

**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: Handling Conflict of Interest among Committee
Members of the Institutional Committee for stem cell
research (IC-SCR), KEM Hospital**

SOP Code:

KEM SOP 03 /V1 dated 12th June 2020

1. Purpose

The purpose of this SOP is to define the process to identify and manage conflict of interest among members of Institutional Committee for stem cell research (IC-SCR), KEM Hospital.

2. Scope

This SOP covers the policy related to identification, declaration and management of conflict of interest and is applicable to all members of IC-SCR, KEM Hospital.

3. Responsibility

All IC-SCR members (regular and alternate) are responsible for understanding the definition of conflict of interest (CoI) and for self-identifying and disclosing the same. The Chairperson would need to ensure that CoI are identified, declared and managed by all members during initial and continuing review of research studies.

4. Definitions and Mandate

4.1 Definition:

Conflict of interest

"A set of conditions in which professional judgment concerning a primary interest like patient's welfare or the validity of research tends to be or appears to be unduly influenced by a secondary interest like non-financial (personal, academic or political) or financial gain is termed as Conflict of Interest (CoI)".

4.1.1.Types of CoI

A personal CoI is said to exist when

- ♥ there is immediate family relationship (spouse, parent or parent of a spouse, child or child of a spouse, sibling or sibling of a spouse, or a dependent - who resides with an IC-SCR member or consultant or who receives 50% or more support from an IC-SCR member, regardless of age) or other close personal relationship ("step" relationships included) with the investigator, or with co-investigators.
- ♥ IC-SCR member or his/her immediate family member serves as a contributor to the

research project as a collaborator, consultant, research staff or financier.

- ♥ research study is submitted by a departmental colleague/senior (may be regarded as a personal conflicting interest if applicable)

A professional CoI is said to exist when

- IC-SCR member or his/her immediate family member serves as trustee, director, manager, or scientific advisor of the funding agency sponsoring the research.
- A financial CoI for IC-SCR members and immediate family exists
- IC-SCR member or the spouse or dependent of a member receives monetary benefits including, but not limited to, salary or payments for other services (e.g., consulting fees or honoraria), equity interests (e.g., stock, stock options, or any other ownership interests) and intellectual property rights (e.g., patents, copyrights, product or service being evaluated).

5. Detailed Instructions

5.1 Voluntary disclosure regarding CoI by IC-SCR member

The IC-SCR member should determine whether he/she has a CoI before reviewing research and declare all certain or potential conflicts of interest prior to engaging in any review process. IC-SCR members should not participate in discussing or decision making on research proposals applications reviewed at any level (exempt, expedited, or full-board) when they have conflicts of interest except to provide information requested by the IC-SCR.

- a) If an IC-SCR member has a CoI for review outside a meeting (e.g., the expedited procedure/ amendments), he or she should notify the IC-SCR Secretariat and return the documents.
- b) If an IC-SCR member has a CoI for a study for which he or she has been assigned as a reviewer, he or she will inform the IC-SCR secretariat so that the review is re-assigned to other members.
- c) If an IC-SCR member has a CoI for review of research study at a meeting, he or she will inform the chairperson and leave the meeting room while discussion of the study takes place. He/she may stay in the meeting room only to answer questions about the research. This is applicable also for IC-SCR meetings at which discussion on serious adverse events, deviations/violations, amendments/ continuing review reports related to studies

Date: 12/06/2020

are discussed.

- d) Recusal - IC-SCR member who declares CoI and leaves the meeting does not count towards the quorum for the vote. The member's absence under these circumstances is called a *recusal*, not an abstention or an absence.
- e) If an IC-SCR member finds that he/she has a COI during the conduct of a research project approved by IC-SCR, he/she shall report the conflict to the IC-SCR at the next IC-SCR meeting.

- At the beginning of each meeting, the IC-SCR chairperson asks the members to disclose any CoI concerning any of the items on the agenda. During the meeting, IC-SCR member having conflict discloses the existence of the conflict just before the review of the relevant item begins.
- If the chairperson has a conflict of interest for a particular project, this should be so declared and handled like any other member's conflict is handled. An acting chair should be appointed for discussion on such a project.
- When determination regarding existence of CoI is uncertain, more information is gathered from relevant sources and determination is done by IC-SCR member with the help of IC-SCR chairperson / member secretary or by IC-SCR chairperson / member secretary (as applicable)
- The IC-SCR chairperson has the final authority to determine whether a CoI has been managed or eliminated appropriately for research participant protection.
- The IC-SCR shall not approve a research study proposal where a CoI is not managed or eliminated

- **Management of CoI**

In case of a CoI,

- IC-SCR members will disclose the COI as discussed above
 - IC-SCR members will not serve as reviewers
 - IC-SCR members will not participate in the discussion and decision making for the concerned study
- **IC-SCR Member Secretary and the Secretariat will record the points related to disclosure and management of CoI of IC-SCR members in the IC-SCR minutes.**

6. Annexure

Annexure 1: AX01/KEMS03/V1 – Conflict of Interest Form/ Declaration for IC-SCR members

Annexure 2: AX02/ KEMS03/V1 – Flow chart of IC-SCR

Annexure 1: AX01/ KEMS03/V1

Conflict of Interest Form/ Declaration for IC-SCR Members

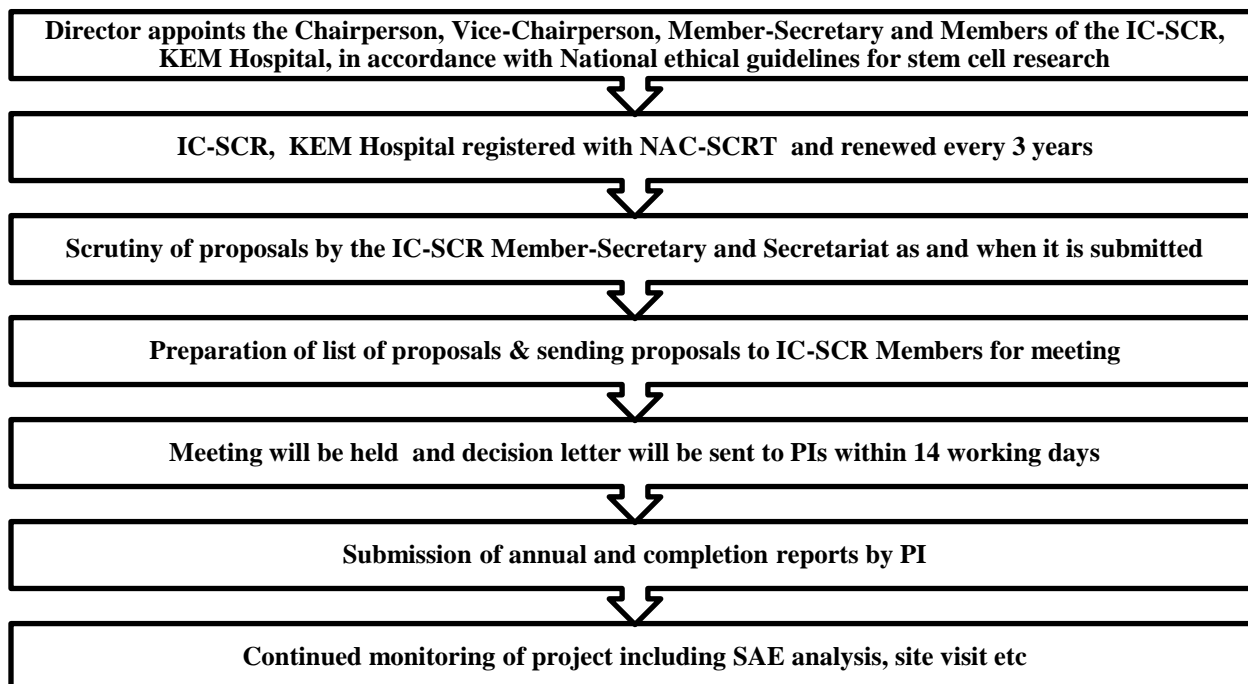
I am aware of the policy of the IC-SCR regarding conflict of interest (CoI) and that no reviewer may participate in the review, comment or participate in decision making of any activity in which he/she has actual/potential conflict of interest except to provide information as requested by the IC-SCR.

I declare _____ (actual or potential CoI) in relation to the proposal entitled “_____” submitted for review to the IC-SCR. The reason for CoI is _____

I will refrain from the review process and /or discussion at the IC-SCR meeting / and also will not take part in ongoing and periodic review and monitoring of this study.

_____ Signature of IC-SCR Member _____ Date

_____ Chairperson’s Signature _____ Date

Annexure 2: KEMS03/V1**Flow chart of IC-SCR****7. Flow Chart**

No.	Activity	Responsibility
1	Determination of Conflict of Interest (CoI)	IC-SCR Member
2	Disclosure and management of CoI	IC-SCR Member
3	Ensuring declaration and management of CoI during review process	IC-SCR Chairperson
4	Recording of CoI in minutes of IC-SCR meeting	IC-SCR Member Secretary/ Secretariat
