1. **Purpose**

   1.1. To define the membership and organizational structure Protocol Review and Monitoring Committee of the DLDCCC.

2. **Scope**

   2.1. This policy applies to all cancer related clinical research in the facilities of the institution(s) that define the DLDCCC.

3. **Definitions and Abbreviations**

   3.1. PRMC  Protocol Review and Monitoring Committee
   3.2. DLDCCC  Dan L Duncan Comprehensive 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. EC  Executive Committee of the PRMC
   3.7. WG  Working Group of the PRMC
   3.8. BISR  Biostatistics and Informatics Shared Resource of the DLDCCC

4. **Materials and Equipment**  None

5. **Description**

   5.1. **Authority**

      5.1.1. Authority for DLDCCC review of clinical cancer related protocols, including initiation, monitoring and termination, has been delegated by the DLDCCC Director to reside with the PRMC. The PRMC Chair will inform the investigator of all PRMC decisions, including any relevant comments, in writing. The DLDCCC Director is informed of all approval and termination actions.

      5.1.2. Protocols may not begin subject accrual until approval by the PRMC has been obtained.

   5.2. **Structure**

      5.2.1. The PRMC consists of an Executive Committee (EC) and three working groups (WG):

         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 - EC**

      5.3.1. The Chair of the PRMC will be appointed by the Director of the DLDCCC, for a term of two years, with no limit to the number of renewals.
5.3.2. The Chair of each WG will be appointed by the PRMC Chair, for a term of two years, with no limit to the number of terms.

5.3.3. Each WG Chair will also serve as Vice-Chair of the EC.

5.3.4. The Executive Committee consists of the PRMC Chair, the WG Chairs, a Vice-Chair from each WG, the Director of the Clinical Trials Support Unit (CTSU), a biostatistician from BISR, the administrative coordinators of each working group (ex officio), the DLDCCC Associate Director for Administration (ex officio), the DLDCCC Associate Director(s) of Clinical Research of the Cancer Center or his/her designee, and at large members that the Director may appoint.

5.3.5. Membership to the EC is for a term of two years with no limit to the number of terms.

5.4. **Membership - WG**

5.4.1. The Chair of each WG will be appointed by the PRMC Chair, for a term of two years, with no limit to the number of renewals.

5.4.2. The Vice-Chair(s) of each WG will be nominated by the WG Chair, for a term of two years, with no limit to the number of terms. WG Vice-Chair appointments must be approved by the EC.

5.4.3. The WG Chair will nominate new WG voting members to the PRMC EC. Upon review and approval by the EC, the WG membership appointment will be made by the PRMC Chair.

5.4.3.1. WG non-voting members will be maintained at the WG level, and do not need EC review and approval.

5.4.4. Membership to the WG is for a term of two years with no limit to the number of terms.

5.5. **Roster Management**

5.5.1. The voting membership roster for the EC and WGs will be maintained by the PRMC Coordinator. At the time of a roster update, the following actions will be taken by the PRMC Coordinator, on behalf of the PRMC Chair:

5.5.1.1. A “thank you for serving” letter will be sent to a removed member; the WG Chair and the WG Coordinator will be copied.

5.5.1.2. 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 WG Chair and the WG Coordinator will be copied.

5.5.1.3. Email distribution lists will be updated to reflect membership changes.

5.5.1.4. The new membership roster will be updated and posted on the PRMC website.

5.6. **Support and Record Management**

5.6.1. The DLDCCC will ensure that adequate staff support is provided to the PRMC EC and WGs.

5.6.2. The DLDCCC Director will receive a copy of the EC minutes (see Section 5.12 of the Protocol Review and Submission SOP).

5.6.3. 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/centers/cancer-center/research/clinical-research/protocol-review-and-monitoring-committee](https://www.bcm.edu/centers/cancer-center/research/clinical-research/protocol-review-and-monitoring-committee)