**Statement of Policy**

The REC shall consider the perspective of the researcher regarding the feasibility and acceptability of REC recommendations including its disapproval. Appeals of researchers shall undergo full review and shall be resolved within six weeks (24 working days) upon receipt of the fully documented appeal

**Objectives of the SOP**

Management of appeals ensures fairness, transparency and comprehensiveness of ethics review that takes into consideration the perspective of the researcher.

**Scope/Applicability**

The SOP on Management of Appeals covers procedures that begin with the receipt of the appeal and ends with communicating the committee’s action to the researcher and updating of the protocol

**Flowchart**

|  |  |  |
| --- | --- | --- |
| **ACTIVITY** | **RESPONSIBILITY** | **TIMELINE** |
| Step 1: Receipt of an appeal | Staff | 1 day |
| Step 2: Retrieval of pertinent protocol file | Staff | 1-2 days |
| Step 3: Notification of Chair and Primary Reviewer/s | Staff | 1 day |
| Step 4: Inclusion in Agenda of the next regular meeting | Chair and Primary Reviewer | 1-2 days |
| Step 5: Discussion of and deliberation on the appeal | Chair and REC Members | 3-7 days |
| Step 6: Communication of committee action (SOP## Communicating REC Decisions) | Chair | 1 day |
| Step 7: Filing of documents and updating of the protocol database | Staff | 1 day |

**Description of Procedures**

Step 1 - Receipt of an Appeal: The staff receives the letter of appeal and enters the pertinent information into the logbook.

Step 2: Retrieval of pertinent protocol file: The staff retrieves the pertinent file for reference in the review. The file includes the initially submitted protocol, ICF, research tools and other related documents.

Step 3: Notification of Chair and Primary reviewers: The staff notifies the Chair and the primary reviewers about the letter of appeal and awaits further instructions.

Step 4. Inclusion in the Agenda of the next regular meeting: The Chair instructs the staff to include the appeal in the agenda of the next meeting, to ensure that the retrieved protocol and related documents are available during the meeting and to inform the researcher to be available on the scheduled meeting in case there is a need for further clarification.

Step 5: Discussion of and Deliberation on the Appeal: The primary reviewer summarizes the protocol and the previous discussion of the issues in the protocol as background to the appeal. The Chair presents the contents of the appeal and leads discussion. The researcher may be called in for further clarification of issues. The researcher is asked to step out after the committee has taken up the issues for clarification. The committee then decides (by consensus) whether to accept any or all of the points raised in the appeal.

Step 6: Communication of Committee Action: Based on the deliberations, the Chair summarizes the decision points and instructs the REC staff to prepare the draft decision letter (Form 008 Decision Letter Template) for his/her finalization and forwarding to the researcher. (SOP 21 Communicating REC Decisions):

Step 7: Filing of Documents and Update of Protocol Database: The staff files all the documents into the appropriate folder and updates the protocol database accordingly.

**Forms:**

Form 008 Decision Letter Template

 **History of SOP**

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