

Title: Agenda preparation, meeting procedures and recording of minutes

SOP Code: SOP08/v4

Effective Date: 01/07/2023

Prepared by:

Dr. Uma Kulkarni Convenor, YEC-1 SOP Subcommittee	Signature with date:  1/6/23
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Approved by:

Dr. Vikram Shetty, Chairperson, YEC-1	Signature with date:  6/6/23
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Notified by:

Registrar, Yenepoya (deemed to be University)	Signature with date:  7/6/23
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Details of superseded SOP08

Subcommittee convenor name	Version	Effective date (dd-mm-yyyy)	Describe the main change(s)
Dr. Vina Vaswani	v1.4	10-08-2015	Major revision
Dr. Ravi Vaswani	v2	01-08-2016	Major revision following FERCAP assessment (2016)
Dr. Uma Kulkarni	v3	03-10-2019	Major revision following introduction of NDCTR-19, FERCAP and NABH assessment

Details of current SOP08/v4

Name of SOP subcommittee convenor	Version	Effective date	Describe the main change(s)
Dr. Uma Kulkarni	v4	01-07-2023	<ol style="list-style-type: none"> Glossary section added in the SOP Option added for conduct of EC meeting online/offline Option added for using online meeting link, Google form for attendance and voting Agenda approval added to agenda & minutes templates Quorum requirements have been elaborated to align with current guidelines

Table of Contents:

SI No	Content	Page
1	Purpose	3
2	Scope	3
3	Responsibility	3
4	Definitions	4
5	Detailed instructions for YEC-1 meetings	4
6	Detailed instructions for extraordinary YEC-1 meetings	11
7	References	12
8	Annexures	13
9	Flowchart	19
10	Glossary	20

1. **Purpose:** The purpose of this Standard Operating Procedure (SOP) is to describe the process and provide detailed instructions for the preparation, review, approval and distribution of the agenda and minutes of the YEC-1 meetings (regular and extraordinary).
2. **Scope:**
 - 2.1. This SOP applies to processes concerning the preparation and distribution of the agenda, and recording of the minutes of the YEC-1 meetings (online, offline or hybrid).
 - 2.2. This SOP also applies to the processes concerning the conduct of extraordinary meetings of YEC-1.
3. **Responsibilities:**
 - 3.1. **The YEC-1 Chairperson will**
 - 3.1.1. Approve the date, time and venue of the YEC-1 ordinary meeting
 - 3.1.2. Review and approve the agenda of the YEC-1 meetings
 - 3.1.3. Call the meeting to order
 - 3.1.4. Ensure that quorum is maintained, especially in the case of clinical trials
 - 3.1.5. Ensure that conflict of interest is appropriately managed
 - 3.1.6. Permit members to attend the meeting online, if they have so requested
 - 3.1.7. Encourage all members to actively participate in the deliberations and discussions
 - 3.1.8. Ensure that no external influence is affecting the deliberations
 - 3.1.9. Ensure that the members vote after the deliberations
 - 3.1.10. Exercise casting vote as and when necessary.
 - 3.1.11. Provide permission for including any other matter not listed in the agenda
 - 3.1.12. Review and approve the minutes of the YEC-1 meetings
 - 3.2. **The YEC-1 Member-Secretary will**
 - 3.2.1. Plan the dates, time and oversee the arrangements for the venue for the ordinary meetings of YEC-1
 - 3.2.2. Prepare the agenda
 - 3.2.3. Record the minutes of the meeting
 - 3.2.4. Get the minutes of the meeting approved by the Chairperson and YEC-1 members
 - 3.3. **The YEC-1 secretarial staff will**
 - 3.3.1. Assist the Member-Secretary in preparing the agenda for the meeting
 - 3.3.2. Table all regulatory clinical trial protocols for the forthcoming meeting, if the complete protocol package is received at least 21 calendar days before the date of the meeting.

- 3.3.3. Table all other full review protocols for the forthcoming meeting, if the complete protocol package is received at least 14 calendar days before the date of the meeting
- 3.3.4. Circulate the agenda of the meeting after Chairperson's approval
- 3.3.5. Prepare the online link in case any member has requested an online attendance
- 3.3.6. Prepare the attendance forms, voting forms and decision forms for each full review protocol
- 3.3.7. 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.
- 3.3.8. Assist the Member-Secretary in recording the minutes of the meeting
- 3.3.9. Circulate the minutes of the meeting after Chairperson's approval
- 3.4. **The YEC-1 members will:**
 - 3.4.1. Read the agenda of the meeting
 - 3.4.2. Read and approve the minutes of the meetings

4. **Definitions:**

- 4.1. Agenda of the YEC-1 meetings: Refers to the systematic list of meeting activities, prepared ahead of the meeting, in the order in which they are to be taken up for discussion in the YEC-1 meeting, starting from greeting and calling the meeting to order to adjournment of the meeting (AnnSOP08/v4).
- 4.2. Minutes of the YEC-1 meeting: Refers to the detailed notes taken by a member of YEC-1 during a meeting as the meeting proceeds, in order to capture accurate and clear record of the proceedings of the meetings in order to ensure transparent functioning of YEC-1.

5. **Detailed instructions for YEC-1 meeting:**

- 5.1. **Calendar of meetings:**
 - 5.1.1. YEC-1 will prepare a calendar of meetings for the year in advance.
 - 5.1.2. The calendar of meetings will be prepared by the Member-Secretary and approved by the Chairperson and circulated among all the members of the YEC-1
 - 5.1.3. The calendar of meetings will be displayed on the YEC-1 website and the notice board of YEC-1 office for easy access by the researchers planning their protocol submissions.
 - 5.1.4. Meetings will be scheduled at least once a month on a day preferably on a fixed week day as per the general convenience of the members
 - 5.1.5. If any rescheduling of the meeting day and time is required for any reason, the Member-Secretary will take approval from the Chairperson and inform the YEC-1 members by email/telephone at least 4 calendar days in advance, unless justified by unavoidable/extraordinary situations.

- 5.1.6. The YEC-1 will hold regular meetings at least once in every month and the interval between two meetings will not exceed 60 calendar days.
- 5.1.7. If YEC-1 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.

5.2. Preparation of the YEC-1 meeting agenda:

- 5.2.1. The Member-Secretary assisted by the secretariat will prepare the agenda for every YEC-1 meeting
- 5.2.2. The agenda is prepared at least 7 calendar days before the scheduled meeting
- 5.2.3. The agenda is sent to the Chairperson at least 7 calendar days before the meeting.
- 5.2.4. The Chairperson will review the agenda and approve it
- 5.2.5. Once approved, the agenda is circulated to all the YEC-1 members at least 5 calendar days before the scheduled meeting.
- 5.2.6. The secretarial staff will keep all the concerned documents ready to be kept for the meeting
- 5.2.7. The secretarial staff will list and schedule the protocols in the agenda as per their receipt
- 5.2.8. 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 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.
- 5.2.9. 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.
- 5.2.10. Resubmitted protocols received at least 7 calendar days before the YEC-1 meeting are included in the agenda
- 5.2.11. Amended protocols received at least 7 calendar days before the YEC-1 meeting are included in the agenda
- 5.2.12. 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
- 5.2.13. Any addition to the agenda within 7 calendar days of the meeting, after circulating the agenda to the YEC-1 members will be done after approval by the YEC-1 Chairperson and many include reports concerning the safety of the participants or other extraordinary issues.
- 5.2.14. YEC-1 members will approve the agenda, at the start of the meeting.

5.3. Format for preparation of the agenda

- 5.3.1. The agenda will be prepared by the secretariat in the format provided in Ann01/SOP08/v4.
- 5.3.2. The agenda will be confirmed by the Member-Secretary and approved by the Chairperson before sending out to the members

5.4. At the meeting:

- 5.4.1. The secretarial staff will make sure that the meeting venue, equipment and facilities are available for the meeting day. In case there is a change in the venue, the secretariat will inform the members as soon as possible.
- 5.4.2. If the meeting is being conducted online, or if some of the members are attending the meeting online, the secretarial staff share a secure meeting link with the members.
- 5.4.3. For online or hybrid meetings, the secretariat will create a Google form to mark the attendance which will be shared with the online members at the beginning of the meeting.
- 5.4.4. For online or hybrid meetings, the secretariat will create a Google form for voting purposes for each protocol, which will be shared with the members at the end of the deliberation of each protocol for initial full review, resubmission for full review and protocol amendments.

5.5. Quorum for the meeting:

- 5.5.1. The main business of 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)
- 5.5.2. The following seven categories of members will constitute the quorum (above and beyond the five mentioned in both, the rules and the guidelines):
 - 5.5.2.1. One basic medical scientist (preferably a pharmacologist)
 - 5.5.2.2. One social worker (or a social scientist, theologian, ethicist, member or representative of a non-governmental voluntary agency or a similar person)
 - 5.5.2.3. A clinician
 - 5.5.2.4. A lay person
 - 5.5.2.5. A legal expert
 - 5.5.2.6. Chairperson or acting Chairperson in the absence of Chairperson
 - 5.5.2.7. Member Secretary/Joint Secretary or any other designated internal member in the absence of Member Secretary/Joint Secretary
- 5.5.3. The quorum will be maintained in line with the current regulatory guidelines and national ethical guidelines, in force, from time to time.
- 5.5.4. If the quorum is not present, the meeting will be adjourned by 15 minutes, until the quorum requirement is met.

- 5.5.5. If the quorum requirement is still not met, the meeting will be rescheduled within the next 7 calendar days, or the next suitable date as decided by the Chairperson..
- 5.5.6. During the deliberation of a protocol, if a member declares conflict of interest and recuses himself, the quorum must be reassessed and must be ensured.
- 5.6. **Guest/observer/Invitee:** Any guest/observer/invitee (including Principal Investigator) to the YEC-1 meeting will be permitted as per SOP05/v4 after
 - 5.6.1. Permission from the Chairperson/Member-Secretary
 - 5.6.2. Signing of the confidentiality agreement form prior to attending the meeting as per Ann03/SOP3B/v4)
- 5.7. **Members' attendance:**
 - 5.7.1. The secretarial staff will take signatures from all the members present in the meeting on the attendance sheet. The online members will fill the attendance on the pre-circulated Google form
 - 5.7.2. The guest/observer will also sign the attendance sheet for the YEC-1 meeting and the same will be included in the minutes of the meetings.
- 5.8. **Conflict of interest:**
 - 5.8.1. The Chairperson will ensure that members who have any conflict of interest for one or more protocols will declare the same before beginning the meeting
 - 5.8.2. For each full review protocol, all members will declare whether or not they have any conflict of interest on the CoI form.
 - 5.8.3. The CoI forms are filed in the respective protocol file
 - 5.8.4. If a member declares CoI for a protocol, the member will step out of the meeting room when the concerned protocol comes up for deliberation.
 - 5.8.5. The conflict of interest will be minuted and be stated in the approval letter.
- 5.9. **Proceedings of the meeting:**
 - 5.9.1. The Chairperson will initiate the meeting
 - 5.9.2. Member-Secretary will proceed in the order as per the agenda of the meeting.
 - 5.9.3. Each point on the agenda will be discussed in order by the members after the primary reviewer provides a plain-language summary of each protocol.
 - 5.9.4. The Chairperson will encourage all members to contribute to the scientific discussion and ethical deliberations..
 - 5.9.5. The secretariat will provide concerned files, as and when necessary.
 - 5.9.6. If the investigator/independent consultant/community representative/guest observer has been invited to the YEC-1 meeting for giving clarifications, they are allotted time to do so, but will not be present during the deliberation and decision-making.
- 5.10. **Decision making:**
 - 5.10.1. The Chairperson will initiate the voting process.

- 5.10.2. The final decisions on initial full review protocols, resubmission for full review and amendments for full review will be done on Google forms, as per the specific SOPs.
- 5.10.3. The final decision will be based on majority voting which is defined as >50% of the members present.
- 5.10.4. In the event of a tie on the decision, the Chairperson will cast an extra vote (known as casting vote)
- 5.10.5. The following persons will not take part in the voting:
 - 5.10.5.1. An independent consultant
 - 5.10.5.2. A guest/observer/special invitee (including principal investigator)
 - 5.10.5.3. Members who have declared a conflict of interest will neither vote, nor will be present during the scientific discussion and ethical deliberation.
 - 5.10.5.4. Any member who has voted against the majority vote and wishes to express his dissent can do via the Google form for voting.
- 5.10.6. The final decisions on subcommittee reports, SAE reports, site monitoring reports and audit reports will also be done as per SOPs, but will be by voice vote of majority.
- 5.10.7. The final decision of ratification of already approved protocols will be done after brief discussion and deliberation
- 5.11. **Recording the minutes of the meeting:**
 - 5.11.1. The secretariat will assist the Member-Secretary in recording the minutes of each matter discussed during the meeting in a concise, clear and appropriate language.
 - 5.11.2. The recording of the minutes will be done on the template for minutes of the meeting real time and displayed on screen for the benefit of YEC-1 members.
 - 5.11.3. After each protocol or issue is discussed and voted, the resolutions and minutes recorded will be read out to ensure correctness of content
- 5.12. **Drafting of the minutes:**
 - 5.12.1. **The following points will be included in the beginning of the minutes of the meeting**
 - 5.12.1.1. Location, date, time and duration of the meeting
 - 5.12.1.2. Meeting number
 - 5.12.1.3. Names of the YEC-1 members and guests attending the meeting, whether in person or online, and the members absent.
 - 5.12.1.4. Name of the individual serving as Chairperson/Co-Chairperson/ Acting Chairperson for the meeting
 - 5.12.1.5. Determination of a duly constituted quorum by the Chairperson
 - 5.12.1.6. Declaration of conflict of interest by any member(s)

5.12.2. The following points will be included in all full review protocols (initial, resubmissions and amendments):

- 5.12.2.1. Protocol number
- 5.12.2.2. Protocol title with version and date
- 5.12.2.3. Investigator's name and department
- 5.12.2.4. Sponsor's name
- 5.12.2.5. Names of the primary reviewers and secondary reviewers who presented their findings
- 5.12.2.6. Discussion by the YEC-1 members, point by point (preferably under the headings of Scientific issues, Ethical issues, PIS/ICF, any other)
- 5.12.2.7. Final decision of the YEC-1 (in the form of resolutions)
- 5.12.2.8. Number of Assent and dissent votes
- 5.12.2.9. Additional decision on follow up action and dates, if required
- 5.12.2.10. Communication to the PI

5.12.3. Requirements for studies listed for ratification (initial expedited and exemption from review, amendment-expedited, study completion, continuing review, extension of studies and shredding of protocols)

- 5.12.3.1. Protocol number
- 5.12.3.2. Protocol title with version and date
- 5.12.3.3. Investigator's name and department
- 5.12.3.4. Sponsor's name
- 5.12.3.5. Final decision taken during expedited review
- 5.12.3.6. YEC-1 decision on ratification
- 5.12.3.7. Number of assent and dissent votes
- 5.12.3.8. Additional decision on follow up action and dates, if required

5.12.4. Requirements for decision on reports (SAE report, site monitoring report, audit report/ protocol deviations/violations, suspension or termination report)

- 5.12.4.1. Protocol number
- 5.12.4.2. Protocol title with version and date
- 5.12.4.3. Investigator's name and department
- 5.12.4.4. Sponsor's name
- 5.12.4.5. Summary of the report
- 5.12.4.6. Decision and recommendation at the initial level
- 5.12.4.7. Final YEC-1 decision on the report
- 5.12.4.8. Number of assent and dissent votes

- 5.12.4.9. Additional decision on follow up action and dates, if required
- 5.12.5. **All other matter including training program, communications, self assessment, etc**
 - 5.12.5.1. Summary and relevant points must be included
- 5.13. **Approval of the minutes of the meeting**
 - 5.13.1. The Member-Secretary will check the correctness and completeness of the minutes drafted
 - 5.13.2. The Member-Secretary will send the draft to the Chairperson within 5 calendar days of the meeting by email
 - 5.13.3. The Chairperson will review and approve the minutes of the meeting within 6 calendar days of the meeting
 - 5.13.4. The secretariat will circulate the approved minutes of meeting to all the members of YEC-1 within 7 calendar days of the meeting by email
 - 5.13.5. The YEC-1 members who were present at the meeting will also approve the minutes by email within a period of 2 calendar days or else their approval is presumed.
 - 5.13.6. The final approval of the minutes is done in the subsequent YEC-1 meeting when the YEC-1 Member-Secretary will read out the minutes of the previous meeting and get it approved by all members.
 - 5.13.7. The secretariat will send out the matter for communication with the various PIs as soon as possible, after the minutes are approved.
- 5.14. **Core minutes of the meeting:**
 - 5.14.1. The Member-Secretary will make a redacted copy of the minutes (known as core minutes) of the meeting consisting of the salient features of the protocol and final decision without the details of the researcher name, affiliation, discussion in the meeting, and names of the primary reviewers.
 - 5.14.2. The Member-Secretary will forward a copy of the core minutes of the meeting to the Registrar of the Yenepeya deemed to be University for information within 10 calendar days.
 - 5.14.3. The secretarial staff will maintain a copy of the core minutes of the meeting in the YEC-1 office.
 - 5.14.4. In case the audit, regulatory bodies or other bodies require copies of the YEC-1 meeting, the Member-Secretary will forward the core minutes of the meeting in order to maintain confidentiality. If requested the full copy of the minutes may be forwarded.
- 5.15. **Filing of documents:**
 - 5.15.1. YEC-1 secretariat will store the files, in a secure manner, in the designated cupboard
 - 5.15.2. The secretariat will file documents in respective files.
 - 5.15.2.1. Approved agenda in the Agenda File

- 5.15.2.2. Approved signed minutes in the Minutes File
- 5.15.2.3. Approved, signed core minutes in the Core Minutes File
- 5.15.2.4. Attendance sheet and leave of absence letters in the Attendance File
- 5.15.2.5. Conflict of interest for each protocol in the respective Protocol File
- 5.15.2.6. Extract of the minutes of the meeting in the respective Protocol File
- 5.15.2.7. Copy of the signed and received approval letter in the respective Protocol File
- 5.15.2.8. Assessment forms, decision forms, and all protocol-related communications in the respective Protocol files.

5.16. Extract of the Minutes of the Meeting

- 5.16.1. The secretarial staff will file the extract of the minutes of meeting for each protocol in the respective file
- 5.16.2. The extract of the minutes of the meeting will contain
 - 5.16.2.1. Details of the YEC-1 meeting
 - 5.16.2.2. Members present
 - 5.16.2.3. Quorum
 - 5.16.2.4. Conflict of interest declared by the members for the protocol
 - 5.16.2.5. Details of the protocol
 - 5.16.2.6. Primary reviewers
 - 5.16.2.7. Discussion and decision making
 - 5.16.2.8. Assent and dissent
 - 5.16.2.9. Recommendations to the PI

6. Detailed instructions for extraordinary meeting of YEC-1

- 6.1. **Decision to conduct the meeting:** The Member-Secretary will decide to call an extraordinary meeting in consultation with the Chairperson for any of the following reasons:
 - 6.1.1. When the SAE subcommittee decides to refer an SAE urgently to the YEC-1 meeting for deliberation and decision
 - 6.1.2. When the site-monitoring subcommittee or YEC-1 members come across a protocol violation which requires urgent attention of the YEC-1
 - 6.1.3. Any other urgent issues about the research protocols that may have an adverse impact on the participants or the community
 - 6.1.4. Alleged misconduct by a member of the YEC-1 in which case, the Chairperson may decide to conduct an extraordinary meeting.
 - 6.1.5. Any other reasons as deemed by the Member-Secretary or the Chairperson

6.2. Timing of the extraordinary meetings

6.2.1. The extraordinary meeting must be called within 2 calendar days of the decision to meet.

6.3. Preparation for the extraordinary meeting:

6.3.1. The secretarial staff will contact all the YEC-1 members and inform them the date, time and venue of the meeting along with the reason for calling the extraordinary meeting.

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

6.3.3. The secretariat will email the concerned documents to all the YEC-1 members

6.4. Conduct of the extraordinary meeting:

6.4.1. The Chairperson will determine the quorum at the scheduled time as in a regular meeting.

6.4.2. If the quorum is not met, the meeting will be adjourned by 15 minutes.

6.4.3. If the quorum is still 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. However, in such a case, a regulatory clinical trial coming under the purview of the NDCT-19 will not be included in the agenda.

6.4.4. If the extraordinary meeting has been called on account of an SAE or PD/PV, the relevant SOPs will be followed:

6.4.4.1. SAE: SOP12/v4

6.4.4.2. Protocol violation/deviation: SOP11/v4

6.4.4.3. Others, as applicable

6.4.5. The minutes of the meeting will be prepared, reviewed, approved, circulated and filed as in the YEC-1 meeting (SOP08/v4)

7. References:

7.1. ICMR's National Ethical Guidelines for Biomedical and Health Research Involving Human Participants

7.2. New Drugs and Clinical Trials Rules, 2019 of the Drugs and Cosmetics Act 1940

7.3. SOP05/v4: Procedures for allowing Guest/Observer to visit the premises of YEC-1 or attend a meeting:

7.4. SOP06/v4: Management of Research Study Protocol and Study Related Documents Submitted for Ethics Review

7.5. SOP07/v4: Categorization of Submitted Protocols for Ethics Review

7.6. SOP11/v4: Protocol deviations/violations

7.7. SOP12/v4: SAE reporting

8. Annexures:

- 8.1. Ann01/SOP08/v4: Format for the agenda of the YEC-1 meeting
- 8.2. Ann02/SOP08/v4: Members' attendance in YEC-1 meeting
- 8.3. Ann03/SOP08/v4: Letter of leave of absence of the YEC-1 members
- 8.4. Ann04/SOP08/v4: Declaration of Conflict of Interest for full review protocols tabled in the YEC-1 meeting
- 8.5. Ann05/SOP08/v4: Template for Minutes of Meeting

Ann 01/SOP08/v4: Format for the agenda of the YEC-1 meeting

Meeting details: Meeting number, date, time, venue, Name of the Chairperson

1. Welcome by Member-Secretary
2. Member's leave of absence information/letter, if any
3. Ensuring quorum by the Chairperson
4. Declaring conflicts of interest, if any, for any protocol tabled in the agenda by the YEC-1 members
5. Approval of the tabled agenda
6. Reading and approving the minutes of the previous meeting
7. Action taken report (if any)
8. Initial Full Review protocols (Protocol details to include protocol number, investigator's name, type of study, sponsor details)
9. Resubmission for full review
10. Amended protocols for full review
11. Continuing review of protocols
12. Number of protocols granted extension of EC approvals
13. Study completion reports
14. Protocol deviations/ violation reports
15. List of protocols which were issued ethical clearance after expedited review for ratification
 - a. Initial expedited review protocols
 - b. Resubmissions for expedited reviews
 - c. Amended protocols
16. Waiver of consent
17. Protocols exempted from review
18. Termination/suspension of studies
19. Site monitoring reports
20. Serious adverse events/ other reports
21. Subcommittee reports, if any
22. List of protocol documents for shredding
23. Any issues raised by the members regarding YEC-1 functioning like YEC-1 policies/training of members/ revising SOPs/etc
24. Training session of the Members: topic and speaker
25. Communications with regulatory authorities/ management or others
26. Self assessment (at year-end only)
27. Any other matter:

Signature: Chairperson/Member Secretary

Ann02/SOP08/v4: Members' attendance in YEC-1 meeting

Meeting details: Meeting number, Date, Time, Venue, Name of the Chair
Names of the members attended: Affiliation: Role in the YEC-1: Signature

S. No.	Name of the YEC-1	Role in the	Internal/ External	Signature with
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	Member	YEC-1		date

List of other person who attended meeting:

S. No.	Name	Reason	Signature; date

Signature of the Member-Secretary/Chairperson; date and time

Ann03/SOP08/v4: Leave of absence letter of YEC-1 member (either letter format or email)

Date:

To
The Member-Secretary,
YEC-1

Subject: Leave of absence for the YEC-1 meeting

Dear Sir/ Madam,

This is to inform you that I will not be able to attend the ____ YEC-1 meeting. Kindly consider the same.

Date of the YEC-1 meeting:

Reason for the leave of absence:

I am/I am not assigned to be the primary reviewer/ reviewer for any protocol:

If yes, Protocol Number:

Name & signature of the YEC-1 member

Ann04/SOP08/v4: Declaration of Conflict of Interest protocols tabled in the YEC-1 meeting

1. Meeting details: Meeting number, Date, Time, Venue
2. Protocol Number:
3. Title of the Protocol
4. Name of the PI
5. Department:
6. Nature of review: Initial full review/ resubmission/ amendment

S. No	Name of the YEC-1 member present in the meeting	Role in the YEC-1	Conflict of interest present? Yes/ No	If yes, CoI form filled? Yes/No	Signature of YEC-1 member with date

Ann05/SOP08/v4: Template for the Minutes of the meeting

Yenepoya Ethics Committee-1 Minutes of the Meeting

The ____ meeting of the Yenepoya Ethics Committee -1 was held on _____ at ____ AM in the _____. _____ chaired the meeting.

The following members were present:

S. No	Name	Designation	Medical/Non-medical/Scientific/	Male/Female	Online/In

		in YEC-1	non scientific		person

The following members were granted leave of absence:

S. No	Name	Designation in YEC-1	Medical/ Non-medical/Scientific/non scientific	Male/Female

The following items as per the agenda were discussed:

1. Member-Secretary welcomed the members and handed over the proceedings to Chairperson.
2. Members were informed about the leave of absence of members.
3. The Chairperson confirmed that the quorum was present and declared the meeting open.
4. The Chairperson clarified whether any member had conflict of interest.

The Chairperson called upon the Member-Secretary to start the business on the agenda.

5. The agenda for the meeting which was circulated prior to the meeting was approved
6. The minutes of the _YEC meeting which were circulated earlier were displayed and approved
7. Action taken report:

No	Meeting	Agenda	Resolution	Action taken	Approved/Ratified

8. Initial full review protocols (n=)

S No	Protocol No	Details
1.		Title: Name of the PI & Department: Type of study: Sponsor: Names of the primary reviewers: Discussion: Conflict of interest: Resolution: Type of modifications/ Type of resubmission/ Choice of resubmission reviewers/ Continuing review (or audit)/ Site monitoring visit Chairperson's casting vote/ Assent vote: Dissent vote: Matter for communication to the PI:

9. Resubmission protocols for full review: (n=)

S No	Protocol No	Details
.1.		Title: Name of the PI and Department: Type of study: Sponsor: Name of the Primary Reviewer: Conflict of interest: Discussion: Resolution: Type of modifications/ Type of resubmission/ Choice of resubmission reviewers/ Continuing review (or audit)/ Site monitoring visit Assent vote: Dissent vote: Matter for communication to the PI:

10. Protocol amendments (for full review) (n=)

Protocol No	Details
	Title: Name of the PI: Type of study: Sponsor: Name of the Reviewer: Nature of amendment: Discussion: Resolution: Assent vote: Dissent vote: Matter for communication to the PI:

11. Periodic review and continuing review:

Protocol No	Details
	Title: Name of the PI: Type of study: Sponsor: Name of the Reviewer: Decision of the reviewer: Discussion: Resolution: Assent vote: Dissent vote: Matter for communication to the PI:

12. Number of protocols granted extension of EC approvals: For ratification (n=)

S. No.	Protocol No	Title of the protocol	PI	Type of study	Date and validity of issue	Ratification

13. Completion reports (for ratification):

S. No.	Protocol No	Title of the protocol	PI	Type of study	Date and validity of issue	Ratification

14. Protocol Deviations / Violations – (n=)

Protocol No	Details
	Title: Name of the PI: Type of study: Sponsor: Name of the Reviewer: Nature of protocol deviation: Recommendation of the reviewer/Member-Secretary: Discussion: Resolution: Assent vote: Dissent vote:



	Matter for communication to the PI:
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15.

A. Expedited Review approved for ratification (n=):

S. No.	Protocol No.	Title of the protocol	PI	Type of study	Date of issue & validity	Ratification

B. Initial full review protocol resubmitted for expedited review and approved:

S. No.	Protocol No.	Title of the protocol	PI	Initial reviewers	Type of study	Date of issue & validity	Ratification

C. Amended protocols approved (for ratification): (n=)

S. No.	Protocol No.	Title of the protocol	PI	Type of study	Nature of amendment	Date of issue	Ratification

16. Waiver of Consent forms approved (n=):

S. No.	Protocol No.	Title of the protocol	PI	Type of study	Ratification

17. Exemption from ethical review (n=):

S. No.	Protocol No.	Title of the protocol	PI	Department	Date of Approval	Ratification

18. Termination/suspension (n=):

S. No.	Protocol No.	Title of the protocol	PI	Type of study	Reason for termination

19. Auditing reports – For review (n=):

	Protocol No	Details
		Title: Name of the PI: Name of the Auditor: Brief summary of the Audit: Decision of the Auditors: Discussion: Resolution: Assent vote: Dissent vote: Matter for communication to the PI:

20. SAE Subcommittee Meeting for YEC-1 review (n=):

		Title: Name of the PI: Brief summary of the SAE subcommittee report :



		Decision of the SAE subcommittee: Discussion: Resolution: Assent vote: Dissent vote: Matter for communication to the PI:
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21. SAE/Safety reports/ DIL for review (n=):

	Protocol No.	Title: Name of the PI: Type of study Sponsor Type: Adverse event/Serious adverse event/ SUSAR/Other Site: Onsite/Offsite Brief summary of the SAE report: Decision of the SAE subcommittee: Discussion: Resolution: Assent vote: Dissent vote: Matter for communication to the PI:
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22. List of protocol documents for shredding (n=):

No.	Protocol No.	Title of the protocol	Completion report ratified meeting	Completion date	Ratification

23. Training Session:

S. No	Training session topic	Resource person	Remarks

24. Correspondence from regulatory authorities, university and other communications: (n=)

S. No	Communication details	Remarks

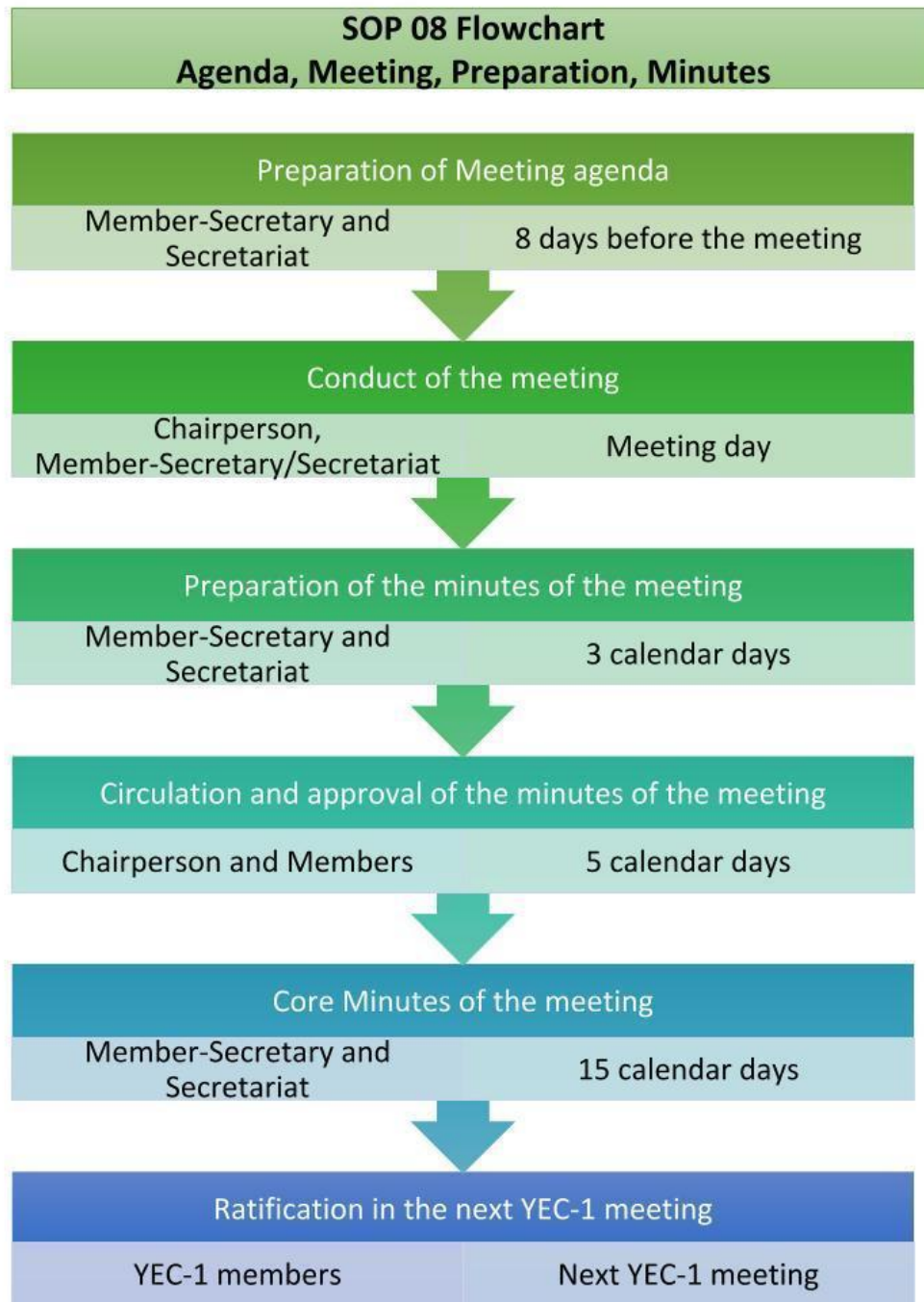
25. Any other matter with the permission of the chair:

Prepared by: Signature of the secretariat staff with date and place

Checked by: Signature of the Member Secretary with date and place

Approved by: Signature of the Chairperson with date and place

9. **Flowchart:**



10.

11. **Glossary:**

Guest/observer: A person who visits YEC-1 secretariat or attends YEC-1 meeting for the purpose of audit, observing, providing inputs or training

IC: Independent Consultant

ICMR: Indian Council of Medical Research

PI: Principal Investigator

Protocol: Protocol refers to a set of documents that contain the detailed components of the proposed study

Protocol Amendment: Any change in any of the protocol components (title, study design, methodology, sample size, sample/data collection, sample/data handling, data analysis or any other change) after YEC-1 approval is referred to as protocol amendment

Protocol Deviation: Any research-related activity by the researchers that is different from that mentioned in the approved protocol that may or may not result in increased risk to participants

Protocol package: The protocol package refers to the set of documents that contain the detailed components of the proposed study

Protocol Resubmission: Any change in any of the protocol components (title, study design, methodology, sample size, sample/data collection, sample/data handling, data analysis or any other change) before YEC-1 approval is referred to as protocol resubmission

Protocol Violation: Any research-related activity by the researchers that is different from that mentioned in the approved protocol that may or may not result in increased risk to participants

SAE: Serious Adverse Event