**CONTINUING REVIEW APPLICATION FORM**

IHEC Project no.:

Date of IHEC approval:

Name of Principal Investigator: -  Coinvestigator**:**

Guide:

Department:

**Type of Study Proposal: Major protocol Short study**

**: In-vivo In-vitro**

**Date of project initiation:**

|  |  |  |
| --- | --- | --- |
| **Summary of Project objectives & methodology (for in-vivo & In-vitro studies)** | | |
| **Objectives as approved** | |  |
| **Deviation in objectives** | |  |
| **Total sample size as approved** | |  |
| **Changes in materials & methodology in the study if present** | |  |
| **Summary of protocol participants (In-vivo study involving human participants)** | | |
| No. of participants screened |  | |
| No. of participants approved by IHEC No. of recruited participants |  | |
| No. of ongoing participants |  | |
| No. of completed participants |  | |
| No. of participants who refused to consent |  | |
| Have any participants been withdrawn from this study?  If no, (state the number and reasons for drop-outs of each participant, attach separate sheet if needed) | Yes No | |
| Have there been any amendments in protocol/ Informed Consent Document since the last review? | Yes No | |
| Were these protocol/ Informed Consent Document (ICD) amendments approved by IEC? | Yes No | |
| Has any information appeared in the literature, or evolved from this or similar research that might affect the IEC/IEC’s evaluation of the risk/benefit analysis of participants involved in this protocol?  If Yes (attach separate sheet if needed) | Yes No | |
| Whether reports of Serious Adverse Events (SAE) so far have been reviewed by the IHEC  Whether reports of SAEs at other sites have been submitted to the IHEC |  | |
| Have any participating investigators been added or withdrawn since last review?  If Yes (Identify all changes in the attached narrative) | Yes No | |
| **Guide allocation** | | |
| Is there a change in guide?  If yes attach letter with signature of guide | Yes No | |
| **Budget allocation** | | |
| Alteration in the budgetary status |  | |

**Note:** Submit the Progress of the study - **brief description**

Signature of the Principal Investigator with Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Guide with Date: