

Initial submission of protocol

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	
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

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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): (as per policy decision 13 March 2014): PI must be a faculty / employee of Seth G. S. Medical College and KEM Hospital, Mumbai and have appropriate graduate/post graduate qualification approved by respective statutory council.]