

**University of California, San Francisco
Helen Diller Family Comprehensive Cancer Center
Policy and Procedure**

PRMS Protocol Review Committee Membership Policy

PRMS Procedure for Constituting Protocol
Review Committee Membership

Purpose

Per the CCSG Guidelines, it is particularly important for Centers involved in clinical research to establish a mechanism for assuring adequate internal oversight of the conduct of all cancer clinical trials in the institution or institutions that formally comprise the Center. The focus of the Protocol Review and Monitoring System (PRMS) is on *scientific merit, priorities and progress* of the clinical research in the Center. The PRMS should have the authority to open protocols that meet the scientific merit and scientific priorities of the center and to close protocols that do not demonstrate adequate scientific progress.

PRMS responsibilities at this institution are carried out on two separate levels to ensure optimal oversight of progress and performance. There is initial review by the applicable Program Site Committee(s), followed by independent review by the Protocol Review Committee (PRC). The purpose of this policy is to document how the membership of the Protocol Review Committee (PRC) is constituted.

Procedures

The Protocol Review Committee consists of a Chair, a Vice Chair, and both Core members and Ad Hoc members. The Chair oversees the entire committee. The Vice Chair provides added coverage and has full signatory authority in the Chair's absence or in case of conflict.

The PRC provides primary, secondary and statistical reviews for all protocols, and consists of two types of members, Core members and Ad Hoc members. All members are required to have clinical research experience.

Core members are faculty members representing all of the major disciplines of medical oncology, including pharmacy and biostatistics, as well as cancer center programs and disease sites (e.g., hematologic malignancies, breast oncology, gastrointestinal oncology, etc.). Core members are expected to attend a minimum of nine meetings per calendar year, and serve renewable two year terms. The Core members of the PRC serve as primary and secondary reviewers of all protocols reviewed by the committee, and for each meeting are assigned individual protocols to review by the Chair. The only exception to this applies to the biostatisticians who perform statistical reviews and are assigned by the PRC Administrator.

The Ad Hoc members of the PRC are also faculty members, but differ from the Core members in that they represent disciplines whose expertise is less frequently required (e.g., population/behavioral science, some surgical subspecialties, interventional radiology, etc.). Ad Hoc members are asked to be available on an as-needed basis, and are assigned by the Chair as primary or secondary reviewers when a protocol applies to their area of expertise. They are expected to attend a minimum of two meetings per calendar year, even if they are not assigned any protocols to review during that year. Ad Hoc members serve renewable two year terms.

Member Selection and Training

The Director of the Investigational Trials Resource (ITR) appoints the PRC Chair. There is no time limit on Chair appointments. The Director of the ITR and the PRC Chair appoint the Vice Chair and all Core and Ad Hoc members for renewable two year terms in order to ensure a diverse membership representing all major modalities and disciplines. The Core membership consists of a minimum of ten (10) members, and a minimum of six (6) members serve as Ad Hoc members.

The PRC Administrator trains all new members on the review process using the secure electronic web-based database, and provides them with a copy of the PRMS Protocol Review Committee Review Policy outlining their responsibilities.

Non-Member Training

All faculty new to the Hematology/Oncology Department, all fellows rotating through the Hematology/Oncology Department, and any Principal Investigator who has never submitted to PRC previously will be asked to attend one PRC meeting and complete one primary review at that meeting. This primary review is not an official PRC review and will not become part of the record; it is used strictly for training purposes.

Alternate Procedure

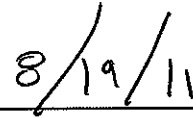
None.

Policy Approval

This policy document was approved by the following personnel on the following dates:



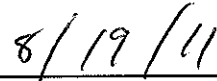
Eric Small, MD
Director, Investigational Trials Resource



Date



Judith Luce, MD
Chair, Protocol Review Committee



Date