**Statement of Policy**

When a decision for early termination of the research has been made, the well-being and safety of study participants that have already been recruited shall be a primary consideration and the plan for termination shall reflect this concern. Early termination reports shall undergo full review. Early termination is defined as the decision of the researcher, principal investigator, the institution, or sponsor to end the implementation of a study before its completion.

**Objectives of the SOP**

Review of early termination reports aims to ensure that the decision takes into consideration the safety and welfare of study participants that have already been recruited and that there is adherence to the principle of fairness for all concerned.

**Scope/Applicability**

This SOP applies to the review of early termination reports. This SOP begins with the receipt and entry to logbook of the early termination reports and ends with the communication of committee action to the researcher/investigator and updating of the protocol database.

**Flowchart**

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| --- | --- | --- |
| **ACTIVITY** | **RESPONSIBILITY** | **TIMELINE** |
| Step 1: Receipt of the early termination report and entry into the logbook (SOP 23 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 Reviewers | Staff | 1-2 days |
| Step 4: Full review (SOP on Full Review (SOP# 05)) | Primary Reviewers and Members | 7-14 days |
| Step 5: Communication of committee action (SOP## Communicating REC Decisions) and update of the protocol database (SOP 23 Management of Active Files) | Chair, Staff | 1-2 days |

**Description of Procedures**

Step 1 - Receipt and entry to the logbook and database of early termination reports, for review: The REC staff receives the early termination report and enters the appropriate information into the log book (SOP 23 Management of Active Files)

Early termination - Defined as the decision of the researcher, principal investigator, the institution, or sponsor to end the implementation of a study before its completion.

REC can decide to terminate the study early.

Step 2 - Retrieval of pertinent protocol file: The REC Staff retrieves the protocol folder and summarizes the documents that have been submitted.

Step 3 - Notification of Chair and Primary Reviewers: The REC staff informs the Chair and the primary reviewers by email about the report and the summary of documents that have been submitted. S/he waits for 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 reviewers are given the necessary documents so that s/he can prepare the presentation during the next meeting (SOP 05 Full Review). The review should ensure implication of the early termination on the rights, safety, and welfare of the study participants, in the form of a termination package with a set of procedures. The procedures may include adapting specific provisions for continued access to protective mechanisms and information by the study participants.

Step 5 - Communication of committee action and Update of the Protocol Database: The REC considers the following possible decisions in the review of an early termination report: acceptance of the decision with no further action; request for additional information; or requirement for further action. The staff prepares a draft of the committee decision based on the minutes of the meeting (SOP 21 Communicating REC Decisions) for signature of the Chair. S/he updates the protocol database accordingly.

**Forms:**

SOP 14 Form 022 Early Termination Report 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 | krva | Creation of SOP |
| 02 | 06/21/2019 | krva | Review of early study termination |
| 03 | 03/05/2021 | krva | Early Termination Report Form 019 |
| 04 | 09/26/2022 | krva | Revision of SOP and Form 022 |