

**APPLICATION FOR CONTINUING REVIEW (FORM 4.7)**

IRB Protocol Code: Date Received (D/M/Y):

Protocol Title: Sponsor:

 Principal & Sub Primary Reviewers:

 Investigators:

*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/violations 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, CV and GCP certificate of the new investigators.)

9. Summary of protocol participants:

 \_\_\_\_ Accrual ceiling set by Sponsor

 \_\_\_\_ 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

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

|  |
| --- |
| **Type of Review**  **Expedited Full Board**  |

 **Summary of Recommendations:**

**( ) Approved**

**( ) Request additional information**

**( ) Submission of an explanation for failure to submit required reports**

**( ) Disapproved**

**Decision:**

**Acknowledged by:**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Name and Signature of IRB MEMBER**