CONTINUING REVIEW WORKSHEET

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

Investigator:	Dr.		
Title of Protocol:			
Date of Protocol:		**Study #:**	

Recruitment Information	
1. Original number of anticipated subjects agreed to with sponsor.	
2. Number of subjects enrolled since this project was initially approved.	
3. Any change to the number of subjects agreed to initially with sponsor? ☐ **No** ☐ **Yes** – new number	
4. How many subjects voluntarily withdrew from study at your site?	
5. How many subjects were withdrawn at the Investigator's request?	
6. If any subjects withdrew or were withdrawn due to Adverse Events, please state reasons (use separate sheet if required).	
7. If applicable, please provide a brief summary of any difficulty obtaining/retaining participants or obtaining: ☐ **Not Applicable** • informed consent during the entire approval period. • Additionally, please indicate if there have been any complaints about the research.	

Adverse Events

1. Have you submitted all SAE reports from your site to Canadian SHIELD Ethics Review Board?
   ☐ **Yes** ☐ **No**

☐ **All SAE's from our site have been reported to Sponsor and Canadian SHIELD.**

☐ **All reports sent to our site by Sponsor have been submitted.**

Any details from my site that Canadian SHIELD should be aware of? ☐ **No** ☐ **Yes (enter below)**

2. If there have been serious adverse drug reactions reported to you by the Sponsor, do you have any concerns with continuing the study at your site? ☐ **No**
   ☐ **Yes:** _____

- In your opinion, do the benefits of the study still outweigh the risks. ☐ **Yes** ☐ **No**
- Explain:

3. Does the current Informed Consent Form require modifications due to the information above? ☐ **No** ☐ **Yes** please state what you think needs to be added:

New Findings

1. Have there been any significant new findings (either good or bad) that should be disclosed to the study subjects? ☐ No ☐ Yes *If yes, please describe*

Changes to Study Site / Staff

1. Have there been any changes to the location of the study that have not been previously reported to Canadian SHIELD Ethics Review Board? ☐ No ☐ Yes *If yes, please describe*

2. Have there been any changes to the site personnel that have not been previously reported to Canadian SHIELD Ethics Review Board? ☐ No ☐ Yes *If yes, please describe*

Consent Document and Protocol

1. Please attach a copy of the **FIRST PAGE of the current informed consent document** and if applicable, one with modifications to address any changes in procedures or information provided to potential subjects. ☐ Attached ☐ Attached revised consent form

2. Please attach a copy of the **current protocol title page**. ☐ N/A ☐ Yes

3. Please attach any new documents you are planning to use for this next approval period (i.e. recruitment materials, etc.) ☐ Attached ☐ N/A

Progress Report

1. Please provide a brief summary of any significant issues brought to your attention by the study Sponsor (i.e. changes to enrollment period, new participating sites or new countries added, etc) that may affect this review. ☐ N/A

_____ _____
Principal Investigator's Signature Date