Title: Exemption from ethics review of research study protocols

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 in consultation with the Chairman (as per SOP 07/V3). Any protocol that carries less than minimal risk and fulfills criteria for exemption from review (SOP 07/V3) is covered in this SOP.

3. Responsibility

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

4. Detailed instructions

4.1 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

4.2 Determine protocols eligible for exemption from review

- The 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 EC. This might be because of requirements of the publisher of the research or the organization which is providing funding resources, data, access to participants etc.

4.3 Exemption Process

- If the protocol and related documents satisfy the above stated criteria, the Member Secretary in consultation with the Chairman 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 / Chairman 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 EC Chairman, 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 EC members of the decision at the next regular meeting and minute it.

5. **References to other applicable SOPs**

   SOP 07/V3: Categorization of Submitted Protocols for Ethics Review

   SOP 07-A/V3: Initial Full-Board Review of Research Study Protocols

6. **Annexure**

   Annexure 1 *AX 01/SOP 7C/V3*- Additional information to be provided with Application Form for Exemption from Review

Annexure 01/SOP/7C/V3

Additional information to be provided with Application Form for Exemption from Review

SMVMCH-EC Ref. No. (for office use) :

Title of study:

Principal Investigator (Name, Designation and Affiliation):

Choose reasons why exemption from ethics review is requested? *(Select the category that applies best to your study and justify why you feel it should be exempted from review. For a detailed understanding of the type of studies that are exempt from review, refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 51Table 4.2.)*

i. Research on data in the public domain/ systematic reviews or meta-analyses. ☐
ii. Observation of public behavior/ information recorded without linked identifiers and disclosure would not harm the interests of the observed person ☐
iii. Quality control and quality assurance audits in the institution ☐
iv. Comparison among instructional techniques, curricula, or classroom management methods ☐
v. Consumer acceptance studies related to taste and food quality ☐
vi. Public health programmes by government 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)
vii. Any other (please specify in 100 words)

Signature of PI with date:

Comments of EC Secretariat:

Signature of Member Secretary with date:

7. Flow Chart

No.	Activity	Responsibility
1	Receive the submitted documents.	EC Secretariat
2	Review of protocol and Exemption Form	Member Secretary
3	Recording the decision on Exemption Form in consultation with the Chairman	Member Secretary
4	Communicate the decision to the Investigator	EC Secretariat
5	Informing the decision to the members in the forthcoming meeting	Member Secretary
6	Recording and filing the decision	EC Secretariat

8. References

1. Forum for Ethics review Committees in India (FERCI). Standard Operating Procedures of Institutional Ethics Committee (cited 22nd October 2018). Available from: http:// www.ferci.org/sops/
2. Ethical guidelines for biomedical research on human participants. (2017). Indian Council of Medical Research. Available from: http://www.icmr.nic.in/guidelines/ ICMR_Ethical_ Guidelines_2017.pdf
3. Ministry of Health and Family Welfare. New Drugs and Clinical Trials Rules, 2019. Available from: https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf

	Name	Designation	Signature
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SOP 2C	MANAKULA VINAYAGAR	
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