Institutional Committee for stem cell research (IC-SCR)
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Title: Initial Review of New Research Study Protocols by Institutional Committee for stem cell research (IC-SCR), KEM Hospital

SOP Code:

KEM SOP 05 /V1 dated 12th June 2020

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how the members Institutional Committee for stem cell research (IC-SCR), KEM Hospital will perform an initial review on a new research study protocol using the assessment Form.

2. Scope

This SOP applies to the initial review and assessment of all stem cell research protocols submitted for review and approval from the investigator .

3. Responsibility

- Member secretary with the help of Secretariat is responsible for creation of a study specific file, distribution of packages along with study assessment forms to members for review and communicate the review results to the investigators.
- members (including Member Secretary) will be responsible for reviewing the research protocols and related documents within the given time frames.
- It is the responsibility of all the members to fill the Assessment form along with comments and recommendation they have after reviewing each study protocol.
- The members are responsible for attending and participating actively in the discussion at the full Board Meeting.
- The Member Secretary is responsible for conducting the meeting on a scheduled date as per the convenience of all the committee members.
- Secretariat is responsible for recording and filing the decision, relevant points and deliberation about a specific protocol, including the reasons for that decision.

Member Secretary is responsible to sign and date the decision in the Decision Form.

4. Detailed instructions

4.1 Appointment of primary reviewers

- The Member Secretary/Chairperson will appoint two or more primary reviewers for each study on the basis of expertise in the related field and experience. They will include one clinician and one non-technical person as applicable. More than two may be appointed if necessary.

4.2 Distribute the protocol package

- The Secretariat will fill in the required details in the cover **letter to the Members requesting initial review along with study assessment form**. Secretariat will send either hard or soft copy of protocol and related documents to the members.

4.3 Receive the distributed protocol package

- members will receive the protocol package with the Study Application Form as hard copy or through email (if desired so).
- Designated primary reviewers will also receive Study Assessment Form for Initial review

4.4 Verify the contents of the package

- member will verify all the contents.
- member will check the meeting date to see if it is convenient to attend the meeting.
- member will notify the Secretariat if any documents are missing or if the specified date of the meeting is not convenient to attend.

4.4 Review by the members

Review of the protocol

- The protocol will be reviewed by each member as per **National guidelines for stem cell research**.
- The member will consider the following criteria when performing the review of the study protocol and the study related documents:
    - Scientific design and conduct of the study
    - Risks and potential benefits
    - Community considerations
    - Qualifications of Investigators and assess adequacy of study sites
    - Disclosure or declaration of potential conflicts of interest
    - All reviewers will fill out the form (AX 01/ KEMS05/V1 - letter to members requesting initial review with study assessment form) and write their comments related to review of the research proposal.
    - In addition, primary reviewers will use the study assessment form
    - Ensure that all elements of research study are reviewed and are accordingly documented during the discussion / meeting.
    - The duly filled, signed and dated assessment forms will be sent either by post or email to the Secretariat at least 7 days prior to the meeting.

4.7 Gather the assessment reports

The Secretariat will collect the assessment forms, comments from each reviewer and file in the original study file and converted into a soft copy for discussion at the meeting. If the comments come as a soft copy these will be collated for discussion at the meeting.

4.8 meeting

- During the discussion at the meeting, the primary reviewer shall brief the members about summary of the study protocol and read out the comments and evaluation provided on the assessment form.
- The comments of an independent consultant (if applicable) will be discussed by member secretary.
- The other members shall give their comments right after the presentation.
- The investigator/sub-investigator may be called in to provide clarifications on the study protocol that he/she has submitted for review to the .
- The members will discuss and clarify the comments and suggestions.
- The Member secretary (assisted by the Secretarial staff) shall record the discussions.
- The final decision on the study will be recorded as: "Approved/ Disapproved/ Suggested recommendations or any other (as per policy" in the meeting shall be made by voting or by majority consensus (as per the policy) and will be recorded in the Decision Form by the Member Secretary.
- A majority vote for approval, disapproval or request for modifications of a study suspension or termination of an ongoing study is defined as 2/3rd of the voting members present at the meeting.

The following will not be eligible to vote

- 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 will not vote or participate in the decision making procedures of the committee.
- The Committee will decide whether the query responses and (if applicable) revised protocol will go only to Member Secretary, to primary reviewers or to Full Board before final approval.
- The response and changes carried out may be considered for discussion at a future meeting.
- If the decision is 'Disapproved' or any other, the decision should be made on the basis of specific reasons, which are communicated by the to the principal investigator in the letter of notification.
- The Secretariat will obtain the signature of all the members and of the Chairperson of the on the Decision Form.
- The Secretariat will list participating members in the meeting and summarize the guidance, advice and decision reached by the members.
- With the study protocol, the Assessment Form from all members and Decision Form will be filed in the study file by the Administrative Officer.
- The Administrative Officer will return the file and the protocol to the appropriate shelves.

4.9 Final communication of the decision taken on the study to the Principal Investigator

- The Secretariat will prepare an approval letter to be sent to the Principal Investigator when the study is approved at an meeting.
- The letter contains:
  - Study reference number
  - Study title
  - A listing of each document approved, the date set by the Committee for frequency of continuing review, and a review of other obligations and expectations from the investigator throughout the course of the study.
  - The approval is provided for the entire duration of the study.
  - List of members present at the meeting when the study was approved.
  - The Chairperson / Member Secretary will sign the approval letter and the Secretariat will give it to the Principal Investigator within 14 days.

If committee disapproves a study, Secretariat immediately notifies investigator in writing about the decision and the reason/s for not approving the study within 7 working days.

A notifying letter to the investigator should state the following:

- "If you wish to appeal to this decision, please contact the and submit your appeal in writing within twelve (12) weeks of the receipt of the committee's decision, addressed to the Chairperson with justification as to why the appeal should be granted. In absence of appeal, the study will be declared closed for the office records."
- If the Committee requires modifications to any of the documents, the Secretariat will send a written request for carrying out specific changes to the investigator asking him or her to make the necessary changes and resubmit the documents to the . The Principal Investigator will be asked to respond to the letter of comments/queries within 60 days of the receipt of the letter by the investigator. In the absence of any response, the study will be declared closed for the office records.
- The Secretariat will verify the correctness of the wordings and spelling in all the letters and process all the above tasks within 14 days after the meeting.

4.10 Storage of Documents

- The Secretariat will keep a copy of the Approval letter/Query letter/Disapproval letter in the study file along with all the reviewed documents for a period of three years. The Administrative officer will store the file on an appropriate shelf in the designated cabinet.

5. Annexures

Annexure 1: AX 01/ KEMS05/V1 - Letter to Members requesting initial review with study assessment form
Annexure 2: AX 02/ KEMS05/V1 - Study assessment form for primary reviewer
Annexure 3: AX 03/ KEMS05/V1 - Decision form
Annexure 4: AX 04/ KEMS05/V1 - Format of study approval letter
Annexure 5: AX 05/ KEMS05/V1- Guidelines for reviewing a study protocol

Annexure 1: AX 01/ KEMS05/V1

Letter to Members requesting initial review with study assessment form

Dear member,

The next meeting of the will be held on ……..at……..in…….

Please note that the package of research proposals is to be circulated in the following order. You are requested to review the same preferably within 5 working days of receiving the package. Please review the protocol and related documents as per the guidelines attached with Annexure 1 and provide your comments below and fill the study assessment form (for primary reviewers only) provided with the package. Kindly confirm your availability for the meeting.

Name of Member	Date of Receipt	Signature	Attending meeting (Y/N)

1. Protocol Number (as per records):
2. Date of receipt at office after review by member (DD/MM/YY):
3. Protocol Title
4. Name of the Principal Investigator:
5. Designation:
6. Department:
7. Name of the Reviewer:
8. Comments:

Annexure 2: AX 02/ KEMS05/V1
Study assessment form for primary reviewer

Protocol Number :		Date (DD/MM/YY):	
Protocol Title :			
Principal Investigator:			
Department :			
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 clear unclear	What should be improved?
2	Need for Human Participants Yes No	Comments:
3	Methodology: clear unclear	What should be improved?
4a	Background Information and Data sufficient insufficient	Comments:
4b	Risks and Benefits Assessment acceptable unacceptable	Comments:
4c	Inclusion Criteria appropriate inappropriate	Comments:
4d	Exclusion Criteria appropriate inappropriate	Comments:
4e	Discontinuation and Withdrawal Criteria appropriate inappropriate	Comments:
5	Involvement of Vulnerable Participants: Yes No	Comments:
6	Voluntary, Non-Coercive Recruitment of Participants Yes No	Comments:
7	Sufficient number of participants? Yes No	Comments:
8	Control Arms (placebo, if any) Yes No	Comments:
9	Are Qualifications and experience of the Participating Investigators appropriate? Yes No	Comments:

10	Disclosure or Declaration of Potential Conflicts of Interest Yes No	Comments:
11	Facilities and infrastructure of Participating Sites Appropriate Inappropriate	Comments:
12	Community Consultation: Yes No NA	Comments:
13	Benefit to Local Communities Yes No	Comments:
14	Contribution to development of local capacity for research and treatment Yes No	Comments:
15	Availability of similar Study / Results: Yes No	Comments:
16	Are blood/tissue samples sent abroad? Yes No	Comments:

Reviewer's Signature with date: _____

Annexure 3: AX 03/ KEMS05/V1
decision form

Date of meeting: _____

Protocol number: _____

Protocol No. and Title:	
Principal Investigator:	Department:
Final Decision at the meeting:	Approved Approved with modifications Resubmission Disapproved Reviewed at the Full Board meeting Review by any 2 / more members Monitoring required Reason:_____

Annexure 4: AX 04/ KEMS05/V1

Format of study approval letter

Date: xxxxxxxxx

To,

Dr. xxxxxxxxxxxxxx,

Dept. of xxxxxxxxx.

Ref: Your project no. **xxxxxxxx** entitled, "xxxxxxxxxxxxxxx".

Dear Dr. xxxxxxxxx,

The following documents of the above mentioned project were reviewed and approved through anfull board review process.

1. xxx
2.xxxxxxx
3.xxxxxxxxx

It is understood that the study will be conducted under your direction, in a total of **xxx** research participants, at as per the submitted protocol.

The approves the above mentioned study.

This approval is valid for the entire duration of the study.

It is the policy of that, it be informed about any onsite serious adverse event or any unexpected adverse event report within 24 hours as per the formats specified in SOP 09 to or by email if there is holiday. The report of SAE or death after due analysis shall be forwarded by the Investigator to the chairman of and the head of the institution where the trial is been conducted within 14 calendar days of SAE or death.

For studies which will continue for more than a year, a continuing review report needs to be submitted (within 1 month of the due date i.e. 11 months from the date of approval) on or before xxxxxx.

A copy of the final report should be submitted to for review.

Sincerely yours

xxxxxxxxxxx

Member Secretary/ Chairperson

Date of approval of the study: xxxxxx

Annexure 5: AX 05/ KEMS05/V1
Guidelines for reviewing a study protocol

Guidelines for reviewing a study protocol

Reviewers should make use of the following points while reviewing research studies which relate to scientific validity, informed consent documents, placebo justification, suitability and feasibility of the study, advertisements review.

1. How will the knowledge, result or outcome of the study contribute to human well-being?
   - Knowledge from the basic research may possibly benefit.
   - A new choice of method, drug or device that benefits the research participants during the study and others in the future.
   - Provide safety data or more competitive choices.
2. Does the study design will be able to give answers to the objectives? Whether
   - The endpoints are appropriately selected.
   - The participating duration of a study participant is adequate to allow sufficient change in the endpoints.
   - The control arm is appropriately selected for best comparison.
   - The placebo is justified.
   - The number of study participants in non-treatment (or placebo) arm is minimized.
   - Unbiased assignment (e.g. randomization, etc.) is in practice.
   - Inclusion and exclusion criteria are carefully selected to eliminate confounding factors as much as possible.
   - The sample group size appropriate with the given statistical assumptions.
   - Predictable risks are minimized.
     - The tests and procedures that are more than minimal risk are cautiously used.
     - Research participants deception is avoid.
     - Instruction and counseling for study participants are included (if needed) when deception is integral to the study design.
     - The study participants are adequately assessed and provided follow-up care, if needed.
3. Who will be the participants in the study? Whether
   - The described population is appropriate for the study.
   - Predictable vulnerabilities are considered.
   - It is completely necessary to conduct the study in a vulnerable population. If not, is there any other way to get the study answers?
   - There will be secondary participants.
4. Do the inclusion and exclusion criteria
   - Selectively include participants most likely to serve the objective of the study?
   - Equitably include participants?
   - Properly exclude participants who can predictably confound the results?

- Properly exclude participants who may predictably be at increased risk in the study due to coexisting conditions or circumstances?

5. Does the study design have adequate built-in safeguards for risks?
   - Appropriate screening of potential participants?
   - Use of a stepwise dose escalation with analysis of the results before proceeding?
   - Does the frequency of visits and biological samplings reasonably monitor the expected effects?
   - Are there defined stopping (discontinuation) / withdrawal criteria for participants with worsening condition?
   - Is there minimized use of medication withdrawal and placebo whenever possible?
   - Will rescue medications and procedures be allowed when appropriate?
   - Is there a defined safety committee to perform interim assessments, when appropriate?
   - Is appropriate follow-up designed into the study? For instance, gene transfer research may require following the participants for years or for their entire lifetime after they receive the gene transfer agent.
6. Is pre-clinical and/or early clinical studies sufficiently performed before this study?
   - The animal study and *in vitro* testing results?
   - Previous clinical results, if done?

- Whether the proposed study is appropriately built on the pre-clinical and/or early clinical results.
  - The selected dose based on adequate prior results?
  - Monitoring tests designed to detect expected possible risks and side effects?

7. Flow Chart

No.	Activity	Responsibility
1	Receive package or research proposal and research related documents package	Secretariat
2	Verify contents and distribute	Secretariat
3	Appointment of primary reviewers	Member Secretary/Chairperson
4	Initial review of documents, Full review assessment form	members
5	board meeting, discussion and decision	members, Member Secretary, Chairperson
6	decision communicated to PI	Secretariat
7	Storage of study related documents with relevant correspondence	Secretariat