Prime Minister's Decree No. 927 of 2022
On Promulgating the Executive Regulation of Law on Regulating Clinical Medical Research
Promulgated by Law No. 214 of 2020

Prime Minister

Having perused the constitution;

- The Civil Law;

- Law No. (376) of 1954 on Professions Practice of the Natural Chemistry, Bacteriology and Pathology, Regulating the Medical Diagnostic Labs, Scientific Research Labs and Biological Products Labs;

- Law No. (415) of 1954 on Medicine Profession Practice;

- Law No. (127) of 1955 on Pharmacy Profession Practice;

- Law on Regulating the Universities Promulgated by Law No. (49) of 1972;

- Law No. (69) of 1973 on Regulating the Scientific Researchers in the Scientific Institutions;

- Law No. (118) of 1975 on Importing and Exporting;

- Law No. (51) of 1981 on Regulating the Medical Facilities;

- The Child Act promulgated by Law No. (12) of 1996;

- Law on Protection the Intellectual Property Rights Promulgated by law no. (82) of 2002;

- Law on Protection of Competition and Prevention of Monopolistic Practices Promulgated by Law No. (3) of 2005;

- Law No. (5) of 2010 on Regulating Human Organ Transplant;

- Law on Facilitating the Procedures of Granting Licenses for Industrial Establishments Promulgated by Law No. (15) of 2017;

- Law on the Disabled Rights Promulgated by Law No. (10) of 2018;

- Law on Regulating the Work in University Hospitals Promulgated by Law No. (19) of 2018;

- Law on Incentives of Science, Technology and Innovation promulgated by Law No. (23) of 2018;

- Law on Establishing Egyptian Authority for Unified Procurement, Medical Supply and Management of Medical Technology & the Egyptian Drug Authority Promulgated by Law No. (151) of 2019;

- Law on Protection the Personal Data Promulgated by Law No. (151) of 2020;

- Law on Regulating Clinical Medical Research Promulgated by Law No. (214) of 2022;

- Law on Regulating Blood Operations and Plasma Assembly to Manufacture and Export its Derivatives Promulgated by Law No. (8) of 2021;

- Having considered the legal opinion of the Council of State;

- Having considered the Cabinet approval

Has Decided

(Article One)

The provisions of the executive regulation attached to this decree shall come into effect regarding Law on Regulating Clinical Medical Research Promulgated by Law No. (214) of 2020.

(Article Two)

The respondents of the attached regulation provisions shall redress the balance of their situations within one year from the date on which it comes into force.

(Article Three)

This decree shall be published in 'Egyptian Chronicles' and shall come into effect from the day following its publication therein.

Prime Minister

(Dr. /Mostafa Kamal Madbouly)

Issued at the Cabinet on Sha'ban 9th, 1443

Corresponding to March 12th, 2022

A copy sent to Mr. Chairman of the Egyptian Drug Authority

President of

Cabinet Advisors Body

(Councilor/ Sherif El Shazly)

The Executive Regulation of the Law on Regulating Clinical Medical Researches

(Chapter One)

(Definitions and General Provisions)

Article (1)

The definitions contained in the Law on Regulating Clinical Medical Researches shall have the same meanings in the implementation of provisions of this regulation. For the purposes of its provisions, **the following words and phrases shall have the meanings respectively indicated following each term**:

The Law: The Law on Regulating Clinical Medical Researches promulgated by Law No. 214 of 2020.

The Quality File: The file which includes information concerning methods of formulation, manufacturing and developing medical intervention under study in accordance with Good Manufacturing Practice, alongside the information concerning raw material used, quality control tests, stability and potency of batches used in the clinical medical research.

The International Regulatory Bodies: The health authorities outside the Arab Republic of Egypt which are responsible for approving the medical interventions, such as: European Medicines Agency (EMA), Food and Drug Administration (FDA) of the United States, Therapeutic Goods Administration (TGA) of Australia, health institution of Canada (Health Canada) and Medicines and Healthcare products Regulatory Agency (MHRA) of the United Kingdom.

Article (2)

Clinical researches shall adhere to domestic and international ethical standards and principals as well as recognized Good Clinical Practice shall be adhered, **particularly the following:**

1) Informed consent of the research human subject or his legal representative shall be obtained.

2) The research plan (protocol) shall conform to the scientific and ethical standards that are domestically and internationally recognized.

3) All health procedures shall be implemented in accordance with applicable technical principles so that the research shall not cause any probable health problem or suffering.

4) The adverse events caused by the research shall be treated.

5) The research human subject's right to non-completion of the research at any time shall not be prejudiced.

6) The research human subject shall not be granted any cash or in-kind rewards or benefits which may force him to be subjected to the research, with the exception of items excluded by the article (14) of the Law.

Article (3)

It is prohibited to limit the conduction of clinical research on certain group of people or vulnerable groups that deserve an additional protection, unless the following conditions are fulfilled:

1) The research shall be necessary.

2) The research shall be related to diseases concerning these groups.

3) Scientific and ethical justifications for engaging these groups shall be present.

4) An informed consent shall be obtained from each one of the research subjects; if the clinical research is conducted on one of the vulnerable groups that deserve an additional protection, an

informed consent shall be obtained from their parents; in the event of the death of one or both parents, an informed consent shall be obtained from the person who has the right of tutelage or guardianship or from the legal representative.

5) The research protocol shall include obvious and accepted procedures to reduce potential risk as much as possible.

Assessing the Results of Pre-Clinical Medical Research

Article (4)

Assessing the results of pre-clinical medical research shall be implemented in accordance with the following procedures:

- The principle investigator or research sponsor, if any, shall submit to Egyptian Drug Authority (EDA) a request including the file of pre-clinical medical researches and their results to be scientifically assessed.

- The authority shall fulfill what it deems necessary for assessment measures by virtue of a notification submitted to the applicant, provided that the said notification shall contain the grace period for submitting the required documents, which period shall be fifteen days at least. Unless the period of submitting the documents is extended by the authority on the basis of the applicant's reasons that the authority deems serious, the requirements of the authority shall be implemented within the aforementioned grace period, otherwise the request shall be considered null and void.

The authority shall complete the assessment within sixty days of the date of fulfilling the required documents. In the case of the authority refusal, the grounds of the authority decision shall be reasonable. In all cases, the authority shall notify in writing the applicant by its decision within thirty days of the date of its issuance.

Research Plan (Protocol)

Article (5)

Before initiating any clinical research, there shall be a research Plan (protocol) to be reviewed and approved in accordance with the nature of research as follow:

1) The protocol shall be reviewed and definitively approved by the competent institutional review board with no need of ratification by any other authority in the case of non-interventional studies and interventional studies which do not include the use of novel, biological pharmaceutical compounds, new indications, new forms, devices or supplements that have never been used before in the human body, including the protocols of master's, doctoral and PhD theses, and free researches.

2) The protocol shall be reviewed and approved by the competent institutional review board, shall be approved by the Egyptian Drug Authority and shall be approved and ratified by the Supreme Council in the case of interventional studies which include the use of novel, biological pharmaceutical compounds, new indications, forms, medical devices or supplements that have never been used before in the human body and that have not been accredited by international bodies.

In the case of researches with foreign bodies as well as joint international studies, the Supreme Council shall consult General Intelligence Service.

Reviewing and Assessing the Research Plan (Protocol)

Article (6)

Research Plan (protocols) shall be reviewed by the Institutional review board as follow:

– The principle investigator or research sponsor, if any, shall submit the research plan (protocol) to the Institutional review board for review and approval.

– The Institutional review board shall fulfill what it deems necessary for assessment measures by virtue of a notification submitted to the applicant, provided that the said notification shall contain the grace period for submitting the required documents, which period shall be fifteen days at least. Unless the period of submitting the documents is extended by the committee on the basis of the applicant's reasons that the committee deems serious, the requirements of the committee shall be implemented within the aforementioned grace period, otherwise the request shall be considered null and void.

The Institutional review board shall issue its decision regarding results of reviewing the research plan (protocol) within sixty days of the date of fulfilling the required documents. The expiry of this period without a response shall be considered as an approval. In the case of the committee refusal, the grounds of the committee decision shall be reasonable. In all cases, the committee shall notify the research Plan applicant and the Supreme Council of its decision in this regard.

Article (7)

Assessing research Plan (protocols) to conduct Clinical medical research at the different phases shall be as follow:

– The principle investigator or research sponsor, if any, shall submit a request to Egyptian Drug Authority to assess the research Plan (protocol) accompanied with the scientific file after being reviewed and approved by the institutional review board.

– Egyptian Drug Authority shall fulfill what it deems necessary for assessment measures by virtue of a notification submitted to the applicant, provided that the said notification shall contain the grace period for submitting the required documents, which period shall be fifteen days at least. Unless the period of submitting the documents is extended by the authority on the basis of the applicant's reasons that the authority deems serious, the requirements of the authority shall be implemented within the aforementioned grace period, otherwise the request shall be considered null and void.

The authority shall issue its decision regarding results of reviewing the research Plan (protocol) within sixty days of the date of fulfilling the required documents. The expiry of this period without a response shall be considered as an approval. In the case of the authority refusal, the grounds of the authority decision shall be reasonable. In all cases, the authority shall notify the research protocol applicant and the Supreme Council of its decision in this regard.

Article (8)

The principle investigator or the research sponsor, if any, shall submit the decision of Egyptian Drug Authority accompanied with the research protocol to the Supreme Council. The Supreme Council shall complete all the procedures from the date of fulfilling the documents and it shall notify and respond to competent bodies within sixty days of the date of notification. The expiry of this period without a response shall be considered as an approval.

Article (9)

No amendments may be made to the content of the previously approved research Plan (protocol) before obtaining the approvals of the competent bodies, as the case may be, in accordance with the procedures referred to in the aforementioned articles.

The competent bodies shall, as the case may be, issue their decisions concerning amendments related to the purpose of the clinical research, its means or its location within the periods specified in the earlier articles. For other modifications to the research Plan (protocol), the competent bodies shall, as the case may be, issue their decisions regarding their assessment results within fifteen days from the date of fulfilling the required documents. The expiry of the above-mentioned periods without a response shall be considered as an approval.

(Chapter Two)

(Competent Bodies)

The Supreme Council for Reviewing the Ethics of Clinical Medical Research

Article (10)

The Supreme Council shall undertake its mandates in the manner prescribed by the law. Specifically, the Supreme Council has right to accomplish the following:

1) Establishing a database for clinical researches which include research protocols with all their related documents, data, and information as well as amendments made thereto.

2) Setting the standards, controls, and regulations related to the ethics of clinical research in order to protect human subjects, their samples and their data and reviewing these regulations in accordance with the national interest and the international scientific developments.

3) Final review of research plan (protocols) submitted by competent institutional review board, which include the use of novel pharmaceutical or biological compounds, new indications, forms, medical devices or supplements that have never been used before in the human body and that have not been approved by international bodies; registering and ratifying the approvals issued by these committees; reviewing the amendments made to these research plan; issuing the final decision of approval or refusal for any of these research protocols and their amendments; and consulting General Intelligence Service in the case of researches with foreign bodies as well as joint international studies.

4) Periodic review and inspection of research bodies conducting clinical medical research and other entities related to these researches with a view to ensuring compliance with the domestic and international recognized standards Good Clinical Practice in accordance with the nature of risks to which a research human subject may be exposed.

5) Examining and adjudicating complaints submitted by individuals or concerned bodies to the council concerning the clinical medical researches

Article (11)

The Supreme Council shall be responsible for following up implementing the law provisions and shall take necessary procedures against violating any of its provisions; for the purpose of achieving that end, it has the right to accomplish the following:

1) Issuing a reasoned decision to suspend the clinical research for a period that does not exceed one year in the event of non-compliance with the terms of the research plan (protocol) or the amendments thereto.

2) Issuing a reasoned decision to refuse the renwal the clinical research or to terminate it early, if it has resulted in adverse events or serious adverse events or any damages that were not expected at the approval time of the research plan (protocol).

In the cases prescribed in the preceding two items, the Supreme Council shall have the right to issue a reasoned decision to ban the principle investigator or the research entity in which the clinical research is being conducted from performing future clinical researches for a period that does not exceed two years.

3) Informing competent investigation authorities in the case of any violation of law provisions immediately upon being aware that a violation has been committed.

The Institutional Review Board for Reviewing the Ethics of Clinical Research

Article (12)

An Institutional Review Board shall be formed within each research entity by a decision of the competent authority in that body. The committee shall consist of a chairman and at least four members, for a term of three years, which may be renewed once. At least two members shall be changed every three years. The committee has a rapporteur who shall be specified in the decision of its constitution.

The following shall be consider at constituting the Institutional Review Board:

1) At least one member shall be of non-medical professionals.

2) At least one member shall be from outside the body in which the research is conducted.

The Institutional Review Board shall hold its meetings periodically in accordance with the provisions of the decision of its constitution or when needed. Its resolutions shall be adopted by the absolute majority of its members. When votes are equal, the opinion favored by the chairman shall be adopted as a resolution.

The research entity shall submit a request to the Supreme Council to register that committee within a period of no more than one month of the date of its constitution.

The Institutional Review Board Competencies

Article (13)

The Institutional Review Board shall be concerned with the following:

1) Maintaining the rights, safety and health of the research human subject.

2) Reviewing the research plan (protocols) submitted thereto and ensuring that they fulfil all required papers, approvals and documents in accordance with each individual case in this regard.

3) Issuing a decision to approve conducting or renewing the clinical research and specifying the term of the decision so that it does not exceed one year and following up on the research until it is complete or otherwise terminated.

4) Monitoring the principle investigator or the research sponsor, if any, to ensure the proper implementation of the clinical research and the appropriate application of Good Clinical Practice standards.

The Institutional Review Board shall be committed to notify the Supreme Council of all submitted researches immediately upon fulfilling their documents, provided that the notification shall include the clinical research (protocol), all related documents and data as well as all procedures taken by the committee in this regard.

Egyptian Drug Authority

Article (14)

Egyptian Drug Authority shall assess the results of pre-clinical and clinical medical researches and shall conduct the scientific review of the pharmaceutical and biological products before initiating the conducting of the clinical medical researches.

Egyptian Drug Authority shall assess the research protocol along with their amendments, review and approve the clinical medical research results in their different phases within the scope of its legally prescribed jurisdiction.

Article (15)

Egyptian Drug Authority shall be responsible for inspecting the research bodies in which the clinical medical research is conducted as well as other related entities with a view to verifying Good Clinical Practice. **For the purpose of achieving that end, it has the right to accomplish the following:**

1) Preparing an inspection plan on the research bodies in which the research is conducted as well as other related entities.

2) Examining and reviewing the documents, installations, records and other sources related to the clinical researches.

3) Ensuring the research protocol implementation and verifying Good Clinical Practice.

4) Ensuring the application of the domestically and internationally recognized standards of Good Clinical Practice.

5) Monitoring any observations or violations, preparing a report of the inspection results and notifying the Supreme Council and other concerned parties.

6) Following up and assessing the periodic reports concerning the clinical medical research under study.

(Chapter Three)

Phases of Clinical Medical Researches and Cases of Using Placebo

Article (16)

It is permitted to move between each one of the four clinical medical research phases, after the Egyptian Drug Authority assesses and approves the results of each phase and permits the transition to the following phasea.

Article (17)

For medical interventions that originate outside the Arab Republic of Egypt, conducting any of phases III or IV of the clinical medical researches shall be permitted after verifying the fulfillment of the following conditions in each phase:

1) The clinical trial of these two phases shall be conducted in a reference country in the same time.

2) Each of these two phases shall be conducted after the Egyptian Drug Authority reviews and approves the results of the pre-clinical researches and after the Egyptian Drug Authority and the Supreme Council review and approve the results of the phase I and II of the clinical medical researches that are conducted in the country of origin.

As for medical interventions related to regional diseases that do not exist in the origin country of the medical intervention and rare diseases, the clinical research related thereto shall be permitted inside the Arab Republic of Egypt starting from phase II and in accordance with what the Supreme Council decides.

Article (18)

Before conducting the research, the research sponsor shall notify Egyptian Drug Authority and the Supreme Council in accordance with the form prepared for this purpose.

After research completion, the principle investigator or research sponsor, as the case may be, shall submit all research-related information, data, and reports to the Institutional Review Board, the Egyptian Drug Authority and the Supreme Council for scrutinizing and reviewing within sixty days of the date of the research completion.

Article (19)

The usage of placebo shall be permitted in the two following cases:

1) Comparison with the new intervention, due to the lack of a marketed product whose effectiveness is proven.

2) Comparison between the standard of care and the new intervention.

Whether the intervention is curative, prophylactic or diagnostic, the usage of the placebo product shall conform with the standards of Good Clinical Practice weather the purpose of intervention is medical, preventive or diagnostic.

The usage of the placebo product shall neither add more risk or harm to the research human subject nor deprive them from the standard of care.

(Chapter Four)

Rights of Research Human Subjects

Article (20)

A research human subject shall have the following rights:

1) The right to withdraw from clinical research whenever he wants without being obliged to express any reasons. The principle investigator shall, in writing, inform the research human subject of the medical harm that may result from his withdrawal.

2) The right of non-disclosure of his identity or any data related thereto except after fulfilling the conditions of the scientific justification approved by the competent institutional review board and ratified by the Supreme Council and after obtaining a written consent from the research human subject or his legal representative.

3) Obtaining a written copy of the informed consent in the mother tongue of the research human subject with an extensively detailed explanation of the research nature and purpose of the investigator who explicates the research benefit for the disease and the probable adverse events that the research human subject may suffer as well as an approximately plausible explanation of the probability of adverse events' occurrence on him.

Article (21)

The research human subject shall not be motivated to participate in any clinical research by granting him cash or in-kind rewards or benefits.

An exception shall be made for benefits granted to the research human subject in return for the burdens of participating in the clinical research, such as expenses for transportation to and from the research entity or absence from work hours due to participation in clinical research. All these items shall, in advance, be specified with complete transparency in the informed consent form submitted to and approved by the competent Institutional Review Board.

(Chapter Five)

The Conditions, Procedures and Commitments Required from the Principle Investigator

Article (22)

The Principle Investigator shall be required to fulfill the following:

1) The principal investigator shall meet all scientific and technical qualifications such as study, training and experience that enable him of undertaking the responsibility of managing the clinical research he conducts; he shall have comprehensive knowledge of the international and domestic guidelines of the scientific research ethics and Good clinical Practice; he shall also be knowledgeable about scientific research rules ethics and how to deal with patients.

2) The principle investigator shall be of good conduct and must have a good reputation.

3) The principle investigator shall never have been convicted of a criminal offence or sentenced to imprisonment for an offence prejudicial to honor or integrity, unless he has been officially rehabilitated.

4) The principal investigator's personal interest in conducting or completing the research shall never conflict with the interest or safety of any of the participating research human subject; he shall disclose in writing his affiliation to anybody which may benefit from the results of the medical research and reveal the research funding source before conducting it. This acknowledgement statement shall be an integral part of the research plan (protocol).

Article (23)

Before conducting the Clinical research, the principle investigator shall be obliged to take the following procedures:

1) Obtaining the required approvals to conduct the clinical research from the competent authorities as the case may be.

2) Obtaining the informed consent from the participating research subject or his legal representative, documenting this consent in the form prepared for that purpose which is signed and dated by the research subject and which is reviewed and approved by the Institutional Review Board.

3) Obtaining the approval of the research plan (protocol) of the clinical research.

4) Recording the research plan (protocol) in the relevant database.

5) Obtaining other required approvals specified by the Law.

6) Selecting the co-principle investigator and his research team in accordance with the scientific efficiency criteria and ensuring that all assistants in the study have sufficient knowledge about the protocol, the research intervention under study, and the duties and tasks entrusted to them to conduct the study.

7) Selecting the research human subjects with complete impartiality and determining the appropriate number for conducting the clinical research in accordance with the approved research plan (protocol).

Article (24)

When conducting the clinical research, the Principal Investigator shall be obliged to commit the following:

1) Conducting, attending and supervising the clinical research in the research site on a regular basis in accordance with the recognized rules in that field.

2) Complying with the relevant laws and regulations and applying the Good Clinical Practice as well as the agreed-upon domestic and international standards in this regard.

3) Managing the clinical research in accordance with the research plan (protocol) approved by the competent authorities as the case may be.

4) Refraining from making any amendments on the research plan (protocol) until after obtaining the approval of the competent authorities as the case may be.

5) Informing the research human subject of an amendments made to the research plan (protocol) that may affect his safety as well as informing him of any unexpected risks that may affect him or any other participating research human subject during conducting the clinical research.

6) Submitting a detailed report about the status of the study to the research sponsor at least once a year or when required.

7) Taking the required procedures aiming at protecting the research human subject's life, physical and psychological health and dignity, reducing the clinical research adverse events through measures including making amendments to the research protocol in the case of serious adverse events that threaten the safety of the research human subject. In such a case, the Principal Investigator shall, within twenty-four hours at most, notify the clinical research sponsor, the Institutional Review Board, the Egyptian Drug Authority and the Supreme Council, in their respective areas of jurisdiction of these effects and the corresponding procedures taken for protecting the research human subject.

8) Preserving the clinical research documents in the entity conducting the clinical research and with the research sponsor, if any, and taking the necessary measures to prevent the loss or destruction of these documents.

9) Publishing the clinical research result upon its completion in a specialized scientific journal, whether it is published in one of the scientific journals and periodicals issued or published by the research entity or the university or one of the specialized scientific journals.

10) Providing the necessary medical care for the participating research human subjects according to their individual cases after the clinical research is finished and whenever it becomes clear to him that some adverse events or serious adverse events are associated with the research; he shall also inform the participating subjects of their need for this care, highlighting that the purpose is to minimize the risks of these effects on them.

(Chapter Six)

Obligations of the Clinical Research Sponsor

Article (25)

The Clinical Research Sponsor shall adhere to the following:

1) Obtaining all approvals required from him in accordance with the clinical research nature and type.

2) Supervising and financing the clinical research from its initiation to its completion.

3) Developing mechanisms for monitoring the performance and its quality; ensuring yielding, documenting and announcing the clinical research results in a manner that conforms to the approved study (protocol) and Good clinical Practice.

4) Submitting periodic reports to the competent Institutional Review Board and the Supreme Council on the functioning and financing of the clinical research, as the case may be.

5) Writing down the agreements that he concludes with all clinical research parties, provided that he shall include them in the clinical research file.

6) Preserving all the main documents and data related to the clinical research. As for key docu-

ments and paper documents, he shall keep them for five years at least. In all cases, the research sponsor shall adhere to deposit these documents and data in the clinical research database in the Supreme Council inside the Arab Republic of Egypt, after he publishes its results.

7) Providing medical intervention for the participating research human subjects during and after the clinical research completion, in accordance with each individual case and in whatever form it may be, as well as transferring, preserving and storing everything related to clinical medical research in the appropriate safe ways.

8) Immediately notifying the research human subjects participating in the clinical research of any amendments thereto and of any results that could negatively affect the safety of the participating subjects as well as of the unexpected serious adverse events of the clinical research.

9) Concluding insurance contracts for the research human subjects participating in the clinical research with a certified insurance company in the Arab Republic of Egypt with a view to addressing the harm that anyone of them may undergo as a result of participating in the clinical research. The contract referred to in this article shall cover the duration clinical research with its follow-up period, provided that this contract shall be valid for one year after the research completion and the amount of this insurance shall be approved by the Supreme Council.

10) Providing compensation and treatment required for the participating research human subjects in the case of an injury related to the clinical research.

11) Completing the required treatment for the participating research human subjects whom their need for treatment is proven even after the clinical research is completed.

Article (26)

The clinical research sponsor may seek the assistance of any of the specialists in the field of clinical research or he may delegate a contract clinical research organization with performing one or more of his mandated clinical research obligations and tasks in accordance with the following conditions:

1) The specialist in the field of clinical research shall have sufficient knowledge, training and experience to perform his work.

2) The contract clinical research organization should be registered with the Supreme Council in accordance with the controls issued by a Supreme Council decision.

3) The research sponsor shall be obliged to monitor the specialist in the field of the clinical research or the contract clinical research organization, as the case may be, in order to guarantee quality assurance, ensure yielding, documenting and announcing the clinical research results, make sure that they conform to the domestic and international guidelines, monitor research control and quality and ensure the effectiveness of the tasks delegated to them.

(Chapter Seven)

Suspension and Early Termination of Clinical Researches

Article (27)

The principle investigator shall notify the medical research sponsor, the Institutional Review Board, the Egyptian Drug Authority and the Supreme Council –in accordance with their respective jurisdictions– of any serious adverse event that threaten the safety of the research human subject and the procedures taken for protecting the research human subject within at most twenty four hours of the date of their occurrence, provided that all information, data and reports related to the case shall be available within seven days of the date of their occurrence. With regard to the adverse events, they shall be included in a report to be submitted to the aforementioned authorities within seven days of the date of their occurrence.

Article (28)

If the research human subject is exposed to adverse events, serious adverse events or any harm that were not expected at the approval time of the research (protocol) or that have occurred as a result of a poor clinical practice, the principle investigator, the clinical research sponsor, the research entity, the competent Institutional Review Board, and the Egyptian Drug Authority –in accordance with their respective jurisdictions and in accordance with each individual case– shall take the required procedures to ensure the safety and protection of the research human subjects, provided that the Supreme Council shall be immediately notified of these developments in writing, so that it shall, in turn, issue the required decisions in this regard in accordance with Article (11) of this regulation.

The principle investigator and the clinical research sponsor shall be obliged to notify in writing the participating research human subject and other parties referred to in the previous paragraph of these procedures.

Article (29)

One or more Grievance Committees shall be formed by a decision of the Supreme Council President as follows:

- A representative of the Supreme Council to be selected by the Council president (Chairman)

- A representative of the Egyptian universities to selected by the competent Minister of Higher Education (Member).

- A representative of the Ministry of Health to be selected by the competent Minister of Health Affairs (Member).

- A representative of the Egyptian Drug Authority to be selected by Chairman of the Authority (Member).

- One of the deputies of the president of the Council of State who shall be delegated in accordance with the rules prescribed in the law regulating the Council of State (Member).

The committee shall be charged with considering grievances submitted by any of the parties referred to in the previous article related to the decisions issued by the Supreme Council regarding suspension and early termination of the clinical research in accordance with Article (11) of this regulation.

The deadline for grievance against a Supreme Council decision shall be within sixty days of the date of the decision notification or the certain knowledge thereof, provided that the committee shall issue its decision concerning the grievance within a date that shall not exceed thirty days of the date of fulfilling the required documents and data.

The committee shall have a secretary to be selected by the committee chairman, which secretary shall set its agenda and circulate it to the members sufficiently in advance of the committee meeting. He shall record the meeting minutes, fulfill its required signatures and inform the concerned parties of the committee decisions.

The committee shall meet at the invitation of its chairman whenever the need arises; it shall take its decisions by a majority of votes. In the case of equal votes, the chairman shall have the casting vote. The committee may seek the assistance of persons whom it deems appropriate and experienced in the field of medical research without having a counted vote.

The committee decision to address grievance shall be final and reasoned. The grievance applicant shall be notified of the committee's decision within a period of no later than fifteen days of the date of its issuance.

(Chapter Eight)

Provisions of the Use of Human Samples of Clinical Research

Article (30)

The use of human samples of clinical research shall be prohibited without obtaining an informed consent in advance from the research human subject or his legal representative without prejudice to the provisions of the relevant laws.

Any human samples obtained for the use in the clinical researches shall be prohibited to be traded in any way.

Such samples or surplus materials thereof may not be stored after the clinical research completion with a view to using them in future research for any purpose without prior approval of the Supreme Council and an independent, informed consent from the research human subject or his legal representative.

In all cases, human samples shall only be stored inside the Arab Republic of Egypt; such samples may be permitted to be moved and stored outside the Arab Republic of Egypt with the approval of the Supreme Council and in compliance with the considerations and requirements of the national security.

In the event of disposal of the remaining surplus human samples, the applicable international standards shall be followed in this procedure which shall be carried out in the presence of an inspector of the Egyptian Drug Authority, and a statement of this procedure shall be submitted to the institutional review board after the clinical research is completed.

The provision of this article shall apply if human samples for clinical research are allowed from abroad to enter the Arab Republic of Egypt.

(Chapter Nine)

Requirements of the research Entity

Article (31)

A research entity shall fulfill the following requirements:

1- It shall be well-equipped and fitted with all the means and devices that enable the clinical research to be conducted efficiently, in accordance with its nature.

2- It shall be fully prepared to respond to emergency situations, or as necessitated by the clinical research nature.

3- It shall deal with a licensed laboratory that is authorized by the Ministry of Health.

4- It shall be provided with the necessary means and equipment to preserve and store everything related to medical intervention in accordance with its nature.

5- It shall be equipped with the necessary devices and means to preserve data and records related to clinical research.

6- The members and assistants of the medical team shall be characterized by efficiency, experience, transparency and impartiality required for conducting clinical research, and they shall be fully aware of the standards of Good clinical Practice.

7- It shall adhere to the best clinical practices to maintain patient's safety.

In all cases, conducting clinical research shall be prohibited except in research entities registered with the Ministry of Health; moreover, clinical research shall be prohibited in private clinics.

Article (32)

A register shall be established in the Supreme Council and the Ministry of Health for recording research entities, which meet the requirements stipulated in the previous article.