

## Standard Operating Procedures for Membership and Structure

---

### 1. Purpose

- 1.1. To define the membership and organizational structure Protocol Review and Monitoring Committee of the DLDOCC.
- 1.2. Authority for DLDOCC review of clinical cancer related protocols, including initiation, monitoring and termination, has been delegated by the DLDOCC Director to reside with the PRMC. The DLDOCC Director is informed of all approval and termination actions. The PRMC Chair will inform the investigator of all PRMC decisions, including any relevant comments, in writing.

### 2. Scope

- 2.1. This policy applies to all cancer related clinical research in the facilities of the institution(s) that define the DLDOCC.
- 2.2. All interventional clinical trials whose primary aim is cancer related, or whose primary target population is cancer patients, must receive approval from by the Protocol Review and Monitoring Committee (PRMC) before subject accrual may begin.

### 3. Definitions and Abbreviations

- |      |        |  |
|------|--------|--|
| 3.1. | PRMC   | Protocol Review and Monitoring Committee                   |
| 3.2. | DLDOCC | Dan L Duncan Comprehensive Cancer Center                   |
| 3.3. | CTSU   | Clinical Trials Support Unit                               |
| 3.4. | IRB    | Institutional Review Board for BCM-affiliated institutions |
| 3.5. | PI     | Principal Investigator                                     |
| 3.6. | QSSR   | Quantitative Sciences Shared Resource of the DLDOCC        |
| 3.7. | PSO    | Patient Safety Office, who serves as the PRMC Coordinator  |

### 4. Materials and Equipment None

### 5. Description

#### 5.1. PRMC Membership

- 5.1.1. The Chair of the PRMC will be appointed by the Director of the DLDOCC, for a term of two years, with no limit to the number of renewals.
- 5.1.2. One or more Vice Chairs may be appointed by the Chair in consultation with the DLDOCC Director, for a term of two years, with no limit to the number of renewals.
- 5.1.3. The PRMC membership is as follows:
  - 5.1.3.1. Voting Members: PRMC Chair, Vice Chair(s), a biostatistician from QSSR, and at large members.
  - 5.1.3.2. Ex officio (non voting) members: Director of the CTSU and DLDOCC Associate Director(s) of Clinical Research.
- 5.1.4. Membership to the PRMC is for a term of two years with no limit to the number of terms.

## **Standard Operating Procedures for Membership and Structure**

---

- 5.1.5. At large members will be appointed by the Chair in consultation with the Director as needed to provide adequate expertise for protocol review.
- 5.1.6. Members may be removed for inability to meet requirements, such as timely protocol review or meeting attendance.

### **5.2. Roster Management**

- 5.2.1. The voting membership roster for the PRMC will be maintained by the PSO. At the time of a roster update, the following actions will be taken by the PSO, on behalf of the PRMC Chair:
  - 5.2.1.1. A “thank you for serving” letter will be sent to a removed or departing member; the Chair will be copied.
  - 5.2.1.2. A “welcome to the committee” letter, a copy of the committee’s meeting schedule, and a copy of the PRMC SOPs will be sent to new members; the Chair will be copied.
  - 5.2.1.3. New members will be added to PRMC calendar invitations and email distribution lists. Removed/departing members will be removed.
  - 5.2.1.4. The new membership roster will be updated and posted on the PRMC website.

### **5.3. Support and Record Management**

- 5.3.1. The DLDCCC will ensure that adequate staff support is provided to the PRMC.
- 5.3.2. The DLDCCC Director will receive a copy of the PRMC minutes (see Section 5.11 of the Protocol Review and Submission SOP).
- 5.3.3. The process for protocol review is described in the PRMC SOP for Protocol Submission and Review.

## **6. References**

- 6.1. These procedures were developed in accordance with the NCI CCSG guidelines for protocol review and monitoring, as required for all NCI cancer centers.
- 6.2. DLDCCC PRMC Website: <https://www.bcm.edu/academic-centers/dan-l-duncan-comprehensive-cancer-center/research/clinical-research/protocol-review-and-monitoring-committee>