

**Sample format of covering letter by Principal Investigator (PI) for initial submission of protocol review for pharmaceutical & GOVT sponsored / Funded studies.**

Date:

To,  
The Member Secretary,  
IEC.

Sub: Submission of clinical trial / trial documents for Ethics Committee review and approval.

Ref: Protocol number XXX Version XX dated XXX entitled, "XXXXXXX".

Sir / Madam,

We are conducting a study in our department. XXX sponsor has approached us for the conduct of the abovementioned study. The study will be conducted as per the ICH-GCP, ICMR guidelines and NDCTR, 2019.

**Please find enclosed the following documents for review and approval:**

Sr. No.	Document title	Version no. and date
1		
2		

**Also kindly note the following:**

1	Co-Investigators: 1) _____ 2) _____ Clinical Research Coordinator: 1) _____ 2) _____	Signature of co-investigator	
2	If PI is retired/promoted/transferred/suspended/intended to leave the institute (during study period) who will take over the responsibility of the project as new PI. (Note: If name of the person is not specified, and the above situation happened, then the study will be transferred to the head of the department for necessary action and appointment of new PI.)		
3	<b>Recruitment Strategy</b> a) Word of mouth b) OPD or IPD c) Notices / Advertisement (English, Hindi and Marathi) d) Consecutive – roll over. e) Collaboration with other departments or institutes f) Departmental database		
4	Collaboration department signature of HOD required if applicable		
5	Study conduct – Sponsor / CRO		
6	Funding agency		
6.a	* <b>Intramural funding</b> (DJST/DDF/Research Society/ any other funding body under KEMH) applied / Status		
	DJST	DDF	Research Society
			MRU
			any other funding body under KEMH
6.b	<b>Extramural funding</b>		
	GOVT	NGO	Pharmaceutical industry
			International body
			Other
7	Approximate budget	per patient budget	overall budget
8	Name & number of the Indian sites		
9	Local laboratory address (if applicable)		

10	Outside KEMH laboratory address (if applicable)	
11	Reprimanding letters from IEC in the last five years inclusive all types of studies (PHARMA, GOVT, OA & Thesis)	
12	Administrative sanction for: 1. Conducting the study: 2. Sending samples outside KEMH: 3. Collaboration with other Indian or foreign laboratory/clinic /Institution:	

Note: \* Any funding from outside will not be treated as intramural funded studies.

**Ongoing trial \* status as PI and as Co-I**

Sr. No.	Project no.	Title	Recruited participants	Time given by PI for the project each day

Note: \* Ongoing trials i.e- Study Approved by IEC.

**Status of trials which are under process as PI and as Co-I**

Sr. No.	Project no.	Title	Participants to be enrolled	Time to be given by PI for the project each day

With this I would like to request you to review this project and consider for approval.

Thanking you,  
Sincerely yours,

**Dr. XXXXXXX**  
Principal Investigator

**Forwarded by Head of the Department**  
Seal

**[Definition of Principal investigator (PI): Refer SOP 05-A section 5.1.1 and 5.1.2.**