

**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: Agenda Preparation, Meeting Procedures and
Recording of Minutes of the Institutional Committee for stem
cell research (IC-SCR), KEM Hospital**

SOP Code:

KEM SOP 07 /V1 dated 12th June 2020

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the administrative process and provide instructions for preparation, review, approval and distribution of meeting agenda, and minutes of Institutional Committee for stem cell research (IC-SCR), KEM Hospital.

2. Scope

This SOP applies to processes concerning preparation of agenda and recording minutes of IC-SCR meetings. This is applicable to IEC, Human studies of KEM Hospital.

3. Responsibility

It is the responsibility of the Member Secretary assisted by Secretariat to prepare agenda for IC-SCR meeting which will be reviewed and approved by chairperson. It is the responsibility of Member Secretary to ensure proper recording and dissemination of minutes after the meeting is

over. It is the responsibility of all members to read and approve the minutes sent to them. The Chairperson will review and finally approve the minutes.

4. Detailed instructions

4.1 Before each meeting

IC-SCR meeting will be regularly scheduled within a month of submission of stem cell research proposals and the dates will be decided by the member secretary with the help of the secretariat considering the convenience of majority of the members.

4.2 Preparation of meeting agenda

The Member Secretary assisted by the Secretariat will prepare the meeting agenda, according to the format in annexure of this document. This should include:

- a. Welcoming of all members by Chairperson
- b. Ensure quorum by Chairperson
- c. Reading and approving minutes of the previous meeting.
- d. All projects for Initial Review
- e. All resubmitted protocols for review.
- f. Review of Amended protocols or protocol-related documents for review.
- g. Issues for consideration.
- h. Continuing review of study protocols.
- i. Review of Study Completion Reports.
- j. Review of premature study termination.
- k. Review of Site Monitoring Visit Reports.
- l. SAE reports submitted, if any.
- m. Issues to be discussed including policies/ training of Members/ revising SOPs/ any other issues raised by member(s).
- n. Any other matter

The Secretariat will collect and verify all documents submitted to IC-SCR for completeness and keep it ready for the meeting.

- The Secretariat will schedule protocols in the agenda as per date of receipt.

- The agenda for the IC-SCR meeting is prepared at least 3 days in advance before the date of meeting.
- In case a meeting is to be rescheduled due to unavoidable circumstances, the date and time will be informed to the IC-SCR members *via* e-mail. The Secretariat will send *via* e-mail to members the agenda of the meeting at least 1 day in advance of the scheduled meeting. The Secretariat will make sure that the meeting venue, equipment and facilities are available for the meeting day.

4.3 For conducting the meeting

Presence of the following members is mandatory for quorum and for decision making:

- Chairperson/Vice-Chairperson,
- Member Secretary,
- experts from law,
- ethics and social sciences,
- community/lay-person and
- two stem cell/cell and molecular biology expert with appropriate expertise and no COI.

Without satisfying this condition, any decision taken by the committee shall remain null and void. In absence of the Chairperson, Co-Chairperson will chair the meeting. In absence of the Member Secretary, alternate member secretary will look after the functions of member secretary in organizing the meeting.

4.4 During the meeting

- The Chairperson will initiate the meeting after ensuring that the quorum has been met. The Chairperson at his/ her discretion will delegate the responsibility of conducting the meeting as per agenda to the Member-Secretary.
- The Chairperson will ask the members whether anyone has any conflict(s) of interest in the projects to be discussed and if so, to declare the conflict.
- The Secretariat will obtain signatures on the Conflict of Interest Agreement Form from members who declare a conflict (e.g. members who are PIs or Co-Is) prior to the start of

the meeting.

- If a conflict of interest has been declared by a member, the Chairperson will ask the concerned member to leave the meeting room when the concerned issue is being discussed.
- The Secretariat will obtain the signatures of all IC-SCR members on the attendance register.
- At the discretion of the Chairman, guests may be allowed to observe the board meetings. These guests may include a student, inspectors, auditors, members of Ethics Committees, surveyors, regulators, members of regulatory agencies, representatives of patient groups, representatives of special interest groups, representatives of accrediting organizations, members of general public etc.
- All guests are required to sign a confidentiality agreement prior to attending the meeting.
- The Secretariat will obtain signatures of Guests/ observers/ Independent Consultants prior to the start of the meeting on the Confidentiality agreement.
- The Member Secretary will ask the members whether any points need to be discussed regarding minutes of the previous meeting. If no points are raised, the minutes will be considered as confirmed.
- The Member Secretary will present the agenda of the day's meeting for discussion.
- The meeting shall generally proceed in the order organized in the agenda. However, the Chairperson may allow adjustments in the order of issues to be discussed depending on the situation.
- Investigators will be asked to attend IC-SCR meeting for presentation and providing clarifications.
- For other points on the agenda, the member secretary will present the gist of the matter/ read the relevant letters from the investigator (if deemed necessary) and request the members to give their comments. The Member-Secretary assisted by the secretarial staff will also record a gist of discussions and decisions arrived on other issues discussed at the meeting.

4.5 Decision making

- The final decision on each proposal/ issue discussed in the meeting shall be by voting. A majority vote is defined as 2/3rd of the members (who have reviewed the project), present at the meeting and voting.
- Decisions will include approval, disapproval, request for modifications of a study, suspension or termination of an ongoing study
- The following will not vote at the meeting:
 - Member(s) of the committee who is/are listed as investigator(s) on a research proposal
 - An investigator or study team member invited for the meeting
 - An independent consultant invited for the meeting to provide opinion
 - Specific patient groups invited for the meeting, if any

4.6 After the meeting

- The Secretariat will compose the summary of each meeting discussion and decision in a concise and easy-to-read style in the minutes within 7 working days of the meeting day.
- The Secretariat will make sure to cover all contents in each particular category to include the following:
 - Name of person preparing the minutes
 - Location where the meeting was held (city, state)
 - Meeting number, date/duration of the meeting (time of commencement and end)
 - Names of the IEC members and guests attending the meeting
 - Name of the individual serving as Chairperson of the meeting
 - Determination of a duly constituted quorum by Chairperson to proceed with meeting
- **Requirements for each study or activity requesting approval:**
 - Sponsor's name, if applicable
 - Protocol number/date/version of protocol, when available
 - Investigator's name
 - Names of the Primary Reviewers who presented their findings
 - Discussion as deemed appropriate by the Chairperson
 - Follow-up action decided upon
 - Reference to the investigator approval letter that lists all changes requested by the board
 - Determination of the next requested continuing review.

- **Requirements for each Continuing Review Report:**
 - Sponsor's name; if applicable
 - Protocol number, if applicable
 - Investigator's name
 - Indication of the committee's determination to continue, terminate, or amend the study
 - Lists of recommendations or actions to be taken up with the investigator, if applicable.

- **Requirements for each Adverse Event notification:**
 - Sponsor's name; if applicable
 - Protocol number, if applicable
 - Investigator's name
 - Report submitted to SAE sub-committee / Institutional ethics committee

- **Requirements for Termination of Approval:**
 - Name of the Sponsor, if applicable
 - Protocol number, if applicable
 - Investigator's name; reason for termination

4.6 Approval of the minutes

- The Secretariat will check the correctness and completeness of the minutes and present the minutes to the Chairperson for review and approval within 7 working days of the meeting day.
- The Secretariat will email the minutes of the meeting to the IC-SCR members and the members will be requested to comment within two days for any corrections. Absence of any reply from the members for more than two days will be considered as implied approval from them.
- The Chairperson indicates approval by signing and dating the minutes 4 days after the minutes was circulated to members of IC-SCR.

4.7 Filing the minutes

- The Secretariat will place the original version of the minutes in the minutes file.
- The Secretariat will file the IC-SCR Decision Forms in the project files and place all correspondence in the appropriate files.
- The Secretariat will send a list of the studies approved and rejected by the IC-SCR (title of the study with name of the Principal Investigator) to the Head of the Institute every month within 21 days of the IC-SCR meeting.

5. Annexures

Annexure 1: AX01/ KEMS07/V1- Agenda format

Annexure2:AX02/ KEMS07/V1- Conflict of Interest form to be signed by IC-SCR member before meeting

Annexure 1: AX01/ KEMS07/V1

Agenda Format

Agenda of the IEC Meeting

Meeting No IC-SCR meeting nn/yyyy

Location of the meeting

Meeting Date & Meeting time

The Board meeting will proceed in the following sequences:

Period 1: Discussion of the points arising from the minutes of the previous meeting and presentation of agenda of the day's meeting and Declaration of Conflict of interest.

Period 2:

A] New Protocol Presentation, Review, Discussion and reaching decision by voting to approve/raise queries

B] Review responses forwarded by the principal investigator to the query letter/ resubmitted protocols

C] Approve protocol amendment and related documents.

D] To review the continuing review report/ completion report/ final clinical trial report/ Annual report / Termination reports.

E] To review other Letters related to projects

F] To review Monitoring reports

G] To inform about the IC-SCR meeting and to review the policy decisions

H] Other points for discussion

Period 3:Issues reviewed and approved by the IC-SCR member Secretary and Chairperson which are to be reported for consideration

Period 4:Issues to be informed to the members which are approved by the IEC member Secretary and Chairperson and letters already sent to the principal investigator.

Period 5: Other issues of interest to the members.

Annexure 2: AX02/ KEMS07/V1

Conflict of Interest form to be signed by IC-SCR member before meeting

Date:

To

The Chairperson,
IC-SCR,
KEM Hospital,
Mumbai -12

I hereby declare the conflict of interest for the project no.

entitled, _____ as :

1. I am the investigator / co-investigator/Author/study team
2. I have Financial interest
3. _____
4. _____
5. _____
6. _____

in the project which will be discussed in today's meeting on .XX day of XX month XX year.

Member, IC-SCR

Chairperson, IC-SCR

7. Flow Chart:		
No.	Activity	Responsibility
1	Preparation of meeting agenda prior to meeting	IC-SCR Secretariat
2	During the Meeting	IC-SCR Secretariat, Members and Chairperson
3	After Meeting and Preparing the minutes	IC-SCR Secretariat/ Member Secretary
4	Approval of minutes	IC-SCR members / Chairperson
5	Filing the minutes	IC-SCR Secretariat
