**AX1- V5/SOP13/V5**

**Premature Termination / Suspension / Discontinuation Report**

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

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* Consent Withdrawn: ­­­­­­­­­\_\_\_\_\_\_\_Reason: (Attach in format below)
* Withdrawn by PI: ­­­­­­­­­\_\_\_\_\_\_\_\_\_Reason: (Attach in format below)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