

Title: Continuing Review of Study Protocols

SOP Code: SOP10/v2

Effective date: 01/08/2016

Prepared by:

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Approved by:

Dr. Sayeegeetha 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 the procedure to be followed by the YUEC for conducting continuing review of protocols which have been previously approved by the YUEC.
- 1.2 The purpose of the continuing review is to periodically monitor the progress of the study, to ensure continuous protection of the rights and welfare of research participants

2. Scope:

- 2.1 This SOP applies to continuing review of all the already approved study protocols
 - Approved protocols
 - Resubmission of protocols
 - Amended protocols
 - Protocols with SAE reports
 - Protocols with reports of deviations
 - Other protocol reports as determined by the YUEC
- 2.2 It applies to the continuing review conducted at pre-specified intervals, at least once a year, as determined by the YUEC for each protocol depending on
 - The degree of risk to the participants
 - The nature of the study
 - The studies on vulnerable participants
 - Duration of the study
 - Other factors as determined by the YUEC members

3. Responsibilities:

3.1 Secretariat:

- 3.1.1 It is the responsibility of the Secretariat to make a note of the dates of continuous reviewing for each protocol as determined by the YUEC at the time of approval of the protocol and as mentioned in the Decision form and minutes of the meeting.
- 3.1.2 It is the responsibility of the secretariat to inform the principal investigators about the dates of continuing review if predetermined or yearly, if not.
- 3.1.3 It is the responsibility of the secretariat to inform the Member-Secretary of all the protocols scheduled for continuing review in that month by the end of first week of every month

3.2 Member-Secretary:

- 3.2.1 It is the responsibility of the Member-Secretary to ensure that the dates for continuing review of each approved protocol are predetermined, if deemed necessary, during the YUEC meeting when the protocol is approved.
- 3.2.2 It is the responsibility of the Member-Secretary to conduct the continuing review at the predetermined dates.
- 3.2.3 It is the responsibility of the Member-Secretary to conduct the continuing review annually, if the dates are not predetermined.

4. Detailed instructions:

4.1 Preparing the schedule:

- 4.1.1 The Member-Secretary will ensure that the dates for continuous review are decided at annual/frequent intervals and noted for each protocol at the time of approval and noted in the Decision form and in the Approval letter.

4.1.2 The Member-Secretary assisted by the secretariat and in consultation with the chairperson will prepare the time table for continuing review of protocols scheduled for every month.

4.2 Notifying the Principal investigator:

4.2.1 The Secretariat will send a reminder to the PI as per the format *Ann01/SOP 10/v2*

4.2.2 The secretariat will send notification to the principal investigator two months prior in case of annual review and one month prior in case of frequent review if predetermined during the YUEC meeting

4.3 Submission of Continuing review report by the Principal investigator

4.3.1 The principal investigator will submit the report for continuing review as per the format continuing Review Application Form (*Ann02/SOP10/v2*)

4.3.2 The principal investigator will send the report for continuing review before the scheduled date as mentioned in the approval letter.

4.3.3 The report will contain the following components:

- Number of patients recruited
- Number of dropped out participants
- Reasons for drop-out of participants
- Occurrence of unexpected events or problems
- Any changes in the selection criteria of participants
- Changes in the protocol/Informed consent Document process
- Any amendments
- Changes in the study team
- Compliance of the investigator regarding YUEC recommendations as spelt out in the approval form
- Any other point as per the YUEC recommendations

4.4 Receipt of the submission for continuing review:

4.4.1 The Secretariat will ensure that the contents of the package include the following documents:

- Continuing Review Application Form (Ann02/SOP10/v2) duly filled with explanations for all the items in the form, wherever applicable
- Any attachments, if applicable

4.5 Review process

4.5.1 The Member-Secretary will do an initial screening and decide in consultation with the chairperson whether the submission for continuing review will be listed for

- Full review
- Expedited review

4.5.2 The submission for continuing review listed under Full review will be managed as per SOP 7B

4.5.3 The submission for continuing review listed under expedited review will be managed as per SOP 7B

4.5.4 The secretariat will send the following to the designated reviewers

- Continuing Review Application Form (Ann02/SOP10/v2) submitted by the principal

4.6 The final decision:

4.6.1 The Member-Secretary will take a final decision either after a full review or expedited review as the case may be, as follows

- a. Approved: The Principal investigator can continue the study without any changes

b. Modifications recommended:

- The study will not proceed until the modifications suggested by the YUEC are made
- The Principal investigator will resubmitted the documents within one month
- The Resubmission will be reviewed and approved by the YUEC
- The study will continue only after the approval of the resubmission as per the new approved version

c. Discontinue the study:

- The project cannot be continued:
- The reasons for discontinuation of the project will be mentioned in the decision letter as per the form Ann02/SOP10/v2

4.6.2 The YUEC Member-Secretary/Chairperson will sign and date the decision letter and send to the Principal investigator within 14 days after the decision

4.6.3 A copy of the submitted form, review forms and the decision letter are filed in the respective protocol file

4.7 Non submission of report for continuing review

4.7.1 Every PI is expected to submit a report at least one month before the date of continuing review as determined by the YUEC and noted in the approval letter

4.7.2 If the PI does not submit the report on the specified date, the secretariat sends a reminder (Ann1 SOP09/v2)

4.7.3 The secretariat may send a second reminder one month after the specified date, in case the principal investigator does not submit the report

4.7.4 The Member-Secretary will send a letter seeking explanation if the principal investigator fails to submit the report despite repeated reminders

4.7.5 The Member-Secretary may include the failure to submit report for continuing review of the protocol for discussion in the YUEC meeting and decide regarding the status of the ethics committee approval.

5. Annexures:

5.1 Annexure 1 Ann01/SOP10/v2- Reminder letter by the YUEC to principal investigator

5.2 Annexure 2 Ann02/SOP10/v2- Continuing Review Application Form

5.3 Annexure 3 Ann03/SOP10/v2- Decision form for review process

Annexures

Ann01/SOP10/v2

Reminder letter by the YUEC to Principal Investigator

Date:

Name of the principal investigator:

Department:

Reference: Your protocol bearing the No. _____ titled _____
approved by YUEC on _____.

Dear Dr./Mr./Ms. _____

You are requested to submit the report to the YUEC for continuing review (Continuing Review Application Form *Ann02/SOP07*) at least one month before the specified date, i.e. on or before _____. Any delay will result in a lapse of ethics committee approval. Data collected in the interim period where the ethics committee approval is not renewed, cannot be included in your final analysis.

Thank you,

Yours sincerely,

Member-Secretary/Jt Secretary/Chairperson, YUEC

Ann02/SOP10/v2

Continuing review application form

Name of the principal investigator:

Department:

Protocol No. _____

Title: _____

Approved by YUEC on _____

Date: _____

A	Summary of protocol participants:	
1.	No. of participants screened:	
2.	No. of participants approved by YUEC:	
3.	No. of recruited participants:	
4.	No. of ongoing participants:	
5.	No. of completed participants:	
6.	No. of participants who refused to consent:	
7.	Have any participants been withdrawn from this study?	Yes <input type="checkbox"/> No <input type="checkbox"/>
8.	If Yes, (state the number and reasons for drop-outs of each participant, attach separate sheet if needed)	
B	Amendments in the protocol	
9.	Have there been any amendments in the protocol or informed consent document since the last review	Yes <input type="checkbox"/> No <input type="checkbox"/>
10.	Were these protocol/Informed Consent Document (ICD) amendments approved by the YUEC	Yes <input type="checkbox"/> No <input type="checkbox"/>
11.	If no, mention the amendments not approved	(Attach separate sheet)
12.	Which protocol amendment is the site following at present?	

13.	Which Informed consent amendment is the site following at present?	
14.	Has any information appeared in the literature, or evolved from this or similar research that might affect the YUEC/YUEC's evaluation of the risk/benefit analysis of participants involved in the protocol?	
15.	Whether reports of SAEs so far have been reviewed by the YUEC	
16.	Have any participating investigators been added or with drawn since last review	
17.	Is report of interim data analysis available?	
18.	Is report of the data safety and monitoring board available?	
19.	Have any investigators developed equity or consultative relationship with a source related to this protocol which might be considered a conflict of interest?	
	Signature of the Principal Investigator with Date:	

Annexure 3

Decision for review process

Assessment of Continuing Review Report by the YUEC:

- Chairperson /Member-Secretary only and informed to the YUEC members at meeting
- Any 2 YUEC members and informed to the YUEC members at meeting

Name of the YUEC members:

1. _____
2. _____

Signature with date:

Chairperson/ Member-Secretary

Final Decision form

YUEC Decision on the Continue Review Report:

Name of the principal investigator:

Department:

Protocol No. _____

Title: _____

Approved by YUEC on _____

Date: _____

Decision on continuing review of the protocol:

- Approved and the project can be continued without any modifications
- Modifications recommended - requiring protocol resubmission
State the recommendations:
- Protocol should be discontinued
State the reasons for discontinuation
- Date of Meeting discussion

Signature with date

Chairperson/ Member-Secretary

6. Flowchart

No.	Activity	Responsibility
1	Determine the date of continuing	Administrative Officer / Secretariat
2	Notify the Principal Investigator or study team	YUEC Secretariat
3	Manage continuing review package upon receipt and verifying its contents	YUEC Secretariat
4	Notify the members of the YUEC	YUEC Secretariat
5	Review of Continuing review report	YUEC Secretariat, Members and
6	Prepare meeting agenda	YUEC Secretariat
7	Communicate the YUEC decision to the Principal Investigator	YUEC Secretariat