

**FORM NO: 30 STUDY ASSESSMENT FORM FOR AMENDED PROTOCOL**

IEC protocol Code	
Name of Principal Investigator	
Protocol Version & Date	
Reviewer's name with Designation:	
Meeting Date (D/M/Y):	

**Mark and comment on whatever items applicable to the study**

Sl. No	Particulars	Appropriate	Inappropriate	NA
<b>Details of Amended Protocol (If Applicable)</b>				
1.	Summary of Changes			
2.	Inclusion Criteria			
3.	Exclusion Criteria			
4.	Vulnerability assessment (If Applicable)			
5.	Analysis of types of samples			
6.	DCGI submission/Approval Letter if Applicable			
<b>Participant Information Sheet and Informed Consent Documents</b>				
1.	Contents of the ICD Translation and back translation certificates			
2.	Language of the ICD: Kannada, Hindi, English and Marathi			
3.	Risks and Benefits			
4.	Period of storage of biological samples if Any			
5.	Privacy & Confidentiality			
6.	Provision for Compensation per subjects in ICFs-TA(INR)			
Reviewer Signature				