Notice to applicant

Central Administration of Biological and Innovative products and clinical studies
General Administration of clinical trials

List of documents submitted for EDA Approval Renewal of clinical trial authorization

2024

Code: EDREX.NP.Bioinn.001
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Effective date: 14 October 2024

1. **A renewal request letter** addressed to EDA signed and dated by the applicant (sponsor or CRO).
2. **Renewal of IRB(s)** of the site(s) of the clinical trial.
3. **Renewal of administrative approvals** of the site(s) of the clinical trial (if found).
4. **Valid / updated:**

   • Insurance certificate, which shall cover the entire period of the medical research and the follow-up period provided however that it shall be valid for one year after the completion of the medical research.

   • GLP accreditation of designated laboratory(ies) used for analysis,

   • The registration of the IRB, the license of the CRC, and the license of the CRO

   • Any other expired documents that were previously submitted to EDA.

5. **Investigational medicinal product (IMP) Identification Form**.
6. **Proof of payments** of the determined fees.

These request for renewal and required documents should be submitted at least one month before expiry of EDA Approval.