1195 Data  
DSMB  
Previous Investigators  
Conditions  
Special Exemptions  
Technology Transfer

**Meeting Date\*** 11/30/2005 (mm/dd/yyyy)

**Accrued Patients**

**Meeting Minutes**

**Notes**

**Save DSMB** **Reset** **Cancel**

If you choose to add a meeting, enter the meeting date and any other information.

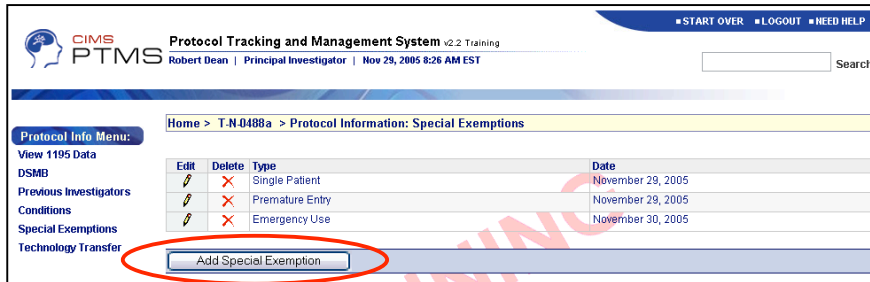
When you have finished, click **[Save DSMB]** and the information will be saved.



# Special Exemptions & Conditions

Begin by going to the Protocol Information screen.

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



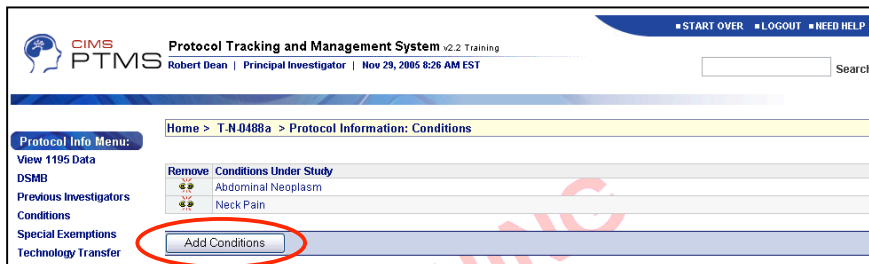
A list of special exemptions within the selected protocol, if any, appears. To add an exemption click **[Add Special Exemption]**.

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

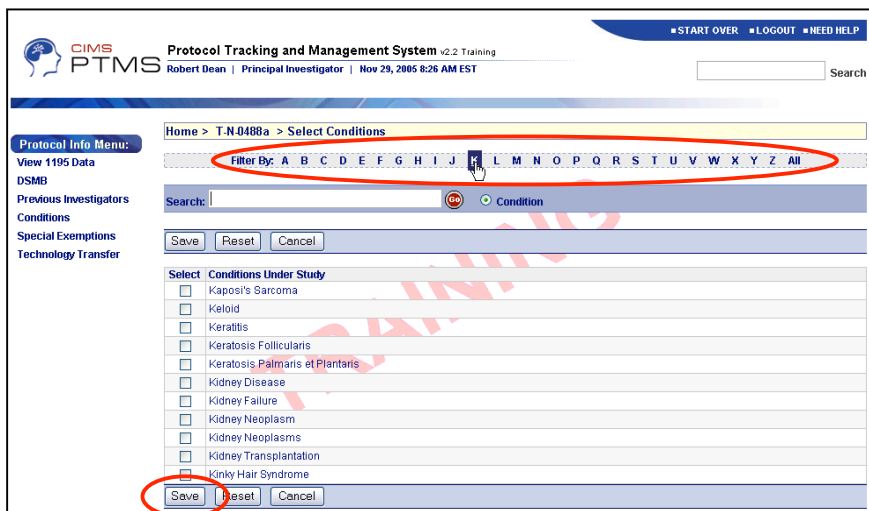
Edit	Delete	Type	Date
		Single Patient	November 29, 2005
		Premature Entry	November 29, 2005
		Emergency Use	November 30, 2005
		Single Patient	November 30, 2005

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]**.



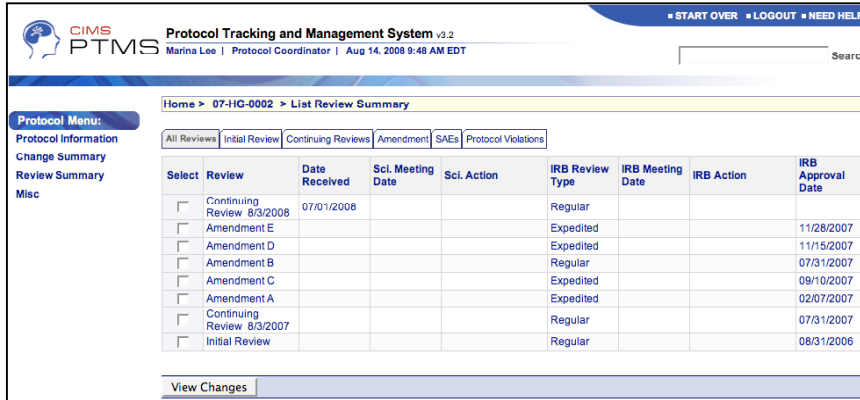
Conditions may be filtered by choosing a letter at the top of the screen, or users may search for conditions by entering a name and clicking **[Go]**.

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.

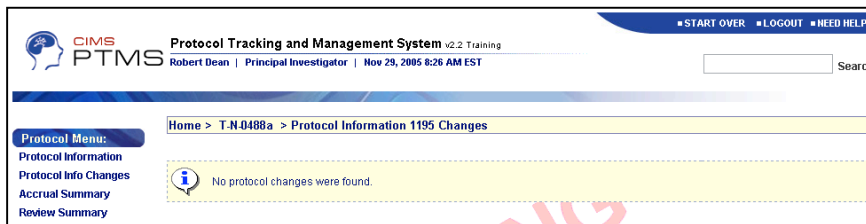


The screenshot shows the PTMS interface for protocol 07-HG-0002. The breadcrumb trail is "Home > 07-HG-0002 > List Review Summary". The "Protocol Menu" on the left includes "Protocol Information", "Change Summary", "Review Summary", and "Misc". The main content area has tabs for "All Reviews", "Initial Review", "Continuing Reviews", "Amendment", "SAEs", and "Protocol Violations". A table lists the following reviews:

Select	Review	Date Received	Sci. Meeting Date	Sci. Action	IRB Review Type	IRB Meeting Date	IRB Action	IRB Approval Date
<input type="checkbox"/>	Continuing Review 8/3/2008	07/01/2008			Regular			
<input type="checkbox"/>	Amendment E				Expedited			11/28/2007
<input type="checkbox"/>	Amendment D				Expedited			11/15/2007
<input type="checkbox"/>	Amendment B				Regular			07/31/2007
<input type="checkbox"/>	Amendment C				Expedited			09/10/2007
<input type="checkbox"/>	Amendment A				Expedited			02/07/2007
<input type="checkbox"/>	Continuing Review 8/3/2007				Regular			07/31/2007
<input type="checkbox"/>	Initial Review				Regular			08/31/2006

At the bottom of the table is a "View Changes" button.

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.



The screenshot shows the PTMS interface for protocol T-N-0488a. The breadcrumb trail is "Home > T-N-0488a > Protocol Information 1195 Changes". The "Protocol Menu" on the left includes "Protocol Information", "Protocol Info Changes", "Accrual Summary", and "Review Summary". The main content area has tabs for "All Reviews", "Initial Review", "Continuing Reviews", "Amendment", "SAEs", and "Protocol Violations". A message box with an information icon states: "No protocol changes were found."

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.

# Protocol Searches

The screenshot shows the PTMS (Protocol Tracking and Management System) interface. At the top, there is a header with the CIMS PTMS logo, the user name Marina Lee, the role Principal Investigator, and the date/time Aug 14, 2008 9:48 AM EDT. There are links for START OVER, LOGOUT, and NEED HELP. A search bar is located in the top right corner. Below the header, there is a navigation bar with tabs for Signature Pending, All Protocols, PI Action Pending, Upcoming CRs, Terminated Protocols, and Advanced Search. The Advanced Search tab is highlighted with a red circle. Below the navigation bar, there is a section for Ad-Hoc Search and a Limited Search section. The Limited Search section contains several search criteria: Protocol Title, Protocol Number, Institute (dropdown), Protocol Status (dropdown), Protocol Type (dropdown), Protocol Keyword, Protocol Precip, Protocol Exclusion (checkbox), and Review (dropdown). The Protocol Status dropdown is open, showing options: Pending, Active Accrual, Follow-Up, Expired, and Terminated. At the bottom of the search section, there are Search and Clear buttons.

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.

The screenshot shows the PTMS search results page. The header is the same as the previous screenshot. The navigation bar is the same, but the Advanced Search tab is no longer highlighted. Below the navigation bar, there is a section for Next Meetings: Sci: September 8, 2008. Below that, there is a section for Ad-Hoc Search and a Limited Search section. The search criteria are the same as in the previous screenshot. At the bottom of the search section, there are Search and Clear buttons.

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

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.

The screenshot shows the PTMS interface. At the top, there is a header with the CIMS PTMS logo, the system name 'Protocol Tracking and Management System v2.2 Training', and user information 'Robert Dean | Principal Investigator | Nov 30, 2005 2:22 PM EST'. There are also links for 'START OVER', 'LOGOUT', and 'NEED HELP', and a search box. The main content area is titled 'Home > T-N.0488a > Continuing Review 06 > Review Manager'. On the left, a 'Review Menu' is visible with options like 'Review Manager', 'Protocol Information', 'Protocol Changes', 'Print Face Sheet', 'CR Attachments' (highlighted with a red arrow), 'View Protocol History', 'View Action History', and 'Download Forms'. The main content area shows the 'PI Submitted' status with a 'State: N/A' and a 'Start' button. Below this are sections for 'Pre-IRB Review', 'Scientific Review', 'IRB Review', 'Protocol Services', and 'Review Notes (for Principal Investigator and Authorized Users):' with an 'Edit PI Notes' button.

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]**.

The screenshot shows a 'Protocol Info Menu' with the following options: 'View 1195 Data', '1195-1 Form' (highlighted with a mouse cursor), 'DSMB', 'Previous Investigators', 'Conditions', 'Special Exemptions', and 'Technology Transfer'. Below this is a 'Continuing Rev. 06:' section with options 'Review Manager' and 'Switch to Current'.

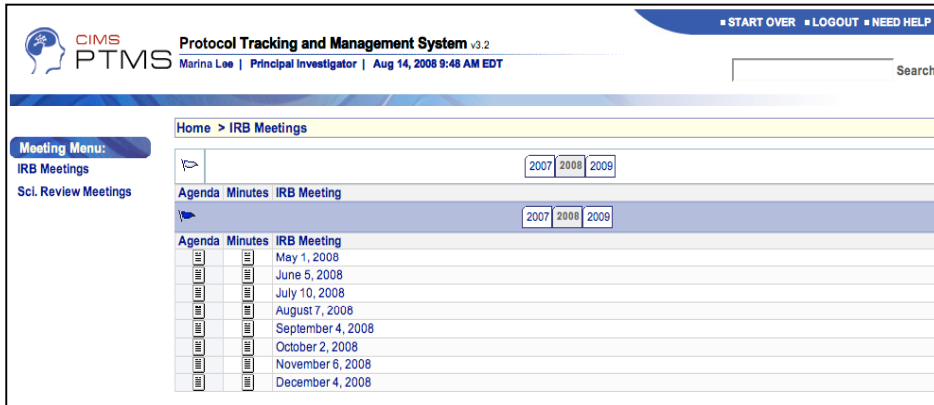
To edit or print the review, first click **[Protocol Information]** then click **[1195-1 Form]** in the Protocol Info Menu.

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.

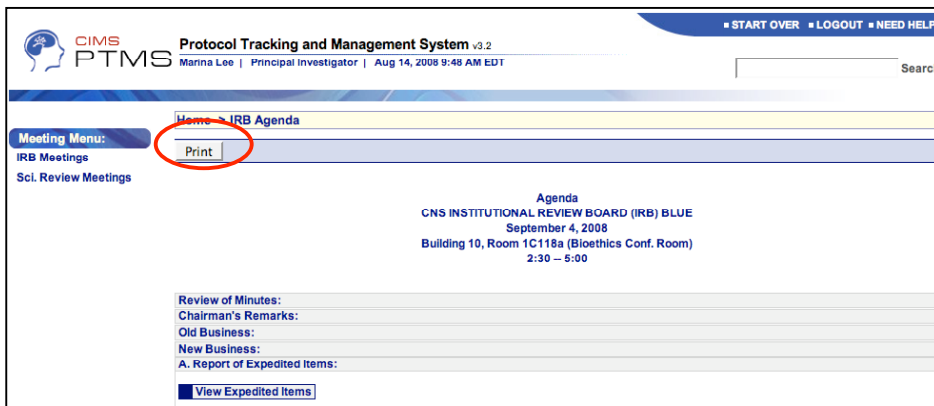


The screenshot shows the PTMS Home page. The top navigation bar includes "START OVER", "LOGOUT", and "NEED HELP". The user is logged in as Marina Lee, Principal Investigator, on August 14, 2008. The Meeting Menu on the left includes "IRB Meetings" and "Sci. Review Meetings". The main content area shows a breadcrumb trail "Home > IRB Meetings" and a table of IRB meetings for the years 2007, 2008, and 2009. The table lists meetings from May 1, 2008, to December 4, 2008, with columns for Agenda, Minutes, and IRB Meeting.


Agenda	Minutes	IRB Meeting
		May 1, 2008
		June 5, 2008
		July 10, 2008
		August 7, 2008
		September 4, 2008
		October 2, 2008
		November 6, 2008
		December 4, 2008

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.



The screenshot shows the PTMS IRB Agenda page. The top navigation bar is the same as the previous screenshot. The Meeting Menu on the left has a "Print" button circled in red. The main content area displays the agenda for the "CNS INSTITUTIONAL REVIEW BOARD (IRB) BLUE" meeting on September 4, 2008, at Building 10, Room 1C118a (Bioethics Conf. Room) from 2:30 to 5:00. Below the agenda, there is a "Review of Minutes" section with sub-sections for "Chairman's Remarks", "Old Business", and "New Business". A "View Expedited Items" button is located at the bottom of the page.

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.

# Editing Contact Information

The screenshot displays the 'My Contact Information' page in the PTMS. At the top, the header includes the CIMS PTMS logo, the system name 'Protocol Tracking and Management System v3.2', the user name 'Marina Lee | Principal Investigator', and the date 'Aug 14, 2008 2:07 PM EDT'. There are links for 'START OVER', 'LOGOUT', and 'NEED HELP'. A search bar is located on the right. The main content area shows the user's contact details in a form. The 'Save' button is highlighted with a red circle.

Home > My Contact Information	
Home Menu: Home	First Name Marina
	Last Name Lee
	Initial
	Local Address 50/5305
	Phone 301-402-4271 (xxx-xxx-xxxx)
	Email jeemarina@mail.nih.gov
	Fax (xxx-xxx-xxxx)
	<input type="button" value="Save"/> <input type="button" value="Cancel"/> <input type="button" value="Reset"/>

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]**.