INSTITUTIONAL ETHICS COMMITTEE
JSS MEDICAL COLLEGE, MYSORE

Documents of Clinical Trial to be submitted & reviewed for IEC Approval
(Checklist)
Clinical Trial (New/ Amendment)

Sl.No	Particulars	Remarks
01	DCGI Approval letter / Application to DCGI for approval	
02	CTRI Registration No. & letter	
03	Title of Clinical Trial Protocol, Clinical Trial Protocol No., Name of PI Version No., Details of sponsoror.	
	Summary of changes for Amendment	
04	ICF / Subject information sheet – 2 Languages (Kannada & any other 1 language) in addition to English & corresponding Translation certificates, Version No.	
05	Investigator brochure :- Product leaflet Version No. / Edition No, Full prescription information :- Prescribing information	**Version/ Details**
06	**CRF**/ Patient data evaluation form / Patient data collection form/ **Subject dairy**	
07	CV of PI	
08	Insurance Details for Study related injuries	
09	Clinical Investigation Agreement CTA	
10	Investigator undertaking IU	
11	Statement describing the details of reimbursement and compensation for the study participants incorporated in the ICF	Contact persons details to be specified. Details of reimbursement (TA/ DA)-
12	GCP Trained certificate of PI/ CO PI with date	
13	Any Other details Methodology:	
14	Risk Benefit	--

15	Remarks of Member Secretary	**Conditional/ Final approval**
16	The IEC review charges for the new drug trial / project (Payment Details)	