



## AX1-V2/SOP-13/V2

### Premature Termination / Suspension / Discontinuation Report

BBCI 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:
Study Participants <ul style="list-style-type: none"><li>○ Target accrual of trial (entire study) _____</li><li>○ Total patients to be recruited at BBCI (IEC ceiling) _____</li><li>○ Screened: _____</li><li>○ Screen failures: _____</li><li>○ Enrolled: _____</li><li>○ Consent Withdrawn: _____ Reason: (Attach in format below)</li><li>○ Withdrawn by PI: _____ Reason: (Attach in format below)</li><li>○ Active on treatment: _____</li><li>○ Completed treatment: _____</li></ul>	

<ul style="list-style-type: none"><li>○ Patients on Follow-up: _____</li><li>○ Patients lost to follow up: _____</li><li>○ Any other: _____</li><li>○ Any Impaired participants<ul style="list-style-type: none"><li>● None _____ <input type="checkbox"/></li><li>● Physically _____</li><li>● Cognitively _____</li><li>● Both _____</li></ul></li></ul>	
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: