7C1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the process for exemption from ethics review and approval of a research protocol.

7C2. Scope

This SOP applies to the review of protocols categorized as suitable for exemption from review by the Member Secretary in consultation with the Chairperson. Any research that carries less than minimal risk and fulfils criteria for exemption from review is covered in this SOP.

7C3. Responsibility

- It is the responsibility of the Member Secretary in consultation with the Chairperson to record the decision in the Exemption Form with reasons.
- The IEC Secretariat is responsible for recording and filing the decision including the reasons for that decision.
- The Chairperson must sign and date letter conveying the decision.

7C4. Detailed instructions

7C4.1 Receive the submitted documents.

- The Secretariat will receive the Exemption from review Application Form, Protocol and other documents submitted by the investigators.
- The Secretariat will check that the package is complete and will forward it to the Member Secretary for review

7C4.2 Determine proposals eligible for exemption from review

- The Member Secretary will screen the research proposal and determine whether the study qualifies for exemption from review based on the criteria laid down in the Ethical Guidelines of Indian Council of Medical Research (ICMR) about the type of research that involve less than minimal risk fall under this category.

- In some circumstances, research that 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 or the organization which is providing funding resources and/or existing data or as a condition for access to participants.

7C4.3 Exemption Process

- If the protocol and related documents satisfy the above stated criteria, the Member Secretary in consultation with the Chairperson will review the brief summary of the project and the Exemption Form.
- The Member Secretary records the decision on the Exemption Form.
- The Secretariat communicates the decision to the investigator.
- The Member Secretary / Chairperson may place the application for review and decision regarding exemption at the next full committee meeting.

7C4.4 Communication

- The decision regarding request for Exemption from review, signed by the Member Secretary of the IEC, will be forwarded by the Secretariat to the Principal Investigator within 14 working days after the decision regarding the exemption is taken.
- The Member Secretary will inform the IEC members of the decision at the next regular meeting and minute it.

7C5. Annexure

Annexure 1 - AX01/SOP 7C/VI - Review exemption application form

Annexure 1 AX01/SOP 7C/VI

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?

- ✔ Proposals with less than minimal risk where there are no linked identifiers, for example;
- ✔ Research conducted on data available in the public domain for systematic reviews or meta-analysis
- ✔ Observation of public behaviour when information is recorded without any linked identifiers and disclosure would not harm the interests of the observed person

- ✔ Quality control and quality assurance audits in the institution
- ✔ Comparison of instructional techniques, curricula, or classroom management methods
- ✔ Consumer acceptance studies related to taste and food quality
- ✔ Public health programmes by Govt agencies such as programme evaluation where the sole purpose of the exercise is refinement and improvement of the programme or monitoring (where there are no individual identifiers). 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**_____

Recommendations by the IEC Member Secretary:

Exemption recommended

Cannot be exempted,

Reasons as discussed in full committee _____

Signature of the Member Secretary: _____Date _____

Final Decision at Full Board meeting held on:

Exemption allowed/

Cannot be exempted,

Reasons_____

Signature of the Chairperson: _____Date _____

NOTE:

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

(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.

7. Flow Chart

No.	Activity	Responsibility
1.	Receive the submitted documents	Secretariat
2.	Determine protocols for Exemption	Member Secretary
3.	Approve the Secretary's recommendation regarding the protocols for Exemption	Chairperson
4.	Exemption process	IEC Members/Chairperson
5.	Decision of IEC	Chairperson
6.	Communicate with the IEC and the Investigator	Member Secretary/ Secretariat