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 1-B

AX 1-B/SOP 05/V5

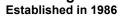
Project submission application form for initial review

for all academic (non-sponsored) studies.

Please fill in the det	ails in legible hand writir	ng		
Tick √ in the box for	the appropriate answer	/ Write NA if qu	uestion is not applical	ble
IEC Protocol no				
Title of the project				
	Name		Designation	Department and Institution
Principal				
Investigator				
Co-Investigator				

"Principal investigator must be a faculty / employee of Seth G. S. Medical College and KEM Hospital and have appropriate post graduate qualification approved by respective statutory council".

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.

If additional collaborators attach details and letter of consent by the collaborator (s) on a separate page.				
Non-sponsored study Sponsored study				
If Non-Sponsored Study: Type of study: Thesis/dissertation				
If sponsored, Total Budget: Rs From where is the study being funded a) Research fund is being utilized from DJST Research Society MRU Others If any other, please give details				
1.Type of Study: Prospective Retrospective Cross-sectional Is the study observational/ Interventional? If interventional, does the study involve any deviation from routine/standard practices?				

Seth GS Medical College and KEM Hospital

Established in 1986



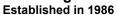
IEC-I Re-registration No. ECR/229/Inst./MH/2013/RR-16,IEC-II registration No. ECR/417/Inst./MH/2013 Issued under rule 122DD of Drugs & Cosmetic rule 1945.

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.

		_				
2. Does the study involve use of : Drug / Vaccine Device Alternative Medicine						
New Technique (surgical/PT/OT, etc) Diagnostic Kit/ Investigations						
If other, please specify						
i) Is the test drug / device marketed in India Yes No						
ii) Does the test drug involve a change in use, dosage, route of administration?						
Yes No						
If yes, data generated intended for submission to licensing authority						
Yes No						
If yes, please attach copy of DCGI permission.						
If no, please attach copy of package insert/product insert.						
3. Subject selection:						
i) Number of subjects at this centre if multicentric, total number of subjects						
ii) Vulnerable subjects Yes No (If yes, tick the appropriate boxes)(Please	refer S	OP no	20/v5)			
pregnant women illiterate seriously/terminally ill						
children neonates mentally challenged						
elderly handicapped economically/socially backward						
institutional employees / students any other						
If other, please specify						
Relevant annexures filled Yes No						
4. Does the study involve use of						
i) fetal tissue or abortus	Yes		No 🗌			
ii) organs or body fluids			No			

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.

iii) Gene therapy		No 🗍
If yes, please submit a copy of Genetic Engineering Advisory Committee (GEAC) permission.		 _
iv) ionizing radiation/radioisotopes	Yes	No 🗌
If yes, please submit a copy of Bhabha Atomic Research Centre (BARC) Permission		
v) infectious / biohazardous specimens		No 🗌
vi) Will pre-existing/stored/left over samples be used?		No 🗌
vii) Will samples be collected for banking/future research		No
viii) Will any sample collected from patient be sent abroad?	Yes	No
If yes, please submit a copy of Director General of Foreign Trade (DGFT)		
permission.		
ix) Is there any collaboration with any foreign lab., clinic or hospital?		No
If yes, please submit a copy of Health Ministry Screening Committee (HMSC) approval.		
5. Will any advertising be done for recruitment of Subjects? (Posters, flyers, brochures, etc.) If yes, kindly attach a copy for IEC review.		No 🗌
6. Is there compensation for participation (traveling allowance)?		No 🗌
If Yes, Monetary In kind		
Specify amount / type:		
7. Are there any arrangements for compensation / treatment of trial related		
injury?		No 🗌
If yes , by sponsor by investigator		
By insurance company by others		
Please submit a copy of the insurance policy if it is available.		

Seth GS Medical College and KEM Hospital

Established in 1986



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.

8. Do you have any conflict of interest in the present study?
(financial / non – financial/ any other)
If yes, specify:
9. Is any other department involved in participant recruitment/investigation, but not co-investigators or collaborators ? Yes/No
If yes, specify
Name and signature of concerned HOD
We hereby declare the information given above is true. A copy of the study report will be submitted at the end of the study.
Signature of Principal Investigator:
Signatures of Co- investigators: 1 2
3 4
Forwarded by Heads of Department(s)
Stamp/Seal of the Department(s)
Please fill the form in legible handwriting or type the information

Please fill the form in legible handwriting or type the information.

Write 'Not Applicable' (NA) wherever necessary.

Incompletely filled form will not be accepted.