

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

**PRMS Protocol Review and Monitoring Committee Membership Policy**

PRMS Procedure for Constituting Protocol  
Review and Monitoring Committee Membership

**Purpose**

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 protocols 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 and Monitoring Committee (PRMC). The purpose of this policy is to document how the membership of the Protocol Review and Monitoring Committee (PRMC) is constituted.

**Procedures**

The Protocol Review and Monitoring 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. Both the PRMC Chair and Vice Chair perform expedited protocol reviews.

The PRMC membership provides primary, secondary and statistical reviews for all protocols reviewed at full committee, 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 PRMC 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 PRMC Administrator.

The Ad Hoc members of the PRMC 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. Ad Hoc members serve renewable two year terms.

The PRMC has the capacity to call in expertise outside of the membership if necessary.

### Member Selection and Training

The HDFCCC Deputy Director and Chief Scientific Officer appoints the PRMC Chair. There is no time limit on Chair appointments. The Deputy Director and the PRMC Chair appoint the Vice Chair and all Core and Ad Hoc members (except for biostatisticians) for renewable two year terms in order to ensure a diverse membership representing all major modalities and disciplines. The Biostatistics Core Director appoints biostatisticians to the PRMC for renewable two year terms. Two to four Biostatistics Core faculty are assigned to serve on the PRMC at any given time. Total membership consists of a minimum of fifteen (15) members, including both Core and Ad Hoc categories, with a maximum of five (5) Ad Hoc members at any one time.

The PRMC Administrator trains all new members on the review process using the secure electronic web-based database, and provides them with a copy of the PRMC Protocol Review and Monitoring 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 PRMC previously can be asked to attend one PRMC meeting and complete one secondary review at that meeting. These reviews are not official PRMC reviews and will not become part of the record; they are used strictly for training purposes.

### **Alternate Procedure**

In instances where the Chair and Vice Chair both have conflicts (due to time off, or protocol-specific, etc.), the PRMC Chair will temporarily appoint an interim Vice Chair from the general membership to ensure adequate coverage.

## Policy Approval

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

<p>DocuSigned by: <i>Eric Small</i> 7ECB32D327E3438</p> <hr/>	<p>8/16/2021</p> <hr/>
<p>Eric Small, MD Deputy Director and Chief Scientific Officer Helen Diller Family Comprehensive Cancer Center</p>	<p>Date</p>
<p>DocuSigned by: <i>Jennifer Clarke</i> 319C5339B99F4F5...</p> <hr/>	<p>8/16/2021</p> <hr/>
<p>Jennifer Clarke, MD Chair, Protocol Review and Monitoring Committee Helen Diller Family Comprehensive Cancer Center</p>	<p>Date</p>
<p>DocuSigned by: <i>Kate Shumate</i> 80D38159E89D41B...</p> <hr/>	<p>8/18/2021</p> <hr/>
<p>Kate Shumate, MPA, CCRP Chief of Staff and Director, Administration &amp; Planning Helen Diller Family Comprehensive Cancer Center</p>	<p>Date</p>

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

**Policy Revision Summary of Changes**

**Policy Title:** PRMS Protocol Review Committee Membership Policy  
**Version Date:** August 6, 2021  
**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~~.

<b>Page No.:</b> All pages	<b>Section:</b> Footer
<b>Original Text</b>	Revision 9 06/22/2015
<b>New Text</b>	Revision <b>910</b> <del>06/22/2015</del>
<b>Reason for Change</b>	Updated text to reflect revised version number and date.

<b>Page No.:</b> 1	<b>Section:</b> Title and Subtitle
<b>Original Text</b>	<b>PRMS Protocol Review Committee Membership Policy</b>  PRMS Procedure for Constituting Protocol Review Committee Membership
<b>New Text</b>	<b>PRMS Protocol Review <i>and Monitoring</i> Committee Membership Policy</b>  PRMS Procedure for Constituting Protocol Review <b><i>and Monitoring</i></b> Committee Membership
<b>Reason for Change</b>	Changed the committee's name.

<b>Page No.:</b> 1	<b>Section:</b> Purpose
<b>Original Text</b>	<p>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 <i>scientific merit, priorities and progress</i> 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.</p> <p>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 Disease 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.</p>
<b>New Text</b>	<p>Per the <b>Cancer Center Support Grant (CCSG)</b> 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 <del>trials</del><b>research protocols</b> in the institution or institutions that formally comprise the Center. The focus of the Protocol Review and Monitoring System (PRMS) is on <i>scientific merit, priorities and progress</i> 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.</p> <p>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 Disease Site Committee(s), followed by independent review by the Protocol Review <b>and Monitoring</b> Committee (PRMC). The purpose of this policy is to document how the membership of the Protocol Review <b>and Monitoring</b> Committee (PRMC) is constituted.</p>
<b>Reason for Change</b>	Matched text to other policies; eliminated the use of “trials”; changed the committee’s name.

<b>Page No.:</b> 1	<b>Section:</b> Procedures
<b>Original Text</b>	<p>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.</p> <p>The PRC provides primary, secondary and statistical reviews for all protocols reviewed at full committee, and consists of two types of members, Core members and Ad Hoc members. All members are required to have clinical research experience.</p>
<b>New Text</b>	<p>The Protocol Review <b>and Monitoring</b> 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. <b>Both the PRMC Chair and Vice Chair perform expedited protocol reviews.</b></p> <p>The PRMC <b>membership</b> provides primary, secondary and statistical reviews for all protocols reviewed at full committee, and consists of two types of members, Core members and Ad Hoc members. All members are required to have clinical research experience.</p>
<b>Reason for Change</b>	<p>Changed the committee's name; added review level oversight of committee Chair and Vice Chair to match language in subsequent paragraph; added membership to distinguish from Chair and Vice Chair.</p>

<b>Page No.:</b> 1-2		<b>Section:</b> Procedures
<b>Original Text</b>	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.	
<b>New Text</b>	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 <b>PRMC</b> 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 <b>PRMC</b> Administrator.	
<b>Reason for Change</b>	Changed the committee's name.	

<b>Page No.:</b> 2	<b>Section:</b> Procedures
<b>Original Text</b>	<p>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. Ad Hoc members serve renewable two year terms.</p> <p>The PRC has the capacity to call in expertise outside of the membership if necessary.</p>
<b>New Text</b>	<p>The Ad Hoc members of the <i>PRMC</i> 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. Ad Hoc members serve renewable two year terms.</p> <p>The <i>PRMC</i> has the capacity to call in expertise outside of the membership if necessary.</p>
<b>Reason for Change</b>	Changed the committee's name.



<b>Page No.:</b> 2	<b>Section:</b> Member Selection and Training
<b>Original Text</b>	<p>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 (except for biostatisticians) for renewable two year terms in order to ensure a diverse membership representing all major modalities and disciplines. The Biostatistics Core Director appoints biostatisticians to the PRC for renewable two year terms. Two to four Biostatistics Core faculty are assigned to serve on the PRC at any given time. Total membership consists of a minimum of fifteen (15) members, including both Core and Ad Hoc categories, with a maximum of five (5) Ad Hoc members at any one time.</p> <p>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.</p>
<b>New Text</b>	<p>The <b>HDFCCC Deputy Director and Chief Scientific Officer</b> of the <del>Investigational Trials Resource (ITR)</del> appoints the <b>PRMC</b> Chair. There is no time limit on Chair appointments. The <b>Deputy</b> Director of the <del>ITR</del> and the <b>PRMC</b> Chair appoint the Vice Chair and all Core and Ad Hoc members (except for biostatisticians) for renewable two year terms in order to ensure a diverse membership representing all major modalities and disciplines. The Biostatistics Core Director appoints biostatisticians to the <b>PRMC</b> for renewable two year terms. Two to four Biostatistics Core faculty are assigned to serve on the <b>PRMC</b> at any given time. Total membership consists of a minimum of fifteen (15) members, including both Core and Ad Hoc categories, with a maximum of five (5) Ad Hoc members at any one time.</p> <p>The <b>PRMC</b> 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 <b>and Monitoring</b> Committee Review Policy outlining their responsibilities.</p>
<b>Reason for Change</b>	Revised a title and changed the committee's name.

<b>Page No.:</b> 2		<b>Section:</b> Non-Member Training
<b>Original Text</b>	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 secondary review at that meeting. These reviews are not official PRC reviews and will not become part of the record; they are used strictly for training purposes.	
<b>New Text</b>	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 <b>PRMC</b> previously <del>can</del> <b>will</b> be asked to attend one <b>PRMC</b> meeting and complete one secondary review at that meeting. These reviews are not official <b>PRMC</b> reviews and will not become part of the record; they are used strictly for training purposes.	
<b>Reason for Change</b>	Changed the committee's name; adjusted fellow and new PI attendance language to fit current practice.	

<b>Page No.:</b> 2		<b>Section:</b> Alternate Procedure
<b>Original Text</b>	None.	
<b>New Text</b>	<b><i>In instances where the Chair and Vice Chair both have conflicts (due to time off, or protocol-specific, etc.), the PRMC Chair will temporarily appoint an interim Vice Chair from the general membership to ensure adequate coverage.</i></b>	
<b>Reason for Change</b>	Added description of process for temporarily providing Chair coverage due to conflict with both the PRMC Chair and Vice Chair.	

<b>Page No.:</b> 3	<b>Section:</b> Policy Approval
<b>Original Text</b>	<p>This policy document was approved by the following personnel on the following dates:</p> <hr/> <p>Eric Small, MD Director, Investigational Trials Resource</p> <p style="text-align: right;">Date</p> <hr/> <p>Andrew Ko, MD Chair, Protocol Review Committee</p> <p style="text-align: right;">Date</p>
<b>New Text</b>	<p>This policy document was approved by the following personnel on the following dates:</p> <hr/> <p>Eric Small, MD <b>Deputy Director and Chief Scientific Officer,</b> Investigational Trials Resource <b>Helen Diller Family Comprehensive Cancer Center</b></p> <p style="text-align: right;">Date</p> <hr/> <p><b>Jennifer Clarke</b> Andrew Ko, MD Chair, Protocol Review <b>and Monitoring</b> Committee <b>Helen Diller Family Comprehensive Cancer Center</b></p> <p style="text-align: right;">Date</p> <hr/> <p><b>Kate Shumate, MPA, CCRP</b> <b>Chief of Staff and Director, Administration &amp; Planning</b> <b>Helen Diller Family Comprehensive Cancer Center</b></p> <p style="text-align: right;">Date</p>
<b>Reason for Change</b>	Updated titles and PRMC Chair signatory; added Chief of Staff as new signatory.