**AX2-V6/SOP06/V6**

**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 □ NoNature 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* Consent Withdrawn: \_\_\_\_\_\_\_Reason: (Attach in format below)
* Withdrawn by PI: \_\_\_\_\_\_\_\_\_Reason: (Attach in format below)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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