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

Title: Preparation of Standard Operating Procedures for Institutional Committee for stem cell research (IC-SCR), KEM Hospital

SOP Code:

KEM SOP 01 /V1 dated 12th June 2020

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to explain the process for writing, reviewing, distributing and amending SOPs of the Institutional Committee for Stem Cell Research (IC-SCR), KEM Hospital. The SOP provides clear, unambiguous instructions so that the related activities of the committee are conducted in accordance with Indian regulations and relevant, national and international ethical guidelines.

2. Scope

This SOP covers the procedures of writing, reviewing, distributing and amending the SOPs of the IC-SCR, KEM Hospital and is applicable only to KEM Hospital.

3. Responsibility

It is the responsibility of the Chairman of the IC-SCR to appoint SOP team to formulate new SOP or to revise existing SOP. The SOP team shall do this by following the standard procedures, format and coding system that is used while drafting or editing any SOP of the IC-SCR. Head of the Institute (Dean /Director) is responsible for implementing this SOP. The responsibilities of various stake holders of IC-SCR namely secretariat, members, member secretary and chairman is given below.

3.1 Responsibilities of Chairman of the IC-SCR

- appoint one or more SOP teams consisting of the member-secretary and two or more members of IC-SCR with thorough understanding of ethical review process
- approve the SOPs, sign and date the approved SOPs

3.2 Responsibilities of SOP team

- assess the request(s) for SOP/s revision in consultation with the Secretariat, Member Secretary and Chairman
- propose new / modified SOP/s as needed
- draft the SOP/s in consultation with the IC-SCR members and involved administrative staff
- review the draft SOP
- submit the draft for approval to Chairman

3.3 Responsibilities of Secretariat of the IC-SCR:

- assist chairman to constitute SOP Team
- co-ordinate activities of writing, reviewing, distributing and amending SOPs
- ensure that all IC-SCR members and involved administrative staff have access to SOPs
- ensure that all IC-SCR members and involved staff work according to current SOP version
- maintain an up-to-date distribution list for each SOP distributed to the IC-SCR members.
- maintain a register to record the names of investigators to whom SOPs are distributed
- maintain a file of all current SOPs and the list of SOPs
- maintain a file of all past SOPs of the IC-SCR

3.4 Responsibilities of IC-SCR members and involved administrative staff

- sign and date the approved SOP when they receive it and maintain a file of all SOPs received

4. Detailed instructions

4.1 Identify the need for new or amendment of current SOP

Any member of IC-SCR or Secretariat who would feel the requirement of a revision or notices an inconsistency/ discrepancy/ has any suggestions on how to improve the existing SOPs or requests to design an entirely new SOP can put forth his/ her request by writing to the IC-SCR Chairperson either as an email/ letter/ verbal request in a meeting. The chairperson will inform all the IC-SCR members about this request at a regular full-board IC-SCR meeting. If the IC-SCR members agree to the request, an appropriate SOP team(s) will be appointed by the chairperson and designated the task to proceed with the revision process/ formulation process of the SOP. If the IC-SCR members do not agree, no further action will be taken. The Chairperson will inform the member of the IC-SCR or Secretariat who made the request for modification of the SOP.

4.2 List of relevant procedures to be carried out by SOP writing team

- Write all the procedures of IC-SCR that are to be standardized in the form of an SOP
- Organize, divide and name each process

4.3 Write and review a new SOP

When the need for a new SOP has been identified and agreed upon, a draft will be written by one or more designated members of the SOP team, appointed by the chairperson. Each SOP should be given a number and a title that is self-explanatory and easily understood. A unique code number (KEM SOPx, where x is the number of the SOP) with the format SOP aa/Vx will be assigned to each SOP item by the Secretariat. "aa" will be a two-digit number assigned specifically to each activity based SOP, "V" will be the version of the SOP and "x" will be a number of the version ie SOP 01/V1 is SOP number 01 with version 1. Each SOP will be prepared according to standard template of SOP 01/V1. Each page of SOP will bear a header with effective date (aa/bb/cccc) i.e. the date of approval of the SOP by the chairman. The SOP number will be on the right-hand corner with the title of the SOP while the footer will bear the page number as page p of q (total) pages. The draft SOP written by one or more members of the SOP team will be reviewed by the remaining members of the SOP team. After incorporating the suggestions put forth by the SOP team members; a copy of the revised draft SOP will be sent to member-secretary to circulate it to all the IC-SCR members.

4.4 Prepare and submit final draft

- SOP team will submit reviewed SOP to IC-SCR Members who will review it at a meeting.
- The suggestions that are agreed upon by the IC-SCR members present at the meeting will be discussed and incorporated in the revised draft SOP and it will be finalized.
- SOP team would stand automatically dissolved once IC-SCR takes final decision on SOP.

4.5 Approve the new / revised SOP

- The final version will be presented to the Chairman for review and approval.
- The authors, reviewers and chairman will sign and date the SOP on the first page of the SOP document. This date of approval will be declared as the effective date from which

the SOP will be implemented. The front page will contain signature of Dean Research and Director of the Institution as having accepted the document.

4.6 Implement, distribute and file SOPs

- The approved SOP will be implemented from the effective date.

- The Member Secretary will discuss the approved SOP with the administrative staff and instruct them to implement it accordingly.

- The approved SOP will be distributed to the IC-SCR members and a log will be maintained.

- One hard copy of complete original set of current version of SOP will be filed in the SOP Master file, by IC-SCR Secretariat in the IC-SCR office.

- Following distribution of revised version, all IC-SCR members will be requested to destroy their earlier version. Only one copy of earlier version will be filed in the file entitled 'Past SOPs of IC-SCR' by IC-SCR Secretariat in IC-SCR office.

- The IC-SCR members and secretariat will review SOPs at least once in every 3 years.

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