May 11, 2026

CDSCO

CDSCO and ethics committees to review trials in parallel

A CDSCO advisory of May 11, 2026 asks applicants to file clinical trial protocols with CDSCO and the ethics committee at the same time, for parallel review.

THE CENTRAL DRUGS Standard Control Organization (CDSCO), Directorate General of Health Services, issued an Advisory through its Ethics Committee Registration Division under file number ETHICS-11011/5/2026-e-office. Its date, May 11, 2026, is stamped on it. Its subject is "Parallel submission and processing of Clinical Trial applications by CDSCO and Ethics Committees registered under NDCTR, 2019". It is signed by Dr. Rajeev Singh Raghuvanshi as Central Licensing Authority (CLA). CDSCO lists it, dated May 11, 2026, on both its Clinical Trial page and its Ethics Committee page.

KEY FACTS

AUTHORITY

CDSCO

PUBLISHED

May 11, 2026

ISSUED BY

Central Drugs Standard Control Organization (Ethics Committee Registration Division), Directorate General of Health Services

DOCUMENT

Advisory, file number ETHICS-11011/5/2026-e-office



CDSCO and ethics committees to review trials in parallel

CDSCO · May 11, 2026

The Central Drugs Standard Control Organization (CDSCO), Directorate General of Health Services, issued an Advisory through its Ethics Committee Registration Division under file number ETHICS-11011/5/2026-e-office. Its date, May 11, 2026, is stamped on it. Its subject is "Parallel submission and processing of Clinical Trial applications by CDSCO and Ethics Committees registered under NDCTR, 2019". It is signed by Dr. Rajeev Singh Raghuvanshi as Central Licensing Authority (CLA). CDSCO lists it, dated May 11, 2026, on both its Clinical Trial page and its Ethics Committee page.

The advisory gives its aim as to "streamline and expedite" the review of Clinical Trial applications. It advises all applicants and stakeholders to submit the Clinical Trial protocol and related documents simultaneously to CDSCO and to the concerned Ethics Committee registered under Chapter III of the New Drugs and Clinical Trials Rules, 2019 (NDCTR, 2019). Chapter III deals with ethics committees for clinical trials and bioavailability and bioequivalence studies, and its rule 8 with their registration. Ethics Committees registered under rule 8 should independently review the protocols submitted to them, and process them under the NDCTR, 2019, without awaiting prior approval from the CLA.

The advisory says this parallel processing is meant to reduce overall approval timelines for Clinical Trial applications and to enhance regulatory efficiency through concurrent review by CDSCO and Ethics Committees. It is also meant to facilitate timely initiation of Clinical Trials and faster access to innovative therapies for patients. It requests all stakeholders and registered Ethics Committees to take note and "ensure compliance in the interest of efficient processing of Clinical Trial applications". It has no addressee line; a copy goes to all concerned stakeholders and Ethics Committees through the CDSCO website.

The document calls itself an advisory and does not amend the NDCTR, 2019; the only parts of the rules it cites are Chapter III and rule 8. It sets no timeline for either review and gives no date from which it applies. It does not say how CDSCO and the Ethics Committee are to share their decisions, what follows if one approves a protocol and the other does not, or whether a trial may begin before both have approved it. It does not mention bioavailability or bioequivalence studies.

Issued by	Central Drugs Standard Control Organization (Ethics Committee Registration Division), Directorate General of Health Services
Document	Advisory, file number ETHICS-11011/5/2026-e-office
Dated	May 11, 2026 (date stamp)
Subject	"Parallel submission and processing of Clinical Trial applications by CDSCO and Ethics Committees registered under NDCTR, 2019"

Applies to	Clinical Trial applicants and stakeholders; Ethics Committees registered under rule 8 of the New Drugs and Clinical Trials Rules, 2019
Applicants	Submit the Clinical Trial protocol and related documents simultaneously to CDSCO and the concerned registered Ethics Committee
Ethics Committees	Review protocols independently and process them under the NDCTR, 2019, without awaiting prior approval from the Central Licensing Authority
Rules cited	New Drugs and Clinical Trials Rules, 2019: Chapter III and rule 8
Takes effect	No date stated
Timelines	None set
Copy to	All concerned stakeholders and Ethics Committees, through the CDSCO website
Signed by	Dr. Rajeev Singh Raghuvanshi, Central Licensing Authority

The advisory (PDF, 345 KB)

Source: CDSCO's own copy.

Checked against the official copy on October 28, 2026.

IndusDesk

hello@indusdesk.com · +91 11 4141 3939

9th Floor, Hemkunt House, Rajendra Place, New Delhi, Delhi 110008, India

Read online: indusdesk.com/cdsco/insights/cdsco-and-ethics-committees-to-review-trials-in-parallel/