

**Title: Exemption of protocols from ethical review**

**SOP Code: SOP07C/v1**

**Effective Date: 20/02/2025**

**Prepared by:**

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**Approved by:**

Dr. Haripriya S, Chairperson, YEC-3	Signature with date:
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**Notified by:**

Registrar, Yenepoya (Deemed to be University)	Signature with date:
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- Purpose:** The purpose of this SOP is to describe the method of exemption from ethical review of a research protocol submitted to the YEC-3 for ethical clearance.
- Scope:** The SOP applies to the initial review of all research protocols submitted to the YEC-3 for ethical clearance

- 2.1. Which are categorized by the Member-secretary under “exemption from review” as per the current guidelines and regulations and fulfil the criteria for ‘exemption from review’ as per SOP07v1.
- 2.2. Where the PI has requested for exemption from ethics review
3. **Responsibility:**
  - 3.1. **The Chairperson will:**
    - 3.1.1. Approve the letter of communication to the principal investigator stating that the protocol is exempted from ethical review.
  - 3.2. **The Member-Secretary will:**
    - 3.2.1. Review and categorize the protocol as “exemption from review” as per the current guidelines and regulations if it fulfils the criteria
  - 3.3. **The Secretariat will:**
    - 3.3.1. Record and file the decision of the Member-Secretary to include the protocol under the category of ‘exemption from review’ including the reasons stated.
    - 3.3.2. List the protocol in the ‘exemption from review’ category in the agenda of the next YEC-3 meeting for ratification
    - 3.3.3. File the decision form and the extract of the minutes of the meeting in the respective protocol file
4. **Detailed instructions:**
  - 4.1. **Receiving a request for “exemption from review” from the PI:**
    - 4.1.1. The Secretariat will receive the complete protocol submission from the principal investigator and the request for exemption from review from the principal investigator
    - 4.1.2. The Secretariat will check for the completion of protocol submission and the application form
    - 4.1.3. The Secretariat will forward the application and the protocol to the Member-Secretary within 3 days
  - 4.2. **Receiving a protocol for initial review which satisfies the criteria for categorization into ‘exemption from review’:**
    - 4.2.1. The member secretary will consider the protocol for exemption from review based on the criteria laid down in the ICMR’s National Ethical Guidelines for Biomedical and Health Research involving Human Participants 2017

- 4.2.2. After the protocol is categorized under the category of ‘exemption from review’ by the Member-Secretary, the Secretariat will record the decision in the file along with the reasons within 3 days

**4.3. Exemption process:**

- 4.3.1. The member secretary will read the protocol for risk assessment
- 4.3.2. If the protocol and related documents fulfil the criteria stated in the current guidelines and fulfil the criteria for inclusion in the ‘exemption from review category as described in SOP07v1, the Member Secretary takes a decision and informs the Chairperson.
- 4.3.3. The Member-Secretary records the decision on the Exemption Form (Ann02/SOP07/C/v1)
- 4.3.4. The Member-Secretary, based on the risk, decides to approve or disapprove the application for exemption from review within 3 days
- 4.3.5. The exemption approval is signed by the Chairperson/Member secretary with date.
- 4.3.6. The protocol is included in the next YEC-3 meeting agenda for ratification of the decision.

**4.4. Communication of the decision:**

- 4.4.1. The decision regarding request for Exemption from review, signed by the YEC-3 Chairperson/Member Secretary, will be issued by the Secretariat to the Principal Investigator within 5 calendar days after the decision regarding the exemption is taken.

**4.5. Post exemption communications by the PI:** It is the responsibility of the researcher to communicate with YEC-3

- 4.5.1. Any changes in the protocol
- 4.5.2. Submit a completion report and summary to YEC-3

**5. References:**

- 5.1. ICMR’s National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017
- 5.2. SOP07/v1: Categorization of Submitted Protocols for Ethics Review


**6. Annexures:**

- 6.1. Ann01/SOP7C/v1 - Application Form for Exemption of Research Protocols from Ethical review

- 6.2. Ann02/SOP 7C/v1 – Assessment and Decision Form for Exemption of Research Protocols from Ethical review
- 6.3. Ann03/SOP 7C/v1 – Certification for Exemption of Research Protocols from Ethical review

### Annexure 1: Ann01/SOP7C/v1

#### Application Form for Exemption of Research Protocols from Ethical review

 <div style="display: inline-block; text-align: center;"> <p><b>Application Form for Exemption from Review</b></p> <p><b>Yenepoya Ethics Committee-3 (YEC-3)</b></p> </div>	
EC Ref. No.	(For office use)
<p>Title of study: .....</p> <p>.....</p> <p>.....</p> <p>Principal Investigator (Name, Designation and Affiliation): .....</p> <p>.....</p> <p>.....</p>	
<p>1. Choose reasons why exemption from ethics review is requested<sup>1</sup>?</p> <p>i. Research on data in the public domain/ systematic reviews or meta-analyses/ any type of reviews <input type="checkbox"/></p> <p>ii. Observation of public behavior/ information recorded without linked identifiers and disclosure would not harm the interests of the observed person <input type="checkbox"/></p> <p>iii. Quality control and quality assurance audits in the institution <input type="checkbox"/></p> <p>iv. Comparison among instructional techniques, curricula, or classroom management methods <input type="checkbox"/></p> <p>v. Consumer acceptance studies related to taste and food quality <input type="checkbox"/></p> <p>vi. Public health programmes by government agencies<sup>2</sup> <input type="checkbox"/></p> <p>vii. Any other (please specify in 100 words): .....</p> <p>.....</p> <p>.....</p> <p>.....</p>	
Signature of PI: .....	<div style="border: 1px solid black; display: inline-block; padding: 2px 5px;">dd</div> <div style="border: 1px solid black; display: inline-block; padding: 2px 5px;">mm</div> <div style="border: 1px solid black; display: inline-block; padding: 2px 5px;">yy</div>
<p>Comments of EC Secretariat: .....</p> <p>(For office use)</p>	
Signature of Member Secretary: .....	<div style="border: 1px solid black; display: inline-block; padding: 2px 5px;">dd</div> <div style="border: 1px solid black; display: inline-block; padding: 2px 5px;">mm</div> <div style="border: 1px solid black; display: inline-block; padding: 2px 5px;">yy</div>
<p><small><sup>1</sup> 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 &amp; Health Research Involving Human Participants 2017, Page 51 Table 4.2.</small></p> <p><small><sup>2</sup> 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)</small></p>	

Version 1.0



	Discussion:
Recommendation at the YEC-3 Meeting	Exemption Cannot be exempted with reasons for no exemption:  Signature of the Chairperson with date

**Ann03/SOP 7C/v1**

**Certificate for Exemption of Research Protocols from Ethical review**

Protocol No:

Title:

Your protocol has been considered for exemption from ethical review and is valid from \_\_\_\_\_ to \_\_\_\_\_.

Any data collected before or beyond the validity period shall not be considered for the study.

It is the responsibility of the researcher to

- a.** Any changes in the protocol
- b.** Submit a completion report and summary to YEC-3

Signature of the Member Secretary

Date:

**7. Glossary:**

ICMR: Indian Council of Medical Research

PI: Principal Investigator

Protocol: Protocol refers to a set of documents that contain the detailed components of the proposed study

