

**Sample format of covering letter by Principal Investigator (PI) for initial submission of protocol review for thesis/dissertations & investigator initiated/ Other Academic (OA) studies.**

Date:

To,

The Member Secretary,

IEC.

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

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

Sir / Madam,

I'm submitting the study entitled, "xxxxxxx". This is a dissertation topic for my post graduate student / an investigator-initiated study. Requesting for review and approval as per IEC SOPs. The study will be conducted as per the ICH-GCP, ICMR guidelines and NDCTR, 2019 whichever is applicable.

**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-Investigator (if applicable): 1) _____ 2) _____	Signature of Co-I
2	If PI is retired/promoted/transferred/suspended/intended to leave the institute who will take over the responsibility of 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	Recruitment Strategy	1 _____ 2 _____
4	Collaboration department signature of HOD required if applicable	
5	Funding agency	
5.a	*Intramural funding (DJST/DDF/Research Society/ any other funding body under KEMH) applied / Status	
5.b	Extramural funding (GOVT/NGO/Pharmaceutical industry/International body)	
6	Approximate budget per patient and overall budget	
7	Name & number of the Indian sites ( if applicable)	
9	Local laboratory address (if applicable)	
10	Outside KEMH laboratory address (if applicable)	
11	Reprimanding letters from IEC in last five years inclusive all type studies (PHARMA, GOVT, OA & Thesis)	

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

**Ongoing trial status as PI and as Co-I (PHARMA, GOVT, OA & Thesis)**

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

**Status of trials which are in under process as PI and as Co-I (PHARMA, GOVT, OA & Thesis)**

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. XXXXXXXX**  
**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.**