

**ETHICS-11011/5/2026-e-office**  
**Government of India**  
**Directorate General of Health Services**  
**Central Drugs Standard Control Organization**  
**(Ethics Committee Registration Division)**

FDA Bhawan, Kotla Road  
New Delhi-110002

Dated: 11 MAY 2026

**ADVISORY**

**Subject:** Parallel submission and processing of Clinical Trial applications by CDSCO and Ethics Committees registered under NDCTR, 2019 – reg.

To streamline and expedite the review process of Clinical Trial applications, all applicants/stakeholders are hereby advised to submit the Clinical Trial protocol and related documents simultaneously to Central Drugs Standard Control Organization (CDSCO) and the concerned Ethics Committee registered under Chapter III of the New Drugs and Clinical Trials Rules, 2019.

Ethics Committees registered under Rule 8 of NDCTR, 2019 should independently undertake review of Clinical Trial protocols submitted to them and process the same in accordance with the provisions of NDCTR, 2019, without awaiting prior approval from the Central Licensing Authority (CLA).

This parallel processing mechanism is intended to:

1. Reduce overall approval timelines for Clinical Trial applications.
2. Enhance regulatory efficiency through concurrent review by CDSCO and Ethics Committees and
3. Facilitate timely initiation of Clinical Trials and faster access to innovative therapies for patients.

All stakeholders and registered Ethics Committees are requested to take note of the above and ensure compliance in the interest of efficient processing of Clinical Trial applications.

  
(Dr. Rajeew Singh Raghuvanshi)  
Central Licensing Authority

Copy to-

1. All concerned Stakeholders/Ethics Committee through CDSCO website.