PRMC | Protocol Review & Monitoring Committee

- About
- Submission Requirements
- Review Schedule
- Decisions and Actions
- Amendments
- PRMS | Protocol Review and Monitoring System
- Resources
- Contacts

The Protocol Review and Monitoring Committee (PRMC) is a multidisciplinary standing committee of the Moores Cancer Center at UC San Diego Health. The PRMC is responsible for the scientific peer review of cancer-related research protocols conducted at UC San Diego Health and/or its affiliate institutions (e.g. the Veterans Administration San Diego Healthcare System and Rady Children's Hospital San Diego). The PRMC is also responsible for monitoring the scientific conduct of institutional cancer clinical trials as required by the National Cancer Institute (NCI).

The PRMC reviews research protocols to be conducted at UC San Diego Health and/or its affiliate institutions that involve:

- Subjects with cancer
- Biological specimens from cancer patients

The PRMC is granted authority by the Moores Cancer Center Director to:

- Approve cancer-related research protocols for activation at UC San Diego Helath and affiliate sites
- Issue binding recommendation for protocol modification or amendment for scientific validity or subject safety
- Defer activation of protocols due to deficiencies in content, design, feasibility
- Recommend closing protocols that show unsatisfactory accrual or scientific progress by predetermined time points after activation, usually coincident with annual Continuing Review

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Please refer to the PRMC Protocol Review List for the studies that require or are exempted from the PRMC review.

Last updated: 26 Mar 2019

The PRMC requires the following documents for the initial review:

- Cover Memo
- Disease Approval Form (for intervention trials)
- Research Plan
- Biomedical Face Page (signature not required)
- Master Protocol
- Package Insert (for the FDA approved drugs)
- Investigator's Brochure

- FDA Correspondence (for Investigator Initiated Trials)

The required documents should be submitted to the PRMC using the webpage https://oncline.ucsd.edu/PRMC. To request an ePRMC account please use the following link: https://oncline.ucsd.edu/PRMC/Request1.asp. For information regarding setting up a user account and instructions for submitting a new protocol, uploading documents to an existing protocol, checking the approval status of a submission and more, review the ePRMC User Manual. The ePRMC User Manual is available on the ePRMC website once logged in.

For frequently asked questions, see the ePRMC FAQs.

For additional information about ePRMC document submission policies and procedures, please contact the PRMC office: 858-657-5924 | 858-657-5925 | prmc@ucsd.edu

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- Protocols subject to PRMC review should be submitted to the PRMC
- The protocols are reviewed in order of the submission date to the PRMC
- PRMC meetings occur twice monthly on the first and third Tuesday from 5:00-7:00 PM.

Last updated: 27 Sep 2017

Industry-sponsored and institutional protocols are presented at PRMC meetings. The Principal Investigator (PI) receives an invitation 14 days prior to the meeting date. When all presenters confirm their participation, the protocol will receive an exact time slot for presentation. The PI receives a Power Point template that contains all necessary information the PRMC requires for review and helps to maintain a time limit of 4 minutes for the presentation. PRMC determination is sent to the PI within 2 business days after the meeting.

- If a study is voted "**Approve Pending**", the investigator's response submission is reviewed administratively
- If the study is "**Deferred**", the investigator's response and appropriately revised study documents must be submitted for review at a convened PRMC meeting.

Last updated: 28 Sep 2017

The PRMC reviews amendments to previously approved protocols that meet the following criteria:

- significant change to eligible subject population

- significant change in study design that impacts the analysis of data (includes major increase in sample size, adding or dropping a study arm, etc.)
- change to study-related procedures that significantly increases risk to subjects

Last updated: 27 Sep 2017

The overall goal of the Protocol Review and Monitoring System (PRMS) is to promote the conduct of scientifically meritorious clinical research under the aegis of the Moores Cancer Center. The mechanism for accomplishing this goal is the establishment of a Protocol Review and Monitoring Committee (PRMC) to provide internal oversight of all clinical and translational research involving subjects with cancer, as required by the National Cancer Institute.

Through specified procedures for protocol scientific review, prioritization approval, and monitoring of clinical trial progress and conduct, the PRMC ensures that MCC resources are effectively utilized to foster clinical cancer research that is of high scientific quality and importance.

The PRMC retains the authority granted by the Center Director to:

- Approve cancer-related research protocols for activation at UCSD and affiliate institutions
- Issue binding recommendations for protocol modification or amendment for reasons of scientific validity or subject safety
- Defer activation of protocols due to deficiencies in content, study design, or feasibility

Last updated: 27 Sep 2017

- PRMC SOPs
- PRMC Protocol Review List
- ePRMC User Manual - Available on the ePRMC website once logged in
- ePRMC Frequently Asked Questions

Last updated: 26 Mar 2019

ePRMC

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