**Statement of Policy**

The REC shall require the submission of proposed amendments for review and approval before their implementation. This requirement shall be explicitly stated in the Approval Letter.

**Objectives of the SOP**

This activity aims to ensure that the conduct of the study is in compliance with the approved protocol such that any change such as amendments does not impact safety and welfare of study participants.

***Scope/Applicability***

This SOP applies to the management and review of protocol amendments submitted by the proponent while the study is on-going. This SOP begins with the receipt and entry of the submission of amendment to logbook of incoming documents and the protocol database and ends with filing of the amendments and committee decision in the protocol file.

**Flowchart**

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| **ACTIVITY** | **RESPONSIBILITY** | **TIMELINE** |
| Step 1: Receipt and entry into logbook of the submission of amendments (SOP # 23 on Management of Active Files).  | Staff | 1 day |
| Step 2: Retrieval of pertinent protocol file | Staff | 1-2 days |
| Step 3: Notification of Chair and Primary Reviewer | Staff | 1-2 days |
| Step 4: Determination of type of review: expedited (SOP# on Expedited Review) or full review (SOP # 05 on Full Review) | Chair and Primary Reviewer | 1-2 days |
| Step 5: Communication of committee action (SOP# 21 on Communication REC Decisions) | Chair | 1 day |
| Step 6: Filing of Amendments and decision letter and update of the protocol database. SOP# 23 on Management of Active Files) | Staff | 1 day |

**Description of Procedures**

Step 1 - Receipt and entry to logbook: The Staff receives Application for Review of Amendments Form 015 and enters the date and pertinent information in the logbook of incoming documents (See SOP 23: Management of Active files).

Step 2 - Retrieval of pertinent protocol file: The Staff retrieves the corresponding protocol file for reference and guidance of the Chair and Reviewers.

Step 3 - Notification of Chair and Primary Reviewer: Within two days after receipt of the Application for Review of Amendments, the Staff notifies and sends the pertinent protocol file to the Chair and the previously assigned Primary Reviewers.

Step 4 - Determination of type of review: expedited or full review: The Chair and the Primary Reviewer, together, decide the type of review and proceed accordingly. For Expedited review, see SOP 4: and for Full review, see SOP 5.

Step 5 - Communication of committee decision: The REC communicates the committee action, see SOP 21: Communicating REC Decisions. For amendments, the committee action may be any of the following “approved”, “additional justification/information required”, “reconsent required” or disapproved. Staff prepares a draft of the committee decision based on either an expedited review report or minutes of a meeting. The Chair signs the decision letter as follows: Approval, request for additional justification/information or specific action/s e.g. reconsent required or disapproved.

Step 6 – Filing of Amendment documents and committee decision and update of the database: The Staff files the Amendment and a copy of the committee decision in the appropriate protocol folder. S/he proceeds to update the pertinent protocol database.

**Forms:**

Form 015 Amendment Form

Form 008 Decision letter template

Logbook

Database

 **History of SOP**

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| --- | --- | --- | --- |
| **Version No.** | **Date** | **Authors** | **Main Change** |
| 01 | 01/28/2015 |  |  |
| 02 | 09/22/2022 | krva | Revision of SOP |