1. BACKGROUND:

The Clinical Investigations Leadership Committee (CLC) provides a regular forum for the senior faculty and administrative leaders across the DF/HCC member institutions to discuss and resolve system-wide issues related to the conduct and support of human subject within DF/HCC.

The CLC reviews clinical and non-clinical investigations activities, processes, and systems, as well as DF/HCC issues that require senior-level, inter-institutional attention. As such, the CLC galvanizes the efforts of the DF/HCC Data and Safety Monitoring Plan (DSMP), which focuses on the auditing, monitoring, and performance of active trials, and the PRMS, which focuses on the scientific merit, feasibility and priority of trials. By looking globally at issues that have an impact on the effectiveness and efficiency of DF/HCC's clinical investigations process, the CLC is in a unique position to identify trends and issues that may not be immediately obvious to committees that are necessarily more focused in purpose.

2. ASSOCIATED DF/HCC POLICIES:

2.1. COM-100

3. PROCEDURE:

3.1. General Procedures and Responsibilities

3.1.1. Each DF/HCC institution delegates authority to the CLC for clinical research oversight as outlined in the written institutional agreements. A written agreement is in place for each DF/HCC institution to accept the CLC as the clinical investigations leadership structure for the respective institution's oncology clinical research.

3.1.2. The CLC meets monthly to discuss issues related to the DF/HCC clinical research process, including but not limited to:

- Concerns that arise from data and safety monitoring review, auditing and monitoring processes and scientific review processes (this includes review of the minutes or findings from DF/HCC oversight committees including the DSMC, DSMB, Audit Committee)
- System-wide, protocol-specific, or PI-specific issues that impact the appropriate conduct of clinical trials
- Organizational capabilities and resources related to clinical trials
- General issues related to trial design that impact the effective conduct of trials
- Inter-institutional policies and practices that impact the conduct of clinical trials
- Issues that individual institutions have regarding the clinical investigations program

- Operational issues that require senior faculty input and institutional consideration on clinical trials issues (these issues may be escalated to the CLC by the Clinical Research Operations Committee)

3.1.2.1. As appropriate, CLC recommendations are routed to the Center Director, Executive Committee, appropriate research administration office, SRC and IRB leaders, senior representatives from DF/HCC member institutions and/or the IRB.

3.1.2.2. The CLC Chair, with the advice of the Medical Director of Clinical Trials Operations, Associate Director for Administration and, as needed, the Center Director, determines the best process for resolving issues and conveying decisions or recommendations to the appropriate individual or group.

3.1.2.2.1. CLC institutional representatives are responsible for following up on issues relevant to their institution that are discussed at CLC meetings or brought to their attention, and of keeping the CLC and/or DF/HCC leadership, as appropriate, apprised of the status and resolution of such matters.

3.1.3. CLC Meetings are confidential, per COM-100. The CLC is administratively managed by the Office of Data Quality (ODQ).

3.1. **Membership and Meeting Structure**

3.1.1. Members and the Chair of the CLC are appointed by the DF/HCC Associate Director for Administration and include representation from all of the DF/HCC Institutions as per COM-100.

3.1.2. Members are appointed for three years and may be reappointed for additional terms by the DF/HCC Associate Director for Administration.

3.1.3. Membership is comprised of a diverse group of individuals, selected for their experience in research and understanding of DF/HCC. At a minimum, members should include:

- DF/HCC Associate Director for Administration
- DF/HCC Medical Director of Clinical Trials Operations
- IRB Chair(s)
- SRC/PSRC Chair(s)
- Director, DF/HCC Research Pharmacy Shared Resource (or designated representative)
- Research Nursing representative
- Director, Office of Human Research Studies
- Director, Office of Data Quality
- Director, Research Informatics Office

- Biostatistics representative
- Pediatric Oncology representative
- Additional faculty leaders in clinical trials
- Administrative representatives from DF/HCC member institutions as needed

3.1.4. The CLC typically meets once a month during the academic year and preferably not less than nine times per year. CLC members will agree on any formal change in meeting date.

3.1.5. The auditing and monitoring review segment of the meeting usually occurs first, followed by the clinical investigations issues segment.

3.1.6. There is no set quorum for this Committee. However, should the Chair determine that the number or composition of the attendees is not appropriate relative to the issue, s/he may table the discussion until the next meeting. The chair may also use email and small group meetings to gather information and build consensus between formal CLC meetings. The CLC Chair, Medical Director for Clinical Trials Operations and Associate Director for Administration serve as the CLC executive committee. This committee is used between CLC meetings to address any issues requiring immediate attention.