

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

PRMS Program Site Committee Membership Policy

PRMS Procedure for Constituting Program
Site 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 all Program Site Committees is constituted.

Procedures

Membership Structure

Program Site Committees will be formed for each CCSG-funded program, and may be formed for non-CCSG-funded programs as well. There are also Program Site Committees available for early phase studies, other cancers (for research programs too small to meet the minimum membership requirements), and symptom management/palliative care/survivorship interventional trials active across multiple cancer types. Research programs large enough to meet the minimum membership requirements may still volunteer to join the Other Cancer Program Site Committee. The ITR Steering Committee will approve the formation of new site committees.

The Chair and Co-Chair are both appointed for two-year terms. Each Program Site Committee in CCSG-funded programs will consist of a Chair appointed by the Program Leader who will have clinical expertise in the relevant disease. In the case of non-CCSG-funded programs, the Chair is selected by the clinical program leaders in consultation with, and approved by, the ITR Director or designee. The Chair will appoint a Co-Chair who will have full signatory authority in the Chair's absence or in case of conflict; consideration should be given to appointment of a Co-Chair from a different disease site than the Chair to encourage cross-disease collaboration. Other members will consist of a minimum of:

- Four clinical investigators
- A research nurse or Clinical Research Coordinator (CRC)
- A statistician, ideally with expertise in the relevant disease
- A relevant laboratory investigator (translational researcher).

A committee membership roster will be provided to the PRC Administrator. In addition, it is strongly recommended that each committee have one patient advocate.

A quorum is required for the conduct of every Program Site Committee meeting. Quorum is defined as 50% of the committee membership roster.

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