

**Institutional Committee for stem cell research (IC-SCR)  
Seth G.S. Medical College and K.E.M. Hospital, Parel,  
Mumbai, Maharashtra, India – 400 012.  
Web: [www.kem.edu](http://www.kem.edu)**

**Title: Management of Submission of Research Study  
Protocol and Study Related Documents by Institutional  
Committee for stem cell research  
(IC-SCR), KEM Hospital**

**SOP Code:**

**KEM SOP 06 /V1 dated 12th June 2020**

**1. Purpose**

The purpose of this Standard Operating Procedure (SOP) is to describe how the Secretariat of the Institute Committee for stem cell research (IC-SCR), KEM Hospital manages protocol and other document submission.

## **2. Scope**

The scope of this SOP includes:

- Submission of Research Project and related documents for initial review of the protocol
- Resubmission of Protocols or Research Projects with corrections
- Submission of Protocol Amendment
- Submissions of written communications related to continuing review of approved protocols
- Protocol completion/Termination of Protocol deviations/violation
- SAE initial/ follow up/ final reports
- Submission of Protocol deviations, Protocol violations

## **3. Responsibility**

It is the responsibility of the IC-SCR Secretariat to receive, record and distribute the received protocols and any other documents for review, act on the instructions given by the appropriate member of the IC-SCR and ensure that the communication reaches the concerned recipient.

## **4. Detailed Instructions**

### ***4.1 Receive study protocols/ documents***

Principal Investigator (PI) will submit a stem cell related research proposal to the IC-SCR secretariat office for review and decision under any of the following sections within the specified time period:

- New Proposals for Initial Review
- Re-submission of Protocols with Corrections
- Amended Protocols and related documents

Projects can be submitted to IC-SCR secretariat throughout the year for consideration of research proposal in the meeting of IC-SCR. As soon as a proposal is submitted meeting will be conducted within a month after finalizing the date for meeting as per the convenience of majority of the committee members.

### ***4.2 Initial Review Application***

**Check for submission items:** The Secretariat will check the hard and soft copies of the following items:

- a) Research proposals (1 original and 1 xerox copy) along with soft copy
- b) Supporting documents if any
- c) Regulatory certificates, if applicable

- **Verification of the contents of Submitted Documents:**

**The Secretariat will:**

Use the checklist to confirm whether all the ticked documents are there in the application and ensure that the application is complete in terms of required documents. All the following documents must be in the file

- 1) Covering letter to Member Secretary/ Chairperson
  - 2) Protocol
  - 3) Amendments to protocol (if any)
  - 4) Administrative sanction from the head of the Institution or Memorandum of Understanding in case of studies involving collaboration with other institutions. (if applicable)
  - 5) A copy of Administration sanction from the head of the Institution or Memorandum of Understanding for sending the samples to laboratories outside the Institution. (if applicable)
  - 6) Brief Curriculum Vitae of all the study team members
  - 7) List of ongoing stem cell research studies undertaken by principal investigator
  - 8) Details of Funding agency / Sponsor and fund allocation, if applicable
  - 9) Clinical Trial Agreement between sponsors, investigators and head of the institution(s), if applicable
  - 10) Memorandum of Understanding (MOU)for collaborative studies (if applicable)
  - 11) Ethics Committee clearance of other centers (if applicable)
- **Complete the submission process:** The Secretariat will:
    - Complete the checklist of submission
    - Stamp the receiving date on the first page/last page of the covering letter and initial it.
    - Keep the copies of the submitted documents with original signatures in the protocol “Submission” file.

- Number the project file as JIP/IC-SCR/SNo of proposal/year
- **Dispatch and Store the received Documents:** The Secretariat will
  - Email protocol and related documents along with checklist to the IC-SCR members along with a copy of Project Assessment Form for Initial Review after the last day of submission is over, ensuring at least 5 days for review before the next meeting.
  - Store the appropriately labeled original protocol documents in the designated storage area in the IC-SCR office.

#### ***4.3 Resubmission of Protocols with corrections and Amendments of protocol/ related documents***

- For resubmitted protocol, the PI will submit soft copy and one hard copy of the amended Protocol and related documents along with the original protocol.
- The Secretariat will verify the completeness of the documents and confirm that the copy contains the modifications highlighted with respect to the earlier protocol submitted mentioning the justification for the amendment.
- The protocol related documents which do not require to be changed and are already submitted for the IC-SCR office during initial review are not required to be submitted again.
- The Secretariat will present the file to the Member Secretary

**The Member Secretary will decide** if a resubmitted protocol

- will follow all steps of initial review
- handle it as decided in the meeting (e.g. Carry out review by one or more member(s) selected by the Chairperson. The selected members are normally those who reviewed and recommended the previous version of that protocol) or keep on next meeting agenda

#### **4.4 Annual Continuing Reviews of Approved Protocols, Amended Protocols and related documents, Study completion/ termination, SAE report, Protocol deviations**

The IC-SCR will receive one soft copy and one hard copy of the Continuing Review Report, Amended Protocols and related documents, study completion/ termination, SAE report, protocol deviations in the prescribed format as given in the applicable SOPs.

## **5. Annexures**

Annexure 1: AX 01/ KEMS06/V1 - Project submission application form for initial review along with checklist of protocol submission

**Annexure 1: AX 01/ KEMS06/V1**

**Project submission application form for initial review along with checklist of protocol submission**

**Seth G.S. Medical College and K.E.M. Hospital,  
Parel, Mumbai, Maharashtra, India – 400 012.**

**FORMAT FOR SUBMITTING RESEARCH PROPOSAL FOR  
CONSIDERATION BY INSTITUTE COMMITTEE FOR STEM CELL  
RESEARCH**

**Version 1.0 dated 12<sup>th</sup> June 2020**

Seth G.S. Medical College and K.E.M. Hospital, Parel, Mumbai, Maharashtra, India – 400 012.

**Format**

**FOR SUBMITTING STEM CELL RESEARCH PROPOSAL FOR CONSIDERATION BY INSTITUTE  
COMMITTEE FOR STEM CELL RESEARCH**

**SECTION- 1**

**(For IC-SCR)**

**PART A – GENERAL INFORMATION**

1. Title of the project:
2. Name, designation and address of PI with mobile number and email ID:
3. Name, designation and address of Co-I with mobile number and email ID:
4. Study duration:
5. Collaborating departments from the same institute:
6. Collaborating Institutions, if any:
7. Consent from the Collaborating Institutions/ MoU if any (Enclose copies of the same):
8. Responsibilities of each collaborating Institution:
9. Details of foreign collaboration with supporting evidence:
10. Details of foreign extramural funding with supporting evidence:
  - A. Details of source(s) of finding
  - B. Details of overall funding
  - C. Details of funding to KEM Hospital with breakup
11. Details of Indian extramural funding with supportive evidence:
  - A. Details of source(s) of finding
  - B. Details of overall funding
  - C. Details of funding to KEM Hospital with breakup

**PART B – TECHNICAL DETAILS**

1. Title of the study:
2. Background with rationale, novelty and application(s):
3. Research question(s):
4. Research hypothesis(es), if any:
5. Aims and Objectives:
6. Brief review of literature:
7. Study participants (Humans, animals or both, cell lines):
8. Inclusion and exclusion criteria:
9. Study design:
10. Number of groups, their names and definitions:
11. Sampling method:
12. Sample size along with calculation method(s) :
13. Randomization details, if any:
14. Methodology in detail:
15. Flow chart, if necessary:
16. Relevant References (Maximum 20 cited sequentially in the text of project as per Vancouver style)
17. Enclosures:
  - a. Brief CV, GCP , MMC of PI and Co-I
  - b. Administrative approval/ MoU/CTA/DCGI approval/HMSC approval /any other authority permission if any
  - c. Copy of signed consent from collaborating institutions, if any

A. Signature of the Investigator

(Name, Designation, Department, Seal and Date)



B. Signature of Head of the Department of the Investigator

(Name, Designation, Department, Seal and Date)

C. Signature(s) of the Co-Investigator(s)

(Name, Designation, Department, Seal and Date)

D. Signature(s) of Head(s) of the Department of the co-investigator(s)

(Name, Designation, Department, Seal and Date)