

**Institutional Committee for stem cell research (IC-SCR)
Seth G.S. Medical College and K.E.M. Hospital, Parel, Mumbai,
Maharashtra, India – 400 012.
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**Title: Maintenance of Active Study Files, Administrative
Records of the Institutional Committee for stem cell research
(IC-SCR), Archival of Closed Files and Retrieval of Documents**

SOP Code:

KEM SOP 09 /V1 dated 12th June 2020

1. Purpose

To provide instructions for preparation and maintenance of active study files and other related documents approved by the Institutional Committee for Stem Cell Research (IC-SCR), as well as IC-SCR administrative documents, archival of closed files and retrieval of documents.

2. Scope

This SOP applies to maintenance, archival and retrieval of all study files and study related documents and IC-SCR administrative documents by the IC-SCR Secretariat of KEM Hospital.

3. Responsibility

It is the responsibility of Member Secretary with assistance of Secretariat to ensure that all active study files and IC-SCR records are prepared, maintained during the study period and kept securely for a period of five years after the closure/ termination of the project.

4. Detailed instructions

4.1. Maintenance of the Active Study Files

- A study master file is the file comprising all essential documents and correspondence related to the study. This should be created for all proposals at the time of initial submission to the IC-SCR office.

- All related documents of the approved study will be gathered, classified appropriately and placed in the study master file: These could include copies of
 - ✓ All original research proposals reviewed and approved
 - ✓ Study approval letter
 - ✓ Reviewed and approved consent documents
 - ✓ Amendments and any other correspondence
 - ✓ Study progress reports and interim reports
 - ✓ Serious adverse event report forms submitted by investigators
 - ✓ Any other reports
 - ✓ IC-SCR correspondence
- Strict confidentiality will be maintained for the contents of the files
- All active files will be kept secured in a file cabinet with controlled access.
- A log-book for accessing the files by authorized staff & members will be maintained.

- A register for documenting all communications including phone conversations (e.g. queries, complaints, questions, etc.) will be maintained.

4.2. Maintenance of the IC-SCR Administrative Records

The IC-SCR records will include the following:

A. IC-SCR members' records

- i. Appointment and acceptance letters of each member
- ii. Signed and dated confidentiality agreements
- iii. Updated Curriculum vitae (hard copy or soft copy)
- iv. Training records for each IC-SCR member (GCP, SOP)
- v. Documentation of resignations / terminations

B. IC-SCR membership list - An IC-SCR list will be maintained which will contain:

- vi. Names of IC-SCR members
- vii. Age
- viii. Gender
- ix. Evidence of qualifications
- x. Role on the IC-SCR

- xi. Status of affiliation to institution (e.g., unaffiliated or affiliated)
- xii. Regular/ Alternate member to the IC-SCR (if applicable)

C. IC-SCR mandate

D. Correspondence related to changes in IC-SCR membership with National Apex Committee for Stem Cell Research and Therapy

E. IC-SCR attendance list

F. Agenda and Minutes of IC-SCR meetings

G. Standard operating procedures (SOPs)

H. Annual reports

I. Documents related to Workshops & conferences organized by IC-SCR (Continuing education for members & staff)

J. SOP training and distribution logs

4.3. Maintenance of Closed Study Files

- Once the study file is closed (following completion/ premature termination), the related study files will be shifted to the IC-SCR archival cupboard.
- All closed study files will be archived in the IC-SCR archival room for a period of five years from the date of closure of the study.
- A log book for archival of study documents will be maintained.

4.4. Accessibility / Retrieval

- Study files and administrative records will be made available for audit, making photocopies (if requested by investigator) or any other purpose (e.g., research on SAEs) on request if authorized by Member Secretary/ Chairperson.
- Representatives of regulatory authorities may have access at all times.
- A log book of retrieval of documents will be maintained.

4.5. Disposal of Closed Files and Copies of Protocols and Documents Submitted for IC-SCR Review

- At the end of the archival period, the closed files will be shredded and disposed of by authorized IC-SCR personnel.
- Extra copies of protocols and documents submitted for IC-SCR review and any other extra copies will be shredded by authorized IC-SCR personnel after the IC-SCR meeting without

any notification to PI.

- A formal disposal log will be maintained, providing details of documents that will be disposed.

5. Annexures

Annexure 1 AX01/ KEMS09/V1 Document Request Form

Annexure 2 AX02/ KEMS09/V1 Log for disposal of study documents

Annexure 1 AX01/ KEMS09/V1**Document Request Form**

Project No.:	
Project Title:	
Name of Principal Investigator (PI) :	
Requested by :	
Documents requested :	
Purpose of the Request	
Signature of Requesting person:	
Signature of PI:	
Signature of Member Secretary / Chairperson with date:	

Annexure 2: AX02/ KEMS09/V1

Log for disposal of study documents

Project No.	Title	Name of Principal Investigator	No. of files	Date of IC-SCR Approval	Date of Study Initiation	Date of Study Closure	Disposed by (Name & Sign) of Authorized Individual

6. Flowchart

No.	Activity	Responsibility
1	Organize the contents of the active study files	IC-SCR Secretariat
2	Maintain the active study files and Administrative Documents	IC-SCR Secretariat
3	Archival of Study files	IC-SCR Secretariat
4.	Authorizing retrieval of archived Documents	IC-SCR Member secretary/ Chairperson
5.	Disposing closed study files and maintaining Document disposal log	IC-SCR Secretariat
