**Statement of Policy**

The REC shall require the submission of the final report not later than 8 weeks after the end of the study. Final reports shall undergo either expedited or full review.

**Objectives of the SOP**

This activity aims to ensure that the conduct of the study was in compliance with the approved protocol and that the safety and welfare of study participants were promoted and the integrity of data protected until the end of the study.

**Scope/Applicability**

This SOP applies to the management and review of final reports submitted by proponents at the end of the study. This SOP begins with the receipt and entry of the final report into the logbook and ends with an update of the protocol database.

**Flowchart**

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| --- | --- | --- |
| **ACTIVITY** | **RESPONSIBILITY** | **TIMELINE** |
| Step 1: Receipt of final report and entry into logbook (SOP on Management of Active Files (SOP# 23)) | Staff | 1 day |
| Step 2: Retrieval of pertinent protocol file | Staff | 1-2 days |
| Step 3: Notification of Chair and Primary Reviewer | Staff | 1 day |
| Step 4: Full review (SOP 05 on Full Review) | Chair, Primary Reviewer, Committee Members | 7 - 14 days |
| Step 5: Communication of committee action (SOP on Communication REC Decisions (SOP# 21) | Chair | 1 day |
| Step 6: Filing of the Final Report and related documents and update of the protocol files. | Staff | 1 day |

**Description of Procedures**

Step 1 - Receipt and entry of final report into logbook : The Staff receives and enters the date of receipt of the final report into the logbook.

Step 2 - Retrieval of pertinent protocol file: The staff retrieves the corresponding protocol file as reference in the review of the Final Report.

Step 3 - Notification of Chair and Primary Reviewer: The staff notifies the Chair and the primary reviewers of the receipt of the Final Report and awaits further instructions.

Step 4 - Full review: The Chair instructs the staff to include the report in the agenda of the next meeting and to ensure that the primary reviewer is given the necessary documents so that s/he can prepare the presentation during the next meeting (SOP 05 Full Review).

Step 5 - Communication of committee action (SOP ## Communicating REC Decisions): It is suggested that the REC consider the following decisions in the review of a final report: acceptance of the Final Report or to require resubmission with corrections.

Step 6 - Filing of the Final Report and related documents and update of the protocol database:

The REC Staff files the Final Report and related documents in the appropriate folder and updates the protocol database.

**Forms:**

SOP 13 Form 023 Final Report Form

Form 008 Decision Letter

**History of SOP**

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| **Version No.** | **Date** | **Authors** | **Main Change** |
| 01 | 03/05/2021 | krva | Creation of new SOP |