

Functionalities:

“A robust Ethics Committee oversight system is essential to maintain public trust in clinical research. CDSCO’s regulatory approach combines facilitation of compliant Ethics Committees with risk-based oversight and proportionate enforcement against non-compliance.”

Ethics Committee division deals with the applications seeking registration, re-registration and post approval changes of Ethics Committee under the ambit of NDCTR 2019. No Ethics Committee shall review and accord its approval to a clinical trial protocol without prior registration with the Licensing Authority as defined in clause (b) of Rule 21.

Regulatory Functions of Ethics Committee Division, CDSCO under New Drugs and Clinical Trials (NDCT) Rules, 2019

Scope:

- Registration of Ethics Committees (ECs)
- Review of EC registration applications
- Review of post approval changes applications viz. (change in constitution, membership, address etc.)
- Oversight of EC functioning
- Handling complaints and non-compliance
- Regulatory inspections planning on Risk Based Inspection
- Corrective and preventive actions (CAPA)
- Suspension or cancellation of EC registration

File Review Process for Grant/Renewal of EC Registration submitted through Sugam portal:

Receipt of Application

- Application submitted in prescribed form (CT-01) along with requisite documents.

Preliminary Scrutiny

Review of:

- Constitution and composition of EC
- Qualifications and experience of members
- SOPs of EC
- Member training records
- Institutional details
- Administrative arrangements
- Conflict of interest policy
- Quorum requirements
- Authority letter along with undertaking in specific format

Deficiency Review

- Deficiencies or clarifications, if any, are communicated to the applicant.
- Applicant submits response and supporting documents.

Recommendation

- EC Division examines compliance and makes recommendations to CLA for grant or rejection of registration.

Grant/Renewal of Registration

The Licensing Authority after being satisfied that the requirements have been complied with, may grant registration to the Ethics Committee subject to such conditions as stated under NDCTR 2019

- Central Licensing Authority grants registration in **Form CT-02**.
- Registration is valid for a period prescribed under NDCT Rules.
- EC is permitted to review clinical trials and BA/BE studies as applicable.

The registration of Ethics Committees is valid for a period of Five years. The re-registration applications need to be made within 90 days before the expiry of registration. Registration remains deemed continued unless otherwise orders are passed or until the registration is Suspended or Cancelled. Accordingly, applicant shall apply to CDSCO for re-registration as per checklist.

Review of Post Approval Changes(PAC) Applications submitted through e-office/email/hard copy

PAC applications i.e. change in membership/constitution/ address, etc has been reviewed and processed through e-office. If documents are submitted in line with NDCTR 2019, approval letter may be issued by Deputy Drugs Controller (India) and if not, query may be raised by Deputy Drugs Controller (India).

Post-Registration Regulatory Oversight

The EC Division continuously monitors:

- Compliance with NDCT Rules.
- Adherence to approved SOPs.
- Timely review of clinical trial protocols.
- SAE review and recommendations.
- Continuing review of ongoing studies.
- Maintenance of records.
- Conflict of interest management.
- Protection of vulnerable participants.

Sources of information:

- Complaints.
- Inspection reports.
- Reports from investigators/sponsors.
- Other regulatory intelligence.

Complaint Handling Mechanism

Receipt of Complaint

Complaints may relate to:

- Improper EC constitution.
- Inadequate ethical review.

- Conflict of interest.
- Failure to review SAE.
- Improper informed consent oversight.
- Violation of NDCT provisions.

Initial Assessment

EC Division evaluates:

- Credibility of complaint.
- Risk to participant safety.
- Need for immediate regulatory intervention.

Proposal for Regulatory Inspection

Where required, the EC Division may propose an inspection to the Central Licensing Authority.

Basis for inspection:

- Serious complaints.
- Previous non-compliance.
- Risk-based selection.
- Verification of submitted information.
- For-cause inspection.

Inspection Team should not be limited but examine at least as per inspection check list :

- EC records.
- Minutes of meetings.
- SOP implementation.
- Membership and quorum.
- Protocol review procedures.
- SAE review records.

Inspection Findings and Non-Compliance (NC) Review

Inspection observations are categorized based on:

- Critical non-compliance.
- Major non-compliance.
- Minor non-compliance.

EC Division reviews:

- Inspection report.
- EC response.
- Root cause analysis.
- Corrective and Preventive Action (CAPA) plan.
- Evidence of implementation.

Show Cause Notice (SCN)

If significant non-compliance is established:

CDSCO may issue a Show Cause Notice asking the EC to explain:

- Reasons for non-compliance.
- Corrective actions taken.
- Preventive measures to avoid recurrence.

The EC is provided an opportunity to submit a written response within the stipulated timeline.

Review of CAPA and Compliance

The EC Division assesses:

Whether CAPA is:

- Scientifically justified.
- Adequate to address root cause.
- Time-bound.
- Effectively implemented.

Possible outcomes:

- If required CAPA may be verified by CDSCO Zonal/Sub-Zonal offices
- CAPA accepted → Matter closed with monitoring.
- CAPA inadequate → Further regulatory action proposed.

Opportunity for Personal Hearing

Before major regulatory action:

- The EC may be provided an opportunity for personal hearing before the Central Licensing Authority.
- EC representatives may present:
 - Explanation of deficiencies.
 - Evidence of corrective actions.
 - Compliance status.

Final Regulatory Action taken by CLA:

After personal hearing if the clarification or justification is not satisfied, CLA may take action such as cancellation/ suspension of RC and/or debarment of EC members as per NDCTR 2019.

