



# National Apex Committee for Stem Cell Research and Therapy

Department of Health Research  
Ministry of Health and Family Welfare  
Government of India



File No. 83/1(55)/2020-NAC-SCRT/BMS  
11<sup>th</sup> September, 2020

Dr. Hemant Deshmukh,  
Dean  
Seth GSMC & KEM Hospital  
Acharya Donde Marg  
Parel  
Mumbai 400012

**Subject: Registration of IC-SCR of Seth GS Medical College & KEM Hospital, Mumbai with the NAC-SCRT**

Sir,

This has reference to your application for registration of the Institutional Committee for Stem Cell Research (IC-SCR). After review of the application and supporting documents submitted by you, the National Apex Committee for Stem Cell Research and Therapy (NAC-SCRT) hereby registers the IC-SCR of Seth GS Medical College & KEM Hospital, Mumbai. Your registration number is **NAC-SCRT/55/20200209**, which must be quoted in all future communications.

The registration is valid for a period of three years (11.09.2020 to 10.09.2023) subject to compliance with National Guidelines for Stem Cell Research and fulfilment of the terms and conditions given overleaf. If the institution or the IC-SCR fails to comply with the existing National Guidelines for Stem Cell Research and the terms and conditions defined, the NAC-SCRT may suspend or cancel the registration of the IC-SCR.

Kindly note that the registration of IC-SCR should not be quoted/ advertised as certification/ recognition/ accreditation from the Government of India.

I take this opportunity to thank you for your interest in stem cell research.

Yours faithfully,

(Dr. Geeta Jotwani)

Member-Secretary, NAC-SCRT Secretariat

Copy to: Dr Yashashri Shetty, Member Secretary, IC-SCR, Department of Pharmacology and Therapeutics, College Building, First Floor, Seth GS Medical College and KEM Hospital, Acharya Donde Marg, Parel, Mumbai 400012

## **Terms and Conditions:**

1. The IC-SCR shall review and approve stem cell research proposals from the institution on scientific and ethical merits.
2. The IC-SCR shall ensure that the research conducted under its ambit is scientifically substantiated based on the ethical principles, and in compliance with the National Guidelines for Stem Cell Research-2017 and New Drugs and Clinical Trial Rules 2019.
3. The IC-SCR shall maintain a record of all stem cell lines and products developed/imported/procured by the institute and should notify the same to NAC-SCRT through its annual report.
4. The IC-SCR shall maintain a registry of all investigators in the institution working in the field of stem cell research and ensure that those engaged in clinical trials have certified Good Clinical Practices (GCP) training from a recognised institution.
5. The IC-SCR shall submit annual report to the NAC-SCRT.
6. The Head of the institute shall allow representatives of the NAC-SCRT/regulatory authorities to enter its premises and co-operate to inspect any record, data or any documents related to IC-SCR and provide necessary clarifications/explanation to the queries raised, if any.
7. The IC-SCR shall inform the NAC-SCRT in writing when there is any change in the constitution of IC-SCR or the change in the mandate of stem cell research activity already notified.
8. In case of clinical trials, it is the responsibility of IC-SCR to notify adverse events or serious adverse events (SAEs/AEs) to IEC, Sponsor, CDSCO and NAC-SCRT. The IC-SCR shall also keep a record of severe adverse events/adverse events.
9. The investigators working in the field of stem cell research and members of IC-SCR should be conversant with the National Guidelines for Stem Cell Research-2017 and New Drugs and Clinical Trial Rules 2019.
10. The IC-SCR members should conduct site visit to review the infrastructure and scientific activities of the investigators as well as of the collaborating entities.