## Data and Safety Monitoring Review Form

<table>
<thead>
<tr>
<th>Date of Quarterly Report</th>
<th>Date Span of Quarterly Report</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principal Investigator</td>
<td>IRB Number</td>
</tr>
</tbody>
</table>

### Study Title

<table>
<thead>
<tr>
<th>Activation Date</th>
<th>Total Target Enrollment</th>
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<tbody>
<tr>
<td>Total # of Patients Enrolled at SLUHN</td>
<td>(If Applicable) Total # of Patients Enrolled at Sub-site &amp; Location</td>
</tr>
</tbody>
</table>

### 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:*

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*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: ________________