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Control Status

1.0 Purpose

To lay down a procedure for monitoring and control of practices and procedures involving Cell or Stem cell based preparations for therapeutic purposes which are not regulated as drug product under New Drugs and Clinical Trial Rules, 2019.

2.0 Scope

This document is applicable to Stem Cell / cell based therapies/ practices/ procedures carried out in same surgical setting in a hospital based on the principles of Evidence based medicine considering the level of evidence except for starndard of care.

3.0 Responsibility:

3.1 The Registered Ethics Committee (EC) shall be responsible for approval of the protocol of the proposed therapies.

3.2 National Medical Commission (NMC) shall be responsible for taking the regulatory action in case of any violation / negligence by the practitioners.

3.3 The designated authority regulating Clinical Establishment Act at State level

3.4 The registered ethics committee of tertiary care hospital / Medical College in that region will act as regional ethics committee for near by hospitals.

4.0 Accountability

- Registered Ethics Committee (EC)
- National Medical Commission (NMC) and
- The designated authority regulating Clinical Establishment Act at State level

5.0 Procedure

5.1 Procedure for Processing:

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5.1.1 Ethics Committee approval is mandatory and all its instruction must be abided.

5.1.2 Patients' right must be protected.

5.1.3 Monitoring of such patients is required for considerable time.

5.1.4 The treating doctor shall be a medical professional registered with NMC and should have NMC approved graduate / post graduate qualification in the domain area with adequate relevant experience.

5.1.5 Written Informed Consent should be obtained from the patient/ care taker in accordance with the current legal definition of consent, preferably in a local language. The doctor should disclose:

i. The nature, purpose, benefits and effect of the procedure;

ii. Alternatives to the procedure if any;

iii. An outline of the risks;

iv. Options to have a second opinion.

5.1.6 All the procedures of cell based therapies including Stem Cell therapies shall be carried out in a facility which is designed in such a manner so as to prevent infection/ extraneous contamination/ impurity.

5.1.7 Quality of the preparations to be administered to the patients is required to be ensured consistently and it is responsibility of the treating doctor.

5.1.8 In process Quality should be checked at various levels.

5.1.9 The cell/tissue processing shall be conducted under the active direction of a medical professional and personal supervision of competent technical staff, which have a Post-graduate degree in Pharmacy, Microbiology, Pathology, Immunology, Biochemistry, Biotechnology or Life Sciences.

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5.1.10 Preparations to be administered to the patient should be stored in an appropriate container with established storage condition so as to retain its potency for intended purpose.

5.1.11 Up to date records of such preparations to be kept for three years or as directed by ethics committee and other related documents shall be maintained for each step of the procedure which includes the details but not limited to the volume of tissue/number of cells collected, procedure used to isolate and / or purify the cell population, cell characterization, the time from cell / tissue collection to administration, the count & viability of cells prior administration.

5.1.12 Control Sample, Histopathology samples wherever possible shall be maintained.

5.1.13 Experience gained with such procedures including the Safety & Efficacy of such preparations should be summarized and if possible should also be published.

5.1.14 A training record of all the personnel shall be maintained.

5.1.15 Labeling to be maintained as per requirement to meet traceability including details like Name of the patient, Name of the Treating Physician, Manufacturing date, Expiring date. etc.,

5.2 Premises Requirements:

5.2.1 The hospital should be registered with Clinical Establishment Act, 2020/ state or city equivalent.

5.2.2 The cell/tissue processing facility must be clarly identified and shall be within the hospital and under the control of the hospital. If the samples are sent outside, it shall be under strict control of practioners concerned and hospital authority.

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5.2.3 The cell/tissue processing facility shall be free of insents and rodents besides preventing cross contamination and spread of infection; attention shall also be given to following:

5.2.3.1. Interior surface (walls, floor, and ceilings) shall be smooth which shall not spread the infection and shall be easy for cleaning and disinfection;

5.2.3.2. Adequate provision is made not only for space and equipment for carrying out necessary test but also for utilities like water, power and gas;

5.2.3.3. Air ventilation system shall ensure dust free environment.

5.2.4 The processing facility shall be provided with adequate lighting and ventilation and if necessary, air-conditioning to maintain satisfactory temperature and relative humidity that will not adversely affect the testing and storage or the accuracy of the functioning of the facilities equipment or instruments.

5.2.5 Table tops shall be constructed with acid, alkali and solvent resistant material and shall be and free from crevices as far as possible.

5.2.6 Access to the cell/tissue processing areas shall be restricted to a minimum number of authorized personnel. Standard operating procedures for entering and leaving the cell processing areas shall be prominently displayed.

5.3 Equipment Requirements:

5.3.1 A Standard Operating Procedure (SOP) is required for the maintenance and operation of all equipment.

5.3.2 The analytical instruments shall be housed in dust-free environment and whenever required conditions of temperature and humidity shall be maintained and periodic checks on temperature and humidity be made and recorded.

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5.3.3 Instruments requiring calibration shall be calibrated at regular intervals and records of such calibration shall be maintained.

5.4 4. **Procedure /Process information to patient:**

5.4.1 Any Cost incurred to the patient should be disclosed and explained to patient or attendant in writing prior to conduction of procedure.

5.5 Registration of Ethics Committee:

5.5.1 All the Ethics Committee (EC) involved in the review and approval of Stem Cell / cell based therapies shall undergo prior registration.

5.5.2 The Ethics Committee shall also co-opt the experts from the concern field/ domain.

5.5.3 EC can approve or reject the proposal other than Standard of Care i.e., Clinical Option/ under development /or strictly for research.

5.5.4 Ethics Committee shall ensure that no advertisement, hype or over claim regarding prognosis of disease shall be made by any means to patient or their relatives.

5.6 National Medical Commission:

5.6.1 NMC regulates the health care practitioner and the medical colleges practicing the Cell based /Stem cell procedure in the country

5.6.2 Practitioner doing such research shall be regulated under NMC Act.

5.7 ICMR:

5.7.1 ICMR may review & provide advice, upon the request by Institution or practitioner on the protocols/proposals and to publish the guidelines on good research practices in this area.

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5.8 Mechanism for Regulatory Action:

5.8.1 **Practitioner:**

5.8.1.1 In case of Non-compliance by the Practitioner: Ethics Committee can disapprove the research of the practitioner and ask him/her to stop all his projects.

5.8.1.2 NMC can cancel/suspend his/her Registration for practice.

5.8.1.3 Further, the police may take necessary action for fake activities on the advice of NMC only.

5.8.2 **In case Ethics Committee does not comply:**

5.8.2.1 Its registration can be cancelled/ suspended permanently.

6.0 Abbreviation

Acronym	Full Form
ICMR	Indian Council of Medical Research
NMC	National Medical Commission
EC	Ethics Committee