Section 1. Policy Statement

Approved protocols need to be continuously reviewed 6 months before the completion of the study. The review process may be expedited or full Committee depending upon the initial approval of the proposal.

Section 2. Objective of the Activity

This activity safeguards the safety and welfare of the participants ensuring that the study was conducted in compliance with the approved proposal. It will also check whether and whether the data they generated is protected beyond its approval till the end of the study.

Section 3. Scope

This SOP describes how the REC should manage an application for Continuing Review (Form 12.1) before a study is terminated. It begins with the application by the proponent for a continuing review and ends with the entry of documents into the protocol folder index (Form 6.1) and the Research Monitoring Surveillance System database (Form 4.7).

Section 4. Workflow

ACTIVITY	***RESPONSIBILITY***	***TIMELINE***
Step 1: Receipt of the application for Continuing Review (Form 12.1) and entry of the application in the Protocol folder Index (Form 4.9) and into the Research Monitoring System (RMSS) database (For 4.7), and the Filing Form Log (Form 4.l7a).	Administrative Secretary	1 day
Step 2: Retrieval of pertinent protocol files	Administrative Secretary	
Step 3: Notification of Chair and Primary Reviewers	Member Secretary	3 days post-receipt
Step 4: Determination of the type of review: expedited (SOP 5 Expedited Review) or full review (SOP 6 Full	Member Secretary Chair	

Review)		
Step 5: Deliberations on the continuing review	Chair REC reviewers	1 day Every 3rd Saturday of the month
Step 6: Communication of REC Decision (SOP 21) (Form 4.6 Decision Letter)	Member Secretary Chair Admin Secretary	7 days post-meeting
Step 7: Filing documents in the appropriate protocol folder, updating the protocol folder index (Form 4.9), Filing Form 4.7a) and RMSS database (Form 4.7),	Administrative Secretary	10 days post-meeting
	TOTAL	22 days

Section 5. Description of Procedures

Step 1: Receipt of the application for Continuing Review (Form 12.1) and entry of the application in the Protocol folder Index (Form 4.9) and into the Research Monitoring System (RMSS) database (For 4.7), and the Filing Form Log (Form 4.l7a).

The Principal Investigator (PI) or authorized research representative formally submits **Form 12.1 (Application for Continuing Review Form)** to the Research Ethics Committee (REC) Secretariat prior to the expiration of the current ethical clearance. Upon delivery, the Administrative Secretary executes an immediate administrative audit:

- **Completeness and Accuracy Check:** The Administrative Secretary meticulously scrutinizes the application to verify that all mandatory fields are thoroughly accomplished, necessary signatures are present, and required cumulative summaries are attached. If the file is incomplete or inaccurate, it is returned to the investigator with an itemized deficiency note.
- **Multi-Platform Intake Logging:** Once verified as complete, the Administrative Secretary officially logs the submission across the institutional tracking ecosystem by:
    1. Entering the intake metadata into the **Research Management Support System (RMSS) Database (Form 4.7)**.
    2. Recording the transaction in the **REC Filing Form Log (Form 4.7a)**.
    3. Formally updating the master **Protocol Folder Index (Form 4.9)** designated for that specific research study.

Step 2: Retrieval of pertinent protocol files.

Following successful logging, the Administrative Secretary accesses the secure archives to retrieve the master protocol folder and compiles all matching files

generated during the preceding period of the protocol's ethical clearance. This assembled dossier must include:

- The originally approved protocol and recent amendments.
- Cumulative progress reports and subject enrollment logs.
- All **Protocol Deviation/Violation Reports (Form 11.1)**.
- All **SAE/SUSAR Reports (Form 11B.1)** and **Reported Negative Events (RNEs - Form 11A.1)**.
- Historical committee decisions, noting specifically the methodology of the initial review (Expedited vs. Full Committee Review).

The Administrative Secretary formally briefs the Member Secretary regarding the arrival of the application and transfers the fully synthesized file dossier to their desk for preliminary administrative assessment.

Step 3: Notification of Chair and Primary Reviewers.

The Member Secretary reviews the assembled dossier to ensure all historical notes from the validation period match the investigator's continuing review summaries. Following this internal evaluation, the Member Secretary coordinates with the Secretariat to formally package and transmit the complete Continuing Review application—along with the compiled historical safety data—to the REC Chair and the designated primary reviewer(s) who were originally assigned to oversee the lifecycle of the study.

Step 4: Determination of type of review: expedited (SOP 5 Expedited Review) or full review (SOP 6 Full Review).

The REC Chair, in formal consultation with the Member Secretary and the primary reviewer(s), establishes the appropriate regulatory review pathway. The determination of the review typology is strictly tied to the initial risk determination and prior review framework of the master protocol:

- **Expedited Review Pathway (SOP 5):** Protocols that were initially approved via an expedited track and have maintained a low-risk profile may undergo an expedited Continuing Review.
- **Full Committee Review Pathway (SOP 6):** Protocols that initially required full Committee oversight, or low-risk protocols that have experienced significant safety developments (such as unresolved SAEs, SUSARs, or critical protocol violations), are mandated to undergo a Full Committee Review.

The assigned primary reviewer(s) thoroughly study the application against the historical data to evaluate ongoing participant safety, study relevance, and ethical compliance. The reviewer(s) synthesize their findings into a formal assessment report, which is signed and submitted to the Member Secretary for committee integration.

Step 5. Deliberations on the Continuing Review:

The Member Secretary integrates the primary reviewer's assessment report into the agenda for the next scheduled REC meeting. During the session, the REC Committee members deliberate on the findings to evaluate if the risk-benefit ratio has shifted and determine whether the study continues to meet ethical benchmarks. The committee votes to implement a definitive regulatory action, which may include, but is not limited to, the following outcomes:

- **No Further Action Required:** The protocol is granted a renewal of its ethical clearance for another defined period (typically 12 months) without modifications.
- **Continuous Monitoring:** Enhanced oversight is mandated, which may include more frequent interval progress reporting.
- **Prepare for a Site Visit:** The Committee orders an unscheduled post-approval monitoring site visit to visually verify compliance.
- **Further Information/Action Required:** Ethical clearance is conditional, pending the submission of clarifying data or revisions.
- **Suspension of Recruitment:** Active subject enrollment is frozen immediately due to pending safety or administrative concerns, while currently enrolled subjects are managed safely.
- **Termination of the Study:** The immediate and total withdrawal of ethical clearance, resulting in the permanent cessation of all research activities due to unmitigated safety hazards or systemic noncompliance.

The Member Secretary precisely documents the deliberations within the official meeting minutes and drafts a formal **Decision Letter (Form 4.6)** mirroring the Committee's mandates.

Step 6: Communication of REC Decision (SOP 21) (Form 4.6 Decision Letter)

The Member Secretary finalizes the **Decision Letter (Form 4.6)** based on the signed expedited report or the approved Full Committee meeting minutes. The letter is routed to the REC Chair for final validation and official signature. Once signed, the Secretariat processes the document and coordinates its formal transmission to the Principal Investigator, institutional sponsors, and relevant institutional authorities in strict compliance with the communication guidelines established under **SOP 21**.

Step 7: Filing documents in the appropriate protocol folder, updating the protocol folder index (Form 4.9), Filing Form 4.7a) and RMSS database (Form 4.7).

Upon the conclusion of the communication cycle, the Administrative Secretary re-collects all physical and digital documentation generated throughout the continuing review process—including the initial application (Form 12.1), primary

reviewer notes, signed meeting minutes, and a copy of the issued Decision Letter (Form 4.6). The Administrative Secretary permanently archives these files within the master protocol folder and executes final synchronizations across all data management platforms by updating the entry status within the **REC Filing Form Log (Form 4.7a)**, the main **RMSS Database (Form 4.7)**, and the physical **Protocol Folder Index (Form 4.9)** to guarantee impeccable regulatory record integrity.

Section 6. FORMS

Form 4.7 – RMSS database
Form 4.6 – Decision letter template
Form 4.9 – Protocol Folder Index
Form 12.1 – Application for Continuing Review

Section 7. History

Version No.	Date	Authors	Main Change
1	11 June 2024	NINO ISMAEL S. PASTOR	1sat Draft
2	16 October 2024	Ms. Maricar Canonigo	Form labels Content
3	05 June 2026	Nino Ismael Pastor	Form Labels Few Content

Section 8. References

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