



Minutes of Meeting
YEC2/SOP08/v2
Effective Date: 25.02.2023

Title: Agenda preparation, meeting procedure and record of minutes

SOP Code: YEC2/SOP08/v2

Prepared by:

Dr. Prasanna Keshava B Chairperson, YEC2	Signature with date <i>Prasanna Keshava B</i> 25/02/2023
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Reviewed by:

Dr. Rashmi Jain Member, YEC2 SOP committee	Signature with Date <i>Rashmi Jain</i> 25/2/23
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Approved by:

Dr. K. Leena Pramod Member Secretary, Convenor SOP Committee YEC2	Signature with Date <i>Leena Pramod</i> 25/02/2023
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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>K. Somayajulu</i> 29/04/23 Registrar Yenepoya (Deemed to be University) University Road, Derlakatte Mangalore - 575 018
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YENEPOYA

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YENEPOYA ETHICS COMMITTEE 2
DCGI Registration No.: ECR/1337/Inst/KA/2020
DHR registration No.: EC/NEW/INST/2020/1216

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Details of superseded SOP 08/v1

Subcommittee Convenor name	Version no	Effective date (dd/mm/yy)	Describe the main changes
Dr. Thippeswamy	V1	14.06.2018	Major revision in the SOP

Details of Current SOP 08/v2

SOP subcommittee convenor name	Version no	Effective date (dd-mm-yyyy)	Describe the main changes
Dr. Rashmi Jain	V2	25.02.2023	Major revision in the SOP

YEC2/SOP7B/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:

- The SOP applies to administrative processes concerning the preparation, distribution of the agenda and recording of the minutes of the YEC 2 meetings.
 - The SOP also applies to the administrative processes concerning the conduct of Emergency meeting of the YEC 2
- **Responsibility:**

3.1. The Chairperson will:

- Approve the date, time and venue of the YEC2 ordinary meeting
- Review and approve the agenda of the YEC2 meetings
- Call the meeting to order
- Ensure that quorum is maintained, especially in the case of clinical trials
- Ensure that conflict of interest is appropriately managed
- Permit members to attend the meeting online, if they have so requested
- Encourage all members to actively participate in the deliberations and discussions
- Ensure that no external influence is affecting the deliberations
- Provide permission for including any other matter not listed in the agenda
- Review and approve the minutes of the YEC2 meetings

3.2. The Member Secretary will:

- It is the responsibility of the Member-Secretary to prepare the agenda for the YEC 2 meeting



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- It is the responsibility of the Member-Secretary to record the minutes of the YEC 2 meeting
- It is the responsibility of the Member-Secretary to prepare the agenda and the minutes in consultation with the Chairperson

3. The YEC2 secretarial staff will:

- Assist the Member-Secretary in preparing the agenda for the YEC 2 meeting
- Circulate the agenda of the meeting after Chairperson's approval
- It is the responsibility of the Secretariat to circulate the agenda of the YEC 2 meetings to all the YEC 2 members
- Prepare the online link in case any member has requested an online attendance
- Make all the arrangements for the meeting at the venue including protocol-related files, refreshments, computers, vehicle for external members and sitting fees for the external members.
- Assist the Member-Secretary in recording the minutes of the YEC 2 meeting
- Circulate the minutes of the meeting after Chairperson's approval
- It is the responsibility of the Secretariat to circulate the minutes of the YEC 2 meetings to all the YEC 2 members.

3.3. The Members will:

- It is the responsibility of the YEC 2 members to read the agenda of the meeting.
- It is the responsibility of the YEC 2 members to read and approve the minutes of the YEC 2 meetings

- **Detailed instructions for YEC2 meeting:**

- **4.1. Scheduling of the YEC 2 Meeting:**

- **4.1.1. Offline meet:**

- The YEC 2 meeting is tentatively scheduled for every month well in advance for the whole calendar year
 - The calendar of meetings will be prepared by the Member-Secretary and approved by the Chairperson and circulated among all the members of the YEC2
 - The calendar of meetings will be displayed on the YEC2 website and the notice board of YEC2 office for easy access by the researchers planning their protocol submissions.



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- The YEC 2 meeting dates are tentatively scheduled on the 2nd Saturday of every month to ensure regularity
- 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.
- The YEC 2 will hold regular meetings at least once in every month and the interval between any two meetings will not exceed 60 days.
- If YEC2 requires to conduct additional regular meetings in view of large numbers of protocols, the Chairperson and Member-Secretary will decide the date and conduct the meeting in the same manner as the regular meeting

4.1.2. Online meet:

- The Online meet of YEC2 2 meeting dates are tentatively scheduled on the 4th Friday of every month .
- Every 4th Friday an online meet may be conducted if the number of protocols are more.
- The YEC2 secretariat will inform the members in advance to the members

4.2. Preparation of the YEC 2 meeting agenda

- The Member-Secretary assisted by the Secretariat will prepare the agenda of the next YEC 2 meeting
- The agenda is prepared at least 1 weeks before the scheduled day
- The agenda is sent to the Chairperson at least 7 calendar days before the meeting.
- The Chairperson will review the agenda and approve it
- Once approved, the agenda is circulated to all the YEC2 members at least 5 calendar days before the scheduled meeting.
- The secretarial staff will keep all the concerned documents ready to be kept for the meeting
- The secretarial staff will list and schedule the protocols in the agenda as per their receipt
- In the case of regulatory clinical trials, if the complete protocol package is received and verified, at least 21 calendar days before the next meeting, the Secretariat will add the



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protocol details in the agenda. Otherwise, the Secretariat will not table the protocol, but will keep it for tabling in the meeting after the next.

- In the case of all other protocols categorized as full review, if the complete protocol package is received and verified, at least 14 calendar days before the next meeting, the Secretariat will add the protocol details in the agenda. Otherwise, the Secretariat will not table the protocol, but will keep it for tabling in the meeting after the next.
- Resubmitted protocols received at least 7 calendar days before the YEC2 meeting are included in the agenda
- Amended protocols received at least 7 calendar days before the YEC2 meeting are included in the agenda
- All other listings on the agenda (ratifications, reports, are included for the meeting when received at least 7 calendar days before the meeting when the agenda is prepared and circulated
- Any addition to the agenda within 7 calendar days of the meeting, after circulating the agenda to the YEC2 members will be done after approval by the YEC2 Chairperson and many include reports concerning the safety of the participants or other extraordinary issues.
- YEC2 members will approve the agenda, at the start of the meeting.

4.3.Format for preparation of the agenda

- The agenda will be prepared by the secretariat in the format provided in Ann01/SOP08/v2.
- The agenda will be confirmed by the Member-Secretary and approved by the Chairperson before sending out to the members

4.4. Quorum of the meeting:

- 4.4.1. The meeting will be conducted only after the quorum is ensured by the Chairperson, as per the NDCTR-19 and the Indian GCP guidelines (whenever regulatory clinical trial protocols are for review) or the ICMR National Ethical Guidelines, 2017 (for all other types of trials)
- 4.4.2. The meeting will be conducted only after the quorum is ensured by the Chairperson.



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4.4.3. 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
- 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 **YEC2/SOP05/v2**
- 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)
- If a conflict of interest is declared, the member will step out of the meeting room when the concerned issue is being deliberated. (SOP)
- The Chairperson will initiate the meeting and the Member-Secretary will conduct the further proceedings of the meeting.
- The Member-Secretary will proceed in the order as per the agenda of the meeting.
- The protocols for initial review are discussed as per YEC2/SOP07A/v2
- The investigators who have been invited to the YEC 2 meeting for giving clarifications are allotted time to do so, but not when the protocol is being deliberated. The YEC 2 members will not discuss the protocol when the investigator is in the meeting room.
- Each point on the agenda is discussed in order by the members after the Member-Secretary provides a summary of each in brief.



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- The Secretariat provides the concerned files as and when deemed necessary.

4.5. Recording of the minutes of the meeting:

- The Secretariat will assist the Member-Secretary or another member of YEC 2 in recording the minutes of each matter discussed during the meeting.
- The Secretariat will record carefully the issues raised, the discussion, the decision and recommendations for each protocol systematically.
- The Member secretary or one of the YEC2 members will record the minutes of the meeting in writing.
- The recording of the minutes may be done on a template for minutes of the meeting in real time

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 the members present
- Name of the members absent (without prior intimation/with prior information)
- Location where the meeting was held (city, state)
- Meeting number, date/duration of the meeting (time of commencement and end)
- Names of the YEC 2 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



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- Researcher 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

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

4.6.5 Requirement for each continued review report

- Researcher 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

- Researcher 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

- Researcher name



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

4.7. Decision making:

4.7.1. The final decision on each protocol/issue is made by voting as per YEC2/SOP7B/v2

4.7.2. The decisions will include

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

4.7.3. 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 YEC 2 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)

4.8. Approval of the minutes of the meeting

- The Secretariat will check the correctness of the report
- The minutes of the meeting will be circulated to all the members present during the meeting to ensure of the content regarding protocol/issue discussed.
- In case of any addition or deletion in the minutes of the meeting member should inform the secretariat in writing/by email within day or 2 of receiving this email
- If no response received from some of the members , it will be considered as approved.



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- 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
- The Minutes of the meeting will be circulated Members who were absent in the meeting for ratification
- The Signature of the members for ratification will be taken in the YEC2 meet (Offline_
- The Chairperson will review the summary and approve the minutes of the meeting by email
- The Secretariat will circulate the approved minutes of meeting to all the members of YEC 2 within 02 working days by email
- The YEC 2 members who were present on the meeting will also approve the minutes by email
- A copy of the minutes of the meeting is forwarded to the Registrar of the Yenepoya University for information within 21 days by email

4.9. Filing of the minutes of the meeting

- The Secretariat will file the original document of the minutes of the meeting duly signed by the Member-Secretary and the Chairperson in the YEC 2 file for Minutes of the meeting
- The Secretariat will file the decision forms for each protocol in the respective protocol files'

5. Detailed instructions for Emergency meeting of YEC 2

5.1 Decision of conducting the meeting:

- 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



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- Other reasons as deemed necessary by the Member-Secretary or the Chairperson

5.2 Preparation for the meeting:

- The Secretariat will contact all the YEC 2 members and inform them the date, time and venue of the meeting along with the reason for calling the emergency meeting.
- The Secretariat will prepare the documents regarding the issue to be discussed along with the concerned protocol, if any, and other supporting files.
- The Secretariat will email the concerned documents to all the YEC 2 members

5.3 Conduct of the meeting:

- The Chairperson will determine the quorum at the scheduled time
- If the quorum is not met, the meeting will be postponed by 15 minutes.
- 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.
- Depending on the matter for discussion, the YEC 2 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
- The minutes of the meeting are prepared, reviewed, approved, circulated and filed as in the YEC 2 meeting



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6. References to other applicable SOPs:

- 6.2. **YEC2/SOP05/v2:** Procedures for allowing Guest/ Observer to visit Institutional Ethics Committee or attend YEC 2 meeting:
- 6.3. **YEC2/SOP06/v2:** Management of Research Study Protocol and Study Related Documents Submitted for Ethics Review
- 6.4. **YEC2/SOP07/v2:** Categorization of Submitted Protocols for Ethics Review

7. Annexures:

- **YEC2/Ann01/SOP08/v2-** Agenda format
- **YEC2/Ann02/SOP08/v2-** Conflict of Interest form to be signed by YEC 2 member before board meeting
- **YEC2/Ann03/SOP08/v2-** Leave absence format

YEC2/Ann 01/SOP08/v2
Agenda format

Agenda of the YEC 2 Meeting:

1. Meeting No: YEC2 mm/yyyy
2. Location of the meeting:
3. Meeting Date:
4. Meeting time:
5. The YEC 2 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 PI 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/



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- 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 YEC 2 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

YEC2/Ann02/SOP08/v2

Conflict of Interest form to be signed by YEC 2 member before the meeting

Date:

To

The Chairperson, YEC 2

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



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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 YEC 2 SOPs.

Signature of the YEC 2 member

Name and date

Signature of the Chairperson/Member-Secretary with date

YEC2/Anno3/SOP08/v2

Leave absence format

To

The Chairperson,

YEC2

Subject: Leave of absence for the YEC2 meeting

Dear Sir/ Madam,

This is to inform you that I will not be able to attend the YEC2 meeting. Kindly consider the same.

Date of the YEC2 meeting:

Reason for the leave of absence:

Are you assigned to be the Lead discussant/ reviewer for any protocol?



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(If yes, details of the protocol) :

Date of informing the same to YEC2

Signature of the YEC2 member with date:



7. Flow chart:

