

Title: Review of Resubmitted and Amended Protocols and Protocol-related Documents

SOP Code: SOP09/v2

Effective Date: 01/08/2016

Prepared by:

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Dr. Sayeegetha Hegde Chairperson, YUEC	Signature with date:
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Notified by:

Registrar, Yenepoya University vide notification no. YU/REG/ACA/YUEC/FERCAP/01/2016 dated 01/08/2016	Signature with date:
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1. Purpose:

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

2. Scope:

2.1 This SOP applies to the review of Study protocols and related documents that have been resubmitted to the YUEC by the Principal Investigator (PI) with clarifications and modifications sought by the YUEC in the initial review

2.2 This SOP also applies to the review of amendments to study protocols and related documents that have been approved earlier by the YUEC

3. Responsibility:

3.1 Secretariat:

3.1.1 It is the responsibility of the YUEC secretariat to ensure that the submissions made by the principal investigator as resubmissions or amendments are complete in all respects

3.2 Member-Secretary:

3.2.1 The member-secretary in consultation with the Chairperson will assign the YUEC members as reviewers for the 'resubmission of protocols' as per the decision taken in the previous YUEC meeting and as recorded in the minutes of the meeting in the Decision form as in SOP.

3.2.2 The member-secretary will do an initial screening and decide whether the submission for 'amendment of protocol and related documents' will be included as a full review/ expedited review in consultation with the Chairperson

3.2.3 The member-secretary in consultation with the Chairperson will assign YUEC members to review the submission for 'amendment of protocols and related documents'

3.3 YUEC members:

3.3.1 The YUEC members will review the submission as per the assessment forms depending on whether it is full review or expedited review

4. Detailed instructions for resubmission of protocols:

4.1 Receipt of resubmitted protocols and its distribution

4.1.1 The secretariat will verify whether or not the principal investigator has resubmitted the documents within 180 days.

4.1.2 The secretariat will check for the following items during resubmission

- Covering letter by the principal investigator responding to the YUEC decision form
- If minor changes, then submission of a letter listing the changes made (SOP)
- If significant changes, then resubmission of the protocol as of the protocol Version 2 and/ informed consent form version 2 and other related documents as version 2(SOP) along with a letter containing the list of changes made.

4.1.3 The secretariat will forward the following to the Member secretary

- The resubmission documents
- The decision letter of the previous YUEC meeting pertaining to the protocol
- Assessment form

4.2 The review process

4.2.1 The YUEC member/Member secretary/Chairperson will review the resubmission in comparison with the recommendations in the decision letter issued during the last YUEC meeting

4.2.2 The YUEC member/Member secretary/Chairperson will review along the items in the assessment forms *Ann01/SOP09/v2*

4.2.3 The YUEC member/Member secretary/Chairperson will make recommendations and provide the decision.

4.3 Decision making

4.3.1 The member secretary will summarize the changes made in the resubmission and categorise it based on the decision made in the previous YUEC meeting.

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

4.3.2 Resubmissions categorized for full review are managed as in SOP 7A, wherein a brief summary of the protocol along with the changes made are presented and the final decision is made in the YUEC meeting

4.3.3 Resubmissions categorized for expedited review are managed as in SOP 7B and the final decision is made by the member secretary in consultation with the chairperson and the decision is ratified in the next YUEC meeting.

4.3.4 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

5. Detailed instructions for amended protocols:

5.1 Receipt of request for amendments in protocols

5.1.1 The secretariat will check for the following items during resubmission

- Covering letter by the principal investigator requesting amendment in the protocol
- Amended protocol documents with highlighting of the amendments.

5.1.2 The secretariat will inform and forward the following to the Member secretary

- The amended protocol submission

- Copy of the approval letter from YUEC for the original protocol decision letter of the previous YUEC meeting pertaining to the protocol
- Assessment form

5.2 Categorisation of review:

5.2.1 The member secretary will do an initial screening of the amendments

5.2.2 In consultation with the chairperson, the member secretary will categorize the amended protocol into

- Full review
- Expedited Review

5.2.3 The member secretary will consider the following criteria for categorisation of an amended protocol in to Full review if the amended protocol has the following features:

- Changes in the risk: benefit assessment through a change in the study design
- Additional interventions or deletion of some interventions
- Changes in the inclusion or exclusion criteria
- Changes in the dosage of the drug like change in dosage, route, etc.
- A significant change in the number of research participants which can affect the fundamental characteristics of the study.

5.3 Review process:

5.3.1 The member secretary will assign two reviewers in consultation with the chairperson

5.3.2 The assessment form used for expedited review is used Ann02/SOP09/v2

5.3.3 The reviewers will complete the review process in 7 days

5.3.4 The provisional decisions taken by the reviewers for Amended protocols would include

- Approved
- Disapproved
- Suggested Recommendation
- Discussion in YUEC meeting

5.3.5 The reviewers will review the protocol, comment, recommend and sign with date and return the assessment form to the secretariat.

5.4 Decision making

5.4.1 For protocols classified under Full review, the protocol is included in the agenda of the next YUEC meeting under the item of 'amended protocols' and the discussion and decision is made as in SOP 7A

5.4.2 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

5.4.3 The final decisions taken got 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

5.4.4 The member secretary records the decision on the decision form (SOP)

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

5.5 Communication of the decision

5.5.1 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. Ann03/SOP09/v2 to the principal investigator.
- For full reviews, the letter is communicated to the principal investigator within 14 days of the YUEC 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 YUEC meeting.

5.5.2 For protocol amendment requests which require modifications:

- The member secretary communicates the decision within 14 days of the YUEC meeting
- The principal investigator is required to respond to the decision letter within 180 days, failing which the protocol would be declared closed.

6. Reference to other SOPs

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

6.2 SOP7B/v2 – Expedited Review of Research Study Protocol

7. Annexures

7.1 Ann01/SOP09/v2 - Assessment of resubmitted protocol

7.2 Ann02/SOP 09/v2 - Protocol amendment request and assessment form

7.3 Ann03/SOP 09/v2 - Protocol Amendment/Document Amendment Approval
letter

Ann01/SOP09/v2 Assessment of resubmitted protocol

Protocol Number	
Protocol Title:	
Number of review: <input type="checkbox"/> 2 nd Review <input type="checkbox"/> 3 rd Review <input type="checkbox"/> 4 th Review	
Principal Investigator:	Department:
Date of Initial Review by YUEC:	Date of Last Review:
The YUEC Decision recorded in the meeting minutes: (meeting held on)	
Name of the reviewer:	
Provisional decision of the reviewer:	
Approved	<input type="checkbox"/> Yes <input type="checkbox"/> No
If disapproved, reasons for disapproval	
Modification required	<input type="checkbox"/> Yes <input type="checkbox"/> No:

Final Decision form for amended protocols

Protocol Number	
Protocol Title:	
Principal Investigator:	Department:
Date of Initial Review by YUEC:	Date of Last Review:
The YUEC Decision recorded in the meeting minutes: (meeting held on)	
Final decision	
Approved	
Not approved	
Modifications needed	
Any other:	
Signature of the Member Secretary/Chairperson:	
Date:	

Annexure 2:Ann02/SOP09/v2

Protocol / Protocol related documents Amendment Request and Assessment Form

YUEC protocol Number
Title of the study
Name of the principal investigator
Department and institution:
YUEC approval date:
State the proposed amended in detail:
Part/parts of the protocol in which amendment proposed:
Reasons for requesting amendment:
Impact of the proposed amendment on you present study at this site:(modifications in the ICD, re-consent of research participants, untoward effects likely to occur because of the amendment or any other)
Have the changes modifications in the amended versions been highlighted/ underlined? Yes <input type="checkbox"/> No <input type="checkbox"/>
Signature of the Principal Investigator:
Name with Date:

Type of review:- (Decision by the Chairperson/Member Secretary)	
Review by Member Secretary/ Chairperson	<input type="checkbox"/>
Review by designated YUEC members	<input type="checkbox"/>
Full Board discussion and review	<input type="checkbox"/>
Decision:	
<input type="checkbox"/> Approved	<input type="checkbox"/> Suggested Recommendation(s)
<input type="checkbox"/> Disapproved	<input type="checkbox"/> Next full board discussion
Name of Reviewer:	
Signature with Date:	

**Ann03/SOP09/v2 - Protocol Amendment/Document Amendment
Approval letter**

<p>Date</p> <p>To,</p> <p>Dr./Mr./Ms.</p> <p>Department:</p> <p>Ref: The study no. YUEC/xxx/20xx entitled, “xxxxxxxxxx”.</p> <p>Sub: Letter no.</p> <p>Dear Dr./Mr.Ms.</p> <p>YUEC meeting number:</p>
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Date:

Venue:

Chairperson:

Number of members present:

Members present:

Name	Position in YUEC	Designation	Qualification	Gender

It is hereby confirmed that neither you nor any of the study team members have participated in the voting/decision making procedures of the committee.

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

1. Xxx
2. Xxx
3. xxx

The YUEC 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 participants:

Site:

Period of validity of ethics approval:

No deviations from, or changes of the protocol and Informed Consent Document should be initiated without prior written approval by the YUEC of an appropriate amendment.

The YUEC expects that the investigator should promptly report to the YUEC 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.

For studies which will continue for more than a year, a continuing review report needs to be submitted (within 1 month of the due date i.e. 11 months from the date of approval) on or before _____.

A copy of the final report should be submitted to the YUEC for review.

The YUEC functions in accordance with ICH GCP, Schedule Y, ICMR guidelines and other applicable regulatory requirements.

Sincerely yours

Member Secretary/ Chairperson, YUEC

(Signed and dated by the YUEC Chairperson or Member Secretary)

Date of approval of the study:

8. Flowchart

No.	Activity	Responsibility
1.	Receive the Protocol amendment / Resubmitted protocol	YUEC Secretariat
2.	Notify the Member Secretary/ Chairperson of the YUEC	YUEC Secretariat
3.	Determine whether full board review / Review by designated members is needed	YUEC Member Secretary/Chairperson
4.	Nomination of Members for review	YUEC Chairperson
5.	Distribution to YUEC members	YUEC Secretariat
6.	Protocol Amendment/Revised documents Review	YUEC Members /Member Secretary/ Chairperson
7.	YUEC Decision	YUEC Member Secretary/Chairperson
8.	Communication of the Decision to the Principal Investigator	YUEC Secretariat
9.	Store documents	YUEC Secretariat