Institutional Committee for stem cell research (IC-SCR)

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Title: Site Monitoring and Post-Monitoring Activities for Institutional Committee for stem cell research (IC-SCR), KEM Hospital

SOP Code:

KEM SOP 11 /V1 dated 12th June 2020

1. Purpose

The purpose of this standard operating procedure (SOP) is to describe the procedures for site monitoring of Institutional Committee for Stem Cell Research (IC-SCR), KEM Hospital approved protocol.

2. Scope

This SOP applies to all IC-SCR approved studies for which a routine or for-cause on-site

monitoring may be undertaken by the IC-SCR.

3. Responsibility

It is the responsibility of the committee or Chairperson and Member Secretary to decide to conduct on-site monitoring. It is further the responsibility of the designated IC-SCR member(s) to perform on-site monitoring of selected study site(s).

4. Detailed instructions

4.1. Selection of study sites

- Routine monitoring for site may be decided at the time of approval of project.
- This is recorded in IC-SCR decision form and in the IC-SCR minutes.
- *"For-cause monitoring"* will be performed at sites for reasons identified by any member of the IC-SCR, after approval by the Chairperson.
- The reasons for identifying a particular site for "*for-cause monitoring*" could include any one or more of the following:

  - High number of protocol violations,
  - Large number of studies carried out at the study site or by the investigator,
  - Large number of Serious Adverse Events (SAE) reports,
  - High recruitment rate,
  - Large number of Protocol deviations,
  - Complaints received from participants or any other person,
  - Frequent failure to submit the required documents
  - Any other cause as decided by IC-SCR.

4.2. Before the visit

Irrespective of the cause for conducting monitoring the following procedure will be followed:

- Chairperson will identify and select one or more IC-SCR members (henceforth referred to as monitors) to conduct monitoring of a site.
- Selected members will be given an appointment letter in this regard.
- Agenda of monitoring will be decided by identified monitors in consultation with Member

Secretary and Chairperson

- Secretariat will decide date of monitoring in consultation with monitors and PI.
- Final date will be communicated to the PI (with a request to be available) and monitors.
- Monitor will receive from secretariat and review relevant project documents and make appropriate notes.
- Secretariat will provide Monitors with relevant reference material / documents related to the project
- Monitors will carry with them Site Monitoring Visit Report Forms and form for monitoring of audiovisual recording of AV consent Process (if applicable) collected from the Secretariat.

4.3. During the visit

- The Monitor will follow the check list and:
  - check the log of delegation of responsibilities of study team,
  - check if the site is using latest IC-SCR approved current versions of the protocol, informed consent documents, case record forms, diaries, advertisements, etc
  - check investigational product accountability is adequately controlled and documented throughout the product flow at the study site (arrival, dispensing, use, return from the subject and return/destruction after the study)
  - check for storage times, conditions and expiry dates to be acceptable and sufficient supplies available, wherever applicable
  - verify that the investigator follows the approved protocol and all approved amendment(s), if any
  - ensure that investigator and investigator's trial staff are adequately informed about the trial,
  - verify that investigator and investigator's trial staff are performing the specified study functions, in accordance with the approved protocol and any other written agreement between the sponsor and the investigator/institution, and have not delegated these functions to unauthorized individuals
  - verify that the investigator is enrolling only eligible subjects
  - determine whether all SAEs are appropriately reported within the time as per the applicable regulatory requirement(s). Case record forms would be checked to review the

safety data i.e. Adverse Events (AEs) and SAEs for the volume or severity of adverse events

- review the project files of the study to ensure that documentation is filed appropriately
- review the source documents for their completeness
- collect views of the study participants, if possible

- The Monitor will fill the Site Monitoring Visit Report Form and form for monitoring of audiovisual recording of AV consent Process (if applicable), sign and date it.

4.4. After the visit

- The Monitor will submit the completed Site Monitoring Visit Report Form to the IC-SCR secretariat within 7 working days of conducting a site monitoring visit or at the time of IC-SCR meeting (whichever is earlier).
- The report should describe the findings of the monitoring visit.
- The Member-Secretary will present the monitoring report at the next IC-SCR meeting and the concerned Monitor will provide additional details/ clarifications to members, as required.
- The IC-SCR will discuss the findings of the monitoring process and take appropriate specific action by voting or combination of actions, some of which are listed below:
    - Continuation of the project with or without changes,
    - Restrictions on enrollment,
    - Recommendations for additional training,
    - Recruiting additional members in the study team
    - Revising/ providing qualifications/ experience criteria for members of study team, termination of the study,
    - Suspension of the study, etc.
- If the Monitor has findings that impact on safety of the participant the Monitor will inform the Member Secretary on the same day. The Member Secretary will discuss with the Chairperson and any one of the actions described above will be taken.
- The final decision taken at the IC-SCR meeting by the Chairperson will be recorded in the Site Monitoring Visit Report Form.

- The Secretariat will convey the decision to the Principal Investigator in writing within 14 working days of the meeting.
- The Secretariat will place the copy of the report in the protocol file.

5. Annexures

Annexure 1: AX01/ KEMS11/V1 - Site Monitoring Visit Report

Annexure 1: AX01/ KEMS11/V1
Site Monitoring Visit Report

IC-SCR project no:	Date of Visit:
Study Title:	
Principal Investigator and Department:	
Government agency	Others
Date of IC-SCR approval	
Date of Initiation of the study	
Duration of study	
Reason for monitoring	Routine: For- Cause (State reason/s):
Last monitoring done, if any	
Project Status	1. Ongoing 2. Completed 3. Recruitment Completed 4. Follow-up, extension study 5. Suspended 6. Terminated
In case of the response to the above question is option 5 or 6, kindly provide reason/s	
Are the present study team members as per the list approved by the IC-SCR?	Yes No Comment
Are site facilities appropriate?	Yes No Comment
Have the eligibility, inclusion exclusion criteria been adhered to ?	Yes No Comment
Any adverse events found?	Yes No Comment
Any SAEs found?	Yes No Comment
No. of deaths reported	Yes No Comment
Any other non-death study related injury	Yes No Comment
Are there any protocol noncompliance, deviations/violations?	Yes No Comment
Are all Case Record Forms up to date?	Yes No Comment
Are storage of data and investigating products	Yes

locked?	No Comment
Any other remarks	Yes No If Yes, Details
Duration of visit:_____ hours	Started at: Finished at:
Name of the study team member/s present	Signature with date
Name of IC-SCR members and representatives who attended monitoring visit	
Completed by:	Signature with date

Final Decision at the IC-SCR meeting held on:
Signature of Chairperson, IC-SCR with date:

- _____

7. Flow chart

No.	Activity	Responsibility
1	Selection of study sites	IC-SCR Member Secretary / Chairperson
2	Identification of IC-SCR members for monitoring during meeting	Chairperson
3	Inform Principal Investigator in writing	Secretariat
4	Review of IC-SCR protocol file prior to visit and collect Site Monitoring visit report from IC-SCR office	IC-SCR member
5	Review or monitoring of site	IC-SCR member
6	Complete the monitoring report and present in IC-SCR meeting	IC-SCR member
7	Communication of IC-SCR decision to PI	Secretariat

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