

Frontier Lifeline Hospital gets approval for cardiac stem cell research by the national Apex committee for stem cell research and clinical trial (heart regeneration)

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Institutional Committee for Stem Cell Research (IC-SCR) of Frontier Lifeline Hospital and Dr K M Cherian's Heart Foundation has been registered and certified by The National Apex Committee for Stem Cell Research and Therapy (NAC- SCRT) to oversee the activities in the field of cardiac stem cell research for a period of three years: according to a communication from Department of Health Research, Government of India.

Frontier Lifeline Hospital (FLL) has been already involved in cardiac stem cell therapy post the approval by Clinical Trial registry of India, Indian Council of Medical Research (ICMR) in 2010. The center performed 100 cases proving the safety and efficacy of cardiac stem cells. And now, NAC-SCRT- the apex body constituted by the Department of Health Research, Ministry of Health and Family Welfare, Govt. of India has registered the Institutional Committee for Stem cell research of the hospital and its research centre- Frontier Mediville for performing Cardiac stem cell therapy treatments.

The Committee has been certified based on its successful adherence to Ethical guidelines and stem cell research done by the department of tissue engineering and regeneration medicine at FLL and Mediville. Frontier lifeline will adhere to the following guidelines by NAC.

1. The IC-SCR shall provide overview of all issues related to Stem cell research as well as its functioning to NAC-SRT
2. The IC-SCR shall review and approve protocols/ proposals on scientific and ethical merits
3. The IC-SCR shall ensure that the research conducted under its ambit is scientific, ethical, and in compliance with the ICMR Ethical Guidelines for biomedical research on Human participants (2006) and National Guidelines for stem cell research 2013 and all relevant regulations.
4. The IC-SCR shall maintain a register of all investigators in the institution working in the field of stem cell research and ensure that those engaged in clinical trials have training on GCP compliance
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 the premises to inspect any record, data or any documents related to IC-SCR and provide adequate clarifications/explanations to the queries raised, if any.
7. The IC-SCR shall update the NAC-SCRT in case of any change in the constitution of IC-SCR or the category of stem cell research being conducted at the institute.
8. The IC-SCR shall record severe adverse event/adverse events (SAEs/AEs), if any, and report the same to NAC-SCRT.
9. The investigators working in the field and members of IC-SCR should be well conversant with ICMR Ethical Guidelines for Biomedical Research in human participants (2006), National Guidelines for Stem Cell Research – 2013 and other existing regulatory framework.
10. All members of IC-SCR should declare their Conflict of Interest (COI), if any, and the same should be minuted.

Speaking on the same, Dr K M Cherian, Founder & Chairman – Frontier Lifeline Hospital, said:

Stem cell clinical trials at FLL has been very much satisfactory over the last years. Safety and efficacy of stem has been proved over 100 patients and now NAC-SCRT has approved our application for registration and certified us for a period of 3 years. Through this certification, FLL has been recognized as one of the Centre for Cardiac stem cell therapies in our country

Recent report says that honorable high court of Chennai has announced that centers who are into stem cell therapies and other research works have to get approval from its concerned health department. Use of stem cells for any other purpose outside the domain will be considered unethical and not permissible. According to the latest ICMR Guidelines, the research on Somatic Stem Cells (SSC) falls under permissible area of research if done with prior approvals. FLL has followed the regulations and have obtained necessary approvals from the NAC-SCRT.

Source:
Frontier Lifeline Hospital
