Data and Safety Monitoring Review Form

Date of Quarterly Report		Date Span of Quarterly Report	
Principal Investigator		IRB Number	

Study Title	

Activation Date		Total Target Enrollment	
Total # of Patients Enrolled at SLUHN		*If Applicable:* Total # of Patients Enrolled at Sub-site & Location	

Quarterly Trial Summary	
Please provide a detailed and comprehensive narrative assessment of the events that have occurred in this trial since the last quarterly report *For example:* • *Describe any changes to trial design* • *Exceptions in eligibility or treatment* • *List of all unanticipated problems (UAPs)* • *List of all protocol deviations* • *Provide causality information in your summary* • *Indicate the possible significance and whether these toxicities have affected the conduct of the trial* • *If study was audited, provide a response to audit* • *If study was completed, provide a brief summary of the life of the study*	
Dose Escalation Information	
Is this a dose escalation study?	☐ Yes ☐ No *(If no, proceed to FDA Information section)*
If yes:	
What is the current dose level?	
Was the dose increased during the reporting quarter?	☐ Yes ☐ No
If yes:	
Was Medical Monitor approval received prior to dose escalation?	☐ Yes ☐ No
If no:	
Please explain why not	
FDA Information	
Is this trial being conducted under an IND/IDE?	☐ Yes ☐ No *(If no, proceed to PI Signature)*
If yes:	
IND/IDE Number:	
Who holds the IND/IDE?	
Have all amendments been submitted to the FDA for review and approval?	☐ Yes ☐ No ☐ N/A *Explanation:*
Was an annual report submitted to the FDA within 60 days of the anniversary date of obtaining an IND/IDE?	☐ Yes ☐ No ☐ N/A *Explanation:*
Was one submitted every year thereafter?	☐ Yes ☐ No ☐ N/A *Explanation:*
Were all AEs and SAEs reported to the FDA in line with the reporting regulations?	☐ Yes ☐ No ☐ N/A *Explanation:*

Please attach a copy of SAE reports and AE tracking logs
****If Applicable, please also attach a copy of Medical Monitor approvals, audit reports, responses and proof of corrective actions, 1571 cover letters submitted to the FDA, and MedWatch forms****
*****If this is a multi-site study, be sure to include information and documentation regarding sub-sites as well*****

Signature of Principal Investigator: _____ Date: _____

Unaffiliated Medical Monitor Signature: _____ Date: _____