Notice to applicant

Central Administration of Biological and Innovative products and clinical studies

General Administration of clinical trials

List of required documents from the investigator, sponsor&/or CRO to be submitted in case of Amendment

2023

Code: EDREX.NP.Bioinn.004
Version No2.0
Issue Date: 5/1/2023
Effective date: 5. Jan. 2023

1. Cover letter to EDA requesting approval of Amendment(s) including list of all modified documents (Original hard copy).
2. IRB(s) Approval of sites at which the CT conducted (Certified original hard copy).
3. Table of changes for each modified document mentioning changes compared to original ones (previously approved by EDA) with rationale for each change).
4. Changed/ modified documents (e.g., Protocol, ICF …etc.).
5. Protocol signature page (in case of new version of protocol amendment) (Original hard copy).
6. Updated IMP accountability form (in case change number of doses or subjects…etc).
7. Quality data of IMPD (if any changes submitted).
8. Fees proof of payment.

The CT package should be submitted via email:

- For IMPs of biological origin via email ctpro.bio@edaegypt.gov.eg and cc for (bio.ct@edaegypt.gov.eg)
- For IMPs of chemical origin via email ctpro.pharma@edaegypt.gov.eg and cc for (bio.ct@edaegypt.gov.eg)
- For other types of IMPs and Medical Device via email (bio.ct@edaegypt.gov.eg)