Law No. 214 for Year 2020 Promulgating the law to regulate Clinical Medical Research

In the Name of the People
The President of the Arab Republic of Egypt,
The House of Representatives passed the following law and accordingly, it was hereby ratified and enacted by us.

Article One

The law herewith enclosed shall take effect and apply with regard to clinical medical research conducted on humans and their medical data at research entities inside Egypt.

Article Two

The prime minister shall issue the executive regulations for the accompanying law within three months from its date of enforcement.

Article Three

This law shall be published in the official gazette and shall enter into force from the next day following its publication.
The law shall be sealed with the coat of arms for the Arab Republic of Egypt and shall be enforceable as one of its laws.

Issued at the presidency of the Republic on 8 Jumada I 1442 AH,
(Corresponding to Dec. 23rd, 2020 AD)
Abdulfattah Al Sisi

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Chapter One
Definitions

Article (1)

In the application of this law; each of the following words and phrases shall have the meaning assigned thereto:

1. **Pre-clinical Research:** Research conducted at an early experimental stage prior to trials on humans, which aims to specify the degrees of safety and effectiveness of the medical intervention to be studied. Preclinical research is conducted through in vitro tests or using experimental animals in accordance with the prescribed international standards in pre-clinical researches.

2. **Clinical Research:** Studies or experiments conducted on human volunteers to evaluate the safety and efficiency of any therapeutic, medicinal, surgical, nutritional, preventive, or diagnostic interventions with the aim of arriving at scientific, preventive, diagnostic, or therapeutic discoveries for diseases, as well as, studies conducted for medical data mining for volunteers to survey the feedback of the effect of a medicine, behavior, or surgical intervention in accordance with internationally recognized research ethical standards.

3.**Good Clinical Practice:** A set of internationally and domestically reorganized principles and standards that apply to planning, management, execution, monitoring, auditing, recording, analysis and

reporting on medical research for the purpose of providing assurances that research declared data and results are precise and credible and ensure the safety of research subjects and their rights and the confidentiality of their information against any harm.

4. **Interventional Medical Research:** a study in which the research subject is incorporated to receive medical intervention for the purpose of evaluating the effect of such intervention on medical results in terms of effectiveness and safety.

5. **Non-interventional Medical Research**: a study in which the research subject records their remarks for the purpose of gathering information on an approved medical intervention or health history of the research subject.

6. **Research or Medical Intervention:** The core of the clinical medical study, which includes medical interventions such as medications, medical devices, vaccines, interferential procedures to the human body and other products that may be a scope for testing or already available. Research intervention may also include ways that do not interfere with the human body such as health surveys, education and questionnaires.

7. **The Research Plan (Research Protocol):** A document that includes a detailed explanation of the plan for conducting medical research and relevant information that were reviewed and approved in accordance with the procedures stipulated under this law.

8. **The Researcher:** A qualified physician, pharmacist, scientist, nurse or others who work in the field of medical research. The researcher works inside a research entity to carry out the works of the research plan in accordance with the directives and instructions of the principle investigator.

9. **The Principle Investigator:** A person qualified in the field of clinical medical research and responsible for the research plan and the execution

and funding thereof in case there was no sponsor available for the medical research.

10. **The Co-Principal Investigator:** A person with the same qualification of the principle investigator assigned by the latter to carry out some of his duties under his supervision. The co-principal investigator replaces the principle investigator in case of the latter's absence or inability to continue performing the research duties.

11. **The Research Group:** a group of qualified researchers working in the field of medical researches and take part in the research works based on their qualifications and expertise.

12. **The Research Subject:** A person subject of medical research who participates in the research whether that person is a patient or a healthy person and whether they are subject of medical intervention or part of the control group. In all cases; on the condition of obtaining the informed consent of the research subject before conducting the research pursuant to the provision of this law.

13. **The Control group:** A group of research subjects who do not receive the medical intervention researched; but rather receive what is called a **"Placebo"** or a standard treatment for the purpose of comparison and measurement of the effect of the new intervention.

14. **Placebo:** An inert product that has not therapeutic effect and completely resembles the product subject of research in form but does not contain the active substance.

15. **The Vulnerable Groups:** Research subjects most vulnerable to coercion or exploitation due to limitations on their will to give knowledgeable consent due to complete or partial incapacitation, poor cognitive power or health condition.

16. **The Legal Representative:** The representative of subjects of the vulnerable groups as described in Article No. 15 for giving knowledgeable consent to conduct the medical research.

17. **Human Samples:** include all biological materials from human origin; including organs, tissue, body fluids, teeth, hair, fingernails, etcetera, as well as, tissues regenerated from cells extracted from human bodies, and materials isolated from a cell such as nucleic acids, ribosomes, etcetera.

18. **The Research Entity:** The entity that conducts medical research, which is registered with the Supreme Council in accordance with the executive regulations of this law.

19. **The Research Sponsor:** A party that assumes responsibility for initiating, management, funding and supervision of medical research; whether this party is a natural person such as the principle investigator or a body corporate such as a company, institution, domestic, regional or international organization, provided however, it is legally represented in the Arab Republic of Egypt.

20. **Contract Research Organizations:** Body corporates that assume the form of an organization, office, or company, that are registered with the Supreme Council and licensed to conduct medical research. The research sponsor executes contracts with contract research organizations to perform any of the duties or tasks of the medical research assigned to the research sponsor. In this regard; contract research organizations are subject to periodic and regular supervision of the Supreme Council.

21. **Informed Consent:** A written statement based on a completely free and voluntary will and issued by a legally competent person to indicate express consent as substantiated by the signature and the fingerprint of that person to take part in the clinical medical research after having been informed and enlightened of all aspects of that research, and particularly, the potential effects or risks that may affect that person's decision to take

part in the research. An informed consent is issued by the legal representative of the person in cases stipulated under provisions of this law.

22. **Adverse Events:** Any minor and medically unwanted effects that are recently experienced by the research subject during the administration of the research intervention on the research subject.

23. **Serious Adverse Events:** Effects recently experienced by the research subject due to the use of the research intervention on the subject, that may result in serious harm or risk to the subject's life.

24. **The Institutional Review board "IRB":** A group of persons with medical and non-medical specializations tasked with the duty of reviewing Research Plans (Protocols) and applying the necessary ethical principles in this regard. The institutional review board shall have its headquarters at the research entity and must be registered with the Supreme Council.

25. **The Supreme Council for Review of the Ethics of Medical Clinical Research (The Supreme Council) :** The council comprising a group of persons with medical and non-medical specializations and who are entrusted with the duty of establishing and following-up on the general policies applicable to conducting medical researches. It is referred to hereinafter as "**The Supreme Council**".

Chapter Two
General Provisions

Article (2)

The provisions of this law aim to outline the necessary principles, standards and controls for conducting clinical medical research and protecting research subjects whether they are preventive, diagnostic,

therapeutic, non-therapeutic, interventional or non-interventional researches.

These researches depend upon the condition of conformity with the provisions of relevant laws, covenants and regulations and consistency with internationally recognized standards and ethical principles in the manner indicated in the executive regulations of this law.

Article (3):
It is prohibited to conduct medical research on a certain group of people or on vulnerable groups unless the research is necessary and is related to a disease affecting these persons as decided by the existence of the scientific and ethical justifications to enlist these persons in the research, and on the condition of obtaining the informed consent of each one of them, and if the medical research shall be conducted on any person who is considered a vulnerable person; then the consent of parents or the guardian or the legal representative is required if one or both parent are deceased, and in all cases in accordance with the controls and procedures provided for under the executive regulations of this law.

Article (4):
A protocol is required prior to starting the procedures for any medical research. The protocol shall be reviewed and approved by the competent institutional review board whose approval shall be final in medical nonclinical researches described hereunder.

The approvals of the Egyptian Drug Authority (EDA) and the Supreme Council are required for conducting clinical medical researches that include the use of new medicinal or biological compounds, or new indications for use, or forms or medical devices that were never used on the human body before and not approved by the international entities specified under the executive regulations of this law, and provided they are being tried and tested at the reference countries at the same time.

The opinion of the General Intelligence Agency shall be obtained in case the research is being conducted with foreign entities and in case of jointly conducted international studies.

Furthermore, the opinion of drug control entities and other relevant entities shall be obtained in accordance with the executive regulations of this law.

All processes shall be completed as of the date of completing the documents and notifying the relevant entities and the receipt of response within 60 days from the date of the notice. If no response is received; then it means that the application is accepted, and in all cases, this is subject to the provisions of this law and the processes specified under the executive regulations thereof.

Article (5)

The Supreme Council shall oversee the enforcement of the provisions of this law and shall take necessary actions with regards to any violation of the provisions of the law and shall notify the competent investigating entity of these violations immediately upon knowledge of the occurrence of such violations.

Chapter Three
The Supreme Council Entrusted to Review the Ethics of Clinical Medical Research

Article (6):

The Supreme Council for Review of Ethics of Clinical Medical Research shall be established by virtue of this law. This council shall be a body corporate affiliated to the prime minister and the prime minister shall

render a decree on the formation of the council, which shall consist of the following members:

1. Three university professors nominated by the minister acting as the minister of higher education.
2. Two professors of the researchers at the research centers, institutes or authorities pertaining to the work of the Supreme Council and nominated by the minister acting as the minister of higher education.
3. Two representatives of the Ministry of Health and Population (MoHP) nominated by the minister acting as the minister of health and population.
4. A representative of the EDA nominated by EDA chairman.
5. A representative of the Ministry of Defense nominated by the minister of defense.
6. A representative of the Ministry of Interior nominated by the minister of interior.
7. A representative of the General Intelligence Agency nominated by Chief of the agency.
8. A deputy for the president of the council of the state nominated by the president of the council of the state.
9. A renowned and experienced public personality nominated by the minister acting as the minister of higher education.
10. A renowned and experienced public personality nominated by the minister acting as the minister of scientific research.

11. A renowned and experienced public personality nominated by the minister acting as the minister of health.

The council shall have a one-time renewable term of four years, and chairman of the council shall be from among its member and as decreed by the prime minister. Chairman of the council shall represent the council before the law and any third parties.

The Supreme Council may appoint any person to assist the council whenever necessary without the right to vote. The council may form committees from amongst its members or from non-members to carry out any of its mandate.

The decree to form the Supreme Council shall determine its headquarters and the honoraria of its chairman and members.

The Supreme Council shall have a general secretariat to carry out the tasks assigned by the council and chaired by a dedicated secretary general. The formation of the general secretariat, the appointment of the secretary general, the regulations governing the work of the general secretariat and the honoraria of the secretary general and the personnel of the general secretariat shall be decreed by the prime minister.

Article (7):

The Supreme Council shall exercise its jurisdictions in the manner described under this law; and particularly may:

1. Create a database for medical research that includes research protocols and all documents, data and information related to research and all amendments thereto.
2. Establish standards, controls and regulations governing the medical research ethics to protect humans, human samples and human data and

to review the same as required for service of the national interest and to keep pace with international scientific developments.

3. Carry out the final revision of the research plans (protocols), which include the use of new medicinal or biological compounds, or new indications for use, or new forms or medical devices not previously used in the human body and not approved by the international entities specified under the executive regulations of this law, and as approved by the competent institutional committees. The Supreme Council shall record and sanction the approvals of these committees, and review the amendments on these research plans, and express a final decision to these committees with the approval of the plans and the amendments thereto or otherwise. The Supreme Council shall also seek the opinion of the General Intelligence Agency if the research is conducted with foreign entities and in case of jointly conducted international researches.

4. Carry out the periodical review and inspection of research facilities conducting clinical medical research and entities relevant to these researches to verify the application of the internationally and locally recognized standards of good clinical practices depending on type of risks that the research subject may be exposed to.

5. Examine and rule on complaints received from relevant individuals or entities regarding the clinical medical researches.

6. Issue causative and justified decisions to suspend medical researches for no more than one year, or to reject the renewal application, or to terminate the research prematurely on instances of failure to conform with the provisions of the research plan (The Protocol) or the amendments thereto, or if the research resulted in adverse events or serious adverse events or damages that were not expected when the research plan was approved. In such instances, the Supreme Council may also bar the principle investigator or the research entity in which the medical research

is conducted from carrying out future medical researches for no more than two years. In all cases, these measures shall go in line with the manner stipulated under the executive regulations for this law.

An amount of Fifty Thousand Egyptian Pounds shall be paid to the Supreme Council in consideration for the clinical medical research revision service for funded researches, and the prime minister may decree to increase this amount to no more than Two Hundred Fifty Thousand Egyptian Pounds depending on the nature of the research. This amount shall be deposited in the treasury in the account of the administrative entity against a payment receipt and under a separate provision in the Unified Treasury Account. The categories for this amount shall be determined pursuant to a prime ministerial decree. In all cases, these measures shall be determined pursuant to the provisions of the executive regulations of this law.

Chapter Four
The Institutional Review Board and
The Egyptian Drug Authority

First: The Institutional Review Board

Article (8) :

A committee named the institutional review board shall be formed in every research entity pursuant to a decision from the competent authority with jurisdiction over this entity. This committee shall be registered with the Supreme Council.

<u>This Committee shall be entrusted with the following jurisdictions:</u>

1. Safeguard the rights, safety and health of research subjects.
2. Review the research plans (protocols) and ensure that they include all the necessary documents and approvals on a case by case basis.
3. Issue the decision to approve or renew the medical research, and determine the term of the research so that it does not exceed one year, and to follow-up on the research until it is complete or otherwise terminated.
4. Monitor the main researcher and the research sponsor (if any) to ensure the correct execution of the medical research and the application of the standards of good clinical practices.

The institutional review board shall notify the Supreme Council of all the researches received thereby. The notice shall include the medical research protocol and all related documents and data, as well as, all actions taken by the committee in this regard. In all cases, all measures shall be pursuant to the provisions of the executive regulations of this law.

Second- The Egyptian Drug Authority (EDA)

Article (9):

In addition to its jurisdictions stipulated under Law No. 151 for Year 2019, the EDA shall exercise the following jurisdictions:

1. Evaluate the results of pre-clinical and clinical medical research.

2. Carry out the scientific review of the medicinal or biological product prior to the clinical medical research.

3. Evaluate the Research Plan "Protocol" and amendments conducted thereto, review the documents of the investigational product subject of the medical research in an endeavour to ensure the accomplishment of the good clinical practice, proper manufacturing , marketing and storage

4. Inspect research entities and other relevant entities in which clinical medical research is carried out for the purpose of verifying good clinical practices.

In consideration for the above said services; EDA shall collect charges not exceeding the charges stipulated in the schedule enclosed with the above said Law No. 151 for Year 2019. The prime minister shall decree the categories for these charges.

The executive regulations of this law shall stipulate the procedures that help EDA exercise its jurisdictions and sustainable coordination between EDA, the competent institutional committees and the Supreme Council, in this regard.

Chapter Five
Clinical Medical Research Phases,
Instances of Placebo Administration

First: Clinical Medical Research Phases Article (10):

Clinical medical research must be preceded by pre-clinical medical research that were scientifically reviewed and approved in writing by EDA.

Clinical Medical Research is divided into four phases as follows:

Phase one:

The first trials on humans in which a group of research subjects, whether healthy or patients are screened. The number ranges from 20 to 80 research subjects and they are divided into smaller groups, provided that movement is from one group to the other and after verifying the safety of the medical intervention results on the previous group. This phase aims to verify the safety of the medical intervention.

Phase Two:

This is the phase in which the clinical medical research is carried out on a larger number of research subjects ranging from two hundred to three hundred suffering from the illness targeted by the clinical medical research.

This phase aims at understanding how the medical intervention works and to continue the research of the phase I on the safety of the medical intervention on larger groups of patients.

Phase Three:

It is the phase in which the clinical medical research is conducted on a number of research subjects (patients) ranging in number between hundreds to thousands of patients.

This phase aims to find out how effective is the medical intervention compared to the best available treatments.

Phase Four:

Which is known as the post-marketing phase, and includes the safe monitoring of the medication after it receives the circulation or trading license.

Conducting all of the above phases is allowed on the condition that the results of each phase are reviewed and EDA gives the approval to move forward to the next phase.

As for the medical interventions that arise outside the Arab Republic of Egypt; Clinical phases III and IV are allowed after review and approval by the EDA and the Supreme Council of the results of the Clinical phases I and II, which were conducted in the country of origin.

As an exemption from this condition; is the medical intervention for endemic diseases that do not exist in the country of the origin of the medical intervention and rare diseases, in which case medical research for cases is allowed in the Arab Republic of Egypt beginning from the clinical phase II and subject to the approval of the Supreme Council.

Second- The Administration of the Placebo

Article (11):

The Administration of Placebo is permitted in the following two scenarios: 1. Comparison with the new intervention, given the absence of an effective treatment in market.

2. Comparison between the administration of a standard treatment and a new intervention.

In the above two cases, the use of placebo may not increase the risk to the research subject or cause the subject any harm, nor that the use of placebo may deny the research subject access to standard treatment, and in all cases, in accordance with the executive regulations of this law.

Chapter Six
Research Subjects' Rights

Article (12):

The rights of the research subjects are as follow:

1. The right to withdraw from the medical research at any time without any obligation to state any reasons and provided the principle investigator informs the research subject of the medical harms resulting from such withdrawal.

2. To protect the confidentiality of the research subject's identity and all other information except on the existence of a scientific justification approved by the competent institutional review board and the Supreme Council and subject to the written consent of the research subject or his or her legal representative.

3. Receive a copy of the informed consent.

The consent of the research subject shall be void in cases that require the correct application of medical research as stipulated under Egyptian laws and bylaws regulating the disclosure and confidentiality of information and without prejudice to the authority of investigating entities or the competent court to request the disclosure of this information for requirements of an investigation or trial in the manner stipulated in details under the executive regulations of this law.

Article (13):
The research subject may not participate in any other medical research unless after the expiration of the period specified by the previous protocol for the research plan.

Article (14):
It is prohibited to motivate or offer the research subject any incentives to participate in any medical research using any rewards or benefits in cash or in kind with the exception to what the research subject receives in consideration for the burden of participating in the medical research; such as transport expenses to and from the research entity or the allowance for absence from work for the time required by the medical research, provided however, it is predetermined and with complete transparency in the informed consent form submitted to and approved by the competent institutional review board and in the manner stipulated under the executive regulations of this law.

Dealing with the Research Subjects' Data and Maintain an Appropriate Level of their Confidentiality

Article (15) :

The main researcher and the research sponsor (if any) shall cause the following:

1. Record, file and maintain all information, data and reports related to the medical research and verify their integrity and accuracy.
2. Make all information, data, and reports related to the medical research during and after completion of the research available to the

competent institutional review board), Supreme Council, General Intelligence Agency, and EDA for the purpose of audit and review.

3. Refrain from publishing any information, data or reports regarding the medical research in newspapers or any media means except after the completion of the research and obtaining the written approval of the competent institutional review board and the Supreme Council, and the written consent of the research subjects in case of disclosure of any data or information related thereto.

Chapter Seven
Conditions, Procedures, Obligations and Liabilities Of the Principle Investigator

Article (16) :

<u>The Principle Investigator shall meet the following conditions:</u>

1. Meet all academic qualifications, training and experience criteria to be able to assume the responsibility of administering medical research and to be fully acquainted with the rules and ethics of scientific research and possess the skills deemed inevitable and necessary to deal with patients.
2. To be of good reputation and conduct.
3. Not to have been sentenced in a penal punishment or incarceration for a crime of honor or honesty unless otherwise exonerated.
4. To be free from any personal conflict of interest against conducting or completing the research or protecting the safety of any of the research subjects, and

In all cases, subject to the provisions of the executive regulations of this law.

Article (17):

Without prejudice to the provisions of Article (4) of this law; the Principle Investigator and prior commencing the medical research; shall cause the following:

1. Obtain the approvals required for conducting the medical research.
2. Obtain the informed consent of research subjects or their legal representatives and document the same using the prepared form, which shall be signed and dated by the research subject and reviewed and approved by the institutional committee.
3. Obtain the approval on the research plan (protocol) of the medical research.
4. Register the research plan (protocol) in the designated database.
5. Obtain the other permits and approvals as stipulated under the law.
6. Choose an assistant to the principle investigator and members of the research team in accordance with the criteria of scientific competence.
7. To choose research subject with complete impartiality and to specify the appropriate number to conduct the medical research in accordance with the approved research plan (protocol).

In all cases, subject to the provisions of the executive regulations of this law.

Article (18):

Without prejudice to the provisions of Article (4) of this law and during conduct of the medical research; the principle investigator shall conform with the following:

1. Conduct the medical research at the research entity and attend and supervise the research on regular basis; in accordance with recognized practices and standards.
2. Conform with the relevant laws and regulations and to apply the principles of good clinical practices, as well as, recognized and relevant local and international standards.

3. Manage the medical research in accordance with the research plan (Protocol) as approved by competent authorities, on a case by case basis.
4. The principle investigator may not cause any amendments to the research plan (Protocol) except after obtaining the approval of the entities concerned, as the case may be.
5. Inform research subjects of any amendments to the research plan that may affect their safety and of any unexpected risks that they, or other research subjects may become exposed thereto in the process of conducting the medical research.
6. Take necessary measures to protect the life, physical, psychological health and dignity of research subjects, as well as, minimize the side effects of the medical research; including the introduction of amendments to the research plan in event of emergence of serious side effects that may place the safety of the research subjects at risk. In such case; the principle investigator shall notify the research sponsor, institutional review board, EDA and the Supreme Council; each in their jurisdiction of the adverse events and the procedures taken to protect the research subjects within no more than 24 hours.
7. Keep the documents of the medical research at the research facility and at the premises of the research sponsor (if any) and take sufficient precautions to protect the same from any loss or damage.
8. Publish the results of the medical research in a peer-reviewed scientific journal after completion of the research.
9. Provide the necessary medical care to research subjects after completion of the medical research on case-by-case basis whenever the principle investigator concludes the occurrence of adverse events or serious adverse events, and to notify research subjects of their need for such medical care; all for the purpose of mitigation of the harmful effects thereof.

In all cases, subject to the provisions of the executive regulations of this law.

Article (19) :
The principle investigator assumes all the tasks, duties and funding of the medical research in case of absence of a sponsor.

Chapter Eight
Obligations of the Research Sponsor

Article (20):

Without prejudice to the provisions of Article (4) of this law; the research sponsor in the medical research shall cause the following:

1. Obtain all the required approvals depending on the nature and type of the medical research.
2. Supervise the completion of the medical research and fund the research from its beginning until its completion.
3. Establish the mechanisms required for monitoring performance and quality of performance and assurance to obtaining, documenting and publication of the results of the medical research in accordance with the approved study protocol and good clinical practices.
4. Serve the competent institutional review board and the Supreme council with periodical reports on the progress of the medical research and the funding made by the sponsor, as the case may be.
5. Enter into agreements with all parties concerned with the medical research and include these agreements in the medical research file.
6. Safe-keep with self, and in the Supreme Council's medical research database inside the Arab Republic of Egypt all the main documents and date related to the medical research after publication of the results.
7. Provide research subjects with medical intervention during and after the completion of the medical research on case-by-case basis and as required.

8. Immediately notify the research subjects of any modifications on the medical research, and of any results that may adversely affect their safety, and of any unexpected adverse events of the medical research.
9. Conclude an insurance contract with the research subjects named as beneficiaries, and with an insurance company chartered in the Arab Republic of Egypt against any damages sustained by the research subject due to their participation in the medical research. The insurance contract stated herein shall cover the entire period of the medical research and the follow-up period provided however that it shall be valid for one year after the completion of the medical research, and the insurance value shall be approved by the Supreme Council.
10. Indemnification and treatment of research subjects in case of injures related to the medical research.
11. Complete the treatment of research subjects proven to be in need of treatment after the completion of the medical research.
In all cases, subject to the provisions of the executive regulations of this law.

Article (21)

The medical research sponsor may retain any specialist in the field of medical research or a contract research organization to perform one or more of the above obligations or the duties of medical research entrusted to the sponsor subject to the provisions of the executive regulations of the law.

Chapter Nine
Suspension and Premature Termination of Medical Researches

Article (22):

In the event the research subject suffered adverse events or serious adverse events or damages that were unexpected when the protocol was approved or if the research subject was exposed to bad medical practices; then the principle investigator, research sponsor, research entity, competent institutional review board, EDA; each within their respective field of jurisdiction and mandate, shall take procedures to suspend or end the research, as the case may be, and the party concerned shall notify the Supreme Council immediately of these procedures, so that the council in its turn; shall take the appropriate decision.

Moreover, the principle investigator and the research sponsor shall notify research subjects and other parties referred to in the previous paragraph of these procedures in writing.

Any of the parties may appeal the Supreme Council's decision on this matter.

All the above is subject to the provisions of the executive regulations of the law.

Chapter Ten
Provisions Applicable to the Use of Human Samples Obtained During Medical Research

Article (22)

It is prohibited to use human samples obtained during medical research to commission any of the following acts:

1. Use of human samples without the prior informed consent of the research subject or their legal representative; without prejudice to relevant laws.

2. Store the samples, or any residual part thereof, after the completion of the medical research for the purpose of using such samples for future researches or for any other purpose without informed consent of the research subjects or their legal representatives and the approval of the Supreme Council.
3. Trade, in anyway whatsoever, in the human samples obtained for the purpose of use in medical research.

The approval of the Supreme Council and considerations and requirements of national security shall be taken into account before the entry or exit of any human samples related to medical research into or out of the Arab Republic of Egypt for any purpose whatsoever.
All the above is subject to the provisions of the executive regulations of the law.

Chapter Eleven
Conditions Applicable to the Research Entity

Article (24)

The Research Entity shall meet the following conditions:
1. To be adequately equipped with all means and equipment to help conduct the medical research efficiently depending on the nature of the medical research.
2. To be fully prepared to deal with emergencies or the requirements depending on the nature of the medical research.
3. To deal with a laboratory licensed and chartered by the ministry acting in the capacity of the Ministry of Health.
4. To be equipped with the necessary means and equipment to keep and store any effects that are related to the medical intervention as the case may be.

5. To be equipped with the necessary means to safe-keep data and records related to the medical research.
6. Members of the medical team and the supporting personnel shall be sufficiently experienced, efficient and completely committed to transparency and impartiality in their conduct of the medical research, as well as, to be fully acquainted with the standards of good clinical practices.

In all cases, it shall be prohibited to conduct medical research except in research entities registered with the ministry acting in the capacity of the Ministry of Health. It is also prohibited to conduct medical research in private clinics.

7. Compliance with the good clinical practices and protecting the safety of patients.

All the above is subject to the provisions of the executive regulations of the law.

Chapter Twelve
Liability and Penalties

Article (25)

Without prejudice to any harsher penalty stipulated under the Penal Law or any other law; crimes described hereunder are punishable by the prescribed penalties.

Article (26)

Any person who conducts clinical medical research without obtaining the informed consent from the research subject or the legal representative for a vulnerable research subject, and the approvals of the entities stipulated under this law shall be punishable by imprisonment.

If the act resulted in permanent disability; then the penalty shall be imprisonment with hard labour. The penalty shall be imprisonment with hard labour for at least ten years if the said act resulted in the death of one or more persons. Penalties shall multiply with the multiplicity of the victims.

Article (27)

Both the researcher and research sponsor shall be punishable by imprisonment and a fine of at least fifty thousand Egyptian Pounds and not more than five hundred thousand Egyptian Pounds for failing to observe any of the provisions of Articles No. 18 and 20 of this law.

Article (28)

Both the researcher and research sponsor shall be punishable by a fine of at least ten thousand Egyptian Pounds and not more than fifty thousand Egyptian Pounds for failing to provide the necessary medical care to any of the research subjects during and after the medical research.
If the crime hereinabove cites resulted in adverse events suffered by the research subject, then the minimum and maximum limits for the penalty shall be doubled; whereas if the crime resulted in serious adverse events suffered by the research subject; then the penalty shall be imprisonment and/or a fine of at least one hundred thousand Egyptian Pounds and not more than five hundred thousand Egyptian Pounds. Penalties shall multiply with the multiplicity of victims.

Article 29

Any research entity that conducts a clinical medical research without meeting any of the conditions applicable to research entities as stipulated

under this law shall be punishable by a fine of at least one hundred thousand Egyptian Pounds and not more than five hundred thousand Egyptian Pounds.

If its conduct resulted in serious adverse events to the research subject; then the penalty shall be not less than five hundred thousand Egyptian Pounds and not more than one million Egyptian Pounds.

Article (20)

Any person who contributes in any way whatsoever in the exit of human samples used in clinical medical research during or after the research without the prior approvals stipulated under the law shall be punishable by imprisonment and a fine of at least five hundred thousand Egyptian Pounds and no more than one million Egyptian Pounds.

Article (21)

The person responsible for the actual management of the body corporate shall be punishable with the same penalties prescribed for the acts committed in violation of the provisions of this law if it was substantiated that they were aware of the acts, and if the failure to perform management duties contributed to the commission of the crime.

The body corporate shall be held jointly liable for the financial penalties and the indemnifications.

Article (22)

The Law Enforcement Officers decreed by the minister of justice and as agreed with the president of the Supreme Council shall be vested with the judicial arrest capacity to enforce this law and its executive regulations for crimes commissioned in violation of the provisions of this law.