

Title: Agenda preparation, meeting procedures and recording of minutes

SOP Code: SOP08/v2

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1. Purpose:

The purpose of this Standard Operating Procedure (SOP) is to describe the administrative process and provide detailed instructions for the preparation, review, approval and distribution of the agenda and minutes of the meeting.

2. Scope:

2.1 The SOP applies to administrative processes concerning the preparation, distribution of the agenda and recording of the minutes of the YUEC meetings.

2.2 The SOP also applies to the administrative processes concerning the conduct of Emergency meeting of the YUEC.

3. Responsibilities:

3.1 Member-Secretary:

3.1.1 It is the responsibility of the Member-Secretary to prepare the agenda for the YUEC meeting

3.1.2 It is the responsibility of the Member-Secretary to record the minutes of the YUEC meeting

3.1.3 It is the responsibility of the Member-Secretary to prepare the agenda and the minutes in consultation with the Chairperson

3.2 Secretariat:

3.2.1 It is the responsibility of the Secretariat to assist the Member-Secretary in preparing the agenda for the YUEC meeting

3.2.2 It is the responsibility of the Secretariat to assist the Member-Secretary in recording the minutes of the YUEC meeting

3.2.3 It is the responsibility of the Secretariat to circulate the agenda of the YUEC meetings to all the YUEC members

3.2.4 It is the responsibility of the Secretariat to circulate the minutes of the YUEC meetings to all the YUEC members

3.3 Chairperson:

3.3.1 It is the responsibility of the Chairperson to review and approve the agenda of the YUEC meetings

3.3.2 It is the responsibility of the Chairperson to review and approve the minutes of the YUEC meetings

3.4 Members:

3.4.1 It is the responsibility of the YUEC members to read the agenda and prepare for the YUEC meetings

3.4.2 It is the responsibility of the YUEC members to read and approve the minutes of the YUEC meetings

4. Detailed instructions for YUEC meeting:

4.1 Scheduling of the YUEC Meeting:

4.1.1 The YUEC meeting is tentatively scheduled for every month well in advance for the whole calendar year.

4.1.2 The YUEC meeting dates are tentatively scheduled on the 3rd Thursday of every month to ensure regularity

4.1.3 The scheduled dates of the next meeting are finalized during the previous YUEC meeting in the presence of the members.

4.1.4 In case the meeting is rescheduled for some reason, all the members are communicated about the new date and time and the reason for rescheduling via telephone or email and the same is recorded.

4.1.5 The YUEC will hold regular meetings at least once in every month and the interval between any two meetings will not exceed 60days.

4.2 Preparation of the YUEC meeting agenda:

4.2.1 The Member-Secretary assisted by the Secretariat will prepare the agenda of the next YUEC meeting

4.2.2 The agenda is prepared at least 2 weeks before the scheduled day

4.2.3 The Chairperson will review and approve the agenda

4.2.4 The format Ann01/SOP08/v2 is used for preparing the agenda

- Apologies
- Ensuring quorum by Chairperson
- Reading and approving minutes of the previous meeting
- All protocols for Initial Full Review
- Revised protocols for full review
- Amended protocols for full review
- Other considerations
 - a. Continuing review of protocols
 - b. Study completion reports
 - c. Premature termination report
 - d. Site monitoring reports
 - e. Serious adverse events/ other reports
- Any issues raised by the members regarding YUEC functioning like YUEC policies/training of members/ revising SOPs/etc
- List of protocols which were exempted from review for ratification
- List of protocols which were issued ethical clearance after expedited review for ratification
- Training session of the Members: topic and speaker
- Any sub-committee report
- Any other matter

4.2.5 The Secretariat will keep all the concerned documents ready to be kept for the meeting

4.2.6 The Secretariat will list and schedule the protocols in the agenda as per their receipt

4.2.7 All the protocols received two weeks before the meeting are included in the YUEC meeting.

4.2.8 Revised and amended protocols received 7 days prior are included in the next YUEC meeting.

4.2.9 The agenda of the YUEC meeting is approved by the Chairperson and circulated among the members at 7 days before the scheduled meeting, but not later than one day before the scheduled meeting.

4.2.10 Only reports concerning safety of the participants or other emergency issues may be included in the meeting even if they reach the YUEC within 3 days of the meeting

4.2.11 The Secretariat will make sure that the meeting venue, equipment and facilities are available for the meeting day

4.3 Conduct of the meeting:

4.3.1 The meeting will be conducted only after the quorum is ensured by the Chairperson.

4.3.2 The quorum will consist of

- One basic medical scientist (preferably a pharmacologist)
- One social worker (or a social scientist, theologian, ethicist, Philosopher, member or representative of a non-governmental voluntary agency or a similar person)
- A clinician
- A lay person
- A legal expert

4.3.3 If a guest is permitted to observe the meeting, then he should have obtained the permission from the Chairperson and Member-Secretary and should have signed the Confidentiality agreement form prior to attending the meeting as per **SOP05/v2**

4.3.4 The Secretariat will mark the attendance of the members and guests present in the meeting and take their signatures on the attendance sheet.

4.3.5 The members will declare any conflict of interest for any of the protocols before the proceedings of the meeting begin. This is ensured by the Chairperson. (SOP)

- 4.3.6 If a conflict of interest is declared, the member will step out of the meeting room when the concerned issue is being deliberated.
(SOP)
- 4.3.7 The Chairperson will initiate the meeting and the Member-Secretary will conduct the further proceedings of the meeting.
- 4.3.8 The Member-Secretary will proceed in the order as per the agenda of the meeting.
- 4.3.9 The protocols for initial review are discussed as per SOP07A/v2
- 4.3.10 The investigators who have been invited to the YUEC meeting for giving clarifications are allotted time to do so, but not when the protocol is being deliberated. The YUEC members will not discuss the protocol when the investigator is in the meeting room.
- 4.3.11 Each point on the agenda is discussed in order by the members after the Member-Secretary provides a summary of each in brief.
- 4.3.12 The Secretariat provides the concerned files as and when deemed necessary.

4.4 Recording of the minutes of the meeting:

- 4.4.1 The Secretariat will assist the Member-Secretary or another member of YUEC in recording the minutes of each matter discussed during the meeting.
- 4.4.2 The Secretariat will record carefully the issues raised, the discussion, the decision and recommendations for each protocol systematically.
- 4.4.3 The recording of the minutes may done on a template for minutes of the meeting real time
- 4.4.4 After each protocol or issue discussed, the minutes recorded are read out to ensure correctness of content

4.5 Decision making:

- 4.5.1 The final decision on each protocol/issue is made by voting as per SOP7B/v2
- 4.5.2 The decisions will include

- Approval
- Disapproval
- Approved with Modifications
- Termination of on-going study

4.5.3 The following members will not take part in the voting

- An independent consultant who has been invited to provide specific opinion
- A guest/observer to the YUEC meeting
- Members who have declared a conflict of interest (they will neither vote, nor will be present during the discussion and voting)
- Investigator who has been invited to offer clarifications on the protocols (they will neither vote, nor will be present during the discussion and voting)

4.6 Drafting the minutes of the meeting

4.6.1 The Secretariat will compose the summary of the discussion of each protocol and item on the agenda of the meeting in a concise, clear and appropriate language.

4.6.2 The following points will be included in the beginning of the minutes of the meeting

- Name of person preparing the minutes
- Location where the meeting was held (city, state)
- Meeting number, date/duration of the meeting (time of commencement and end)
- Names of the YUEC members and guests attending the meeting
- Name of the individual serving as Chairperson of the meeting in the absence of the Chairperson
- Determination of a duly constituted quorum by the Chairperson to proceed with the meeting

- Declaration of conflict of interest

4.6.3 The following points will be included in each case study

- Sponsor's name
- Protocol number/date/version of protocol, when available
- Investigator's name
- Names of the Primary Reviewers who presented their findings
- Discussion and decision as deemed appropriate by the Chairperson
- Follow up action decided upon
- Reference to the investigator approval letter that lists all the changes requested during the meeting
- Determination of the next requested continuing review

4.6.4 Requirements for each study or activity requesting Expedited Review

- Sponsor's name
- Protocol number/date/version of protocol, when available
- Investigator's name
- Decision

4.6.5 Requirement for each continued review report

- Sponsor's name
- Protocol number/date/version of protocol, when available
- Investigator's name
- Decision to continue, terminate or amend the study
- Recommendations

4.6.6 Requirement for each adverse event notification and final report

- Sponsor's name
- Protocol number/date/version of protocol, when available
- Investigator's name
- Summary of the report

- Decision to continue, terminate or amend the study
- Recommendations

4.6.7 Requirement for each termination of approval

- Sponsor's name
- Protocol number/date/version of protocol, when available
- Investigator's name
- Summary of the report
- Reason for termination

4.7 Approval of the minutes of the meeting

4.7.1 The Secretariat will check the correctness of the report

4.7.2 The Member-Secretary will review the summary of discussion in detail and forward it to the Chairperson within 7 days of the meeting by email

4.7.3 The Chairperson will review the summary and approve the minutes of the meeting by email

4.7.4 The Secretariat will circulate the approved minutes of meeting to all the members of YUEC within 10 days by email

4.7.5 The YUEC members who were present on the meeting will also approve the minutes email

4.7.6 A copy of the minutes of the meeting is forwarded to the Registrar of the Yenepoya University for information within 21 days by email

4.8 Filing of the minutes of the meeting

4.8.1 The Secretariat will file the original document of the minutes of the meeting duly signed by the Member-Secretary and the Chairperson in the YUEC file for Minutes of the meeting

4.8.2 The Secretariat will file the decision forms for each protocol in the respective protocol files

5. Detailed instructions for Emergency meeting of YUEC

5.1 Decision of conducting the meeting:

5.1.1 The Member-Secretary will decide to call an emergency meeting in consultation with the Chairperson and Vice Chancellor, Yenepoya University, for any of the following reasons

- Upon receiving an information about an adverse event
- Urgent issues which need urgent decision to avoid adverse impact on the patient or public safety or national economy
- Other reasons as deemed by the Member-Secretary or the Chairperson

5.2 Preparation for the meeting:

5.2.1 The Secretariat will contact all the YUEC members and inform them the date, time and venue of the meeting along with the reason for calling the emergency meeting.

5.2.2 The Secretariat will prepare the documents regarding the issue to be discussed along with the concerned protocol, if any, and other supporting files.

5.2.3 The Secretariat will email the concerned documents to all the YUEC members

5.3 Conduct of the meeting:

5.3.1 The Chairperson will determine the quorum at the scheduled time

5.3.2 If the quorum is not met, the meeting will be postponed by 15 minutes.

5.3.3 If even at the end of 15 minutes, the quorum is not met, the meeting will be held without a quorum, given the urgency of the situation, but in the presence of at least four members.

5.3.4 Depending on the matter for discussion, the YUEC emergency meeting is conducted, discussed and decision taken upon, as per the relevant SOPs

- Expedited review: SOP
- SAE review: SOP

- Protocol violation/deviation: SOP
- Others, as applicable

5.3.5 The minutes of the meeting are prepared, reviewed, approved, circulated and filed as in the YUEC meeting (SOP 8 Previous section Number)

6. References to other applicable SOPs:

- SOP05/v2:** Procedures for allowing Guest/ Observer to visit Institutional Ethics Committee or attend YUEC meeting:
- SOP06/v2:** Management of Research Study Protocol and Study Related Documents Submitted for Ethics Review
- SOP07/v2:** Categorization of Submitted Protocols for Ethics Review

7. Annexures:

Ann01/SOP08/v2- Agenda format

Ann02/SOP08/v2- Conflict of Interest form to be signed by YUEC member before board meeting

Ann 01/SOP08/v2

Agenda format

Agenda of the YUEC Meeting:

1. Meeting No: YUEC mm/yyyy
2. Location of the meeting:
3. Meeting Date:
4. Meeting time:
5. The YUEC meeting will proceed in the following sequence:
 - a. Discussion of the points arising from the minutes of the previous meeting and presentation of agenda of the day's meeting and Declaration of Conflict
 - b. New Protocol Presentation, Review, Discussion and reaching a decision by voting to approve/raise queries
 - c. Review the responses forwarded by the principal investigator to the query letter/ resubmitted protocols

- d. Approve protocol amendment and related documents
- e. To review the continuing review report/ completion report/ final clinical trial report/
Annual report / Termination reports
- f. To review Protocol Deviations / Violations
- g. Expedited reviews approved since last meeting – for ratification
- h. To review other Letters related to projects
- i. To review Monitoring reports
- j. To inform about the YUEC meeting and to review the policy decisions
- k. To inform about the SAE Subcommittee meetings and to review
 - l. SAE/Safety reports
 - m. Other points for discussion
6. Non-protocol related correspondence
7. In-house training sessions
8. Any other issues raised by the members

Ann02/SOP08/v2

Conflict of Interest form to be signed by YUEC member before the meeting

Date:
To
The Chairperson, YUEC
I declare conflict of interest with the protocol specified below, which is scheduled for
discussion in today's meeting
Date:
Meeting Number:
Following are the details of the protocol:
1. Protocol Number:
2. Title of the project:
I declare conflict of interest for the following reason (Tick as applicable)
1. I am the investigator
2. I am the co-investigator/guide/member of the study team
3. I have financial interest

4. Any other (specify):

I declare that I will not participate in the discussion and decision making process of the same protocol and step out of the meeting room as per the YUEC SOPs.

Signature of the YUEC member

Name and date

Signature of the Chairperson/Member-Secretary with date

9. Flowchart:

No .	Activity	Responsibility
1	Preparation of meeting agenda prior to a board meeting	YUEC Secretariat
2	During the Meeting	YUEC Secretariat, Members and Chairperson
3	After the Board Meeting and Preparing the Minutes	YUEC Secretariat/ Member-Secretary
4	Approval of minutes	YUEC members / Chairperson
5	Filing the minutes	YUEC Secretariat
6	Calling an emergency meeting	Member Secretary in consultation with Chairperson