**Statement of Policy**

Access to the REC confidential files shall be regulated and limited to REC members and staff. Other persons with legitimate interest in these files (e.g. institutional authorities, regulatory agencies, sponsors) shall be allowed to access specific files with proper justification. Researchers/Investigators shall be allowed access only to their own protocol files upon request.

**Objectives of the SOP**

Management of access to confidential files helps protect the intellectual property rights of researchers and enhances the credibility and integrity of the REC.

**Scope/Applicability**

This SOP consists of procedures for accessing confidential files including document handling and distribution. This SOP begins with the receipt of the request to access and ends with the return of the documents to the protocol folder.

**Flowchart**

|  |  |  |
| --- | --- | --- |
| **ACTIVITY** | **RESPONSIBILITY** | **TIMELINE** |
| Step 1: Receipt and logging of request for access to confidential files | Staff | 1 day |
| Step 2: Approval of requests for access and retrieval of documents | Member Secretary or Chair | 1-2 days |
| Step 3: Supervision of use of retrieved document | Staff | 1-2 days |
| Step 4: Return of document to the files | Staff | 1-2 days |

**Description of Procedures**

Step 1 - Receipt and logging of request for access to confidential files: The staff receives the request letter to access specific files and refers this to the Chair or Member Secretary.

Step 2 - Approval of requests for access and retrieval of documents: The Chair or Member Secretary considers the indicated reason for the request and when found satisfactory approves it. The staff asks the individual requesting to sign the confidentiality agreement and proceeds to retrieve the pertinent document.

Step 3 - Supervision of use of retrieved document: The staff asks the user to sign the logbook, enforces the restriction to room-use of documents and limits photocopying to concerned researchers/principal investigators.

Step 4 - Return of document to the files: The staff returns the retrieved files to the protocol file.

**Forms:**

Request Letter

SOP 24 Form 028 LOGBOOK OF PROTOCOL SUBMISSIONS

 **History of SOP**

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