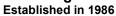
Seth GS Medical College and KEM Hospital





IEC-I Re-registration No. ECR/229/Inst./MH/2013/RR-16,IEC-II registration No. ECR/417/Inst./MH/2013 Issued under rule 122DD of Drugs & Cosmetic rule 1945.

Recognized by:

The Strategic Initiative for Developing Capacity in Ethical Review (SIDCER).

Forum for Ethical Review Committees in Asia and the Western Pacific Region (FERCAP)

for its compliance with international and local standards in ethical review.

#### **Annexure 2**

AX 02/SOP 05/V5

#### **Check List for Protocol Submission**

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

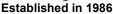
Protocol submission for initial review.

(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).		_		_

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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.			 _

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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 or 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				1	T	
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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	П