

**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: Selection and Responsibilities of Independent
Consultants invited as special invitee to Institutional
Committee for stem cell research (IC-SCR), KEM Hospital**

SOP Code:

KEM SOP 08 /V1 dated 12th June 2020

1. Definition of Independent Consultant

An independent consultant is a subject expert in a specified field who gives advice, comments and suggestions upon review of the study protocols. He/she has no affiliation to the investigators proposing the research protocols.

2. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe procedures for selecting and engaging expertise of medical professionals as 'Independent Consultants' (IC) to the Institutional Committee for stem cell research (IC-SCR), KEM Hospital.

3. Scope

This SOP covers the procedures for selecting, appointing ICs and getting their expert opinion for the review process of IC-SCR, KEM Hospital. It also defines the responsibilities of IC.

4. Responsibility

It is the responsibility of the Chairperson/ Member Secretary/ IC-SCR member/s to nominate the name of one or more IC/s. The Chairperson is responsible for endorsing the choice of IC nominated by IC-SCR Member Secretary/ IC-SCR member/s. The administrative procedures regarding selection, confidentiality agreement and maintenance of list of ICs will be carried out by IC-SCR secretariat.

5. Detailed instructions

5.1 Recommendation of names of ICs and making a list of ICs for the IC-SCR

- Chairperson/ Member Secretary/ IC-SCR members will nominate the names of ICs from different specialties of Medicine.
- Member Secretary in consultation with Chairperson will select a panel of IC(s) for the IC-SCR.
- Member Secretary will issue an appointment letter to the IC(s) after confirming their willingness through telephonic/ electronic communication.

After receiving written acceptance from ICs, a list of specialty wise ICs will be maintained by the secretariat in the IC-SCR records. The details of each IC (Name, designation, affiliation, contact details and updated curriculum vitae) will be maintained in the IC-SCR records.

5.2 Consulting an IC during IC-SCR review process

- a) An IC-SCR member/ Member Secretary/ Chairperson may suggest that the opinion be sought from one or more IC(s) and may suggest the name of a particular IC(s) from the list of ICs maintained by the IC-SCR or from outside the roster; if during the review process of any given research study if it is felt that the study involves procedures or information that is not within the area of collective expertise of the IC-SCR members.
- b) The Member Secretary in consultation with Chairperson (or at full board meeting; as deemed necessary) will decide identify and select the IC(s) outside the list to be invited based on area of expertise, independence and availability.
- c) Member Secretary on behalf of the IC-SCR will invite IC(s) in writing to assist in the review of the research study and provide his/ her independent opinion in writing. This may be done after seeking concurrence and confirming availability of the IC through telephonic/ electronic communication.

5.3 Communication with ICs

- The Secretariat may request a copy of the updated curriculum vitae of the IC (those outside list) for IC-SCR records and future reference.
- The Member Secretary will request IC to declare conflict of interest, if any, in writing and sign confidentiality and conflict of interest agreements.
- The Secretariat will forward copies of the Confidentiality Agreement and Conflict of Interest Agreement for careful reading, understanding and signing.
- The Member Secretary will provide explanations/ clarifications (telephonically or in writing) to the IC(s) if any doubts or questions are raised. Any further explanations can be provided by the Chairperson/ Legal expert/ IC-SCR members.

5.4 Reading, understanding and signing the Conflict of Interest document and Confidentiality Agreement

- The IC(s) will sign and date the Confidentiality and Conflict of Interest Agreement.
- The Secretariat will obtain the signed Confidentiality Agreement and Conflict of Interest Agreement and forward it to Chairperson.
- The Chairperson will sign and date the Confidentiality and Conflict of Interest Agreements. The original copies of these agreements will be retained by the Secretariat and photocopies will be sent to IC(s).

5.5 Review of research study proposal

- The Secretariat will provide study protocol documents along with the Study Assessment Form for IC(s) to the IC(s).
- The IC(s) will be requested to complete and provide the Assessment Form (duly signed and dated) to the Secretariat within a stipulated period or by a stipulated date.
- The assessment report provided by the IC(s) becomes a permanent part of the study file.
- The assessment report will be reviewed by Member Secretary in the IC-SCR meeting when the concerned study is being discussed.
- If deemed necessary, the Chairperson or Member-secretary may seek additional information or clarifications from the IC in writing. Additional Information provided by the IC will be considered as a part of the Assessment Report.
- If deemed necessary, the Chairperson or Member-secretary may invite the IC(s) to attend an IC-SCR meeting for providing additional information or clarifications that may be sought by IC-SCR members or Chairperson. However, the IC will not participate in the decision-making process on the research study.
- If deemed necessary, IC may be reimbursed for expenses on travel, time spent, documents referred to in library/ internet or any other incidental expenses, etc.

5.6 Tenure of Services of IC

- The roster of ICs maintained at the IC-SCR office will be updated every 5 years or as required. For IC appointed for a particular study, the services of IC get automatically

terminated once the final decision regarding the study is taken by the IC-SCR. The IC-SCR will document the termination of the services of IC by providing a letter thanking the IC for the services rendered.

5.7 Responsibilities of IC

- If IC agrees to review a research proposal, he/she will comply with IC-SCR requirements of signing confidentiality and conflict of interest agreements.
- IC will review the research study and complete the Assessment Form (duly signed and dated) within a stipulated period or by a stipulated date.
- IC will attend an IC-SCR meeting for providing additional information or clarifications, if invited by Member Secretary/ Chairperson. However, the IC will not participate in the decision making process on the research study.
- IC will remain available for telephonic and email communication till the review process of the given research proposal is complete.

6. Annexures

Annexure 1: AX01/ KEMS08/V1- Confidentiality Agreement for an IC

Annexure 2: AX02/ KEMS08/V1- Conflict of Interest Agreement for an IC

Annexure 3: AX03/ KEMS08/V1- Study Assessment Form for an IC

Annexure 2: AX02/ KEMS08/V1

Conflict of Interest Agreement for an IC

Conflict of Interest Agreement Form for Independent Consultants

- I understand that it is the policy of the IC-SCR that no reviewer may participate in the review, comment or approve of any activity in which he/she has a conflict of interest except to provide information as requested by the IC-SCR.
- I do not have any actual or potential conflict of interest in relation to the particular proposal submitted for review by the IC-SCR to me.
- In the event that I develop any conflict of interest in relation to the particular proposal during the review process, I will declare it to IC-SCR and refrain from reviewing it.

I, _____ (name) have read and accept the
aforementioned terms and conditions as explained in this Agreement.

Signature of IC

Date

Chairperson's Signature

Date

I acknowledge that I have received a copy of this Agreement signed by the IC-SCR Chairperson and me.

Signature

Date

[The original (signed and dated Agreement) will be kept on file in the custody of the IC-SCR. A copy will be given to you for your records]

Annexure 3: AX03/ KEMS08/V1**Study Assessment Form for an IC**

Protocol Number :		Date (DD/MM/YY):	
No. of Participants at the site:		No. of Study site(s):	

Mark and comment on whatever items are applicable to the study.

1	Objectives of the Study		What should be improved?
	clear	unclear	
2	Need for Human Participants		Comments:
	Yes	No	
3	Methodology:		What should be improved?
	clear	unclear	
4a	Background Information and Data		Comments:
	sufficient	insufficient	
4b	Risks and Benefits Assessment		Comments:
	acceptable	unacceptable	
4c	Inclusion Criteria		Comments:
	appropriate	inappropriate	
4d	Exclusion Criteria		Comments:
	appropriate	inappropriate	
4e	Discontinuation and Withdrawal Criteria		Comments:
	appropriate	inappropriate	
5	Sufficient number of participants?		Comments:
	Yes	No	
6	Are Qualifications and experience of the Participating Investigators appropriate?		Comments:
	Yes	No	
7	Facilities and infrastructure of participating Sites		Comments:
	Appropriate	Inappropriate	
8	Contribution to development of local capacity for research and treatment		Comments:
	Yes	No	
9	Availability of similar Study / Results:		Comments:
	Yes	No	

Independent consultant's Signature with date:

7. Flow Chart

No.	Activity	Responsibility
1	Recommendation of a name of one or more IC(s)	IC-SCR Member, Member Secretary or Chairperson
2	Selection and Appointment of IC(s)	Member Secretary in consultation with Chairperson
3	Invitation to IC(s) on behalf of IC-SCR	Chairperson/ Member-Secretary
4	Co-ordination with IC(s) for fulfilling administrative requirements	IC-SCR Secretariat
5	Reading, understanding and signing the Conflict of Interest document and Confidentiality agreement	IC, Chairperson
6	Maintenance of a specialty-wise list/ roster of ICs	IC-SCR Secretariat
7	Reviewing documents pertaining to research project	IC
