Section 1. Policy Statement

The site(s) of high-risk studies, studies with significant deviation reports, studies with non-receipt of required after-approval reports from the REC, multiple study sites conducted by a researcher and/or studies with participant/family/stakeholder complaints need to be visited.

Section 2. Objective of the Activity

Site visits enable the REC to monitor compliance with approved protocols, and the ICF process to protect and promote participants' dignity, rights, and well-being.

Section 3. Scope

This SOP begins with the identification of the site to be visited and ends with the filing of Site-Visit Reports (Form 16.1) in the protocol folder index (Form 4.9), recording the entry into the Filing Form log (Form 4.7a), and updating of the RMSS DATABASE.

Section 4. Workflow

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Selection of site to visit	Any REC Member(s)	1 day
Step 2: Creation of Site Visit Team	Chair	Every 3rd Saturday of the Month or Special meeting
Step 3: Notification of researcher	Member Secretary Chair	14 days post-meeting
Step 4: Conduct of site visit	Site Visit Team members	7 days post-notification
Step 5: Draft of report and presentation of report during meeting and discussion for recommendations	Site Visit Team (members)	7 days post-visit
Step 6: Transmittal of Final Report and Recommendations to the	Chair/ Member Secretary	

Researcher/Investigator		
Step 7: Filing of Site-Visit Reports in the protocol folder index (Form 4.9), and update of the RMSS DATABASE (For 4.7) and the Filing Form Log (Form 4.7a).	*Administrative Secretary*	10 days post-visit
	TOTAL	39 days

Section 5. Description of Procedures

Step 1: Selection of site to visit

Study sites are strategically identified and selected for routine or targeted inspections during the formal ethical review of ongoing research proposals. The Research Ethics Committee (REC) employs a risk-based approach to trigger a site visit. A site inspection will be mandated if a study meets one or more of the following criteria:

- High-Risk Research: Protocols involving vulnerable populations, novel investigational products, invasive procedures, or high-level clinical interventions.
- Protocol Deviations: Studies with documented histories of significant or frequent protocol deviation and non-compliance reports.
- Reporting Delinquency: Ongoing failure to submit mandatory, post-approval follow-up reports required by the REC (e.g., progress reports, final reports).
- Principal Investigator (PI) Workload: Researchers simultaneously overseeing multiple active study sites or an exceptionally high volume of concurrent protocols.
- Participant or Family Grievances: Formal or informal complaints lodged by study participants, their immediate family members, or legal representatives.
- Community Concerns: Issues, complaints, or negative feedback raised by local community members, leaders, or stakeholders at the study site.

- Overwhelming Sample Sizes: Protocols tracking exceptionally large participant cohorts that increase the statistical margin for administrative or ethical oversight errors.

- Critical Safety Events: Studies experiencing a cluster of Serious Adverse Events (SAEs), Suspected Unexpected Serious Adverse Reactions (SUSARs), or Related Negative Events (RNEs).

- Continuing Review Failure: Absolute failure by the PI to submit mandatory continuing review requirements ahead of protocol expiration timelines.

Step 2: Creation of Site Visit Team
Associated Forms: Site Visit Briefing Dossier

When a directive for a site inspection is formally passed during an ethics review meeting, the REC panel elects specialized members to form the dedicated Site Visit Team.

The Committee Chair formally appoints a Team Leader, a role preferentially assigned to the protocol's original Primary Reviewer to maintain continuity of oversight. The Team Leader is then tasked with selecting at least two additional qualified committee members to round out the inspection unit. S/he also prepares the Site Visit Report (Form 16.1).

Prior to deployment, the entire REC panel reviews the baseline protocol to align on the focus of the inspection. The chosen Site Visit Team members then undergo a thorough familiarization process with all historical study data, previous stipulations, and critical compliance files to ensure an informed, targeted investigation.

Step 3: Notification of researcher

The Member Secretary is responsible for drafting and dispatching a formal letter of notification to the principal investigator exactly two (2) weeks prior to the scheduled inspection date. This notification is delivered via secure institutional email or verified postal mail. The communication must clearly explicitly include:

- The exact ethical or administrative justification triggering the site visit.

- A formal request outlining any additional documents or updated logs that the PI must prepare for inspection.

- The names and designations of the REC panel members constituting the Site Visit Team.

- Logistics, scheduling windows, and relevant travel or entry arrangements established for the team.

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Step 4: Conduct of site visit

The Administrative Secretary serves as the administrative backbone, organizing and compiling all internal REC records alongside the investigator's file versions to be used on-site. Once at the research facility, the Site Visit Team collaborates with the PI to perform a thorough review of the infrastructure and records. The inspection evaluates the following dimensions:

- Protocol Version Control: Verification that the study site is actively utilizing and executing the absolute latest version of the REC-approved protocol.

- Informed Consent Management: Auditing signed informed consent documents to confirm that the site is administering the most recently approved, unexpired version to active participants.

- Post-Approval Document Trail: Verifying that all modifications, amendments, and updates were submitted to and formally approved by the REC prior to field implementation.

- Data Security and Participant Privacy: Auditing physical and digital infrastructure to ensure data confidentiality, double-locked cabinet storage, password protection, and adherence to privacy regulations.

- Facility Sufficiency: Assessing the physical site facilities to confirm they remain safe, adequate, and well-equipped to support the parameters of the research.

- Participant Welfare Assessment: Making an overarching ethical determination regarding the absolute protection of the rights, safety, physical, and mental welfare of human participants currently enrolled in the trial.

Step 5: Draft of report and presentation of the report during meeting and discussion for recommendations

During the visit, team members record individual findings using the Site Visit Report (Form 16.1). Following the inspection, the Team Leader collates these distinct forms into a synchronized, single consensus report and officially submits it to the Committee Chair.

The Team Leader transforms this consensus report into a comprehensive overall draft within one (1) week of the visit. The Team Leader then presents these findings to the Full Committee panel during the next regularly scheduled meeting or an emergency session if urgent safety concerns were discovered.

The panel deliberates on the findings to reach a consensus decision, establishing formal, binding recommendations that align strictly with REC-approved ethical guidelines and institutional protocols.

Step 6: Transmittal of Final Report and Recommendations to the Researcher/Investigator.

Following the committee's final deliberations, the Member Secretary documents the exact proceedings within the official meeting minutes and creates a formal summary of the REC's findings and binding recommendations.

The Member Secretary adapts these points into a formal Decision Letter (Form 4.6). The Committee Chair reviews, approves, and signs this final transmittal letter. The finalized document is then sent to the PI through secure communication channels in strict compliance with SOP 21: Communicating REC Decisions, providing clear directives and deadlines for any required corrective and preventive action (CAPA) plans.

Step 7: Filing of Site-Visit Reports in the protocol folder index (Form 4.9), and update of the RMSS DATABASE (For 4.7) and the Filing Form Log (Form 4.7a).

To close out the site visit cycle, the Administrative Secretary gathers all related materials, including the individual and synthesized copies of the Site Visit Report (Form 16.1), meeting minutes excerpts, and the signed final decision letter.

The Administrative Secretary permanently files these physical and digital records into the investigator's primary protocol folder to maintain an uncompromised audit trail.

Finally, the secretary reflects the completion of the action by logging the entry into the physical Filing Folder Log (Form 4.7a) and updating the tracking indexes within both the Protocol Folder Index (Form 4.9) and the institutional RMSS Database (Form 4.7).

Section 6. Forms

Form 4.6 – Decision Letter
Form 4.7 – RMSS database
Form 4.7a – Filing form log
Form 4.9 – Protocol Folder Index
Form 15.1 – Site Visit Report

Section 7. History of SOP

Version No.	***Date***	***Authors***	***Main Change***
1	6.27.24	NINO ISMAEL S. PASTOR	DRAFT
2	10.17.24	NINO ISMAEL S. PASTOR	Form labels Content
3	06.11.26	Nino Ismael Pastor	Form labels Few content

Section 8. References

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