

**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: Review of Resubmitted and Amended Protocols and
Protocol-related Documents by Institutional Committee for
stem cell research (IC-SCR), KEM Hospital**

SOP Code:

KEM SOP 10 /V1 dated 12th June 2020

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how the Institutional Committee for stem cell research (IC-SCR), KEM Hospital manages resubmitted & amended study protocols.

2. Scope

This SOP applies to the review of

- A. Study protocols and related documents that have been **resubmitted** to the IC-SCR, KEM Hospital by the Principal Investigator (PI) with clarifications and modifications sought by the IC-SCR in initial review.
- B. **Amendments** to study protocols and related documents that have been approved earlier.

3. Responsibility

- It is the responsibility of the IC-SCR Secretariat to ensure the completeness of the documents submitted to the IC-SCR.
- A re-submitted protocol and related documents will be emailed to all the members of IC-SCR for their approval. After 5 days if there are no objections from the members it will be approved. If any one or more members raise any concern regarding the corrected version, chairperson's opinion will be sorted out to take a decision on approval of the revised proposal by voting through email for or against approval of the corrections in the revised proposal.
- In the case of an amended study protocol and related documents, Member Secretary/Chairperson will decide whether the proposed protocol amendment(s) needs to undergo a full board review or can be send to all members of IC-SCR through email for their approval. After 5 days if there are no objections from the members the amendment will be approved. If any one or more members raise any concern regarding the amended version, chairperson's opinion will be sorted out to take a decision on approval of the amended proposal by voting through email for or against approval of the amended proposal. If majority of the members are against the amendment, a full board meeting will be conducted within a period of 30 days to give an opportunity for the PI to clarify and explain the reason behind amendment and the decision will be taken.
- If the amendment(s) is / are of administrative nature the Member Secretary/Chairperson can recommend for sending through email to all the members of IC-SCR for their approval. However if the amendment/s relate to participant safety or data capture, it will be recommended for full board review. Additionally, primary reviewers who had reviewed the initial submission may be asked to review the resubmitted protocol.

4. Detailed instructions

For resubmitted protocols***4.1 Receipt of resubmitted protocol and its distribution***

- The Secretariat will verify if the PI has replied to IC-SCR queries within 60 days of receipt of the letter of comments by the IC-SCR.
- The Secretariat will check the resubmitted protocol & related documents (hard and soft copy) for the following items
 - Reply to the IC-SCR letter of comments
 - Revised version of protocol and/ or any other related documents submitted with the changes made to the documents either underlined or highlighted.
- The Secretariat will refer to the IC-SCR Decision Form on the given protocol and distribute the documents containing the reply to the query letter, revised protocol and related documents along with Assessment Form for resubmitted protocol to Member Secretary for approval.

4.2. Review of revised protocol by IC-SCR member/ Member Secretary/Chairperson:

- IC-SCR member/ Chairperson will refer to query letter/ comments as guidance for review of the corrections sent to them through email by Member Secretary and consider whether recommendations of IC-SCR have been followed or adequately responded to.
- In case the committee members decide to discuss the revised protocol at the full board meeting, Member Secretary will present a brief oral summary of the study design and the comments of the IC-SCR members/Chairperson in the IC-SCR Full Board meeting.
- Chairperson shall entertain discussion on the protocol revision from all the IC-SCR members.
- The final decision regarding the research project shall be reached by voting (2/3rd majority of the members present and voting) and shall include one of the following:
 - a) Approved
 - b) Modifications to items noted at the convened meeting and follow-up by the Chairperson/ Member Secretary/IC-SCR members after receipt of the requested modifications:
 - c) Disapproved giving reasons for disapproval

- In case the revised protocol is already approved through expedited review, the decision is informed to the members through email as well as at the next full board meeting.

4.2 Receipt of protocol for amendments

- The documents for amendments (hard and soft copy) forwarded by the PI will be received by the Secretariat and verified.
- The Secretariat will confirm the request for review of amended Protocol/Protocol related documents from the Principal Investigator on previously approved Protocol/Protocol related documents as per the form AX 02/ KEMS10/V1.
- The administrative staff will confirm that the amended version of the protocol and related documents are attached with the application and that the changes or modifications in the protocol are underlined or highlighted in the amended version.

4.3. Notify Member Secretary

- The Secretariat will inform the Member Secretary of receipt of the protocol amendment

4.4. Determine whether full review or review by designated members.

- After review of the materials, the Member Secretary will determine whether the protocol requires a full board review or review through circulation by email to all the members. The Member Secretary will indicate this decision on the Protocol Amendment Assessment Form AX 02/ KEMS10/V1.
- The amended protocol/ protocol related document will require Full Board review if any of the following criteria are met:

The Protocol amendment changes the risk-benefit assessment such as

- a change in study design,
- additional treatments or the deletion of treatments
- changes in inclusion/exclusion criteria.
- change in method of dosage formulation
- significant change in the number of research participants (if the decrease/increase in the number of research participants alters the fundamental characteristics of the study, it is significant)

- For regulatory studies, a protocol amendment with above changes would require DCGI approval

4.5. IC-SCR Decision on Amended Protocols

- In case the project is kept for full board review, the Member Secretary / designated member will present a brief oral summary of the study design and read the comments on the amended protocol/ protocol related documents in the meeting.

The decision by the designated reviewers may be

- Approved
- Disapproved

Suggested Recommendation

- Next full board discussion

The final decision regarding the research project shall be reached by voting (2/3rd majority of the members present and voting) and shall include one of the following:

- Approve the protocol amendment
- Require a modification to the proposed amendment or informed consent documents, stating the reason and action required to sustain the study with a follow-up IC-SCR review.
- Not approve the amendment request, stating the reason – but allow the study to continue as previously approved.
- Suspend the study, until further information is obtained

4.6. Recording of the decision

- IC-SCR decision will be recorded by the Secretariat in the IC-SCR Decision Form.

4.9. Communication of the Decision to the Principal Investigator

- If the IC-SCR approves the protocol/ other documents submitted for amendment, the Secretariat staff will send a signed and dated Amendment Approval Letter i.e. AX 03/ KEMS10/V1 to the Principal Investigator (PI) within 14 working days of the meeting.

The decision regarding disapproval (stating reasons) or request for modifications (stating specific changes needed) shall be communicated in writing to the investigator within 14 working days of the meeting.

- The letter of comments sent to the investigator shall state that the reply to the letter is expected within 60 days of date of receipt of the letter and in the absence of any response, the project will be declared closed for the IC-SCR office records.
- The Member Secretary shall inform other members about the decision taken on the amended document/s at the next full board meeting.

5. Annexures

Annexure 1: AX 01/ KEMS10/V1 - Assessment of resubmitted protocol

Annexure 2: AX 02/ KEMS10/V1- Protocol amendment request and assessment form

Annexure 3: AX 03/ KEMS10/V1- Protocol Amendment/Document Amendment Approval letter

**Annexure 1: AX 01/ KEMS10/V1
Assessment of resubmitted protocol**

Protocol Number:

Protocol Title:

Number of review	2 nd Review	3 rd Review	4 th Review
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Principal Investigator:		Department:
Date of Initial Review by IC-SCR:	Date of Last Review:	
The IC-SCR Decision recorded in the meeting minutes: (meeting held on _____)		

Opinion of the reviewer:

Revision or Modification according to the recommendation	Yes	No: Explain:
Approved	Yes	No
If disapproved, reasons for disapproval		
Further revision or modification required		
To be discussed at the forthcoming full board meeting		
Any Other		

Name of the Reviewer: 1)

Signature:

Date:

Name of the Reviewer: 2)

Signature:

Date:

Final Decision: Approved Yes / No

If disapproved, reasons for disapproval:

Further revision or modification required / Resubmission:

Any other reason(s):

Signature of the Member Secretary/ Chairperson:

Date:

Annexure 2: AX02/ KEMS10/V1

Protocol amendment request and assessment form

IC-SCR Protocol Number:

- a) Protocol Title:
- b) Principal Investigator and Department:
- c) Approved date:
- d) No. of amendment:
- e) State/describe the amendment: type of document/ part of document amended:
- f) Reasons for the amendment:
- g) Impact of amendment on present study at this site: (modifications in the ICD, re-consent of research participants, untoward effects likely to occur because of amendment or any other):
- h) Have the changes / modifications in amended versions been highlighted/ underlined?

Yes

No

Name of Principal Investigator:

Signature with Date:

Type of review :- (Decision by the Chairperson/ Member Secretary)

- Review by Member Secretary/ Chairperson
- Review by designated IC-SCR members
- Full Board discussion and review

Comments of the reviewer :

Decision:

Disapproved

Next full board discussion

Approved

Suggested Recommendation(s)

Name of IC-SCR Member / Member Secretary/ Chairperson reviewing project:

Signature with Date:

Date: 12/06/2020

Final Decision: Approved

Yes

No

If disapproved, reasons for disapproval:

Further revision or modification required:

Any Other

Signature of the Member Secretary:

Date:

Date: 12/06/2020

Annexure 3: AX03/ KEMS10/V1

Protocol Amendment/Document Amendment Approval letter

To

Name of PI

Department

Ref: - IC-SCR No. Project title

Dear Dr. _____

We have received from you the following document(s).

- 1.
- 2.

At the IC-SCR meeting held on _____ the above mentioned documents were reviewed.

After consideration, the IC-SCR has decided to approve:

(a) The aforementioned study-related documents OR

(b) The following documents:

- 1.
- 2.

The members who attended this meeting held on _____ at which the above mentioned document was discussed are listed below.

- 1.
- 2.

It is to be noted that neither you nor any of your proposed study team members were present during the decision-making procedures of the IC-SCR.

OR

After reviewing the documents, the IC-SCR has decided to approve the aforementioned study-related documents.

Yours truly,

(Signature of Member Secretary with Date)

Date: 12/06/2020

7. Flowchart

No.	Activity	Responsibility
1.	Receive the Protocol amendment / Resubmitted protocol	IC-SCR Secretariat
2.	Notify the Member Secretary / Chairperson of the IC-SCR	IC-SCR Secretariat
3.	Determine whether full board review / review by designated members is needed	IC-SCR Member Secretary / Chairperson
4.	Nomination of Members for review	IC-SCR Chairperson
5.	Distribution to IC-SCR members	IC-SCR Secretariat
6.	Protocol Amendment/ Revised documents Review	IC-SCR Members / Member Secretary / Chairperson
7.	IC-SCR Decision	IC-SCR Member Secretary / Chairperson
8.	Communication of the Decision to the Principal Investigator	IC-SCR Secretariat
9.	Store documents	IC-SCR Secretariat
