Data Monitoring Committee: Participating Site Data Compliance Policy

All sites that participate in clinical trials initiated by Northwestern University (NU) must be familiar with and comply with all data submission requirements specified by each individual NU protocol. The Lurie Cancer Center’s Data Monitoring Committee (DMC) monitors data submission for all NU interventional investigator-initiated protocols, including data for all local sites that participate in these trials.

Phase I Trials, On-Study Data and Toxicity Data

On-study and toxicity data must be submitted no later than one week after a subject is registered and no later than one week after a subject completes each cycle, respectively. Failure to submit on-study and toxicity data at these time points will result in immediate and automatic suspension of accrual. The local PI and the NU PI will be notified of the suspension. If a local PI believes that there are extenuating circumstances as to why on-study or toxicity data cannot be submitted within the respective time frames, he or she is responsible for contacting the study’s Quality Assurance Monitor (QAM) immediately.

Phase I, All Other Data and Pilot Trials

Excluding on-study and toxicity data, all other data for phase I trials, and all data for pilot trials must be submitted within 30 days of the due date as defined by the protocol. Failure to submit the required data by the due date will result in the local site’s suspension of accrual. The local PI and NU PI will be notified.

Phase II & III Trials

Data must be received within 90 days. Data submitted 90 days past the due date (as the due date is defined by the protocol) are considered to be severely delinquent. The DMC may suspend subject accrual for the site and study for which data are considered severely delinquent. The DMC will provide the local PI with written notification of a suspension and will outline all the requirements the PI must fulfill to reinstate accrual privileges, or follow-up with any additional questions or requests for information. The NU PI will also be notified.

In addition to the compliance policy detailed above, if local sites use the NU IRB as the IRB of record, they must also follow the adverse event reporting requirements established by the NU IRB.

If accrual privileges have been suspended, they may only be reinstated once all required data is satisfactorily submitted, and DMC members have voted to reinstate accrual privileges for the trial. The DMC will send written notification when accrual privileges have been reinstated.

Please note, sub-contracts executed between local sites and NU may include language that connects data submission to local site payment. If the terms of the sub-contract tie data submission to payment, and the participating site is not considered to be data compliant, payment will or will not be made according to terms dictated by the subcontract. If the affiliate will not be paid because of failure to comply with data submission requirements, the participating site will be informed of non-payment in writing.

As the Principal Investigator of [NU Trial Number] at [Participating Site], I acknowledge that I have reviewed and understand the Data Monitoring Committee’s Participating Site Data Compliance Policy.

_____________________________  __________________________
Local PI Signature                  Date

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Local PI Name [Printed]              Participating Site Name