The Legality of Medical Experiments on the Human Body According to the Algerian Health Law

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Abstract:
The subject of medical experiments on the human body is one of the important topics that have raised a great jurisprudential controversy about the legality of carrying them out as they relate to the human body, which must be protected and not touched, and therefore the process of medical experiments on humans raises the problem of balancing between two basic considerations, namely the freedom of scientific research and the need to respect the physical integrity of humans and not to prejudice it, which we will present in this study through a statement of conditions and guarantees The legality established by the Algerian legislator for the legality of these experiments.
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Introduction:
In recent years, modern medical methods have emerged that have exceeded the limits of traditional medical work, and the most important of these scientific achievements are medical experiments on humans, which are necessary for the progress of medicine and surgery, and to reduce many incurable diseases that ancient medicine was unable to treat. The human body is the fertile field that a doctor resorts to find a cure for a particular disease or to reach new scientific results.

Medical experiments on humans raise the problem of balancing two basic considerations: freedom of scientific research on the one hand, and the need to respect human physical integrity and not infringe on it on the other.

Therefore, we decided to research this subject to find out the legality of medical experiments on humans in comparative legislation and Algerian legislation. What are the conditions and legal guarantees established by the Algerian legislature for the legality of such experiments?

To answer these and other questions, we divided this study into two sections, the first of which was devoted to the conditions for permitting medical experiments on the human body, in the second we explained the legal controls for conducting these medical experiments.

The first topic: the conditions for the permissibility of medical experiments on the human body

Jurisprudence and the judiciary require the patient's consent to any medical work to which he is subject, as the person who undergoes the experiment is a free human being, who has sacred rights over his body that no one may infringe on without his consent, based on safeguarding his right to the integrity of his body and respect for his freedom.

Since it is a duty to respect the human person, in the field of medical experiments, the doctor or researcher cannot be consideredsolelyresponsible for making thedecisionto conduct a medical intervention or experiment on the patient or person under experimentation, but the latter must also have a role in deciding on conducting medical experiments on him, and he must have full capacity to do so unless his illness is critical and needs rapid intervention, then the doctor may intervene without his consent or even his absolute refusal to intervene, and this is what we will address in the following two requirements.

The first requirement: the consent of the person subject to the experiment

The principle of the inadmissibility of touching the human body is one of the most important basic principles that the legislator is keen on, as every person has the right to defend himself and his body against any attack he may be exposed to, and therefore it is considered the decisive decision on the extent to which his body is provided for treatment or any medical intervention or not.

One of the most important principles advocated by international conventions, including the Nuremberg Code.[1]Required considering the free and enlightened consent of the person subject to the experiment before conducting it, consent represents a moral and legal rule, as it is linked to the right of the individual to the integrity of his body, and self-determination regarding his personality and body when the necessary conditions are met, including writing, which we will present in two sections.

Subchapter I: The nature and conditions of consent in medical trials

We address the definition of the condition of consent in light of medical experiments first, and then we indicate the conditions that must be met by the consent of the person subject to the experiment to be a projected second.

First: The definition of consent requirement in medical trials

The patient's consent means expressing his will, explicitly, either by agreeing to the doctor's intervention to perform the associated treatment or rejecting it, and it may be personally or by his legal representative, and in this sense,it precedes medical work, and therefore medical intervention in medical experiments is not legitimate unless the person subject to the experiment agrees to it, and this condition is unanimously agreed upon by international declarations and conventions(2)and comparative health legislation(3) Including Algerian legislation, where the legislator stipulated that the person subject to the experiment must consent before testing it on him in Article 386/1 of the Algerian Health Code(4),which reads as follows: "Clinical studies can only be carried out if the persons willing to undergo the clinical study or, failing that, their legitimate representatives, express their free, express and informed consent, in writing..."

Second: The conditions of consent in the field of medical trials

We have seen that the doctor, to carry out the medical experiment on the person, must take his consent, that is, consult him and choose between experimenting on him or not, whether this experience is therapeutic(5)or non-therapeutic(6),and for this consent to be legitimate, jurisprudence and the judiciary require the availability of certain conditions in it, so that consent must be free, informed, insightful, issued by a competent person, and issued in written form, and that the doctor obtains it permanently, so it is not permissible to dispense with it. About him at any stage of the medical trial, which we will explain in turn.

01- Consent should be free

Freedom of consent means that it is not based on any coercion or pressure resulting from incapacity, or from psychological, social, or economic submission to the person subject to the experiment(7), and therefore any medical experiment carried out without obtaining the consent of the person concerned, represents an error on the part of the doctor responsible for the experiment, resulting in civil and criminal liability(8),even if this experiment is a medical necessity in the interest of the patient.

Consent must be free and insightful, i.e. By choice, and informed of the circumstances and results associated with conducting a medical experiment, and therefore the doctor experimenting must – as we will see – explain to his patients undergoing his experiments that the consent required of them is consent to conduct non-therapeutic trials(9).

Therefore, the doctor must refrain from exerting some economic or psychological pressure (10)on the person subject to the experiment to obtain his consent to experiment, such as paying him a sum of money(11) or deceiving him(12),as experimenting must be free of charge, except for compensation for damages that the person subject to the experiment may suffer, and this is what is stipulated in comparative legislation.(13)The Algerian legislator in Articles 392 and 398 of the Algerian Health Code (14).

02- Consent should be insightful

Forconsent to be valid, the doctor, before starting the experiment, must commit to informing him and providing him with all the necessary information about this experience, so that he can make his final decision to approve or reject with a free, informed, and conscious will.

The phrases used by the doctor must also be clear and understandable to the patient without ambiguity, or technical phrases that are difficult for the average person to realize and understand, taking into account the patient's intelligence, cultural, psychological, and health condition, social conditions, age and gender[15].

The principle of the obligation to inform the patient is an agreed condition in the international[16] and national domains[17], due to its importance of respecting the entity of persons and preserving their rights.

The Algerian legislation has addressed and confirmed this condition, and the legislator stipulated it in the Health Code[18]and the Code of Medical Ethics[19].By reviewing these texts, it is clear to us that the Algerian legislator obligated the doctor to inform his patient of all the honest and clear information about the medical work to be performed on him, with the need to respect the moral and professional rules applied in that, and did not even neglect the right of minors or incompetent people to inform, which made him Guaranteed to their legal representative according to the cases prescribed by law[20].

Accordingly, the doctor responsible for the experiment must inform the patient of the nature and subject of the experiment, the scientific method used in conducting it, the duration of time it takes, the desired benefits, and its risks, and explain the new treatment methods that may be resorted to when needed, while giving him the right to reject the experiment and withdraw satisfaction at any moment. If the doctor informs the person concerned of all these elements and information, and gives consent, then this consent is free, informed, and insightful.

It should be noted here that some of the elements of the media may raise some practical problems, in that the experimenter himself may be ignorant of some of its aspects, such as his lack of real and accurate knowledge of the potential risks of the experiment, due to the special nature of medical experiments, it is impossible to predict the risks, and thus the question arises about how he adheres to the duty of information and insight towards the person subject to the experiment?

In this regard, some argue that in therapeutic medical experiments, a person must realize that he is the subject of a medical experiment, and if the doctor omits this element, he has violated his duty to inform, and therefore he is considered responsible for this[21].

As for the scope of non-therapeutic scientific medical experiments, it is well established in jurisprudence and judgment that the doctor is obliged to inform comprehensive information, as he is obligated to inform the person subject of the experiment of all expected and potential risks, no matter how small the percentage of their achievement, and the person remains free to accept to undergo the experiment or not[22].

The burden of proving the obligation to gain insight lies with the doctor responsible for the experiment[23],which is recognized and adopted by the Algerian legislator[24].

Subchapter II: Form of Consent in Medical Experiments and Freedom to Withdraw from it

Jurisprudence and comparative law[25] argue that it is required that the consent issued by the person subject to the medical experiment be in writing, to ensure the minimum necessary for his protection, especially since these experiments are considered a non-therapeutic act, in which the subject often has no direct interest, as the risks that may result from the experiment may not be expected, and therefore consent must be obtained in a fixed and specific form, containing all the data related to the patient and the doctor, the type of medical intervention, and the subject of the medical experiment, and the dangers arising therefrom so that the person concerned signs from which he consents to the medical intervention or experiment. [26]

It is noted that the requirement of form has a double benefit, both for the person subject of the experiment as it allows him sufficient time to see the content of the experiment to be conducted on him, and thus slow down in making the right decision or for the experimenter to justify his action if the dispute occurs after the medical experiment.

Regarding Algerian law, we find that the legislator stipulates in article 386 of the Health Code that: "Clinical studies can only be carried out if the persons who are willing to undergo the clinical study or, if this is not possible, their legal representatives express their free, express and informed consent in writing", which indicates that consent must be emptied in a written document, as the consent of the person subject to the experiment must be in writing, whether therapeutic or non-therapeutic and in this condition to protect the experimental subject. And a reminder to the experimenterthe importance of medical intervention and its danger to the safety of people.

It should be noted here that the consent of the person subject to the experiment, which is written in a specific bond, is not limited to before the experiment only, but must remain present during all stages of the experiment until its end, and therefore the person may withdraw his consent at any time without entailing any responsibility[27], as the condition of writing - for those who stipulated it - is a necessary condition for the validity of consent, but it must be preceded by sufficient information to be considered a right of insightful consent, and the experimenter must prove it.

Perhaps the reason for the revocation of consent in the field of medical experiments, at any stage of the experiment, is due to the seriousness of these medical acts and their prejudice to the integrity of the human body [28].

The Algerian legislator has affirmed – in the Health Code – that consent may be withdrawn at any moment of the experiment, as long as the consent of the person subject to the experiment must continue until the last stage of it [29].

Therefore, consent is a prerequisite for the legality of medical and scientific experiments on the human body, and as a result, the medical experiment is illegal if the consent of the patient or

person subject to experimentation and its conditions are not met, and the responsibility of research doctors who conduct medical experiments without obtaining the consent of those subject to them [30].

Second requirement: the person's eligibility to conduct the medical experiment

The expression of will and ensuring the individual's freedom of choice is one of the requirements of freedom, which is considered a fundamental right of the individual, so eligibility - in addition to the condition of consent - is a necessary condition for the legalization of medical experiments on humans. For consent to produce its effect, it must be issued by the person subject to the experience himself, and this person must be able to perceive and choose, but this right is transferred to his legal representative in cases of young age or suffering from a symptom of capacity, which we will discuss in the next two sections.

Subchapter I: Permissibility of conducting medical experiments on minors

Most legislationrequires full capacity [31] in the person undergoing the experiment, for the consent issued by him to consent to the doctor to experiment on him or her to be valid. But the problem that arises here is when the person subject of the experimentation is incapacitated, can he express his consent by accepting the medical experimentation on his body himself or through his legal representative, and if so, what are the conditions or controls due to express his will?

It is known that the legal loss of capacity includes minors due to young age, and adults who lost their capacity due to an accident that affected them after reaching the age of majority.

According to Algerian law, a minor is a person who has not reached the age of majority[32], is unable to act on his personal and financial affairs, and is called incompetent or incapacitated[33].

By reviewing the provisions of the Algerian Health Code, it becomes clear that the legislator explicitly allowed the legality of medical experimentation on minors and the like, but did not specify a certain age to be considered as eligibility for the person subject to medical experimentation, as the text of Article 386/1 mentioned above was vague and unclear, as the legislator only mentioned the phrase "legitimate representative" without indicating the category of minors to whom this text applies, nor did it distinguish between the type of medical experiments to which the minor will besubjected, therapeutic or scientific[34], and therefore it is necessary to refer to the general rules in this regard.

According to the general rules, if the subject of the experiment is a minor, who does not have full legal capacity, everything related to the medical experiments that are practicedon him, must be carried out with his legal guardianfor the experiment to be considered legally legitimate. Thus, free consent and consent to conduct the medical experiment must be issued by the legal representative of the minor, and the doctor experimenting must be obliged to inform the latter of all the information that must be communicated to the patient.

It is noticeable here that the Algerian legislator is reproached for not setting sufficient guarantees to protect the safety of the minor's body and secure it from the risks of medical experiments, contrary to what is in force in comparative health legislation[35], as it should have set stricter controls and conditions for the authorization of experimentation on the minor's body,

and not left it vague in the hands of their legitimate representatives, and clarifying the provisions of the prosecution regarding the requirement of consent to medical experiments, given the danger that the subject of medical experiments poses to the human body.

Subchapter II: Permissibility of conducting medical experiments on insane persons

Insanity is a disorder in the structure or functions of the brain, which leads to a total or partial imbalance, permanent or temporary, in the scientific functions and abilities of a person, such as cognition, as a result of physiological or genetic factors, and leads to an imbalance in the ability to distinguish and control the will, resulting in a lack of awareness and will [36].

Most legislations have been concerned with the issue of the legality of therapeutic or scientific medical experiments that may be conducted on the mentally ill[37], because of the relevance of this subject to the principle of the sanctity of the human body, especially if this person is incapable of perception and unwilling, and the Algerian legislator has taken the direction of these legislations when he mentioned a separate section in the Algerian health law entitled "Protection of patients with mental or psychological disorders" in which he gave the patient's legal representative the obligation to obtain consent to experiment. Medical when it is not possible to obtain it from the patient himself due to the conditions of his illness [38].

These legislations show us that they are mostly unanimous that it is not permissible to conduct therapeutic medical experiments on insane persons except in case of necessity, provided the agreement of their legal representatives. As for scientific medical experiments, it is not permissible under any circumstances to permit them, even if the approval is issued by the legal representatives.

The second topic: legal controls for conducting medical experiments

Saying that it is possible and legitimate to conduct medical experiments on man does not mean that it is permissible to experiment with them at all, because if conducting a medical experiment is in the general interest of society in scientific progress that benefits humanity as a whole, it intersects with the interest of the individual - on whom the experiment is conducted - in preserving his life and body.

To achieve a balance between the interest of society and the interest of the individual, it was necessary to set legal conditions or controls governing these experiences, which must be adhered to legitimize them, and these conditions, some are formal and some are objective, which we will present in two demands.

First requirement: formal conditions for conducting medical experiments

The conduct of medical experiments and scientific research on the human body in the service of humanity - within the framework of legality - is an exception to the principle of the sanctity of the body, which requires the inviolability and disposal of it, and on this basis declarations, international agreements and comparative health legislation have stipulated the availability of a set of formal conditions for conducting medical experiments on the human body, which we mention successively.

Subchapter I: Condition of Licensing to Practice Medicine

It is known that the law regulating the medical profession is the one that defines the conditions for practicing the profession of medicine and surgery, and specifies how a person obtains a "doctor's certificate" that authorizes him to perform all medical work authorized by law. Since medical experiments are a type of medical work, they can only be carried out by qualified persons, experienced in medical sciences, specialists in the field of scientific research, under specialized medical supervision, and aware of diseases and appropriate medicines(39).

Accordingly, the experimenter must be a person who has obtained a license to practice the medical profession; otherwise, he is considered an infringer of the human right to the integrity of his body (40)and has obtained the approval of the Medical Syndicate or other scientific and professional bodies.

This condition has been confirmed by various internationaldeclarations(41) and comparative legislation(42), including the Algerian legislation in the Health Code and the Code of Medical Ethics, as the legislator stipulates the conditions that must be met to obtain a license to practice the medical profession in Article 166 of the Health Code, namely: Algerian nationality, possession of the required Algerian diploma or equivalent certificate, enjoyment of civil rights, and non-exposure to any penal judgment. Incompatible with the practice of the profession, the enjoyment of physical and mental abilities that do not conflict with the practice of the health profession, registration in the schedule of the Deanship of Doctors. It also stipulated the need to register in the accreditation list for anyone who requests a license to practice the medical profession, except for doctors and surgeons working in the military sector and those who do not practice the profession(43).

Subchapter II: Licensing Medical and Scientific Experiments(44)

The Algerian legislator stipulates in Article 379 of the Health Code the necessity of conducting medical experiments on the human body in structures approved and licensed for this purpose, according to the modalities specified by the Minister of Health, and these experiments are subject to the authorization of the Minister in charge of Health, who decides on the request, either by acceptance or rejection(45), within three months, and the application is submitted by the promoter, based on a medical and technical file, and a declaration regarding the completion of these medical experiments on the human body following Article 381/1 of the Same law.

These medical experiments shall be the subject of a protocol, drawn up and provided by the promoter(46), and signed by the research physician after expressing his consent to express his acceptance of the protocol and his commitment to respect the conditions of achievement(47).

In the event of an amendment or change to the research protocol, after obtaining the license, (48) the promoter must notify the Minister in charge of Health of this amendment to obtain his approval again (49), such as changing the person subject to the experiment, changing the subject or objective of the experiment, increasing the time required to conduct it, changing the place of conducting it, etc.

Perhaps the reason that prompted the Algerian legislature to approve this pre- and post-control of licenses to conduct medical experiments is to prevent any abuses in respect of them, such as if the doctor in charge violates the objective of the experiment mentioned in the license, which may cause harm and danger to the person subject to the experiment.

Projects submitted for medical experiments are subject to the opinion of the Medical Ethics Committee for Clinical Studies[50], a committee created by the Algerian legislator under article 382 of the Health Code No. 18/11, established at the level of external services in charge of health, an independent body, whose task is to give an opinion on projects of medical and scientific experiments on humans, and whose activities are subject to control by the competent services of the Ministry in charge of health.

The legislator has stipulated that the tasks, composition, organization, and functioning of this committee shall be through the organization that has not yet been issued and that we ask the legislator to intervene urgently to enact it[51].

In this regard, it should be noted that the Algerian legislator stipulated that medical experiment projects should be subject to the Medical Ethics Committee for Clinical Studies to express its opinion, and also stipulated that the draft be placed before the Minister of Health to give a license to carry it out, but did not indicate which is earlier, the license or the expression of an opinion, what considered a legal loophole by the Algerian legislator.

A doctor is also held civilly and criminally liable if he conducts medical or scientific experiments on the human body without obtaining a license from the Minister in charge of Health, following article 438 of the Health Code.

Based on the foregoing, the scientific certificate provided to the doctor and his experience is not sufficient to carry out medical experiments on the human body, unless he is previously legally authorized to do so.

Subchapter III: The Requirement to Conduct the Medical Experiment in Qualified Hospitals

Hospitals and specialized medical centers are the most appropriate place to carry out medical and scientific experiments, as they are places that have the necessary material and technical capabilities, and the security conditions necessary for the safety of the persons subject to these experiments, and they are public institutions, and they may bear civil and criminal responsibility when they violate the legal controls due to their legality.

The Algerian legislature has taken this requirement into account when it stipulates in article 379 of the Health Code that such experiments and research shall be carried out in the structures approved and authorized for this purpose, following the modalities specified by the Minister of Health.

These structures must be subject to the necessary conditions [52] and be equipped with modern technical equipment and qualified and specialized medical staff, to ensure the success of the experiment with the least possible damage.

Second requirement: objective conditions for conducting medical trials

Because of the danger of medical experiments on the human body, jurisprudence and law have stipulated other objective conditions, in addition to the formal conditions mentioned above, to legitimize them, which we mention respectively:

Subchapter I: The Condition of Availability of the Authority for Conducting Medical Experiments [53]

The patient's recovery and pain relief is considered the main goal of legalizing medical work, and if this goal is not achieved, the doctor's intervention becomes illegal, and therefore it is not permissible to conduct medical research or experiments that entail unjustified risks to the patient [54], such as if the experiment is aimed at achieving fame or scientific glory, for example, if he does so, he is considered to have committed a professional error that entails responsibility. Therefore, for medical experiments to be legitimate, the intended benefits must outweigh their potential harms, as stipulated by the Algerian legislation in the Health Code [55] and the Code of Medical Ethics [56].

By reviewing these texts, it is clear to us that the legislator attached great importance to this condition, as it allowed medical experiments to be carried out on the human body, whether these experiments are therapeutic or scientific, to treat and heal the patient, and was keen not to expose the person to medical or scientific treatments and experiments in which the risk rate is high compared to the desired benefit[57], to preserve the health of the person subject to treatment or medical experiments[58].

Subchapter II: The Requirement of a Doctor Competence and Scientific Knowledge

The doctor responsible for the medical experiment must have the scientific competence necessary to experiment [59], as confirmed by the Algerian legislature in Article 380 of the Health Code when it stipulated that medical experiments on the human body be carried out by a research doctor who proves appropriate expertise. Accordingly, the experimenter must be a researcher in the medical field, aware of all the findings of science in the field of the experiment he wants to conduct, familiar with modern scientific assets, and have practical experience, for example, it is not permissible for a student in the Faculty of Medicine to experiment or a junior doctor who does not have the necessary competence to conduct it [60].

It is also required to experiment on humans, first in laboratories on experimental animals, as it is not permissible for a doctor to carry out an experiment in which he does not know [61].

Subchapter III: The Requirement to Observe Scientific Principles When Conducting a Medical Experiment [62]

Medical experimenters must adhere to scientific principles[63]and rules recognized theoretically and practically among doctors in renowned scientific institutes and institutions[64], and are aware of the latest scientific research in their biomedical experiments[65].

This condition was confirmed by the Algerian legislatures in Articles 378 and 380/1 of the Health Code[66] and settled by the Algerian judiciary so that the Supreme Court ruled in its decision issued on January 23, 2008[67] as follows: "The doctor must make sincere and consistent efforts, existing conditions and established scientific principles to heal the patient and improve

his health condition as a general asset, except in special cases in which the doctor is responsible for achieving results".

Subchapter IV: Non-Disclosure of Medical Confidentiality (68)

The doctor must commit not to disclose the professional secret in the field of medical experiments, whether this secret is what his patient has shared with him, or known on the occasion of practicing his profession unless there is a judicial decision or a legal text that requires the doctor to disclose that secret, and the Algerian legislator has confirmed this condition in several legal texts(69).

Therefore, if a doctor discloses the secret of his patient without justification, he is considered to have committed a professional error, which entails civil and criminal liability following Article 301 of the Penal Code, to which Article 417 of the Health Law referred (70).

Subchapter V: Oversight by Specialized Organizations on Medical Experiments

This condition means that medical experiments in which the human body is replaced must be subject to prior independent oversight, whose task is to ensure whether the experiment observes the necessary legal and ethical rules or not.

This requirement has been confirmed by international conventions and various comparative health legislation, which stipulate clear rules regarding the control of experimenters, to protect the subjects of the experiment and preserve their rights, as described above.

Regarding Algerian legislation, the legislator has entrusted the task of monitoring medical experiments on human beings to the Medical Ethics Committee for Clinical Studies under Act No. 18/11 on health.

Pending the promulgation of the regulation of the work of this Commission, the National Council for the Ethics of Medical Sciences continues to serve following the provisions of Law 85/05 of February 16, 1985 (71) to exercise its powers following Articles 446 and 447 of Law No. 18/11 on Health. Accordingly, we refer to the provisions of this law in all matters related to the control process vested in the National Council for the Ethics of Medical Sciences on medical experiments, its composition, and its functions (72).

The National Council for the Ethics of Medical Sciences must be consulted concerning all medical experiments on the human body, to give its approval or refusal to conduct them, taking into account the extent to which the experiment project respects the ethical and scientific principles governing medical practice during the conduct of the experiment on humans.

Conclusion:

At the end of this study, we concluded that medical experiments are a branch of medicine, and like any medical intervention, they are accompanied by some risks that may be expected, or beyond expectation and probability, and may sometimes lead to greater harm to the integrity of the organs of the human body.

To legitimize medical and scientific experiments, some conditions and controls are required before they can be conducted, settled by international conventions and comparative health

legislation after long discussions on the subject of medical experiments on humans, which are of two types: conditions related to the person subject to the experiment, which is consent and eligibility, and conditions related to the experimenter, which require the doctor to practice his work within the framework of respect for the legal rules established and regulating the medical profession, which is what the Algerian legislator has adopted in the Health Code and several special executive and regulatory legal texts. On the subject of medical experiments on the human body.

Marginalization list:

(1)The legal basis for medical experimentation on humans goes back to the principles and rules established by the Nuremberg Tribunal in 1949 following the trial of Nazi doctors for war crimes committed during World War II in the name of medical experiments. For more details on the facts of the issuance of this regulation, see: Bin Al-Nouei Khaled, International Conventions and Conferences Regulating Medical Experiments on Man, Al-Ijtihad Journal for Legal and Economic Studies, Issue 7, University Center Latamangst, Algeria, January 2015, pp. 245-246.

(2)The requirement of consent is contained in Rule I of the Nuremberg Norm, Article VII of the International Covenant on Civil and Political Rights, and Rule IV of the Helsinki Declaration.

(3)Such as the French Public Health Law, the Egyptian Code of Professional Ethics in Article 65 thereof, the Libyan Medical Liability Law (Article 15/2 of the Medical Liability Law No. 17 of 1986), the UAE Federal Law No. 10 of 2008 (Article 2/10 thereof), the Constitution of Iraq and others.

(4)Promulgated by Law No. 18/11 of 18 Shawwal 1439 corresponding to 02 July 2018 on health, published in the Official Gazette of the Republic of Algeria, No. 46, issued on 29 July 2018, p. 3.

(5) Therapeutic medical experiments are those experiments conducted by a physician to treat a person's illness, and therefore aimed at healing the patient. It is divided into two parts: scientific medical experiments of personal benefit, and others that are not of direct personal benefit. See Salha Omari, The Civil Liability of Doctors for Medical Experiments in Algerian Law, Journal of Jurisprudence, No. 15, Mohamed Khider University, Biskra, September 2017, p. 230.

(6) Non-therapeutic (scientific) medical experiments are those experiments conducted on volunteers, whether healthy or sick, who have no personal interest in experimenting, to apply a modern purely scientific method, or simply to satisfy a scientific curiosity to discover a new method in the field of diagnosis, treatment or prevention of expected risks. See: Mahmoud Mahmoud Mustafa, The Criminal Responsibility of Doctors and Surgeons, Dar Al-Isra, Jordan, 1998, p. 22.

(7)SuhairMontaser, Civil Liability for Medical Experiments in the Light of the Civil Liability Rules for Doctors, Dar Al-Nahda Al-Arabiya, Cairo, 1990, p. 25.

(8) This was decided by the French judiciary, where the Paris Court of Appeal ruled in its judgment of 20 February 1997 that a doctor who subjected a patient to an AIDS test without his consent, and who did not respect the patient's will, represents a mistake that may be

accompanied by either material or moral harm. Referred to: Anas Mohamed Abdel Ghaffar, Civil Liability in the Medical Field (A Comparative Study between Law and Islamic Law), Dar Al-Kutub Al-Qanoon, Egypt, 2010, p. 668.

(9) See p. Of this paper.

(10) Psychological pressure may make the patient in a state of moral coercion, pushing him to accept treatment or medical experience on him, and this pressure, for example, is caused by fear of negligence in health care, so the doctor influences him on the pretext that his disagreement with the experiment may make him feel guilty towards himself and his family, or that he undertakes the experiment, for example, despite his full knowledge that it will not bring him any direct personal benefit, but will make him famous or rich.

(11) Paying a fee in advance to the experimenter, especially if he is in dire need of money, has a coercive effect and is often considered a means used by the experimental doctor to influence these people in need of consent to subject them to his experiments.

- For more details on the issue of the impact of economic and psychological pressures on the satisfaction of the experimenter, see Barakat Imad El-Din, Scientific and medical experiments on the human body in the light of the rules of civil liability, a comparative study, a thesis submitted to obtain a doctorate in law, Ahmed Deraya University - Adrar, 2018/2019, pp. 127 ff.

(12) Deception here means that the doctor in charge conceals the truth of the experiment that he will conduct on the subject, or omits to inform him of an important fact related to it.

(13) Such as the Libyan Medical Liability Code (Article 4) and the French Public Health Code (Article 209/8-15).

(14) Article 392 states: "In the case of a clinical study without direct individual benefit, the promoter may pay to the persons who are willing to undergo it compensation for the difficulties they endure according to the conditions and modalities determined by the Minister in charge of Health," and Article 398 states: "Clinical studies, except those without direct individual benefit, shall not entail any direct or indirect financial compensation for the persons subject to them, except for the compensation of expenses paid by them. People".

(15) Ehab Yusr Anwar Ali, Civil and Criminal Responsibility of the Doctor, Ph.D. Thesis in Law, Cairo University, 1994, p. 65.

(16) It is covered by the International Covenant on Civil and Political Rights (article 7), the Universal Declaration of Human Rights (art. 3), the European Convention on Human Rights and Fundamental Freedoms, and the American Convention on Human Rights.

(17)Such as French legislation (Article 1111/4 of the Public Health Code) and Egyptian legislation (Articles 17, 55, 56 of the Code of Medical Ethics).

(18) See the text of Articles 23 and 343 of Law No. 18/11 on Health.

[19] See the text of Articles 43 and 48 of the Code of Medical Ethics issued by Executive Decree No. 92/276 of 5 Muharram 1413 corresponding to 6 July 1992, published in the Official Gazette of the Republic of Algeria, No. 52 issued on: 7 Muharram 1413, p. 1419.

(20) Article 343/4-5 of the Health Law states: "The provision of information shall ensure that all health professionals, within the framework of their powers, shall be provided within the framework of their powers within respect for the ethical and professional rules applicable to them. The doctor or dental surgeon must strive to provide his patient with clear and honest information about the reasons for each medical action."

(21) Barakat Imad al-Din, previous reference, pp. 136 ff.

(22)DaoudiSahra, Legal Aspects of New Methods in Medicine and Surgery, Ph.D.Thesis, University of Abou Bakr Belkaid - Tlemcen, without the year of publication, p. 173.

(23) The basis of this rule is due to the French judiciary, which relied on the text of Article 1315 of the French Civil Code as a justifying legal basis for the judgment issued by the French Court of Cassation on February 20, 1997, in the case of Hédrule, a person who was suffering from stomach pain, so his doctor decided to operate on him using an endoscope, but he continued to suffer from severe pain, which after examination turned out to be due to a hole in the intestine, which is a risk The expert's report determined the degree of probability of its occurrence in this type of operation at 3%, so the patient filed a lawsuit against the doctor demanding compensation because he did not inform him of the potential risks of the operation, and the Court of Cassation ruled in his favor on the basis that whoever has a legal or agreement with a special obligation to inform, must provide evidence that he has implemented this obligation. For more details on the facts of this case, see Barakat Imad al-Din, op. cit., p. 144.

(24)The Algerian legislator did not explicitly provide for this principle in the Health Code, but concerning the general rules provided for in the Civil Code, article 323 of the Code states: "The creditor must prove the obligation and the debtor must prove its disposal," which implies that the burden of proving the obligation of insight lies with the doctor and not with the patient or the person subject to the experiment.

(25) Such as French, Canadian, American, Tunisian, Iraqi, Emirati, and other legislation, the Helsinki Declaration (Article 3), and the Tokyo Declaration (Article 9).

(26)JarbouaMounira, The Modern Obligations of the Doctor in Medical Work, Ph.D. Thesis in Law, University of Algiers 1, 2016, p. 319.

(27) This is confirmed by Articles 209 and 1122/1-2 of the French Health Code, the Declaration of Helsinki in Article IV, and the Nuremberg Code in Article IX.

(28) Bin Al-Nowi Khaled, Controls of the legality of medical experiments and their impact on medical liability, publisher Al-Fikrwal-Qanoun, Mansoura, 2010, p. 128.

(29) Article 386/3 of the Algerian Health Code states: "... their right to refuse to participate in a research or to withdraw their consent at any time without incurring any responsibility and without prejudice to their care."

(30) Article 439 of the same law states: "A research physician who initiates a clinical study without the consent of the person listed in the research protocol shall be punished by imprisonment from two (2) to five (5) years, and a fine of 100,000 to 500,000 dinars."

(31) Capacity here means the capacity to act, which enables a person to express his or her will to consent to medical intervention or experiment.

(32) The age of majority according to article 40/2 of the Algerian Civil Code is 19 years.

(33)A person is considered incompetent if he has not attained the age of thirteen years following Article 42 of the Civil Code, and is considered incapacitated if he exceeds the age of discrimination and has not reached the age of majority following Article 43 of the same Code, and in both cases, the incompetent and incompetent persons cannot carry out legal acts themselves or are not fit to carry out some of them, so the law subjects these persons to the authority of other persons who have the authority to conduct these acts on their behalf and their behalf.

(34)The distinction between the type of medical experiments to which a minor is subjected is of great importance, because in therapeutic experiments the experiment may be conducted on the minor if it is in his favor and will benefit him, but in scientific experiments, the principle is that it may not be conducted on minors because their purpose is not therapeutic, and an exception may be carried out if it is necessary to conduct it on a specific minor by necessity, in which case the legislator must establish guarantees to protect the safety of the minor's body and secure it from risks. Experiment.

(35) For more details on the position of comparative legislation on the issue of medical experiments on minors, see Barakat Imad al-Din, previous reference, pp. 160 ff.

(36) Sabri Mohamed Khalil, Madness between the Common and Scientific Concepts, published on the website:
https://drsabrikhalil.wordpress.com/2015/06/17/

(37) For more details on the position of comparative legislation on the issue of medical experiments on the insane, see Barakat Imad al-Din, previous reference, pp. 168 ff.

(38) See articles 128 and 129 of the Algerian Health Code.

(39)RahliSouad, The Legal System of Medical Experiments on Human Embryos, Ph.D. Thesis, University of Algiers 1, 2015, p. 220.

(40) The human body is inviolable, and therefore may not be a laboratory or a field for medical experiments, as confirmed by the Algerian legislatures in articles 414, 415, and 416 of the Health Code, and in article 5 of the Code of Medical Ethics.

(41) Helsinki Declaration, Nuremberg Norm (Article 8).

(42) Such as French and Egyptian legislation (Article 54 of the Egyptian Code of Professional Ethics of 2003).

(43) See Article 204 of the Algerian Code of Medical Ethics.

(44) Most comparative legislation does not allow medical and scientific experiments to be conducted on the human body unless the doctor responsible for experimenting, holder of a medical degree, and has sufficient experience, has a license to experiment by the competent authority, such as the French Health Law (Articles 209 and 1123), Article 53 of the Egyptian

Code of Professional Ethics, Article 2 of the UAE Federal Law No. 10 of 2008 on Medical Liability. And others.

(45) It is noticeable that the legislator did not clarify the procedures to be followed in the event that the Minister of Health refuses to grant a license to conduct medical experiments on humans, and whether his decision may be appealed or not. And before whom is the appeal made?

(46) A promoter is a natural or legal person who initiates a medical experiment obligatorily and can be a service provider approved by the Ministry of Health, a treatment institution, a scientific society or research body, or a natural person who has the required qualifications and competencies.

(47) See article 385 of the Algerian Health Code.

(48) According to article 385, the Minister of Health permits the promoter after submitting the application that includes the search protocol.

(49) See article 381/2 of the Health Law.

(50) The National Council for the Ethics of Medical Sciences was tasked with studying projects submitted for medical experiments, before the promulgation of Law No. 18/11 on Health.

(51) Article 446 of the Health Law states, "The external health services shall be installed within a maximum period of two years from the date of publication of this law in the Official Gazette," noting that this law was published on July 2, 2018, so we expect the regulation to be issued soon.

(52) Such as the ability to ensure adequate surveillance of persons, securing some beds commensurate with planned activities, a good organization to ensure the confidentiality of information and data related to research and persons participating in experiments, provision of equipment and hygiene and maintenance conditions, the competence of persons working in these places to ensure the safety of persons, and the establishment of a quality assurance system. Ashraf Rammal, Medical Experiments on Humans, Journal of Law and Political Science, No. 15, Modern Book Foundation, Lebanon, 2017, p. 75.

(53)This requirement has been stipulated by numerous international agreements and most comparative health legislation, such as the Helsinki Declaration (Article 4), the Tokyo Declaration (Article 3), the French legislation (Article 1121), the Egyptian legislation (Article 54 of the Code of Professional Ethics of 2003), and others.

(54) See article 17 of the Code of Medical Ethics.

(55) See articles 377, 392, 393, 394, and 398 of Law No. 18/11 on Health.

(56) Article 18 of the Code of Medical Ethics states, "The use of a new treatment may be considered for the patient, only after appropriate biological studies, under strict control, or when it is determined that such treatment is of direct benefit to the patient."

(57) Article 380 of the Health Law states: "Clinical studies on human beings may only be carried out if the interest rate for the foreseeable risk is in favor of the person concerned with the study."

(58) The risks allowed in therapeutic trials are higher than in non-therapeutic trials. For more details on this issue, see Barakat Imad al-Din, op. cit., pp. 217 ff.

(59) Scientific competence here does not mean simply obtaining a doctorate in medicine and surgery, but rather having sufficient experience of training and training in modern methods before applying them to humans, to protect them from the dangers that may befall them after conducting a medical experiment on them.

(60) This was recognized by the French judiciary, where the French court of Lyon, in its judgment issued on 15/12/1859, ruled that a medical student who operated under the supervision of a doctor was responsible for lacking the scientific and practical competence necessary to start this experiment. Referred to: Ibn al-Nuwi Khalid, op. cit., p. 158.

(61)Mervat Mansour Hassan, Medical and Scientific Experiments in the Light of the Sanctity of the Physical Entity, A Comparative Study, New University Press, Alexandria, 2016, p. 205.

(62) This requirement was confirmed by the Helsinki and Tokyo Declarations, French legislation (Article 1121 of the Health Code), Libyan legislation (Article 2 of the Medical Liability Law No. 17 of 1986), and Iraqi legislation (Section 11 of the Medical Professional Conduct Instructions of 2002).

(63) These principles lie in the rules that must be observed by the doctor, which impose on him the duty of attention, caution, and due diligence toward the patient.

(64) Barakat Imad al-Din, previous reference, p. 224.

(65)DaoudiSahra, previous reference, p. 192.

(66) Article 378 states, "Clinical studies must observe the ethical and scientific principles and ethics and literature governing medical practice." Article 380 states: "Clinical studies on human beings may only be carried out if: They are based on the latest clinical research, scientific knowledge, and sufficient preclinical experience."

(67) Referred to Barakat Imad al-Din, previous reference, p. 226.

(68) This condition was stipulated in the Universal Declaration of Medical Ethics and Human Rights at the UNESCO meeting in Paris on October 19, 2005, where the attendees stressed the need to adhere to the preservation of medical confidentiality, respect for privacy, and confidentiality of information obtained during the conduct of the experiment, as addressed by the federal regulation issued by the US Health Administration on January 26, 1981, and confirmed by most comparative legislation, including French legislation (Article 1110 of the Health Law) and UAE legislation (Article 2/10 of Federal Law No. 10 of 2008).

(69) See the text of Articles 24, 196, and 395 of Law No. 18/11 on Health.

(70) Article 417 of the Health Law states, "Failure to observe medical and professional secrecy shall expose the person to the penalties provided for in article 301 of the Penal Code."

(71)Law No. 85/05 of 26 Jumada I 1405 corresponding to February 16, 1985, on the protection and promotion of health, amended and supplemented, published in the Official Gazette of the Algerian Republic, No. 8, issued on February 17, 1985.

It should be noted that the provisions of this law have been repealed, but the provisions adopted for its application remain in force until the issuance of the regulatory texts provided for in the Health Act No. 18/11 following article 449 thereof.

[72]In this regard, the legislator issued Executive Decree No. 96/122 of 18 Dhu al-Qa'dah 1416 corresponding to 6 April 1996 on the formation, organization, and functioning of the National Council for the Ethics of Health Sciences, published in the Official Gazette of the Republic of Algeria, No. 22, issued on 10/04/1996, p. 18.

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