**Statement of Policy**

The REC shall require the submission of progress reports at a frequency based on the level of risk of the study. Progress reports of protocols approved by full board at initial review shall undergo full review. 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 and that the safety and welfare of study participants are promoted.

**Scope/Applicability**

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

**Flowchart**

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| --- | --- | --- |
| **ACTIVITY** | **RESPONSIBILITY** | **TIMELINE** |
| Step 1: Receipt and entry into logbook of the progress report (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 Reviewers | Staff | 1-2 days |
| Step 4: Determination of type of review: expedited (SOP on Expedited Review (SOP# 04)) or full review (SOP on Full Review (SOP# 05)) | Chair and Primary Reviewers | 1-2 days |
| Step 5: Communication of committee action (SOP on Communication REC Decisions (SOP# 21)) | Chair | 1-2 days |
| Step 6: Filing of Progress report and decision letter and update of the protocol database. SOP on Management of Active Files (SOP# 23)) | Staff | 1 day |

**Description of Procedures**

Step 1 - Receipt and entry to logbook: The Staff receives the progress report written in the Progress Report Form 016 and enters the date and pertinent information in the logbook of incoming documents (See SOP 21: 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 Reviewers: Within two days after receipt of the progress report, 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 Reviewers, together, decide the type of review and proceed accordingly. Progress reports of protocols approved by full board at initial review shall undergo full review. 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 19: Communicating REC Decisions. For progress reports, the committee action may be “approved” or “additional information required” or “specific action/s required from the researcher”. 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 information or specific action/s.

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

**Forms:**

SOP 8 Form 016 Progress Report Form

SOP 21 Form 008 Decision letter template

Logbook

Database

 **History of SOP**

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| --- | --- | --- | --- |
| **Version No.** | **Date** | **Authors** | **Main Change** |
| 01 | 02/28/2017 |  |  |
| 02 | 06/22/2019 | krva | Revision of SOP |