

**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: Establishing and Constituting the Institutional
Committee for stem cell research, KEM Hospital**

SOP Code:

KEM SOP 2/V1 dated 12th June 2020

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the terms of reference for constitution, selection, roles and responsibilities of the Institutional Committee for stem cell research (IC-SCR) as well as procedures for maintaining confidentiality of all activities and documents.

2. Scope

This SOP applies to constitution of IC-SCR, KEM HOSPITAL, selection, roles and responsibilities of members of IC-SCR, KEM HOSPITAL and maintenance of confidentiality of all activities and documents.

3. Responsibility

The selection of Chairperson, member secretary and IC-SCR will be done by the Head of the Institution (Dean/Director.). It is the responsibility of all IC-SCR members and Secretariat to read, understand, follow and respect this SOP.

4. Detailed Instructions for composition of the Institutional Committee for stem cell research and therapy, Human studies

IC-SCR will be established by Head of the Institution (Dean/Dean/Director.). Chairperson and IC-SCR members can suggest names of potential members but final decision will remain with the Dean/Dean/Director. . IC-SCR will be multidisciplinary and multi-sectoral in composition and will be constituted as per the National Guidelines for Stem Cell Research, 2017. It will be composed of a minimum of 11 members. Dean/Director. will select and nominate the Chairperson and Member Secretary for IC-SCR, KEM Hospital. The IC-SCR will be constituted by the Dean/ Dean/Director. in consultation with the Chairperson. Dean/Dean/Director. will invite the members to join IC-SCR by sending the official request letter. Members will confirm their acceptance to the Dean/Director. by providing all the required information for membership. The Dean/Director. will ensure that the IC-SCR is established in accordance with the applicable laws and regulations of the state, country and in accordance with the value and principles of

communities they serve. Dean/Director. will designate and instruct Chairperson of IC-SCR or his representative to conduct the regular proceedings of IC-SCR for the institute. At regular intervals, Dean/Director. will review the functioning of IC-SCR.

The IC-SCR members will

- be a combination of medical, non-medical, scientific and non-scientific persons including lay persons to represent the different points of view.
- have different backgrounds to promote complete and adequate review of research.
- have required qualifications as prescribed by applicable regulations and guidelines from time to time.
- have the expertise, time and commitment to perform all functions.
- have representation that is varied in terms of gender, age and social background to safeguard the interests and welfare of all sections of the community / society.

The IC-SCR may invite member(s) of specific patient groups or other special interest groups for IC-SCR meeting (if required, based on requirement of research area, e.g. HIV, genetic disorders, etc.) for eliciting their views. Such individuals will have to sign confidentiality agreement and declare in writing, conflicts of interest, if any prior to attending the meeting. They will attend the meeting in the capacity of 'Guest/ Observer' and will not have right to vote.

5. The Composition of IC-SCR, Human studies shall be as follows:

1. Only member secretary as institute member.
Representatives of the public and persons with expertise in
2. Clinical medicine
3. Hematology
4. Immunology
5. Developmental biology
6. Stem cell research
7. Molecular biology

8. Assisted reproduction technology
9. Toxicology, other related disciplines (as per the institutional research mandate),
10. Ethics
11. Social sciences
12. Law.

Other experts will be invited as per the subject area of the projects under consideration.

[IC-SCR composition is as per National guidelines for stem cell research obtained from https://bic.icmr.org.in/nacsrt/downloads/National_Guidelines_for_Stem_Cell_Research_2017.pdf]

6. Criteria for selection of members of IC-SCR

A. Chairperson

- must be from outside the institution
- should have biomedical qualification with a postgraduate (medical)/doctorate degree (non-medical) with minimum of ten (10) years' experience after obtaining the postgraduate/doctorate degree.

B. Vice-Chairperson (optional)

- from outside the institution
- should have biomedical qualification with a postgraduate (medical)/doctorate degree (non-medical) with minimum of ten (10) years experience after obtaining the postgraduate/doctorate degree.

C. Member-Secretary (and Joint Member-Secretary [optional])

- staff member of the institution
- medical professional with a state medical council recognized postgraduate degree
- should have domain specialty experience, clinical research and ethics knowledge, personal interest and capacity, good communication skills

D. Members

Members will be selected in their personal capacities based on their qualification, experience in domain field, interest, ethical and/or scientific knowledge and expertise, as well as on their commitment and willingness to volunteer the necessary time and effort for the IC-SCR. They should not have any known record of professional misconduct. Medical scientists and clinicians should have recognized post graduate qualifications. Conflict of interest should be avoided while making appointments, but where unavoidable, there will be transparency with regard to such interests. Members from law, ethics, social sciences and community/lay-person must be from outside the institute and with no COI.

All members should have a minimum of five (5) years' experience after postgraduation in their respective areas of proficiency except for community/lay-person. The legal expert should be a law graduate with five (5) years of experience. S/he should be well versed with the existing acts, rules, regulations and guidelines. The social scientist should have a postgraduate/doctorate degree in social sciences/social work. The ethics expert should have a minimum six months training or demonstrable experience in bioethics.

7. Agreement regarding maintenance of Confidentiality

It is the responsibility of each IC-SCR member, reviewing research project or attending IC-SCR meetings, to read, understand, accept and sign the agreement contained in the confidentiality form. The staff of the secretariat will sign confidentiality agreement which should be filed with the IC-SCR. The secretariat will obtain the signature of the IC-SCR Chairperson on the Confidentiality form. The secretariat will email IC-SCR member soft copy of the Confidentiality Form for their records (duly signed and dated by them and IC-SCR Chairperson) and acknowledge the receipt of agreement with their signature. The secretariat will keep the original copies of the signed agreements in the IC-SCR office in the file entitled '**Confidentiality Agreement file**' for members and photocopies of the agreement in the individual member's files.

8. Tenure of membership

The tenure of IC-SCR will be for a continuous period of 3 years from the date of appointment.

9. Appointment of new members

9.1 The IC-SCR members will be appointed by the Head of the Institute.

9.2 New members will be appointed under the following circumstances:

- when a regular member completes his/ her tenure.
- if a regular member resigns before the tenure is completed.
- if a regular member ceases to be a member for any reason (eg. resignation or retirement or disqualification or death).
- to fulfill the membership requirements as stated in this SOP.

9.3 New members will be identified by the Chairperson according to the membership requirement after discussion in the IC-SCR. The names of new members to be appointed may be suggested by the IC-SCR members and the Chairperson to the Head of the Institute. The final decision regarding appointment of members will be taken by the Head of the Institute.

10. Conditions to be fulfilled by a member after appointment

Members to be appointed on the IC-SCR will need to fulfill the following conditions:

- Submit a recent signed CV
- Willing to publicize his/her full name, profession and affiliation.
- Agreeing to sign the Confidentiality Agreement and maintain confidentiality regarding meetings, deliberations, research proposals, information on research participants and related matters.
- Agreeing to read, understand, accept and follow the conflict of interest (CoI) policy and sign the Conflict of interest agreement/form.

11. Resignation and Disqualification of Members

11.1. Resignation:

An IC-SCR member may resign from membership by submitting a letter of resignation to the Chairperson. The member may or may not assign reasons for resignation. The resignation will become effective from the day it is accepted by the Chairperson.

11.2. Disqualification for conduct unsuitable of an IC-SCR member/ not attending IC-SCR meetings:

A. Disqualification for conduct unsuitable of an IC-SCR member:

A member may be disqualified from continuance if IC-SCR decides by a three-fourth majority specifically called for the purpose that the member's conduct has been inappropriate to be considered as an IC-SCR member.

- The process will be initiated if IC-SCR Chairperson or Member-secretary receives a communication in writing (provided by IC-SCR member or a member of the public) alleging misconduct by a member.
- The Chairperson will satisfy himself/ herself that a prima facie case exists before initiating action. If, in the opinion of the Chairperson, the matter is of grave significance where integrity of IC-SCR could be questioned, the Chairperson may suspend the membership of the concerned IC-SCR member till final decision is taken by IC-SCR. During the period of suspension, the concerned individual will not have any rights, privileges or responsibilities of an IC-SCR member and will not perform any duties of IC-SCR member.

Date: 12/06/2020

- The Chairperson may call for a meeting of the IC-SCR specifically to discuss this issue or the matter will be taken up for discussion during one of the regular IC-SCR meetings. The meeting convened will follow the general rules of quorum. The allegation will be
- discussed at the IC-SCR meeting and the member alleged of misconduct will be provided adequate opportunity to defend himself / herself.
- The member would stand disqualified, if members present approve of disqualification by voting (voting by 2/3rd of majority of members present in the meeting). The Chairperson will convey the disqualification to the concerned member through a written communication.

B. Disqualification for not attending IC-SCR meetings:

A member may be disqualified from IC-SCR membership if the member fails to attend more than 3 regular consecutive IC-SCR meetings without prior intimation. The process conducted will be as follows:

- The Member Secretary will inform Chairperson, in writing, if a member has not attended more than three consecutive regular meetings of the IC-SCR without prior intimation to the IC-SCR.
- The Chairperson will initiate the process of review of membership of such a member by including the matter in the agenda of the next regular IC-SCR meeting.
- A written communication will be sent to the concerned IC-SCR member informing him/her that the issue of disqualification would be discussed at the meeting inviting the member to be present at the meeting to put up his/ her case. Alternately, the concerned IC-SCR member will be allowed to state his/ her arguments regarding unauthorized absence in writing by a letter addressed to the Chairperson.
- The matter will be discussed and reviewed at the IC-SCR meeting. The concerned member will be provided adequate opportunity to represent his/ her case. A written communication, if received from the concerned member will be read and reviewed at the meeting.

- The Chairperson or Member-Secretary will inform the IC-SCR members about the cessation of membership by a confidential written communication to other members of IC-SCR or at the next meeting of IC-SCR.

12. Training of the IC-SCR Members in Research

- An individual selected as a new member of the IC-SCR will be required to attend one meeting as an 'Observer' before being inducted as a member of the IC-SCR.
- Member Secretary or an IC-SCR member will provide introductory training in research Ethics, GLP, GCP and SOPs to the new member.
- A newly inducted member should submit certificate of training in 12 months.
- All members including Chairperson and Member Secretary will be encouraged to receive continued training by participating in a workshop, conference and/ or re-training program related to research ethics, as a delegate, faculty, facilitator, etc.
- IC-SCR will conduct workshops on ethics in stem cell research, GCP, GLP and SOPs from time to time to impart training and update the IC-SCR Members and Institutional faculty members involved in stem cell research.
- IC-SCR may nominate *and / or sponsor the expenses of (as applicable)* an IC-SCR member or prospective members for attending conference, continuing education session workshop and/ or training program etc.

13 Hierarchy

- One Chairperson, one Member Secretary and one Joint Member Secretary (wherever applicable) appointed amongst the members.
- The Chairperson will head the committee.
- The Member Secretary and the Joint Member Secretary (whenever applicable) will be the guardian of all documents in the possession of the committee.
- Other IC-SCR members will be regular committee members with equal ranking.

13.1 Functions of Chairperson

The Chairperson will

- be responsible for conducting committee meetings, leading all discussions and deliberations pertinent to the review of research proposals.
- preside over all elections as well as administrative matters pertinent to the committee's functions.
- represent the IC-SCR at various meetings and forums.
- sign documents and communications related to IC-SCR functioning.
- delegate his/ her responsibilities to the Co-Chairperson in accordance with IC-SCR SOPs.

In case of anticipated absence of both Chairperson and Co-Chairperson at a planned meeting, the Chairperson will nominate a committee member as an Acting Chairperson or the members present may elect the chairperson. The Acting Chairperson will have all the powers of the Chairperson for that meeting.

13.1 Functions of Co-Chairperson

- To act as Chair in the absence of Chairperson and to perform all functions of Chairperson.

13.2 Functions of the Member secretary

- Receive research proposals
- Organize an effective and efficient tracking procedure for each proposal received
- Prepare, maintain and distribute of study files
- Schedule and organize IC-SCR meetings
- Prepare and maintain meeting agenda and minutes
- Maintain IC-SCR documentation and to archive them
- Sign documents and communications related to IC-SCR functioning
- Communicate with the IC-SCR members and applicants/ investigators

- Notify Principal Investigator regarding IC-SCR decisions related to submitted research proposal
- Arrange for training of personnel and IC-SCR members
- Organize the preparations, review, revision and distribution of SOPs and guidelines
- Provide necessary administrative support for IC-SCR related activities to the Chairperson
- Provide updates on relevant and contemporary issues to ethics in health research as well as relevant contemporary literature to the committee members
- Delegate various responsibilities to appropriate and authorized individuals
- Ensure adherence of IC-SCR functioning as per SOPs
- Prepare for audits and inspections
- Prepare and make available for scrutiny by auditors/ inspectors annual reports/ annual financial statements of the IC-SCR

13.3 Functions of the Alternate Member Secretary (whenever appointed)

- The Alternate Member Secretary will perform the same functions of Member Secretary in his/her absence.

13.4 Functions of IC-SCR members

- Attend IC-SCR Meetings and participate in discussions and deliberations so that appropriate decisions can be arrived at.
- Review, discuss and consider research Proposals submitted for evaluation.
- Monitor Serious Adverse Event reports, if any with respect to therapy and recommend appropriate action(s)
- Review the progress reports and monitor ongoing studies as appropriate
- Do onsite visits wherever needed
- Evaluate final reports and outcomes
- Maintain confidentiality of the documents and deliberations of IC-SCR meetings
- Declare any conflict of interest in writing to the Chairperson, if any, at each meeting
- Participate in continuing education activities in biomedical ethics and research

- Provide information and documents related to training obtained in animal ethics, biomedical ethics and stem cell research to the IC-SCR secretariat
- Provide an updated CV when requested for by the IC-SCR secretariat
- Carry out work delegated by Chairperson, Member-secretary and Alternate Member-secretary
- Assist Chairperson, Member-secretary and Alternate Member-secretary in carrying out IC-SCR work as per SOPs
- Be updated on relevant laws and regulations

13.5 Secretariat

The Secretariat will be composed of the scientific officer/s, the administrative Officer/s and other administrative supporting staff. The Secretariat will support the Member Secretary and Alternate Member Secretary (if applicable) in all their functions. All the staff of the Secretariat will sign confidentiality agreement which should be filed with the IC-SCR.

13.6 Types of projects reviewed by IC-SCR

The IC-SCR will review scientific and ethical aspects of all types of studies involving stem cell research;

13.7 Quorum Requirements

- The meeting will be held as scheduled provided there is quorum.

Presence of the following members is mandatory for quorum and for decision making:

- Chairperson/Vice-Chairperson,
- Member Secretary,
- experts from law,
- ethics and social sciences,
- community/lay-person and
- two stem cell/cell and molecular biology expert with appropriate expertise and no COI.

Without satisfying this condition, any decision taken by the committee shall remain null and void. In absence of the Chairperson, Co-Chairperson will chair the meeting. In absence of the Member Secretary, alternate member secretary will look after the functions of member secretary in organizing the meeting.

13.8 Honorarium to the members

Reimbursement of travelling expense and /or reasonable honorarium for attending the IC-SCR meetings will be given to the external IC-SCR members.

13.9 Preparing an annual activity report of the IC-SCR for submission to the Head of the Institute

The Member Secretary will make an annual report to brief the yearly activity report for submission to the Head of the Institute with the following elements:

- a) Number and dates of the IC-SCR meetings
- b) Number and type of proposals reviewed in a year
- c) status of each study proposal whether completed / ongoing / terminated
- d) number of approvals for review with decisions
- e) brief details about workshops, training programmes and other activities undertaken by the IC-SCR and those attended by IC-SCR members
- f) Miscellaneous activities, if any

13. Scope of the committee

- Review and approve the scientific merit of research protocols.
- Function in compliance with the existing regulations and guidelines for stem cell research.
- Maintain a record of all research activities involving stem cells conducted at the institution.
- Maintain a registry of pluripotent stem cell lines (hESC/iPSC) derived or imported by individual investigators and notify the same to NAC-SCRT.
- Submit report of the institutional stem cell research activities to NAC-SCRT annually.

- Report all AEs/SAEs to NAC-SCRT.
- Seek advice from NAC-SCRT on any contentious issue.
- Facilitate training of investigators and other stakeholders engaged in stem cell research about current knowledge, international status, relevant guidelines and regulations through regular Continuing Medical Education (CME) programs, public lectures and seminars.

14. Annexure

Annexure 1: AX01/KEMS02/V1– Working rules for the administrative staff of IC-SCR

Annexure 2: AX02/ KEMS02/V1 – Organizational flow chart of IC-SCR

Annexure 3: AX03/ KEMS02/V1 – Confidentiality Agreement Form for IC-SCR members

Annexure 4: AX04/ KEMS02/V1 – Confidentiality Agreement Form for staff of IC-SCR secretariat

Annexure 1: AX01/ KEMS02/V1**Working rules for the administrative staff of IC-SCR**

There will be administrative assistant who will help the IC-SCR Chairperson and Member-Secretary/ alternate member secretary in executing functions of the IC-SCR. Additional staff may be appointed and duties can be assigned as and when required by the IC-SCR. The eligibility criteria for new staff to be appointed will be laid down depending on the required job profile. The need for appointment of administrative staff, job profile, qualifications and office timing may be recommended by IC-SCR members during regular IC-SCR meeting and the same will be recorded in minutes. The administrative staff will report to the Member Secretary. The administrative staff will be appointed by the Dean/Director. .

Duties of administrative assistant

- Correspondence with IC-SCR members and external experts
- Correspondence with the investigators
- Preparing agenda and minutes of the IC-SCR meetings
- Answering queries of the investigators
- Filing study related documents
- Archiving and maintaining the study files, SOPs, all correspondences
- Maintaining electronic database of the IC-SCR records

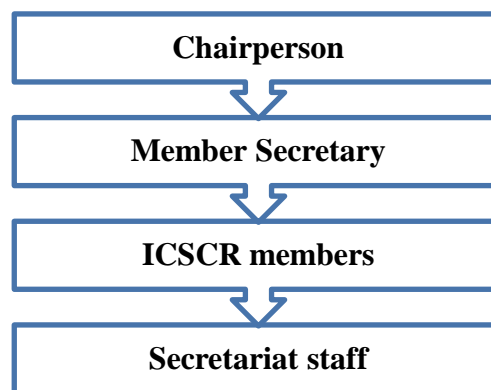
Duties of the attendants /helpers

- Assisting the secretariat in arranging the IC-SCR meetings
- Dispatching sets of study documents to IC-SCR members and external experts
- Receiving study related documents from and dispatching IC-SCR letters to investigators
- Filing study related documents
- Archiving and maintaining the study files
- Assisting the Secretariat during the meetings

Annexure 2: AX02/ KEMS02/V1

Organizational flow chart of IC-SCR, Human studies

After the Dean/Director., constitutes the IC-SCR, it will function in the following hierarchical order.



Annexure 3: AX03/ KEMS02/V1

Confidentiality Agreement Form for IC-SCR Members

In recognition of the fact, that I, _____ (Member’s name, his/her position on IC-SCR and affiliation) herein referred to as the “undersigned”, have been appointed as a member of the IC-SCR and have been asked to assess research studies involving research participants in order to ensure that they are conducted in a humane and ethical manner, adhering to the highest standards of care as per the national, and local regulations and institutional policies and guidelines and international and national guidelines. The appointment of the undersigned as a member of the IC-SCR is based on individual merits and not as representative of a home province, territory or community or as a delegate of any organization. The IC-SCR must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of research participants and the undersigned, as a member of the IC-SCR, is expected to meet the same high standards of ethical behavior to carry out its mandate.

This agreement encompasses any information deemed Confidential provided to the Undersigned in conjunction with the duties as a member of the IC-SCR. All Confidential information (and any copies and notes thereof) shall remain the sole property of the IC-SCR. The undersigned agrees to hold all confidential information in trust or confidence and agrees that it shall be used only for contemplated purposes and shall not be used for any other purpose or disclosed to any third party. Written confidential information provided for review shall not be copied or retained.

I, _____ (name of the IC-SCR member) have read and accept the aforementioned conditions as explained in this Agreement.

Signature: _____ Date: _____

Chairperson’s Signature: _____ Date: _____

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

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

Signature: _____ Date _____

Date: 12/06/2020

Annexure 4: AX04/ KEMS02/V1**Confidentiality Agreement Form for staff of IC-SCR secretariat**

In recognition of the fact, that I, _____ (Member's name, position on IC-SCR and affiliation) herein referred to as the "undersigned", have been appointed as a member of the IC-SCR and have been asked to assess research studies involving research participants in order to ensure that they are conducted in a humane and ethical manner, adhering to the highest standards of care as per the national, and local regulations and institutional policies and guidelines and international and national guidelines. The appointment of the undersigned as a member of the IC-SCR is based on individual merits and not as representative of a home province, territory or community or as a delegate of any organization. The IC-SCR must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of research participants and the undersigned, as a member of the IC-SCR, is expected to meet the same high standards of ethical behavior to carry out its mandate.

This agreement encompasses any information deemed Confidential provided to the Undersigned in conjunction with the duties as a member of the IC-SCR. All Confidential information (and any copies and notes thereof) shall remain the sole property of the IC-SCR. The undersigned agrees to hold all confidential information in trust or confidence and agrees that it shall be used only for contemplated purposes and shall not be used for any other purpose or disclosed to any third party. Written confidential information provided for review shall not be copied or retained.

I, _____ (name of IC-SCR member) have read and accept the aforementioned conditions as explained in this Agreement.

Signature:

Date:

Chairperson's Signature Date:

[The original (signed and dated Agreement) will be kept on file in the custody of the IC-SCR. A soft copy of the same will be sent by email to the Undersigned.]

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

Signature:

Date:

IC-SCR Composition**Quorum*

Sl. No.	Name	IC-SCR Designation	Area(s) of expertise	Qualification(s)	Affiliation(s)
1.	Dr Vasantha Muthuswamy	Chairperson and Ethics Expert*	Ethics	MD (OBGY)	Senior Deputy Director General, ICMR(Former)
2.	Dr Medha Rajadhyaskha	Vice-Chairperson*	Cell Biology, Life Sciences	MSc, PhD	Professor of Life Sciences, Sophia College, Mumbai
3.	Ms Tanu Mehta	Legal Expert*	Law	LLB, MA in Conflict Resolution	Advocate, Bombay High Court
4.	Dr Mrunal Marathe	Social Scientist*	Social Sciences	PhD	Free lance social scientist and counselor. Currently working for Asha Sadan [Palliative Care], Mumbai
5.	Dr Jyoti Kode	Stem Cell Expert*	Stem Cell Biology	MSc, PhD	Assistant Professor, Tata Memorial Center, ACTREC, New Bombay
6.	Dr Deepa Bhartiya	Stem Cell Expert*	Stem Cell Biology	MSc, PhD	Scientist G, ICMR NIRRH, Mumbai
7.	Dr Yashashri Shetty	Member Secretary and Ethics Expert*	Pharmacology, Ethics, Clinical Research	MBBS, MD, DBM	Associate Professor, Department of Pharmacology and Therapeutics, KEM Hospital, Mumbai

8.	Mrs Manisha Naik Dalal	Layperson*	Ethics – served for the last ten years as lay person on several IECS	MCom	Currently layperson on Tata Memorial Hospital IEC
9.	Dr Deepak Modi	Immunologist	Molecular and Cellular Biology, Immunology	MSc, PhD	Scientist F and Head Molecular and Cellular Biology Laboratory , NIRRH
10.	Dr Kishori Apte	Toxicologist	Toxicology	PhD	Technical Director APT Testing & Research Pvt Ltd , Pune
11.	Dr Taruna Madan	Immunologist	Immunology, Innate Immunity	M Pharm PhD	Scientist F and Division of Innate Immunity, NIRRH
12.	Dr Rashmi Dalvi	Paediatrician /Clinician	Paediatrics	MBBS, MD	Professor of Pediatrics, Bombay Hospital, Mumbai
13	Dr Pushkar Shikharkane	Internal Medicine/Clinician	Internal Medicine	MBBS, MD	Practicing clinician with own practice/self employed Attached to Sushrusha Hospital, Mumbai

*** For queries / enquiry – Contact Dr Yashashri Shetty, Member Secretary – IC-SCR, GSMC -KEM H, Parel, Mumbai**

Processing fees – 50,000/- to be deposited in Stem cell committee account of Diamond Jubilee Society Trust (DJST).