SITE CLOSE-OUT REPORT

Canadian SHIELD
Ethics Review Board Inc.
FDA Registration IRB00004157
OHRP Registration IORG0003491
Registered with CAREB, NCEHR

Investigator: **Dr.** **Study #:**

Title of Protocol:

Date of Protocol:

Date of Last Visit of Last Participant:_____ ☐ **N/A** **Date of Sponsor Close-out Visit:**_____ ☐ **N/A**

Have all study Medications been returned to Sponsor? ☐ **N/A** ☐ **Yes** ☐ **No** Explain: _____

Summary of Participants/Recruitment	
1. Original number of anticipated participants agreed to with sponsor	
2. Total number of participants enrolled at your site	
3. Any change to the number of participants agreed to initially with sponsor? ☐ **No** ☐ **Yes** – new number	
4. How many participants voluntarily withdrew from study?	
5. How many participants were withdrawn at the request of the PI?	
6. If participants were withdrawn, please state the reason for their withdrawal.	

Adverse Events

1. Please provide a tabulated list of Adverse Events (serious & non-serious, unexpected and drug related) since Initial IRB / REB Review

☐ **Sponsor Report Attached**

Details from my site (if no sponsor report available, use attachments if required)

Final Comments

_____ _____

Principal Investigator's Signature Date