Gullas College of *Medicine* **RESEARCH ETHICS COMMITTEE**	Version No:	Draft
	Date of Approval:	
	Effectivity Date:	

SOP NO. 19 - CONDUCT OF MEETINGS

Section 1. Policy Statement

The Chair, or as the case maybe, the Vice-Chair, or Chairperson-designate shall preside over a meeting after a quorum is declared. The order of meetings shall follow the approved agenda and follow Robert's Rules of Order. All members should disclose no conflict of interest before they approve the Provisional meeting agenda. To ensure all Committee members are thoroughly prepared to facilitate an efficient review process, the distribution of meeting materials must follow a strict administrative timeline and protocol

Section 2. Objective/s of the Activity

Meetings allow the REC to reach collegial decisions regarding study protocols, REC operations, and information about GCM research proposals and REC administrative matters.

Section 3. Scope

This SOP begins with the distribution of meeting documents. It describes how meetings will be prepared, conducted, called to order, and adjourned. It ends with the collection, storage, and disposal of meeting materials.

Section 4. Workflow

ACTIVITY	***RESPONSIBILITY***	***TIMELINE***
Step 1: Distribution of meeting materials	Administrative Secretary	4 days before monthly meetings (3rd Saturday every month)
Step 2: Declaration of quorum (formal start)	Chair or designate	During meeting
Step 3: Approval of the provisional agenda	REC Members	
Step 4: Declaration of conflict of interest (COI)	REC Members	During meeting
Step 5: Approval of minutes of the previous	REC Members	

meeting		
Step 6: Discussion of "Business arising from the minutes"	REC Members	During meeting
Step 7: Review of protocols and protocol-related submissions (SOP 6, Full Committee review)	REC Chair and Members	During meeting
Step 8: Report of results of expedited review (SOP 4 on Expedited Review (SOP 5).	Designated Reviewers	During meeting
Step 9: Discussion of operations-related and administrative matters	REC Chair and Members	During meeting
Step 10: Adjournment	Chair	During meeting
Step 11: Collection, storage, and disposal of meeting materials	Administrative Secretary	1 day post-meeting
	TOTAL	6 Days

Section 5. Description of Procedures

Step 1: Distribution of meeting materials

The Member Secretary shall officially transmit the finalized Notice of Meeting (Form 17.1) and the Provisional Agenda (Form 18.1) to the Administrative Secretary. S/he is responsible for gathering all pertinent physical and digital documents—including protocols, investigator brochures, informed consent forms, and previous review notes—from the Chair, Member Secretary, and assigned reviewers. The Administrative Secretary shall also generate the official meeting attendance sheet. All compiled materials must be systematically distributed to assigned primary reviewers, independent consultants, and other concerned committee members.

For protocols requiring a full-board Committee review, a complete physical copy of the dossier must be explicitly prepared and delivered to the Chair.

To accommodate remote participants, the Administrative Secretary must transmit secure electronic or digital copies of all meeting materials on or before the second Wednesday of each month. For special or emergency meetings, electronic dossiers must be dispatched no later than 24 hours prior to the scheduled meeting time.

Step 2: Declaration of quorum (formal start)

The formal commencement of any Research Ethics Committee (REC) meeting is strictly contingent upon the establishment and declaration of a valid quorum by the Chair. quorum is officially established when a simple majority—specifically at least five (5) out of the eight (8) voting members—is actively present. This presence may be fulfilled either face-to-face (in person) or via synchronized online video-conferencing platforms.

If a voting member is entirely unable to attend the session (either in person or online) but has submitted a comprehensive, written protocol review evaluation report prior to the call to order, their submission may be counted toward the establishment of the quorum for that specific protocol slot.

For protocols that target vulnerable populations or require specific cultural/societal context, the presence of a guest advocate or subject-matter representative is mandatory. The Chair must ensure this representative is present before the specific protocol review begins. Guest advocates, subject-matter experts, and independent consultants are present in an advisory capacity only; they do not constitute part of the official quorum and do not possess voting privileges.

Step 3: Approval of the provisional agenda

Once a quorum is formally declared, the Chair will officially open the floor to finalize the session's agenda.

The Chair will direct all members to examine the distributed Provisional Agenda. Members may propose modifications, such as reordering the sequence of protocols to accommodate guest speakers or adding urgent administrative items. If no further changes are requested, or once all accepted amendments are integrated, the Chair will call for a formal motion to approve the agenda. A committee member must explicitly move to approve the agenda, and another member must second the motion. The Chair will ask the floor for any objections or abstentions. Hearing none, the Chair will formally declare the provisional agenda approved as the definitive, binding agenda for the current meeting.

Step 4: Declaration of conflict of interest (COI)

To preserve the absolute integrity, objectivity, and credibility of the review process, the Chair must strictly enforce the committee’s Conflict of Interest policy.

The Chair ensures that all participating REC members maintain complete independence from the principal investigators, co-investigators, research staff, and funding sponsors associated with the protocols under review. A Conflict of Interest occurs when a member’s personal, professional, financial, familial, or social factors could compromise, or reasonably appear to compromise, their professional judgment and objectivity. Members are permitted to discuss and vote only on research submissions where they have absolutely no conflicting interests. Any

member possessing a COI for a specific protocol must declare it immediately during this part of the meeting.

When the conflicted protocol is called for review, the affected member must physically or digitally exit the meeting room. They may only rejoin the session after the discussion, voting, and final decision-making for that specific protocol have concluded.

The Administrative Secretary is accountable for documentation and must explicitly record the exact timestamps when the conflicted member exits and rejoins the meeting room within the official minutes.

Step 5: Approval of minutes of the previous meeting.

The Committee must review and validate the minutes of the preceding meeting to maintain an accurate legal and institutional record.

The Member Secretary shall present or digitally project the minutes of the previous meeting for collective review. Members will evaluate the text for accuracy regarding past decisions, modifications, and attendance records. Any identified errors or omissions will be noted by the Secretariat and corrected on the master document. Following the integration of corrections, the Chair will request two separate members to formally move and second the approval of the minutes. The Chair will call for objections. In the absence of any dissent, the Chair will officially declare the minutes approved, confirming them as a true and verified historical record of the committee's business.

Step 6: Discussion of Business arising from the minutes.

The Chair will systematically lead the committee through matters left pending, deferred, or requiring follow-up from previous sessions.

The Chair will report on the status of action items identified in the newly approved minutes, such as investigator responses to conditional approvals or outstanding site monitoring requests. The Chair will moderate the floor discussions regarding these ongoing issues. If a policy interpretation or final decision is required to clear an item, the Chair will call for a formal vote to resolve the matter and guide the committee toward a definitive resolution.

Step 7: Review of protocols and protocol-related submissions (SOP 5 – Expedited Review, SOP 6 Full Review)

This step represents the core evaluative component of the meeting. To preserve the accuracy of the deliberations, the Member Secretary shall ensure the entire session is audio recorded.

The Chair will recognize the assigned Primary Reviewers, request them to present their comprehensive evaluations of their designated protocol dossiers. To maintain consistency, presentations must be systematically driven by institutional criteria, utilizing the REC Reviewer Checklist (Form 4.4) and the Informed Consent Form (ICF) Evaluation Worksheet (Form 4.5). Each protocol evaluation must strictly prioritize patient safety and rights by addressing issues in the following hierarchical order:

- Ethical issues, risk-benefit ratios
- Scientific validity.
- Informed consent process
- Documentation flaws, and
- Language accessibility.

The primary author or principal investigator of a protocol undergoing full committee review may be invited into the session. Their presence is strictly limited to providing real-time clarifications regarding their study design or safety measures; they must exit before the committee deliberates on a decision. If a protocol requires highly specialized technical knowledge, independent consultants may be invited to present their expert opinions (per SOP 4 & 5). However, they are barred from proposing motions or participating in the final vote.

Following floor discussions, the Chair will steer the committee toward a consensus on one of the following official board actions:

- Approval: The protocol is ethically and scientifically sound; no further modifications are required.
- Minor Modification: The protocol requires simple, specific administrative corrections or text clarifications that can be vetted via an expedited secretariat review.
- Major Modification: The protocol exhibits significant ethical or design flaws and must undergo substantial revisions before being brought back for a full-board review.
- Disapproval: The protocol fails to meet crucial ethical or safety standards, posing unjustifiable risks to human participants.
- Needs More Information: The committee cannot render a fair judgment due to severe data omissions and requests a comprehensive resubmission from the investigator

If an absolute consensus cannot be reached naturally through floor discussions, the Chair will call for a formal vote. The decision will be carried by a simple majority of the voting members present.

The Member Secretary shall record the meeting.

Step 8: Report of results of expedited review (SOP 5).

Protocols that qualified for and underwent expedited review pathways since the last full-board meeting must be officially entered into the committee's record.

The assigned Primary Reviewers for expedited research will present a streamlined summary of their evaluations and final determinations to the full board. This reporting is strictly for the information of the full committee and to maintain total organizational transparency. Because these protocols have already been vetted and approved via the expedited pathway, floor discussions are generally unnecessary unless a full-board member identifies a critical safety oversight that warrants re-classification. All expedited review outcomes must be formally recorded and appended to the current meeting's minutes.

Step 9: Discussion of operations-related and administrative matters

To prevent administrative matters from encroaching upon the time allocated for critical protocol reviews, general operations will be handled systematically.

The Chair will lead brief discussions regarding pressing institutional operations, including incoming/outgoing external communications, upcoming bioethics training programs, committee accreditation statuses, and membership appointments. To ensure a thorough treatment of institutional governance, a standalone meeting dedicated strictly to administrative, financial, and operational policy matters shall be independently convened at least once every three (3) months.

Step 10: Adjournment

A meeting can only move toward adjournment once every single item listed on the approved agenda has been fully discussed, resolved, or formally deferred to a future session.

The Chair will formally request a motion for adjournment from the floor. One committee member must move for adjournment, and another must second it. The Chair will ask the body if there are any outstanding objections or emergency items. Hearing none, the Chair will officially state the final timestamp and declare the meeting adjourned.

Step 11: Collection, storage, and disposal of meeting materials

To maintain data privacy, institutional confidentiality, and an uncompromised audit trail, post-meeting clean-up must follow strict document-retention guidelines.

Immediately following adjournment, the Administrative Secretary is tasked with collecting all distributed physical notes, provisional documents, and draft checklists used during the session. In strict compliance with SOP 23 - Managing Active Files, the Administrative Secretary will oversee the secure filing and long-term storage of official documents (such as signed attendance sheets, approved agendas, and finalized evaluation checklists). Any duplicate physical printouts, scratch papers, or redundant copies containing confidential investigator data or patient identifiers must be immediately destroyed via secure industrial shredding to prevent data breaches. Digital draft files must be scrubbed from temporary local drives and safely archived in the committee's encrypted cloud database.

Section 6. Forms

Form 19.1 - Attendance Sheet
Form 4.4 - Protocol Reviewer Form
Form 4.5 - INFORMED Consent worksheet

Section 7. History of SOP

Version No.	***Date***	***Authors***	***Main Change***
1	6.21.24	NINO ISMAEL S. PASTOR	DRAFT
2	10.29./24	Aljoriz Dublin & Nino Ismael Pastor	Form labels, Content
3	06.05.26	Nino Ismael Pastor	Form labels Few Content

Section 8. References

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