

**File No. M-11019/5/2026-CG**

भारत सरकार / Government of India

स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare

स्वास्थ्य अनुसंधान विभाग / Department of Health Research  
(NECRBHR)

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IRCS Building, Red Cross Building, New Delhi

Dated the 1.12.2026 March, 2026

To,

All Institutional Ethics Committees  
Registered with the Department of Health Research (DHR)  
Government of India

**Subject: Compliance with the Hon'ble Supreme Court Judgment dated 30.01.2026 – Regulation of Stem Cell Therapy for ASD and Other Indications.**

Madam/Sir,

This has reference to the judgment dated 30.01.2026 of the Hon'ble Supreme Court of India in the matter of *Yash Charitable Trust & Ors. versus Union of India & Ors.* in W.P. (C) No. 369 of 2022, concerning issues related to the use of stem cell therapy for the treatment of Autism Spectrum Disorder (ASD). This judgment has important implications for giving stem cell therapy in India. The directions of the Hon'ble Court are being conveyed to ensure strict compliance as under:

- Stem cell therapies in routine practice shall be permitted only for disease conditions specified in the list of MoHFW-approved indications as Standard Care (enclosed herewith).
- Other than the approved indications, Stem cell therapy is permissible only in the context of research. If stem cells have undergone more than minimal manipulation, the research will be regulated by CDSCO. If stem cells have undergone less than minimal manipulation, research will be regulated by Department of Health Research (DHR), and in this case, in addition to the recommendations of the Ethics Committee (IEC) registered with DHR, the trials will have to be approved by the National Stem Cell Research Regulation Committee. The levels of manipulation for stem cell therapy have been defined by CDSCO.
- Stem cell research shall be permissible only as part of an approved clinical trial. This research will be required to comply with all ICMR ethical guidelines, including written informed consent, no cost to the patient and provision of compensation in case of injury or death.
- Any stem cell treatment not included in the list of standard care indications, or not approved by CDSCO, or DHR, shall be deemed illegal and liable to action in accordance with law. It is reiterated that biomedical research can only be approved by an IEC registered with DHR.

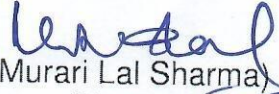
2. All Ethics Committees registered with DHR are hereby directed to ensure strict adherence to the above directions while reviewing, approving, or monitoring any research protocol involving stem cell-based interventions. All ECs registered with DHR should submit the recommended clinical trials on stem cell research to the National Stem Cell Research Regulation Committee for approval through the National Ethics Committee Registry for Biomedical and Health Research at DHR.

मुरारी लाल शर्मा / MURARI LAL SHARMA  
निदेशक / Director  
स्वास्थ्य अनुसंधान विभाग / Deptt. of Health Research  
स्वास्थ्य एवं परिवार कल्याण मंत्रालय  
Ministry of Health and Family Welfare  
भारत सरकार / Govt. of India

3. This issues with the approval of the competent authority.

Enclosure: As above

. Yours faithfully,

  
(Murari Lal Sharma)  
Director (DHR)

11/3/2026

Copy to:

1. PSO to Secretary, Department of Health Research /DG, ICMR, New Delhi.
2. PPS to Additional Secretary, (AN), Department of Health Research, New Delhi.
3. Head , ICMR- Bioethics Unit.
4. All stakeholders/public at large.

मुरारी लाल शर्मा / MURARI LAL SHARMA  
निदेशक / Director  
स्वास्थ्य अनुसंधान विभाग / Dept. of Health Research  
भारत सरकार / Ministry of Health and Family Welfare  
नई दिल्ली / Govt. of India  
New Delhi

**LIST OF MOHFW APPROVED DISEASE CONDITIONS FOR STEM CELL THERAPY**  
**AS STANDARD CARE**

Only safe and appropriately performed hematopoietic stem cell transplantation is recommended as Standard of Care for the following indications\*\*. Mesenchymal stem cell transplantation is not recommended for any disease condition.

**Adults:**

1. Acute Myeloid Leukemia
2. Acute lymphoblastic leukemia
3. Chronic Myeloid Leukemia
4. Myelofibrosis
5. Myelodysplastic syndromes
6. Chronic lymphocytic leukemia
7. Diffuse Large b cell lymphoma
8. Follicular lymphoma
9. Mantle cell lymphoma
10. Peripheral T cell lymphoma
11. Hodgkin's Lymphoma
12. Multiple Myeloma
13. Acquired Severe Aplastic Anemia
14. Constitutional Severe Aplastic Anemia
15. Aplastic Anemia/Paroxysmal hemoglobinuria
16. Germ Cell tumors
17. Multiple Sclerosis
18. Systemic Sclerosis

**Pediatrics:**

1. Acute Myeloid Leukemia
2. Acute lymphoblastic leukemia
3. Chronic Myeloid Leukemia
4. Myelodysplastic syndromes/ Juvenile myelomonocytic leukemia
5. Non-Hodgkin Lymphoma
6. Hodgkin lymphoma
7. Primary immunodeficiency diseases
8. Mucopolysaccharidoses
9. Thalassemia/ SCD
10. Osteopetrosis
11. Acquired Severe Aplastic Anemia
12. Inherited Bone Marrow failure syndromes
13. Ewings Sarcoma
14. Neuroblastoma

\*\*For details, refer to ICMR Hematopoietic Cell Transplantation Guidelines 2021 (Annexure I- Standard of Care only)

