Ethics Committee Re-Registration Check List

File Number : EC/RENEW/INST/20XX/XXXX
CDSCO File Number : EC/XX/000XXX

1. Authority under which the Ethics Committee has been constituted (upload authority letter from authorised person of hospital/Institute).

2. If the committee has been audited or inspected before by CDSCO, give details (If no, mention the facts clearly).

3. whether the Ethics Committee, while approving and according Clinical Trials, BA-BE study protocols and subsequent monitoring of Clinical Trials, examine and ensures.

3.1. The appropriateness of investigator including his/her qualification and experience for conduct of Clinical Trial/BA-BE Study.

3.2. The appropriateness of Clinical Trial site for conduct of clinical trial/BA-BE study including the facilities available.

3.3. That the effective compensation mechanism exists for payment of compensation in case of Clinical Trial/BA-BE Study related injury or death of the study subject.

3.4. That the due analysis/ causality assessment of Serious Adverse Events (SAE) reported in Clinical Trial, BA-BE study are examined and recommended for payment of compensation and medical management is made as per the Rules.

3.5. That the informed consent is designed and administered properly as per rules.

3.6. That the monitoring of Ethics Committee's own conduct, functioning is done and records are maintained to fulfil the objective and responsibilities of Ethics Committee and also to ensure timely disposal of cases.

4. Detailed report of functioning of the Ethics Committee.

4.1. Titles of Clinical Trial/BA-BE Study Protocols reviewed under the New Drugs and Clinical Trials Rules, 2019 along with protocol number, brief summary, date of approval, name of Sponsor, name of Trial site/BA-BE Centre, whether part of global trial, NCE/non NCE trial.

4.2. Details of SAE reviewed as per the Rules {along with protocol no, protocol title, SAE (death/other than death), result of review (related/non-related), further action with respect to providing compensation/medical management etc.}.

4.3 List of trial sites/BA-BE Centres and investigators approved for conduct of trials.

5. Information regarding any changes in composition/ members of the Ethics Committee, if any.

6. Information regarding any change in location/address of the Ethics Committee. If yes, provide the details in this regard including date of change in address.

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 to ensure 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. Method used by Ethics Committee for monitoring the Clinical Trials/BA-BE Studies. (Upload SOP/policies regarding clinical trial/BA-BE study site visit and Good Clinical Practices guidelines compliance monitoring by the Ethics Committee for the approved/on-going clinical trials).

9. 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

10. 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).

11. WHETHER ANY CHANGES DONE IN THE DOCUMENTS FURNISHED AT THE TIME OF GRANT OF INITIAL REGISTRATION: Yes/No (if no, please submit a certificate to that effect indicating that there is no change in the documents).

12. Whether the 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.

13. The standard operating procedures to be followed by the committee in general (upload copy of policy/SOP).

14. Standard Operating Procedures to be followed by the committee for vulnerable population (upload relevant SOP).

15. Policy regarding training for new and existing committee members along with Standard Operating Procedures (upload relevant SOP).

16. Memberships requirements of the Ethics Committee (upload relevant SOP/Documents).

17. The terms of reference of the committee (upload relevant SOP/Documents).

18. Conditions of appointment and the quorum requirement (upload relevant SOP/Documents).

19. Procedure for resignation, replacement or removal of members (upload relevant SOP/Documents).