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8.1 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.

8.2 Scope

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

8.3 Responsibility

- It is the responsibility of the Member Secretary assisted by the Secretariat to prepare the agenda for the IEC meeting
- The Chairperson will review and approve the agenda
- 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 all members to read and approve the minutes sent to her/him.
- The Chairperson will review and finally approve the minutes


8.4 Detailed instructions

8.4.1 Committee meeting

- The IEC Full Board meeting will be scheduled once in six months or as per requirements whichever is earlier.
- If there is a long gap between two meetings the reason for the gap should be documented

8.4.2 Preparation of meeting agenda of full committee


The Member Secretary assisted by the Secretariat will prepare the meeting agenda with date, time and venue of the meeting and will include following subtopics as given below:

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- A. Declaration of COI and quorum
- B. Ratifying minutes of the previous meeting.
- C. New research proposals for Initial Review
- D. Resubmitted amended proposals and/or related documents
- E. Protocol extensions, deviations and violations
- F. Review of protocols with related documents referred for Full Committee review after expedited review.
- G. SAE reports as per Schedule Y/CIOMS forms/Safety letters if any, with minutes of SAE committee if applicable
- H. Continuing review of approved protocols
- I. Review of Study Completion Reports and premature study termination
- J. Review of Site Monitoring Visit Reports
- K. Any other matter e.g.
 - a. Emergency concerns
 - b. IEC policies
 - c. Training of Members
 - d. Revising SOPs
 - e. Any other issues raised by Member(s) or issues to be informed to the members.
 - f. Report of any other subcommittee or group appointed/ designated by Chairperson for any specific or general purpose

NOTE:


- Chairperson shall ensure availability of prescribed quorum.
- The Secretariat will collect and verify all forms/documents for completeness and make them available in the meeting.
- The Secretariat will schedule protocols in the agenda as per date of receipt.

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- The agenda for the IEC meeting is prepared at least 5 days in advance before the date of meeting.
- Answers to the IEC queries, amended study related documents (Protocol, ICD, CRF and IB) or matter related to safety of participant received from the investigators in due time (4 days prior to the date of the meeting) and any item in emergent and very exceptional circumstances will be included in the additional agenda. This would be done at the discretion of the Chairperson.
- Any study-related document which is not presented in due time will not be considered for the meeting.
- In case a meeting is to be rescheduled due to unavoidable circumstances, the date and time will be informed sufficiently in advance to the IEC members through telephone, SMS/Whatsapp /e-mail or any other electronic means.
- The Secretariat will normally send the final agenda along with notice of the meeting 14 days before the scheduled meeting.
- The Secretariat will make sure that the meeting venue, equipment and facilities are available for the meeting.

8.4.3 During the meeting


- Meeting will be held as scheduled provided the required quorum is available.
- The Secretariat will obtain the signatures of all the IEC members on the attendance register.
- The Chairperson will initiate the meeting after ensuring that the quorum has been met. The Chairperson at her/his discretion will delegate the responsibility of conducting the meeting as per agenda to the Member-Secretary.
- The Chairperson will ask the members whether anyone has any conflict(s) of interest in the projects to be discussed and if so, to declare the conflict.
- If a member has declared conflict of interest, the Chairperson will ask the member concerned to leave the meeting room when the concerned issue is being discussed.

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- The Secretariat will obtain signatures on the Conflict of Interest Agreement Form from members who declare a conflict. The fact that a member excused himself from the meeting on the ground of conflict of interest will be specifically noted in the minutes.
- 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 of the previous meeting 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 Chairperson may allow adjustments in the order of issues to be discussed depending upon the needs.
- In case of projects submitted for initial review; the detailed instructions given in this SOP will be followed.
- Investigators who have been asked by the IEC secretariat to provide additional information or clarifications related to their project may do so and attend the IEC meeting if permitted to do so. The discussion amongst IEC members will not be done while the investigator is in the meeting room.
- Any other matter will be presented by the Member Secretary for comments by the members which will be noted.
- The Member-Secretary assisted by the secretarial staff will record the gist of discussions and decisions arrived at for each item in the agenda.

8.4.4 Decision making

- The final decision on each proposal/ issue discussed in the meeting shall be by broad consensus. In case there is absence of consensus for any reason the majority view recorded as per vote shall be accepted as the decision of the IEC.
- Decisions will include approval, disapproval, revision with minor or major amendments, suspension or termination of an ongoing study

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- The following persons shall not have the right to vote at the meeting:
 - Member(s) of the committee who is/are listed as investigator(s) on a research proposal that comes up before the particular meeting of IEC.
 - An investigator, special invitee (expert) or study team member invited for the meeting

8.4.5 After the Committee meeting

- The Secretariat will prepare the minutes of the meeting in a concise and easy-to-read style soon after the meeting.
- The Secretariat will make sure to cover all contents in each particular category to include the following:
 - Name of person preparing the minutes
 - Venue of the meeting.
 - Meeting number, date/duration of the meeting (time of commencement and end)
 - Names of the IEC members and invitees attending the meeting.
 - Name of the individual serving as Chairperson of the meeting
 - Details of the study including Sponsor's name and name of investigator.
 - Protocol number/date/version of protocol.
 - Names of the Primary Reviewers who presented their findings, if any.
 - Follow-up action, if any.
 - Reference to the investigator approval letter that lists all changes requested by the IEC.
 - Determination of the date for continuing review, if any.

Requirements for each study or activity requesting Expedited Review:

- Sponsor's name.
- Protocol number.
- Investigator's name
- Lists of expedited approval requests and outcomes.

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Requirements for each Continuing Review Report:

- o Sponsor’s name, if applicable.
- o Protocol’s EC number.
- o Investigator’s name.
- o Indication of the Board’s determination to continue, terminate, or amend the study.
- o Lists of recommendations or actions to be taken up with the investigator, if applicable.

Requirements for each Adverse Event notification and Final Report:

- o Sponsor’s name, if applicable.
- o Protocol’s EC number.
- o Investigator’s name.
- o Report or summary of report provided by the SAE sub-committee.
- o Actions deemed appropriate by the IEC.

Requirements for Termination of Approval:


- o Name of the Sponsor.
- o Protocol’s EC number.
- o Investigator’s name and reason for termination.

8.4.6 Approval of the minutes

- The Secretariat will check the correctness and completeness of the minutes and present the minutes to the Chairperson for review and approval within 7 working days of the meeting day.
- The Chairperson indicates approval by signing and dating the minutes.
- On receipt of approval from the Chairman, the Secretariat will email the minutes of the meeting to the IEC members.

8.4.7 Filing the minutes


- The Secretariat will place the approved versions of the minutes in the minutes file.

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- The Secretariat will file the IEC 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 IEC at its monthly meetings along with the details of the study including name of the Principal Investigator, to the Head of the Institute, within 21 days of the IEC meeting.

8.4.8 Calling an Emergency Meeting of IEC

- The Member Secretary in consultation with Chairperson 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 with concurrence of the Chairperson.
- The Secretariat will endeavour to contact each and every IEC 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 Chairperson/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 (including one scientific and one non-scientific member) are present, given the urgency of the matter under consideration. The IEC members will act according to the relevant IEC 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

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meeting would be prepared, distributed, approved and filed as described in the steps above for regular full committee meeting.

8.4.9 Releasing IEC Decision Letters

- IEC decision letters will be prepared by the secretariat SOP 7A/V8
- Member Secretary will sign the decision letters & it will be released to the investigators within 14 working days after the meeting day.

8.5 References to other applicable SOPs

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

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


SOP 07/VI: Categorization of Submitted Protocols for Ethics Review

SOP 07A/VI: Initial Full Board Review of New Research Study Protocols

8.6 Annexures

Annexure 1 AX 01/SOP 08/VI - Agenda format

Annexure 2 AX 02/SOP 08/VI- Conflict of Interest form to be signed by IEC member before board meeting

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Annexure 1 AX01/SOP 08/V1:AGENDA FORMAT

Agenda of the IEC Meeting

Meeting No. IEC meeting


Venue of the meeting

Meeting Date

Meeting time

The Committee meeting will proceed in the following sequences:

- 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.
- 2: Consideration of other agenda items.
- 3: Other items, if any, permitted by the Chair.

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Annexure 2 AXO2/SOP 09/V1

Conflict of Interest form to be signed by IEC member before board

Date:

To,

The Chairperson,

IEC,

I hereby declare the conflict of interest for the project no. EC/ /

Entitled, _____ as :

1. I am the investigator / co-investigator/Author/member of research team
2. I have the following interest in the subject matter of the study under review

1) _____

2) _____


3) _____

4) _____

Member, IEC

Countersigned

Chairperson, IEC

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8.7 *Flowchart*

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