**Statement of Policy**

The meeting minutes shall be based on the approved agenda and shall be the basis of the decision letter on protocols

**Objectives of the SOP**

The preparation of the minutes of the meeting ensures the proper documentation of the procedures and decisions in an REC meeting.

**Scope/Applicability**

This SOP includes REC actions related to the documentation of the proceedings of a meeting, the final output of which is the minutes of the meeting. This SOP begins with the entry of preliminary information on the minutes template and ends with the filing of the approved minutes.

**Flowchart**

|  |  |  |
| --- | --- | --- |
| **ACTIVITY** | **RESPONSIBILITY** | **TIMELINE** |
| Step 1: Entry of preliminary information on the minutes template | REC Staff | 1-2 days |
| Step 2: Preparation of the draft minutes | REC Staff and Member Secretary | 1-3 days |
| Step 3: Notation of the draft minutes | Chair | 1-2 days |
| Step 4: Approval of the minutes in the next REC meeting | Chair and Members | 1 day |
| Step 5: Filing of the approved minutes (SOP on Managing Active Files (SOP# 23)) | REC Staff | 1-2 days |

**Description of Procedures**

Step 1- Entry of preliminary information on the minute’s template: The REC Staff will utilize the Minutes of the meeting form 026. The document would be organized by filing it out with preliminary or relevant information ahead of the meeting (protocol related information and other matters). The Chair and Member secretary supervises the REC Staff in fulfilling this task.

Step 2 - Preparation of the draft minutes: During the meeting, the REC Staff is tasked with documentation of proceedings in accordance with the agenda. The REC Staff document all board opinions and actions by taking down notes or project the template on screen and or do real-time note-taking in all specific sections of the agenda. With the consent of everyone present in the meeting the REC staff would record proceeding using a tape recorder to ensure that the REC staff documents the discussion as the agenda is developed and discussed, with respective reasons for protocol-related actions. Comments and recommendations on the scientific issues, ethical issues, and informed consent form issues must be documented. Opinions and actions included in the minutes are understood to be collective and need not be attributed to specific members. The REC staff is given 1-3 days to accomplish such task. The Chair and Member secretary has oversight on the fulfillment of this task by the REC staff.

Step 3 - Notation of the draft minutes: The draft minutes should be prepared for notation of the Chair. After completing the draft of the minutes, the REC Staff submit the draft to the Member secretary and the Chair. In 1-2 days the REC should complete, correct, and finalize the draft.

The following items are included in the minutes of the meeting:

* Date and venue of meeting
* Members attendance (members present and absent)
* Presence of Independent consultants, primary investigators, guests, and observer’s attendance (if any)
* Time when the meeting was called to order
* Declaration of Quorum
* Name of Presiding officer
* Conflict of Interest (COI) declaration
* Items discussed, issues raised, and resolutions
* REC decisions and recommendations
* Name and signature of person who prepared the minutes
* Name and signature of the Chair and date of notation

Step 4 - Approval of the minutes in the next REC meeting: Approval of the minutes is done through a formal motion from any member of the committee and seconded accordingly.

Step 5 - Storage of the approved minutes: The REC maintain a central file of all meeting minutes by year to facilitate retrieval. See SOP on Managing Active Files (SOP# 23).

**Forms:**

SOP 20 Form 026 Minutes Template

 **History of SOP**

|  |  |  |  |
| --- | --- | --- | --- |
| **Version No.** | **Date** | **Authors** | **Main Change** |
| 01 | 01/28/2015 | krva | Creation of SOP |
| 02 | 09/26/2022 | krva | Revision of SOP |