Decree of the President of the Egyptian Drug Authority No. (111) of 2022 Concerning Approving the Egyptian Guideline for Regulatory Procedures of Good oversight on Clinical Research Practices

President of Egyptian Drug Authority,

Having considered

- Law No. (127) of 1955 on Pharmacy Profession Practice and its amendments;
- Law on Establishing Egyptian Drug Authority Promulgated by Law No. (151) of 2019 and its Executive Regulation;
- Law on Regulating Clinical Medical Researches Promulgated by Law No. (214) of 2020;
- Ministerial Decree No. (436) of 2006 concerning the Egyptian Guidelines for assessing the clinical trials of biological products, sera and vaccines;
- Ministerial Decree No. (399) of 2010 concerning rules, criteria and procedures of assessing clinical studies of biological products and vaccines by the National Authority for Research and Control of Biological Products;
- Ministerial Decree No. (734) of 2016 concerning the Egyptian Guidelines of good clinical practices of pharmaceutical products;
- Ministerial Decree No. (132) of 2017 on rules, criteria and procedures concerning assessment of good clinical studies of pharmaceutical products;
- Board of Chairman Minutes of meeting held on 20/07/2020;
- Material presented by chairman of the Central Administration of Biological and Innovative Products and Clinical Trials;
- Having considered the interest of work;

Has Decided

(Article One)

Egyptian Drug Authority shall be committed to the regulatory standards of Good Clinical Practice according to rules of World Health Organization, the International Council for Harmonization and their updates as a scientific reference.

(Article Two)

This decree applies to supervisory procedures of the Egyptian Drug Authority on the clinical trials subjected to the Law Regulating Clinical Medical Researches Promulgated by Law No. (214) of 2020.

(Article Three)

The Investigational medicinal product used in clinical medical research under study shall be manufactured in accordance with Good Manufacturing Practices which are consistent with the rules of World Health Organization and the rules applied in the Egyptian Drug Authority, whether the product was locally manufactured or imported provided to comply with the rules and procedures of importing applied by the Egyptian Drug Authority.

(Article Four)

Good Storage and Distribution Practice "GSDP" and safe and proper waste disposal management specifically the Investigational medicinal products and devices used in clinical medical research under study, in accordance with the applied rules in the Egyptian Drug Authority. An Egyptian Drug Authority inspector shall be present during the destruction of the residual samples of the product under study in the Arab Republic of Egypt.

(Article Five)

The Egyptian Drug Authority is responsible for inspection of the research institutions and relevant entities which the clinical medical research being conducted for verifying the compliance with the good clinical practice. The Egyptian Drug Authority has the right, for achieving that, to check, examine and revise all research-related documents; records and installations and collect the necessary evidences to guarantee applying law provisions and regulated rules.

(Article Six)

In cases of public health emergencies' internationally or domestically or in cases of epidemics spread, the Egyptian Drug Authority has the right to take exceptional procedures and measures other than that the rules of assessing the clinical studies which are in the jurisdiction of the authority to guarantee the quick availability of relevant products and medical devices for the public benefits.

(Article Seven)

The Egyptian Drug Authority has the right to rely on rules, reports and data of stringent regulatory authorities in accordance with that determined by the Technical Committee for Drug Control pursuant to the international standards, in order to adopt a decision concerning assessing and approving a clinical medical research submitted for carrying it out within the Arab Republic of Egypt. The relying on decision of aforementioned bodies will neither diminish the Egyptian Drug Authority's independency nor its responsibility for the issued decision by it.

(Article Eight)

The chairman of the Central Administration of Biological and Innovative Products and Clinical Trials shall issue a guideline for good regulatory oversight of clinical trials within five days of the date of approving this decree.

(Article Nine)

The principle investigator, co – principle investigator, the researcher, the research team, the research institutions and the entities conducting clinical trials shall comply to all technical requirements and procedures mentioned in the aforementioned regulatory guideline. They can redress the balance of their situations within three months from the date of the issuance of this decree and they shall notify the competent administration in the Egyptian Drug Authority.

(Article Ten)

This DECREE shall be published in Al-Waqa'i' Al-Misriyya 'Egyptian Chronicles', shall enter in force from the day of its publication therein and any other decrees that may contradict this decree shall be null and void.

President

Egyptian Drug Authority

Prof /Tamer Mohamed Essam

Written on 21/2/2022