10.1 Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how continuing review of previously approved protocols should be managed by the Institutional Ethics Committee (IEC). The purpose of the continuing review is to periodically monitor the progress of the study, to ensure continuous protection of the rights and welfare of research participants.

10.2 Scope

This SOP applies to conducting any continuing review of already approved study protocols at pre-specified intervals. All the projects approved by the IEC will be reviewed at least once a year. Depending upon the degree of risk to the participants, the nature of the studies, the vulnerability of the study participants and duration of the study, the IEC may choose to review or monitor the protocols more frequently.

10.3 Responsibility

It is the responsibility of the IEC Secretariat to remind the PIs and Member Secretary regarding continued review of protocols at the correct interval. All the approved protocols will be reviewed annually. It is the responsibility of the Member Secretary to ensure during the IEC meeting in which the project is finally approved that a decision is taken whether the project needs to be reviewed more frequently or not. This must be recorded in the minutes. A fresh decision to increase frequency of review may be taken if required based on the SAE reports, monitoring reports, or safety concerns. This is the responsibility of the SAE subcommittee and Member Secretary.

The IEC is responsible for reviewing the progress made in the protocol (number of patients recruited, dropped out, reasons for drop-out), the occurrence of unexpected events or problems, and compliance of the investigator regarding IEC communication.

10.4. Detailed instructions

10.4.1 Determining the date of continuing review

- The date of the continuing review will always be at least once in the year.
- The IEC may recommend more reviews during the approval process depending on the level of risk. This will be documented in the minutes.

- The Secretariat will inspect the minutes of meeting to set a timetable for continuing review.
- The Secretariat will identify and record the due dates for each project.

10.4.2 Notifying the PI or the study team

The Secretariat will send a reminder to the PI as per the prescribed format at least one month prior (if an annual review) or less as appropriate (if any special additional reviews are required) to the due date of continuing review.

10.4.3 Managing the continuing review package upon receipt

The Secretariat will receive a package (soft and hard copy) submitted by the PI for continuing review of each approved protocol. Only one set (soft and hard copy) of continuing review report shall be submitted by the PI to the IEC as per the prescribed format.

10.4.4 Verifying the contents of the package

- The Secretariat will ensure that the contents of the package include the following documents:
    - Continuing Review Application in the prescribed Form
    - The Continuing Review Application Form duly filled with an explanation for any "yes" (ticked on the Continuing Review Application in the prescribed form), answers on the application form and a discussion of scientific developments, either through the conduct of this study or similar research that may alter risks to research participants. The changes in the selection criteria of participants, protocol/Informed consent Document amendments, changes in the study team, any unexpected complications etc. must be discussed in the attached narrative.
- The Secretariat will confirm that complete information is appended and signed by the Principal Investigator in the Continuing Review Application form.

4.5 Review process

- The Continuing review submission may undergo expedited review or full committee review as deemed appropriate by the IEC Chairperson/ Member Secretary.
- The IEC Chairperson/ Member Secretary/ Member/s will use the Continuing Review Application Form to guide the review and deliberation process.
- The Secretariat will send the Continuing Review Application Form to the designated IEC members.

- The IEC Chairperson/ Member Secretary/ Member/s could reach one of the following decisions after review:
    1. Noted - The IEC approves the continuation of the project without any modifications.
    2. Modifications recommended: The study protocols that have been suggested or modification suggested by the IEC may not proceed until the conditions set by the IEC have been met. The amendments and the required documents should be appended and submitted to the IEC within one month for re-review.

- The project cannot be continued: The reasons for discontinuation of the project should be mentioned in the letter notifying the decision to the Principal Investigator. This decision shall be recorded by the Member Secretary.
- The IEC Chairperson/ Member Secretary will sign and date the IEC decision on Continuing Review Report after a decision has been reached.
- The decision on continuing review taken by the Chairperson/ Member Secretary/ Member/s will be informed to all IEC members at the next full committee meeting.
- The continuing review report may be discussed at full committee meeting by Member Secretary/PI.
- The IEC Secretariat will maintain and keep the IEC Decision forms and minutes of the meeting relevant to the continuing review as part of the official record of the review process in the project file.

10.4.6 Communicating IEC Decision to the PI

- The Secretariat will notify the PI of the decision within 14 days of the meeting at which the report was discussed or of the date of review by the Chairperson/ Member Secretary/ IEC Member/s.

10.4.7 Non-submission of continuing review report by principal investigator before due date.

- If a PI fails to submit the continuing review report within one month of the due date (i.e. 11 months from the date of approval, or earlier on the dates as specified), the Secretariat will send a telephonic and /or email reminder at least 15 days prior to due date of review. If there is no response, the IEC secretariat will put up the matter for discussion at the

forthcoming full committee meeting for appropriate action. This may consist of but not limited to sending:

a) A fresh reminder letter
b) A letter asking explanation for non-submission
c) A letter asking the PI to put recruitment of new participants on hold till report is submitted
d) Any other action as deemed appropriate by IEC

5. Annexures

Annexure 1– *AX1/SOP 10/VI* Reminder letter from the IEC to the principal investigator

Annexure 2 - *AX2/SOP 10/VI* Continuing Review Application Form

Annexure 1 AX1/SOP 10/VI

Reminder letter by the IEC to principal investigator

Date:-

Name of Principal Investigator:-

Department:-

Ref: - Project no.

Title: ----------

The above referenced project was approved by the IEC on ----------and is due for Continuing Annual/ Periodic Review by the IEC. You are requested to submit an Annual/ Periodic status report in the prescribed format which is enclosed on or before ---------- (1 month period)

Signature with date _____

Member Secretary _____

Project No.:	**Date of IEC approval:**
Project Title:	
Principal Investigator : **Department :**	

Annexure 2 AX2/SOP 10/VI

Continuing Review Application Form

Project no. _____ Date of IFC approval_____

Summary of protocol participants: No. of participants screened No. of participants approved by IEC No. of recruited participants _____ No. of ongoing participants _____ No. of completed participants ____ No. of participants who refused to consent Have any participants been withdrawn from this study? Yes No If no, (state the number and reasons for drop-outs of each participant, attach separate sheet if needed) Have there been any amendments in protocol/ Informed Consent Document since the last review? Yes No Were these protocol/ Informed Consent Document (ICD) amendments approved by IEC? Yes No If no, mention the amendments not approved Which protocol amendment is being followed at the site at present _____ Which ICD amendment is being followed at the site at present _____	Has any information appeared in the literature, or evolved from this or similar research that might affect the IEC/IEC's evaluation of the risk/benefit analysis of participants involved in this protocol? Yes No If Yes (attach separate sheet if needed) Whether reports of SAEs so far have been reviewed by the IEC- _____ Whether reports of SAEs at other sites have been submitted to the IEC-_____ Have any participating investigators been added or withdrawn since last review? Yes No If Yes (Identify all changes in the attached narrative) Is report of interim data analysis available? Yes (submit as an attachment) No Is report of the data safety and monitoring board available? Yes (submit as an attachment) No

Date of meeting: _____

Signature of the Principal Investigator with Date: _____

Assessment of Continuing Review Report by the IEC To be reviewed by

- Chairperson /Member Secretary only and informed to the IEC members at Full Committee meeting
- Full Committee meeting
- Any 2 IEC members and informed IEC members at Full Committee

Names of IEC members:

1._____

2._____

Signature with date

Chairperson/ Member Secretary

IEC Decision on the Continue Review Report

Decision

Approved and the project can be continued without any modifications

Modifications recommended - requiring protocol resubmission

State the recommendations:

Protocol should be discontinued

State the reasons for discontinuation

Date of Full Board discussion

Date of Full Committee meeting- ----------

Signature of reviewer/s with date:

_____

Signature with date Chairperson / Member Secretary

6. Flow Chart

No.	Activity	Responsibility
1	Determine the date of continuing review	Administrative Officer / Secretariat
2	Notify the Principal Investigator or study team	IEC Secretariat
3	Manage continuing review package upon receipt and verifying its contents	IEC Secretariat
4	Notify the members of the IEC	IEC Secretariat
5	Review of Continuing review report	IEC Secretariat, Members and Chairperson
6	Prepare meeting agenda	IEC Secretariat
7	Communicate the IEC decision to the Principal Investigator	IEC Secretariat