



Gullas College of *Medicine*
**RESEARCH ETHICS
 COMMITTEE**



Ethos Universitas
 HONORARY COMPANION

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Date of Approval:	
Effectivity Date:	

SOP NO. 18 - PREPARING THE MEETING AGENDA

Section 1. Policy Statement

Documents submitted on or before the 2nd Wednesday of the month shall become part of the provisional meeting agenda every 3rd Saturday of the month. Issues and concerns about a proposal that requires immediate consideration may become part of an emergency or special meeting agenda. When the Chair approves the provisional agenda, its items become part of the Notice of Meeting (Form 17.1). It shall follow an established template for meeting agenda. The provisional agenda shall be included in the Notice of Meeting. This provisional agenda shall be approved by a majority vote of the REC members present and becomes the agenda of the meeting.

Section 2. Objective/s of the Activity

Meetings should be proactively prepared to ensure a smooth, orderly, inclusive, and efficient conduct of meetings.

Section 3. Scope

This SOP starts with the drafting of a provisional agenda of a regular, special or emergency meeting and ends with its approval **by REC member present during the meeting** as the final meeting agenda.

Section 4. Workflow

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Preparation of the draft meeting agenda	Administrative Secretary and Member Secretary	1 day Every 2 nd Friday of the month or Emergency meet
Step 2: Preparation of the provisional meeting agenda	Chair	
Step 3: Distribution of the provisional meeting agenda (SOP 17 - Preparing for a Meeting)	Administrative Secretary	1 day Every 3 rd Tuesday of the month
Step 4: Approval of the provisional meeting agenda	REC Members	1 day Every 3 rd Saturday

		of the month
Step 5: Filing of the final meeting agenda (SOP 23 on Management of Active Files)	Administrative Secretary	1 day post-meeting
	TOTAL	4 days

Section 5. Detailed Procedures

Step 1: Preparation of the provisional agenda.

To ensure a structured and efficient review process, all incoming research protocols and administrative documents must adhere to a strict submission timeline.

Submission Cut-off and Classification: Only documents submitted to the Research Ethics Committee (REC) Secretariat on or before the second Saturday of each month will be officially classified and considered for inclusion. Submissions received after this deadline will automatically be deferred to the following month's cycle.

Drafting Timeline: Under the direct supervision of the Member Secretary, the Administrative Secretary is responsible for compiling these classified documents and preparing the initial draft of the Provisional Agenda using Form 18.1. This draft must be finalized on or before the second Friday of each month.

Preliminary Review: The Member Secretary will comprehensively review the compiled draft to ensure appropriate categorization of items and execute any necessary administrative or technical modifications before processing.

The Provisional Agenda must strictly follow the standardized institutional format detailed below:

1. Call to Order
2. Declaration of Quorum
3. Approval of the Provisional Agenda
4. Disclosure of Conflict of Interest (COI)
5. Review and Approval of the Minutes of the Previous Meeting
6. Business Arising from the Minutes (Updates on ongoing actions or deferred items)
7. New Business:
 - a. Initial Review of Full Review Protocols
 - b. New Protocols
 - c. Protocols for Modification
 - d. Protocols for Clarification
 - e. Report on Expedited Review of Protocols
 - f. New Protocols
 - g. Protocols for Modification
 - h. Protocols for Clarification
 - i. Report on Exempted Protocols

- j. Review of NEW & OLD Resubmissions
 - k. Review of Post-Approval Submissions
 - l. Protocol Withdrawals / Terminations
 - m. Protocol Amendments
 - n. Queries, Grievances, and Complaints
 - o. Serious Adverse Events (SAEs) / Suspected Unexpected Serious Adverse Reactions (SUSARs) / Protocol Deviations and Violations (RNE Reports)
 - p. Appeals of REC Decisions
 - q. Final Study Reports
 - r. Report on Site Visits and Monitoring Actions
 - s. Tracking of Borrowed Institutional Files
8. Other Matters (General announcements or non-protocol discussions)
 9. Adjournment

Step 2: Preparation of the provisional meeting agenda

Once the initial draft of the Provisional Agenda (Form 18.1) has been vetted by the Member Secretary, it is formally transmitted to the REC Chair.

The Chair will critically review the document to ensure that all critical items are appropriately prioritized and that the scheduled topics align with the committee's scope and current operational capacity. Upon the Chair's official sign-off and approval, the document is elevated from a draft to the official Provisional Meeting Agenda.

Step 3: Distribution of the provisional meeting agenda (see also SOP 17 Preparing for a Meeting).

To grant committee members sufficient time to review the protocols and associated documentation thoroughly, a strict distribution timeline must be maintained:

- **Timeline:** The Administrative Secretary must distribute the approved Provisional Meeting Agenda on or before the third Tuesday of each month.
- **Documentation Packet:** The agenda must be accompanied by an official Notice of Meeting (Form 17.1), the minutes of the previous meeting, and all relevant protocol dossiers assigned to specific reviewers.
- **Delivery Logistics:** Distribution may be executed via two primary channels depending on the member's preference and location:
- **Digital Distribution:** Sent via secure, confidential institutional email or uploaded to the committee's secure document-sharing portal.

- Physical Distribution: Delivered as printed hard copies via a trusted courier service.

Step 4: Approval of the provisional meeting agenda

During the opening segments of any regular, special, or emergency REC meeting, the Provisional Meeting Agenda is presented to the floor for final validation. REC members present may propose last-minute amendments, such as the deferral of an item, the addition of urgent "Other Matters," or reordering the sequence of business to accommodate guest presenters or specific expertise availability. Following any agreed-upon modifications, a formal motion to adopt the agenda must be made and seconded. Approval requires a simple majority vote (calculated as 50% of present members + 1) among the voting members present, provided a quorum has been established. The entire voting and amendment process shall strictly observe Robert's Rules of Order to ensure democratic and transparent parliamentary procedure. Once approved, the document serves as the definitive roadmap for the session.

Step 5: Filing of the final meeting agenda (SOP 23 on Management of Active Files)

Following the adjournment of the meeting, the approved agenda—reflecting any changes made during Step 4—becomes the permanent Final Meeting Agenda.

The Administrative Secretary is charged with the proper archiving of this document to maintain an airtight institutional audit trail. The Final Meeting Agenda (Form 18.1) must be filed in the dedicated corporate folder designated for committee agendas. Filings must be arranged in strict chronological order to ensure rapid retrieval during internal quality checks or external regulatory audits, in full compliance with SOP 23 - Managing Active Files.

Section 6. Forms:

- Form 17.1 – Notice of Meeting
- Form 18.1 – Meeting Agenda Template
- Form 19.1 – Attendance Sheet
- Form 20.1 – Minutes of the Meeting

Section 7. History

<i>Version No.</i>	<i>Date</i>	<i>Authors</i>	<i>Main Change</i>
01	6.21.24	NINO ISMAEL S. PASTOR	DRAFT
02	10.22.24	Dr. Marie Fe Abejar	Form labels Contents
03			

Section 8. References

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