**AX1- V5/SOP13/V5**

**Premature Termination / Suspension / Discontinuation Report**

|  |  |
| --- | --- |
| TMC Project No.: | |
| Protocol Title: | |
| PI: | |
| E-Mail: | |
| Study Site: | |
| Sponsor/Funding agency: | |
| IEC Approval Date: | Date of Last Progress Report Submitted to IEC |

|  |  |
| --- | --- |
| Please tick the appropriate  🞎 Premature Termination  🞎 Suspension  🞎 Discontinuation  Reason for Termination/Suspension/Discontinuation: | |
| Study Start Date: | Termination / Suspension / Discontinuation Date: |
| Study Participants   * Target accrual of trial (entire study) \_\_\_\_\_\_\_\_\_\_\_\_\_\_ * Total patients to be recruited at TMC ­­­­­­­(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* Screen failures: ­­­­­­­­­\_\_\_\_\_\_\_\_\_\_ * Enrolled: ­­­­­­­­­\_\_\_\_\_\_\_\_\_\_ * Consent Withdrawn: ­­­­­­­­­\_\_\_\_\_\_\_Reason: (Attach in format below) * Withdrawn by PI: ­­­­­­­­­\_\_\_\_\_\_\_\_\_Reason: (Attach in format below) * Active on treatment: \_\_\_\_\_\_\_\_\_\_ * Completed treatment : \_\_\_\_\_\_\_\_\_\_ *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 \_\_\_\_\_ | |
| Total number of SAEs reported (if applicable):  Type of SAEs reported:  Have any adverse events or outcomes reported to the IEC- 🞎 Yes 🞎 No 🞎 NA | |
| Have any Protocol deviation/ violation reported to the IEC- 🞎 Yes 🞎 No 🞎 NA  If yes, please provide the list of reports in tabular form. | |
| Have there been participant complaints or feedback about the study  🞎 Yes 🞎 No 🞎 NA If yes Describe \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Had there been any suggestions from the DSMSC  🞎 Yes 🞎 No 🞎 NA  If yes, have you implemented that suggestion  🞎 Yes 🞎 No 🞎 NA  Whether procedures for withdrawal of enrolled participants take into account their rights and welfare (e.g., making arrangements for medical care off a research study): 🞎 Yes 🞎 No 🞎 NA  If No- provide reasons- | |
| Summary of Results (if any) : | |
| Budget sanctioned-  Budget utilized-  (please enclose UC duly signed by Accounts officer) | |
| PI Signature: | Date: |