DMC Administrative Guidelines and Processes

1.0 OBJECTIVES

1.1 This procedure details the administrative guidelines and processes of the Robert H. Lurie Comprehensive Cancer Center’s (Lurie Cancer Center) Data Monitoring Committee (DMC).

1.2 This procedure is intended to comply with all federal regulations, National Cancer Center (NCI) guidelines, the Clinical Protocol Scientific Review and Monitoring System’s (CPSRMS) Operating Manual, and the Lurie Cancer Center’s Data and Safety Monitoring Plan (DSMP).

2.0 RESPONSIBILITY

2.1 This SOP applies all DMC members and attendees and to the Clinical Research Office (CRO) employees responsible for providing administrative support to the DMC.

3.0 APPLICABLE REGULATIONS AND GUIDELINES

3.1 May 9, 1997 International Conference on Harmonisation; Good Clinical Practice: Consolidated Guideline

3.2 CPSRMS Operating Manual

3.7 Data and Safety Monitoring Plan of the Robert H. Lurie Comprehensive Cancer Center

4.0 REFERENCES TO OTHER APPLICABLE SOPs

4.1 DMC Responsibilities

4.2 Publication Policies and Processes

4.3 Data Compliance Policies and Processes

4.4 Low Accrual Policy

5.0 DEFINITIONS

5.1 Clinical Protocol Scientific Review and Monitoring System (CPSRMS): This system is comprised of three committees that work collaboratively to provide
oversight of all aspects of clinical research conducted at the Lurie Cancer Center. These committees include: the Scientific Review Committee (SRC), the Data Monitoring Committee (DMC), and the Audit Committee.

5.2 **Clinical Research Office (CRO):** The CRO provides a centralized resource to facilitate the development, conduct, quality assurance monitoring, compliance with regulatory agency requirements, and evaluation of clinical trials at the Lurie Cancer Center. As such, the office coordinates the majority of clinical research conducted in medical oncology, malignant hematology, gynecologic-oncology, neuro-oncology, radiation oncology, surgical oncology, and chemoprevention.

5.3 **Data Monitoring Committee (DMC):** The DMC is a part of the Lurie Cancer Center’s Clinical Protocol Scientific Review & Monitoring System (CPSRMS) and is an independent committee responsible for data and safety review of all institutional clinical trials. This responsibility includes the review of audit reports generated by the Audit Committee.

5.4 **Scientific Review Committee (SRC):** The SRC is part of the Lurie Cancer Center’s Clinical Protocol Scientific Review and Monitoring System (CPSRMS) and is an independent committee responsible for reviewing new clinical trials to ensure that they are scientifically sound. The SRC conducts a full scientific review of all clinical trials that have not received peer review by other NIH-approved peer-review bodies.

6.0 **PROCEDURES**

6.1 **Membership**

6.1.1 The DMC is a multidisciplinary committee that consists of a core group providing the necessary expertise in the principal disciplines of clinical oncology with additional representation from Biostatistics and Laboratory Science. Members are selected by area of expertise to form a diversified group of clinicians and other professionals able to provide rigorous monitoring of studies. A patient representative is also available to provide perspective on patient advocacy and communication issues that arise during the conduct of a trial. The committee is chaired by an oncologist and is co-chaired by biostatistician. Members serve indefinite terms. A full member listing is provided in attachment 7.1.

6.1.2 The CRO’s Scientific Review Coordinator (SRCC) provides administrative support for the committee. The Administrative Director (AdD) of the CRO provides oversight of the administrative coordination of the committee and also acts as a liaison between the committee and the CRO.

6.1.3 Two Quality Assurance Monitors (QAMs) employed by the CRO are responsible for the ongoing review of all clinical trial data for NU IITs, concentrating on data completeness, protocol adherence, and safety review. The QAMs report on all monitored clinical trials at each DMC, specifically focusing on subject toxicity and outcomes, accrual updates, and compliance issues.
6.2 Meetings

6.2.1 The DMC meets on a semi-monthly basis. The DMC is attended by the QAMs, AdD, and SRCC as well as voting members. The DMC must meet quorum in order to pass any binding resolution. In order to meet quorum, a minimum of one physician member and one biostatistician must be present at the meeting.

6.3 Formal Communications

6.3.1 The SRCC is primarily responsible for distributing formal communications on behalf of the DMC. Informal communications or certain formal communications may be sent by the SRCC, QAMs, chair, co-chair or other personnel as appropriate.

7.0 ATTACHMENTS

7.1 DMC Committee Listing