Decree of the Chairman of the Egyptian Drug Authority No. (158) of 2026

The Chairman of the Egyptian Drug Authority,

After Perusing:

- The Pharmacy Practice Law promulgated by Law No. (127) of 1955;

- The Egyptian Drug Authority Law promulgated by Law No. (151) of 2019;

- The Clinical Medical Research Regulation Law promulgated by Law No. (214) of 2020;

- Presidential Decree No. (28) of 2026 regarding the formation of the Board of Directors of the Egyptian Drug Authority;

- The Chairman of the Egyptian Drug Authority Decision No. (456) of 2024;

- And upon the submission of the Head of the Central Administration for Biological and Innovative Products and Clinical Studies,

- and in the interest of work;

It is hereby decided

(Article One)

The Inspection teams shall be composed of the individuals named below, for inspecting research institutions and relevant entities which conduct the clinical medical research for the purpose of verifying compliance with Good Clinical Practice (GCP) standards:

1.	**Ph. Rania Ibrahim Hassan Ibrahim**	**General Manager of General Administration of Clinical Trials**	**Member**
2.	**Ph. Ola Abd El-Ghany Abd El-Aziz**	Manager of Administration of Clinical Trials Evaluation	Member
3.	**Ph. Aya Mohamed Mahmoud Hamouda El-Abd**	Manager of Administration of Scientific Committees and Technical Support	Member
4.	**Ph. Rania Ibrahim Ahmed Shousha**	Manager of Administration of Protocols and Clinical Studies follow-up	Member
5.	**Ph. Omnia Ayman Abd El-Khalek**	Manager of Biological protocols Unit	Member
6.	**Dalia Kamal Abdulwahab Mohamed**	Manager of Pharmaceutical Protocols Unit	Member
7.	**Hebatallah Mohamed Ahmed abdel latef**	Manager of Medicinal Herbs Unit	Member
8.	**Norhan Gamal Abdel Naser Hussein**	Manager of Medical Devices Unit	Member
9.	**Ph. Michael Kamal Ibrahim**	Manager of Pre-Clinical Studies Evaluation Unit	Member
10.	**Ph. Hayat Mohamed Mahmoud Salem**	Manager of Clinical Studies Evaluation Unit	Member
11.	**Ph. Nehal Hazem Farid**	Manager of Technical Support Unit	Member
12.	**Ph. Nouran Atef Fouad**	Member of Clinical Trials Evaluation Administration	Member

13.	Ph. Khadija Ahmed Riyad	Member of Clinical Trials Evaluation Administration	Member
14.	Ph. Mostafa Ahmed Faysal	Member of Clinical Trials Evaluation Administration	Member
15.	Ph. Kholoud Mamdouh Abdel Fattah	Member of Clinical Trials Evaluation Administration	Member
16.	Ph. Asmaa Ramadan Hussein	Member of Clinical Trials Evaluation Administration	Member
17.	Ph. Khaled Osama El-Amir	Member of Protocols and Clinical studies follow-up Administration	Member
18.	Ph. Salma Hassan Mohamed	Member of Protocols and Clinical studies follow-up Administration	Member
19.	Ph. Ahmed Ragaey Huseein	Member of Protocols and Clinical studies follow-up Administration	Member
20.	Ph. Sarah Ahmed Mohamed Attia	Member of Protocols and Clinical studies follow-up Administration	Member
21.	Ph. Sohaila Gamal Gaber	Member of Protocols and Clinical studies follow-up Administration	Member
22.	Ph. Mennatuallah Wael Mohamed Adel	Member of Protocols and Clinical studies follow-up Administration	Member
23.	Ph. Amany El-Shahawy Abdel Maged	Member of Scientific Committees and Technical Support Administration	Member
24.	Ph. Hebatullah Ibrahim Abdel Aziz	Member of Scientific Committees and Technical Support Administration	Member

The execution of the assigned inspection duties pursuant to this decision shall be carried out by no fewer than two members from among those referred to in paragraph (1) of this Article. When necessary, the team may seek the assistance of external experts who are not part of the team, subject to the approval of the Head of the Central Administration for Biological Products, Innovative Products, and Clinical Studies.

(Article Two)

The inspection team referred to in Article (One) of this Decision shall undertake inspection activities at research entities conducting clinical medical research and related entities for the purpose of verifying compliance with Good Clinical Practice (GCP) standards. For this purpose, the team shall be authorized to undertake the following:

1. Prepare inspection plans for research entities conducting clinical medical research and related entities.

2. Conduct inspections of research entities conducting clinical medical research and related entities.

3. Examine and review documents, equipment, installations, and other sources related to clinical medical research.

4. Ensuring the research protocol implementation and verifying Good Clinical Practice.

5. Ensuring the implementation of domestically and internationally recognized Standards of Good Clinical Practice.

6. Document any observations or violations, prepare inspection reports, and notify the Supreme Council and other concerned parties.

7. Following up and evaluating the periodic reports concerning the clinical medical research under study. Submit the results of planned and triggered inspection reports to the EDA Advisory Scientific Committee of Evaluation of the Results of Clinical and Pre-Clinical Medical Researches of the Biological and Pharmaceutical Products to take actions that may be necessary whenever a scientific opinion is required regarding matters referred to it and fall within its area of competence.

(Article Three)

This Decision shall come into effect from the date of its issuance. All competent departments shall implement it, in accordance with their respective jurisdiction, and any other provisions that may contradict this Decision shall be null and void.

Chairman of the Egyptian Drug Authority

Dr. Ali El Ghamrawy

Issued on: 1/4/2026