



Gullas College of *Medicine*
RESEARCH ETHICS COMMITTEE



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Date of Approval:	
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SOP NO. 10 - REVIEW OF AMENDMENTS

Section 1. Policy Statement

The REC must approve changes in the protocol procedures, titles, forms, and materials of an approved proposal from the proponent.

Section 2. Objective of the Activity

The purpose of this SOP is to describe REC review procedures of amendments to ensure that such amendments do not impact on the safety and welfare of the participants.

Section 3. Scope

This SOP begins with the receipt of an application for amendments and ends with its entry to the RMSS DATABASE (Form 4.7), Filing Form log (Form 4.7a), and Protocol Folder Index (Form 4.9).

Section 4. Workflow

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Receipt and evaluation of the Amendment form (Form 10.1 - Amendment Form). Entry Form 10.1 to the Protocol Folder Index (Form 4.9), RMSS (Form 4.7) and Filing Folder Log (Form 4.7a)	Administrative Secretary	1 day
Step 2: Retrieval of pertinent protocol file	Administrative Secretary	
Step 3: Notification of Chair and Primary Reviewer (Form 4.3, Notice of Review)	Administrative Secretary Member Secretary Chair Reviewers	7 days post-receipt
Step 4: Review of amendments & determination of the need and type of review: expedited (SOP 4 on Expedited Review) or full review (SOP 5 on Full Review)	Chair and Primary Reviewer	10 days post-receipt

Step 5: Discuss in the REC meeting	Chair and Primary Reviewer	1 day every 3 rd Saturday of month
Step 6: Communication of committee action (Form 4.6 - Decision Letter Template)	Member Secretary Administrative Secretary	7 days post-meeting
Step 7: Filing of Amendments and decision letter in the correct protocol folder and updating the RMSS database (Form 4.7), Filing Form log (Formk4.7a), and the Protocol Folder Index (Form 4.9).	Administrative Secretary	
TOTAL		19 days

Section 5. Description of Procedures

Step 1: Receipt and evaluation of the Amendment form (Form 10.1 - Amendment Form). Entry Form 10.1 to the Protocol Folder Index (Form 4.9), RMSS (Form 4.7) and Filing Folder Log (Form 4.7a)

The amendment lifecycle is initiated when a Principal Investigator (PI) seeks to modify an already approved research protocol. The investigator must accomplish and submit the formal **Protocol Amendment Form (Form 10.1)** alongside all modified study components (such as revised protocols, updated informed consent scripts, or newly translated recruitment ads).

The Administrative Secretary serves as the primary receiving officer and must immediately perform a completeness screening on the submitted packet. S/he notes the following items:

- **The Completeness Audit:** The Administrative Secretary verifies that all sections of Form 10.1 are completely filled out, signed, and dated, and that all modified documents are attached with changes clearly marked (e.g., via track changes or a side-by-side comparison matrix).
- **Deficiency Routing:** If the submission package is missing crucial components or lacks clear justification, the Administrative Secretary will reject the application at the desk and return it to the PI with an itemized deficiency notice.

Step 2 - Retrieval of pertinent protocol file:

Once the amendment application passes the initial completeness screening, the Administrative Secretary formally accepts the dossier. The secretary locates the study's physical master folder within the secure archive repository and begins integrating the new paperwork into the active document-control tracking system under **SOP 23 - Management of Active Files**). S/he updates **the following:**

1. **The Protocol Folder Index (Form 4.9):** The physical ledger bound to the inside cover of the master folder is updated to log the receipt and description of the modification request.
2. **The Filing Form Log (Form 4.7a):** Document movement is recorded to flag that the file has been pulled from deep storage and is actively under review.
3. **The RMSS Database (Form 4.7):** The central electronic database is synchronized in real time, shifting the protocol's active status flag to "Amendment Submitted – Pending Review."

The Administrative Secretary withdraws the historical approval documents and previous versions of the protocol from the folder, attaches the new Amendment Form (Form 10.1) securely to the top of the history stack, and passes the compiled reference package to the Member Secretary.

Step 3 - Notification of Chair and Primary Reviewer (Form 4.3, Notice of Review).

The Member Secretary reviews the compiled amendment dossier to assess its operational background. Within a strict deadline of **seven (7) calendar days post-receipt** of the submission, the Member Secretary briefs the Chairperson and the historically assigned Primary Reviewer(s) regarding the scope of the requested modifications.

The Administrative Secretary then generates and dispatches a formal **Notice to Review (Form 4.3)** along with the amendment dossier to the assigned primary evaluators to initiate the technical assessment phase.

Step 4: Review of amendments & determination of the need and type of review: expedited (SOP 4 on Expedited Review) or full review (SOP 5 on Full Review)

The Primary Reviewer independently evaluates the modifications to determine if they alter the study's overall risk-benefit ratio. The reviewer routes a technical review track recommendation to the Chairperson, who exercises final authority over the review pathway.

Modifications that do not impact participant safety, study design, or data integrity (e.g., minor typographic corrections, administrative contact detail changes, personnel updates or basic logistical updates) are routed via the expedited path. The Primary Reviewer evaluates the file independently under **SOP 4 (Expedited Review)** and returns their final decision directly to the Chair.

Modifications that materially change the protocol's core methodology, title changes, introduce new safety risks, or alter participant interactions must undergo full Committee re-evaluation under **SOP 5 (Full Committee Review)**.

The Chairperson signs off on the final tracking track and instructs the Administrative Secretary to either process the expedited approval papers or calendar the protocol for the next general Committee session.

Step 5. Discuss in the REC meeting.

If an amendment is classified as a major modification, it must be placed on the agenda of the next regular REC session for open floor debate.

In compliance with the **PHREB National Ethical Guidelines (2022)**, modifications that trigger a mandatory Full Committee Review include, but are not limited to:

- Material changes to the core study design, statistical frameworks, or research objectives.
- Title changes after REC approval
- The introduction of new or increased physical, social, or psychological risks to participants.
- Changes in drug choices, dosages, administration routes, or clinical interventions.
- Any modifications to the pre-approved participant inclusion or exclusion criteria.
- The introduction of new vulnerable populations into an active study that is classified as greater than minimal risk.
- *Contextual/Borderline Cases*: Depending on their complexity and impact on participant welfare, items such as localized translations of approved consent forms, changes to recruitment methods, the removal or transfer of study sites, clarifications of study procedures, or the enrollment of a single participant under a sponsor-approved eligibility variance may also be flagged by the Chair for full Committee discussion.

Following formal floor deliberations and a collective vote, the committee will issue one of four explicit determinations:

1. **Approved:** The amendment is cleared as written and updated ethical clearance parameters are established.
2. **Additional Justification/Information Required:** The amendment is deferred until the PI provides satisfactory written clarifications or data to justify the structural changes.
3. **Re-consent Required:** The amendment is approved conditional upon the requirement that all currently enrolled participants are re-consented using an updated, approved Informed Consent Form reflecting the new modifications.

4. **Disapproved:** The amendment is rejected due to safety concerns or structural flaws. The investigator must continue using the previously approved version of the protocol.

Step 6: Communication of committee action (Form 4.6 - Decision Letter Template)

Following the review (either via the expedited track or after the validation of the Full Committee meeting minutes), the Member Secretary drafts the formal institutional notification using the **Decision Letter Template (Form 4.6)**. The draft must reflect the precise conclusions, conditions, or mandates issued by the committee.

The completed letter is routed to the Chairperson for final review and signature. The Chairperson signs the Decision Letter, explicitly checking the box corresponding to the Committee's action: **Approved, Additional Justification Required, Re-consent Required, or Disapproved**. The REC office must ensure this official signed notification is dispatched and delivered to the Principal Investigator within **seven (7) calendar days following the committee session**.

Step 7: Filing of Amendments and decision letter in the correct protocol folder and updating the RMSS database (Form 4.7), Filing Form log (Formk4.7a), and the Protocol Folder Index (Form 4.9).

To satisfy regulatory audits and preserve a flawless institutional history, all physical and digital materials generated during the amendment lifecycle must be systematically archived.

The Administrative Secretary retrieves all deployed review sets and integrates the executed Amendment Form (Form 10.1), completed reviewer checklists, relevant meeting minutes excerpts, and a copy of the final signed Decision Letter (Form 4.6) into the protocol's physical master folder.

The Administrative Secretary will execute the following document control updates to finalize the transaction cycle:

1. **The Protocol Folder Index (Form 4.9):** The physical ledger bound to the inside cover of the master folder is meticulously updated to record the exact date of final amendment action and the document version changes.
2. **The Filing Form Log (Form 4.7a):** Updated to confirm the secure return and filing location of the updated folder within the active archive repository.
3. **The RMSS Database (Form 4.7):** The central electronic database is updated in real time, shifting the status from "Pending Review" back to

"Approved & Active," while appending an administrative suffix to the database line to track the newly approved protocol version number.

Section 6. Forms

Form 10.1 – Amendment Form
Form 4.9 – Protocol Folder Index
Form 4.7 – RMSS Database
Form 4.6 - Decision letter
Form 4.3 - Notice to Review

Section 7. History

<i>Version No.</i>	<i>Date</i>	<i>Authors</i>	<i>Main Change</i>
1	5.2.24	NINO ISMAEL S. PASTOR	<i>Draft</i>
2	10.11.24	Maricar Canonigo	Contents, Form labels
3			

Section 8. References

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