Title: Expedited Review of Research Study Protocols

SOP Code: YEC2/SOP07B/v2

Prepared by:

Dr. Rashmi Jain Member, YEC2 SOP committee	Signature with date 25/02/2023

Reviewed by:

Dr. K. Leena Pramod Convenor, YEC2 SOP committee	Signature with Date

Approved by:

Dr. Prasanna Keshava B Chairperson , YEC2	Signature with Date Pra Keshava B 25/02/2023

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 24/04/23 Registrar Yenepoya (Deemed to be University) University Road, Deralakatte Mangalore - 575 018

YEC2/SOP07B/v2 Page 1

Details of superseded SOP 07B/v1

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

Details of Current SOP 07B/v2

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

Table of Content:

1. Purpose

The purpose of this SOP is to describe in detail the method of "expedited review" of a research protocol submitted to the YEC2 for ethical clearance.

2. Scope

- The SOP applies to the initial review of all research protocols submitted to the YEC 2for ethical clearance categorized by the Member-Secretary under" expedited review" as per the ICMR Ethical guidelines for research on human participants here the protocol carries not more than minimal risk to the participants and fulfils the criteria for expedited review as per YEC2/SOP07/v2 .

- The proposals that pose "no more than minimal risk" are considered for expedited review. Expedited review will be conducted by chairperson, member secretary and 1-2 designated members. The approval granted through expedited review will be ratified at the next full committee meeting.

3. Responsibility

The YEC2 Chairperson will

- Oversee the timely review submissions
- Ensure that each member reviews the protocol from his/her role in the YEC2, as has been defined in the terms of reference

The YEC2 Member-Secretary will

- The Member-Secretary will do an initial screening of the protocol
- The Member-Secretary/Joint Secretary will assign one or two reviewers for each study protocol.
- The Member-Secretary/Joint Secretary will communicate the name(s) of the reviewers to the YEC 2 Secretariat.
- If any of the YEC 2 members assigned to review the protocol declares a conflict of interest or declares inability to complete the assessment of the protocol within one week, he/she will communicate the same to the YEC 2 Secretariat within 2 days of receipt of the document package

- Reassign the reviewers if any of the reviewers either declare a conflict of interest or declare inability to review the protocol on time, or fail to review the protocol in the Assigned time
- Include the approved expedited review protocols in the agenda of the YEC2meeting as per SOP08/v2 for ratification

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The YEC2 Secretariat will

- YEC 2 Secretariat will create a folder for each research protocol as soon as the completed protocol submission is received.
- YEC 2 Secretariat will distribute the complete protocol submission to the reviewers assigned by the Member-Secretary via the email id of YEC 2, **yec2@yenepoya.edu.in** or as a hard copy, as per the preference declared by the YEC 2 members
- YEC 2 Secretariat will distribute the assessment form along with the protocol to each reviewer, with a covering letter (YEC2/Ann01/SOP7B/v2).
- YEC 2 Secretariat will list the protocol in the „expedited review for ratification" in the agenda for the next YEC 2 meeting after issue of ethics committee approval.
- YEC 2 Secretariat will inform the Member-Secretary of any communication from the assigned reviewer regarding the completed assessment form, inability to complete the review process in one week or issues of conflict of interest as communicated by the members.
- If the reviewer does not return the assessment form within one week, the Secretariat will send a reminder to the reviewer by mail/telephonic call.
- The Secretariat will record and file the assessment form and the decisions of the reviewers in the protocol file.
- The Secretariat will communicate the observations of the reviewers after masking the name of the reviewer to the PI through an email with a request to respond within a 15 days

The YEC2 Members will:

- The YEC 2 member identified to do the „expedited review" will declare any conflict of interest with the protocol received for initial review, within 2 working days after receiving the protocol for review.
- If the YEC 2 member foresees an inability to complete the initial review process within one week, he/she will declare it within 2 days of receiving the protocol for review.
- The YEC 2 members assigned to review a protocol will do it as per the assessment form (YEC2/Ann02/SOP7B/v1).
- The YEC 2 members will record their observations and comments in detail on the assessment forms.
- The YEC 2 members after reviewing the protocol will declare their endorsement on the assessment form as
  - Approved
  - Approved with modifications
  - Minor in nature
  - Resubmission
- The YEC 2 member after reviewing the protocol will sign and date the assessment form.
- The YEC 2 member will return the completed assessment form as soft copy by email to **yec2@yenepoya.edu** or as hard copy to the secretariat, as the case may be.
- The YEC 2 member will complete the review process within the time frame of 15days from receiving the protocol for review.
- After reviewing, if the reviewer feels that the protocol categorized under „expedited review" by the Member-Secretary should be considered for „full review", the members have the freedom to communicate the same to the Member-Secretary entering the same suggestion in the assessment form.
- Request Member-Secretary to assign an independent consultant (wherever deemed necessary)

4. Detailed Instructions:

. Procedure for appointment of reviewers:

- The Member-Secretary is responsible for assigning one or two primary reviewers for each protocol categorised as requiring „expedited review".

- If selecting 2 reviewers, the Member-Secretary will preferably include one clinician and one non-clinician for reviewing each protocol

- The Member-Secretary will assign the reviewers based on each study topic, the expertise of the members in reviewing such studies and relation to the field of study.
  a. Informed consent and the translation thereof by the layperson

  b. MOUs, agreements, Insurance documents, indemnities, etc by the legal expert

  c. Adverse events reported in the periodic review by the clinician

  d. Social, religious, cultural issues by the social scientist/theologist

  e. If necessary, the Member-Secretary will assign additional reviewers, depending on the merit and complexity of each protocol.

- The Member-Secretary can also additionally assign the protocol for review by an independent consultant. Even reviewing members can suggest this if necessary. The decision of the Member-Secretary is final.

- The Member-Secretary will communicate the names of the reviewers to the secretariat within two working days of protocol submission

Re appointment of reviewers:

- The reviewers will inform YEC-2 of their inability to review the protocol in the given timeframe as follows:

a. Conflict of interest (within 2 calendar days)
b. Inability to review within the given timeframe (2 calendar days)
c. Secretariat will inform the Member-Secretary of any communication from the reviewers about inability to review the protocol.

- The Member-Secretary will reassign the reviewers in case of any of the following situations:
  - The assigned reviewers communicate their inability to complete the review process in the given timeframe
  - The assigned reviewers declare a CoI for the protocol
  - The initially assigned reviewer fails to review the protocol in the given time, despite reminders.

5. Distribution of protocols for review:

- The YEC 2 Secretariat will record the names of the reviewers, as recommended by the Member-Secretary for each protocol in the assessment forms.
- The YEC 2 Secretariat will send the duly completed request letter to the reviewer with details of the protocol and the date by which the review has to be completed.
- The secretariat will send the complete submission to the reviewers along with the assessment forms.
- If the reviewers have opted for soft copies of the protocols, they will be emailed to them at their official email id from the official email id of YEC 2 **yec2@yenepoya.edu.in**
- If the reviewers have opted for hard copies of the protocols, then they will be reviewed by the reviewers in the YEC 2 safe room or in the office of the reviewer.
- The following documents will be sent to the reviewer:
  - The request letter for reviewing the protocol
  - The protocol submission form and related documents
  - The assessment form
  - Conflict of interest form

6. Receiving the complete protocol submission for review

- The reviewer will receive the complete protocol submission and verify the contents.

- The reviewer will notify the YEC 2 Secretariat, immediately, if any of the documents are found missing.
- The reviewer will inform the YEC 2 Secretariat if he/she has a conflict of interest within 2 days of receiving the protocol.
- The reviewer will inform the secretariat within 2 days if he/she is unable to complete the assignment of reviewing the protocol within 15 calendar days of receiving the protocol.

6. Review process

The reviewers will review the protocols within the stipulated time of 15 days and as per the current ethical guidelines and regulations

The YEC2 members will review the protocol and specifically address issues related to the protocol based on their designation/role in the YEC-2

- Scientific members: Scientific and ethical issues
- Social scientist/theologist/bioethicist: social/religious and ethical issues
- Legal person: Legal documents and ethical issues
- Layperson: Informed consent documents and ethical issues

Each reviewer will review the protocol and make comments/suggestions and recommendations in the assessment form

7. Reviewing of the informed consent (YEC2/Ann06/SOP7A/v1 and YEC2/Ann2A/SOP7B/v1)

- Content and language of the participant information sheet including clarity of methodology and the risks and benefits associated
- Statement of voluntariness
- Statement of choice of Refusal or withdrawal from study
- Statement of comprehension of the information and clarification of doubts from the PI
- Procedure of informed consent process
- Translation of the informed consent and participant information sheet
- Contact persons and their phone numbers
- Statement of maintaining privacy
- Statement ensuring confidentiality

- Compensation for participation, whether there is a chance of undue inducement
- Provision of medical and psychosocial support
- Medical management of study related injuries, if any
- Compensation of study related injuries, if any
- Use of biological material, its use, its storage and possibility of future use
- Possibility of deriving sensitive information from the biological samples, if any and the possible harm
- Provision of signatures of participants, investigator or the person conducting the informed consent process, the witness with dates

8. Reviewing of the protocol:

- The reviewer will consider the following criteria while reviewing the protocol and the submitted documents (YEC2/Ann06/SOP7A/v1 and YEC2/Ann2A/SOP7B/v1):
  - Potential risks and harm to participants
  - Potential benefits
  - Selection of participants and method of recruitment especially for studies involving vulnerable population
  - Inducements, financial benefits and compensation
  - Protection of privacy of the participants and their data
  - Methods of ensuring confidentiality
  - Community considerations
  - Qualification of the investigators and adequacy of site facilities
  - Disclosure of conflicts of interest

9. Communication with the Principal Investigator:

In case of approved protocols:

- The approval letter is issued as per the format Ann05/SOP7A/v4
- Approval letter is issued within 7 calendar days of YEC2 meeting

In case of resubmission of protocols:

- . Member-Secretary will compile the suggestions, clarifications and recommendations of reviewers and communicate with the PI.
- The resubmission is managed as per SOP9A/v4.
- The letter asking for resubmission is sent to the PI as per the format in Ann01/9A/v4. The communication is sent within 7 calendar days of the decision
- The Member-Secretary will inform the PI to respond to resubmit the protocol within 180 calendar days, failing which the protocol will be considered as cancelled.
- If the PI resubmits after 180 calendar days, then the PI is requested to submit a fresh protocol

10. Approval letter:

- The approval letter is drafted as per the template Ann05/SOP7A/v4
- The Member-Secretary will sign the approval letter within 7 calendar days of approval decision
- The Secretariat will inform the principal investigator by email within 2 calendar days of signing of the approval letter
- The principal investigator is requested to collect the approval letter within 07 calendar days from the date of information.
- The principal investigator is requested to read the approval letter in detail, clarify doubts, look for typo errors or factual errors in the approval letter at the time of receiving the approval letter
- The Secretariat will keep a scanned copy of the Approval letter ready on which the principal investigator will sign stating “Read and Received”
- The signed copy with the acknowledgement of receipt is filed in the respective protocol filled

➢ The approval letter, printed on the approved letterhead, will contain the following matter:

- Study reference number
- Study title
- A list of the versions of the protocol documents approved

- Validity of the approval
- Sample size approved
- Summary of the guidance, advice and decision that the YEC2 members have reached in the meeting.
- Need for submission of periodic review, continuing review and closure of the study and the timelines.
- A box highlighting the important dates (for the researcher)
- Signature of the YEC member secretary with date

11. Storage of documents:

- The Secretariat will maintain all documents related to the protocol review (assessment forms by both reviewers, statements of the subject expert, decision form, and copy of the approval letter/resubmission request and all other communications in the study file in a sequential manner.
- The Secretariat will store the file on an appropriate shelf in the designated cabinet

12. References:

- SOP 06/v2: Management of Research Study Protocol and Study Related documents Submitted for Ethics Review
- SOP 07/v2: Categorization of Submitted Protocols for Ethics Review
- SOP 08/v2: Agenda Preparation, Meeting Procedures and Recording of Minutes
- 5SOP 9A/v2: Review of Resubmissions of protocols
- ICMR"s National Ethical Guidelines 2017

13. Annexures:

- Ann01/SOP7B/v2 : Decision form for expedited review (For reviewer)
- Ann02/SOP7B/v2: Format of study approval letter

Ann01/SOP7B/v2 :
Decision form for expedited review (For reviewer)

(Annexure YEC2/Ann2A/SOP7B/v2)

Reviewer Assessment form

PART A: Protocol information

*1. **YEC2 Protocol No***	
*2. **Title***	
*3. **Date of receipt protocol***	
*4. **Reviewer name***	
5. Conflict of interest of reviewer (Yes/No) ***If yes comment***	

PART B: Project details

(Please comment if the following details have been mentioned by the investigator in the submitted protocol and give remarks wherever necessary)

6. Project details	*YES*	*NO*	*Remarks*
a. Executive summary			
b. Introduction			
c. Need for the study			
d. Research question/alternate and null hypothesis			
e. Aim			
f. Objectives			
g. Review of literature			
7. Methodology			
a. Study design			
b. Study site			

c. Funding details				
d. Study duration				
8. Participant details				
a. Source of data				
b. Sample size with statisticians' approval letter				
c. Method of sampling				
d. Randomization				
e. Inclusion criteria				
f. Exclusion criteria				
g. Withdrawal criteria				
h. Discontinuation criteria				
9. Study tool				
a. Study tool described with relevant references				
b. Proforma /annexure included as an annexure				
c. Validation				
d. Pretesting				
10. Methods				
a. Details of methodology				
b. Details of analysis				
11. Timeline/ Work plan				
a. Has a timeline been provided				
b. Gantt chart present				
c. Appropriate headings in Gantt chart/work				
12. Budget				
a. Has a budget been provided				
b. Has the split of the budget been mentioned				
13. Ethical issues				
a. How ethical guidelines followed				
b. How ethical approval will be obtained				
c. How informed consent will be obtained				

d. Vulnerable population with justification			
e. Standard of care			
f. Harms			
g. Benefits			
h. Risk-benefit ratio mentioned as favourable or not			
i. Privacy			
j. Confidentiality			
k. Requisite permissions/approval			
l. Biosafety issues			
m. Utilization of results			
n. References in Vancouver format			
14. Participant information sheet			
a. Participant information sheet written in simple language without the use of jargon, such that a student of standard VIII would be able to understand			
b. Adequate information provided about			
c. The title of the study			
d. PI details with email and phone number			
e. The purpose of the study			
f. Duration of the study			
g. Why they are being selected			
h. Voluntary nature of the enrolment			
i. Participants' responsibilities and expected cooperation			
j. Details of the intervention			
k. The likely benefits to the participant			
l. Compensation for time lost			
m. Risks, harms and compensations			

n. Protection of privacy of the participant			
o. Confidentiality of the data			
p. Anonymity of the data when shared			
q. Invitation to seek clarification after			
r. Adequate time provided			
s. Details of the person who will clarify			
t. Details about future use of samples or data			
u. Participant Information Sheet on a separate sheet (Local language- Kannada, Malayalam)			
15. Informed consent			
a. Is the language simple such that an 8th-standard student (English or vernacular) will find it easy to understand			
b. Whether contact person details are provided in the ICF			
c. Whether the PG/PI has assured the privacy of participants & confidentiality			
d. Is the language simple such that an 8th-standard student (English or vernacular) will find it easy to understand			
e. Whether contact person details are provided in the ICF			
f. Whether the PG/PI has assured the privacy of participants & confidentiality			
g. Has the PG/PI mentioned compensation for time taken to participate			
h. Has the PG/PI mentioned how study-related injuries will be managed			
i. Has the PG/PI mentioned how such study-related injuries will be Compensated			

j. In case a participant is illiterate, has the PG/PI made provision for an independent witness to countersign			
k. Has the PG/PI taken consent for publication			
l. Has the PG/PI made specific mention of whether data will be shared and how			
m. Informed consent documents in Regional languages			
16. Conflict of Interest			
Is there a conflict of interest? If yes, does the protocol spell out how it will be mitigated?			

Part C: Reviewers provisional comments

17. Please assess the risk that the participant is being subjected to if they are recruited in the study, as per the ICMR guidelines:			
a. The risk involved is:	***Yes***	***No***	***Remarks***
i. Less than minimal			
ii. Minimal			
iii. More than minimal			
b. Is the overall risk-benefit ratio acceptable?			

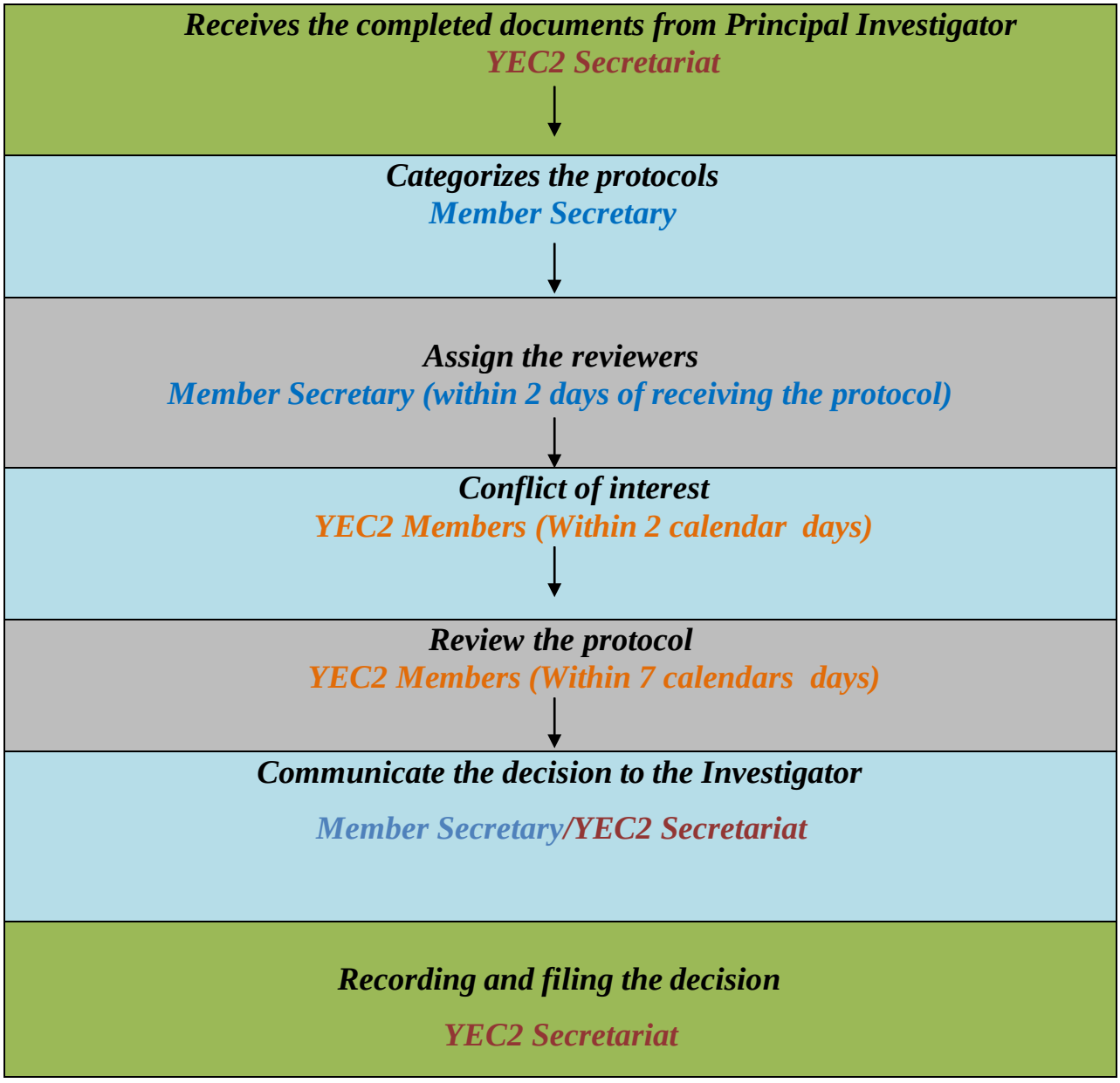
18. Comments of the reviewer
1.
2.
3.
4.
5.
(Add additional rows, if required)

***19. Provisional Decision**:*	*Yes*	*No*	*Remarks*
a. Approved			
b. Approved with modification			
If modification suggested			

c. Minor			
d. Resubmission			
e. Full Review			
f. Disapproved			

Signature and Date (Mandatory):

7. Flow chart:


Receives the completed documents from Principal Investigator
YEC2 Secretariat
Categorizes the protocols
Member Secretary
Assign the reviewers
Member Secretary (within 2 days of receiving the protocol)
Conflict of interest
YEC2 Members (Within 2 calendar days)
Review the protocol
YEC2 Members (Within 7 calendars days)
Communicate the decision to the Investigator
Member Secretary/YEC2 Secretariat
Recording and filing the decision
YEC2 Secretariat