



Title: Resubmissions Amendments

SOP Code: YEC2/SOP09/v2

Prepared by:

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

Dr. Sridevi K Member, YEC2 SOP committee	Signature with Date <i>Sridevi</i> 25/04/2023
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Approved by:

Dr. Prasanna Keshava B Chairperson, YEC2	Signature with Date <i>Prasanna Keshava B</i> 28/02/2023
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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>Bhoomayon</i> 29/04/23 Registrar Yenepoya (Deemed to be University) University Road, Deralakatte Mangalore - 575 014
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Details of superseded SOP 9A

Subcommittee Convenor name	Version no	Effective date (dd-mm-yyyy)	Describe the main changes
Dr.H.Hari Kishore Bhat	v1	14.06.2018	Major revision in the SOP

Details of Current SOP 9A/v2

SOP subcommittee convenor name	Version 02	Effective date (dd-mm-yyyy)	Describe the main changes
Dr. K. Leena Pramod	v2	25.02.2023	1. Modify in the Responsibility 2. Modification in the details instructions 3. Added annexures

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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how the YEC 2 manages the review of resubmitted & amended study protocols.

2. Scope

- This SOP applies to the review of Study protocols and related documents that have been resubmitted to the YEC 2 by the Principal Investigator (PI) with clarifications and modifications sought by the YEC 2 in the initial review.
- This SOP also applies to the review of amendments to study protocols and related documents that have been approved earlier by the YEC 2.

3. Responsibilities

3.1. Role of the Chairperson, YEC 2

It is the responsibility of the Chairperson, YEC 2 to

- Ensure that the resubmissions and amended protocol are reviewed in a timely manner

3.2. The Member-Secretary will:

- Categorize the resubmissions as per the decision of the initial review
- Assign the reviewers as per the decision of the initial review
- Include all “resubmissions for full review” in the agenda of the subsequent YEC2 meetings
- Categorize the amended protocol as per the criteria laid down for initial review, based on the change in risk for participants
- Communicate the decision of YEC2 to PI within 7 calendar days

3.3. YEC2 Members will:

- Review the resubmissions when assigned, fill the assessment form, and provide the provisional decision as per the form
- Review the protocols and assess whether the amendments are acceptable with respect to the risk-benefit analysis

3.4. YEC2 Secretariat will:

- Receive the amended protocol and check for completeness of the protocol, amendment related documents and the protocol amendment form
- Check for protocol amendment sitting fee payment (in the case of sponsored, regulatory clinical trials or funded studies)
- Check the completeness of the resubmitted documents
- Send the relevant documents to the initial reviewers (or Member-Secretary)

4. Definitions

4.1. Resubmission: Resubmission of protocol refers to the protocol and/or the protocol related documents which are submitted to YEC2 in response to clarification sought by the YEC2 or to the recommendation made by YEC2 following the review of

- 4.1.1. Initial review
- Review of resubmission

4.2. Amendment: Any proposed change in the previously approved protocol which may include partial or complete, addition, deletion or modification in any one or more components of protocol including the title, research team, delegation log, study site, objectives, study design, methodology, intervention, sampling, sample size, inclusion-exclusion criteria, informed consent process, agreements, funding, or any other related document/procedure is referred to as an amendment (before the changes are implemented).

5. Detailed instructions for amendment of protocols:

5.1. Receipt of application for amendment of protocols:

- The Secretariat will verify the completeness of the protocol amendment application form including signatures
- The Secretariat will also verify whether the amended protocol with an updated version has been submitted after highlighting the changes made in the protocol/related document

- The Secretariat will also verify whether the application for amendment is within the validity period of YEC2 study approval.
- The Secretariat will forward the file to the Member-Secretary

5.2. Instructions to PI for resubmissions:

- Protocol or related documents with changes incorporated (hard and soft copy)
- Updated version number for each resubmitted document
- Page numbers
- Date of resubmission
- All changes highlighted
- Signatures wherever required

5.3. Timelines for resubmission:

- All resubmissions must be done at least 7 calendar days before a YEC2 meeting if it is considered for a full review.
- Any resubmission which is received later will be considered for the subsequent YEC2 meeting.
- All resubmissions must be done within 180 calendar days of the last YEC2 communication, failing which, the file will be considered as closed.
- The review time for resubmission must be completed within 7 calendar days

5.4. Receipt of the resubmission:

- Secretariat will check resubmission form completeness
- The Secretariat will check whether version number, page number and highlighting is done in the resubmitted documents
- The Secretariat will verify whether the date of resubmission falls within 180 calendar days from the date of the last YEC2 communication

6. The review process

- The YEC 2 member/Member secretary/Chairperson will review the resubmission in comparison with the recommendations in the decision letter issued during the last YEC 2 meeting
- The YEC 2 member/Member secretary/Chairperson will review along the items in the assessment forms **YEC2/Ann01/SOP09/v1**
- The YEC 2 member/Member secretary/Chairperson will make recommendations and provide the decision.

7. Decision making

The Member Secretary will summarize the changes made in the resubmission and categorise it based on the decision made in the previous YEC 2 meeting.

- Full review
- Expedited review
- Approved with recommendations subject to review only by the member secretary/Chairperson

7.1. Resubmissions categorized for full review are managed as in YEC2/SOP7A/v2 wherein a brief summary of the protocol along with the changes made are presented and the final decision is made in the YEC 2 meeting

7.2. Resubmissions categorized for expedited review are managed as in YEC2/SOP7B/v2 and the final decision is made by the Member Secretary in consultation with the chairperson and the decision is ratified in the next YEC 2 meeting.

7.3. For protocols classified under Full review, the protocol is included in the agenda of the next YEC 2 meeting under the item of 'amended protocols' and the discussion and decision is made as in YEC2/SOP7A/v1

7.4. For protocols classified under Expedited review, the Member Secretary will discuss the recommendation of the reviewers and in consultation with the chairperson will take a decision about its recommendations

7.5. The final decisions for Amended protocols would include

a. Approved

b. Requires modifications to sustain the ethical committee approval In Protocol/ informed consent

- Reasons for the modifications
- Actions to be taken
- Continuing review if needed

c. Not approved the amendment request

- With Reasons
- Allow the study to continue as previously approved
- Continuing review if needed.

d. Suspend the study, until further information is obtained

7.6. The Member Secretary records the decision on the decision form (SOP)

7.7. The Decision is signed by the Member secretary/Chairperson with date.

8. Communication of the decision

8.1. For protocol amendment requests which are approved:

- The Member Secretary communicates the approval letter of amendment of protocol through a duly signed and dated Amendment Approval Letter i.e. YEC2/Ann03/SOP09/v1 to the principal investigator.
- For full reviews, the letter is communicated to the principal investigator within 14 days of the YEC 2 meeting.
- For expedited reviews, the letter is sent within 7 days of decision by the member secretary/chairperson and the same is ratified in the next YEC 2 meeting.

8.2. For protocol amendment requests which require modifications:

- The Member Secretary communicates the decision within 14 days of the YEC 2 meeting
- The principal investigator is required to respond to the decision letter within 180 days, failing which the protocol would be declared closed.

8.3. Resubmissions categorized as ‘Approved with recommendations subject to review only by the Member Secretary/Chairperson’ are reviewed.

- If approved, then a decision is made to issue ethical clearance
- If not approved, then the comments are again sent to the principal investigator for further resubmission

7. Annexures

7.1. YEC2/Ann01/SOP9/v2: Application for resubmission

7.2. YEC2/Ann02/ SOP9/v2: Assessment of resubmitted protocol

7.3. YEC2/Ann03/SOP9/v2: Categorisation, Assessment and Decision of Amended protocol

7.5. YEC2/Ann03/SOP9/v2: Approval letter for Protocol Amendment

YEC2/Ann01/SOP9/v2 **Application for resubmission**

Protocol Number:

Protocol title:

Name of the PI:

Department:

Date of communication of YEC2 comments: Resubmission

Number:

Type of Resubmission: Resubmission for full review: Resubmission for expedited review: Reviewers:	
Documents submitted and the updated version numbers: Protocol Version: Case record form version: PIS version: ICF version: Questionnaire version: Any other: (Specify with version)	
Note to the PI: It is the responsibility of the PI to <ol style="list-style-type: none"> 1. Respond to every clarification sought /recommendation made by the YEC2 point by point 2. Respond at least one week before the next YEC2 meeting. 3. Highlight all the changes made in the protocol documents, update the version number, insert page numbers and reflect these changes in the table given above. 4. If the PI does not wish to/ is unable to make a particular change, then the PI may provide a justification/ explanation for the same. 5. Declare any changes made in the protocol which are not recommended by YEC2 6. Inform the guide and other members of the research team about all the changes made in the documents and seek their approval before submitting to YEC2 7. Respond to the YEC2 comments within a maximum of 180 calendar days, failing which, the protocol will be considered as closed. 	
Comments and Response Sheet	
Yenepoya Ethics Committee 2, Yenepoya (Deemed to be University) Mangalore	
Protocol No:	
Title:	
Name of the PI and Co-PI	
Name of the Guide / Co-guide	

Date of communication of review comments:	
Date of response from the PI:	
Decision of the reviewer: <ol style="list-style-type: none"> 1. Approved: 2. Minor modification 3. Major modifications: Disapproved (to be discussed in the YEC2 meeting)	
Signature of the reviewer	

YEC2/Ann02/SOP9/v2:

Assessment of resubmitted protocol

Protocol Number (as assigned by YEC2): Protocol title (as approved by YEC2): Name of the PI: Department: Names of all the research team members: Issue and expiry dates of YEC2 initial approval: Issue and expiry date(s) of YEC2 extensions of approval (list all):Date(s) of previous amendment approvals, if any: Continuing review application form submitted along with this amendment application to update the study status: Yes/No
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List of documents (with version numbers) previously approved (keep adding numbered rows):

- 1.
- 2.

Overview of section/document in which the amendment is proposed:

Protocol:

Change in title:	Yes/No
Change in research team members (persons or order of investigators):	Yes/No
Change in guide (for postgraduate studies):	Yes/No
Change in sample size:	Yes/No
Change in sampling technique:	Yes/No
Change in inclusion/exclusion criteria:	Yes/No
Change in data collection/analysis/storage	Yes/No
Change in any other part of the methodology:	Yes/No

Case record form: Yes/No

Participant Information Sheet: Yes/No

Informed Consent Form: Yes/No

Questionnaire (if any): Yes/No

Any other (specify): Yes/No

Detailed description of the amendment(s) (add rows as necessary):

S. No.	Name/part of the document (Specify)	Original approved content	Amendment proposed	Justification	Reviewer's comment: Acceptable/ Not acceptable/ More information needed

Part B (Additional ethical considerations):

		Details/justification (Provide separate sheet if required)	Reviewers' assessment -each item
Will the amendment affect the scientific integrity of the study?	Yes/ No		
Will the amendment change the risk to the participants?	(Increase/ decrease no change)		
Will the amendment change the benefits to participants?	(Increase/ decrease no change)		
Will the amendment require change in the content of the participant information sheet and/or the informed consent form?	Yes/ No		
What does the PI propose to do with the samples/data already collected?	Include/ exclude in data analysis		
If included, how would it impact the consent already provided	No impact/ re-consent will be taken		

Note to the PI and responsibility of the PI

1. Any request for amendment of protocol will only be considered if applied for prospectively
2. Submit continuing review application form along with the application for protocol amendment (Ann04/SOP10/v2)
3. Include every change in the protocol/ related document clearly in the application form for amendment point by point
4. Submit the application for protocol amendment, at least one week before the YEC-1 meeting, so as to be included in that meeting.
5. Highlight all changes made in the amended protocol documents (soft and hard copy), update the version number, insert page numbers and reflect these changes in the table given above.
6. Inform the other research team members (or guide where applicable) about all the changes made in the documents and seek their approval before submitting to YEC2.

7. *Implement the amended version of the protocol only after it is approved by YEC2.*
8. *Any changes made in the protocol without prior YEC2 approval will be considered as protocol deviation/violation and is therefore strongly discouraged.*
9. *PI should ensure concordance in the application form for amendment and the amended protocol version*

YEC2/Ann03/SOP9/v2:

Categorisation, Assessment and Decision of Amended protocol

Part A: Categorization
Type review: Expedited/Full review:
Names of the reviewers:
<ol style="list-style-type: none"> 1. 2.
Signature of the Member-Secretary with date:
B. Assessment and provisional decision of the Reviewer
Assessment of the resubmission based on the change in risk to participants and impact on scientific validity of the proposed amendment:
<ol style="list-style-type: none"> 1. All the proposed amendments are acceptable: 2. The following amendments are not acceptable 3. Following are the additional queries/recommendations: <ol style="list-style-type: none"> a. b. 4. The justification/explanation is not acceptable:
Provisional decision by the reviewer:
<ol style="list-style-type: none"> 1. Approve



Resubmissions Amendments
YEC2/SOP09/v2
Effective Date: 25.02.2023

2. Minor modifications	
3. Major modifications	
4. Disapprove	
Signature of the Reviewer:	Date:
Part C: Final Decision in the YEC2	
1. Approve	
2. Minor modifications	
3. Major modifications	
4. Disapprove	
Signature of the Chairperson/ Member-Secretary	

YEC2/Ann04/SOP9/v2:
Approval letter for Protocol Amendment

To,

Ms. (Principal Investigator Name)

Title:

Department:

Ref:

YEC 2 meeting number:

Date:

Venue:

Chairperson:

Number of members present:



Resubmissions Amendments
YEC2/SOP09/v2
Effective Date: 25.02.2023

Members Present

Sl. no	Name	Position in YEC2	Qualification	Gender
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It is here confirmed that neither you nor any of the study team members have participated in the voting/decision making procedures of the committee.

The YEC 2 has reviewed and approved the following documents submitted for the above mentioned clinical study.

No	Document Name	Version	Date
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The YEC 2 hereby approves the amended proposal entitled “

It is understood that the study will be conducted under your direction as per the submitted protocol.

Number of samples:

Site:

Period of validity of ethics approval:

1. No deviations from, or changes of the protocol and Informed Consent Document should be initiated without prior written approval by the YEC 2 of an appropriate amendment.
2. The YEC 2 expects that the investigator should promptly report to the YEC 2 any deviations from, or changes of, the protocol to eliminate immediate hazards to the research participants and about any new information that may affect adversely the safety of the research participants or the conduct of the trial.
3. For studies which will continue for more than the validity period of the YEC2 approval, it is responsibility of the Principal Investigator to submit the continuing review within one month of the due date i.e.,
4. A copy of the final report should be submitted to the YEC 2 for review.



Resubmissions Amendments
YEC2/SOP09/v2
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5. The YEC 2 functions in accordance with ICH GCP, Schedule Y, ICMR guidelines and other applicable regulatory requirements.

Important Dates:

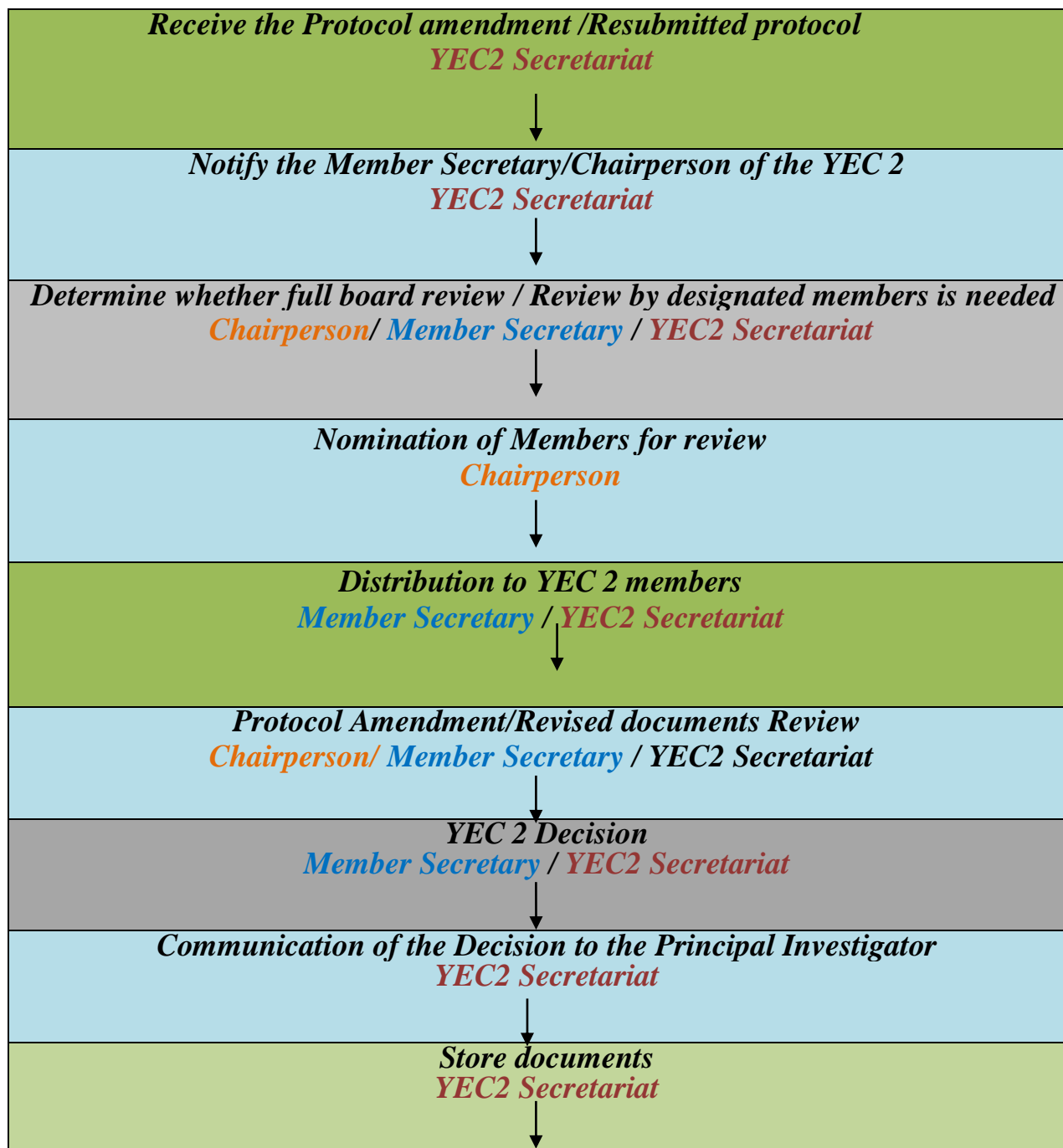
Date of YEC2 Approval:

Date of Continuing review/Study Completion report:



Resubmissions Amendments
YEC2/SOP09/v2
Effective Date: 25.02.2023

09. Flow Chart





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

Resubmissions Amendments
YEC2/SOP09/v2
Effective Date: 25.02.2023

7. References

Indian Council of Medical Research (ICMR). National Ethical guidelines for biomedical and health research involving human participants, October 2017 (cited 6 th October 2019) available from: http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf