

Ethics Committee Registration Check List

File Number : EC/NEW/INST/20XX/XXXX

CDSCO File Number : EC/XX/000XXX

1. Application in Form CT-01 for grant of registration of Ethics Committee, constituted under Rule-7 of the New Drugs and Clinical Trials Rules, 2019 (Upload Form CT-01).
2. Authority under which the Ethics Committee has been constituted (upload authority letter from authorised person of hospital/Institute).
3. Memberships requirements of the Ethics Committee (upload relevant SOP/Documents).
4. The terms of reference of the committee (upload relevant SOP/Documents).
5. Conditions of appointment and the quorum requirement (upload relevant SOP/Documents).
6. Procedure for resignation, replacement or removal of members (upload relevant SOP/Documents).
7. Detailed Curriculum Vitae (CV) and documents/training certificates to ensure that member of the Ethics Committee are conversant with the provisions of the New Drugs and Clinical Trials Rules, 2019, Good Clinical Practices (GCP) Guidelines and other regulatory requirements to safeguard the rights, safety and well-being of trial subjects. (Upload copy of recent CV & training certificate showing that all members are conversant with the provisions of GCP and the New Drugs and Clinical Trials Rules, 2019).

7.1. **NAME** (Chair Person)

7.1.1. Curriculum Vitae (CV)

7.1.2. Training Certificate/ Records (GCP, New Drugs and Clinical Trials Rules, 2019)

7.2. **NAME** (Member Secretary)

7.2.1. Curriculum Vitae (CV)

7.2.2. Training Certificate/ Records (GCP, New Drugs and Clinical Trials Rules, 2019)

7.3. **NAME** (Medical Scientist)

7.3.1. Curriculum Vitae (CV)

7.3.2. Training Certificate/ Records (GCP, New Drugs and Clinical Trials Rules, 2019)

7.4. **NAME** (Clinician)

7.4.1. Curriculum Vitae (CV)

7.4.2. Training Certificate/ Records (GCP, New Drugs and Clinical Trials Rules, 2019)

7.5. **NAME** (Social Scientist)

7.5.1. Curriculum Vitae (CV)

7.5.2. Training Certificate/ Records (GCP, New Drugs and Clinical Trials Rules, 2019)

7.6. **NAME** (Lay person)

7.6.1. Curriculum Vitae (CV)

7.6.2. Training Certificate/ Records (GCP, New Drugs and Clinical Trials Rules, 2019)

7.7. **NAME** (Legal Expert)

7.7.1. Curriculum Vitae (CV)

7.7.2. Training Certificate/ Records (GCP, New Drugs and Clinical Trials Rules, 2019)

7.8. **NAME** (Woman Member)

7.8.1. Curriculum Vitae (CV)

7.8.2. Training Certificate/ Records (GCP, New Drugs and Clinical Trials Rules, 2019)

8. The Standard Operating Procedures to be followed by the committee in general (upload copy of policy/SOP).

9. Standard Operating Procedures to be followed by the committee for vulnerable population (upload relevant SOP).
10. Policy regarding training for new and existing committee members along with Standard Operating Procedures (upload relevant SOP).
11. If the committee has been audited or inspected before, give details (upload relevant Document, if No, upload justification).
12. Undertaking by the committee as per the format (upload the undertaking duly filled in). [https://cdsco.gov.in/opencms/export/sites/CDSCO WEB/Pdf-documents/Ethics-Committee/Checklist-Document/New-undertaking.pdf](https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/Ethics-Committee/Checklist-Document/New-undertaking.pdf)
13. Whether Ethics Committee has fifty percent of its members who are not affiliated with the institute or organization in which such committee is constituted. Yes/No