**Statement of Policy**

Active files shall be kept in a secured cabinet, arranged in an orderly manner that shall allow easy identification and retrieval. Access to the active files shall be governed by SOP on Managing Access to Confidential Files (SOP# 25)

**Objectives of the SOP**

The management of active files ensures accessibility, easy retrieval of current files, and protection of those that require confidentiality.

**Scope/Applicability**

This SOP covers procedures done related to protocols accepted for review, undergoing review, or has been approved by the REC. This SOP begins with the classification and coding of active files and ends with the periodic updating of the file.

**Flowchart**

| **ACTIVITY** | **RESPONSIBILITY** | **TIMELINE** |
| --- | --- | --- |
| Step 1: Classification and coding of Active Files | Member Secretary and Staff | 1-2 days |
| Step 2.: Preparation of the Protocol Folder | Staff | 1-2 days |
| Step 3: Periodic updating of the Protocol File | Member Secretary and Staff | 1-2 days |

**Description of Procedures**

Step 1. Classification and coding of active files: The staff under the supervision of the member secretary classifies active files as follows:

* + Initial Submission
  + Resubmission
  + Progress Report
  + Amendment
  + Protocol Deviation
  + Protocol Violation
  + SAE Serious Adverse Event (SAE
  + SUSAR – Suspected Unexpected Serious Adverse Reaction –
  + Early Termination –
  + Continuing Review
  + Final Report/ Close Out Report

The staff assigns a code to the Initial Submission and indicates the same for the rest of the submissions related to the initial submission. The code consists of the year and the serial member that indicate the sequence order of receipt. For example, a protocol received in 2019 as the 10th submission in that year will be coded as 2019-010.

Step 2. Preparation of the Protocol Folder: The staff files all documents pertaining to a study in a vertical folder that is labelled on the front cover and along the spine with: Protocol Code- Study Title - Proponent’s Family Name - Sponsor or Funding Agency. The staff attaches a protocol index on the inside front cover that indicates the contents of the folder.

Step 3. Periodic Updating of the Protocol File: The staff ensures that the documents are filed in chronological order such that the most recent documents are topmost. These documents include the following:

* + Protocol (Original and Revised) versions
  + Informed consent (Original and Revised) versions
  + Reports: Progress, Protocol Deviation/Violation, SAE/SUSAR, Final, Amendment, Early Termination, Site Visit Reports
  + Assessment Forms for each of the submitted and reviewed reports which should be signed and dated
  + Excerpts of Minutes of Meetings when the protocol and reports were included in the agenda
  + Decision and Approval Letters
  + Communications

The staff updates the protocol index each time a new document is added to the file. The protocol folder is periodically checked for orderliness and completeness.

**Forms:**

SOP 22 Form 029 Protocol Index

**History of SOP**

|  |  |  |  |
| --- | --- | --- | --- |
| **Version No.** | **Date** | **Authors** | **Main Change** |
| 01 | 09/26/2022 | krva | New SOP |