

Annexure 8

Checklist Documents

The applicant of the proposal, generally the principle investigator is required to submit his/her application letter, 2 hardcopies of the project and submit the project online at the Ethics Committee website www.iecmanager.org, at least 20 days before a scheduled meeting.

Item No.	Documents	Yes	No	NA
1	A letter of intent or proposal by the Principle Investigator			
2	Study protocol.			
3	Case Record Form			
4	Summary of protocol (in not more than 500 hundred words)			
5	Participant Information Sheet and Informed consent forms in English, and Hindi (and if required any other language)			
6	Any written information to be provided to subjects including patient emergency card, study related questionnaire			
7	Insurance policy			
8	DCGI approval letter/DCGI submission letter			
9	NOC from DCGI/DGFT/ICMR			
10	Investigator's Brochure.			
	A. Investigators Declaration/ Undertaking by the Investigator Appendix VII (Schedule Y)			
	B. Conflict of Interest Statement			
	C. Consent of Head of the PI's			
11	Clinical Trial Agreement (CTA)/Memorandum of Understanding(MOU)/ Material Transfer Agreement(MTA)if applicable			
12	Import license, where applicable			
13	Brief resume of PI and Co-investigators			
14	IEC processing fee(applicable for sponsored trials).			
15	Budget Sheet for the Proposed Study			