



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.

Annexure 1

AX 01/SOP 05-C/V5

Review Exemption Application Form

1 Principal Investigator's Name: _____

2 Department: _____

3 Title of Project: _____

4 Names of other participating staff and students: _____

5 Brief description of the project:

Please give a brief summary (approx. 300 words) of the nature of the proposal, including the aims/objectives/hypotheses of the project, rationale, participants' description, and procedures/methods to be used in the project:-

6 State reasons why exemption from ethics review is requested?

- ✓ Audits of educational practices
- ✓ Research on microbes cultured in the laboratory
- ✓ Research on immortalized cell lines
- ✓ Research on cadavers or death certificates provided such research reveals no identifying personal data
- ✓ Analysis of data freely available in public domain
- ✓ Any other

(This should include justification for exemption e.g. study does not involve human participants. If exemption is being requested on the basis of low risk involved in the study please refer to the backside of this annexure.)

Principal Investigator's signature: _____ Date _____

Forwarded by the Head of the department:

Name: _____ Signature: _____ Date _____



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.

Recommendations by the IEC Member Secretary:

- ☐ Exemption
- ☐ Can not be exempted, Reasons _____
- ☐ Discussion at full board

Signature of the Member Secretary: _____ Date _____

Final Decision:

- ☐ Exemption
- ☐ Can not be exempted,
Reasons _____
- ☐ Discussion at full board

Signature of the Chairperson: _____ Date _____

Final Decision at Full Board meeting held on _____

Signature of the Chairperson: _____ Date _____

No research 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 offence
- (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.