THE LEGAL FRAMEWORK FOR PRACTICING SCIENTIFIC EXPERIMENTATION ON PEOPLE IN LIGHT OF EGYPTIAN LAW NO. 214 OF 2020 AND COMPARATIVE LEGISLATION

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ABSTRACT:
Clinical medical research plays a vital role in advancing medical science and addressing incurable diseases, yet it must operate within the boundaries of human rights and ethical principles. This review explores the tension between the right to physical integrity and the societal need for medical progress. It examines international legal frameworks, including the Declaration of Helsinki and Egyptian Law No. 214 of 2020, which provide ethical and regulatory guidelines for conducting medical research. Key focus areas include informed consent, preclinical and clinical trial stages, and the integration of good clinical practices to ensure safety and efficacy. The study emphasizes the collaborative role of law and medicine in fostering innovation while safeguarding human dignity. It also underscores the importance of rigorous ethical oversight to reconcile individual rights with societal benefits.

KEYWORDS : Clinical medical research, Human rights, Physical integrity, Ethical guidelines,
Egyptian Law No. 214 of 2020, Good clinical practices, Informed consent, International agreements and treaties.

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RECEIVED: 11.01.2025 **ACCEPTED:** 17.02.2025 **AVAILABLE ONLINE:** 02.03.2025

DOI : 10.21608/SUODMJ.2025.364278.1004

ISSN : 3062-5041 SOUDMJ 2025 ; 1(1) :25-49

INTRODUCTION

The human right to physical integrity is considered one of the most important human rights and is one of the rights inherent to the personality, and is considered one of the foundations of public order. The general principle approved by jurisprudence and the judiciary is that it is not permissible to touch the human body except with his explicit and written consent: (1). International agreements and constitutions have been devoted to this right throughout the ages and times. This right requires that it is not permissible to touch the human body or assault his physical or moral entity, in any circumstances, and under any justification. Therefore, it is not permissible to conduct medical research on him without his consent. Since medical research is necessary to develop medical sciences and benefits the entire society (patients and healthy), it clashes with a basic rule in the extent to which it guarantees the protection of the human right to physical integrity: (2). The participation of individuals in such medical research is considered the most important means of its success, as it is the fastest means of developing medical sciences and discovering the appropriate treatment for diseases, as clinical medical research aims to achieve a direct personal benefit for patients by finding a cure for them from a disease that has been difficult for doctors and with which treatment by other methods has failed. Traditional, as these medical researches aim to benefit society and prevent the spread of diseases and epidemics by treating them. Therefore, international organizations have established many international agreements concerned with human rights in the face of medical research and experiments, standards and guidelines that those conducting medical research must adhere to, which are considered an ethical law that researchers must adhereto when conducting medical experiments on humans: (3), including

the Declaration of Helsinki issued by the World Medical Association in 1864, and the Tokyo Declaration issued in 1975, which are principles and rules related to conducting medical and scientific experiments on humans, the European Parliament's Charter of Patient Rights in 1984, and others: (4). The European Union has also issued many regulations related to clinical trials, including regulations (536/2014, 745/2017, 746/2017) : (5), as these regulations support the administrative procedures of the authorities and sponsoring bodies throughout the stages of clinical trials through tools for cooperation and communication between sponsoring bodies and authorities as well as between authorities. It also provides workflow features, document management and reporting. In line with European trends and international agreements, France issued the (Jardé) law, effective from 11/18/2016, which aims to develop biological and medical knowledge and evaluate the mechanisms of the human body's normal or pathological functioning, the effectiveness and safety of performing work, using or administering products to offer diagnosis, treatment or prevention of disease conditions, and interventional research that includes intervention on a person who does not receive usual care: (6). The French Code of Medical Ethics (CODE DE DÉONTOLOGIE MÉDICALE) also confirmed in Article R.4127-15 that: (7): A physician may not participate in biomedical research on people except under the conditions stipulated by law; he must ensure the regularity and importance of this research as well as the objectivity of its conclusions. The treating physician who participates in biomedical research as an investigator must ensure that conducting the study does not change the relationship of trust between him and the patient or the continuity of care. In line with international trends regarding setting standards for conducting medical research and many countries issuing regulating legislation for this purpose: (8), therefor, it was imperative for the Egyptian legislator to follow the example of these countries, as Law No. 214 of 2020 is considered an important national legislative shift due to the benefits it provides to patients, healthy people, doctors and society as a whole: (9), as it helps to promote more studies that focus on widespread diseases and limit their exacerbation and increases the chances of access to treatments that affect all of humanity. This is done by establishing the principles of human rights and preventing any person from being exposed to any of his rights on the one hand and on the other hand, and establishing a system for conducting medical research without conflicting with human rights.

The importance of the study:

The importance of the study stems from the nature of the interest subject to protection, which is the human right to physical integrity, which is the essence of human rights and one of their foundations, and the impact of conducting modern medical experiments on it as it poses a danger to his life. The legislative regulation of clinical medical experiments aims to reconcile two basic interests: the first and most important is the human right to physical safety and the preservation of his organs, and from this right stems the prohibition of touching his body except with his written consent, the second is the right of society to develop its scientific capabilities and therapeutic research in order to keep pace with the civilized world in scientific progress and benefit from the results of scientific research and develop it, and this is a social function performed by members of society to achieve the public interest: (10) The importance of the study is highlighted in what is required by the interest of society in reaching a treatment for incurable diseases that traditional treatments have not succeeded in, and establishing a regulation for joint efforts between medicine and law in order to reconcile conflicting interests, and not deprive society of the benefits resulting from clinical medical research without violating the sanctity of the body : (11). The study is directed to researchers who conduct medical research to encourage them to innovate and create research in light of their good knowledge of the limits of their rights in order not to fall under the burden of legal accountability. This requires searching for how to strike a balance between protecting the human right to physical integrity and the right of society to treat incurable

diseases in which traditional methods of medical treatment may fail. Since the basis for permitting medical work is to treat the patient as the goal of medical work: (12),), developing treatment is primarily in the interest of the patient before the interest of society. The recent spread of many diseases has highlighted the need to search for a cure for these diseases, without infringing on the human right to physical integrity. The study focused on the regulatory and legal controls for conducting clinical medical research set by international agreements, Law No. 214 of 2020 and its executive regulations and legislation. The legislator has created medical guarantees and reinforced them with legal guarantees through monitoring them and methods of compensating the resulting damages. Talking about scientific experiments, especially clinical research, is of interest to many researchers in the medical field who hope to reach innovations in the world of medicine to reach treatments for diseases prevalent in society and try to advance science within society, after medical studies no longer live up to the aspirations of society, which hopes that all diseases will have their own treatments and vaccines. The study combines two main axes: [1] The legal axis concerned with preserving society and the human entity from tampering with and harming humans, [2] The professional and technical medical axis concerned with treating diseases and epidemics and advancing human health. The study receives great attention from all those wishing to equalize the many rights related to this topic. The study emphasizes the fruitful cooperation between medicine and law and the establishment of a medical-legal system, as medicine provides hope and the law provides protection (13), The study was enriched by many European regulations that regulate these clinical medical researches, as well as the ethics of medical work set by the World Health Organization.

The problem of the study:

The problem of the study stems from how to balance the necessity of medical and clinical experiments and the resulting harm to the patient, and the extent of the effectiveness of laws in achieving the difficult balance between the freedom of scientific research and medical experiments on the one hand, and protecting the human right to physical safety on the other. As well as the lack of clarity of visions regarding the behavior and dealing with the human body through clinical medical research, while adhering to the medical ethics drawn up by doctors and lawyers, and not deviating from scientific research. Therefore, the study raises the extent of the effectiveness of guarantees of both the medical and legal types and their impact on the scientific medical movement to conduct medical experiments and the extent of their compatibility with the desired goal. As well as the mechanisms adopted by the legislator and their effectiveness in organizing medical work.

STUDY METHODOLOGY:

The study relied on the descriptive analytical comparative method by collecting information and facts about clinical medical research and comparing the legal organization of the subject of the study between Egypt and other countries that have established a regulation for clinical medical research and analyzing the texts that address the problem and trying to find legal solutions for it, while studying the phenomena and scientific results and describing them accurately and knowing the extent of the positivity of the legal and regulatory rules in controlling clinical medical research and the extent of benefiting from them.

Study Plan:

The first section:

The infallibility of the body betwee clinical medical research and human rights

The second section:

Legal and regulatory controls for clinical medical research

The third section:

Civil liability for damages from clinical medical research

The first section

The infallibility of the body between clinical medical research and human rights

Introduction:

The human body has a prominent position in legal jurisprudence, and many legal studies have addressed the legal protection of the human body that is called the

principle of the infallibility of the body (14); This is because the human body is a gift from God to him, so he is not allowed to dispose of it, as it is outside of legal transactions, and some (15) point out that the human body is not only a material thing but it is the human being himself in it embodied and through it, and this does not diminish the fact that the human being is represented by the spirit and mind as well because they are all components of the human personality, there is no mind and spirit without the body, while the body can exist without a spirit or mind like the dead. Since the human being is the focus of the law, as the law aims to regulate human relations, without touching the human body except with his consent, the legislator granted doctors the right to treat the human being and set rules regulating work of the doctor.Since there are common interests and a relationship between medicine and law, each of them affects and is affected by the other (16), and as a result of that relationship, the law has been affected by medical progress, so there are things that have become permissible, such as organ transplantation, after it was illegal (17), and a trend in jurisprudence (18) goes to the fact that the doctor who works must do his work without fear and dread of responsibility, otherwise medical work will never advance, so the law must establish a framework of protection so that medicine advances, and from here the legal organization of clinical medical research was found (19), where the researcher is granted the right to conduct this research on the subjects in order to achieve much good for humanity that aspires to this progress, and clinical medical research on humans comes after ensuring the safety of pre-clinical research and after doctors use many animals as a field for their experiments, then they try to convince patients and healthy people to use treatments that were previously tested on animals to ensure their suitability for humans and their expected results for them, and accordingly, conducting clinical medical research must be with the informed consent of the subject, as a person cannot be forced to undergo any medical experiments (20). Despite the potential benefits that may accrue to humanity from medical research, many people fear - as we mentioned earlier - what happened during World War II, which was demonstrated by the Nuremberg trials, that the Germans conducted medical experiments on prisoners. Since the end of that war, talk has begun about the need to develop legal texts that regulate the conduct of such experiments by setting controls for them, and the restrictions that must be adhered to when conducting the experiment, and reconciling the rights of the individual and society with the continuation of scientific activity without interruption. This is what was emphasized by the rules issued by international organizations such as the UNESCO Universal Declaration on Bioethics and Human Rights(21), and the standards and practical directions for reviewing the ethics of research related to public health with human participants issued by the World Health Organization (22), We will discuss this through the following: First requirement: The nature of medical research on humans Second requirement: The human right to physical integrity between medical research and the law Third requirement: The stages of conducting medical research on humans

The first requirement
The nature of medical research on humans

Introduction:

The development in the field of scientific research in medical sciences has become noticeable as it opens new horizons for reaching a cure for many diseases, and interest in it increased after what happened in the Nuremberg trials, as doctors were tried for their activity in the field of medical research, which caused doctors to refrain from research work, fearing the same fate as their colleagues, and since medical research has a special importance and achieves a three-dimensional interest: the interest of society, the interest of patients and the interest of the researcher, which necessitated the establishment of a legal regulation for it (23). Conducting medical research is one of the important topics that would give preference to the institutions that conduct it,and it is also used to measure the progress of countries, and knowing the main methodological

principles that govern medical research is essential for researchers and non-researchers (24). It will allow the development of medical scientific research, as this research is conducted on experimental animals by doctors, scientists and researchers in these fields. The efforts of scientists in this field have had great merit in eliminating many epidemics and diseases and in completing many complex operations. If research has had great merit in the emergence of many drugs and medicines, this is due to their testing on humans after their successful testing on animals (25), and research is tested on humans through simple doses of treatments that are doubled until they reach the required dose that benefits patients, so the success of the research has a probabilistic nature (26). Research is generally defined as: those experimental or theoretical technical procedures and works that aim to reveal the truth or collect practical data or choose the extent of the validity of a certain hypothesis or reach knowledge about a condition, phenomenon, event or a certain thing (27). The medical research experiment is defined as(28) the collection of data or personal information about each individual or group of individuals for scientific purposes. This collection of data results in interference in the person's private life, followed by conducting experiments on him to find the best method of treatment. There is no difference between medical experimentation and medical research, as both mean scientific and technical experimental work in the field of medicine that aims to develop biological and medical sciences (29).However, there is a linguistic difference between medical research and scientific research, because scientific research may not be medical, but rather in other sciences(30). Medical research is defined as: direct research according to scientifically correct rules and principles, whereby the human being is subject to methods and techniques without necessity dictated by his condition, whether in the field of disease prevention, preventive treatment, or treatment(31). It is also defined as (32): any research that is likely to achieve progress that leads to scientific innovation, with regard to the functions of human organs, whether in a state of health or disease, and is capable of being applied to it. The legislator has distinguished between a group of concepts related to medical research, whether prior to medical research or subsequent to medical research, as follows:

[1] Pre-clinical research:

Article 1/1 of Egyptian Law No. 214 of 2020 defined pre-clinical research as: Research conducted in an early experimental stage prior to human experimentation, and aims to determine the degrees of safety and effectiveness of the medical intervention to be studied, and is carried out through laboratory tests or the use of laboratory animals, in accordance with the international standards established in pre-clinical research. The Egyptian legislator did not establish special rules for the protection of animals subject to scientific experiments, while the European Parliament established special rules for the protection of animals subject to scientific experiments (33), but some universities have established rules for their researchers regarding dealing with laboratory animals (34).

[2] Clinical research:

Clinical research is defined as (35): a set of scientific data through which scientists and doctors in the field of practicing medicine try to discover a specific hypothesis for scientific medical purposes and verify its validity(36), and clinical medical experiments are considered part of the experimental method on the human body, and they differ according to their purpose, whether therapeutic or non-therapeutic. Article 1/2 of Egyptian Law No. 214 of 2020 defines clinical research as: studies or experiments conducted on human volunteers to evaluate the safety and efficiency of any therapeutic, pharmaceutical, surgical, nutritional, preventive or diagnostic interventions, with the aim of reaching scientific, preventive, diagnostic or therapeutic discoveries for diseases, as well as studies conducted to explore the medical data of volunteers to survey a retrospective evaluation of the effect of a drug, behavior or surgical intervention, in accordance with internationally recognized ethical standards for research. The European Directive referred to clinical studies (37), where Article 2/2/1 defined

clinical study as any investigation involving humans that aims to: discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products; determine any adverse reactions to one or more medicinal products; or study the absorption, distribution, metabolism and excretion of one or more medicinal products; with the aim of ascertaining the safety and/or effectiveness of those medicinal products. The European Directive referred in Article 3 to a general principle (38), which is that a clinical trial may only be conducted if: (a) the rights, safety, dignity and well-being of persons are protected and prevail over all other interests; (b) the trial is designed to generate reliable and robust data. Clinical studies aim to evaluate new treatments or methods that make existing treatments more effective (Ils permettent d'évaluationr de nouveaux traitements ou de nouvelles façons de render more efficaces des traitements existants.). Many studies have also referred to the Guidelines for Responsible Conduct of Clinical Studies and Trials, which are the so-called guidelines for responsible conduct in clinical studies and trials. It is concerned with setting a special description of the best practices in clinical research for researchers and institutions, and it enhances integrity in research and explains to researchers what is expected of them. It also guides and helps researchers, subjects, clinical research ethics committees, research institutes, pharmaceutical companies and society to understand and know what they have and what they are required to do and how to avoid errors and conduct the best clinical research. It preserves the rights and safety of subjects and ensures that research is conducted to achieve the public interest of society (39).

[3] Good medical practice:

Since it is impossible to establish a detailed system that can be controlled in medical research, especially since the problems that may occur to the cases under study cannot be determined, and the problems resulting from the research, medical research may expose one of the subjects to danger; Therefore, the expected risks for the subject must be expected and acceptable, and the researcher must achieve a degree of balance between the research results and the symptoms and consequences of the disease. A comparison is made between the expected risks and the potential benefits. This is called achieving a balance between the two poles of comparison, benefit and risk. Then, the individual interest must be achieved first (40), because it is the interest that is most important to care for. This requires that the medical practice be good, so the researcher chooses the best means and appropriate treatment methods from a technical standpoint (41), and determines the expected risks for the subject. The more the research is consistent with the research controls, ethics and morals that must be observed, and maintains a reasonable percentage of risks and benefits, while ensuring the absence of risk and seeking the interest of the subject before the interest of medicine and society, this will reduce the risk to the subject. However, unexpected risks may arise that occur despite the researcher's commitment (42). Article 1/3 of Egyptian Law No. 214 of 2020 defines a good medical practice as: a set of internationally and locally recognized principles and standards that are applied in the planning, management, implementation, monitoring, auditing, recording, analysis and reporting of medical research with the aim of providing confidence in the reliability and accuracy of the data and announced results of the research and protecting the safety and rights of volunteers and theconfidentiality of their data from any harm (43). Article 2/30 of the European Directive of 2014 also defines good clinical practice as a set of detailed ethical and scientific quality requirements for the design, conduct, implementation, monitoring, auditing, recording, analysis and reporting of clinical trials to ensure the protection of the rights, safety and well-being of participants, and that the data resulting from the clinical trial are reliable and robust(44). The ICH-E6 Good Clinical Practice (GCP) has indicated a number of good clinical practices, including: [1] Designing and conducting trials in a way that ensures the rights, safety and well-being of participants, [2] Reviewing the safety of participants periodically, as new safety information

becomes available that has an impact on the participant or the conduct of the trial, [3] Balancing the expected risks and inconveniences against the expected benefits to individual participants and society. The trial should only be initiated and continued if the expected benefits justify the risks, [4] Carefully considering the scientific goal and purpose so that certain groups of participants are not unnecessarily excluded, [5] The physician is qualified and generally responsible for the medical care provided to participants and the medical decisions made on their behalf, [6] Protecting the confidentiality of information that can identify participants in accordance with applicable privacy and data protection regulations.

[4] Interventional medical research:

Article 1/4 of Egyptian Law No. 214 of 2020 defines interventional medical research as: A study in which the subject is enrolled to receive a medical intervention with the aim of evaluating the effects of this intervention on medical outcomes in terms of effectiveness and safety. Interventional medical research aims to evaluate the direct effects of treatment and preventive measures on the disease with the aim of measuring specific results, including the effectiveness of treatment and transition from one treatment stage to another. It is defined as an activity carried out with the aim of improving human health by preventing disease, treating or reducing the severity or duration of an existing disease, or restoring lost function due to disease or injury(45). The researcher provides doses of the proposed treatment in specific proportions to the subjects and measures the degree of the subjects' response to the proposed treatment and the extent of benefit and evaluates those results to first determine the extent of the treatment's success and then the appropriate doses for treatment for each case.

[5] Non-interventional medical research:

Article 1/5 of Egyptian Law No. 214 of 2020 defines non-interventional medical research as: a study in which the subject is included for observation with the aim of collecting information about an approved medical intervention or health data about him. The European Directive of 2014 defines a non-interventional study as: a study that does not include clinical trials, and is referred to as an observational study. It is a type of study in which all participants receive routine clinical care and are not exposed according to the protocol to a specific treatment or health intervention. Data from these studies are often evaluated using epidemiological methods (46). The researcher examines cases that have been treated with traditional treatments to determine their response to traditional treatments. He prepares and monitors these studies to benefit from them in subsequent studies when trying the new treatment on those cases previously studied, and then reaches knowledge of the benefit that can be achieved for the subjects when trying the new treatment on them. These are studies prior to conducting clinical medical research on them. Observational studies aim to make observations and collect information on humans (examine human behavior, analyze health data, etc.) in order to develop health knowledge. Observational studies can be used to better understand a medical condition, or to see if people are following their usual treatment. No new drugs are given and no interventions are performed during an observational study. Observational studies are carried out in collaboration between specialized medical bodies and formulate hypotheses about the causes and risk factors of a particular disease or medical condition. Article L1121-8-1 of the French Health Code, as amended by Law 800 of 2016, provides that uninsured persons may participate in non-interventional research, and mayenter interventional research with an exception; this article states that: Persons who are not members of the social security system or beneficiaries of this scheme may be asked to participate in non-interventional research. As an exception, the Personal Protection Commission may authorize a person who is not members of the social security system or beneficiary of this scheme to participate in interventional research and this authorization is justified. It must be based on at least one of the following conditions: [1] The importance of the expected benefit to these persons is such that it justifies the expected risks incurred; [2] This research is

justified in light of the expected benefit to other persons who find themselves in the same legal situation. In this case, the expected risks and limitations of the research must be minimal.

[6] Research or medical intervention:

Article 1/6 of Egyptian Law No. 214 of 2020 defines research or medical intervention as: the focus of clinical medical study, and includes medical interventions such as medicines, medical devices, vaccines, interventional procedures in the human body and other products that are subject to testing or are already available. This research intervention may also include non-invasive methods such as health surveys, education and questionnaires. In order for the research intervention to have its effect, the aspects of the disease, symptoms, risk factors and pathophysiology must be evaluated, and evaluation studies must be conducted for the necessary treatments to manage, control or prevent the disease. Research or medical intervention is defined as any activity carried out with the aim of improving human health by preventing disease, providing treatment, reducing the severity or duration of disease, or restoring functions that are present due to disease. It includes all necessary health measures, including providing medications and preventing diseases and injuries. Intervention is divided into two types(47): (a) Preventive interventions, which aim to prevent or reduce the occurrence of disease, including vaccines, which provide long-term protection against disease by stimulating a variety of immune mechanisms, protecting against subsequent infection, and are provided to healthy individuals, infants, or pregnant women (48), (b) Therapeutic interventions, which aim to treat, mitigate, or postpone the effects of disease and thus reduce mortality, disability, or disease. These also include improving the foods consumed by research subjects, fortifying foods with essential substances such as iron and vitamin D, and changing nutritional pathways. Therapeutic interventions include: surgical and radiological treatment, diagnosis to guide treatment (49), and disease assessment and development of a treatment plan. Research and medical intervention also includes educating subjects about the causes of diseases and how to prevent them, and participating in behavioral change programs such as smoking cessation, avoiding infectious diseases, and medications used to prevent diseases and antivirals. The French legislator, in Article L1121-1, divided research involving human subjects into three categories of research: [1] Interventional research involving an intervention on the subject that is not justified by his usual care; [2] Interventional research involving minimal risks and restrictions, the list of which is set by decision of the Minister responsible for health, after advice from the Director General of the National Agency for the Safety of Medicines and Health Products; [3] Non-interventional research involving no risks or restrictions where all procedures are carried out and products are used in the usual way.

The second requirement

The human right to physical safety between medical research and the law

Introduction:

The human body is considered one of the most important elements of its existence. God Almighty said: {By the fig and the olive. And Mount Sinai. And this secure city. We have certainly created man in the best stature.} (50), so the Almighty Creator created man and made him the best so the body is the pillar of the person himself according to the origin, and the law does not only protect the human right to life, but also protects the safety of his body by criminalizing acts of aggression against him (51). The human right to physical safety gives him a legal status that authorizes him, within the limits of the law, to monopolize the elements of physical safety that focus on the human being maintaining his physical integrity and maintaining the level of health that he lives in and his freedom from physical and psychological pain(52). Therefore, practicing medical procedures on a human being requires touching the human body. If it aims to achieve the safety of the body in the first place, then it is legitimate because it achieves a confirmed interest; It is the maintenance and preservation of the body's substance, not the waste of its interest or harm to it.

The purpose of treatment is to achieve the body's interest, and any medical procedure that is not justified by a therapeutic purpose that takes into account proportionality is considered a breach by the doctor of his obligation to maintain physical safety (53). The established and stable principle is that the body's safety may not be violated except in order to maintain its entity and complete its existence (54). The meaning of the right to physical safety is that the human body remains in a certain form that it has chosen for itself according to what the Almighty Creator created it to be, and that it maintains the physical structure according to the natural course of its functions. This is the essence of physical integration, where its complete objective value is integrated, represented in its preservation of all its parts (55). Conducting medical research on humans is the most dangerous thing that a human being is exposed to, because medical research is not guaranteed to succeed or fail, and it also carries many risks that affect those subjected to it. Therefore, the legislator, in agreement with international agreements, requires those who carry out this work to avoid prohibition while conducting research work and respect the ethics of medical work and respect the human entity and the necessity that such research be preceded by extensive studies on animals, and that it can be carried out under direct supervision by the relevant authorities, through a comprehensive medical and technical file that includes studies, benefits and expected risks, and the procedures that will be followed in the event of any risks. We will address this topic through the following:

[1] Definition of the right to physical integrity

The right to physical integrity is defined as: the legal status that entitles its occupant, within the limits of the law, to monopolize his physical integrity, health level, and physical and psychological tranquility. Legislation prohibits all forms of tampering with the substance of the body unless there is a therapeutic necessity that justifies it (56). It is also known as the legal interest protected by law in that his body continues to perform all its functions in the natural physical manner so that none of these functions is disrupted, even if it is the least important or the disruption is temporary, and that the method of performance does not deviate from the manner specified by natural laws (57). Some (58) believe that this right has three aspects: the first is objective and is represented by the physical integrity of the human body, the second is individual and is represented by the individual's right to have his body protected and no one attacks him, and the third is related to society, which has the right to protect the body of any human being from attacks that occur to it. Some (59) believe that the human right to physical safety is based on three elements: [1] The right for the body's organs to continue to perform their functions in a normal and natural manner, and therefore any interference that leads to a malfunction in the natural course of these organs is considered an attack on the human right to the safety of his body. . [2] The right to keep all body parts intact, and therefore any act that leads to compromising this integrity, whether by amputation or removal of a part of it, or simply making a change that undermines the cohesion of cells or tissues or weakens them, is also considered an assault on the human right to the integrity of his body. [3] The right to be free from physical pain, and thus from any act that leads to harming the human feeling of comfort and tranquility, is considered an assault on the human right to the integrity of his body(60). We see that the right to physical integrity is a right with two characteristics: it is a material right based on its connection to the human body, and a moral right based on the human being himself, and this right gives the individual an interest that the law protects against any interference with the vital functions of the human body and his freedom from the pain that may befall him (61). Physical integration is not in the absence of the organ or the loss of its ability to perform its function, but it can be due to the occurrence of pain as a result of an assault on the body, which causes the person to lose peace, tranquility and comfort, and is considered an infringement of the right to physical safety. The feeling and sense of a degree of comfort must be due to freedom from physical pain, and the degree of comfort is determined on the basis

of the ratio of pain that the person suffers or feels and that which he does not suffer or feel, and this degree decreases if it increases and increases if it decreases(62). Therefore, it is not permissible to interfere with the integrity of the body except in order to preserve its entity, complete its existence and flourish, and for this reason surgical intervention that targets the therapeutic interest of the patient is considered legitimate, and the law has licensed the doctor to practice medicine by providing him with a license to practice the profession of medicine(63), and this is the basis for permitting the practice of medical work for the doctor (64), as the law licenses him to practice work that targets the preservation of the human body and its interest in proceeding normally and naturally, as these works target the maintenance of his body regardless of the outcome of the treatment, and the condition for the availability of the reason for permission is that the purpose of the medical intervention is to treat the patient, and accordingly the reason for permission does not exist if the goal is to conduct a scientific experiment for the purpose of satisfying a scientific desire or achieving personal propaganda(65). [2] Protecting the body from medical progress As previously mentioned, the principle of the inviolability of the body is one of the established principles in jurisprudence, law and divine laws, which prohibits touching the human body except in cases of necessity. The inviolability of the body means not neglecting it, tampering with it, violating it, or touching its elements and properties except in cases of necessity, and that any exception to this is for the benefit of the body and within the narrowest limits (66). The legislator has prohibited harming the human body, whether by beating, wounding, or giving harmful substances. With the development of medical sciences, the human body has become a subject of medical and scientific research, and it has become necessary to research how to balance the right of the person to the integrity of his body with the interest of society in medical research, as the right to physical integrity justifies the rejection of any touching of the integrity of the body and subjection to medical experiments on it, and this is what all international agreements and Egyptian legislation have emphasized (67). In order to touch the sanctity of the human body, it is required to obtain the consent of the person subject to it, in order to legitimize medical research. Some (68) point out that the right to protect the body may be against the owner of the body himself; It is not permissible for a person to conclude an agreement with a doctor to interfere with his body, as the body is outside the scope of dealing, as the right of a person over his body is limited by the rights of the group and the laws regulating it in society because they are laws related to public order. A person suffering from severe pain has no right to request that his death be hastened, no matter how much suffering he is exposed to, and it is prohibited for the treating doctor to agree to that, even out of compassion, even if he is hopeless. Article 36 of the Doctors' Regulations in Egypt states that: It is prohibited for a doctor to waste life under the pretext of compassion or mercy (69). The World Medical Association's code of ethics has permitted non-therapeutic experiments on humans (70), and has set certain conditions that must be adhered to in order to preserve the body of the subject, namely (71): [1] The doctor must ensure the protection of the life and health of the subject of the experiment. [2] The subject of the experiment must be a volunteer in good health or a patient with a disease different from the disease under study or research. [3] The experiment must be stopped if the experimenter sees that continuing it poses a risk to the subject. [4] The benefits of science and society may not outweigh or outweigh the interests or benefits of the individual in medical research. The Egyptian Court of First Instance ruled in its ruling issued on October 3, 1941 that a doctor's choice of one method of treatment over another cannot lead to his liability for the method of treatment he followed as long as this method is actually followed in treating patients, and the doctor's liability for a treatment error is not based absolutely on the typeof treatment he chooses because this is considered interference in the assessment of scientific theories and methods, which is not permissible to research (72).

[3] Medical research and the right to health

With the continued pace of medical research, its development and the expansion of its scope, the need arose to discuss this new type of medical practice on a wide scale from all its legal and ethical aspects. Therefore, conferences and seminars were held frequently between legal and medical men in an attempt to find a legal system that balances the requirements of this scientific development on the one hand and preserving the safety, integrity and health of the body on the other hand (73). Therefore, it was necessary for the humanities to keep pace with the successive scientific developments continuously so that there would be no conflict between science and law. If each society has its values, heritage and traditions that are glorified by legal rules, then medical research must be consistent with these values and traditions and contribute to preserving the right to health. It has become a stable and fixed principle that the continuation of scientific progress should draw a new picture of a future that preserves physical safety and the right to health (74). If the human being is the focus of the protection of the law, then this protection requires that he enjoy the necessary amount of health and the development of health policies for him to ensure that the human being performs his function in society. Some point out that a disturbance in the integrity of the body necessarily means a disturbance in the health of the human being, which reveals that the integrity of the body and health go in one direction (75). The right to health is the logical way to preserve the human right to life, and the right to physical safety is the most important component of this right and is included in the content of this right. Violation of this right constitutes an attack on the physical and psychological entity of the human being in its various forms, a flagrant violation of his right to health, whether this attack is limited to merely affecting his physical safety or leads to him contracting one of the diseases or various types of disability (76). Scientific medical research works to develop knowledge of medical aspects to reach solutions to some of the problems that patients suffer from, and includes a group of medical studies related to human health in general, practical physiological studies, or biochemical studies, etc. Therefore, legal and medical men agreed on the necessity of scientific medical research through the use of ethical methods and rules, and includes establishing ethics for scientific research that include strategies to ensure the compatibility of scientific research with maintaining physical safety and thus protecting the health and safety of patients participating in the research, so it is considered important to prevent harm to patients or participants, so legislation requires compatibility between scientific research and the right to health and thus the right to physical safety.

[4] Ethics of medical research

The Nuremberg trials showed that medical research was conducted either in secret by researchers who dealt with poor subjects and became victims of a violation of their rights, or openly by the ruling authority, which exploited prisoners and detainees to conduct experiments on them as if they were lab rats. Researchers were busy with medical research that would bring them wealth without regard for human rights. Since medical research became an important part of developing the medical system, it was necessary for the subjects in charge of the clinical medical research system to be reassured about the medical research being conducted on them, and at the same time for researchers to work according to a correct legal medical system (77). This required serious consideration regarding research ethics, and the question that arises is whether the research ethics committee is able to meet the requirements of the new scientific environment? Will ethical and legal standards be able to prevent what happened during World War II? Therefore, it was necessary to form a research ethics committee inspired by society, determined by biologists alone and called on the entire society to participate in the public discussion of medical research. These deliberations ended with the need to form research ethics committees to review the research presented and ensureits compatibility with human rights. In fact, the sociologist John H. Evans put forward the hypothesis that the fault lies with bioethics and the experts it created, i.e. bioethicists. Their presence led to the exclusion of citizens from the discussion, and it seems that the presence of

experts in law and human rights provides better protection for the public through citizen participation (78). The French health law stipulates that medical research may not be conducted on a clinically dead person without prior consent from him or his family, as Article (L1121-14) of the law amended by Law 300 of 2012 stipulates that: No research may be conducted on a brain-dead person without his consent during his lifetime or through the testimony of his family. However, when the deceased person is a minor, this consent shall be expressed by both parental authorities. If it is impossible to consult one of the parental authorities, the inspection may be carried out provided that the other authority approves. The provisions of Article 225-17 of the Penal Code (referred to above) do not apply to this research. Law 214 of 2020 stipulates in Article 2 the objective of the law, which is to establish the foundations, standards and controls necessary for conducting clinical medical research and protecting subjects, whether this research is preventive, diagnostic, therapeutic, or non-therapeutic, interventional or non-interventional. It includes the commitment of research to internationally recognized ethical standards and principles. The World Health Organization has developed a document on standards and practical guidelines for reviewing the ethics of health-related research with human participants(79), and UNESCO has developed the Universal Declaration of Bioethics and Human Rights, both of which, along with other trends related to medical research, seek to preserve physical integrity and provide a framework of principles and procedures that guide countries when formulating their legislation and policies, while recognizing the freedom of scientific research and the benefits derived from it, with the aim of achieving a high level of health without harming humans.

We can address a number of points regarding the ethics of medical research, including:

- Full respect for human dignity and human rights and giving priority to the interests and safety of the individual over the interests of science.
- Enabling research participants to obtain the maximum direct and indirect benefits resulting from the research.
- Obtaining prior approval from medical committees specialized in medical research ethics.
- Human weakness should be taken into account when applying and developing scientific knowledge, medical practices and related technology, and respecting their physical integrity.
- Equality, justice, fairness, and non-discrimination should be taken into account when selecting research participants.
- Confidentiality of medical work and respect for the privacy of participants in medical research, and not knowing the identity of the participant except within the limits required by medical work.
- Complete independence of the committees specialized in discussing the ethics of medical research and supporting them in performing their tasks.
- Absence of conflict of interest between participants in medical research and those in charge of the research, as well as members of the medical committees specialized in medical research ethics.
- Legitimacy of funding medical research and that the goal is to reach treatments that serve humanity and patients and not for other purposes.
- Emphasis on providing care to the subjects before, during and after medical work.
- Continuous evaluation of the results of medical research to ensure its effectiveness and its compatibility with scientific and medical knowledge.
- Written and voluntary informed consent of the persons participating in the research and documenting that consent before the competent committees. With the approval of the legal guardian of the person who is unable to consent (80). And to the extent necessary to benefit from the research for their treatment(81).

We believe that a curriculum should be developed for students of practical colleges who conduct clinical medical research, in which all the ethics and duties that researchers are committed to after graduation are determined, and they are not allowed to graduate until they are fully aware of the ethics of medical research.

[5] The philosophy and purpose of issuing a law to regulate clinical research (82)

The progress of medical sciences is linked to research, exploration, observation and experimentation. Allowing the practice of medical research would lead to the discovery of new treatment methods that contribute to the elimination of epidemics and diseases. Although medical research had gone through a period of terror due to what happened in World War II,

it has returned and regained its status and importance, and the international community has come to recognize its legitimacy and organize it internally and internationally(83). For scientific necessity there is no escape, and experimentation on humans has returned as an indispensable act due to the physiological differences between humans and animals (84). The philosophy of enacting a law to regulate clinical research stems from setting specific and comprehensive rules to regulate clinical research and organize supervision and control over it, with the establishment of mechanisms for supervision and control over the practices of research activity related to human health and safety, placing those in charge of it under the law. If clinical research aims to serve the medical system, it is considered a positive step to push Egypt to the ranks of advanced countries that are aware of the importance of these clinical trials and is a basic and effective factor in developing and advancing the pharmaceutical industry, and establishing guarantees to serve the clinical research system for the researcher and the researched, as it opens the way for innovation and creativity and inventing new drugs and increasing competitiveness between pharmaceutical companies, and then providing various treatments with Egyptian origin and the ability to create a new health policy and prevent the spread of diseases and grant security to the citizen and confidence in the Egyptian drug product (85). Enacting legislation to regulate clinical research also aims to protect the human entity, personality and health in the context of clinical medical research, which preserves the freedom of research and scientific study, and at the same time protects human dignity. Article 60 of the Constitution states that: The human body is inviolable, and assaulting, mutilating, or mutilating it is a crime punishable by law. Trafficking in human organs is prohibited, and no medical or scientific experiment may be performed on it without the free, documented consent of the person, and in accordance with the established principles in the field of medical sciences, as regulated by law. Article 66 of the Constitution also states that: Freedom of scientific research is guaranteed, and the state is committed to sponsoring researchers and inventors, protecting their innovations, and working to implement them. Article 2 of Egyptian Law No. 214 of 2020 states that the provisions of this law aim to establish the foundations, standards, and controls necessary for conducting clinical medical research and protecting subjects, whether this research is preventive, diagnostic, therapeutic, or non-therapeutic, interventional or non-interventional. The law aims to set the standards and controls that must be followed when conducting clinical medical research, which is the primary way researchers discover whether a new treatment is safe and effective in overcoming a particular disease or not. The researcher studies a new treatment in the laboratory, then applies the treatment to laboratory animals. If its safety and effectiveness are proven, he tests it on volunteers through clinical trials after obtaining approval from the competent authorities specified in the law. Therefore, the Clinical Medical Research Regulation Law provides a high degree of protection for volunteers. Before starting clinical research, the volunteer's informed consent must be obtained. He also has the right to withdraw at any time without giving reasons, provided that the researcher informs him of the medical damages resulting from his withdrawal. The law prohibits disclosing the volunteer's identityor publishing or announcing any information or reports related to medical research, and motivating volunteers in any medical research by granting them rewards or monetary benefits. There is no doubt that there are healthy or sick people who may request to conduct medical experiments on them. These may be people who are exhausted by the disease and the treatment that does not work, so they hope that the new treatment will have a quick result in overcoming the disease, so they join clinical trials because the treatments being tested may solve health problems that have not been overcome under the old and known treatments. Also, through this experiment, they will receive treatment easily andconveniently before it becomes available at high prices that they cannot afford.

Some aim to find new methods and treatments and help find ways to prevent the disease and protect others from the cursed disease. Healthy people may also participate to serve science or to encourage sick people from their relatives to enter medical research. It is noteworthy that the law does not make medical and clinical research at the doctor's discretion, but rather is subject to a work plan and a clinical research study. The doctor is bound by the study protocol approved by the Supreme Council for Reviewing the Ethics of Clinical Medical Research. The doctor does not have the authority to amend this protocol. Also, the clinical experiment is just an experiment, which means that the result is still unknown. The volunteer may or may not benefit from his participation in clinical research.

Third requirement

Stages of conducting medical research on humans

Introduction:

Researchers in medical research conduct many studies with the aim of testing new drugs or verifying the validity of a new drug for human use, as medical research begins with detecting the disease, diagnosing it and measuring the speed of its spread, and since medical research ultimately requires testing it on humans, because they are the primary beneficiaries of the success of the research, medical research goes through more than one stage before approving the new treatment being tested, and the stages related to conducting clinical medical research on humans, or what is called clinical research, are preceded by the pre-clinical research stage. The US Food and Drug Administration (FDA) (86) indicated in its report on clinical research that (87): Where it indicates that: Preclinical research answers basic questions about a drug's safety, it is not a substitute for studies of the ways the drug will interact with the human body. "Clinical research" refers to studies, or trials, that are done in people. As the developers design the clinical study, they will consider what they want to accomplish for each of the different Clinical Research Phases and begin the Investigational New Drug Process (IND), a process they must go through before clinical research begins. which is the process they must go through before starting clinical research. Since the stages of medical research require conducting research on humans, international agreements and Egyptian legislation have emphasized the necessity of preceded by experiments on cells and animals before testing them on humans (88). Article 10/1 of Egyptian Law No. 214 of 2020 stipulates the stage prior to conducting medical research on humans, stating that: Clinical medical research must be preceded by pre-clinical medical research, which has been scientifically reviewed and approved in writing by the Egyptian Drug Authority. The legislator has stipulated four successive stages of clinical medical research(89).

First: Defining the stages of conducting medical researchThese stages are defined as(90):

The steps that researchers take during medical research with medical intervention in an attempt to obtain sufficient evidence about the suitability of a drug for use as a medical treatment. In the case of a pharmaceutical study, the stages begin with designing the drug and discovering the drug, then it is tested first on animals. If the experiment is successful, the clinical stage begins by testing safety on a few individuals from humans, then expanding the tests to a large number of participants to determine whether the treatment is effective or not(91).Some point out the necessity of informing the person undergoing the experiment at every stage of its stages and the doses he receives, whether limited or increasing, as well as the expected side effects (92), and the insight must be strict and detailed and provide the patient with a wider opportunity to choose between acceptance and rejection (93). This is because these stages may take a period of time, so the person being investigated must be prepared for these studies. There is no doubt that clinical research is a mixture of scientific experiments and therapeutic experiments, based on healthy and sick people. Healthy people help scientists achieve scientific goals, so they are free from individual interest and present the public interest. Scientific experiments aim to apply modern methods of a purely scientific nature with the aim of discovering the effectiveness of a certain method in the field of diagnosis, treatment or prevention. Although these experiments may be fraught with serious risks,

the procedures stipulated and regulated by the legislator, and the methods of dealing with them have put an end to the potential risks.

Second: Stages of conducting clinical medical research Clinical medical research goes through a number of stages, as follows:

[A] The stage prior to clinical research (laboratory studies)

Pre-research studies include studies on cells (Cell studies) and these studies are conducted in laboratories and are tested on (sick cells) obtained from the body of a sick person, such as cancer cells, and are mixed with the new treatment, where researchers learn about the effect of the new treatment on the sick cells grown in a laboratory dish or test tube. These studies can be conducted on human cancer cells or animal cancer cells. After the initial experiments are conducted on these cells, the researcher moves on to conduct studies on animals (Animal studies). Treatments that appear promising in cell studies are then tested on cancers in living animals. This gives researchers an idea of the safety of the new treatment in living organisms. These studies provide a lot of useful information in the preliminary stage, and it is not necessary for the studies applied to animals to be consistent with similar studies on humans, as humans and mice may differ greatly in the way they absorb, process and get rid of drugs or treatments. A treatment that works against cancer may succeed in laboratory animals such as mice but not in humans, and side effects and other problems may appear when tested on humans that did not appear when the treatment was used in mice but appear in humans (94). After the laboratory studies are completed, the principal researcher presents the scientific results he reached through the experiment on cells and the experiment on animals to the Egyptian Drug Authority, which reviews the results of the research and verifies all the information and data provided by the researcher. The Drug Authority must approve in writing to the researcher what he has done before conducting clinical medical research (95), as Article 9/1 of the law stipulates that the Authority is competent to evaluate the results of pre-clinical and clinical medical research(96).

[B] The first phase of clinical research

This phase is considered the most dangerous phase in the research, because it answers the following question: Is the treatment safe or not? If it is safe, what is the appropriate dose? Does the appropriate dose not cause side effects for the subject? The safety of the subjects is the main concern, as the research team closely monitors the subjects and monitors the side effects that may occur as a result of using the treatment. After completing the procedures for approving the completion of the research, the first phase begins, which is designed to test safety, side effects, and the best dose (so that the new treatment does not become toxic) and the method of implementing the treatment, as the experimental treatment is tested on a small group of people who are usually healthy to later judge the safety of the treatment and its side effects and determine the appropriate dose of the drug. Some patients can be added to ensure the positivity of the new treatment after the failure of traditional treatment to solve their problems. This participation helps researchers to know the results of the new treatment and its effectiveness. Accordingly, the treatment is tested on a small group, then the number increases, and the doses are progressive and gradual so that the subjects do not suffer from poisoning due to the high dose rate. The participation of healthy people is often to ensure the safety of the treatment before their sick relatives participate, or to help researchers in their studies, or as a contribution to science (97). The subjects receive medical care 24 hours a day so that complications do not occur as a result of the new treatment, and they are directed to specialized medical centers for periodic examination. Nutrition specialists are used, as the treatment is tested before and after meals to ensure the effect of food on the doses.Researchers also use specialists in other scientific fields, such as specialists in selecting participants in a random and proportionate manner in each research group, and in statistics, chemistry, and other specialties related to the research. Article 10 of Egyptian Law No. 214 of 2020 referred to this stage, which is called the first stage

of human trials, in which a group of subjects, whether healthy or sick, is selected, ranging in number from twenty to eighty subjects, and they are divided into small groups, provided that the transition from one group to another is after ensuring the safety of the results of the medical intervention on the group preceding it. This stage aims to ensure the safety of the medical intervention. It is noted that the research team must be honest in the presentation, examination and verification, and it has the right to stop the research immediately if it discovers an error and review the research, either ending it or completing it after discovering the error and treating it (98), and the research team is also responsible for informing those concerned of the serious side effects observed during the treatment test. Article 22 of Egyptian Law No. 214 of 2020 states that: If the subject is exposed to side effects, serious side effects, or damages that were not expected at the time of approval of the protocol or poor medical practice, the principal investigator, the research sponsor, the research entity, the competent institutional committee, and the Egyptian Drug Authority must - each in his own capacity - take measures that would suspend or terminate the research, according to each case, provided that the person taking these measures immediately notifies the Supreme Council in writing of them, so that it may issue the necessary decisions in this regard. The principal investigator and the study sponsor are also obligated to notify the participating subjects and the rest of the parties referred to in the previous paragraph in writing of these measures (99).

[C] The second phase of clinical research

After the completion of the first phase and the success of the research target, the new question comes: How effective is the treatment on a larger number of subjects? The research team presents the initial results and the results of the first phase to the competent authorities and obtains the approval of the Drug Authority and ensures the safety of the medical intervention and the safety and quality of the new treatment, where the second phase is moved, and in this phase the treatment is offered to larger groups and is not selected either, but rather in a random, unselected manner, and in this phase the research team ensures the safety and safety of the new treatment and its effect on the recipients, and it is tested on patients who suffer from the failure of traditional treatment to cure them. This study takes longer because it depends on the expected benefit of the research, in terms of improving the results and the recovery of patients after receiving the doses, and the disease not returning to them again after stopping treatment. Article 10 of Egyptian Law No. 214 of 2020 referred to the second phase, which is the phase in which clinical medical research is conducted on a larger group of subjects ranging in number from two hundred to three hundred subjects who suffer from the disease targeted by clinical medical research. This stage aims to help in knowing how the medical intervention works, and to complete what was studied in the first stage of the safety of the medical intervention in larger groups of patients.

[D] The third stage of clinical research

After completing the first and second phases, and after reviewing the results of the new treatment and the extent to which patients benefit from it, and after the approval of the competent authorities to move to the new phase, the third phase begins. In this phase, the availability of the new treatment to the public and the success of its effectiveness, and the safety and effectiveness of the new treatment compared to previous treatments are confirmed (100), where the research team tests the drug randomly and monitors it on larger groups reaching thousands, and in it, multiple medical centers and more and more patients areused to identify the final results of the treatment before putting it on the market. The research team conducts a survey and comparison between those who received the new treatment and those who took the old treatment, with the aim of reaching the acceptable result, which is acceptance of the new treatment. This phase must be carefully designed by choosing the people, places, treatment method, and how to identify the results, and obtaining a license to trade, where marketing procedures for the treatment were taken and it was put on the market through specialized centers and pharmacies (101). Article 10 of Egyptian Law No. 214 of 2020 referred

to the third phase, which is the phase in which clinical medical research is conducted on larger groups of subjects (patients) ranging in number from hundreds to thousands. This phase aims to determine the effectiveness of the medical intervention compared to the best available treatments.

[e] The fourth phase of clinical research

After completing the previous three phases and after reviewing the results with the competent authorities and the Drug Authority and launching the new treatment for marketing, the fourth and final phase begins, usually known as the post-marketing phase or the awareness or drug control phase. The drug can be withdrawn even if it has been marketed in the event of serious cases of side effects or death. At this stage, approved drugs are monitored by the competent authorities over a long period of time. Even after testing a new drug on thousands of people, not all effects of the treatment may be known. There may still be a need to know whether the new treatment requires larger doses to prevent the disease from returning again? Does this mean that those who receive it are more likely to live longer? Are there rare side effects that have not yet been seen, or side effects that only appear after a person has been taking the drug for a long time? Answering these questions may take many years. Therefore, the possibility of introducing large quantities of the new treatment and the costs of treatment are being reviewed compared to its results if there are other treatments that have the same effect. Article 10 of Egyptian Law No. 214 of 2020 referred to the fourth stage, which is the stage in which clinical medical research is conducted and is known as the post-marketing stage, and includes continuous safe monitoring of the drug after it has obtained a trading license.

[m] Licensing the stages of medical research coming from outside the country:

There is no doubt that the previous four stages are stages of clinical research conducted within the country, which are under the sight and insight of the competent authorities, and those in charge of them are permitted after evaluating the results of pre-clinical medical research and reviewing the pharmaceutical and biological preparations and the competent authorities evaluating the protocols and verifying all documents and results to achieve good medical practice, manufacturing, trading and storage, but there are some medical experiments conducted outside the country, and since the new treatments that appear outside the country are necessary for citizens due to the spread of this disease within the country, such as what happened during the (Corona) treatments, therefore the competent authorities may allow some research from abroad to enter the country and conduct one or more stages of medical research and approve those medical interventions. Also, in the event that there are diseases in Egypt that do not exist in the countries in which the researchers conducted the study, the legislator has allowed them to be present, and here the studies that have been conducted abroad are reviewed and thus the new studies are allowed to complete their stages within the country (102). The last paragraphs of Article 10 of Egyptian Law No. 214 of 2020 indicated that medicalinterventions originating outside the Arab Republic of Egypt are permitted to conduct the third and fourth phases after reviewing and approving the results of the first and second phases conducted in the country of origin by the Egyptian Drug Authority and the Supreme Council.This is with the exception of medical interventions related to regional diseases do not present in the country of origin of the medical intervention and rare diseases, as medical research on any of them is permitted to be conducted within the Arab Republic of Egypt starting from the second phase, and according to what is approved by the Supreme Council.

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2. Medical research was linked to the international trial of German doctors that took place after World War II, in which they were accused of violating the right to respect for the human body due to conducting medical research on prisoners

1. of war from the Allied countries without taking into account legal and ethical rules. The Nuremberg trials came to confirm a set of principles that must be taken into account in order for medical experiments to be morally and legally acceptable. The trial indicated that the research conducted was atrocious crimes against humanity. The number of defendants was 23, most of whom were famous doctors, surgeons, bacteriologists, and university researchers. They conducted experiments and research in prisons and concentration camps. The experiments included euthanasia of the mentally ill, vaccine testing on prisoners, inoculation with poisons or infectious diseases, forced sterilization, and collecting the skeletons of deportees. The crimes were carried out with the approval of the German authorities and with the help of German public funds and in close cooperation with the largest research institutions in Germany. This resulted in the issuance of the decisions of the Nuremberg Tribunal, which were ratified by the United Nations General Assembly on 12/11/1946. It is noteworthy that the World Medical Association (WMA) adopted an international code of medical ethics in 1948. It is known as the Geneva Oath, which is a new version of the Hippocratic Oath. This oath did not stipulate the controls for medical experiments and the voluntary consent of a healthy person - see in this regard:

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5. The Gardi Law for all other clinical trials (studies related to other products and studies not related to a product).

6. The number (UE) 2017/745 for European treatment and the availability of medical devices, the registration (UE) 2017/746 for European treatment and the availability of medical devices for in vitro diagnostics

7. ARTICLE R.4127-15, The medicine does not participate in biomedical retrieval on people in the conditions present at home; It is necessary to ensure the regulation and the persistence of these findings as well as the objective of its conclusions. The treating physician who is involved in biomedical research, just as the investor, must ensure that the realization of the study is neither altered nor the relationship of trust that lies with the patient nor the continuity of care.Some point out that: The law must enact the ethical rules of the medical profession as a code that is used by the judiciary in cases of medical liability to grant the injured party compensation for shortcomings in medical aspects. See in this regard:E. TERRIER: Medical Dentistry and Law. Hospital Studies, coll. Theses, Bordeaux 2003.

8. See the report of the Joint Committee of the House of Representatives issued on 5/3/2018 and what was mentioned regarding the legislation of some Arab and foreign countries.The executive regulations of the law were issued by Prime Ministerial Resolution No. 927 of 2022 on 3/12/2022.

9. Abdel Aziz Abdel Moati Alwan: Constitutional and legal controls for conducting clinical medical research - a study published in the journal Spirit of Laws, Issue 96 - October 2021 - p. 281, Mervat Mansour Hassan: Medical and practical experiments in light of the sanctity of the physical entity - organ transplantation and transplantation - cloning - stem cells - Dar Al-Jamia Al-Jadida - Alexandria - 2016 - p. 10.

10. Claude Ameisen (J.): Ethics, medicine and society: understand, reflect, decide, ethical space, edition., 2007 p. 279.The researcher refers in his book on (Ethics, Medicine and Society) to how to deal with ethical issues and reconcile theoretical foundations with concrete and circumstantial analyses, in light of what has been achieved by biomedical progress.

11. Essam Ahmed Mohamed: The General Theory of the Right to Bodily Integrity - Dar Al Fikr Wal Qanun - Mansoura - 2008 - p. 992 and beyond.Medical work is defined as any activity that affects the human body or soul and is consistent with its nature and quality with the scientific principles and rules known theoretically and practically in the science of medicine, and is performed by a legally authorized physician with the aim of detecting, diagnosing and treating the disease to achieve recovery or alleviate or limit the pain of the disease or prevent the disease or aims to maintain the health of individuals or achieve a social interest provided that the person on whom this work is performed consents. See in this regard - Osama Abdullah Qaid: Criminal Liability of Doctors - 2nd ed. - Dar Al-Nahda Al-Arabiya - Cairo - 1990 - p. 12. And the ruling of the Court of Cassation: Appeal No. 249 for the year 44 Q, Session 11/3/1974, Technical Office 25, Vol. 1, p. 263.

12. Hossam El-Din Kamel El-Ahwani: Legal Problems Raised by Human Organ Transplantation Operations - A research published in the Journal of Legal and Economic Sciences, Issue 1 - Series 17 - Ain Shams University Press - 1975 - p. 10 and beyond.

13. Hamdi Abdel Rahman: The infallibility of the body - a research published in the Journal of Legal and Economic Sciences - Ain Shams University - July 1980 - Volume 22 - Issue 1 - Page 59 and beyond, where he indicates that the human body is the physical landing place for life itself and therefore the principle of the infallibility of the body targets life in addition to supporting the individual health of the person; therefore, it is permissible to touch the body for health considerations, however, it is not permissible to force him to undergo a surgical operation or to pressure his will by force.

14. Tariq Sorour: Transferring human organs between living beings - Dar Al Nahda Al Arabiya - Cairo – 2001, p. 78.

15. Some indicate that there is a reciprocal relationship between medicine and law and that medicine has played a large and vital role in developing medicine - Khaled bin Al Nawa: Controls of the legitimacy of medical experiments and their impact on civil liability - Dar Al Fikr and Law - Mansoura - 2010 - Page 55.

16. The legislator regulated human organ transplantation by Law No. 5 of 2010 - see in this regard - Khaled Mustafa Fahmy: The Legal System for Human Organ Transplantation and Combating Human Organ Trafficking - Dar Al Fikr Al Jami'i - Alexandria - 2012.

17. Samira Ayed Al-Diyat: Human Organ Transplantation and Transfer Operations between Sharia and Law - Dar Al Thaqafa Library for Publishing and Distribution - Amman - Jordan - 1999 - p. 16.

18. Cayron (J.): Human Experimentation and Biomedical Research Two Years After Application of the Law, the Right of Human Biology Newly Arranged Under Direction alain Serial Edition, 2000, p. 19.

19. Hassan Kireh: Introduction to the Law - Mansha'at Al Maaref - Alexandria - 2000 - p. 449.

20. The declaration was issued by the UNESCO General Conference in October 2005 at its thirty-third session held in Paris, where it addressed the ethical issues imposed by medicine, life sciences and related technologies applied to humans, taking into account their social, legal and environmental dimensions.

21. international rules and declarations on the Internet:

- Nuremberg Code (Available at: http://ohsr.od.nih.gov/guidelines/nuremberg.html, accessed 17 January 2009).
- Declaration of Helsinki (Available at http://www.wma.net/en/30publications/ 10policies/ b3/index).
- CIOMS: International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002) (Available at http://www.cioms.ch/ publications/layout_guide2002.pdf.
- UNESCO Universal Declaration on Bioethics and Human Rights (2005) (Available at http://portal.unesco.org/en/ev.php-URL.
- Nuffield Council on Bioethics: the Eth ics of Research related to Healthcare in Developing Countries (2002) (Available at http:// www.nuffieldbio

22. Mervat Mansour Hassan: The previous reference - p. 23.

23. Some indicate that the researcher must study the methodological principles in medical research, so he must be a student of epidemiology and pathological phenomena, and potential risk factors from studies, and develop a protocol that includes the important points in medical research, and conduct statistics and test hypotheses, and the best way to ensure the existence of a causal relationship between taking the treatment and the observed result at the end point, see in this regard:L.-M. Joly et C. Joly: Principles of méthodologie en recherche biomédicale, www.link.springer.com/content/pdf/10.1007/978-2-287-99129-5_40.pdf.Where he points out that: Biomedical research is about describing and understanding the functioning of the organism and its diseases (their causes, their manifestations, the way to diagnose and treat them)

24. See in this regard - Ashraf Fawzy Youssef: Rules and Ethics of Scientific Research in the Medical Field - Dar Al Nahda Al Arabiya - Cairo - 1993 - p. 27,where he refers to experimentation on animals prior to experimentation on humans and the ethical rules of scientific research and the ethical problems facing the researcher.

25. See in this regard: Convention on the Laws of Man and Biomedicine, Strasbourg, November 1996, Art. 15-17. pp. 21-24.

26. Medical experimentation or medical research differs from scientific research, as scientific research is a tool for analyzing information and knowledge with the aim of reaching certain facts - Abdul Qader Al-Shaikhli: Rules of Legal Research - Dar Al-Thaqafa - 1999 - 1st ed. - p. 8, and experimentation in research methods means intervening in the course of phenomena to uncover a hypothesis or to verify its validity, and it is part of the experimental method, and it was said that it is what is done first to avoid the deficiency in something and fix it.

27. See in this regard: Georges Leroux: La deontologie de l'experimentation chez l'humain Ottawa, 1978, p. 7.

28. Ashraf Jaber: Insurance against civil liability for doctors - Dar Al-Nahda Al-Arabiya - Cairo - 1999 - p. 294.

29. Directive 2010/63/UE of the European Parliament and Council of September 22, 2010 relating to the protection of animals used for scientific purposes.This directive sets out measures to protect animals used for scientific or educational purposes.This Directive establishes measures for the protection of animals used for scientific or educational purposes.

30. Cairo University has issued the draft Egyptian guide for the ethical treatment of experimental animals in education and scientific research, within the framework of ethical values and renewed knowledge.

The guide includes all aspects of animal care, use and treatment for scientific purposes in the specializations of medicine, pharmacy, veterinary medicine, biology and agriculture. It also includes the principles of animal care and use, the basics of humane treatment of animals in scientific activities and sources of obtaining them, and the responsibilities of researchers and institutions. The guide includes several axes related to the responsibilities of researchers and teachers, the acquisition of animals in accommodation and shelter facilities, reducing pain and suffering, euthanasia, identification and numbering records, examination of dead animals and safe disposal of carcasses, by establishing a set of principles to guide and advise researchers, teachers, institutions and ethical committees for the care and use of animals in education and scientific research in accordance with international standards, and enhancing justified motives for using animals to achieve a balance between the desired scientific benefits and the potential harmful effects on animal welfare, in addition to encouraging the development and application of alternative technologies for the use of animals for educational and research purposes and using the minimum number of animals that do not negatively affect the educational and research process. The university is currently establishing the integrated facility for experimental animals, as the first technological incubator according to the Science, Technology and Innovation Incentives Law, which includes: laboratories and entities that support scientific research based on animals, innovation in clinical studies, and providing business services and technical and practical facilities for scientific research projects to reach prototypes that can be manufactured, especially in diagnosing diseases and producing medicines. Referred to: cu.edu.eg › ar › Cairo-University-News-12530

31. Abdel Aziz Abdel Moati Alwan: The previous reference - p. 300.

32. The concept of clinical research is the same as clinical trials, which is an ancient concept that was first carried out by the Persian philosopher and physician Ibn Sina at the beginning of the first quarter of the eleventh century AD and addressed in his book The Canon of Medicine; where he set the experimental rules and limited the medical drugs and medicines used at that time in these experiments and provided them with an accurate guide to reveal the extent of their success in treating incurable diseases in his era - see the report of the Joint Committee of the House of Representatives issued on 5/3/2018 - p. 5.

33. Khaled Mustafa Fahmy: The previous reference - p. 115, where he refers to the difference between medical therapeutic experiments and scientific experiments.The French legislator in Article (L209-1) of Law No. 1138 of 1988 had indicated the difference between therapeutic and non-therapeutic medical research, stating that: Biomedical research that is expected to have a direct therapeutic benefit for the person participating in it is research with a direct therapeutic purpose. All other research, whether related to patients or not, has no direct therapeutic purpose.The biomedical research that awaits a direct therapeutic benefit for the person who is preparing are research to a direct therapeutic conclusion. All other research, whether related to sick or not, is without direct therapeutic conclusion.

34. Registration (UE) no. 536/2014 of European Parliament and Council on April 16, 2014 to contact other clinics...,

35. The principle states that: General principle, A clinical trial may be conducted only if: (a) the rights, safety, dignity and well-being of subjects are protected and prevail over all other interests; and (b) it is designed to generate reliable and robust data.

36. Clinical Trials Guidance Documents issued by the FDA at www.fda.gov › science-research › clinical-trials-and, NIH and Other Federal Guidelines & Policies for Clinical Research at www.niams.nih.gov › grants-funding › conducting

37. Khaled Hamdi Abdel Rahman: Medical Experiments - Dar Al Nahda Al Arabiya - Cairo - 2000- p. 405.

38. Khaled Bin Al-Nawa: The previous reference - p. 154 and following.

39. Mohamed Eid Al-Gharib: The previous reference - p. 101 and following.

40. The guide issued by the Supreme Council for the Review of Ethics of Clinical Medical Research emphasized the commitment of the authorities to provide evidence of following good medical practice, including the Declaration of Helsinki.

41. Smith PG, Morrow RH, Ross DA, editors. Oxford (UK):Field Trials of Health Interventions, A Toolbox. 3rd edition, OUP Oxford; 2015 Jun 1, (any activity undertaken with the objective of improving human health by preventing disease, by curing or reducing the severity or duration of an existing disease, or by restoring function lost through disease or injury) Where it refers to a medical intervention that may be preventive to prevent the occurrence or spread of a disease, or therapeutic to treat or alleviate the effects of a disease.

42. Study on interventional and non-interventional clinical research at (acrpnet.org › 2020/02/11 › interventional-or-non) Interventional or Non-Interventional? Analyzing the Differences Between Clinical Studies Using Medicines in the European Union A non-interventional study (also referred to as an observational study) is a type of study in which all participants receive routine clinical care and are not assigned per protocol to a specific treatment or health intervention. Data from these studies are often evaluated using epidemiological methods. Article 2 of the repealed European Directive DIR 2001/20/EC defines a “non-interventional study” as a study in which the medicinal product(s) is prescribed independently of the study participant’s enrolment and as part of a therapeutic strategy, including diagnostic and monitoring procedures, which is not pre-specified by the study protocol, but is applied in accordance with clinical practice. As such, these studies seek to understand the use of a marketed product in real-world settings, including risks/benefits, use of healthcare resources, and patient/caregiver satisfaction. This is consistent with (REG 536/2014) where non-interventional studies do not fall within the EU requirements, and are not required to be registered in its database, but are included in EU legislation.

43. Smith PG, Morrow RH, Ross DA: Field Trials of Health Interventions: A Toolbox. 3rd edition.Oxford (UK): OUP Oxford; 2015 Jun 1.

44. Some point out that the mother and fetus must be protected when conducting medical research on a pregnant woman and that it does not lead to abortion and with the pregnant woman's informed consent - Khaled Bin Al-Nawa: The previous reference - p. 148. Article L1121-5 of the French Health Code, amended by Law No. 300 of 2012, states that: Pregnant women, postpartum women and breastfeeding mothers may not be asked to participate in interventional research except under the following conditions: [1] The importance of the expected benefit to them or to the child is such that it justifies the expected risks incurred; [2] This research is justified in light of the expected benefit to other women in the same situation or to their children and provided that it is not possible to conduct research with similar effectiveness on another group of the population. In this case, the expected risks and limitations involved in the research must be minimal.

45. Some refer to the multiple and varied errors of doctors, whether in the field of initial examinations, diagnosis, prescribing and following up on treatment, or following up on the medical condition and surgical intervention - Munir Riad Hanna: The previous reference - p. 460 and following.

46. Surat At-Tin - Verses 1:4.

47. Mervat Mansour Hassan: The previous reference - p. 77.

48. Essam Ahmed Mohamed: The previous reference - p. 477.

49. Mohamed Hassan Qasim: Proving Error in the Medical Field - Dar Al-Jamia Al-Jadida - Alexandria - 2016 - p. 192.

50. Habeeba Saif Salem Rashid Al-Shamasi: The Legal System for Protecting the Human Body - PhD Thesis - Ain Shams University - 2005 - p. 239.

51. Khaled Mustafa Fahmy: The previous reference - p. 5 and beyond.

52. Mahmoud Naguib Hosni: The Right to Bodily Safety and the Extent of Protection Guaranteed by the Penal Code - Journal of Law and Economics - Vol. 29 - No. 3 - 1959 - p. 571.

53. Mohamed Eid Al-Gharib: The previous reference - p. 48 and beyond.

54. Samira Ayed Al-Diyat: Human Organ Transplantation Operations Between Sharia and Law - Dar Al-Thaqafa Library for Publishing and Distribution - Amman - Jordan - 1999 - p. 41.

55. Ahmed Shawqi Abu Khatwa: Criminal Law and Modern Medicine - Dar Al Nahda Al Arabiya - Cairo - 1986 - p. 20 and after, Muhammad Saad Khalifa: The Right to Life and Bodily Safety - Modern Arab Press - Cairo - 1996 - p. 48.

56. The Court of Cassation ruled that a doctor was responsible for causing the death of a child as a result of his diagnosis of the condition as rheumatism in the knee and not because he was infected with rabies, as the doctor knew that he had previously been bitten by a dog and refused to take him to the dog hospital, which resulted in his death. This ruling was based on the fact that the doctor had committed a technical professional error by making a wrong professional diagnosis and not taking precautions for analysis and clinical examination to verify the nature of the disease, despite the existence of strong reason to suspect it, and a material error because after the appearance of rabies, he refused to send him to the dog hospital for fear of being punished for his delay in presenting him - Court of Cassation ruling on 6/30/1953, Collection of Cassation Rulings, Vol. 4, Issue 3, p. 1033, referred to by - Munir Riad Hanna: The previous reference - p. 567.

57. Khaled Mustafa Fahmy: The previous reference - p. 13.

58. Mahmoud Naguib Hosni: The previous reference - p. 546.

59. Article 10 of Law 415 of 1954 regarding the practice of medicine stipulates that practicing medicine without a license shall be punished by imprisonment for a period not exceeding two years and a fine not exceeding two hundred pounds, or by one of these two penalties.

60. The medical profession aims to treat the patient, alleviate the pain of illness, and maintain the health of patients. It includes diagnosis, performing surgical operations, and prescribing treatment under traditional medical treatments without innovation or introducing new medical arts. It is any activity that occurs to the human body that is consistent in its origins and nature with the rules approved medically by a person authorized to do so in order to detect, diagnose, and treat the disease to achieve complete or partial recovery, or with the intention of preserving the health of individuals or achieving an interest or merely preventing the disease - see in this regard - Khaled Mustafa Fahmy: The previous reference - p. 57 and following.

61. Hossam El-Din Kamel El-Ahwani: Problems raised by human organ transplants - Journal of Legal and Economic Sciences - Issue 1 - Vol. 17 - 1975 - p. 26.

62. Tariq Surur: The previous reference - p. 88.

63. For more details on the right to physical safety in Egyptian legislation and international agreements, see: Khaled Mustafa Fahmy: The previous reference - p. 27 and beyond.

64. Mervat Mansour Hassan: The previous reference - p. 223, where she refers to a case in France regarding the consent of the family of a young man whose condition was hopeless and in the final stages of CJD to conduct an experiment on him, despite the fact that the risks or benefits of this experiment was conducted on animals, so the court considered the consent of the family of the young man whose recovery was hopeless - see the same reference - p. 230

65. The Egyptian legislator has set deterrent penalties in Book Three of the Penal Code regarding any assault on the body of persons. A doctor commits an intentional error that is punishable if he takes the life of a patient under the pretext of compassion - see: Munir Riyad Hanna: The previous reference - p. 394 and beyond.

66. Scientific experiments or non-therapeutic experiments are those experiments conducted on healthy or sick volunteers who have no direct interest in conducting the experiment, but rather the direct goal is to apply a modern method of a scientific research nature, simply to satisfy a scientific desire or scientific curiosity or with the aim of discovering the effectiveness of a certain method in the field of diagnosis, treatment or prevention and the extent of the expected risks in these cases. Some define them as: "Those experiments that aim to create a pathological condition in a healthy volunteer and subject him to experiments and research to reach the optimal method of treatment, or prevention and the extent of the expected risks in these cases. Some define them as: "Those experiments that aim to create a pathological condition in a healthy volunteer and subject him to experiments

and research to reach the optimal method of treatment, or a modern method may be applied to him to demonstrate its effectiveness" - Ramisa Kahoul: Ramisa Kahol: Criminal liability of the legal person for medical experiments - University of the Mentouri Brothers - Constantine 1 - Volume 9 - Issue 4 - October 2022.

67. Referred to by - Muhammad Eid al-Gharib: The previous reference - p. 28 and following, Khaled Mustafa Fahmy: The previous reference - p. 142.

68. Referred to by - Habeeba Saif Salem: The previous reference - p. 299.

69. Muhand Salah Al-Ezza: Criminal Protection of the Human Body - Dar Al-Jamia Al-Jadida - Alexandria - 2002 - p. 59.

70. The World Health Organization defined the right to health as: a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity. The enjoyment of the highest attainable standard of health is one of the basic rights of every human being, without discrimination based on race, religion, political belief, economic or social condition - Constitution of the Organization - Official Documents No. 240 - approved at the New York Conference on 7/22/1946.

71. Tariq Surur: Transplantation of Organs Between Living Persons - 1st ed. - Dar Al-Nahda Al-Arabiya - Cairo - 2001 - p. 47.

72. 72. Adel Yahya: Criminal Protection of the Right to Health between Theory and Practice - Dar Al-Nahda Al-Arabiya - Cairo - 2010 - p. 53.

73. Thouvenin (D.): The judicial construction of a legitimate human body, Dalloz Recueil, From Series, Justices, May 2001, p. 113. The researcher refers to ensuring the priority of the human being and his dignity and ensuring respect for him since birth and the non-commercial nature of dealing with the human body and prohibiting some illegal practices on it, and adds that the human body cannot be the subject of trade, ownership, sale or rent, and that dealing must be for medical treatment necessity. Jean René BINET, Droit et progrès scientifique. Science du droit, valeurs et biomédecine, Paris, PUF, 2002, p. 20-24.The text of the law of December 19, 2008 in France amending articles 225-17 of the Penal Code and 16-1-1 of the Civil Code and others. As follows: Article 16-1-1, [1] The respect due to the human body does not stop at death. [2] The remains of deceased persons, including the ashes of those whose bodies have been cremated, must be treated with respect, dignity and decency. Paragraph 1 of Article 225-17 of the Penal Code also states: "Any attack on the integrity of a corpse by any means whatsoever shall be punishable by one year's imprisonment and a fine of 15,000 euros." See also a published article on trespass and violation of corpse integrity: Philippe Dupuis: The violation of sépulture and the attack on the integrity of the corpse: when can we retain these infractions?, Publication, Résonance n° 145, December 10, 2018.

74. Evans, John H: Playing God? Human Genetic Engineering and the Rationalization of Public Bioethical Debate, Chicago, 2002, Vol. 52, No. 3 (FALL 2002), pp. 421-427 (7 pages), Published By: University of North Carolina Press.

75. 75. Publications of the World Health Organization - Regional Office for the Middle East - This document aims to provide guidance on the research ethics review process and to enhance the quality of research ethics committees, by setting 10 standards for the research ethics review system. Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants. See the website - www.emro.who.int › ar › rpc, www.who.int › publications.

76. 76. Article L1122-2 of the French Health Code, as amended by Law 232 of 2020, provides for certain protections for minors who are unable to express their will to carry out or not to carry out research, as follows: [1] Minors who are not emancipated, protected adults or adults who are unable to express their consent and who are not subject to legal protection measures, receive, when considering their participation in research involving human beings, the information provided for in Article L. 1122-1 adapted to their capacity to understand, whether from the investigator or the persons, bodies or authorities responsible for assisting, representing or authorizing them for the research, who are themselves informed by the investigator. They are consulted as much as their condition allows. Their personal support is requested for their participation in research involving human beings. In any case, their refusal or their consent cannot be ignored. [2] When research involving human subjects is carried out on a minor who is not emancipated, consent is given, where appropriate, by those exercising parental authority. However, this consent may be given by the sole holder of parental authority present, subject to compliance with the following conditions: [a] the research involves only minimal risks and limitations; [b] the minor is not suitable for research as a healthy volunteer; [c] the other holder of parental authority cannot give his authorization within time limits compatible with the methodological requirements for carrying out the research in relation to its purposes. When the minor participating in the research becomes an adult during his participation, his consent must be confirmed after providing the appropriate information.When research involving human subjects is carried out on a minor, where applicable under guardianship, authorization is given by his legal representative and, if the committee referred to in article L. 1123-1 considers that the research involves the importance of the limitations or the privacy of the interventions it leads to, or a serious risk of attack on private life or the integrity of the human body, by the family council if it has been established, or by the guardianship judge.When the minor who participated in it, on the date of completion of the research, acquires legal capacity, he or she personally becomes the recipient of any information transmitted by the researcher or promoter. [3] A person subject to judicial preventive measures may not be required to participate in research involving human beings.When research involving human beings is carried out on an adult under guardianship, consent is given by the interested party with the assistance of his or her guardian. However, if the adult subject to guardianship is requested to participate in research that the Commission referred to in article L.1123-1 considers to involve, due to the importance of the restrictions or the privacy of the interventions that lead to a serious risk of harm to private life or the integrity of the human body, the guardianship judge is referred to in order to ensure that the adult is able to consent. In the event of incapacity, the judge decides whether or not to authorize research involving human beings.When research involving human beings is carried out on an adult subject to a future guardianship, family authorization or guardianship measure, with representation relating to the person, the authorization is given by the person responsible for representing him or her. However, if the committee referred to in article L. 1123-1 considers that the research involves, by virtue of the importance of the restrictions or the specificity of the interventions it leads to, a serious risk of invasion of the private life or integrity of the person. The body, the authorization is granted by the family council if it has been established or by the guardianship judge. When research involving a human being who meets the conditions provided for in article L. 1121-8 is carried out on an adult who is unable to express his consent and is not subject to legal protection measures, authorization is granted by the trusted person provided for in article L. 1111-6, failing which, by the family, or by a person who maintains close and close relations with the person concerned. The party concerned is informed as soon as possible and his consent is requested for the possible continuation of this research if he regains his capacity to consent. However, if the committee referred to in article L. 1123-1 considers that the research involves, by virtue of the importance of the restrictions or the specificity of the interventions it leads to, a serious risk of invasion of the private life or integrity of the human being. body, authorization is granted by the guardianship judge.[4] The consent provided for in paragraph II of III is granted in the manner provided for in article L. 1122-1-1. The authorizations provided for in paragraphs I and VI of II and paragraphs III and IV of III are submitted in writing.

69. Referred to by - Muhammad Eid al-Gharib: The previous reference - p. 28 and following, Khaled Mustafa Fahmy: The previous reference - p. 142.

70. Referred to by - Habeeba Saif Salem: The previous reference - p. 299.

71. Muhand Salah Al-Ezza: Criminal Protection of the Human Body - Dar Al-Jamia Al-Jadida - Alexandria - 2002 - p. 59.

72. The World Health Organization defined the right to health as: a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity. The enjoyment of the highest attainable standard of health is one of the basic rights of every human being, without discrimination based on race, religion, political belief, economic or social condition - Constitution of the Organization - Official Documents No. 240 - approved at the New York Conference on 7/22/1946.

73. Tariq Surur: Transplantation of Organs Between Living Persons - 1st ed. - Dar Al-Nahda Al-Arabiya - Cairo - 2001 - p. 47.

74. Adel Yahya: Criminal Protection of the Right to Health between Theory and Practice - Dar Al-Nahda Al-Arabiya - Cairo - 2010 - p. 53.

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76. Evans, John H: Playing God? Human Genetic Engineering and the Rationalization of Public Bioethical Debate, Chicago, 2002, Vol. 52, No. 3 (FALL 2002), pp. 421-427 (7 pages), Published By: University of North Carolina Press.

77. Publications of the World Health Organization - Regional Office for the Middle East - This document aims to provide guidance on the research ethics review process and to enhance the quality of research ethics committees, by setting 10 standards for the research ethics review system. Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants. See the website - www.emro.who.int › ar › rpc, www.who.int › publications.

78. Article L1122-2 of the French Health Code, as amended by Law 232 of 2020, provides for certain protections for minors who are unable to express their will to carry out or not to carry out research, as follows: [1] Minors who are not emancipated, protected adults or adults who are unable to express their consent and who are not subject to legal protection measures, receive, when considering their participation in research involving human beings, the information provided for in Article L. 1122-1 adapted to theircapacity to understand, whether from the investigator or the persons, bodies or authorities responsible for assisting, representing or authorizing them for the research, who are themselves informed by the investigator. They are consulted as much as their condition allows. Their personal support is requested for their participation in research involving human beings. In any case, their refusal or their consent cannot be ignored. [2] When research involving human subjects is carried out on a minor who is not emancipated, consent is given, where appropriate, by those exercising parental authority. However, this consent may be given by the sole holder of parental authority present, subject to compliance with the following conditions: [a] the research involves only minimal risks and limitations; [b] the minor is not suitable for research as a healthy volunteer; [c] the other holder of parental authority cannot give his authorization within time limits compatible with the methodological requirements for carrying out the research in relation to its purposes. When the minor participating in the research becomes an adult during his participation, his consent must be confirmed after providing the appropriate information.When research involving human subjects is carried out on a minor, where applicable under guardianship, authorization is given by his legal representative and, if the committee referred to in article L. 1123-1 considers that the research involves the importance of the limitations or the privacy of the interventions it leads to, or a serious risk of attack on private life or the integrity of the human body, by the family council if it has been established, or by the guardianship judge. When the minor who participated in it, on the date of completion of the research, acquires legal capacity, he or she personally becomes the recipient of any information transmitted by the researcher or promoter.[3] A person subject to judicial preventive measures may not be required to participate in research involving human beings.When research involving human beings is carried out on an adult under guardianship, consent is given by the interested party with the assistance of his or her guardian. However, if the adult subject to guardianship is requested to participate in research that the Commission referred to in article L.1123-1 considers to involve, due to the importance of the restrictions or the privacy of the interventions that lead to a serious risk of harm to private life or the integrity of the human body, the guardianship judge is referred to in order to ensure that the adult is able to consent. In the event of incapacity, the judge decides whether or not to authorize research involving human beings. When research involving human beings is carried out on an adult subject to a future guardianship, family authorization or guardianship measure, with representation relating to the person, the authorization is given by the person responsible for representing him or her. However, if the committee referred to in article L. 1123-1 considers that the research

involves, by virtue of the importance of the restrictions or the specificity of the interventions it leads to, a serious risk of invasion of the private life or integrity of the person. The body, the authorization is granted by the family council if it has been established or by the guardianship judge. When research involving a human being who meets the conditions provided for in article L. 1121-8 is carried out on an adult who is unable to express his consent and is not subject to legal protection measures, authorization is granted by the trusted person provided for in article L. 1111-6, failing which, by the family, or by a person who maintains close and close relations with the person concerned. The party concerned is informed as soon as possible and his consent is requested for the possible continuation of this research if he regains his capacity to consent. However, if the committee referred to in article L. 1123-1 considers that the research involves, by virtue of the importance of the restrictions or the specificity of the interventions it leads to, a serious risk of invasion of the private life or integrity of the human being. body, authorization is granted by the guardianship judge.[4] The consent provided for in paragraph II of III is granted in the manner provided for in article L. 1122-1-1. The authorizations provided for in paragraphs I and VI of II and paragraphs III and IV of III are submitted in writing.

77. Some point to the distinction between the therapeutic goal for the benefit of the incompetent or partially incompetent, in which case the consent of his legal representative is binding. However, if the purpose is preventive or to test a new method, the consent of his legal representative is not sufficient. The opinion of the person undergoing the experiment can be taken into account if possible if he objects to the experiment, even if his legal representative agrees. His will must be respected - Soheir Montaser: Civil Liability for Medical Experiments in Light of the Rules of Civil Liability for Doctors - Dar Al Nahda Al Arabiya - Cairo - 1990 - p. 25 and beyond.

78. The explanatory memorandum of the Egyptian Law No. 214 of 2020 indicated that the goal of clinical medical research is to provide the most efficient and safe treatments for the patient, prevent the spread of diseases in society, and provide the ability to develop a health policy based on evidence. The memorandum added that in order to achieve the state's role in promoting and protecting the health, welfare and rights of patients, including those participating in medical research, with the identification of special protection rules for groups and participants from categories deserving additional protection, i.e. protecting subjects in clinical medical research, preserving their rights, enhancing the expected benefit of medical research by providing distinguished medical care, establishing evidence-based medicine, and promoting the national pharmaceutical industry.

79. Muhammad Sami Al-Shawa: The Responsibility of Doctors and Its Applications in the Penal Code - Dar Al-Nahda Al-Arabiya - Cairo - 2003 - p. 129.

80. Khalid bin Al-Nawa: The previous reference - p. 60.

81. See the report of the Joint Committee of the House of Representatives issued on 5/3/2018 and what was mentioned regarding the legislation of some Arab and foreign countries.

82. The FDA is responsible for protecting and promoting public health through the control and supervision of food safety, tobacco products, caffeine products, dietary supplements, prescription and over-the-counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices (ERED), cosmetics, animal foods & feed and veterinary products.

83. FDA report on 4/1/2018 (The Drug Development Process) - on its website - (www.fda.gov).

84. Some point to the importance of testing drugs on humans after testing them on animals, as the researcher learns about the effect and reflection of the new treatment after the experiment on humans so that it can be marketed - Muhammad Eid Al-Gharib: The previous reference - p. 8.

85. 85. Some studies have dealt with a stage prior to the four stages called the zero stage, and it deals with a number of up to 10: 15 participants in the research, and its purpose is to ensure that the treatment behaves as desired in humans. When pre-clinical research results in a promising drug, it is confirmed that the drug behaves as expected when given to humans. The focus is on how the body processes the drug and what effects it has on the body. The doses are very small and only a small number of participants are given. See: www.cancertodaymag.org ›,The Five Phases of Clinical Research.

86. As we have already mentioned, in France the Gardi law applies and defines RIPH as organized research carried out on healthy, volunteer subjects. Or patients with the aim of developing biological or medical knowledge and aiming to evaluate: [1] The mechanisms of the human body, normal or pathological. [2] The effectiveness and safety of carrying out actions or using or administering products for the purpose of diagnosing, treating or preventing pathological conditions.According to the Gardi law, there are three categories of research involving humans: [1] Interventional research which involves an intervention on a person who is not provided with usual care, [2] Interventional research which is not related to drugs and involves only minimal risks and limitations, [3] Non-interventional research in which all procedures and products are carried out in the usual way, without additional or unusual diagnostic or therapeutic procedures or monitoring.See: National Consultation Report of the Clinical Trials Base for Stakeholders in the Clinical Research Ecosystem January 18, 2023, p. 16.

87. Abdel Aziz Abdel Moati Alwan: The previous reference - p. 367

88. Article 1/22 of Egyptian Law No. 214 of 2020 defines side effects as: any minor medically undesirable effects that arise on the subject during the use of the research intervention on him. Article 1/23 of the same law defines serious side effects as: effects that arise on the subject due to the use of the research intervention on him, and result in causing serious harm to him, or endangering his life.

89. Sohair Montaser: The previous reference - p. 42 and following.

90. See: A report issued by the American Cancer Society on the stages of clinical trials on the website: www.cancer.org › phases-of-clinical-trials Types and Phases of Clinical Trials - American Cancer Society.

91. The US Food and Drug Administration (FDA) in the United States of America and its affiliated countries grants permission to researchers before testing the treatment on humans and after reviewing the results of the studies so that it can determine whether the treatment is safe for testing on humans or not, as well as how to manufacture the drug and the protocols for the study and to know the capabilities and skills of the clinical trial team as follows:

- Results from studies so that the FDA can decide whether the treatment is safe for testing in people.

- How the drug is made, who makes it, what's in it, how stable it is, and more.
- Detailed outlines for the planned clinical studies, called study protocols, are reviewed to see if people might be exposed to needless risks.
- Details about the clinical trial team to see if they have the knowledge and skill to run clinical trials.
- See in this regard - The investigative new drug (IND) application, Types and Phases of Clinical Trials, on www.cancer.org › phases-of-clinical-trials

92. Article (L1121-2) of the French Code states that: No research involving human subjects can be effected:

- if it is not based on the last state of scientific knowledge and on sufficient preclinical experimentation;
- If the risk is clearly visible to the people who have entered the search est hours in proportion to the beneficiary required for these people or the operator of this search;
- If it does not go to the scientific environment of the human being and those who are susceptible to this condition;
- If the search is applicable to the human being, it is not possible to tell the façon that is affected by the minimum of the douleur, the designs, the pain and all the more inconvenient it is possible to lie in the malady or in the search, in the tenant of a particulièrement of the degree Maturité for the mineurs and the comprehension capacity for the masters who have the right to express their consent.
- There are people who are interested in a search that applies to the person who is most important to those who are interested in science and society. The research involves the human being only if all these conditions are met. Their compliance must be strictly adhered to.

93. The research team explains the details of the experiment to the research participants, who sign a form stating their knowledge and informed consent to all the data and information indicated by the research team, the duration of the research and its time plan from beginning to end. Medical and laboratory examinations are conducted on the participants to verify their health conditions and record this in a special file for monitoring their health status. The competent authorities are notified of those accepted for the research and those excluded and the reasons for exclusion, if their participation will not benefit the research or harm them. The researched person does not participate in more than one experiment at a time. Appointments are set for them and they are registered in random groups without selection. The participants in the research are diversified and not from one age group. Reduced doses of the new treatment being tested are provided, and the results are compared by the researchers.

94. The Office of Research Integrity of the US Department of Health and Human Services has found Dr. Poisson, a physician and researcher at Saint-Luc Hospital and professor at the Faculty of Medicine of the University of Montreal, guilty of "crimes in which he falsified numerous clinical trial data over a period of thirteen years as part of the largest breast cancer research in North America." He asserts that he was motivated by a deep compassion for women suffering from breast cancer, and that he falsified patient data that he submitted to the NSABP (National Surgical Adjuvant Breast and Bowel Project) as part of a large multicenter study on the breast and bowel. This case is referred to in: Hubert Doucet: « De l'éthique de la recherche à l'éthique en recherche », Éthique publique, vol. 12, n° 1 | 2010, 13-30.

95. One American court ruled on the patient's right to information and self-determination regarding his health, the case of Schloendorff v. New York Hospital in 1914. The landmark ruling on the above-mentioned legal issue stated that "...every adult and sane person has the right to determine what shall be done with his body; and a surgeon who performs an operation

96. Some point out that doctors do not yet know which treatment is better, as the standard treatment and the new treatment are given in a double-blind study, so the patient does not know which treatment to take. www.cancer.org › phases-of-clinical-trials Types and Phases of Clinical Trials - American Cancer Society.

97. In the United States, when a Phase III clinical trial (or sometimes Phase II clinical trial) shows that a new drug is more effective or safer than an existing treatment, a New Drug Application (NDA) is submitted to the Food and Drug Administration (FDA) for approval. The FDA reviews the clinical trial results and other relevant information. Based on the review, the FDA decides whether to approve the treatment for use in patients with the disease for which the drug is being tested. If approved, the new treatment becomes the standard of care, and newer drugs may be tested against it before they are approved. If the FDA feels that more evidence is needed to prove that the benefits of the new treatment outweigh its risks, it may request more information or even order additional studies. See www.cancer.org › phases-of-clinical-trials Types and Phases of Clinical Trials - American Cancer Society.

98. Abdel Aziz Abdel Moati Alwan: Ibid. - p. 374.