



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



Ethos Universitas
 HONORARY COMPANION

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SOP NO. 6 - FULL COMMITTEE REC REVIEW

Section 1. Policy Statement

This SOP applies to the review and approval of proposals and amendments to proposals that (1) pose beyond minimal risk to participants, (2) use study participants belonging to vulnerable groups, and/or (3) create vulnerability to human participants. Major revisions in a submitted proposal or its informed consent are also included. Primary reviewers will be required to conduct the review processes. A full review ensures compliance with the technical and ethical standards for research on human participants, their identifiable data, and materials.

Section 2. Objective of the Activity

To describe the REC's procedures when conducting a full Committee meeting.

Section 3. Scope

This SOP begins with the researcher filing for an initial, resubmission, or any post-approval concern needing an ethical review. Primary reviewers or independent consultants will then be assigned. It ends with the filing of research documents in the protocol folder, updating the Protocol Folder Index (Form 4.9) and Form 4.7 (RMSS DATABASE).

Section 4 - Workflow

Listed below are the steps involved in conducting a FULL COMMITTEE review, which begins after the researcher(s) submit(s) an initial, resubmission, or post-approval request needing an ethics review.

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Assignment of primary reviewers (Form 4.3) or Independent Consultant/s (Form 3.1 Invitation tech exert w conforme)	Member Secretary Chair	2 days from receipt of submission
Step 2: Notification of primary reviewers or Independent Consultants	Member Secretary	
Step 3: Provision of protocol and protocol-	Administrative	2 days

related documents and assessment Forms to reviewers	Secretary	
Step 4: Presentation of review findings and recommendations during a committee meeting (SOP 19. Conduct of Meeting)	Primary Reviewers	1 day: every 3 rd Saturday of the month
Step 5: Documentation of Committee deliberation and action (Form 20.1 - Minutes of the meeting)	Member Secretary Administrative Secretary	6 days
Step 6: Communication of Committee Action to the researcher (Form 4.6 – Decision letter template)	Chair, Member Secretary, and Administrative Secretary	9 days after the monthly REC meeting
Step 7 - Step 7: Filing of protocol-related documents and Updating of the Protocol Database (Form 4.7), RMSS (Form 4.7) and filing Form Log (Form 4.7a) (See SOP 19 – Management of Active Files).	Administrative Secretary	
TOTAL		20 days

Section 5. Description of Procedures

Step 1: Assignment of primary reviewers (Form 4.3) or Independent Consultant/s (Form 3.1 Invitation tech exert w conforme)

The formal ethical review lifecycle for protocols requiring comprehensive evaluation is initiated upon the investigator's submission of necessary documentation to the REC office:

- Initial Protocols: Requiring the execution of the Application for Ethics Review (Form 4.1).
- Protocol Amendments/Revisions: Requiring the Resubmission Form (Form 7.1).
- Post-Approval Amendments: Tracking deviations, renewals, or adverse events demanding structural review.

Upon administrative intake, the Member Secretary shall evaluate the submission to determine if the study presents more than minimal risk to human participants, thereby requiring a Full Committee review. The Member Secretary formally presents this assessment to the REC Chairperson.

Upon concurrence, the Chairperson officially authorizes the Full Committee track and assigns at least one (1) Primary Reviewer—or an external Independent Consultant pursuant to SOP 3 (Appointment of Independent Consultants)—whose specialized scientific, medical, or socio-cultural credentials directly align

with the proposal's subject matter. For legacy or post-approval protocols, the Chairperson identifies the historically assigned Primary Reviewer to maintain continuity of oversight and instructs the Member Secretary to initiate notification protocols.

Step 2 - Notification of and acceptance by primary reviewers and/or Independent Consultants:

To maintain strict adherence to institutional review timelines, the Member Secretary must rapidly transmit the protocol to the assigned evaluators:

- Document Generation: Within two (2) calendar days of receiving the submission, the Member Secretary shall fill out the Notice of Review (Form 4.3) along with the accompanying Conformance (Form 1.2).
- The Response Window: The designated Primary Reviewer or independent technical expert must review the assignment and return the executed Conformance block within two (2) calendar days of receipt. The Conformance (Form 1.2) represents a formal commitment to evaluate the protocol thoroughly and confirms the absence of any conflicting interests.

Step 3 - Provision of protocol and protocol-related documents and assessment Forms to primary reviewers/independent consultants.

Immediately upon receiving the signed Conformance from the reviewer, the Administrative Secretary assumes responsibility for assembling and distributing the complete protocol evaluation documents. This standardized packet must include:

- The primary Research Proposal and all appended investigator profiles
- REC Review Checklist (Form 4.4)
- Informed Consent Form Evaluation Worksheet (Form 4.5)
- Proposal Summary Sheet (Form 4.8)
- *For resubmissions or modifications:* The Resubmission Form (Form 7.1) alongside previous committee notes.

Distribution Modalities & Timelines:

- Primary Reviewer Packet: The Administrative Secretary shall print, package, and hand-carry complete physical hard copies of the dossier directly to the designated Primary Reviewer.

- General Membership Packet: Concurrently, secure soft copies of the protocol packet must be compiled and distributed via secure electronic channels to all other active REC Committee members to facilitate independent pre-meeting evaluations.
- Regulatory Deadline: The complete distribution workflow—both physical and digital—must be concluded within seven (7) calendar days of initial application intake.

Step 4: Presentation of review findings and recommendations during a committee meeting (SOP 19. Conduct of Meeting)

The assigned Primary Reviewer must perform an independent, comprehensive evaluation of the protocol's ethical and scientific merits prior to the convened assembly. All general committee members are expected to review their digital packets to participate meaningfully in floor deliberations.

The Primary Reviewer must formalize their critiques, questions, and recommendations using the provided institutional evaluation worksheets and submit these findings to the Chairperson at least three (3) days prior to the meeting, or precisely on the third Wednesday of the month.

The general committee will officially convene to debate, vote on, and settle the protocol's status on the third Saturday of the month.

In the event that an assigned Primary Reviewer or Independent Consultant faces an emergency and cannot attend the scheduled session, the Chairperson exercises executive prerogative to assume the role of Primary Reviewer. This ensures that the review proceeds smoothly without compromising institutional timelines or leaving the protocol in an unaddressed bottleneck.

Step 5 - Documentation of Committee deliberation and action Meeting (SOP 20 – Preparing the Minutes of the Meeting).

During the official session, the committee's cross-disciplinary discussions must focus heavily on core ethical pillars: informed consent process validity, vulnerable population protections, data confidentiality matrices, and, where applicable, institutional biosafety guidelines and animal welfare protocols.

The Member Secretary is responsible for recording all Committee actions, motions, and collective arguments to generate the official document under SOP 20 (Preparing the Minutes of the Meeting).

To maintain clear systemic boundaries, the Administrative Secretary will compile an independent registry of all protocols that achieved approval through the parallel expedited track during the prior month. The Member Secretary will formally present this list during the Full Committee meeting to ensure that it is recorded in the permanent institutional minutes.

Step 6: Communication of Committee Action to the researcher (Form 4.6 – Decision letter template)

Following the adjournment of the review session, the Member Secretary translates the raw session notes into a clean administrative draft for the Chairperson's review. The Chairperson will review the notes, summarize the complex ethical issues or data clarifications raised during the floor debates, and call for an explicit vote on each pending resolution.

The definitive outcomes, explicit provisos, and specific reviewer critiques are transposed into the formal Decision Letter (Form 4.6). This letter must be signed by the Chairperson and dispatched to the primary investigator via secure email or courier within seven (7) calendar days post-meeting. The committee must issue one of the following four standardized operational actions:

1. Approval: The protocol is cleared, and an ethical clearance certificate is issued.
2. Minor Modifications: The protocol requires simple, non-structural clarifications, which may be vetted via an expedited review path upon resubmission.
3. Major Modifications: The protocol exhibits material ethical or scientific gaps and must be revised by the researcher and routed back to a Full Committee meeting for re-evaluation.
4. Disapproval: The protocol is rejected due to severe ethical violations or insurmountable structural flaws.

Any protocol receiving a recommendation for disapproval or requiring major overhauls will automatically be placed on the action agenda for the subsequent monthly REC session.

Step 7: Filing of protocol-related documents and Updating of the Protocol Database (Form 4.7), RMSS (Form 4.7) and filing Form Log (Form 4.7a) (See SOP 19 – Management of Active Files).

To satisfy national regulatory bodies and internal audit controls, all documentation generated through this lifecycle must be preserved securely in accordance with SOP 19 / SOP 23 (Management of Active Files). The Administrative Secretary shall execute the following archiving protocols:

- Physical File Management: Gather all signed application sheets, completed checklists, meeting notes, and copy sets of the final Decision Letter, and file them within a uniquely serialized protocol folder.
- Log Control Updates: Fill out the physical Protocol Folder Index (Form 4.9) and register the transaction within the Filing Form Log (Form 4.7a).
- Digital Registry Synch: Log the terminal action, meeting dates, voting outcomes, and expiration data within the Research Management **Summary Sheet (RMSS) Database (Form 4.7) to maintain real-time tracking metrics.**

Section 6. Forms

Form 1.2 – Conforme
 Form 3.1 – Invitation Tech Expert
 Form 4.1 – Application for Ethics Review
 Form 4.4 – REC Review Checklist
 Form 4.5 – ICF Eval Worksheet
 Form 4.6 - Decision Letter Template
 Form 4.7 – RMSS DATABASE
 Form 4.7a – Filing Form log
 Form 4.8 – Proposal Summary Sheet
 Form 6.1 – Protocol folder Index
 Form 7.1 – Resubmission

Section 7. History of SOP

<i>Version No.</i>	<i>Date</i>	<i>Authors</i>	<i>Main Change</i>
1	4.22.2024	NINO ISMAEL S. PASTOR	Draft
2	10.04.2024	Faith Yee	Contents, Forms, and Forms label
3			

Section 8. References

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