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**Title: Agenda Preparation, Meeting Procedures and Recording of Minutes**

**SOP Code: SOP 08/V1**

**Effective Date:** aa/bb/cccc

*[The IEC members (author/s, reviewer/s) and Chairperson will sign and date the SOP on this first page]*

**Prepared by:**

Dr. Padmaja Marathe, FERCi Member	(Signature with Date)
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**Reviewed by:**


Dr. U. M. Thatte, FERCi Secretary	(Signature with Date)
Dr. S. K. Kamat, FERCi Treasurer	(Signature with Date)

**Approved by:**

Dr. Vasantha Muthuswamy, FERCi President	(Signature with Date)
Dr. Nandini Kumar, FERCi Vice President	(Signature with Date)

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## **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 IEC meetings.

## **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 him/her.
- The Chairperson will review and finally approve the minutes


## **4. Detailed instructions**

### ***4.1 Before each Board meeting***


- The IEC Full Board meeting will be regularly scheduled once every month/ once in two months (*as applicable*).
- In every meeting, the date of the next meeting will be decided. (*It is preferable to keep a fixed day in a month such as 4<sup>th</sup> Friday or 3<sup>rd</sup> Tuesday of every month for convenience and to ensure regularity*).

### ***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/V1 to include:

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1. Apologies
2. Ensure quorum by Chairperson
3. Reading and approving minutes of the previous meeting.
4. All projects for Initial Review
5. All resubmitted protocols for full board review.
6. Review of Amended protocols or protocol-related documents for Full Board review.
7. Issues for consideration
  - Continuing review of study protocols
  - 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)
8. Issues to be discussed including emergency concerns/ IEC policies/ training of Members/ revising SOPs/ any other issues raised by Member(s).
9. Any other matter referred for IEC opinion or issues to be informed to the members.
10. Report of any other subcommittee or group appointed/ designated by Chairperson for any specific or general purpose.
11. 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 protocols in the agenda as per date of receipt.
  - Answers to the IEC queries and amended study related documents (Protocol, ICD, CRF and IB) from the investigators received 7 days before and other types of


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documents received 3 days prior to the date of full board IEC meeting will be included in the agenda. *(The timelines can be changed as per each committee policy)*


- The agenda for the IEC 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 month's 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 IEC Secretary or Chairperson.
- In case a meeting is to be rescheduled due to unavoidable circumstances, the date and time will be informed to the IEC 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***

- The committee will endeavor to hold regular meetings at least once every month. The gap between any two meetings will not exceed 60 days. *(as per IEC policy)*
- Even if there are no research proposals for review, the gap between two meetings will not exceed 12 weeks. *(as per IEC policy)*
- Meeting will be held as scheduled provided there is quorum.
- For the IEC meeting, **besides the Member Secretary and the Chairperson** the quorum will consist of:

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- One basic medical scientist (preferably a pharmacologist),
  - One social worker (or a social scientist, theologian, ethicist, Philosopher, member or representative of a non-governmental voluntary agency or a similar person),
  - A clinician,
  - A lay person from the community and
  - A legal expert
- At the discretion of the Chairman, guests may be allowed to observe the Board meetings (See SOP 05/V1). 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/V1).
  - The Secretariat will obtain signatures on the Confidentiality Guests/ observers/ Independent Consultants prior to the start of the meeting (SOP 05/V1)
  - 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 his/ her 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.
  - 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 (SOP 05/V1)
  - If a conflict of interest has been declared by a member the Chairperson will ask the concerned member to leave the meeting room when the concerned issue is being discussed.

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- 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 Chairperson may allow adjustments in the order of issues to be discussed depending on the situation.
- In case of projects submitted for initial review; the detailed instructions given in SOP 07/V1 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 by attending the IEC meeting. The discussion amongst IEC 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/V1)
- The following will not vote at the meeting:

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- 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
- 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 each meeting discussion and decision 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 IEC members and guests attending the meeting
  - Name of the individual serving as Chairperson of the meeting
  - Determination of a duly constituted quorum by the Chairperson 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 Chairperson

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- 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



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- 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 Chairperson for review and approval within 7 working days of the meeting day.
- The Secretariat will email the minutes of the meeting to the IEC members
- The Chairperson 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 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 the monthly meetings (title of the study with name of the Principal Investigator) to the Head of the Institute every month within 21 days of the IEC meeting.

#### ***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/Chairperson.
- The Secretariat will endeavor 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.

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- 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 (at least one scientific and one nonscientific 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 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/V1:** Procedures for allowing Guest/ Observer to visit Institutional Ethics Committee or attend IEC meeting


**SOP 06/V1:** Management of Research Study Protocol and Study Related Documents Submitted for Ethics Review

**SOP 07/V1:** Categorization of Submitted Protocols for Ethics Review

#### **6. Annexures**

Annexure 1 *AX 01/SOP 08/V1* - Agenda format

Annexure 2 *AX 02/SOP 08/V1*- Conflict of Interest form to be signed by IEC member before board meeting

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***Annexure 1: AX 01/SOP 08/V1***

***Agenda Format***

**Agenda of the IEC Meeting**

**Meeting No IEC 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 protocols

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 projects

G] To review Monitoring reports

G] To inform about the IEC 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

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

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

Period 5: Other issues of interest to the members

***Annexure 2: AX 02/SOP 08/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/study team
2. I have Financial interest
3. \_\_\_\_\_
4. \_\_\_\_\_
5. \_\_\_\_\_
6. \_\_\_\_\_

in the project which will be discussed in today's meeting i.e. XX day of XX month XX year.

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Dr. \_\_\_\_\_

Member, IEC

\_\_\_\_\_  
Chairperson, IEC

**7. Flow Chart:**

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 and Preparing the minutes	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