Title: Agenda Preparation, Meeting Procedures and Recording of Minutes

1. Purpose

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

2. Scope

This SOP applies to administrative processes concerning the preparation of the agenda and recording minutes of all EC meetings.

3. Responsibility

- It is the responsibility of the Member Secretary assisted by the Secretariat to prepare the agenda for the EC meeting
- The Chairman will review and approve the agenda
- Ensure adherence of SMVMCH-EC functioning to the SOP/s and the agenda of the meeting.
- It is the responsibility of the Member Secretary to ensure proper recording and dissemination of the minutes after the meeting is over.
- It is the responsibility of the Member Secretary to ensure accurate and complete documentation
- It is the responsibility of all members to read and approve the minutes sent to him/her.
- The Chairman will review and finally approve the minutes

4. Detailed instructions

4.1 Before each Board meeting

- The EC Full Board meeting will be scheduled every 3 months (4 meeting/ year)
- The date of the next meeting will be intimated to the EC members well in advance.

- The Member Secretary should ensure the risk assessment and type of review required for the proposal as per ICMR 2017 guidelines and allocate ample time to the proposals for discussion.

4.2 ***Preparation of meeting agenda***

- The Member Secretary assisted by the Secretariat will prepare the meeting agenda, according to the format in AX 01/SOP 08/V4 to include:
  1. Apologies
  2. Ensure quorum throughout the meeting by Chairman (preferably for each proposal)
  3. Reading and approving minutes of the previous meeting.
  4. All proposals for Initial full board Review
  5. Ratification of expedited and exempt for review proposals
  6. All resubmitted proposals for full board review.
  7. Review of Amended proposals related documents for Full Board review.
  8. Issues for consideration
     - Continuing review of study proposals
     - Review of Study Completion Reports
     - Review of premature study termination
     - Review of Site Monitoring Visit Reports
     - SAE reports/CIOMS forms/Safety letters
     - Minutes of SAE Subcommittee (if applicable)
  9. Issues to be discussed including emergency concerns/ EC policies/ training of Members/ revising SOPs/ any other issues raised by Member(s).
  10. Any other matter referred for EC opinion or issues to be informed to the members.

11. Report of any other subcommittee or group appointed/ designated by Chairman for any specific or general purpose.
12. Any other matter

- The Secretariat will collect and verify all forms/documents for completeness and keep ready in these papers in the meeting.
- The Secretariat will schedule proposals in the agenda as per date of receipt.
- Answers to the EC queries and amended study related documents (Protocol, ICD, CRF and IB) from the investigators received 7 days before and other types of documents received 3 days prior to the date of full board EC meeting will be included in the agenda.
- The agenda for the EC meeting is prepared 3 days in advance before the date of meeting
- Any study-related document (except if related to safety of a participant including SAE report) received within 3 days preceding the date of meeting will not be considered for the meeting. It will be deferred to the next EC meeting for discussion except in some cases when the matter is urgent and important (having direct bearing on the safety of the research participants such as SAE report or major protocol violation) in the opinion of the EC Secretary or Chairman.
- In case a meeting is to be rescheduled due to unavoidable circumstances, the date and time will be informed to the EC members telephonically and/ or *via* e-mail.
- The Secretariat will send *via* e-mail to members the agenda of the meeting at least 1 day in advance of the scheduled meeting.
- The Secretariat will make sure that the meeting venue, equipment and facilities are available for the meeting day.

4.3 During the meeting

- Meeting will be held as scheduled, provided there is required quorum.

- ✓ A minimum of five members present in the meeting room.
- ✓ The quorum should include both medical, non-medical or technical or/and non-technical members.
- ✓ Minimum one non-affiliated member should be part of the quorum.
- ✓ Preferably the lay person should be part of the quorum.
- ✓ The quorum for reviewing regulatory clinical trials should be in accordance with current CDSCO requirements (NDCT rules 2019).
- ✓ No decision is valid without fulfillment of the quorum.
- ✓ If the quorum is not met during the meeting the clinical trial proposals will not be deliberated during the meeting and will be taken up for the next meeting for the review.

- At the discretion of the Chairman, guests may be allowed to observe the Board meetings (See SOP 05/V4). These guests may include a student, inspectors, auditors, members of other Ethics Committees, surveyors, regulators, members of regulatory agencies, representatives of patient groups, representatives of special interest groups, representatives of accrediting organizations, members of general public etc. All guests are required to sign a confidentiality agreement prior to attending the meeting (SOP 05/V4).
- The Secretariat will obtain signatures on the Confidentiality Guests/ observers/ Independent Consultants prior to the start of the meeting (SOP 05/V4)
- The Secretariat will obtain the signatures of all the EC members on the attendance register.
- The Chairman will initiate the meeting after ensuring that the quorum has been met. The Chairman at his/ her discretion will delegate the responsibility of conducting the meeting as per agenda to the Member-Secretary.
- The Chairman will ask the members whether anyone has any conflict(s) of interest in the proposals to be discussed and if so, to declare the conflict.

- The Secretariat will obtain signatures on the Conflict of Interest Agreement Form from members who declare a conflict (e.g. members who are PIs or Co-Is) prior to the start of the meeting
- If a conflict of interest has been declared by a member the Chairman will ask the concerned member to leave the meeting room when the concerned issue is being discussed.
- The Member Secretary will ask the members whether any points need to be discussed regarding minutes of the previous meeting. If no points are raised, the minutes will be considered as confirmed.
- The Member Secretary will present the agenda of the day's meeting for discussion.
- The meeting shall generally proceed in the order organized in the agenda. However, the Chairman may allow adjustments in the order of issues to be discussed depending on the situation.
- In case of proposals submitted for initial review; the detailed instructions given in SOP 07/V4 will be followed.
- Investigators who have been asked by the EC secretariat to provide additional information or clarifications related to their project may do so by attending the EC meeting. The discussion amongst EC members will not be done while the investigator is in the meeting room.
- For other points on the agenda, the member secretary will present the gist of the matter/ read the relevant letters from the investigator (if deemed necessary) and request the members to give their comments. The Member-Secretary assisted by the secretarial staff will also record a gist of discussions and decisions arrived on other issues discussed at the meeting.

4.4 Decision making

- The final decision on each proposal / issue discussed in the meeting shall be by voting. A majority vote is defined as 2/3rd of the members (who have reviewed the project), present at the meeting and voting.

- Decisions will include approval, disapproval, request for modifications of a study, suspension or termination of an ongoing study (SOP 06/V4)
- The following will not vote at the meeting:
  - ✓ Member(s) of the committee who is/are listed as investigator(s) on a research proposal
  - ✓ An investigator or study team member invited for the meeting
  - ✓ An independent consultant invited for the meeting to provide opinion Specific patient groups invited for the meeting

- SMVMCH-EC can give one of the following decisions:
  - ✓ Approved – with or without suggestions or comments;
  - ✓ Revision with minor modifications/amendments – approval is given after examination by the Member Secretary or expedited review, as the case may be;
  - ✓ Revision with major modifications for resubmission – this will be placed before the full committee for reconsideration for approval; or
  - ✓ Not approved (or termination/revoking of permission if applicable) – clearly defined reasons must be given for not approving/terminating/ revoking of permission.

- The schedule of the next meeting will be discussed and finalized by the members.

4.5 After the Board meeting

- The Secretariat will compose the summary of discussion and decision/s arrived in the meeting in a concise and easy-to-read style in the minutes within 7 working days of the meeting day.
- The Secretariat will make sure to cover all contents in each particular category to include the following:
  - ✓ 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 EC members and guests attending the meeting
- ✓ Name of the individual serving as Chairman of the meeting
- ✓ Determination of a duly constituted quorum by the Chairman to proceed with the meeting

- Requirements for each study or activity requesting Approval:
  - ✓ Sponsor's name, if applicable
  - ✓ Protocol number/date/version of protocol, when available
  - ✓ Investigator's name
  - ✓ Names of the Primary Reviewers who presented their findings
  - ✓ Discussion as deemed appropriate by the Chairman
  - ✓ Follow-up action decided upon
  - ✓ Reference to the investigator approval letter that lists all changes requested by the board
  - ✓ Determination of the next requested continuing review.

- Requirements for each study or activity requesting Expedited Review:
  - ➢ Sponsor's name; if applicable
  - ➢ Protocol number, if applicable
  - ➢ Investigator's name
  - ➢ Lists of expedited approval requests and outcomes.
- Requirements for each Continuing Review Report:
  - ➢ Sponsor's name; if applicable
  - ➢ Protocol number, if applicable
  - ➢ Investigator's name
  - ➢ Indication of the Board's determination to continue, terminate, or amend the study
  - ➢ Lists of recommendations or actions to be taken up with the investigator, if applicable.

- Requirements for each Adverse Event notification and Final Report:
  - Sponsor's name; if applicable
  - Protocol number, if applicable
  - Investigator's name
  - Report or summary of report provided by the SAE sub-committee
  - Actions deemed appropriate by the Board's review
- Requirements for Termination of Approval:
  - Name of the Sponsor, if applicable
  - Protocol number, if applicable
  - Investigator's name; reason for termination.

4.6 Approval of the minutes

- The Secretariat will check the correctness and completeness of the minutes and present the minutes to the Chairman for review and approval within 7 working days of the meeting day.
- The Secretariat will email the minutes of the meeting to the EC members
- The Chairman indicates approval by signing and dating the minutes (after approval in the next meeting).

4.7 Filing the minutes

- The Secretariat will place the original version of the minutes in the minutes file.
- The Secretariat will file the EC Decision Forms in the project files and place all correspondence in the appropriate files.
- The Secretariat will send a list of the studies approved and rejected by the EC at the EC meetings (title of the study with name of the Principal Investigator) to the Head of the Institute every month within 21 days of the EC meeting.

4.8 Calling an Emergency Meeting of EC

- The Member Secretary in consultation with Chairman may decide to call an emergency meeting for any one or more of the following reasons:
  - ✓ Urgent issues (which, if not decided upon early could adversely affect or have adverse impact on patient safety, public safety or national economy etc.)
  - ✓ Occurrence of unexpected serious adverse event(s).
  - ✓ Other reasons, as deemed appropriate by the Member Secretary/Chairman.
- The Secretariat will endeavor to contact each and every EC member and inform about the date, time and venue of the meeting as well as the reason for calling for the meeting.
- The administrative officer will prepare packets for distribution to the members containing the information and documents about the matter(s) for which emergency meeting is scheduled or send the relevant details via email.
- During the meeting, the Chairman/Secretary will determine if there is a quorum.
- If a quorum is not met, the meeting will be postponed for 15 minutes. However, if there is no quorum at the end of 15 minutes; the meeting would be held without a quorum provided at least four members (at least one scientific and one nonscientific member) are present, given the urgency of the matter under consideration. The EC members will act according to the relevant EC SOPs (Expedited Review, SAE review, Review of Protocol deviations/violations etc.) for discussion and decision-making on the matter under consideration. The minutes of the emergency meeting would be prepared, distributed, approved and filed as described in the steps above for regular full board meeting.

5. References to other applicable SOPs

SOP 05/V4 : Procedures for allowing Guest/ Observer to visit Institutional Ethics Committee or attend EC meeting

SOP 06/V4 : Management of Research Study Protocol and Study Related Documents Submitted for Ethics Review

SOP 07/V4 : Categorization of Submitted Proposals for Ethics Review

6. **Annexures**

Annexure 1 *AX 01/SOP 08/V4* - Agenda format

Annexure 1: AX 01/SOP 08/V4

Agenda Format

Agenda of the EC Meeting

Meeting No EC meeting nn/yyyy

Location of the meeting

Meeting Date

Meeting time

The Board meeting will proceed in the following sequences:

Period 1: 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.

Period 2: A] New Protocol Presentation, Review, Discussion and reaching a decision by voting to approve/raise queries,

B] Review the responses forwarded by the principal investigator to the query letter/ resubmitted proposals

C] Approve protocol amendment and related documents.

D] To review the continuing review report/ completion report/ final clinical trial report/ Annual report / Termination reports.

E] To review Protocol Deviations / Violations

F] To review other Letters related to proposals

G] To review Monitoring reports

G] To inform about the EC meeting and to review the policy decisions

H] To inform about the SAE Subcommittee meetings and to review

SAE/Safety reports.

I] other points for discussion

Period 3: Issues reviewed and approved by the EC member Secretary and Chairman which are to be reported **for Consideration**

Period 4: **Issues to be informed to the members at Full Board** which are approved by the EC member Secretary and Chairman and letters already sent to the principal investigator

Period 5: Other issues of interest to the members

7. Flow Chart:

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

8. References

1. Forum for Ethics review Committees in India (FERCI). Standard Operating Procedures of Institutional Ethics Committee (cited 22nd October 2018). Available from: http:// www.ferci.org/sops/

2. Ethical guidelines for biomedical research on human participants. (2017). Indian Council of Medical Research. Available from: http://www.icmr.nic.in/guidelines/ICMR_ Ethical_ Guidelines_2017.pdf
3. Ministry of Health and Family Welfare. New Drugs and Clinical Trials Rules, 2019. Available from: https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf

	Name	Designation	Signature
Prepared	Dr. Girija. S	Member	
	Dr. Nishanthi. A	Member	
Reviewed	Dr. Vimal. M	Member Secretary	
Approved	Dr. Thiagarajan. T	Chairman	
Issued	Dr. R. N. Kagne	Dean	