#### AX02-V1/SOP06/V1

**Post approval Amendment Reporting Form**

**(Kindly tick in the boxes provided)**

|  |
| --- |
| Project No. : |
| Title: |
| Principal Investigator : |
| Date of IEC Approval: |
| Start Date of Study:Status of Study:Validity of IEC approval- |
| No. of amendment:Have the changes modifications in the amended versions been highlighted/ underlined?* Yes ☐ No Nature of amendment
* Major ☐ Minor
 |
| Does this amendment entail any changes in Informed Consent Form (ICF) | * Yes ☐ No
 |
| If yes, whether amended ICFs are submitted pl. specify ICF Version No. & Date and its IEC approval |  |
| Please mention version no. and date of amended Protocol / Investigators Brochure / ICF Addendum/ Case Record Form / Any other documents |  |
| * Does the revision entail any change in the Risk vs Benefit Analysis
 | * Yes ☐ No
 |
| * Target accrual of trial (entire study) \_\_\_\_\_\_\_\_\_\_\_\_
* Total patients to be recruited at BKLWH (IEC celling) \_\_\_\_\_\_
* Screened: \_\_\_\_\_\_
* Screen failures: \_\_\_\_\_\_\_\_\_\_
* Enrolled: \_\_\_\_\_\_\_\_\_
* Consent Withdrawn: \_\_\_\_\_\_\_ Reason: (Attach in format below)
* Withdrawn by PI: \_\_\_\_\_\_\_\_\_ Reason: (Attach in format below)
* Active on treatment: \_\_\_\_\_\_\_
* Completed treatment:\_\_\_\_\_
* Patients on Follow-up:\_\_\_\_\_\_
* Patients lost to follow up: \_\_\_\_\_\_
* Any others:
* Any Impaired participants:
* None: \_\_\_\_\_
* Physically\_\_\_\_\_\_
* Cognitively\_\_\_\_\_\_
* Both\_\_\_\_\_
 |  |

(**Important note:** Please submit summary list of changes should include document/Revised version no Section, page no, change(s) and risk/benefit or justification.

####

#### Table 1: Summary List of Changes

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Name of document** | **Revised version/Date** | **Section** | **Page No** | **Change(s)** | **Risk/Benefit Assessment****/Justification** |
|  |  |  |  |  |  |

**Signature of the Principal Investigator & Date:**