**Statement of Policy**

The REC shall require the submission of RNE reports, at the latest three (3) days after the event has come to the attention of the researcher. A special meeting shall be considered depending on the level of risk involved.

**Objectives of the SOP**

Review of RNE reports aims to ensure that the safety and welfare of human participants and the research team are safeguarded and that information on RNEs are properly documented and evaluated.

**Scope/Applicability**

This SOP applies to the review of RNE reports. This SOP begins with the receipt and documentation of submission of RNE report in the logbook and ends with the filing of all related documents and update of the protocol database.

**Flowchart**

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| **ACTIVITY** | **RESPONSIBILITY** | **TIMELINE** |
| Step 1: Receipt and documentation of submission of RNE report in the logbook. | Staff | 1 day |
| Step 2: Retrieval of pertinent protocol file | Staff | 1-2 days |
| Step 3: Notification of Chair  | Staff | 1 day |
| Step 4: Call for a Special Meeting | Chair | 1-3 days |
| Step 5: Deliberation on the RNE  | REC members | 1 day |
| Step 6: Communication of REC action to the researcher (SOP 21 on Communication of REC Decisions) and to the Institutional authority | Chair | 1-2 days |
| Step 7: Filing of all related documents (SOP 23 Management of Active Files) and Update of the protocol database | Staff | 1 day |

**Description of Procedures**

Step 1 - Receipt and documentation of submission of the RNE report in the logbook/database: The Staff receives the accomplished RNE report form (Form 018) and enters the submission into the logbook. The Staff notes whether the submission is within the required timeline.

Step 2 - Retrieval of pertinent protocol file: The Staff retrieves the approved protocol file and checks the identity of the primary reviewers.

Step 3 - Notification of Chair: The Staff notifies and sends the report and the retrieved documents to the Chair who may decide to call for a special meeting.

Step 4 - Call for a Special Meeting. The staff prepares for a special meeting (SOP 17). The researcher and other members of the study team may be invited for a clarificatory meeting.

Step 5 - Conduct of the Special Meeting. The Chair leads the discussion of the special meeting, summarizes the RNE report and informs the REC members regarding the presence of the research team for clarificatory meeting. The safety issues are evaluated, i.e., identification of risks to the participants / research team, nature and effectivity of preliminary interventions with or without the help of community constituents/authority, impact on integrity of data and completion of the research. The Research team is excused and the REC members deliberate on possible options, as follows:

 - recommend suspension of the study until risk is resolved.

 - withdrawal of ethical clearance

 - submission of a plan to mitigate risk/harm

 - require an amendment to the protocol

 - uphold original ethical clearance

Step 6 - Communication of REC recommendation to the researcher: See SOP 21 on Communicating REC decisions.

Step 7 - Filing of all related documents and update of the protocol database: See SOP 23 on Managing Active Files (SOP 23).

**Forms:**

SOP 11 A Form 018 RNE Report

SOP 17 Form 024 Notice of Meeting

Form 008 REC Decision Letter

 **History of SOP**

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| --- | --- | --- | --- |
| **Version No.** | **Date** | **Authors** | **Main Change** |
| 01 | 01/28/2015 |  |  |
| 02 | 06/21/2019 | krva | Inclusion of Reportable Negative Events (RNE) |
| 03 | 09/26/2022 | krva | Creation of a New SOP on RNE |