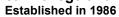
INSTITUTIONAL ETHICS COMMITTEE (IEC)

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

AX 01/SOP 05-C/V5

Review Exemption Application Form

1	Pri	Principal Investigator's Name:							
2	De	partment	:						
3	Tit	le of	Project:					<u>-</u>	
4	Na	mes of ot	her participating	staff and students:				-	
5	 Bri	ef descrip	tion of the projec			<u>-</u>			
	ain	ns/objecti		of the projec			posal, including th description, an		
6			s why exemption f educational prac	from ethics review	is requested?				
	\checkmark	Research	n on microbes cult	ured in the laborate	ory				
	\checkmark	Research	n on immortalized	cell lines					
	✓	Research personal		r death certificate	s provided su	ch research rev	veals no identifyin	g	
	✓	Analysis	of data freely ava	ilable in public dom	ain				
	✓	Any oth							
	ex	his should emption	l include justificat	tion for exemption	e.g. study doe	s not involve hu	uman participants. please refer to th		
Pri	Principal Investigator's signature:					Date			
Foi	war	ded by the	e Head of the dep	artment:					
Na	me:			Signature:		_ Date			

INSTITUTIONAL ETHICS COMMITTEE (IEC)





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.

Re	<u>comn</u>	nendations by the IEC Member Secretary:						
	Exe	mption						
	Can	not be exempted, Reasons						
	Disc	cussion at full board						
Sig	Signature of the Member Secretary: Date							
Fin	al De	ecision:						
	Exemption							
	Can	not be exempted,						
Rea	asons	3						
	Disc	cussion at full board						
Signature of the Chairperson:Date								
Fin	al De	ecision at Full Board meeting held on						
Sia	natuu	re of the Chairperson: Date						
Jig	iiatui	Date						
No	rese	arch can be counted as low risk if it involves:						
	(i)	Invasive physical procedures or potential for physical harm						
	(ii) Procedures which might cause mental/emotional stress or distress, moral or cultural offer							
	(iii)	Personal or sensitive issues						
	(iv)	Vulnerable groups						
	(v)	Cross cultural research						
	(vi)	Investigation of illegal behaviour(s)						
	(vii)	Invasion of privacy						
	(viii)	Collection of information that might be disadvantageous to the participant						
	(ix)	Use of information already collected that is not in the public arena which might	be					

disadvantageous to the participant

INSTITUTIONAL ETHICS COMMITTEE (IEC)



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.

- (x) Use of information already collected which was collected under agreement of confidentiality
- (xi) Participants who are unable to give informed consent
- (xii) Conflict of interest e.g. the researcher is also the lecturer, teacher, treatment-provider, colleague or employer of the research participants, or there is any other power relationship between the researcher and the research participants.
- (xiii) Deception
- (xiv) Audio or visual recording without consent
- (xv) Withholding benefits from "control" groups
- (xvi) Inducements
- (xvii) Risks to the researcher

This list is not definitive but is intended to sensitize the researcher to the types of issues to be considered. Low risk research would involve the same risk as might be encountered in normal daily life. Please check that your application / summary has discussed:

- Procedures for voluntary, informed consent
- Privacy & confidentiality
- Risk to participants
- Needs of dependent persons
- Conflict of interest
- Permission for access to participants from other institutions or bodies
- Inducements

In some circumstances research which appears to meet low risk criteria may need to be reviewed by the IEC. This might be because of requirements of:

- The publisher of the research
- An organisation which is providing funding resources, existing data, access to participants etc.