

CHECKLIST FOR RE-REGISTRATION OF CLINICAL RESEARCH ORGANISATION (Form CT-07B Check List)

File number: CRO/RENEWAL/CT07B/YEAR/SERIAL NO.

CDSCO File number: CT07B/CT/YEAR/UNIQUE NO.

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1. Details of the authorized person and authorization letter of the person in-charge as per Ninth Schedule of New Drugs and Clinical Trials Rules, 2019.
 2. Details of the constitution of the CRO (Ltd/Pvt Ltd/proprietorship etc.) along with Name & Address of the Director, Memorandum of association, Article of Association, list of Directors to be provided and
 3. Copy of previous permission issued by CLA.
 4. Application in Form CT-07B generated on portal with digital signature which is duly signed by the competent person as per Ninth Schedule of New Drugs and Clinical Trials Rules, 2019.
 5. Bharat Khosh receipt for the fees Rs. 5, 00,000 /-.
 6. Details of facilities, resources, personnel, training etc.
 - 6.1 Details of CRO facilities, resources and staff for handling any oversight of clinical trials and bioavailability or bioequivalence studies.
 - 6.2 Educational qualification, training records of CRO staff.
 7. CRO Site Master File.
 - 7.1 Organogram of the organization including brief Curriculum Vitae of key personnel.
 - 7.2 SOP for implementing of quality assurance and quality control as per standard operating procedures designed for the purpose and such standard operating procedures shall be well documented.
 - 7.3 SOP for maintaining complete data, documentations and other related records accurately including checking and ensuring that the essential documents required for the conduct of the trial are maintained properly by the investigators.
 - 7.4 SOP for ensuring the investigators receive all documents and trial or study related supplies needed to conduct the clinical trial or bioavailability or bioequivalence study properly.
 - 7.5 SOP for transferring and assuming study related duties by CRO.
 - 7.6 SOP for maintenance of records (written documents, electronic, magnetic or optical records, scans, etc.), such as protocols, approvals from the Central Licensing Authority and Ethics committee, investigators particulars, blank consent forms, monitor reports, audit certificates, relevant correspondence, reference pages, completed and the final reports.
 - 7.7 List of Standard Operating Procedures with salient highlights about specific areas to be scrutinized.
 - 7.8 Details of accreditation or approval of other regulatory agencies, if any, (self-attested copy of certificate).
 - 7.9 A brief profile of the specific activities or services undertaken by the organization including facilities, resources and infrastructure.
 8. Detailed report of functioning of the CRO.

8.1. 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.

8.2. 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.}.

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

9. Copy of agreement with third party service providers for site management, translation, biostatistics, data management, and laboratory services etc.

10. Undertakings to be submitted for the following:

10.1 Undertaking for all documentation and communication shall be dated, filed and preserved safely for a period of five years after completion of such study or for at least two years after the expiration date of the batch of the new drug or investigational new drug studied, whichever is later.

10.2 Undertaking for strict confidentiality shall be maintained during access and retrieval procedures.

10.3 Undertaking for constitution or ownership of the Clinical Research Organization, the organization shall intimate about the change in writing to the Central Licensing Authority within thirty days of such change.

10.4 Undertaking to comply with the conditions imposed on the registration certificate along with the adherence to other guidelines like Good Clinical Practices guidelines and provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940), and the New Drugs and Clinical Trials Rules, 2019.

10.5 Undertaking to comply with such further requirements, if any, as may be specified by the Government of India, under the Act and the rules made there under.

10.6 Undertaking to allow the Central Licensing Authority or any person authorized by him in that behalf to enter and inspect the premises and to examine the process or procedure and documents in respect of any clinical trial conducted by us.

11. Detail of Accreditation, if any.