

DSMC Data Release Policies and Processes

1. OBJECTIVES

- 1.1. This procedure details the data release policies and processes for the Robert H. Lurie Comprehensive Cancer Center's (Lurie Cancer Center) Data and Safety Monitoring Committee (DSMC).
- 1.2. This procedure is intended to comply with all federal regulations, National Cancer Center (NCI) guidelines, FDA Guidance, and the Lurie Cancer Center's Data and Safety Monitoring Plan (DSMP).

2. RESPONSIBILITY

- 2.1. This procedure applies to all DSMC members and attendees, and to the Clinical Trial Office (CTO) employees responsible for providing administrative support to the DSMC.
- 2.2. This procedure applies to all Investigators that initiate or participate in studies that adhere to the Lurie Cancer Center DSMP.

3. APPLICABLE REGULATIONS AND GUIDELINES

- 3.1. May 9, 1997 International Conference on Harmonisation; Good Clinical Practice: Consolidated Guideline
- 3.2. Code of Federal Regulations 21 CFR 314.126(b)(5) (drugs) and 21 CFR 860.7(f)(1) (devices)
- 3.3. Data and Safety Monitoring Plan of the Robert H. Lurie Comprehensive Cancer Center

4. REFERENCES TO OTHER APPLICABLE SOP's

- 4.1. DSMC Administrative Processes
- 4.2. DSMC Responsibilities
- 4.3. Data Compliance Policies and Processes
- 4.4. Low Accrual Policy

5. 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 and Safety Monitoring Committee (DSMC), and the Clinical Trial Audit Committee (CTAC).



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- 5.2. **Clinical Trial Office (CTO):** The CTO 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 and Safety Monitoring Committee (DSMC):** The DSMC 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 Clinical Trial Audit Committee (CTAC).
- 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. PROCEDURES

- 6.1. All data for potential data release (e.g. manuscripts, abstracts, posters, ClinicalTrials.gov releases, and data analyses) 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 set for each NU IIT for DSMC 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.
- 6.3. If an investigator would like data release to be approved by the DSMC prior to when study design specifies, 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 requested. Requests must be made a minimum of six to eight weeks in advance of the expected deadline, and include: type of data being requested, where the data will be disseminated, the deadline for submission, and if the trial is ongoing, and the reason the data should be released prior to completion.
- 6.4. Any release of confidential study outcome data outside the DSMC prior interim or final analysis as specified per protocol, must be reviewed and recommended for approval by the DSMC. Such requests include the following:



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- a. Requests for clinical information, such as baseline characteristics or secondary outcomes, for publication or presentation of laboratory data or other non-therapeutic data from any patients accrued to a monitored trial. The DSMC review of these requests will not be confined to the cycle of regularly scheduled DSMC meetings, but will be ongoing, to accommodate abstract and grant deadlines and manuscripts in preparation.
- b. Requests for data from sponsoring organizations.
- c. Requests from disease team chairs and prospective study chairs for confidential access to interim results to aid in planning future studies.

The DSMC considers each request based on the importance and usefulness of the requested information and the potential risk to the integrity of the study. Access to interim outcome results is not allowed until all patients have reached their primary endpoint for interim or final analysis as specified in the protocol. For examples of what data can and cannot be released, please see the Quantitative Data Sciences Core's (QDSC's) Clinical Trials Data Release Policy.

- 6.5. The QA Department will relay all formal DSMC decisions regarding data release to the Investigator.
- 6.6. If the request is approved, the QAM will present the data set to the DSMC for approval. The DSMC will review the data set and: approve the data for release, approve an amended version of the data set for publication, or disapprove the data release.
- 6.7. The Investigator is expected to use only DSMC approved data sets and statistical analyses any time they are disseminating trial data. The Investigator will send the final draft abstract/poster/manuscript to the study's biostatistician and QAM to confirm that DSMC approved data and statistical analyses are used appropriately in the publication. Once the study's biostatistician and QA department give final approval, the publication may be submitted to the external publisher.