

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?	
<input type="checkbox"/> Yes <input type="checkbox"/> No	
Nature of amendment	
<input type="checkbox"/> Major <input type="checkbox"/> Minor	
Does this amendment entail any changes in Informed Consent Form (ICF)	<input type="checkbox"/> Yes <input type="checkbox"/> 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	
<ul style="list-style-type: none"> • Does the revision entail any change in the Risk vs Benefit Analysis 	<input type="checkbox"/> Yes <input type="checkbox"/> No
<ul style="list-style-type: none"> • 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to be recruited at TMH (IEC ceiling) _____ • Screened: _____ • Screen failures: _____ • Enrolled: _____ • Consent Withdrawn: _____ Reason: (Attach in format below) • Withdrawn by PI: _____ Reason: (Attach in format below) 	

<ul style="list-style-type: none"> • Active on treatment: _____ • Completed treatment : _____ • Patients on Follow-up: _____ • Patients lost to follow up: _____ • Any other: _____ • Any Impaired participants • <input type="checkbox"/> 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

Signature of the Principal Investigator & Date: