



INSTITUTIONAL ETHICS COMMITTEE (IEC)

Bharatiya Vidya Bhavans Sardar Patel Institute of Technology
Munshi Nagar, Andheri (West), Mumbai 400 058
(91)-(022)-26707440, 26287250

Annexure 2

Check List for Protocol Submission

Check List of Documents for Protocol Submission to the Institutional Ethics Committee to be filled in by the study team.

Protocol submission for initial review.

(Tick accordingly, compulsory documents have to be submitted by ticking in the box marked as 'Yes') *
Compulsory documents for initial review.

Sr. No.	Document	Yes	No	Date by which it will be submitted if pending	NA
1	*Project submission application form duly filled.	—	—	_____	—
2	*Letter to Member Secretary/ Chairperson.	—	—	_____	—
3	*Summary of protocol (in not more than 500 words).	—	—	_____	—
4	*Protocol.	—	—	_____	—
5	*Informed consent document in English,	—	—	_____	—
6	*Informed consent documents in Regional languages (Total No:-) Hindi, Marathi.	—	—	_____	—
7.	*Case Record Form.	—	—	_____	—
8.	*Research participants recruitment procedures: advertisement, notices (If applicable).				
9.	*Research participants Questionnaire/s (If applicable).	—	—	_____	—
10.	Undertaking by Principal Investigator regarding compensation for study related injury (applicable for academic interventional studies).	—	—	_____	—
11	*Clinical Trial Agreement for drug trial / Memorandum Of Understanding, as applicable, for collaborator & Govt sponsored trials (draft if final not ready)	—	—	_____	—



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	(Final MOU: On Rs. 100/- stamp paper, tripartite with terms of agreements specified clearly).				
12	*Signed and dated brief current curriculum vitae of the entire study team members. (for regulatory studies and for non regulatory if needed)	—	—	_____	—
13	Valid MMC registration certificate of medical faculty	—	—	_____	—
14	*Ethics Committee clearance of other centers (Total No _____)	—	—	_____	—
15	*Log of delegation of responsibility of the study team members - Annexure3)	—	—	_____	—
16	*Document Receipt Form (Annexure5)	—	—	_____	—
16	*Current Status of Ongoing Studies approved by IEC and conducted by principal investigator (Attach separate sheet including information as Project registration number, title, no of participant approved by IEC, no of participants recruited, SAE at the site)	—	—	_____	—
17	*GCP training certificates of study team members (last 3years, for regulatory studies and for non regulatory if needed)	—	—	_____	—
18	HMSC permission for International collaboration (required in case of studies involving collaborations with foreign Laboratory/ Clinic/Institution)	—	—	_____	—
19	Any other Documents submitted	—	—	_____	—



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To be filled in by the IEC – Checklist for EC form:

1. Contact Address of Sponsor
2. Total Budget
3. Information on Clinical Trials
4. Information on Protocol of the proposal
5. Research participants selection
6. Privacy and confidentiality
7. Use of biological/ hazardous materials
8. Consent
9. Risks & Benefits
10. Data Monitoring
11. Compensation for participation
12. Compensation for injury
13. Statement on conflict of interest