**AX2-V6/SOP06/V6**

**Post approval Amendment Reporting Form**

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

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| --- | --- |
| 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 TMH (IEC ceiling)\_\_\_\_\_\_\_\_\_\_ * Screened: \_\_\_\_\_\_\_\_\_\_ * Screen failures: \_\_\_\_\_\_\_\_\_\_ * Enrolled: \_\_\_\_\_\_\_\_\_\_ * Consent Withdrawn: \_\_\_\_\_\_\_Reason: (Attach in format below) * Withdrawn by PI: \_\_\_\_\_\_\_\_\_Reason: (Attach in format below) * Active on treatment: \_\_\_\_\_\_\_\_\_\_ * Completed treatment : \_\_\_\_\_\_\_\_\_\_ * Patients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 other: \_\_\_\_\_\_\_\_\_\_ * 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 (Comparison Chart)**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Name of document** | **Revised version/Date** | **Section** | **Page No** | **Previous/Old text** | **New text** | **Risk/Benefit Assessment /Justification** |
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