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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

14. Issues/ problems encountered

15. 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