

GMERS Medical College, Gandhinagar

(Managed by Gujarat Medical Education and Research Society, an Undertaking of Govt. of Gujarat)

INSTITUTIONAL ETHICS COMMITTEE (IEC)

CHECKLIST OF DOCUMENTS FOR PROTOCOL SUBMISSION

Protocol submission for initial review

(Tick accordingly)

Sr. No.	Documents	Yes	No	NA
1	Letter to Member Secretary/ Chairperson			
2	Brief Summary of protocol (about 1-2 pages, 15 copies)			
3	Complete Protocol			
4	Informed consent document in English			
5	Informed consent documents in Regional languages			
6	Participant Information sheet in English			
7	Participant information sheet in regional language			
8	Case Record Form			
9	Subject recruitment procedures: advertisement, notices or any other			
11	Patient/Subject Questionnaire/s, if applicable			
12	Investigator Brochure			
13	Insurance policy in sponsored clinical trials			
14	DCGI approval for clinical trials on "new drug"			
15	Investigator's agreement with sponsor (Copy of the Final Signed Document)			
16	FDA marketing/manufacturing license for herbal formulations/nutraceuticals			
17	For studies involving multiple institutes / centers / authorities a MoU / agreement / letter of permission between the collaborating partners			
18	Ethics Committee clearance of other centers			
19	Documentation of CTRI registration/ any other WHO platform registry (whenever applicable)			
20	Any other Documents submitted (specify)			