

Initial submission of protocol

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 PI	
3	Recruitment Strategy	1. _____ 2. _____
4	Collaboration department signature of HOD required if applicable	
5	Study conduct – Sponsor / CRO	
6	Funding agency	
6.a	*Intramural funding (DJST/DDF/Research Society/ any other funding body under KEMH) applied / Status	
6.b	Extramural funding (GOVT/NGO/Pharmaceutical industry/International body)	
7	Approximate budget per patient and 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 last five years inclusive all type studies(PHARMA, GOVT, OA & Thesis)	
12	Copy of approval of head of institution for conducting study in the department & send sample outside KEMH	

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

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): (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.]