**Statement of Policy**

The REC shall require the submission of an application for Continuing Review at least 4 weeks before the expiration of the ethical clearance of a protocol. Protocols that underwent Full review in its initial submission shall undergo Full review in its application for Continuing review. Similarly, protocols that underwent Expedited review shall undergo Expedited review in its application for Continuing review.

**Objectives of the SOP**

This activity aims to ensure that the conduct of the study is in compliance with the approved protocol and that the safety and welfare of study participants are promoted and the integrity of data protected beyond the period of initial ethical clearance and up to the end of the study.

**Scope/Applicability**

This SOP applies to the management of an application for Continuing review submitted by the proponent while the study is still on-going but whose ethical clearance is about to expire. This SOP begins with the receipt of an application for continuing review and ends with the entry to logbook and protocol database.

**Flowchart**

|  |  |  |
| --- | --- | --- |
| **ACTIVITY** | **RESPONSIBILITY** | **TIMELINE** |
| Step 1: Receipt of the application for Continuing Review and entry to logbook(SOP # 23 Management of Active Files) | Staff | 1 day |
| Step 2: Retrieval of pertinent protocol files | Staff | 1-2 days |
| Step 3: Notification of Chair and Primary Reviewers | Staff | 1-2 days |
| Step 4: Determination of type of review: expedited (SOP # 04 Expedited Review ) or full review (SOP # 05 Full Review) | Chair and Primary Reviewers | 1-2 days |
| Step 5: Communication of committee action (SOP on Communication REC Decisions (SOP# 21)) | Chair | 1 day |
| Step 6: Filing of documents in the appropriate protocol folder and Update of the Protocol Database | Staff | 1 day |

**Description of Procedures**

Step 1 - Receipt of the application for continuing review and entry to logbook: The Staff receives, logs and enters in the protocol database the information included in the application for Continuing review (Form 020: Application for Continuing Review).

Step 2 - Retrieval of pertinent protocol file: The Staff retrieves the approved protocol and prepares a summary of the progress reports, protocol deviation/violation reports, SAE/SUSAR reports, report of negative events (RNEs) and corresponding decisions including the type of initial review during the period of effectivity of the initial ethical clearance.

Step 3 - Notification of Chair and Primary Reviewers: The Staff notifies the Chair and the Primary Reviewers regarding the submission and the summary of the reports submitted and decisions made during the period of effectivity of initial ethical clearance.

Step 4 - Determination of type of review: expedited or full review: The Chair shall determine the type of review based on the policy that protocols that underwent Full review in its initial submission shall undergo Full review in its application for Continuing review. Similarly, protocols underwent Expedited review shall undergo Expedited review in its application for Continuing review (see SOP 04: Expedited Review and SOP5: Full Review).

Step 5 - Communication of committee action: For example, The Staff prepares the draft decision based on the report of the expedited review or the minutes of the meeting in the full review. The Chair finalizes and signs the decision letter (Form 008). Possible decisions include the following: Approval, Additional information required, submission of an explanation for failure to submit required reports or disapproval.

Step 6 – Filing of documents in the appropriate protocol folder: For example, The Staff files the application for Continuing review, the recommendations of the reviewers and decision letter in the appropriate protocol folder.

**Forms:**

SOP 12 Form 020: Continuing Review Application Form

Logbook

Database

Form 008: Decision letter template

**History of SOP**

|  |  |  |  |
| --- | --- | --- | --- |
| **Version No.** | **Date** | **Authors** | **Main Change** |
| 01 | 03/05/2021 |  |  |
| 02 | 09/26/2022 | krva | Revision of SOP |