#### 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\_\_\_\_\_\_ * Screened: \_\_\_\_\_\_ * Screen failures: \_\_\_\_\_\_\_\_\_\_ * Enrolled: \_\_\_\_\_\_\_\_\_ * Consent Withdrawn: \_\_\_\_\_\_\_ Reason: (Attach in format below) * Withdrawn by PI: \_\_\_\_\_\_\_\_\_ Reason: (Attach in format below) * Active on treatment: \_\_\_\_\_\_\_ * Completed treatment:\_\_\_\_\_ * Patients on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.

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#### 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:**