UCSF Helen Diller Family Comprehensive Cancer Center

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

PRMS Site Committee Membership Policy

PRMS Policy for Constituting Site Committee Membership

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Purpose

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

Scope

This policy applies to all faculty and staff serving on and supporting HDFCCC Site Committees.

Definitions

Cancer Center Clinical Research Oversight Committee (CCCROC): All clinical research activities in the HDFCCC, including strategic planning, policy development, and operational oversight, are overseen by the CCCROC. Members include the Deputy Director, Associate Director for Clinical Research; Associate Director for Community Outreach and Engagement; and Associate Director for Administration; faculty and staff clinical research leaders representing the Clinical Research Support Office (CRSO), Clinical Research Network Office (CRNO), Protocol Review and Monitoring System (PRMS), and Data and Safety Monitoring Committee (DSMC), and UCSF IRB; clinical and translational leaders from medical, surgical, radiation and pediatric oncology; and population science investigators.

Protocol Review and Monitoring Systems (PRMS): The HDFCCC organizational unit responsible for scientific and feasibility review and prioritization of studies across the HDFCCC. PRMS activities include a two stage review of protocols, first at the Site Committee level (see below) and second, centrally through the Protocol Review and Monitoring Committee (PRMC). Full responsibilities of the PRMC are detailed in the PRMS Protocol Review Committee (PRC) Review Policy.

Site Committees: Disease specific or discipline specific clinical research working groups consisting of faculty members, clinical research staff and support staff (e.g., pharmacy, nursing) charged with oversight of all clinical research studies in the designated research area. Site Committees are responsible for the first stage of scientific and feasibility protocol review, and protocol conduct and monitoring. Full PRMS responsibilities of the site committee are detailed in the PRMS Site Committee Review Policy. Site Committees also are responsible for protocol development and activation, undertaken in coordination with the CRSO, and for any subsequent protocol audits and monitoring, undertaken in coordination with the DSMC. Site Committees will also interface with UCSF clinical research network sites, in coordination with CRNO.

Background

Per the Cancer Center Support Grant (CCSG) Guidelines, it is particularly important for centers involved in clinical research to establish a mechanism for ensuring adequate internal oversight of the conduct of all cancer clinical research protocols in the institution or institutions that formally comprise the center. The focus of the 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 and Monitoring Committee (PRMC).

Procedures

1.0 Committee Formation

Site Committees are formed at the recommendation of the CCCROC; some oversee research studies crossing multiple cancer sites, while others are disease-focused; some are housed in CCSG-designated programs, and others in non-CCSG-designated programs.

2.0 Membership Structure

Site Committee Chairs are appointed by the PRMC Chair in consultation with the Deputy Director. The site committee Chair then appoints Co-Chairs, in consultation with the PRMC Chair and Deputy Director, and subsequently all members. Site committee Chairs can appoint up to three Co-Chairs, depending on the size of the site committee and its portfolio. Co-Chairs have full signatory authority in case of the Chair's absence or conflict of interest. Selection of Co-Chairs from other discipline(s) within that committee is encouraged to promote cross-disciplinary collaboration.

Chairs and Co-Chairs are appointed for renewable two-year terms and must be clinical investigators with expertise in the relevant domain. Site Committee Chairs and Co-Chairs must be a UCSF Faculty Member (Assistant Professor or higher) for a minimum of one year (rare exceptions may be approved by the Deputy Director and PRMC Chair). Any proposed changes to the site committee Chair and Co-Chair should be emailed to the HDFCCC Deputy Director and PRMC Chair for consideration.

Leaders can be re-appointed in Chair or Co-Chair role for additional two-year terms, not to exceed three consecutive terms (6 years) in a single role. Additionally, no individual can hold more than five consecutive terms (or 10 years) in a leadership role on the site committee.

Succession planning is critical for scientific continuity: in general, it is expected that early career stage investigators will be appointed as a Co-Chair, prior to assuming the Chair role. To eliminate leadership overlap, Chairs and Co-Chairs cannot simultaneously hold more than one Chair or Co-Chair position on different site committees.

3.0 Site Committee Roster

Appointments (and any changes) to the Chair and Co-Chair position are noted on the site committee roster, and the roster serves as documentation of two-year re-appointments. The roster should be updated at least annually even if there are no changes in membership, in order to document re-appointment of the Chair and Co-Chairs, as applicable.

The remaining site committee 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 conduct or recruitment

- A statistician, ideally with expertise in the relevant disease
- A relevant laboratory investigator or translational researcher
- MERIT champion (as described below)

The Director of the 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 if the Primary reviewer, Secondary reviewer, Chair or Co-Chair request help with assessing the statistical section of any protocol undergoing review.

In addition, each committee should have a MERIT champion (required), and one patient or community advocate (strongly recommended). MERIT champions are identified by the Site Committee Chair to work closely with the Associate Director for Clinical Research and the Associate Director for Community Outreach and Engagement to identify accrual disparities across all research studies in the site committee portfolio, engage the site committee in discussions to address the disparities, and provide input, at the time of protocol review, regarding the feasibility of participant recruitment based on the race and ethnicity of participants in the HDFCCC catchment area. Those site committees that are associated with HDFCCC CCSG-supported Research Programs, and who therefore have already identified a Community Outreach and Engagement (COE) Liaison, may choose to ask that individual to also serve as MERIT champion.

4.0 Site Committee Meeting Quorum

A quorum is required for the conduct of every Site Committee meeting. Quorum is defined at least 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.

Policy Exemptions

None

References

Cancer Center Support Grants (CCSGs) for NCI-designated Cancer Centers (PAR-21-321)

Appendices

Appendix 1 – Site Committee Roster template

Policy Approval

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

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12/19/2022

Eric Small, MD
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Date

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Date

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Appendix 1 – Site Committee Roster Template

<<Insert Site Committee Name>> Site Committee

Membership Roster

Month-Year

LEADERSHIP

First Name	Last Name	Credentials	Role (e.g. Chair, Co-Chair)	Term start date
e.g. Joe	Smith	MD	Chair	September 2022
			Co-Chair	

CORE MEMBERS

First Name	Last Name	Credentials
e.g. Joe	Smith	MD

AD HOC MEMBERS

First Name	Last Name	Credentials
e.g. Joe	Smith	MD

Clinical Research Policy Revision
Summary of Changes

Policy Title: **PRMS Site Committee Membership Policy**
Version Date: 12/12/2022
Version Number: Revision 12

Section(s)	Summary of Change	Rationale
All	Updated to revised policy format	As per Policy on Clinical Research Policies (17 Sep 2021)
Definitions	Added definitions for Cancer Center Clinical Research Oversight Committee (CCCROC), Protocol Review and Monitoring System, and Site Committee	New section required as per Policy on Clinical Research Policies (17 Sep 2021)
	Separated Site Committee roster	Section 3
2.0	Site Committee Chairs are appointed by the PRMC Chair in consultation with the Deputy Director. The site committee Chair then appoints Co-Chairs, in consultation with the PRMC Chair and Deputy Director, and subsequently all members.	Clarified process and responsibility for identifying and appointing Site Committee chair and co-chair positions.
2.0	Added term limits to the Site Committee chair and co-chair positions.	Added process to ensure succession planning for Site Committee leadership.
3.0	Appointments (and any changes) to the Chair and Co-Chair position are noted on the site committee roster, and the roster serves as documentation of two-year re-appointments.	Clarified documentation of Site Committee leadership appointments.
3.0	MERIT Champions are required members of the Site Committee.	Added information about the purpose and qualifications for the MERIT Champion.
Appendix 1	Appendix 1 – Site Committee Roster template	Included in policy to standardize rosters across Site Committees and document leadership term start dates

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Editor Delivery Events	Status	Timestamp

Agent Delivery Events	Status	Timestamp

Intermediary Delivery Events	Status	Timestamp

Certified Delivery Events	Status	Timestamp

Carbon Copy Events	Status	Timestamp

Witness Events	Signature	Timestamp

Notary Events	Signature	Timestamp

Envelope Summary Events	Status	Timestamps
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Signing Complete	Security Checked	12/12/2022 3:15:09 PM
Completed	Security Checked	12/19/2022 1:21:07 PM

Payment Events	Status	Timestamps