#### AX1-V1/SOP 07/V1

**Continuing Review Application**

IEC Proposal Number: \_\_\_\_\_\_\_\_\_\_\_

Study Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of PI: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Department:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Duration of Study:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Account No:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of IEC Approval: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of Starting the Study:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Period of Progress Report (Date): From: \_\_\_\_\_\_\_ To: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Are you applying for extension for the same: □ Yes □ No

If yes- period of extension requested?\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Project Status

□ Ongoing

□ Active accrual on going

□ Accrual completed /Follow-up

□ Analysis on going

□ Not started/Not initiated

If ‘Not started’ state reasons\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Progress:

Major Adverse Events:

Amendments (if any): □ Yes □No □ NA

If ‘YES’, please provide in format below

|  |  |  |
| --- | --- | --- |
| Amendment No. Version Dated | Date of submission | Date of IEC Approval |
|  |  |  |

Have any participating investigators been added or deleted since the last status report was submitted to BKLWH?

□ Yes (Kindly attach a sheet with details)

□ No

□ NA

Has there been any presentation/publication related to the data generated in this trial?

□ Yes □ No □NA

(If, ‘YES’, kindly attach a sheet enclosing the details)

Details regarding the budget- : (kindly attach consolidated account summary duly

Signed by Accounts Officer): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Total budget proposed for the project: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Total budget sanctioned for the project: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Total budget utilized for the project: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Reason for Discontinuation of Study: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Any other information: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |
| --- | --- |
| Sign & Date of Principal Investigator |  |