



Exemption from Ethics Review
YEC2/SOP07C/v2
Effective Date: 25.02.2023

Title: Exemption from Ethics Review

SOP Code: YEC2/SOP07C/v2

Prepared by:

Dr. K. Leena Pramod Convenor, YEC2 SOP committee	Signature with date <i>Leena</i>
---	-------------------------------------

Reviewed by:

Dr. Rashmi Jain Member, YEC2 SOP committee	Signature with Date <i>Rashmi</i> 25.02.2023
---	--

Approved by:

Dr. Prasanna Keshava B Chairperson, YEC2	Signature with Date <i>Prasanna Keshava B</i>
---	--

Notified by:

Registrar, Yenepoya (Deemed to be university) Notification No: Ref: No/YU/REG/ACA/YEC-2/SOP/2023 Date: 25.02.2023	Signature with Date <i>K. S. Somayaj</i> 29/02/23 Registrar Yenepoya (Deemed to be University) University Road, Deralakatte Mangalore - 575 018
--	---



Exemption from Ethics Review
YEC2/SOP07C/v2
Effective Date: 25.02.2023

Details of superseded SOP 7C/v1

Subcommittee Convenor name	Version no	Effective date (dd/mm/yy)	Describe the main changes
Dr. H.Hari Kishore Bhat	V1	14.06.2018	Major revision in the SOP

Details of Current SOP 7C/v2

SOP subcommittee convenor name	Version no	Effective date (dd-mm-yyyy)	Describe the main changes
Dr. Prasanna Keshava B	V2	25.02.2023	Major revision in the SOP

YEC2/SOP07C/v2



Exemption from Ethics Review
YEC2/SOP07C/v2
Effective Date: 25.02.2023

Table of Content:

No	Contents	Page No.
1	Purpose	3
2	Scope	3
3	Responsibility	3
4	Detailed instructions	4
5	References to other SOPs	5
6	Annexures	5
7	Flowchart	9



Exemption from Ethics Review
YEC2/SOP07C/v2
Effective Date: 25.02.2023

1. Purpose

The purpose of this SOPs to describe in detail the method of exemption from ethics review of a research protocol submitted to the YEC 2 for ethical clearance.

2. Scope:

The SOP applies to the initial review of all research protocols submitted to the YEC 2 for ethical clearance

- Categorized by the Member Secretary under “exemption from review” as per the ICMR Ethical guidelines for research on human participants and fulfils the criteria for „exemption from review „as per SOP 07/v2 version
- Where the PI has requested for exemption from ethics review

3. Responsibility:

• **The Chairperson will:**

Approve the letter of communication to the principal investigator stating that the protocol is exempted from ethical review

The Member Secretary

The Member Secretary will do an initial screening of the protocol

The Member Secretary will categorise the protocols into „exemption from review“ as per the ICMR ethical guidelines for research on human participants based on the initial screening and in consultation with the Chairperson.

The Member Secretary will record the reasons for include the protocol under the category of „exemption from review“.

The secretariat will list the protocol in the „exemption from review“ category in the agenda of the next YEC 2 meeting.

The Secretariat will :

It is the responsibility of the secretariat for recording and filing of the decision of the Member Secretary and the chairperson to include the protocol under the category of „exemption from review“ including the reasons stated.

List the protocol in the „exemption from review“ category in the agenda of the next YEC2 meeting for ratification



Exemption from Ethics Review
YEC2/SOP07C/v2
Effective Date: 25.02.2023

File the decision form and the extract of the minutes of the meeting in the respective protocol file

4. Detailed instructions:

Receiving the submission of protocol

Once the secretariat receives the complete protocol submission from the PI, the secretariat will check for the completion of protocol

The secretariat will also file any request for exemption from review from the PI

4.1.3. The Secretariat will forward the application and the protocol to the Member-Secretary within 2 days

Categorization of protocol into 'exemption from review':

The Member Secretary will consider the protocol for exemption from review based on the criteria laid down in the ICMR ethical guidelines for research on human participants, when the protocol involves less than minimal risk

After the protocols are classified under the category of „exemption from review“ by the Member-Secretary in consultation with the chairperson, the secretariat records the decision in the file along with the reasons

Exemption process:

The member secretary will read the protocol for risk assessment

The Member Secretary in consultation with the chairperson goes through the project summary and the exemption request.

If the protocol and related documents satisfy the criteria stated in the ICMR ethical guidelines for research on human participants and fulfil the criteria for inclusion in the „exemption from review category as described in YEC2/SOP 7, the Member Secretary in consultation with the Chairperson, takes a decision.

The Member Secretary records the decision on the Exemption Form (form reference)

4.3.5 The exemption approval is signed by the Chairperson/ Member Secretary with date.



Exemption from Ethics Review
YEC2/SOP07C/v2
Effective Date: 25.02.2023

4.3.6. The protocol is included in the next YEC 2 meeting agenda for ratification of the decision.

4.4. Communication of the decision:

4.4. The decision regarding request for Exemption from review, signed by the YEC 2 Chairperson, will be forwarded by the Secretariat to the PI within 02 working days after the decision regarding the exemption is taken.

5. References to other SOPs:

YEC2/SOP07c/v2: Application Form for Exemption of Research Protocols from Ethical review

YEC2/SOP07/v2: Categorization of Submitted Protocols for Ethics Review

YEC2/SOP07A/v2: Initial Full-Board Review of Research Study Protocols

6. Annexures:

6.1. YEC2/Ann01/v2: Application Form for Exemption of Research Protocols from Ethical review

YEC2/Ann02/SOP7C/v2 - Review Exemption Application Form and Decision form for review exemption

YEC2/Ann03/SOP 7C/v2 - Certification for Exemption of Research Protocols from Ethical review



Exemption from Ethics Review
YEC2/SOP07C/v2
Effective Date: 25.02.2023

YEC2/Ann01/v2:

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 behavior 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		



Exemption from Ethics Review
YEC2/SOP07C/v2
Effective Date: 25.02.2023

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)		



Exemption from Ethics Review
YEC2/SOP07C/v2
Effective Date: 25.02.2023

YEC2/Ann02/SOP7C/v2

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 YEC2	
A brief summary of the protocol	
Assessment of risk	Less than minimal risk Minimal risk More than minimal risk
Part B	Provisional decision form



YENEPOYA
[DEEMED TO BE UNIVERSITY]
Recognized under Sec 3(A) of the UGC Act 1956
NAAC Accredited A+ with CGPA3.47

YENEPOYA ETHICS COMMITTEE 2
DCGI Registration No.: ECR/1337/Inst/KA/2020
DHR registration No.: EC/NEW/INST/2020/1216

Exemption from Ethics Review

YEC2/SOP07C/v2

Effective Date: 25.02.2023

YEC2/Ann03/SOP 7C/v2

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. responsibility of the researcher to

- a. Any changes in the protocol
- b. Submit a completion report and summary to YEC2

Signature of the Member Secretary

Date:



Exemption from Ethics Review

YEC2/SOP07C/v2

Effective Date: 25.02.2023

7. Flow chart:

