

Annexure 16

Protocol / Protocol related documents Amendment Request and Assessment Form

IEC Protocol Number: _____	
Protocol Title: _____	
Principal Investigator and Department: _____	
Approved date: _____	No. of amendment: _____
○ State/describe the amendment :type of document/ part of document amended _____	
○ Reasons for the amendment _____	
○ Impact of your amendment on your present study at this site: (modifications in the ICD, re-consent of research participants, untoward effects likely to occur because of the amendment or any other) _____	
Have the changes modifications in the amended versions been highlighted/ underlined? Yes <input type="checkbox"/> No <input type="checkbox"/>	
Name of Principal Investigator: _____ Signature with Date: _____	
Type of review :- (Decision by the Chairperson/ Member Secretary) Review by Member Secretary/ Chairperson <input type="checkbox"/> Review by designated IEC members <input type="checkbox"/> Full Board discussion and review <input type="checkbox"/>	
Comments of the reviewer :- _____	
Decision:	<input type="checkbox"/> Approved <input type="checkbox"/> Suggested Recommendation(s) <input type="checkbox"/> Disapproved <input type="checkbox"/> Next full board discussion
Name of IEC Member / Member Secretary / Chairperson reviewing the project: _____ _____	
Signature with Date: _____	

Final Decision: Approved Yes No If disapproved, reasons for disapproval _____
Further revision or modification required: _____
Any Other _____
Signature of the Chairperson/Member Secretary: _____ Date: _____