

AX1- V6/SOP13/V6

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 <input type="checkbox"/> Premature Termination <input type="checkbox"/> Suspension <input type="checkbox"/> Discontinuation	
Reason for Termination/Suspension/Discontinuation:	
Study Start Date:	Termination / Suspension / Discontinuation Date:

<p>Study Participants</p> <ul style="list-style-type: none">○ 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patients to be recruited at TMC (IEC ceiling) _____○ Screened: _____○ Screen failures: _____○ Enrolled: _____○ Consent Withdrawn: _____ Reason: (Attach in format below)○ Withdrawn by PI: _____ Reason: (Attach in format below)○ Active on treatment: _____○ Completed treatment : _____○ Patients on Follow-up: _____○ Patients lost to follow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: _____

<ul style="list-style-type: none">○ Any other: _____○ Any Impaired participants<ul style="list-style-type: none">● None _____ <input type="checkbox"/>● Physically _____● Cognitively _____● Both _____	
Total number of SAEs reported (if applicable): Type of SAEs reported: Have any adverse events or outcomes reported to the IEC- <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	
Have any Protocol deviation/ violation reported to the IEC- <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA If yes, please provide the list of reports in tabular form.	
Have there been participant complaints or feedback about the study <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA If yes Describe _____	
Had there been any suggestions from the DSMU <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA If yes, have you implemented that suggestion <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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): <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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: