



DMC Data Compliance Policies and Processes

1.0 OBJECTIVES

- 1.1 This procedure details the data compliance 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, 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.
- 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 CPSRMS Operating Manual
- 3.3 [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 DMC Data Publication 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 Children's Memorial Hospital (CMH). All such trials must be monitored according to the Lurie Cancer Center's DSMP.

6.0 PROCEDURES

- 6.1 All trials that adhere to and are monitored by the Lurie Cancer Center DSMP must also adhere to the DMC Internal Data Compliance Policy (see 7.1), the DMC Participating Site Data Compliance Policy (see 7.2), and the NU IRB policies [regarding the reporting of adverse events](#). The Northwestern University (NU) Principal Investigator (PI) must sign the Internal Data Policy before his or her trial can be opened at NU. Any affiliate PI must sign the Affiliate Data Compliance Policy before he or she can participate in a NU IIT.
- 6.2 Phase I Studies and Pilot Studies
 - 6.2.1 For phase I studies, if the Quality Assurance Monitor (QAM) assigned to the study has not received the required data by the different time points specified in the policies, the QAM assigned to the study will suspend accrual for the delinquent site on behalf of the DMC. When a site is suspended, a notification of the study's suspension will be sent to the Principal Investigator (PI).
 - 6.2.2 The QAM will report all automatic suspensions of accrual for phase I trials at the next scheduled DMC meeting. When all overdue data have been satisfactorily submitted, the QAM will notify the NU PI, local site PI (if applicable) and other study team members as appropriate that accrual privileges have been reinstated.
- 6.3 Phase II and III Studies

- 6.3.1 In accordance with the data compliance policies, data for phase II and III trials that are submitted 90 days past the due date (as the due date is defined by the protocol) are considered to be severely delinquent.
- 6.3.2 QAMs are responsible for routinely querying PIs regarding delinquent data. QAMs will first query PIs regarding delinquent data when data is 30 days overdue. QAMs will again query PIs regarding data when data are 60 days overdue. If satisfactory data is not submitted 80 days after the data was due, the QAM will send a written warning informing the PI that the DMC may suspend accrual at a site if data are not submitted by the 90-day deadline.
- 6.3.3 If satisfactory data are not submitted by the 90-day deadline, the QAM will present the severely delinquent study's information to the DMC at its next scheduled meeting. The presentation will include all information regarding outstanding data and all the QAM's documented attempts to contact the PI.
- 6.3.4 The DMC will vote to suspend or not to suspend accrual for the site. The DMC will provide the PI with written notification of its decision, outline all the requirements the PI must fulfill to reinstate accrual privileges, or follow-up with any additional questions or requests for information.
- 6.3.5 When the PI has satisfactorily submitted all outstanding data, the QAM will present this information to the DMC and accrual privileges will be reinstated. The Scientific Review Coordinator (SRCC) will send written notification to the PI on behalf of the DMC when accrual privileges have been reinstated.