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

PRMS Site Committee Membership Policy

PRMS Procedure for Constituting
Site Committee Membership

Purpose

The purpose of this policy is to document how the membership of all Site Committees is constituted.

Background

Per the Cancer Center Support Grant (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 research studies 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 Site Committee(s), followed by independent review by the Protocol Review Committee (PRC).

Procedures

Committee Formation

Site Committees will be formed for each CCSG-funded program, and may be formed for non-CCSG-funded programs as well. There are specialized Site Committees available for interventional studies active across multiple cancer types, i.e., early phase, cancer immunotherapy, radiation oncology, pediatrics, and supportive care (symptom management/palliative care/survivorship). The Cancer Center Clinical Research Oversight Committee (CCCROC) approves the formation of new site committees.

Membership Structure

The Chair and Co-Chair are both appointed for two-year terms. Each Site Committee consists of a Chair, appointed by the CCCROC Chair in consultation with the PRC Chair, who will have clinical expertise in the relevant disease. Changes to Chair appointments should be emailed by the current Site Committee Chair to the CCCROC and PRC Chairs for approval prior to implementation. Following approval, the Site Committee roster should be modified to document the Chair change, provided to the PRMS Manager, and added to the shared server. The Site Committee Chair will appoint at least one Co-Chair who will have full signatory authority in the Chair's absence or in case of conflict (a maximum of three Co-Chairs may be appointed to provide expanded coverage). Consideration should be given to appointment of a Co-Chair from a different disease site than the Chair to encourage cross-disease collaboration. The Site Committee roster should be modified to document all Co-Chair changes, provided to the PRMS Manager, and added to the shared server. The roster can serve as documentation of two-year reappointments. There can be no duplication or overlap of leadership on separate committees; i.e, neither Chairs nor Co-Chairs may simultaneously hold more than one Chair or Co-Chair position on different Site Committees.

The remaining membership is made up of both Core members and Ad Hoc members; Ad Hoc members should be individuals whose expertise is infrequently required and only need to be available on an as-needed basis.

The Core membership will consist of a minimum of:

- Four clinical investigators
- A research nurse, Clinical Research Coordinator (CRC), research associate/analyst, or other staff position involved in research recruitment
- A statistician, ideally with expertise in the relevant disease
- A relevant laboratory investigator or translational researcher.

The Director of the Helen Diller Family Comprehensive Cancer Center (HDFCCC) Biostatistics Core appoints at least one biostatistician to each Site Committee, taking biostatisticians' prior program affiliation and relevant expertise into consideration. Statisticians are assigned primarily to provide statistical expertise on study design considerations, but may also be expected to participate in the Site Committee meeting for their assigned Site Committee only if the Primary reviewer, Secondary reviewer, Chair and/or Co-Chair request help with assessing the statistical section of any protocol undergoing review.

In addition, it is strongly recommended that each committee have one patient advocate.

A committee membership roster will be provided to the PRC Administrator.

A quorum is required for the conduct of every Site Committee meeting. Quorum is defined as 50% of the Core committee membership roster. Ad Hoc members should be recorded as such on the roster; they are not used to calculate what the quorum figure should be, but may be used to meet quorum.

Alternate Procedure

None.

Policy Approval

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

Eric Small, MD
Deputy Director and Chief Scientific Officer,
Helen Diller Family Comprehensive Cancer Center

2/7/20
Date

Kate Shumate, MPA, CCRP
Chief of Staff and Director, Administration & Planning
Helen Diller Family Comprehensive Cancer Center

1/27/20
Date

University of California, San Francisco
Helen Diller Family Comprehensive Cancer Center

Policy Revision Summary of Changes

Policy Title: **PRMS Site Committee Membership Policy**

Version Date: January 27, 2020

Version Number: Revision 10

Notes: Page number corresponds to page number in updated version (Revision 10). New text in modified paragraphs is shown as ***bold italics*** and deleted text is shown as ~~strikethrough~~.

Page No.: All pages	**Section**: Footer
Original Text	Revision 9 09/27/2019
New Text	Revision ~~9~~***10*** 0~~9~~***1***/27/20~~19~~***20***
Reason for Change	Updated text to reflect revised version number and date.

Page No.: 2	**Section**: Purpose
Original Text	The Core membership 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).
New Text	The Core membership will consist of a minimum of: • Four clinical investigators • A research nurse***,*** ~~or~~ Clinical Research Coordinator (CRC)***, or other staff position involved in research recruitment*** • A statistician, ideally with expertise in the relevant disease • A relevant laboratory investigator ***or*** ~~(~~translational researcher~~)~~.
Reason for Change	Clarification of staff membership minimums, as existing wording did not fit all Site Committees.

Page No.: 3	**Section**: Policy Approval
Original Text	**Policy Approval** This policy document was approved by the following personnel on the following dates: _____ _____ Eric Small, MD Date Deputy Director and Chief Scientific Officer, Helen Diller Family Comprehensive Cancer Center
New Text	**Policy Approval** This policy document was approved by the following personnel on the following dates: _____ _____ Eric Small, MD Date Deputy Director and Chief Scientific Officer, Helen Diller Family Comprehensive Cancer Center _____ _____ ***Kate Shumate, MPA, CCRP*** ***Date*** ***Chief of Staff and Director, Administration & Planning*** ***Helen Diller Family Comprehensive Cancer Center***
Reason for Change	Signatory updates.