Title: Amendment of Protocols and Protocol-related documents: Review

SOP Code: SOP9B/v1

Effective Date: 20/02/2025

Prepared by:

Dr. Rokeya Sultana Members, YEC-3 SOP Subcommittee	Signature with date

Reviewed by:

Dr. Asir John Samuel Convenor, YEC-3 SOP Subcommittee	Signature with date

Approved by:

Dr. Haripriya S, Chairperson, YEC-3	Signature with date

Notified by:

Registrar, Yenepoya (deemed to be University)	Signature with date:

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1. **Purpose:** The purpose of this Standard Operating Procedure (SOP) is to describe how the YEC-3 manages the review of amended protocols and its related documents

2. **Scope:** This SOP applies to the review of protocols and related documents that have been amended by the PI after initial approval from the YEC-3.

3. **Definitions:**

   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).

4. **Responsibility:**

   4.1. **YEC-3 Chairperson will**

   4.1.1. Ensure that all the amended protocol submissions are reviewed in a timely manner

   4.2. **YEC-1 Member-Secretary will**

   4.2.1. Categorize the amended protocol as per the criteria laid down for initial review, based on the change in risk for participants

   4.2.2. Communicate the decision of YEC-3 to PI within 7 calendar days

   4.3. **YEC-3 Secretariat will**

   4.3.1. Receive the amended protocol and check for completeness of the protocol, amendment related documents and the protocol amendment form (Ann01/SOP9B/v1)

   4.3.2. Check for protocol amendment sitting fee payment (in the case of sponsored, regulatory clinical trials or funded studies) (refer Ann03/SOP06/v1).

   4.4. **YEC-3 members will**

   4.4.1. Review the protocols and assess whether the amendments are acceptable with respect to the risk-benefit analysis

5. **Detailed instructions for amendment of protocols:**

   5.1. **Receipt of application for amendment of protocols:**

   5.1.1. The Secretariat will verify the completeness of the protocol amendment application form including signatures

   5.1.2. 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

   5.1.3. The Secretariat will also verify whether the application for amendment is within the validity period of YEC-3 study approval.

   5.1.4. The Secretariat will forward the file to the Member-Secretary

5.2. **Categorization of the application for amendment of protocols:**

5.2.1. The Member-Secretary will do an initial screening of the amendments in order to assess the change in the risk: benefit ratio to the participants

5.2.2. Depending on the change in the risk to the participants, the amendments are categorized as given in SOP07/v1

5.2.2.1. Major amendment: Full review

5.2.2.2. Minor amendment: Expedited Review

5.2.2.3. Except in the case of approved on-going regulatory clinical trials, every amendment will be taken up for full review in the forthcoming meeting, provided the amendment, in all completeness, is submitted at least 7 calendar days in advance.

5.2.3. The categorization will be done within 2 calendar days of receiving the application for amendment of the protocol

5.3. **Review process:**

5.3.1. The Member-Secretary will assign reviewers based on the type of categorization of the protocol

5.3.2. The Member-Secretary will assign primary reviewers whenever possible.

5.3.3. For full review of amended protocols, two reviewers are assigned depending on the expertise and the type of protocol

5.3.4. For expedited review: One reviewer is assigned depending on the type of protocol and protocol amendment

5.3.5. As assessed by the Member-Secretary, or as requested by the reviewer(s), the Member-Secretary may assign the amendment to an Independent Consultant, for scientific, administrative or bureaucratic clarifications

5.3.6. The review of the amended protocols will focus on change on risk:benefit ratio to the participants owing to the amendment, if approved. The risk: benefit analysis will be done as per SOP7A/v1

5.3.7. The review of the amended protocols will also include an assessment of how the samples/data already collected will be treated. (excluded from the study, included in the study). If included, how it would affect the scientific integrity and how it would impact the informed consent and the need for re-consent)

5.3.8. The reviewers will assess the protocol amendment within 7 calendar days.

5.3.9. The reviewers will return the completed and signed assessment form *(Ann01/SOP9B/v2)* with the provisional decision to the YEC-3

5.4. **The provisional decision made by the reviewers:**

5.4.1. Approved

5.4.2. Minor modifications

5.4.3. Major modifications: Requires discussion in the YEC-3 meeting

5.4.4. Disapproved: Requires discussion in the YEC-3 meeting

5.5. **The final decision on the amendment of protocols:**

5.5.1. For expedited review, the Member-Secretary will make the final decision based on the decision of the reviewers as detailed in SOP7B/v1. The final decision of approval is ratified in the subsequent YEC-1 meeting

5.5.2. For full review, the protocol amendment is included in the agenda of the subsequent YEC-1 meeting under the item of 'amended protocols'.

5.5.3. Member-Secretary or one of the reviewers will summarise the amendment of the protocol along with the risk:benefit assessment. The final decision is made as in SOP7A/v1.

5.5.4. For all applications for amendments, additional decisions should also be made on whether

5.5.4.1. The protocol requires audit/ site monitoring

5.5.4.2. The protocol requires increased frequency of continuing review

5.5.5. The final decision is recorded in the decision form

5.5.6. A copy of the approval letter is filed in the protocol file.

5.6. **Final Decision:** The final decision would include:

5.6.1. Approved

5.6.2. Minor modifications

5.6.3. Major modifications

5.6.4. Disapproved (with reasons).

5.6.5. At any level of decision making, if delay is expected, the study may be suspended temporarily, till a formal decision is made. (SOP14/v1)

5.7. **Communication with the PI:**

5.7.1. The decision will be communicated with the PI within 7 calendar days of the final decision

5.7.2. If the decision of suspension of the study is made, the decision is communicated to the PI within 5 calendar days.

5.7.3. The approval letter must be as per the format Ann02/SOP9B/v1

5.7.4. For protocol amendment requests requiring modifications, emails will be sent.

6. **References:**

6.1.1. ICMR's National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017

6.1.2. SOP7A/v2 – Initial Full-Board Review of Research Study Protocols

6.1.3. SOP7B/v2 – Expedited Review of Research Study Protocol

6.1.4. SOP14/v1 - Termination/Suspension/Discontinuation of a research protocol

7. **Annexures**

7.1. Ann01/SOP9B/v1 - Application for Protocol Amendment

7.2. Ann02/SOP9B/v1 - Categorisation, Assessment and Decision of Amended protocol

7.3. Ann03/SOP9B/v1 -Approval letter for Protocol Amendment

Ann01/SOP9B/v1

Application for Protocol Amendment

Application/Notification form for Amendments

Yenepoya Ethics Committee-3 (YEC-3)

EC Ref. No. *(For office use)*

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Date of EC approval: dd mm yy Date of start of study dd mm yy

2. Details of amendment(s)

S.No	Existing Provision	Proposed Amendment	Reason	Location in the protocol[1]

3. Impact on benefit-risk analysis Yes ☐ No ☐

If yes, describe in brief: .....

.....

4. Is any reconsent necessary? Yes ☐ No ☐

If yes, have necessary changes been made in the informed consent? Yes ☐ No ☐

5. Type of review requested for amendment:

Expedited review (No alteration in risk to participants) ☐

Full review by EC (There is an increased alteration in the risk to participants) ☐

6. Version number of amended Protocol/Investigator's brochure: .....

Signature of PI: ..... dd mm yy

[1]*Location implies page number in the protocol where the amendment is proposed.*

Version 1.0

Ann02/SOP9B/v1:

Categorisation, Assessment and Decision of Amended protocol

Part A: Categorization
Type review: Expedited/Full review:
Names of the reviewers: 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: 1. All the proposed amendments are acceptable: 2. The following amendments are not acceptable 3. Following are the additional queries/recommendations: a. b. 4. The justification/explanation is not acceptable:
Provisional decision by the reviewer: 1. Approve 2. Minor modifications 3. Major modifications 4. Disapprove
Signature of the Reviewer: **Date:**
Part C: Final Decision in the YEC-3
1. Approve **2. Minor modifications** **3. Major modifications** **4. Disapprove**
Signature of the Chairperson/ Member-Secretary

Ann 03/SOP9B/v1

Approval letter for Protocol Amendment

Subject: YEC-3 Protocol Amendment Approval Letter

Ref: Protocol no. YEC-3/ titled, " "

This approval letter is in continuation with and is applicable in conjunction with the YEC-3 Approval letter dated (DD/MM/YY) for the same protocol.

This approval is applicable to the protocol or protocol-related documents that have been amended and approved as listed below. Those protocol or protocol-related documents, not amended, will continue to be approved for this protocol as per the YEC-3 approval letter dated (DD/MM/YY).

Names of all research team members *(including Guides)*

No	Name	Role in the research team	Designation/ Affiliation
		Principal investigator	
		Guide/ Co-I	

(Insert rows to add more names)

YEC-3 reviewed the protocol and related documents submitted with amendments as listed below:

No	**Document name**	**Version**	**Date**

(Insert rows to add more documents)

YEC-1 hereby approves the amended protocol no. YEC-3/_____/20___ and the related documents as listed above and this approval valid from _____ to _____.

Any data collected beyond the validity period shall be considered as protocol deviation and liable to action.

It is the responsibility of the Principal Investigator to:

1. Provide updated contact details and respond to YEC-3 communications without delay.
2. Adhere to the current regulatory guidelines
3. Adhere to the undertaking signed by the PI.
4. Adhere to the approved version of the protocol (and related documents)
5. Adhere to the compensation plan as per the approved protocol
6. Restrict recruitment to the approved sample size of _____*(approved sample size)*
7. Inform the YEC-3 at the time of recruitment of the first participant.
8. Obtain written approval of YEC-3 before any proposed change in the protocol (amendment) is implemented in the prescribed format **(Ann01/SOP9B/v1)**
9. Report to YEC-3 any deviation from the guidelines/approved version of the protocol without delay (including change in research team members) in the prescribed format **(Ann01/SOP11/v1** - Initial report and **Ann02/SOP11/v1 -** Detailed report**)**

10. As per the current regulatory guidelines, report to YEC-3 all serious adverse events in the prescribed format **(Ann01/SOP12 v1** - Onsite SAE and **Ann02/SOP12/v1** - Offsite SAE**)** and their follow-up actions.
11. Submit the periodic review as specified by YEC-3 in the prescribed format **(Ann04/SOP10/v1)**
12. Submit continuing review form one month before the end of validity of this approval **(Ann04/SOP10/v1)**
13. Report to YEC-3 any adverse event/change in risk to participants (excluding SAEs) that may occur during the study in the periodic review
14. Submit a completion report to YEC-3 when the data/sample collection is completed in the prescribed format **(Ann01/SOP13/v1)**
15. Submit a summary of the study when the data analysis is completed.
16. Maintain the privacy of the participants/ samples and confidentiality of data.
17. Securely retain the original of YEC-3 approval letter and the approval letter for the amendment, as issuing duplicate approval letter is liable to a fee
18. Respond to communication from YEC-3 pertaining to the study/auditing/site monitoring/others.

All communications with YEC-3 should be by email to yec3@yenepoya.edu.in

YEC-3 functions in accordance with *(insert names of the current regulations and guidelines).*

YEC-3 is registered with *(insert names of the currently approved regulatory authorities, letter number and validity)* and recognized by *(insert names of the recognizing bodies with validity)*.

Member-Secretary/Chairperson, YEC-3 Date:

Important Dates:
Date of YEC-3 approval: *XX/XX/20XX*
Date of YEC-3 amendment approval: *XX/XX/20XX*
Date of expiry of the validity of YEC-3 approval: *YY/YY/20YY*
Date for initiation of continuing review (if needed): *(write date a month prior to YY/YY/20YY)*

8. **Glossary:**

ICMR: Indian Council of Medical Research

PI: Principal Investigator