Decree of the President of the Egyptian Drug Authority No. (136) of 2022

President of Egyptian Drug Authority,

Having **considered**

- Law No. (127) of 1955 on Pharmacy Profession Practice and its amending Laws;

- Law on Establishing the 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 Code on Assessing 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;

- Ministerial Decree No. (614) of 2016, concerning the role of the Central Administration for Research and Health Development on conduct a formal revision (on-site inspection) on Facilities, Installments, Documents, Records and Quality Assurance Procedures Related to Clinical Researches and Stages & Procedures of inspection conducted by the inspection team of the Central Administration for Research and Health Development;

- Decree of the Board of Directors' Chairman of the National Authority for Research and Control of Biological Products No. (45) of 2010 on Forming Inspection Team for the Quality of Clinical Studies;

- Decree of the President of the Egyptian Drug Authority No. (111) of 2022, concerning Approving the Egyptian Code of Regulatory Procedures of Practices of Good Control on Clinical Researches;

- Minutes of the Authority's Board of Directors meeting held in its session 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)

Inspection teams shall be formed, from the following names, for inspecting the research institutions and relevant entities which conduct the clinical medical research, in order to verify of the Good Clinical Practice (GCP):

1	Pharmacist/ Rania Ibrahim Ahmed Shousha	Manager of Administration of Protocols and Studies follow-up	Member
2	Pharmacist/ Aya Mohamed Mahmoud Hamouda El-Abd	Manager of Administration of Scientific Committees and Technical Support	Member
3	Pharmacist/ Omnia Ayman Abd El-Khalek	Manager of Biological protocols Unit	Member

4	Pharmacist/ Ola Abd El-Ghany Abd El-Aziz	Manager of Administration of Clinical Trials Evaluation	Member
5	Pharmacist/ Dalia Kamal Abdulwahab Mohamed	Manager of Pharmaceutical Protocols Unit	Member
6	Pharmacist/ Salma Salah Fekry Mahmoud	Manager of Medical Devices Unit	Member
7	Pharmacist/ Nesma Gamal Mahmoud Mohamed	Manager of Medicinal Herbs Unit	Member
8	Pharmacist/ Mona Essam Hanafi El-Meligy	Manager of Innovative protocols Unit	Member

The inspection procedures regulated by this decree shall be conducted by at least two members of the team. They are entitled to use the required experts by a decision of the Chairman of Central Administration of Biological and Innovative Products and Clinical Trials.

(Article Two)

The aforementioned inspection team shall undertake the inspections of the clinical trials and studies in order to verify the Good Clinical Practice (GCP), for that purpose the team may undertake the following:

- Preparing the inspection plan on the research institutions that conduct the medical clinical research and the relevant entities.

- Reviewing the study protocol and required documents before inspection.

- Reviewing and examining the documents, Facilities, records, other related to clinical study sources and collecting the required evidences.

- Conducting the routine and triggered inspection on the research institutions that conduct the medical clinical research and the relevant entities.

- Presenting the results of the routine and triggered inspections to the Scientific Committee for Assessment and evaluation of Clinical Trials in the Authority for taking the required procedures whenever necessary.

- Providing a scientific opinion on the issues transmitted to it which is within the preview and the scope of its work.

(Article Three)

This decree shall come into effect from the date of its issuance, and all competent departments shall implement it in accordance with their respective jurisdictions. Any other provisions that may contradict this DECREE shall be null and void.

President

Egyptian Drug Authority

Prof /Tamer Mohamed Essam

Written on 2/3/2022