Annexure 2

AX 02/SOP 05/V5

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	Approval of Departmental Review Board (DRB)(for thesis/dissertations proposals).	__	__	_____	__
3	*Letter to Member Secretary/ Chairperson.	__	__	_____	__
4	*Summary of protocol (in not more than 500 words).	__	__	_____	__
5	*Protocol.	__	__	_____	__
6	*Informed consent document in English,	__	__	_____	__
7.	*Informed consent documents in Regional languages (Total No:-) Hindi, Marathi.	__	__	_____	__
8.	Back translation of Informed Consent Documents.	__	__	_____	__
9	Translation and Back translation certificates.	__	__	_____	__
10	*Case Record Form.	__	__	_____	__
11	*Research participants recruitment procedures: advertisement, notices (If applicable).	__	__	_____	__

12	*Patient instruction card, identity card, diary etc.	__	__	_____	__
13	*Research participants Questionnaire/s (If applicable).	__	__	_____	__
14	*Investigator Brochure.	__	__	_____	__
15	*Entire Insurance policy with certificate (applicable for interventional studies).	__	__	_____	__
16	Undertaking by Principal Investigator regarding compensation for study related injury (applicable for academic interventional studies).	__	__	_____	__
16	*Investigator's undertaking to DCG(I)	__	__	_____	__
17	DCG(I) approval [if DCGI approval is awaited, the application to DCGI needs to be submitted].	__	__	_____	__
18	*Clinical Trial Agreement for drug trial / Memorandum Of Understanding, as applicable, for collaborator & Govt sponsored trials (draft if final not ready) (Final MOU: On Rs. 100/- stamp paper, tripartite with terms of agreements specified clearly).	__	__	_____	__
19	FDA marketing/manufacturing license for herbal formulations/ nutraceutics.	__	__	_____	__
20	Bhabha Atomic Research Centre (BARC) approval in case study involves use of radioisotopes/ ionizing radiations.	__	__	_____	__
21	Genetic Engineering Advisory Committee (GEAC) approval in case study involves use of gene therapy.	__	__	_____	__

22	Administrative sanction from the Head of the Institution for the samples to be sent to outside KEM Hospital (one copy) For non-collaborative and non-regulatory studies	__	__	_____	__
23	**Signed and dated* brief current curriculum vitae of the entire study team members. (for regulatory studies and for non regulatory if needed)	__	__	_____	__
	Valid MMC registration certificate of medical faculty	__	__	_____	__
24	*Ethics Committee clearance of other centers (Total No _____)	__	__	_____	__
25	*Log of delegation of responsibility of the study team members - Annexure3-SOP5)	__	__	_____	__
26	*Document Receipt Form (Annexure4-SOP5 for regulatory studies and for non regulatory if needed)	__	__	_____	__
27	*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)	__	__	_____	__
28	Documentation of CTRI registration/ any other WHO platform registry (whenever applicable)	__	__	_____	__
29	*GCP training certificates of study team members (last 3years, for regulatory studies and for non regulatory if needed)	__	__	_____	__
30	HMSC permission for International collaboration (required in case of studies involving collaborations with foreign Laboratory/ Clinic/Institution)	__	__	_____	__
31	Any other Documents submitted	S	__	_____	__

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 ☐