

ePRMC User Manual
For Investigators and Research Staff

Table of Contents

How to Get an Account.....	3
Logging In.....	3
Overview of the ePRMC Database.....	4
Searching for a Protocol.....	5
Adding a New Protocol.....	5
Uploading Documents to an Existing Protocol.....	6
List of Documents to be uploaded in ePRMC for PRMC Review.....	6
1. Documents required for the PRMC Review of a New Study:.....	6
2. Documents required for the PRMC Review of a PI Response:.....	7
3. Documents required for the PRMC Review of an Amendment:.....	7
4. Documents required for the PRMC Review of an Annual Continuing Review:.....	7
5. Documents required at Study Closure:.....	8
Checking the Approval Status of a Submission.....	8
Removing Documents Uploaded in Error.....	9
Help/Support.....	9

How to Get an Account

Using a UCSD computer:

- 1) To obtain a Username and Password for ePRMC, go to the following internet address :
<https://online.ucsd.edu/PRMC/Request1.asp>
 - Complete the *ePRMC Account Request Form* and click the “Submit Request” button
 - Confirmation of your account activation will be emailed to you within 3 working days from the date you requested access
 - **Note: Your username and password for ePRMC are your UCSD Active Directory username and password (the same information you use to access your UCSD email)**

Using a computer outside of the UCSD system:

The UCSD Virtual Private Network (VPN) offers a protected connection over public networks via encryption and other security checks to help protect computer data transmissions from being intercepted. It also helps ensure that only authorized users have access to campus networks. Links clicked on this page and while the VPN toolbar is displayed at the top of the page are encrypted between your browser and UCSD. If you need to access the ePRMC website from outside of UCSD, please do so through the VPN by following these instructions.

- 1) To request a Username and Password for ePRMC:
 - Using your internet browser, type **VPN.UCSD.EDU** in the address bar
 - Sign on using your active directory account (your username will be the beginning of your UCSD email address, for example, *jsmith* and your password will be the same password as signing into your UCSD email account)
 - In the address bar, type in the link <https://online.ucsd.edu/PRMC/Request1.asp> and choose “Browse”
 - Complete the *ePRMC Account Request Form* and click the “Submit Request” button
 - Confirmation of your account activation will be emailed to you within 3 working days from the date you requested access
 - **Note: Your username and password for ePRMC are your UCSD Active Directory username and password (the same information you use to access your UCSD email)**

Logging In

Using a UCSD computer:

Once you have your username and password, go to <https://online.ucsd.edu/PRMC/> and choose “Log In”

Using a computer outside of the UCSD system:

The UCSD Virtual Private Network (VPN) offers a protected connection over public networks via encryption and other security checks to help protect computer data transmissions from being intercepted. It also helps ensure that only authorized users have access to campus networks. Links clicked on this page and while the VPN toolbar is displayed at the top of the page are encrypted between your browser and UCSD. If you need to access the ePRMC website from outside of UCSD, please do so through the VPN by following these instructions.

Once you have your username and password:

- Using your internet browser, type **VPN.UCSD.EDU** in the address bar
- Sign on using your active directory account
- In the address bar, type in the link <https://online.ucsd.edu/PRMC/> and choose “Browse”. Once on the ePRMC home page, choose “Log In”

Overview of the ePRMC Database

Purpose

The electronic PRMC database allows investigators and research staff to submit protocols electronically to the Moores Cancer Center Protocol Review and Monitoring Committee. Protocols should be submitted according to current PRMC guidelines. For more information on submission requirements, see the “About ePRMC” page.

Design

The ePRMC database is designed to limit user access to only those functions needed to perform your job. As an **investigator or research staff member**, you will have access to submit new studies, edit existing protocols, upload documents, and view the status of a study. For each protocol, you may authorize 3 staff members to view and edit that protocol (the investigator, study contact and product manager). *Only those individuals will see that protocol on their menu.*

Navigating the Database

Once you have successfully logged in to the ePRMC website, you should be on the welcome screen, also called the Main Page. On the left side of the screen are several links which will help you navigate the database. Here is a brief overview of the function of each link:

1. **Main Page** – The main page is the first page you will see when you log-in to the ePRMC system.
2. **Select Protocol** – On this page you may view and edit any protocols for which you have been assigned a role. You may upload documents for an existing protocol on this page.

3. **New Protocol** – This page allows protocol PIs and research staff to enter a new protocol, that was not previously saved in the database.

4. **About ePRMC** – On the “About ePRMC” page you will find information about the PRMC, submission guidelines and templates, and instructions for using this database.

Searching for a Protocol

There are 2 ways to search for studies in the database:

1. Search for Protocols for which you have been assigned a Role

Step 1) Choose “Select Protocol” on the Main Menu.

All protocols for which you have been assigned a role will be listed. You can re-sort the list by clicking a column title. Click the protocol number to select a protocol.

2. Search All Protocols in the ePRMC Database

Step 1) Choose “New Protocol” on the Main Menu.

Step 2) Enter the HRRP # in the box and click “Submit”. (The HRPP number is the project number assigned by the UCSD IRB).

* If the protocol is already in the ePRMC database, you will receive a message to contact the database administrator who can grant you access to that study.

Adding a New Protocol

To add a new protocol to the database:

1. Select the “New Protocol” link on the left side of the screen.

2. Enter the HRRP # in the box and click “Submit”. (The HRPP number is the project number assigned by the UCSD IRB).

* If the protocol is already in the ePRMC database, you will receive a message to contact the database administrator who can grant you access to that study.

3. If the protocol is NOT in the ePRMC database, you will receive instructions to proceed with entering the new study into the database. Click on “**Click here**” to continue entering data for this protocol.

4. Fill in all of the data fields on the screen, and choose “Save”.

5. Follow the link on the next page to begin uploading study documents, as appropriate.

Helpful Tips:

- Fields that are listed in **BOLD** type are required
- **SPONSOR NAME:** In the event that a new sponsor needs to be added to this list, please email the PRMC system administrator at prmc@ucsd.edu. Include the full SPONSOR NAME in the text of your email.
- If a staff member (Principal Investigator or Study Contact) is not listed in the drop down list, it is most likely because they do not have an ePRMC user account set up. Please complete the ePRMC Account Request Form.
- The **STUDY CONTACT** can be any staff member who has been delegated the responsibility of submitting to the PRMC by the protocol PI. If the PI is submitting directly to PRMC, a study contact person may not be needed. Therefore, this field is not required.
- Please enter the **REGULATORY BACK-UP** contact and **PROJECT MANAGERS** in ePRMC.

To change an existing study contact or PI, click on “People” and ad/change the name. Please remember to change the study contact in case of personnel change. Uploading Documents to an Existing Protocol

To upload documents to an existing protocol:

1. Select the “Select Protocol” link on the left side of the screen.
2. This page will display all protocols for which you have been assigned a role.
3. Select the protocol that you would like to view or edit by choosing the HRPP number.
4. Select the “Documents” link.
5. Browse and upload all study documents.

The list of documents will automatically sort by the date and time that they were uploaded. Most recent documents will be listed at the top.

If you have uploaded a document erroneously and it has to be deleted, please contact the PRMC system administrator at prmc@ucsd.edu.

List of Documents to be uploaded in ePRMC for PRMC Review

1. Documents required for the PRMC Review of a **New Study:**
 - Cover Memo

- Disease Team Protocol Approval Form
- Research Plan
- Biomedical Face Page
- Master Protocol
- Package Insert (for the FDA approved drugs)
- Investigator's Brochure
- FDA Correspondence (for Investigator Initiated Trials)

- Tissue Collection Manual, if available

- Tissue Collection SOP for all protocols, i.e. institutional, cooperative group/peer-reviewed or industry sponsored, that require prospective [new] fresh or frozen tissue biopsy

- Informed Consent Form for reference

- Cover Memo stating study is participating on an Institutional site the lead site has already approved the study with their approved PRMC (if applicable)

Note: Research Plan is not required for cooperative group studies. Studies that were peer-reviewed (NIH recognized organizations) are exempted from the PRMC review. Nevertheless, the study documents have to be uploaded in ePRMC. The PRMC will then send an exempt letter.

Starting from March 21, 2017, PRMC only accepts new studies with a Disease Team Prioritization Score under 3. DTAF is required for any new studies regardless of being interventional or non-Non-interventional (except studies that will be completely exempt from PRMC review).

2. Documents required for the PRMC Review of a **PI Response**:

- Cover Memo with the questions to the PI repeated and PI answers (PI Signature)
- Revised Research Plan – with tracked changes and clean version
- Revised Master Protocol – with tracked changes and clean version
- Revised Biomedical Face Page

3. Documents required for the PRMC Review of an **Amendment**:

- Cover Memo with the description of changes
- Revised Research Plan – with tracked changes and clean version
- Revised Master Protocol - with tracked changes and clean version
- Revised Investigator's Brochure
- Summary of Changes

4. Documents required for the PRMC Review of an **Annual Continuing Review**:

- Cover Memo
- Continuing Review Facepage
- Continuing Review Narrative (incl. Subject Summary, if applicable)
- Any publications and posters, preliminary study data, or any new scientific information that became available since last review

Remember: Fill out the fields “Local activation date,” “Initial HRPP approval date,” “Closed to accrual date” (if applicable), and “Annual Target Accrual” in the “Protocol” section.

Note: Continuing Reviews of interventional trials that are closed to accrual as well as non-interventional trials are not reviewed by the PRMC and do not need to be uploaded in ePRMC. Exceptions are active, non-interventional institutional trials.

For the studies that are under the purview of WIB, CIRB, or UC Reliance, please use the Continuing Review Form on the left side bar in ePRMC.

5. Documents required at **Study Closure:**

- Cover Memo notifying IRB about the Study Closure
- IRB Acknowledgement Response

Remember: Fill out the field “Closed to accrual date” in the “Protocol” section.

General Tips:

- Always include a cover memo describing your submission (this may be the same cover memo sent to the IRB)
- The FILE TYPE must match the type of file that is uploaded. ePRMC accepts the following document formats: .pdf, .doc, .docx, .xls, .xlsx, .ppt, .pptx.
- If an appropriate description is not available in the drop-down menu field, you may enter a description manually under “Other”
- Upload a **Disease Team Approval Form** for all new studies (see the “About ePRMC page for more information) at the time of submission and the Prioritization list when the protocol is scheduled for the PRMC review.
- Submit both clean and track changes versions of documents that have been amended
- If a study is changing in IRB number due to expiration but no scientific content change, update the new IRB number in field “Current HRPP#” and move the old number to field “Previous HRPP #”. Then upload a Cover Memo to ePRMC to explain the change of IRB number. We will then issue an acknowledgement letter.

Checking the Approval Status of a Submission

To check the approval status of an existing protocol:

1. Select the “Select Protocol” link on the left side of the screen.

2. This page will display all protocols for which you have been assigned a role.
3. Select the protocol that you would like to view by choosing the HRPP number.
4. The **CURRENT STATUS** field will be displayed in the top section of the page, under “Protocol”.

When an investigator submits a new study or uploads new documents to an existing protocol, the study status is automatically set to “PENDING”. Once the PRMC committee has made their final determination, the status will be updated, as appropriate.

Removing Documents Uploaded in Error

If documents are uploaded in error, please contact the database administrator at prmc@ucsd.edu. Only the database administrator can remove documents from the database.

Help/Support

For help using this website and
general PRMC questions:

PRMC Office
Moore Cancer Center
Phone: (858) 657-5924/5925
Email: PRMC@ucsd.edu