DMC Publication Policies and Processes

1.0 OBJECTIVES

1.1 This procedure details the publication policies and processes for 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, 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.

2.2 This SOP applies to all Investigators that initiate or participate in studies that adhere to the Lurie Cancer Center DSMP.

3.0 APPLICABLE REGULATIONS AND GUIDELINES

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

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

4.0 REFERENCES TO OTHER APPLICABLE SOPs

4.1 DMC Administrative Processes

4.2 DMC Responsibilities

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 **Northwestern University Investigator-Initiated Trial (NU IIT):** A trial initiated by an investigator at Northwestern University or by an investigator at Lurie Children’s Hospital (LCH). All such trials must be monitored according to the Lurie Cancer Center’s DSMP.

6.0 PROCEDURES

6.1 All data for potential publications (e.g. manuscripts, abstracts, posters, ClinicalTrials.gov releases) for NU investigator-initiated trials (IITs) that adhere to and are monitored by the Lurie Cancer Center DSMP must be approved in accordance with the policies and processes set in the SOP.

6.2 The Quality Assurance Monitors (QAMs) are responsible for preparing a preliminary data summary for each NU IIT for DMC approval no later than three months after a study’s primary completion date, as it is defined by ClinicalTrials.gov. This is the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the pre-specified protocol or was terminated. In collaboration with the Principal Investigator (PI), and other study team members as is appropriate, the QAMs are responsible for determining this unique date for each NU IIT and the estimated date to the DMC.

6.3 If an investigator would like data to be approved by the DMC prior to when study design dictates, and/or prior to three months after a study’s primary completion date, he or she must send a written request for data approval to the QAM, providing a reason that an earlier approval is required. Requests must be made a minimum of four weeks in advance of the expected deadline.
6.4 For ongoing phase I trials, requests to approve data will be considered on a case by case basis. The DMC will generally approve novel and/or significant toxicity data.

6.5 For all other ongoing trials, the DMC will only approve data when 50% the trials’ patients have met the primary endpoint according to protocol-specific statistical plan and relevant data has been submitted.

6.6 If the Investigator intends to submit preliminary results for ongoing trials, approvals may be granted to studies submitted formally as a “trial in progress” or for which the draft publication otherwise indicates the trial is not yet completed.

6.7 The QAM will present the data summary to the DMC for approval. The DMC will review the data summary, approve the data for publication, approve an amended version of the data summary for publication, or disapprove of the data. The QA Department will relay all formal DMC decisions regarding publications to the Investigator.

6.8 The Investigator is expected to use only DMC approved data in a potential publication. The Investigator will send the manuscript to the study’s biostatistician to confirm that DMC approved data are used appropriately in the manuscript. Once the study’s biostatistician gives his or her final approval, the manuscript may then be submitted to the external publisher for approval.