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**APPLICATION FOR CONTINUING REVIEW (FORM 4.4)**

| | | | |
|---|---|---|---|
| IRB Protocol No. | | Date Received (D/M/Y): | |
| Protocol Title: | | Sponsor: | |
| Principal & Sub Investigators: | | Primary Reviewers: | |

*Instructions to the Researcher: Please accomplish this form and ensure that you have included in your submission the following documents:*

***Basic requirements:***

☐ Letter request for review
☐ Full proposal / study protocol
☐ Summary of Amendments and the dates
☐ Total number of SAE's on-site from the time of approval up to present
☐ Total number of SUSARs off-site from the time of approval up to present
☐ Number of Safety reporting and the dates
☐ Number of Protocol deviations submitted and the dates
☐ Number of progress reports and the dates
☐ Number of site visits and the dates

***SECTION 1: TO BE FILLED UP BY PRINCIPAL INVESTIGATOR***

**Please filled up and check (√) each of the boxes that pertains to your report.**

1. Start of the study _____ Expected end of study _____

2. Number of enrolled participants _____

Number of required participants _____

3. Any change in participant population, recruitment or selection criteria since the last review?
____Yes ____No
(Explain the changes)

4. Any change in the Informed consent process or documentation since the last review?
____Yes ____No
(Explain the changes)

5. Is there any new information in recent literature or similar research that may change the risk/benefit ratio for participants in the study?
____Yes ____No

6. Are there any unsuspected complications or side effects noted since the last review?
____Yes ____No

7. Did any participant withdraw from this study since the last approval?
____Yes ____No
(If Yes, state the number of participants who withdrew and give the reasons for withdrawal.)

8. Any new investigator that has been added to or removed from the study research since the last review?
____Yes ____No
(Pls. submit the name and the CV of the new investigators.)

9. Summary of protocol participants:
____ Accrual ceiling set by IRB
____ New participant accrued since last review
____ Total participant accrued since protocol began _____

10. Total participants excluded since protocol began
ACCRUAL EXCLUSION
_____None
_____Male
_____Female

11. Are there other new sites that were added or deleted since the last review?
____Yes ____No
(Pls. identify the sites and note the addition or deletion.)

12. Impaired Participants

_____None
_____Physically
_____Cognitively
_____Both

13. Deviations from the approved protocol

15. Issues/ problems encountered

16. Justification for application for Continuing Review

**INVESTIGATOR'S ATTESTATION**

I certify that the information provided in this report is complete and accurate.

_____ _____

Signature Over Printed Name of Principal Investigator Date

*(IRB Use only)* Received by:

_____ _____

Signature Over Printed Name Date

***SECTION 2: TO BE FILLED UP BY RESPECTIVE IRB MEMBER***

**Type of Review**

**Expedited** ☐ **Full Board** ☐

**Reviewer's Comments:**

**Final Action:**

**( ) Approved**
**( ) Request additional information**
**( ) Submission of an explanation for failure to submit required reports**
**( ) Disapproval**

**Acknowledged by:**

_____

**Name of Reviewer**
IRB Member

_____

**Signature**

_____

**Date**