


Title: Agenda preparation, meeting procedures and recording of minutes

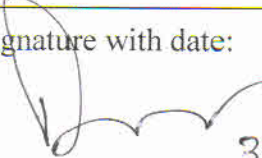
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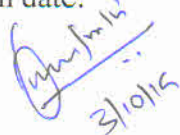
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- 1. Purpose:** The purpose of this Standard Operating Procedure (SOP) is to describe the administrative process and provide detailed instructions for the preparation, review, approval and distribution of the agenda and minutes of the YEC-1 meetings (regular and emergency meetings).
- 2. Scope:**
 - 2.1. The SOP applies to administrative processes concerning the preparation, distribution of the agenda and recording of the minutes of the YEC-1 meetings.
 - 2.2. The SOP also applies to the administrative processes concerning the conduct of emergency meeting of the YEC-1.
- 3. Responsibilities:**
 - 3.1. The YEC-1 Chairperson will**
 - 3.1.1. Review and approve the agenda of the YEC-1 meetings
 - 3.1.2. Review and approve the minutes of the YEC-1 meetings
 - 3.2. The YEC-1 Member-Secretary will**
 - 3.2.1. Prepare the agenda
 - 3.2.2. Record the minutes of the meeting
 - 3.2.3. 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. Circulate the agenda of the meeting
 - 3.3.3. Assist the Member-Secretary in recording the minutes of the meeting
 - 3.3.4. Circulate the minutes of the meeting
 - 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 an order in which they are to be taken up for discussion in the YEC-1 meeting, starting from greetings and calling the meeting to order to adjournment of the meeting.

- 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 an 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 is displayed on the YEC-1 website, the notice board of YEC-1 office for easy access by the researchers planning their studies
- 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/emergency situation.
- 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. Clinical trials received at least 21 calendar days before the YEC-1 meeting are included
 - 5.2.9. Other full review protocols received at least 15 calendar days before the YEC-1 meeting are included in the agenda
 - 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 emergency issues
 - 5.2.14. The Secretarial staff will make sure that the meeting venue, equipment and facilities are available for the meeting day.
- 5.3. Format for preparation of the agenda**
- 5.3.1. Welcome & leave of absence information/letter, if any
 - 5.3.2. Ensuring quorum by the Chairperson
 - 5.3.3. Declaring conflicts of interest, if any, for any protocol tabled in the agenda by the YEC-1 members
 - 5.3.4. Reading and approving the minutes of the previous meeting
 - 5.3.5. Action taken reports (if any)
 - 5.3.6. Initial Full Review protocols
 - 5.3.7. Resubmission for full review
 - 5.3.8. Amended protocols for full review

- 5.3.9. Continuing/periodic review of clinical trials
 - 5.3.10. List of protocols which were issued ethical clearance after expedited review for ratification
 - 5.3.10.1. Initial expedited review protocols
 - 5.3.10.2. Resubmissions for expedited reviews (initial full reviews)
 - 5.3.10.3. Amended protocols
 - 5.3.11. List of protocols which were exempted from review for ratification
 - 5.3.12. Waiver of consent approved (for ratification)
 - 5.3.13. Continuing reviews (extensions)
 - 5.3.14. Study completion reports (including time lapse of 180 days)
 - 5.3.15. Termination/suspension of studies
 - 5.3.16. Site monitoring reports
 - 5.3.17. Serious adverse events/ other reports
 - 5.3.18. Protocol deviations/ violation reports
 - 5.3.19. List of protocol documents for shredding
 - 5.3.20. Duplicate EC approval issued
 - 5.3.21. Post-approval communications
 - 5.3.22. Any issues raised by the members regarding YEC-1 functioning like YEC-1 policies/training of members/ revising SOPs/etc
 - 5.3.23. Training session of the Members: topic and speaker
 - 5.3.24. Communications with regulatory authorities/ management or others
 - 5.3.25. subcommittee reports, if any
 - 5.3.26. Any other matter:
- 5.4. **Quorum for the meeting:**
- 5.4.1. The meeting will be conducted only after the quorum is ensured by the Chairperson.
 - 5.4.2. The quorum will consist of
 - 5.4.2.1. One basic medical scientist (preferably a pharmacologist)
 - 5.4.2.2. One social worker (or a social scientist, theologian, ethicist, member or representative of a non-governmental voluntary agency or a similar person)
 - 5.4.2.3. A clinician
 - 5.4.2.4. A lay person

- 5.4.2.5. A legal expert (in case of regulatory clinical trial)
- 5.4.3. The quorum will be maintained in line with the current regulatory guidelines
- 5.4.4. If the quorum is not present, the meeting will be delayed by 15-30 minutes, until the quorum requirement is met.
- 5.4.5. If the quorum requirement is still not met, the meeting is rescheduled within the next 7 calendar days.
- 5.5. **Guest observer/Invitee:** Any guest observer to the YEC-1 meeting will be permitted as per SOP05/v3 after
- 5.5.1. Permission from the Chairperson/Member-Secretary
- 5.5.2. Signing confidentiality agreement form prior to attending the meeting as per SOP3B/v3
- 5.6. **Members' attendance:**
- 5.6.1. The Secretarial staff will take signatures from all the members present in the meeting on an attendance sheet, or alternately on a Google form circulated on the social media group of YEC-1.
- 5.6.2. 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.
- 5.7. **Conflict of interest:**
- 5.7.1. The Chairperson will ensure that all members who have any conflict of interest for one or more protocols will declare the same before beginning the meeting
- 5.7.2. For each full review protocol, all members will declare whether or not they have any conflict of interest on the CoI form.
- 5.7.3. The CoI forms are filed in the respective protocol file
- 5.7.4. If a member declares CoI for a protocol, the member will step out of the meeting room when the concerned protocol is being deliberated and voted on.
- 5.8. **Proceedings of the meeting:**
- 5.8.1. The Chairperson will initiate the meeting
- 5.8.2. The Member-Secretary will proceed in the order as per the agenda of the meeting.
- 5.8.3. The protocols for initial review are discussed as per SOP7A/v3

- 5.8.4. Each point on the agenda is discussed in order by the members after the lead discussant provides a summary of each in brief.
- 5.8.5. The Secretariat provides the concerned files as and when deemed necessary.
- 5.8.6. If an investigator has been invited to the YEC-1 meeting for giving clarifications, they are allotted time to do so, but not when the protocol is being deliberated and not during decision making.
- 5.8.7. Others invited to the meeting including the Independent expert or community representatives and guest observers are permitted to sit through the deliberation of the protocol, but will not take part in the decision making.
- 5.9. **Decision making:** The final decision on each protocol/issue is made by voting as per SOP7A/v3, using a Google form, circulated on the social media group of YEC-1.
 - 5.9.1. The final decisions on initial full review protocols, resubmission for full review and amendments for full review are done as per the specific SOPs.
 - 5.9.2. The final decisions on subcommittee reports, SAE reports, Site monitoring reports and audit reports will also be done as per SOPs.
 - 5.9.3. The final decision of ratification of already approved protocols is done after brief discussion and deliberation
 - 5.9.4. The final decision is based on majority voting which is defined as >50% of the members present. The Chairperson has an additional casting vote in case of a tie.
 - 5.9.5. The Chairperson initiates a voting process.
 - 5.9.6. The following members will not take part in the voting:
 - 5.9.6.1. An independent consultant
 - 5.9.6.2. A guest/observer to the YEC-1 meeting
 - 5.9.6.3. Members who have declared a conflict of interest (they will neither vote, nor will be present during the discussion and voting)

5.9.6.4. Investigator who has been invited to offer clarifications on the protocols (they will neither vote, nor will be present during the discussion and voting)

5.10. Recording of the minutes of the meeting:

5.10.1. The Secretariat will assist the Member-Secretary or another member of YEC-1 in recording the minutes of each matter discussed during the meeting in a concise, clear and appropriate language.

5.10.2. The Secretariat will record carefully the issues raised, the discussion, the decision and recommendations for each protocol systematically

5.10.3. The recording of the minutes will be done on the template for minutes of the meeting real time

5.10.4. After each protocol or issue discussed, the minutes recorded are read out to ensure correctness of content

5.11. Drafting of the minutes:

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

5.11.1.1. Location, date, time and duration of the meeting

5.11.1.2. Meeting number

5.11.1.3. Names of the YEC-1 members and guests attending the meeting

5.11.1.4. Name of the individual serving as Chairperson of the meeting in the absence of the Chairperson

5.11.1.5. Determination of a duly constituted quorum by the Chairperson to proceed with the meeting

5.11.1.6. Declaration of conflict of interest

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

5.11.2.1. Protocol number

5.11.2.2. Protocol title with version and date

5.11.2.3. Investigator's name and department

5.11.2.4. Sponsor's name

5.11.2.5. Names of the lead discussants and reviewers who presented their findings

- 5.11.2.6. Discussion by the YEC-1 members point by point
- 5.11.2.7. Final decision of the YEC-1
- 5.11.2.8. Assent and dissent votes
- 5.11.2.9. Additional decision on follow up action and dates (including periodic reviews and site monitoring visits), if required
- 5.11.2.10. Matter for communication to the PI
- 5.11.3. **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)**
 - 5.11.3.1. Protocol number
 - 5.11.3.2. Protocol title and type of study
 - 5.11.3.3. Investigator's name and department
 - 5.11.3.4. Sponsor's name (wherever applicable)
 - 5.11.3.5. Duration of validity of YEC-1 approval
 - 5.11.3.6. YEC-1 decision on ratification
 - 5.11.3.7. Nature of the amendment (in case of amended protocols)
 - 5.11.3.8. Date of completion (in case of completed protocols)
- 5.11.4. **Requirements for decision on reports (SAE report, site monitoring report, audit report/ protocol deviations/violations, suspension or termination report)**
 - 5.11.4.1. Protocol number
 - 5.11.4.2. Protocol title with version and date
 - 5.11.4.3. Investigator's name and department
 - 5.11.4.4. Sponsor's name
 - 5.11.4.5. Summary of the report (details of the event)
 - 5.11.4.6. Reason (in case of terminated/suspended protocols)
 - 5.11.4.7. Recommendation at the initial level
 - 5.11.4.8. Final YEC-1 decision on the report
- 5.11.5. **All other matter including training program, communications, self assessment, etc**
 - 5.11.5.1. Summary and relevant points must be included
- 5.12. **Approval of the minutes of the meeting**

- 5.12.1. The Member-Secretary will check the correctness and completeness of the minutes drafted
- 5.12.2. The Member-Secretary will send the draft to the Chairperson within 3 calendar days of the meeting by email
- 5.12.3. The Chairperson will review the summary and approve the minutes of the meeting by email within 5 calendar days of the meeting
- 5.12.4. The Secretariat will circulate the approved minutes of meeting to all the members of YEC-1 within 5 calendar days of the meeting by email
- 5.12.5. 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 (within 7 calendar days of the meeting)
- 5.12.6. 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. Core minutes of the meeting:

- 5.13.1. The Member-Secretary will make a copy of the minutes of the meeting consisting of the salient features of the protocol and final decision without the details of the discussion, names of the lead discussants is made
- 5.13.2. The Member-Secretary will forward a copy of the core minutes of the meeting to the Registrar of the Yenepoya deemed to be University for information within 15 calendar days by email
- 5.13.3. The Secretarial staff will maintain a copy of the core minutes of the meeting in the YEC-1 office.
- 5.13.4. 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

5.14. Filing of documents: The Secretariat will file documents in respective files

- 5.14.1. Approved agenda in the Agenda File
- 5.14.2. The Secretarial staff will file the original document of the minutes of the meeting duly signed by the Member-Secretary and the Chairperson in the YEC-1 file for Minutes of the meeting
- 5.14.3. The Secretarial staff will file the original document of the core minutes of the meeting duly signed by the Member-Secretary and the Chairperson in the YEC-1 file for Core Minutes of the Meeting
- 5.14.4. Attendance sheet and leave of absence letters in the Attendance File
- 5.14.5. Conflict of interest for each protocol in the respective Protocol File
- 5.14.6. Extract of the minutes of the meeting in the respective Protocol File
- 5.14.7. For approved protocols, a copy of the approval letter of the Protocol in the respective Protocol File
- 5.14.8. The assessment forms, decision forms, and all communications will be filed in the respective Protocol files
- 5.14.9. YEC-1 Secretariat will store the file in the designated cupboard

5.15. Extract of the Minutes of the Meeting

- 5.15.1. The Secretarial staff will file the extract of the minutes of meeting for each protocol in the respective file
- 5.15.2. The extract of the minutes of the meeting will contain
 - 5.15.2.1. Details of the YEC-1 meeting
 - 5.15.2.2. Members present
 - 5.15.2.3. Quorum
 - 5.15.2.4. Conflict of interest declared by the members for the protocol
 - 5.15.2.5. Details of the protocol
 - 5.15.2.6. Lead discussants
 - 5.15.2.7. Discussion and decision making
 - 5.15.2.8. Assent and dissent
 - 5.15.2.9. Matter for communication with the PI

6. Detailed instructions for Emergency meeting of YEC-1

- 6.1. **Decision of conducting the meeting:** The Member-Secretary will decide to call an emergency 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 emergency meeting.
 - 6.1.5. Any other reasons as deemed by the Member-Secretary or the Chairperson
- 6.2. **Timing of the Emergency meetings**
 - 6.2.1. The emergency meeting must be called within 2 calendar days of the decision of the meeting
- 6.3. **Preparation for the 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 emergency 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 Emergency 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 postponed by 15-30 minutes.
- 6.4.3. 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.
- 6.4.4. Depending on the matter for discussion, the YEC-1 emergency meeting is conducted, discussed and decision taken upon, in line with the YEC-1 meeting and the nature of the issue related to the protocol.
 - 6.4.4.1. SAE: SOP12/v3
 - 6.4.4.2. Protocol violation/deviation: SOP11/v3
 - 6.4.4.3. Others, as applicable
- 6.4.5. The minutes of the meeting are prepared, reviewed, approved, circulated and filed as in the YEC-1 meeting (SOP08/v3 as in point 5.4 to 5.12)

7. References to other applicable SOPs:

- 7.1. SOP05/v3: Procedures for allowing Guest/ Observer to visit Institutional Ethics Committee or attend YEC-1 meeting:
- 7.2. SOP06/v3: Management of Research Study Protocol and Study Related Documents Submitted for Ethics Review
- 7.3. SOP07/v3: Categorization of Submitted Protocols for Ethics Review
- 7.4. SOP11/v3: Protocol deviations/violations
- 7.5. SOP12/v3: SAE reporting

8. Annexures:

- 8.1. Ann01/SOP08/v3: Format for the agenda of the YEC-1 meeting
- 8.2. Ann02/SOP08/v3: Members' attendance in YEC-1 meeting
- 8.3. Ann03/SOP08/v3: Letter of leave of absence of the YEC-1 members
- 8.4. Ann04/SOP08/v3: Declaration of Conflict of Interest for full review protocols tabled in the YEC-1 meeting
- 8.5. Ann05/SOP08/v3: Template for Minutes of Meeting

Ann 01/SOP08/v3: Format for the agenda of the YEC-1 meeting

1. Meeting details: Meeting number, date, time, venue
2. Welcome and 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. Reading and approving the minutes of the previous meeting
6. Action taken report (if any)
7. Initial Full Review protocols
8. Resubmission for full review
9. Amended protocols for full review
10. Continuing/periodic review of clinical trial protocols
11. List of protocols which were issued ethical clearance after expedited review for ratification
 - a. Initial expedited review protocols
 - b. Resubmissions for expedited reviews (initial full reviews)
 - c. Amended protocols
12. List of protocols which were exempted from review for ratification
13. Waiver of consent issued (for ratification)
14. Continuing review (extensions)
15. Study completion reports and closed studies (due to 180 days time lapse)
16. Termination/suspension of studies
17. Site monitoring reports
18. Serious adverse events/ other reports
19. Protocol deviations/ violation reports
20. List of protocol documents for shredding
21. Duplicate EC approval issued
22. Post approval communications (from PI/Sponsor/DSMB)
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. Any other matter:

Ann02/SOP08/v3: Members' attendance in YEC-1 meeting

1. Meeting details: Meeting number, Date, Time, Venue
2. Names of the members: Affiliation: Role in the YEC-1: Signature

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

3. List of any other person who attended the meeting:

S. No.	Name of the other Member	Reason for attending the meeting	Part taken in the discussion Yes/No	Part taken in voting Yes/No	Signature with date

4. Signature of the Member-Secretary/ Chairperson with date and time

Ann03/SOP08/v3: Letter of leave of absence of the YEC-1 members

To
The Chairperson,
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:
Are you assigned to be the Lead discussant/ reviewer for any protocol:
If yes, details of the protocol: Protocol Number:
Date of informing the same to YEC-1:
Signature of the YEC-1 member with date:

Ann04/SOP08/v3: Declaration of Conflict of Interest for full review 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/ IC present in the meeting	Role in the YEC-1	Conflict of interest present Yes/ No	If yes, CoI form filled. Yes/No	Signature of the YEC-1 member with date

Ann05/SOP08/v3: Template for the Minutes of the meeting

Minutes of the ___th Meeting of Yenepeya Ethics Committee-1

The ___th meeting of the Yenepeya Ethics Committee -1 was held on _____
at ___ AM in the _____.

The following members were present:

Mention member names and designations

The following members were granted leave of absence:

Mention member names and designations

The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.

The Chairperson confirmed that the quorum was present and declared the meeting open.

The Chairperson clarified whether any member had conflict of interest.

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

The following items as per the agenda were discussed:

1. The minutes of the ___th YEC meeting were approved and passed by the members.

Action taken report: SI No; Meeting; Agenda; Resolution; Action taken; Decision

1. Full review protocols (new)(n=)

	Protocol No	Details
		Title: Name of the PI and Department: Type of study: Names of the lead discussants: Discussion (including a brief summary): Resolution (Decision): Assent vote: Dissent vote:

4. Periodic review and continuing review (for clinical trials):

Protocol No	Details
	Title: Name of the PI: Title of the study: Status: YEC-1 decision

5. Initial Expedited Review approved for ratification (n=):

S. No	Protocol No.	Title of the protocol	PI	Type of study	Date of Approval	YEC-1 decision

6. Resubmissions for expedited review (after initial full review):

S. No	Protocol No.	Title of the protocol	PI	Initial lead discussants	Type of study	Date of Approval	YEC-1 decision

7. Amended protocols:

S. No.	Protocol No.	Title of the protocol	PI	Type of study	Nature of amendment	Date of Approval	YEC-1 decision

8. Exemption from ethical review (n=):

S. No.	Protocol No.	Title of the protocol	PI	Type of study	Date of Approval	YEC-1 decision

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

S. No.	Protocol No.	Title of the protocol	PI	Type of study	YEC-1 decision

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

S. No.	Protocol No.	Title of the protocol	PI	Type of study	Date of approval of extension	YEC-1 decision

11. Completion reports (for ratification):

S. No.	Protocol No.	Title of the protocol	PI	Type of study	Date of Completion	YEC-1 decision

12. Study closure reports (including 180 days time lapse) (for ratification):

S. No.	Protocol No.	Title of the protocol	PI	Date of closure	YEC-1 decision

13. Termination/Suspension reports (N=) – for ratification

S. No.	Protocol No.	Title of the protocol	PI	Type of study	Reason for termination	YEC-1 decision

14. Site Monitoring reports (N=) – for ratification

S. No.	Protocol No.	Title of the protocol	PI	Date of SMV	SMV team	Recommendation	YEC-1 decision

15. SAE report/other report (Off-site/on-site) (n=) (for ratification/approval):

S. No.	Protocol No.	Title of the protocol	PI	Type of study	Details of the SAE	Recommendations of SAE subcommittee	YEC-1 decision

16. Protocol Deviations / Violations – (n=)

S. No.	Protocol No.	Title of the protocol	PI	Type of study	Nature of PD/PV	Recommendations	YEC-1 decision

17. List of protocol documents for shredding (n=) (for ratification)

S. No.	Protocol No.	Title of the protocol	Date of completion	YEC-1 decision

18. Duplicate EC clearance issued (n=) (for information)

S. No.	Protocol No.	Title of the protocol	PI	Type of study	Date of issue	YEC-1 decision

19. Post approval communications (n=) (for ratification)

S. No.	Protocol No.	Title of the protocol	PI	Subject	YEC-1 decision

20. Other administrative issues/request for SOP change/etc:

21. Training Session:

S. No	Training session topic	Resource person	Remarks

22. Correspondence from regulatory authorities, university and other communications: (Nil)

S. No	Communication details	Remarks

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

Date:
Place:

Member Secretary

9. Flowchart:

