**Statement of Policy**

All communications shall be recorded accurately and appropriately in a physical logbook and electronic database. Protocol-related communications are separated from administrative communications. Incoming communications shall be acted upon promptly.

**Objectives of the SOP**

The management of REC incoming and outgoing documents/communications aims to establish accountability and an efficient and effective tracking system.

**Scope/Applicability**

This SOP covers REC actions related to organizing incoming and outgoing documents and ensuring an appropriate REC response. This SOP begins with the sorting of incoming/outgoing communications and ends with the storing or filing of incoming/outgoing communications.

**Flowchart**

|  |  |  |
| --- | --- | --- |
| **ACTIVITY** | **RESPONSIBILITY** | **TIMELINE** |
| Step 1: Sorting of incoming/outgoing communications | REC Staff | 1 day |
| Step 2: Recording of incoming/outgoing communications | REC Staff | 1 day |
| Step 3: Acting on incoming communications | Chair or Member Secretary | 1-2 days |
| Step 4: Filing of incoming/outgoing communications and Updating of respective Databases | REC Staff | 1 day |

**Description of Procedures**

Step 1 - Sorting of incoming/outgoing communications: Communications can come in the form of letters, official memoranda, or emails. The REC staff screen and sorts all communications received and prepares them for recording. The source (e.g. researchers, sponsors, regulators) of the communication would be documented. Protocol-related communication would be separated from process-related communication. The REC Chair oversees this process.

Step 2 - Recording of incoming/outgoing communications: The REC Staff documents the date received, source source (person who sent communication), subject, person who received communication, action taken (with details of who received it from the REC), such as logbook. The Chair oversees this process.

Step 3 - Acting on communications: The Chair or Member Secretary is responsible for initiating response on incoming communications. The Chair or the Member Secretary finalizes these responses. The Chair is the usual signatory for outgoing communications.

Step 4 - Storing or filing of incoming/outgoing communication: Protocol-related communications are filed in the study protocol file while non-protocol-related documents are filed in the appropriate administrative file. The REC staff is responsible for this action. The REC Chair oversees this process.

**Forms:**

Logbook for Incoming Communications

Logbook for Outgoing Communications

SOP 22 Form 029 Index of Protocol File

**History of SOP**

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