

 (Logo of the Institute/ EC)	SOP Template for Management of Continuing Review, Study Monitoring and SAE Reports <i>(Name of the Institutional EC)</i> Version No: _____ Date: _____
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(SOP may be adapted for institutional requirements and ethical requirements)

1. **Purpose:** The purpose of this Standard Operating Procedure (SOP) is to establish the framework for the Single EC to carry out continuing review, monitoring and management of Serious Adverse Event (SAE) reports in multicentre research, to maintain continuous vigilance over participant rights and welfare.
2. **Scope:** This SOP applies to the Single EC Secretariat as well as all members of the Single EC for conducting continuing review of approved multicentre research and review of SAEs and unexpected events.
3. **Responsibility:**
 - 3.1 The Single EC has primary role for ensuring participant welfare throughout the multicentre study through continuous evaluation of the progress of ongoing proposals. The Single EC will monitor study progress, review unexpected events, participant recruitment, protocol deviations/violations and non-compliance, as well as management of SAE reports and where required, administrative checks at sites. It will also examine any new information pertaining to the study and assess final reports of all research activities.
 - 3.2 It is the responsibility of the Single EC Secretariat to remind the Coordinating PI (c-PI) regarding timely submission of continuing review reports, as per timeline determined by Single EC during initial review.
4. **Detailed Instructions**
 - 4.1 **Continuing Review**
 - 4.1.1 The Single EC will conduct continuing review of the multicentre study at appropriate periodic intervals proportionate to the degree of risk, at least once a year.
 - 4.1.2 The Single EC will determine the date(s) of continuing review and clearly specify the date(s) at the time of initial review, and indicate this in the approval letter/ communication letter to the c-PI.
 - 4.1.3 The Single EC Secretariat will notify the c-PI a month in advance of the date(s) determined by the Single EC for submission of continuing review reports. This will ensure timely continuing review.
 - 4.1.4 The Single EC Secretariat will check completeness of the continuing review reports submitted, and share with primary and /or secondary reviewers at least one week prior to next the scheduled Single EC meeting.
 - 4.2 **Study Monitoring**
 - 4.2.1 Depending on the degree of risk to the participants, the nature of research, vulnerability of study participants, and duration of study, the Single EC can choose to review the study more frequently or conduct on-site monitoring visits.

- 4.2.2 Where necessary, the Single EC will seek report(s) from the Data Safety and Monitoring Board (DSMB)/ or monitoring/ audit reports by the sponsors.
- 4.2.3 During monitoring, the Single EC will verify adherence to the approved version of the common protocol and informed consent process, recruitment of participants, concerns or complaints (if any), and compliance with requirements for medical management as well as compensation for research - related injury/ SAEs (if any).
- 4.2.4 Site Monitoring can also be done and it can be routine or “for cause” and will be decided at a full committee meeting of the Single EC. “For cause” monitoring at specific sites may be required in situations where there are high number of protocol violations/deviations and/or SAE reports, adverse information/complaints received from participants, media reports or any other source, non-compliance with Single EC directions; misconduct by the researcher(s), and any other cause as decided by the Single EC.
- 4.2.5 Any findings from monitoring that impact participant safety will be shared by the Single EC with all participating Site PIs and their respective institutional authorities immediately upon knowledge.

4.3 Managing SAE Reports

- 4.3.1 The Single EC is responsible for the review of SAEs at the site, and when required, subject experts, pharmacologist members, primary and secondary reviewers may be involved in the review and causality assessment. The single EC may constitute a SAE sub-committee (optional).
- 4.3.2 The Single EC requires the site PI to inform the c-PI, who shall notify the single EC and sponsor (if applicable) within 24 hours of becoming aware of the SAE. The follow-up detailed report with PI’s opinion on relatedness of SAE to the study shall be submitted by the c-PI within 14 calendar days of submission of the initial report.
- 4.3.3 The Single EC/ SAE sub-committee will promptly review the SAE to assess causality, to ensure participant’s safety and to check adequacy of site response. They will examine the measures taken for the medical management of SAEs. Participants should not have to bear costs for the management of study-related injury.
- 4.3.4 The Single EC/ SAE sub-committee will determine compensation for research participants for research-related injuries as per applicable timelines/ regulatory requirements.

4.4 Protocol Deviations

- 4.4.1 The Single EC will examine protocol deviations/violations at any site(s) reported by the c-PI and suggest corrective actions. If the violations are serious, the Single EC may halt the study temporarily or permanently at all/ specific site(s).
- 4.4.2 The EC may report to the relevant institutional head(s)/government authorities where there is continuing non-compliance to ethical standards.

4.5 Addition of New Study Site(s)

- 4.5.1 The Single EC Secretariat shall examine the need for the addition of new sites or justification provided by c-PI.
- 4.5.2 Upon receipt of a request for the addition of new site(s) from the c-PI, the Single EC will review site-specific details (investigator CVs, infrastructure, local ICD translations, etc.) for the new site before approving the site(s) addition.

4.5.3 It will determine if there is an additional risk to research participants in view of local requirements or determine the need for full ethics review or otherwise, if there are no additional risks, plan an expedited review primarily to verify suitability of site investigator qualifications and to check site preparedness for inclusion in the study.

4.6 Study Completion and Archival

4.6.1 The Single EC will verify the plans for data analysis and reporting of results, plan for benefit sharing and translation of results and sample archival, and ensure the c-PI maintains records for the duration required by relevant guidelines/ regulations.

4.6.2 Upon study conclusion, the Single EC Secretariat will seek a Study Completion Report, publications (if any) and a summary of results for the Single EC's perusal.

Prepared by:

Approved by:

Effective Date:

Review Date: