

1.Where to apply EC Registration Certificate on Sugam Portal?

Ans. Applicants can log in to the SUGAM Portal submit application in Form CT-01 for EC Registration at Sugam Portal and check the status under submitted applications.

4. What category should be selected during registration?

Ans. Applicants should select the appropriate category either Institutional if EC is attached with any hospital, medical /college/ university, or independent, if EC is constituted by individual members who are not part of EC as member's other option i.e. limited /Proprietary /others as case to case basis may be opted.

3.What is the validity period of Ethics Committee registration for clinical trials BA/BE Protocol?

Ans. Registration granted in Form CT-02 is valid for a period of 5 years from the date of issue, unless it is suspended or cancelled by the Central Licensing Authority.

4.When should an Ethics Committee apply for renewal of registration?

Ans. An Ethics Committee should apply for renewal in Form CT-01 at least 90 days before expiry of registration. If applied on time, the registration remains valid until the Central Licensing Authority passes an order. Fresh documents are not required if there are no changes in previously submitted documents.

5.If renewal application is submitted prior to 90 days of expiry of validity. Whether registration will be continue?

Ans. Yes, if the renewal application submitted prior to 90 days of expiry of validity registration shall be continue in force until an order is passed by CLA.

6. How will the registration certificate be received?

Ans. After approval, the registration certificate can be downloaded from the SUGAM Portal or Naitik Portal.

7.What category should be selected during registration?

Ans. Applicants should select the appropriate category either hospital if EC is attached with or limited, other or proprietary if EC a hospital, medical college, university, or research institution to review research conducted within that institution.

8. How can application status be checked?

Ans. Applicants can log in to the SUGAM Portal and check the status under submitted applications.

9. Whether Form CT-01 is required to be digitally signed for Ethics Committee registration?

Ans. Yes. Form CT-01 should be digitally signed by the authorized signatory before submission on the SUGAM Portal, as per applicable CDSCO requirements

10. Can the Chairperson or Member Secretary perform dual roles in an Ethics Committee?

Ans. Yes. The Chairperson and Member Secretary may also perform additional roles in the Ethics Committee based on their qualifications, such as clinician, legal expert, basic scientist, social scientist, or lay person.

11. Is inclusion of a social scientist and clinician required in an Ethics Committee?

Ans. Yes. An Ethics Committee should include qualified clinicians and at least one independent member from a related field such as a social scientist, to ensure proper scientific and ethical review of research proposals.

12. Can a clinical trial be conducted at a site that does not have its own Ethics Committee?

Ans. Yes. If a clinical trial site does not have its own Ethics Committee, the trial may be initiated after obtaining approval from:

- the Ethics Committee of another clinical trial site; or
- an Independent Ethics Committee constituted as per applicable regulatory provisions. However:
- the approving Ethics Committee will be responsible for oversight of the trial at that site; and
- the approving Ethics Committee and the clinical trial site/bioavailability-bioequivalence centre must be located within the same city or within a radius of 50 km from the trial site.

13. Can an Ethics Committee appeal against an order issued by the Central Licensing Authority?

Ans. Yes. If an Ethics Committee or any of its members is aggrieved by an order issued by the Central Licensing Authority, an appeal may be filed before the Central Government within 60 working days from the date of receipt of the order.

14. Who should apply for Ethics Committee registration?

Ans. Both Institutional Ethics Committees and Independent Ethics Committees can be registered either with CDSCO as per Chapter III or with DHR Ministry of Health and Family Welfare as per Chapter IV of NDCTR 2019.

15. What documents are required for registration?

Ans. Common documents include:

- Authority letter
- Constitution of Ethics Committee
- SOPs
- Member list
- CVs of members
- Qualification certificates
- Undertaking by Head of Institution/Authority
- Legal documents as proof of Institutional/Independent Ethics Committee

16. What is the minimum composition required for an Ethics Committee for clinical trials?

Ans. An Ethics Committee for clinical trials must consist of at least 7 members from medical, non-medical, scientific, and non-scientific backgrounds. The Committee should include at least:

- One lay person
- One-woman member
- One legal expert
- One independent member from a related field such as:

Social scientist, Representative of a non-governmental voluntary agency, Philosopher, Ethicist, Theologian.

17. What qualifications should medical scientists and clinicians in an Ethics Committee possess?

Ans. Members representing medical scientists and clinicians in an Ethics Committee should possess:

- At least a postgraduate qualification in their respective area of specialization and Ethics Committee should include a medical scientist member, preferably a pharmacologist
- Adequate experience in their respective fields; and
- Required knowledge and clear understanding of their roles and responsibilities as Ethics Committee

18. Who can be appointed as the Chairperson and Member Secretary of an Ethics Committee?

Ans. The Chairperson of the Ethics Committee should be a member who is not affiliated with the institute or organization and shall be appointed by the institute or organization.

- The Member Secretary should be a member who is affiliated with the institute or organization and shall be appointed by the institute or organization. Further, the Ethics Committee must include:

19. What are the essential requirements for an Independent Ethics Committee (Ind EC)?

Ans. An Independent Ethics Committee (Ind EC) should:

- Be a registered legal entity with independent governance;
- Function according to SOPs and national EC guidelines;
- Review proposals from institutions having their own EC only when an MoU exists;
- Have rights and responsibilities for all projects reviewed;
- Have access to research records and participants;
- Conduct continuing review and site visits, where required; and
- Be familiar with local socio-cultural norms to protect research participants.

20. What should be done if an Ethics Committee member has a Conflict of Interest (COI) in a research proposal?

Ans. If a member has a Conflict of Interest (COI) in a proposal, the member should declare it in writing to the Chairperson before the meeting. The declaration should be recorded in the meeting minutes.

- The concerned member must withdraw from the meeting while the proposal is being discussed, and the quorum should be rechecked and recorded in the minutes.

21. Whether any change in the constitution/membership of registered ethics committee to be intimated to CLA.

Ans. Yes, any change in the constitution/membership of registered ethics committee shall be intimated to CLA within 30 working days of such changes.

22. Whether independent Ethics Committee can approved clinical trial protocols.

Ans. Yes. As per NDCTR 2019, Rule 25.1 of NDCTR 2019, the Ethics Committee of another clinical trial site; or

- an Independent Ethics Committee constituted as per applicable regulatory provisions. However:
- the approving Ethics Committee will be responsible for oversight of the trial at that site; and
- the approving Ethics Committee and the clinical trial site/bioavailability-bioequivalence centre must be located within the same city or within a radius of 50 km from the trial site.