



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



Ethos Universitas
HONORARY COMPANION

Version No:	Draft
Date of Approval:	
Effectivity Date:	

SOP NO. 9 - MANAGEMENT OF PROGRESS REPORT

Section 1. Policy Statement

The REC shall require the submission of progress reports at least one month before the study ends or if the level of risk of the study requires it ((PHREB, 2020 PHREB SOP, 2020).

The study will be deemed at risk’ if the research:

- is experiencing progress difficulties
- fails to meet agreed research goals
- fails to meet requirements at the first attempt
- fails to submit their research output by the expected submission date or end of the grace period
- caused adverse reactions compromised the safety of the participants (see SOP 11A – Review of RNE Reports; SOP 11B – Review of RSAE & SUSAR Report)

The frequency of progress reports of protocols at risk will be determined by the REC.

Progress will be deemed as unsatisfactory if the proponent:

- fails in their second attempt
- fails for a second time to meet the requirements of any research milestone

In this case, early termination of the research may be necessary to protect the safety of the participants.

Section 2. Objective of the Activity

This procedure describes the Progress Reporting process, which protects the safety and wellness of study participants and Confirms Database that the study is performed in accordance with the approved protocol.

Section 3. Scope

This SOP begins with the acceptance of the progress report, updating the RMSS DATABASE (Form 4.7), Filing form long (Form 4.7a) and ends by updating the protocol folder index (Form 4.9), updating the RMSS DATABASE (Form 4.7), and Filing form long (Form 4.7a).

Section 4. Workflow

<i>ACTIVITY</i>	<i>RESPONSIBILITY</i>	<i>TIMELINE</i>
Step 1: Receipt and entry of the progress report (Form 8.1) into the protocol folder, updating the protocol folder index, (Form 4.9), Filing Form log (Form 4.7a) and RMSS DATABASE (Form 4.7).	Administrative Secretary	2 days
Step 2: Retrieval of pertinent protocol file	Administrative Secretary	
Step 3: Notification of Chair and Primary Reviewers	Member Secretary Chair	7 days post-receipt
Step 4: Meeting (SOP 17 - Preparing the Meeting Agenda, SOP 4 – Expedited review, SOP 5 – Full Committee Review)	Chair and Primary Reviewers	1 day 3 rd Saturday of the month
Step 5: Communication of committee action (Form 4.6 - Decision letter template)	Administrative Secretary Chair	7 days post-meeting
Step 6: Filing the progress report and decision letter (Form 4.6) and updating the protocol database. (Form 6.1) – Protocol Index File; & RMSS DATABASE (Form 4.7)	Administrative Secretary	10 days post-meeting
TOTAL		20 DAYS

Section 5. Description of Procedures

Step 1: Receipt and entry of the progress report (Form 8.1) into the protocol folder, updating the protocol folder index, (Form 4.9), Filing Form log (Form 4.7a) and RMSS DATABASE (Form 4.7).

To ensure uninterrupted ethical clearance, the Research Ethics Committee (REC) maintains strict monitoring overactive research portfolios.

The Administrative Secretary shall monitor the expiration milestones of all active protocols and formally issue a reminder to the Principal Investigator (PI) exactly one (1) month prior to the scheduled conclusion or annual anniversary of the research. This notification instructs the PI to submit a comprehensive progress report.

Upon submission by the PI, the Administrative Secretary receives the formal Progress Report Form (Form 8.1). The secretary performs an immediate intake audit to ensure the form is fully accomplished, signed, and dated.

Once verified, the Administrative Secretary logs the exact intake metrics across the committee's internal systems to maintain a clean tracking history:

1. The Protocol Folder Index (Form 4.9): The physical log attached to the inside cover of the protocol's master folder is updated with the date of report receipt.
2. The Filing Form Log (Form 4.7a): Document movement is logged to note that the folder is active and undergoing continuing review.
3. The RMSS Database (Form 4.7): The central electronic registry is updated to change the protocol's operational metric flag to "Progress Report Submitted – Under Review."

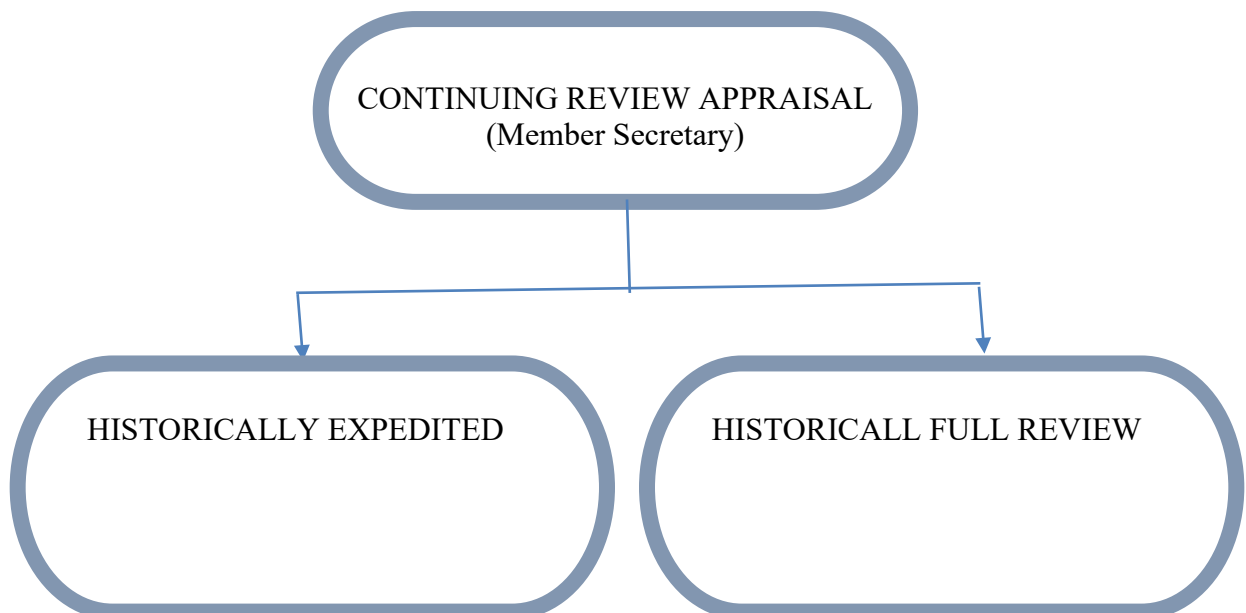
Step 2 - Retrieval of pertinent protocol file:

To facilitate a contextual and accurate review, the Administrative Secretary shall locate and retrieve the physical master protocol file(s) corresponding to the resubmitted progress report from the secure archive repository.

This retrieved historical dossier—which contains the initial proposal, previous decision letters, approved consent forms, and any prior amendments—is compiled alongside the new Form 8.1. The complete reference package is then forwarded directly to the Member Secretary for initial evaluation.

Step 3 - Notification of Chair and Primary Reviewers:

Upon receiving the compiled continuing review packet, the Member Secretary conducts an initial technical appraisal of the progress report. The review track for continuing oversight is strictly determined by the protocol's historical risk classification and approval history:



REVIEW

1. Minimal Risk
2. Simple data collection

1. Greater than minimal risk
2. Vulnerable groups

EXPEDITED CONTINUING REVIEW CONTINUING REVIEW

Assigned to a Primary Reviewer via
Agenda

Notice to Review (Form 4.3).

If the protocol was initially approved via the expedited track and maintains a minimal-risk profile with no reported adverse events, it qualifies for an expedited continuing review. If the protocol originally required full Committee oversight, or if the progress report indicates new participant risks, structural deviations, or unresolved ethical issues, it must be routed to the Full Committee.

FULL COMMITTEE

Placed on the Full Committee

for open floor deliberation.

The Member Secretary must complete the technical evaluation and brief the Chairperson within seven (7) calendar days post-receipt of the progress report. The Chairperson then issues a formal Notice to Review (Form 4.3) to the historically assigned Primary Reviewers, tracking their confirmation and setting the protocol on the committee's operational calendar.

Step 4: Meeting (SOP 17 - Preparing the Meeting Agenda, SOP 4 – Expedited review, SOP 5 – Full Committee Review)

The evaluation of the progress report is governed by its assigned review track, adhering strictly to SOP 17 (Preparing the Meeting Agenda), SOP 4 (Expedited Review), or SOP 5 (Full Committee Review):

- **The Review Process:** The assigned Primary Reviewers independently evaluate Form 8.1 against the historical master file to ensure the study is progressing according to the approved ethical parameters. They check for issues such as slow recruitment numbers, unapproved modifications, or newly surfacing participant risks.
- **Floor Discussions:** The reviewers present their comments, evaluations, and final recommendations during the scheduled monthly REC session. The committee discusses any flagged issues and votes to determine whether to extend the ethical clearance, demand modifications, or suspend the study.
- **Minutes & Documentation:** The Member Secretary records the floor debates, motions, and official votes to draft the comprehensive Minutes of the Meeting. Under the direct supervision of the Member Secretary, the Administrative Secretary is instructed to draft the corresponding institutional decision letter based on these finalized minutes.

Step 5: Communication of committee action (Form 4.6 - Decision letter template)

Following the closure of the review session and the validation of the minutes, the Administrative Secretary transposes the committee's final determination into the official Decision Letter (Form 4.6). The completed draft is routed directly to the Chairperson for review and signature.

The Chairperson evaluates the drafted text against the finalized meeting minutes. Upon verification, the Chairperson signs the document to formalize the committee's action (e.g., Continuing Approval Granted, Revisions Required, or Study Suspended).

The REC office must ensure that the signed Decision Letter is formally dispatched and delivered to the Principal Investigator within a strict deadline of seven (7) calendar days post-meeting.

Step 6: Filing the progress report and decision letter (Form 4.6) and updating the protocol database. (Form 6.1) – Protocol Index File; & RMSS DATABASE (Form 4.7)

To maintain a clean institutional audit trail and satisfy national regulatory standards, all physical and digital records generated during this continuing review cycle must be systematically archived.

The Administrative Secretary gathers the executed Progress Report (Form 8.1), the completed reviewer checklists, relevant excerpts of the meeting minutes, and a copy of the signed final Decision Letter (Form 4.6) and integrates them securely into the protocol's physical master folder.

The Administrative Secretary will perform the following final document control updates to close out the transaction cycle:

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 of the progress report and the date the corresponding decision letter was issued.
2. The Filing Form Log (Form 4.7a): Updated to confirm the physical return and storage location of the master folder within the secure archive room.
3. The RMSS Database (Form 4.7): The central digital database is synchronized in real time, changing the protocol's status line from "Under Review" to "Approved & Active" (with the new ethical clearance extension date recorded) or "Terminated/Closed" depending on the final action of the Committee.

Section 6. Forms

Form 4.3 - Notice to Review
 Form 4.6 - Decision letter
 Form 4.7 - RMSS DATABASE
 Form 4.7a – Filing Form log
 Form 4.9 - Protocol Folder index
 form 8.1- Progress Report Form

Section 7. History

<i>Version No.</i>	<i>Date</i>	<i>Authors</i>	<i>Main Change</i>
1	5.2.2024	Nino Ismael S. Pastor	1 st DRAFT
2	10.10.24	Nino Ismael S. Pastor	Content, Form Labels
3	06.05.26	Nino Ismael S. Pastor	Content, Form Labels

Section 8. References

CIOMS. (2016). *Intl Ethical guidelines for Health-Related Research Involving Humans*. Geneva: CIOMS.

NCPHBBR. (1979). *The Belmont Report*. Washington: DHHS.

PHREB. (2020). *2020 PHREB SOP*. Taguig: PHREB.

PHREB. (2022). *NATIONAL ETHICAL GUIDELINES FOR RESEARCH INVOLVING HUMAN PARTICIPANTS*. Taguig: DOST.

UPMREB. (2012). *SOPs & Formks*. Retrieved from UPMREB: <https://reb.upm.edu.ph/sops-and-forms>

WHO. (2011). *Standards & Operational Guidance for Ethics Review of Health-related Research with Human Participants*. Geneva: WHO.

WHO. (2024, November 12). *ERC templates for Informed Consent*. Retrieved from WHO ERC: <https://www.who.int/groups/research-ethics-review-committee/guidelines-on-submitting-research-proposals-for-ethics-review/templates-for-informed-consent-forms>

WMA. (1964). Declaration of Helsinki. *18th WMA General Assembly* (p. 4). Helsinki: WMA.