Annexure-18

Documents Checklist for Clinical Trial

INSTITUTIONAL ETHICS COMMITTEE – CHARUSAT

Sr. No.	Documents	Submission		
		Yes	No	NA
01	Clinical Trial Protocol (with name of all investigators)			
02	Current CV, GCP and MRC of Investigator			
03	Investigator's Undertaking			
04	Investigator's Brochure			
05	Case Report Form			
06	Valid Insurance Policy			
07	DCGI Submission Letter/Approval letter			
08	CTRI Number/Submission letter			
09	Participant Information Sheet (PIS) along with Informed Consent Form=Informed Consent Document (ICD) in English			
10	Participant Information Sheet (PIS) along with Informed Consent Form=Informed Consent Document (ICD) in Vernacular Language			
11	ICD Translation Certificate (English to vernacular language)			
12	ICD back translation Certificate (Vernacular language to English)			
13	Participant Recruitment Procedure (e.g. Advertisement, wherever applicable).			
14	Clinical Trial Agreement (Investigator's agreement with sponsor and site) – Draft/final			
15	Copy of IEC-CHARUSAT Fees submission (Receipt)			
16	Declaration of Conflict of Interest (from investigators, if any)			
17	Copy of Feasibility Report to sponsor.			

Sr. No	Comments

Signature of Member Secretary
IEC-CHARUSAT