CONTINUING REVIEW APPLICATION

To the Principal Investigator:

To ensure continued protection of study participants, the IEC conducts a continuing review of previously approved protocols at intervals appropriate to the degree of risk involved, but at least annually.

Please be advised that no research-related activities may continue after the IEC approval has expired. To avoid lapse in approval, applications for continuing review must be filed 60 days prior to the expiry date of the current IEC approval.

Please obtain an electronic copy of this Form, fill-out the requested information, and make your submission both in electronic version and hard copy. Print in letter-sized paper with printer default set at A4.

I. PROTOCOL INFORMATION	**IEC Protocol Tracking No.**
Study Protocol No.	Protocol Approval Date: <dd/mm/yy>
Study Initiation Date: <dd/mm/yy>	Expected End Date: <dd/mm/yy>
Title:	Version Number, Date
Name of Principal Investigator	Contact Nos.:
Sponsor/CRO	
Study Site	
Type of Review (*To be determined by IEC*) ☐ Full Board ☐ Expedited	

II. INFORMATION REQUIRED	**CONTINUING REVIEW APPLICATION SUBMISSION DATE <dd/mm/yy>**
1 Status of the Study ☐ On-going ☐ Still open to additional enrollment ☐ Closed to additional enrollment, protocol-related interventions/treatments completed, study still active for long-term follow-up ☐ Remaining research activities limited to data analysis ☐ Others (specify) ☐ Not started/Not Initiated (*state reasons*) ☐ Suspended (*state reasons*) ☐ Terminated/Canceled/Aborted (*PI should submit instead an Early Study Termination Application [DLSMHSI-IEC Form 3F/V1/2012]*)) ☐ Closed/Completed (*PI should submit instead Final Report [DLSMHSI-IEC Form 3D/V1/2012])*	

2. Since the last IEC review, have there been any amendments in the research design, methodologies, interventions, data analysis, participant population, recruitment procedures?
   - ☐ No
   - ☐ Yes (*explain/give reasons for the amendments, indicate dates of Protocol Amendment Submission and Approval, and append the IEC-approved amendments)*

3. Since the last IEC review, have any participating investigators been added or deleted?
   - ☐ No
   - ☐ Yes *explain/give reasons for the changes, provide the names of the study personnel, and indicate dates of Protocol Amendment Submission and Approval, and append the updated version)*

4. Since the last IEC review, have any new collaborating sites been added or deleted?
   - ☐ No
   - ☐ Yes (*explain/give reasons for the changes, enumerate the sites, and indicate dates of Protocol Amendment Submission and Approval, and append the updated version)*

5. Since the last IEC review, have there been any changes in the Informed Consent process/document?
   - ☐ No
   - ☐ Yes (*explain/give reasons for the changes, indicate dates of Protocol Amendment Submission and Approval, and append the updated version)*

6. Since the last IEC review, have all Informed Consents/Assents obtained from all research participants?
   - ☐ No (*explain/give reasons)*
   - ☐ Yes

7. Since the last IEC review, have any participants withdrawn from the study?
   - ☐ No
   - ☐ Yes (*append a summary describing the number and reasons for each of the participant's withdrawals)*

8. Summary of Protocol Participants

8.1. Accrual ceiling set by IEC	
8.2. New participants accrued since last review/approval	
8.3. Total participants accrued since study began	
8.3.1. Active Patients	
8.3.2. Patients Who have Completed the Study	
8.4. Number of drop-outs	
8.5. Withdraw	
8.6. Death	

9. Accrual Exclusions
   - ☐ None
   - ☐ Male
   - ☐ Female
   - ☐ Others (specify)

10. Impaired Participants
    - ☐ None
    - ☐ Male
    - ☐ Female
    - ☐ Others (specify)

11. Since the last IEC review, have there been any SAEs that were not previously reported to the IEC?
    - ☐ No
    - ☐ Yes (*append a summary describing the number and nature of the SAEs)*

12. Since the last IEC review, have there been any unanticipated problems, adverse events, and minor deviations that were not been previously reported to the IEC?

☐ No
☐ Yes (*append a summary describing the number and nature of the problems, adverse events, and minor deviations)*

13. Since the last IEC review, have there been any participant complaints that were not previously reported to the IEC?
☐ No
☐ Yes (*append a summary describing the number and nature of the complaints, and state whether they have been resolved or if not, specify the aspect(s) of the compliant that have not been resolved*

14. Since the last IEC review, has any new information emerged either from your study or from other sources that could alter IEC's previous risk-benefit assessment?
☐ No
☐ Yes (*append a summary of the new information)*

15. Since the last IEC review, have any changes been made in the data safety monitoring plan?
☐ No
☐ Yes (*append a summary of the changes, and state whether the changes are likely to affect*

16. Since the last IEC review, has there been new/additional investigational drug/device registrations associated with this study?
☐ No
☐ Yes (*indicate the registration information*)
☐ IND
☐ IDE

17. Since the last IEC review, have there been other changes that have not been mentioned?
☐ No
☐ Yes (*explain/give reasons for the changes, indicate dates of Protocol Amendment Submission and Approval, and append the updated version)*

18. Since the last IEC review, have there been any changes in the financial/non-financial interests of the study personnel which may be considered as Conflict of Interest?
☐ No
☐ Yes (*append a statement of disclosure)*

I declare that the above information/statements are true and correct to the best of my knowledge.

_____ _____
Signature Over Printed Name of Principal Investigator ***Date***

III. IEC RECOMMENDATION	**Justification for the Recommendation**
☐ UPHOLD ORIGINAL WITH NO FURTHER ACTION ☐ REQUEST INFORMATION (*specify information*) ☐ RECOMMEND FURTHER ACTION (*specify action*)	
Reviewer ☐ Primary ☐ Secondary	_____ _____ *Reviewer's Signature Over Printed Name* *Date*