


Title: Exemption of protocols from ethical review


SOP Code: SOP07C/v4

Effective Date: 01/07/2023

Prepared by:

Dr. Uma Kulkarni Convenor, YEC-1 SOP Subcommittee	Signature with date:  1/6/2023
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Reviewed by:

Dr. Viji Prasad Member, YEC-1 SOP Subcommittee	Signature with date:  01/06/2023
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Approved by:

Dr. Vikram Shetty, Chairperson, YEC-1	Signature with date:  6/6/23
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Notified by:

Registrar, Yenepoya (deemed to be University)	Signature with date:  7/6/23
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Details of superseded SOP7C

Subcommittee convenor name	Version	Effective date (dd-mm-yyyy)	Describe the main change(s)
Dr. Vina Vaswani	v1.4	10-08-2015	Major revision
Dr. Ravi Vaswani	v2	01-08-2016	Major revision following FERCAP assessment (2016)
Dr. Uma Kulkarni	v3	03-10-2019	Major revision following introduction of NDCTR-19, FERCAP and NABH assessment

Details of current SOP7C/v4

Subcommittee convenor name	Version	Effective date	Describe the main change(s)
Dr. Uma Kulkarni	v4	01-01-2023	1. Glossary section added in the SOP 2. Responsibilities of investigator post exemption specified

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1. **Purpose:** The purpose of this SOP is to describe the method of exemption from ethical review of a research protocol submitted to the YEC-1 for ethical clearance.
2. **Scope:** The SOP applies to the initial review of all research protocols submitted to the YEC-1 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 SOP07v4.
 - 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-1 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 2 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 2 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 SOP07v4, the Member Secretary takes a decision and informs the Chairperson.
- 4.3.3. The Member-Secretary records the decision on the Exemption Form (Ann02 SOP07Cv4)
- 4.3.4. The Member-Secretary, based on the risk, decides to approve or disapprove the application for exemption from review within 2 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-1 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-1 Chairperson/Member Secretary, will be issued by the Secretariat to the Principal Investigator within 2 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-1

- 4.5.1. Any changes in the protocol
- 4.5.2. Submit a completion report and summary to YEC-1

5. References:

- 5.1. ICMR's National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017
- 5.2. SOP07/v4: Categorization of Submitted Protocols for Ethics Review

6. Annexures:

- 6.1. Ann01/SOP7C/v4 - Application Form for Exemption of Research Protocols from Ethical review
- 6.2. Ann02/SOP 7C/v4 – Assessment and Decision Form for Exemption of Research Protocols from Ethical review
- 6.3. Ann03/SOP 7C/v4 – Certification for Exemption of Research Protocols from Ethical review

Annexure 1: Ann01/SOP7C/v4

Application Form for Exemption of Research Protocols from Ethical review

Part A: Investigator details

1	Name of the Principal investigator:	
2	Designation:	
3	Department:	
4	Affiliation/ Institution:	
5	Contact details: Phone: Email id:	
6	Title of the project:	
7	Name, designation, affiliation and contact details of all co-investigators	

Part B: Reasons for requesting for Exemption of the research protocol from ethical review (Please submit this along with the protocol)

		Yes/ No	Remarks by the PI
1	Research poses less than minimal risk		
2	No linked identifiers		
3	Research on data available in the public domain for systematic reviews or meta-analysis		
4	Observation of public behaviour when information is recorded without any linked identifiers and disclosure would not harm the		

	interests of the observed persons		
5	Quality control and quality assurance audits in the institution		
6	Comparison of instructional techniques, curricula or classroom management methods		
7	Consumer acceptance studies related to taste and food quality		
8	Public health programme or monitoring without any individual identifiers		
9	Any other (Please describe)		

Ann02/SOP 7C/v4

Assessment and Decision Form for Exemption from Ethical review

Part A:	Assessment form
Protocol No:	
Title of the project:	
Name of the Principal investigator:	
Designation:	
Department:	
Affiliation/ Institution:	
Date of submission to YEC-1	
A brief summary of the protocol	
Assessment of risk	Less than minimal risk Minimal risk More than minimal risk
Part B	Provisional decision form

Recommendation of the YEC-1 Member secretary	Exemption Cannot be exempted with reasons for no exemption: Signature of the Member secretary with date
Part C:	Final decision form
Discussion at the YEC-1 Meeting	YEC-1 Meeting number Date: Discussion:
Recommendation at the YEC-1 Meeting	Exemption Cannot be exempted with reasons for no exemption: Signature of the Chairperson with date

Ann03/SOP 7C/v4

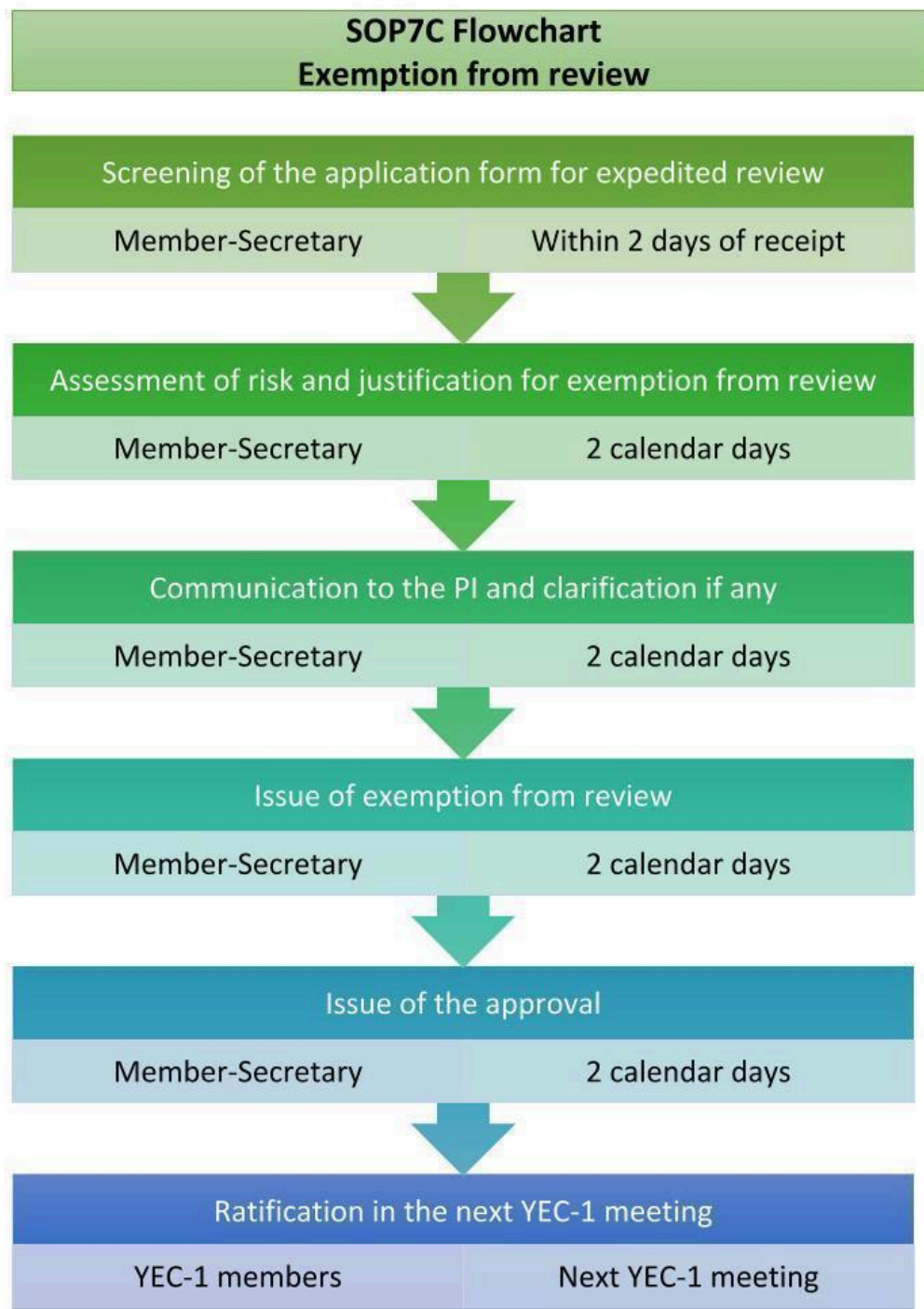
Certificate for Exemption of Research Protocols from Ethical review

<p>Protocol No:</p> <p>Title:</p> <p>Your protocol has been considered for exemption from ethical review and is valid from _____ to _____.</p> <p>Any data collected before or beyond the validity period shall not be considered for the study.</p> <p>It is the responsibility of the researcher to</p> <ul style="list-style-type: none"> a. Any changes in the protocol b. Submit a completion report and summary to YEC-1
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Signature of the Member Secretary

Date:

7. Flowchart:



8. 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