

**Dan L. Duncan Cancer Center**  
**Protocol Review and Monitoring Committee (PRMC)**  
**Structure SOP**

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**1. Purpose**

- 1.1. To define the membership and structure of the Protocol Review and Monitoring Committee of the Dan L. Duncan Cancer Center.

**2. Scope**

- 2.1. This policy applies to all clinical cancer related protocols in the facilities of the institution(s) that define the Dan L. Duncan Cancer Center.

**3. Definitions and Abbreviations**

- 3.1. PRMC Protocol Review and Monitoring Committee
- 3.2. CC Dan L. Duncan Cancer Center
- 3.3. CAGT Cell and Gene Therapy
- 3.4. IRB Institutional Review Board for BCM-affiliated institutions
- 3.5. PI Principal Investigator
- 3.6. WG Working Group

**4. Materials and Equipment:** N/A

**5. Description**

**5.1. Authority**

- 5.1.1. Authority for Cancer Center (CC) review of clinical cancer related protocols, including initiation, monitoring and termination, has been delegated by the CC Director to reside with the PRMC. The PRMC Chair will inform the investigator of all PRMC decisions, including any relevant comments, in writing. The CC Director is informed of all approval and termination actions. Protocols may not begin subject accrual until approval by the Protocol Review and Monitoring Committee (PRMC) has been obtained.

**5.2. Structure**

- 5.2.1. The PRMC consists of an Executive Committee and three working groups:
  - 5.2.1.1. The Cell and Gene Therapy (CAGT) working group will be responsible for reviewing adult and pediatric protocols which involve the infusion of whole cells or vectors designed to modify the existing genetic structure of cells in patient subjects.
  - 5.2.1.2. The Pediatric working group will be responsible for reviewing all protocols that target patients under the age of 21 that are not reviewed by the CAGT working group.
  - 5.2.1.3. The Adult working group will be responsible for reviewing all protocols that target patients over the age of 21 that are not reviewed by the CAGT working group.

**5.3. Membership**

- 5.3.1. The Chair of the PRMC will be appointed by the Director of the CC, for a term of two years, with no limit to the number of renewals.
- 5.3.2. The Chair of the PRMC will appoint two Executive Committee Vice-Chairs.
- 5.3.3. The Chair of each working group will be appointed by the PRMC Chair, for a term of two years, with no limit to the number of renewals.
- 5.3.4. Members of the Adult, CAGT and Pediatric working groups will be appointed by the Chair of that working group.

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- 5.3.5. The Executive Committee consists of the PRMC Chair, the Chairs of the Adult, CAGT and Pediatric working groups, the Director of the CTSU, a biostatistician, the administrative coordinators of each working group, the Associate Director of Clinical Research of the Cancer Center or his/her designee, and such at large members as may from time to time be appointed.
- 5.3.6. Membership lists for the working groups will be maintained by the CC.

**5.4. Support and Record Management**

- 5.4.1. The CC will ensure that appropriate staff support is provided to the Executive Committee and the working groups.
- 5.4.2. Protocols will be distributed for working group review by the administrative coordinator of each working group.
- 5.4.3. Working group meeting minutes will be created and forwarded to the administrative coordinator of the Executive Committee, who will collate these recommendations for the Executive Committee.
- 5.4.4. The PRMC Chair will inform the investigator of the committee's decision in writing, including any relevant comments.
- 5.4.5. All correspondence related to protocol review by the PRMC will be maintained by the administrative coordinator.
- 5.4.6. The CC Director will receive a list of all reviewed protocols including the committee's decisions.

**6. References**

- 6.1. This process was developed in accordance with the NCI guidelines for protocol review and monitoring, as required for all comprehensive cancer centers.