**Statement of Policy**

The REC shall communicate its decisions to the researcher within 4 to 6 weeks (reasonable timeframe not later than six weeks) after the receipt of complete set of submission documents. The communication document shall include clear instructions/recommendations for guidance of the researcher, must be written on an official stationery of the REC and signed by the chair.

**Objectives of the SOP**

The management of communicating REC decisions ensures that all stakeholders are appropriately, accurately and promptly informed of the results of deliberations of the REC

**Scope/Applicability**

This SOP covers REC actions related to the communicating REC decisions (e.g. actions to applications submitted to the REC). This SOP begins with the finalization of recommendations of the committee or the reviewers and ends with the filing of the decision document in the protocol file.

**Flowchart**

|  |  |  |
| --- | --- | --- |
| **ACTIVITY** | **RESPONSIBILITY** | **TIMELINE** |
| Step 1: Finalization of recommendations of the committee (in case of full review) (SOP # 05 Full Review) ) or Finalization of recommendations of reviewers (in case of expedited review) (SOP # 04 Expedited Review) | Chair | 1-2 days |
| Step 2: Transfer of information from meeting minutes or reports to REC decision forms or templates | REC Staff, Member Secretary | 1-3 days |
| Step 3: Approval of the REC decision document | Chair | 1-2 days |
| Step 4: Transmittal of REC decision to researcher | REC Staff | 1-2 days |
| Step 5: Filing of the decision document in the protocol file (SOP # 23 Managing Active Files ) and Update of Protocol Database | REC Staff | 1-2 days |

**Description of Procedures**

Step 1 - Finalization of recommendations of the committee (in case of full review) or reviewers (in case of expedited review): The REC Staff drafts the letter based on returned electronic or hard copy review / evaluation forms. For finalization of Committee’s Recommendations See SOP# 05 on Full Review or for finalization of Reviewers’ Recommendations, see SOP # 04 Expedited Review).

Step 2 - Transfer of information from meeting minutes to REC decision forms or templates: Upon approval of the draft minutes, or finalization of the reviewers’ recommendations, REC relay the information to the researchers through an email with an attached certificate of approval, or notoce of action indicating REC recommendations. A Decision Letter Form 008 would be sent to the researcher. The member secretary drafts the document. The Chair oversees this process. This process should take around 1-3 days.

Step 3 - Approval of the REC decision document: The Chair reviews and approves the decision documents by affixing his/her signature. A decision letter Form 008 would be attached in an email sent to the researcher. This will take around 1-2 days.

Step 4 - Transmittal of REC decision to researcher: The researchers get the results of the review through email and or hand-delivered or pick up at the REC office, which ever is most available. This process will take 1-2 days. The Chair oversees this process.

Step 5 - Filing of the decision document in the protocol file and Update of the Protocol Database: The REC maintains all protocol related decisions or actions in the protocol folder to facilitate retrieval. The action should also be noted in the protocol database. For hard copies, a physical storage cabinet with lock and key would be utilized. For electronic copies, a cloud storage or electronic drive that is password protected. Documentation is done through protocol coding in a database. See SOP on Managing Active Files (SOP# 23).

**Forms:**

SOP 21 Form 008 Decision Form/Letter

SOP 21 Form 009 Approval Form/Letter

**History of SOP**

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