Title: Exemption from Ethics Review of Research Study Protocols

SOP Code: SOP 7C/V2

Effective Date: 21-10-2019

SOP Constitution and Approval:

Prepared by:	Signature and Date:
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Reviewed by:	**Signature and Date:**
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Dr. Sivagnanam G, IHEC Co-Chairperson	
Approved by:	**Signature and Date:**
Dr. Jambulingam, P IHEC Chairperson	21.10.19
Dr. Adithan C, Dean Research, SBV	21/10/19
Dr. Ravishankar M, Dean, MGMCRI	21/10

1. 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.

2. Scope

This SOP applies to the review of protocols categorized as suitable for exemption from review by the Member Secretary/Additional Member Secretary in consultation with the Chairperson (as per SOP 07/V2). Any protocol that carries less than minimal risk and fulfills criteria for exemption from review (SOP 07/V2) is covered in this SOP.

Proposals that may be considered for exemption from review are those with less than minimal risk where there are no linked identifiers, like

- comparison of instructional techniques, curricula, or classroom management methods
- research conducted on data available in the public domain for systematic reviews or meta-analysis;
- observation of public behavior 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;

2.1 A researcher cannot decide that her/his proposal falls in the exempted, category. Researchers can approach the EC with appropriate justification as exempt, from review, but the decision on the type of review required rests with the EC.

2.2Research proposals that have received exemption from review, should be ratified by the full committee, which has the right to reverse/or modify any decision taken by the subcommittee.

3. Responsibility

- It is the responsibility of the Member Secretary/Additional Member Secretary in consultation with the Chairperson to record the decision in the Exemption From review with reasons.
- The IHEC 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 AX 03/SOP 7A/V2.

4. Detailed instruction

4.1 Receive the submitted documents

- The Secretariat will receive the Exemption from review Application From AX 03/SOP 7A/V2, 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/Additional Member Secretary for review.

4.2 Determine protocols eligible for exemption from review

- The Member Secretary/Additional Member Secretary will screen the research study proposal and determine whether the study qualifies for exemption from review based on the criteria laid down in the Indian Council of Medical Research (ICMR) 2017 Ethical Guidelines. The proposals 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 IHEC. This might be because of requirements of the publisher of the research or the organization which is providing funding resources, data and access to participants etc.

4.3 Exemption Process

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

4.4 Communication

- The decision regarding request for Exemption from review, signed by the ERC Chairperson, 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/Additional Member Secretary will inform the IHEC members of the decision at the next regular meeting and minute it.

5. Glossary

Exemption from review	A research study is said to be exempt from review when it does not require the Ethics Committee approval for its conduct

6. Annexure

Annexure 1: AX 01/SOP 7C/V2 – Review Exemption Application Form

Annexure 1: AX 01/SOP 7C/V2

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, ad 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 bases 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: _____

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 behavior(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 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 IHEC. This might be because of requirements of:

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

Official Use only

Recommendations by the IHEC Member Secretary/Additional Member Secretary:

□ Exemption

□Cannot be exempted, Reasons_____

□ Discussion at full board

Signature of the Member Secretary/Additional Member Secretary:
_____Date: _____

Final Decision:

□ Exemption

□ Cannot be exempted, Reasons _____

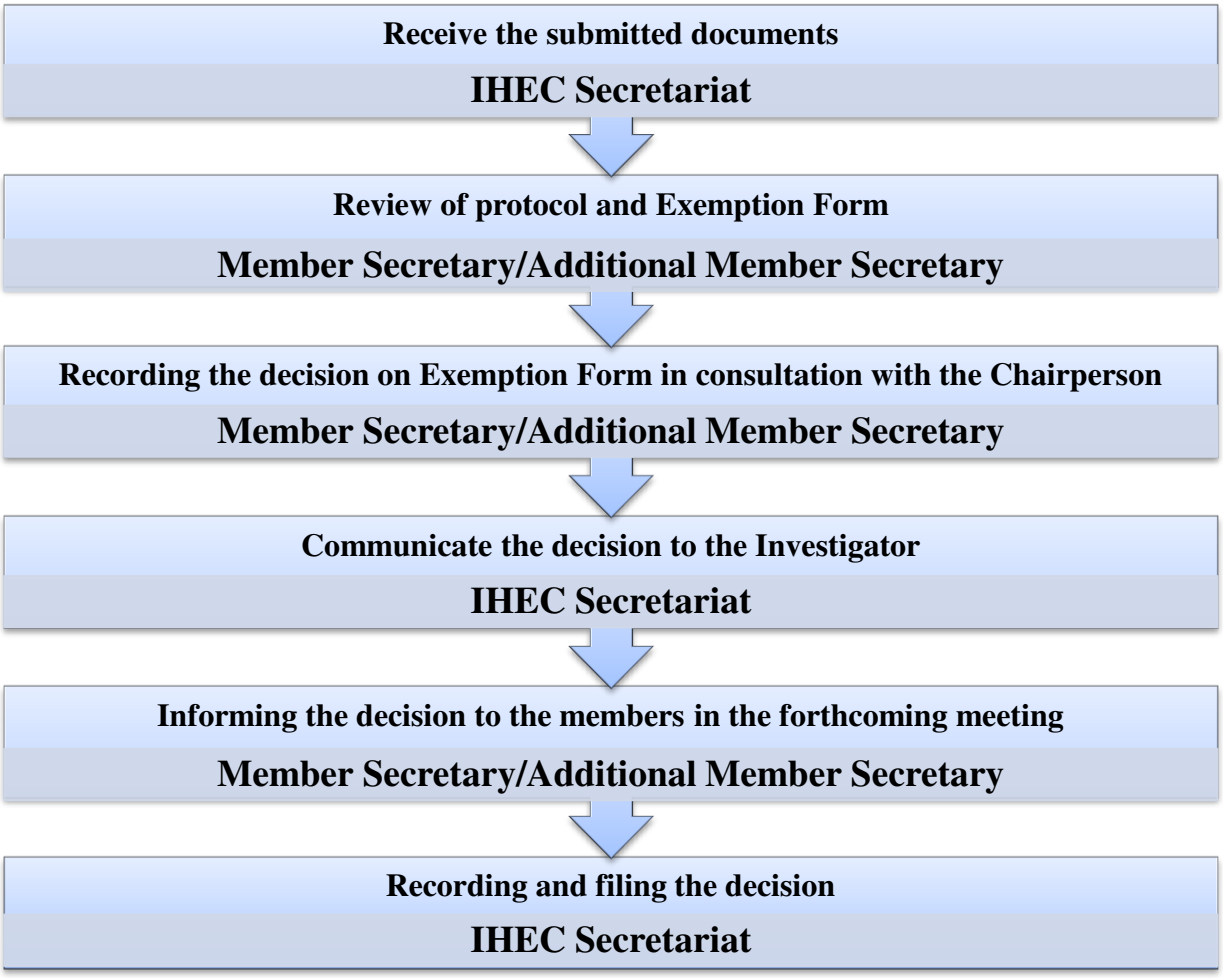
□ Discussion at full board

Signature of the Chairperson: _____Date: _____

Final Decision at Full Board meeting held on
_____
_____
_____

Signature of the Chairperson: _____Date: _____

7. Flow Chart



8. References

- *Forum for Ethics review Committees in India (FERCI). Standard Operating Procedures of Institutional Ethics Committee (cited 5th October 2019). Available from: http://www.ferci.org/sops/*
- *Indian Council of Medical Research (ICMR). National Ethical guidelines for biomedical and health research involving human participants, October 2017 (cited 6th October 2019) available from: http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf*