


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

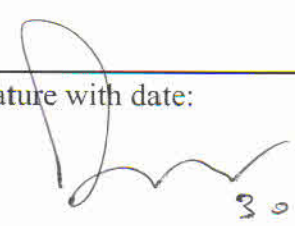
**SOP Code: SOP07C/v3**

**Effective Date: 03/10/2019**

**Prepared by:**

Dr. Uma Kulkarni Convenor, YEC-1 SOP Subcommittee	Signature with date:  31/10/2019
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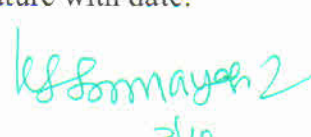
**Reviewed by:**

Dr. Ravi Vaswani Member, YEC-1 SOP Subcommittee	Signature with date:  3 OCT 19
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**Approved by:**

Dr. Vikram Shetty, Chairperson, YEC-1	Signature with date:  3/10/19
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**Notified by:**

Registrar, Yenepoya deemed to be University	Signature with date:  3/10
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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” are as per the current guidelines and regulations and fulfils the criteria for ‘exemption from review ‘as per *SOP07v3*.
  - 2.2. Which the PI has requested for exemption from Ethical 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 the protocol categorized as “exemption from review” or assign reviewers
  - 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

**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
- 4.2.2. After the protocols are classified under the category of ‘exemption from review’ by the Member-Secretary, the Secretariat will record the decision in the file along with the reasons

**4.3. Exemption process:**

- 4.3.1. The member secretary read the protocol for the risk
- 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 SOP07v3, the Member Secretary takes a decision and informs the Chairperson.
- 4.3.3. The Member-Secretary records the decision on the Exemption Form (Ann02 SOP07Cv3)
- 4.3.4. The Member-Secretary assesses the risk and decides to approve or disapprove the application for exemption from review.
- 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 14 calendar days after the decision regarding the exemption is taken.

**5. References to other SOPs:**

- 5.1. SOP07/v3: Categorization of Submitted Protocols for Ethics Review

**6. Annexures:**

- 6.1. Ann01/SOP7C/v3 - Application Form for Exemption of Research Protocols from Ethical review

- 6.2. Ann02/SOP 7C/v3 – Assessment and Decision Form for Exemption of Research Protocols from Ethical review
- 6.3. Ann03/SOP 7C/v3 – Certification for Exemption of Research Protocols from Ethical review

**Annexure 1: Ann01/SOP7C/v3**

**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: <b>Phone:</b> <b>Email id:</b>	
6	Title of the project:	
7	Name, designation, affiliation and contact details of all co-investigators	

**Part B: Project summary**

**Brief description of the project:** Please give a brief summary of the nature of the proposal under the following headings

1	Introduction	
2	Rationale/ Need for the study	
3	Hypothesis/ Research question	
4	Aims/ Objectives	
5	Participant/ sample description	
6	Study site (s)	
7	Study duration and timeline	

8	Methodology in brief	
9	Describe the method of anonymization of samples/participants	
10	Analysis and statistical methods	
11	Expected outcomes	
12	Funding details	
13	Conflict of interest	
14	Permission letters for obtaining samples/ data/participants	
15	Maintenance of privacy and confidentiality	

**Part C:**

**Reasons for requesting for Exemption of the research protocol from ethical review:**

		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		
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**Part D. Declaration**

	Name and designation of all the investigators/ co-investigators/ guides/ co-guides	Signature	Date and place
<b>1</b>			
<b>2</b>			
<b>3</b>			
<b>4</b>			
<b>5</b>			

**Ann02/SOP 7C/v3**

**Assessment and Decision Form for Exemption from Ethical review**

<b>Part A:</b>	<b>Assessment form</b>
<b>Protocol No:</b>	
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 and risk assessment	
Assessment of risk	<b>Less than minimal risk</b> <b>Minimal risk</b> <b>More than minimal risk</b>
<b>Part B</b>	<b>Provisional decision form</b>
Recommendation of the YEC-1 Member secretary	Exemption Cannot be exempted with reasons for no exemption:  Signature of the Member secretary with date
<b>Part C:</b>	<b>Final decision form</b>
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
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**Ann03/SOP 7C/v3**

**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 adhere to the current regulatory guidelines and to the protocol version submitted to YEC-1.

It is the responsibility of the researcher to report to YEC-1 any deviation from the guidelines/ protocol without delay

It is the responsibility of the researcher to report to YEC-1 any adverse event/ change in risk to participants that may occur during the study without delay

It is the responsibility of the researcher to send a continuing review report at the end of the validity period and seek an extension of validity for the study, if the study is not completed.

It is the responsibility of the researcher to submit a completion report to YEC-1 when the data collection is completed.

It is the responsibility of the researcher to submit a summary of the study when the data analysis is completed.

It is the responsibility of the researcher to maintain the privacy of the participants/ samples and confidentiality of data.

It is the responsibility of the researcher to respond to any communication from YEC-1 pertaining to the study/ auditing/ site monitoring/ others.

Signature of the Member Secretary

Date:

6. Flowchart:

