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Satisfaction of Persons Undergoing Clinical Trials

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ABSTRACT: *In this study, the researcher dealt with the free and explicit consent of the subject of the experiment and pointed to the effect of paying for money in advance on the validity of the satisfaction and the status of the person who is in a state of dependency and exploitation of the attribute or trust and then the researcher studied the tightening of the obligation to displace in the field of clinical trials and the consequent obligation of the experimenter to inform the person subject to the experiment and the method of informing the person subject to the experiment and cases in which it is permissible not to inform the person subject to the experiment and finally the rules related to tightening the content of the obligation to perform And the right of the person subject to experimentation to deny his previous satisfaction.*

KEYWORDS: COVID-19, clinical trials, donor's consent, patients.

INTRODUCTION

The human body is one of the most essential elements of its existence, so it is one of the most important and sacred elements of life, the human body may be the subject of any agreement, except for its safety and maintenance, and its infringement is a violation of the infallible physical entity.

Since man is the end of social organization, protecting him in his physical and moral being a fundamental of the legal system, as such protection is based on the values and elements of his existence for society to continue progressing and flourishing.

Throughout different ages, human beings have been subjected to the most horrible experiences of doctors practicing their sadistic identities in their experiences, as was evident during the World War at the hands of the Nazis. Some harmful experiments were conducted on human beings, which sometimes resulted in their disability or

death, the exploitation of human beings as experiments, and the covert conduct of such experiments by some States, often victims of poor peoples, resulting in human rights violations, to discover a new type of experiment. Drugs or attempted human cloning, or for the use of embryos in stem cell research, however, clinical trials are of great importance in discovering some of the drugs necessary for human life and alleviating their pain, as well as developing diagnostics and treatment for some intractable and serious diseases with which available medical treatments have not worked.

The importance of the study

The importance of this study appears to be by seeking to develop a disciplined legal framework for regulating and regulating clinical trials on humans experiment, within a unified law, identifying permitted and simply prohibiting the conduct and criminalizing them, restraining scientists in moving towards any to prove a particular scientific theory and recognizing the adequacy of national legislation to limit the conduct of prohibited clinical trials and the exploitation of humans, whether by seeking the benefits and financial benefits they will receive or by intimidating by coercing persons subjected to experiment to undergo some dangerous experiences on their health and lives, which the law did not allow to take place.

The problem and questions of the study

Technological development, the development of the pharmaceutical industry and the manufacture of medical equipment and machines have led to a tremendous development in theories of disease treatment. Pharmaceutical laboratories have produced new generations of medicines, and technical development in the field of medical devices has produced some diagnostic devices and some advanced devices that are used either for surgery or treatment. It is known that all these preparations, whether pharmaceutical or technical, require clinical studies conducted on humans to prove their effectiveness in diagnosing or treating disease, and since these studies are permitted to a certain extent permitted by law. Hence, the research problem consists of a central and important question:

1. What is the concept of clinical trials?
2. Who can conduct clinical trials?
3. To what extent are clinical trials permitted?

Who is responsible for conducting unauthorized clinical trials?

8. How appropriate is the legislation in place to prevent unauthorized clinical trials?

Curriculum

In his study of this subject, the researcher followed various research approaches, to remedy the legislative shortcomings in Jordanian law in its treatment of clinical trials, and to develop a nucleus for researchers later to complete the road in terms of our completion, as follows:

1. Analytical approach: It was used to review the position of international organizations and comparative legislation, the circumstances that occurred, and the attempt to describe, analyze and root them, based on the assumptions preceded by previous studies.
2. Comparative approach: It was used to highlight the positions of different states on clinical trials, how such legislation addressed those trials and legislative shortcomings, how they could be addressed and remedied under amendments to existing laws, or to pass a unified law regulating the issue in all its aspects

Introduction

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Since man is the end of social organization, protecting him in his physical and moral being become fundamental of the legal system, as such protection is based on the values and elements of his existence for society to continue to progress and flourish.

And The Bath concluded its study with a conclusion and a set of recommendations and conclusions.The consent issued by the person subject to the experiment must be explicit and clear without any material or moral compulsion, and this consent is required to be informed after being informed of the aspects of the experiment, before conducting the experiment and to continue until its completion, as follows:

Section I Free and explicit satisfaction of the subject of the experiment

The validity of the consent issued by the person subject to the experiment shall be required to be free and not subject to coercion [(1)] or a victim of fraud, fraud, deception, error, exploitation, or any other reason that would defect or nullify the choice, and that the consent shall be clear and frank, and shall be understood unambiguously or ambiguously, whether by accepting or rejecting the experiment, as affirmed in the International Convention on Civil and Political Rights, adopted by the General Assembly of the United Nations on 16 December 1966 in its article (7). It is as follows:

" No one may be subjected to torture, punishment or cruel, inhuman or degrading treatment, and in particular no individual without his free consent may be subjected to medical and scientific experiments", and article 5 of the European Convention on Human Rights and Biomedicine, which contains the following basic provisions: "Any interference in the field of health requires that the person being experiment be given his free and informed consent, and before this the person concerned shall be given information appropriate to the purpose, nature of the intervention as well as its effects and risks, and the person may Meaning, at any time the withdrawal of consent freely"[(2)], as required by the Basic Law of the" Le code DE Nuremberg", principle of the inadmissibility of medical experimentation on any individual without his consent, and it is deduced from the rules established by the Nuremberg Tribunal that they recognize non-therapeutic or scientific experiments conducted on humans, but it has set conditions for such experiments, including: -

[(1)] However, coercion in the field of medical experimentation is not intended to have the specific meaning of the provisions of the obligation as stated in the Civil Code, but rather to create the will to submit to any kind of effective pressure that marries the patient's freedom to choose with any amount of pressure. The pressure may be medical, social or economic, Abdel Rashid Maamoun, The Contract of Medical Treatment between Theory and Practice, Dar al-Nahda al-Arabiya, Cairo, 1986.

[(2)] Voir, conseil de l'Europe: La protection de l'embryon humain in vitro, rapport du groupe de travail sur la protection de l'embryon et du fœtus humains, comite directeur pour la bioéthique(CDBI), Strasbourg le 19 Juin 2003 ,page 20 et au – delà.

- Scientific experiments should have a practical benefit to humanity that is impossible to obtain without experimentation on man.
- The method of practicing the experiment should be specific.
- Experience is necessary.

The Helsinki Declaration[1] adopted by the World Medical Association (the world organization representing the National Medical Associations) replaced the Nuremberg Laws in 1964, and the Helsinki Declaration set out a number of principles governing experimentation in human beings, including free and informed consent.[2]

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[1] The U.S. Food and Drug Administration (F.D.A.) has removed the Helsinki Declaration from its review of clinical trials outside the United States, replacing it with less stringent references to the International Coordination Conference's Good Clinical Practice Guidelines (I.C.H.G.C.P.), while EU legislation takes the Helsinki Declaration as its reference, and since the United States and the European Union constitute the world's largest drug market, their controls significantly affect drug manufacturers. Encourage them to conduct experiments in foreign countries. Mohammed Al-Ammari, Second Report Joint Committee of the Health Affairs Committee and the Offices of the Education and Scientific Research Committees, and Constitutional and Legislative Affairs, on a draft law submitted by the government on "Issuing the Law on the Organization of Clinical Medical Research", 20/4/2018, p. 5

[2] Among the most important general principles of the Helsinki and Tokyo Declarations are: -

- Medical experiments must be conducted in accordance with the principles of ethics and science that justify research in human medicine, nor

The experiment on humans can be started only after laboratory tests and experiments on animals, or on any other scientifically stable data.

- The project of human medical experiments and the stages of their implementation must be specified in a protocol experimental, which is supervised by an independent committee specifically appointed for this purpose for opinion and advice.
- Medical experiments on humans must be carried out by scientifically qualified persons and under the supervision of a medical specialist in the field in which the experimentation is to be carried out. Francis Fukuyama, ff., Beringer LaSalle, Michel Boudot Rabkour, Jean-Marc Rocks, Marc Broche, Dr. Anne Tessier,

Article 9 of the Arab Charter on Human Rights [1] stipulates that: " No one may conduct medical or scientific experiments or exploit his organs without his free consent and full awareness of the complications that may result from them, taking into account moral, humanitarian and professional controls and rules, and adhering to medical procedures to ensure his personal safety, in accordance with the legislation in force in each State Party, and in no case shall human organs be trafficked."

The Charter on Fundamental Rights of the European Union also states in Article (3/2): " In the field of medicine and biology – the following shall be respected in particular:

- The free and informed consent of the person concerned – in accordance with the procedures established by law." The French Public Health Law No. 2004-806 of August 9, 2004 stipulates in Article (1122-1-1) that: "No biological research may be conducted on a person without obtaining his free and clear consent, which is carried out after the information is provided to him in accordance with Article 1122-1. Satisfaction is obtained by writing, or by the testimony of others whenever it is impossible to write... " [2].

Christian Giovanangel, Translation / Ahmed Mohamed Eid, Beringer LaSalle, Michel Bodot Ricoeur, Jean-Marc Rocks, McBroach, Anne Tessier, Christian Giovanangel, Human Biological Law / Translated and revised by Ahmed Mohamed Eid, Dar al-Thaqafa for Publishing and Distribution, 1435 AH – 2014

- Voir, Garcia Victor, Mailland Quentin, Robert Antoine, Thiery Florian, François Régis Mahieu: Le clonage thérapeutique, sans l'éditeur, 2009 م– 2010 م, page 17.

[1] The Arab Charter on Human Rights, adopted by the Sixteenth Arab Summit hosted by Tunis on May 23, 2004.

[2] Art 1122-1-1 C.S.P.F: " aucune recherche biomédicale ne peut être pratiquée sur une personne sans son consentement libre et éclairé, recueilli après que lui a été délivrée l'information prévue a l'article 1122-1 "

.- Berenger LaSalle, Michel Baudot Rabkour, Jean-Marc Roux, Marc Broch, Dr. Anne Tessier, Christian Giovannigel, translation / Ahmed Mohamed Eid: The Law of Human Biology, Culture House for Publishing and Distribution, 1435 AH - 2014 AD, p. 269.

The Egyptian legislator in the 2014 Constitution stipulates in Article (60) the following: "The human body has the inviolability, assault, mutilation or representation of the human body is a crime punishable by law. Trafficking in its organs is prohibited, and no medical or scientific experiment may be carried out on it without its free and documented consent and in accordance with the established foundations in the field of medical sciences, as regulated by law."(1)

In its Article (61) it made the consent of the documented free researcher the basis for his participation in medical or scientific research, prepared in accordance with the stable in the field of medical sciences; and for the realization of the role of the State in promoting and protecting the health, well-being and rights of patients including those who participate in medical research, while specifying special protection rules for groups and participants of categories entitled to additional protection."

The Constitution also stipulates that the trade in organs is prohibited, and that no medical or scientific experiment can be conducted without documenting the free consent of the participants in the experiment, in accordance with the principles in force in the medical field as regulated by Law No. 71 of 2009, which regulates the rights of psychiatric patients, and articles (8 and 6) of it stipulate the importance of obtaining prior approval from the Research Ethics Committee, such as exposing psychiatric patients to any clinical experiment and in the event of obtaining consent it is necessary to submit A thorough explanation to the patient about the experience.

The law also prohibits trials of patients undergoing compulsory treatment Article (59, 65) of Law No. 127 of 1955, which provides for the prohibition of the entry of any foreign medicines into Egypt unless they are licensed and registered by the Egyptian Ministry of Health.

In Part IV of the Code of Conduct, or the regulation of professional ethics issued by Ministerial Decision No. 238 of 2003, there is a set of instructions for clinical trials in humans.8(2)

(1) - Khaled Gamal Ahmed Hassan: The will of the patient in medical work between divorce and restriction, Journal of Rights, Volume Five - Number Two - July 2008.p. 246,

(2) Mohammed Al-Ammari, Second Report Joint Committee of the Health Affairs Committee and the Offices of the Education and Scientific Research Committees, and Constitutional and Legislative Affairs, on a draft law submitted by the

Ministerial Decree No. 95 of 2005 also prohibits the conduct of clinical trials before obtaining the approval of the Research Ethics Committee of the Ministry of Health, followed by a number of constitutive and regulatory laws.

Article (28) of the Egyptian Medical Ethics Regulation stipulates that: "The doctor may not conduct the medical examination or treatment of the patient without the consent (based on knowledge) of the patient or his legal representative, if the patient is not eligible for it, and the patient's going to the doctor at his place of work is considered an implicit consent to this, and in cases of surgical or semi-surgical intervention it is necessary to obtain approval (based on knowledge) from the patient or his legal representative in writing except for reasons. Save lives. A doctor who is invited to a minor's clinic, incapacitated or an unconscious patient in a serious situation must do what is within his reach to save him even if he is unable to obtain in a timely manner the consent (based on knowledge) of his guardian, guardian or trustee. He should not step down from his treatment unless the danger is gone, or if the patient is entrusted to another doctor."

Whereas, Law No. 214 of 2020[(1)]9) was recently issued promulgating the Law on the Organization of Clinical Medical Research, where Article (3) of this Law reads as follows:[(2)]) "The conduct of medical research may not be limited to a particular group of human beings or to groups entitled to additional protection, unless the research is

government on "Issuing the Law on the Organization of Clinical Medical Research", 20/4/2018, p. 8.

(1) Official Gazette – Issue 5 bis (f) of December 23, 2020.

(2) In this article, the Council approved the proposal of MP Mohamed El Sewedy, Chairman of the Coalition to Support Egypt "Parliamentary Majority", on the conditions for conducting medical research on children, and according to the proposal, the law requires the consent of parents in the event of a medical research on any of the natural or disabled children, along with other requirements, instead of requiring the consent of only one of them, with a view to = = increasing the protection of these groups, Mohamed El Ammari, Second Report Joint Committee of the Health Affairs Committee and the Offices of the Education and Scientific Research Committees, and Constitutional and Legislative Affairs, About a draft law submitted by the government on "Issuance of the Law on the Organization of Clinical Medical Research", 20/4/2018.

necessary and relates to diseases of their own, and with the availability of scientific and ethical justifications for their use, and provided that the informed consent of each of them is obtained, and if the medical research is on one of them

While free consent does not raise a problem for therapeutic experiments, it is different for scientific (non-therapeutic) experiments, since a person's free consent is a prerequisite for undergoing that experiment.(1)

First: Does paying for money in advance affect the validity of the consent issued by the person subject to the experiment?

Second: What is the situation of some sects that are in a state of association or dependency, which facilitates their exploitation in conducting experiments on them?

Third: - What is the impact of the exploitation of the attribute or trust granted to the doctor, which facilitates the impact on the person subject to the experiment

(1)A-Legal aspects of the donor's consent, including:

The legal provisions relating to the consent of the donor revolve around a set of legal conditions necessary for the validity of the consent.

The first condition: that it be fixed in writing:

The manifestations of the formality differ from one legislation to another. In France, the consent of the subject to the trial is required to be proven before the President of the Court of First Instance in whose jurisdiction the place of residence is located, or before a judge appointed by the President of this court for this purpose. This consent is proven in writing and signed by the donor and the judge..(2)

With regard to the form of consent in Jordanian legislation, the Jordanian legislator in the Law on the Use of Human Body Organs No. 23 of 2000 A.D. required that the approval be in writing, which is stipulated in Article (4/A/3) (that the donor agrees in

(1)Shawqi Zakaria Al-Salhi, Implications of IVF, Science and Faith for Publication and Distribution, 2007, p. 41.

-Voir, Garcia Victor, Mailland Quentin, Robert Antoine, Thiery Florian, François Régis Mahieu: Le clonage thérapeutique, sans l'éditeur, 2009 م– 2010 مpage 17.

(2) Dr. Ahmed Shawki Abu Khatwa, Criminal Law and Modern Medicine, Arab Renaissance House, 2007, p. 70.

writing while he is fully willing and able to transfer an organ body, prior to the procedure.

That is, the legislator has embraced the idea that consent must be issued in a written form, in addition to being issued by a free and conscious will free from the defects of consent.

The meaning of this text regarding the form of consent, the legislator has reaped two ways to prove the validity of consent.

1- It must be confirmed by a written acknowledgment that includes the approval of the organ donation, supported by the testimony of two first-degree relatives.

2- That this declaration be ratified before the real estate registry.

The second condition: that consent is the result of a free will:

The third condition: the satisfaction must be perceptive:

(2) The effect of paying for money in advance on the health of satisfaction

The acceptance of the subject of clinical trials must be free of charge, because the human body is not considered to be one of the things that cannot be acted upon pursuant to the principle of "the departure of the human body from the circle of dealing"[(1)] This on the one hand, and on the other hand the prepaid financial remuneration may have a hated effect on the person subject to the experiment, as may lead him to put himself at the disposal of doctors to conduct various clinical experiments.[(2)]

This is confirmed by the French legislator in the law of December 20, 1988, on the regulation of experiments on man from emphasizing this principle with the intention of excluding the motive of profit, or the idea that the human body is trafficked. This does not preclude the permissibility of paying an amount as compensation to the

(1) The principle of "the departure of the human body from the circle of dealing" is reviewed in detail in chapter I of Part One of the Letter p. 86 et seq.

(2) See, Oonagh Corrigan , Kathleen Liddell , John Mcmillan , Alison Stewart , susan Wallaca: Ethical legal and social issues in stem cell research and therapy , Cambridge Genetics Knowledge Park , 2 nd Edition , March 2006م , page 19

person being experiment for damages to which he may suffer, such as the cessation of work for a specified period or his undergoing remedies requiring expenses.(1)

In the first paragraph of article 1121-11 of the Public Health Code, it authorized the payment of certain compensation by the experienced doctor or company to persons volunteering for the experiment to redress the financial burdens and expenses incurred during the experiment, without extending this compensation to the bodily damage suffered by them. That if the assessment of the amount of compensation were left to the parties to the contract freely in application of the principle of pacta sunt servanda, it would open a wide door for dealing in the human body and violating its sanctity; because the application of this principle in such matters in an absolute way would implicitly enshrine the consideration of the human body by the objects in which it could be dealt with, thus the principle of the authority of the will would serve as a legal cover that would encourage research doctors. Companies have to exert financial pressure on individuals in order to subject them to medical experiments.(2)

The Egyptian Medical Ethics Regulation affirms this in Article (56): "The research physician is obliged to obtain approval (based on knowledge) from the volunteer to conduct the research on him, and to obtain this approval in an official manner, and in the presence of prosecution witnesses, and in the event that the volunteer is a minor, disabled or incapacitated, it is necessary to obtain approval from the official guardian or trustee, and the research is required to be specific to his pathological condition."(3)

Article (14) of Law 214 of 2020 promulgating the Law on the Organization of Clinical Medical Research, known as "Clinical Trials", also stipulates the following:

(1) Alaa Ali Hussein Nasr, The process of human cloning and genetic engineering from a legal point of view, Ph.D. thesis, Cairo University, 2006, p. 81.

(2) Art 1121-11 alinéa 1 C.S.P.F: " La recherche biomédicale ne donne lieu a aucune contrepartie financière directe ou indirecte pour les personne qui s'y prêtent, hormis le remboursement des frais exposés et, le cas échéant, l'indemnité en compensation des contraintes subis versée par le promoteur. Le montant total des indemnités qu'une personne peur recevoir au cours d'une même année est limité à un maximum fixé par le ministre de la santé ".

(3) Egyptian Medical Ethics Regulation No. 238 of 2003 issued on 5 September 2003.

"It is forbidden to motivate the researcher to participate in any medical research, by granting him rewards or benefits in cash or in kind.

Exceptions to the above shall be made for the consequences of participation in medical research, such as transportation expenses to and from the research body, or absence from the working hours required by the medical research, provided that this is specified in advance and in full transparency in the informed consent form submitted to the competent institutional committee and its approval.

All this is as set out in the Executive Regulations of this Law."[(1)]

(3) The status of a person who is in a state of dependency

One of the problems raised by the requirement that consent be free is the extent to which the administrative nature of participation in work is respected for some communities of persons who are in a subordinate state, namely persons who lack liberty such as prisoners of war and prisoners who are often paid to participate as volunteers in medical trials, especially those sentenced to death.[(2)]They have been admitted, as well as patients who visit hospitals for treatment, and agree to conduct

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(1) Mohammed Al-Ammari, Second Report Joint Committee of the Health Affairs Committee and the Offices of the Education and Scientific Research Committees, and Constitutional and Legislative Affairs, on a draft law submitted by the government on "Issuing the Law on the Organization of Clinical Medical Research", 20/4/2018

(2) An American delegate proposed that the death sentence be carried out by anesthetizing the convict as the Ptolemaic did in Alexandria in order to conduct medical research and experiments on the convict in the hope of discovering more hidden truth about the brain structure of the murderous killer and the source of his criminal tendencies.

The same delegate added that the same method could be followed with those who had sentenced themselves to death, i.e. who intended to commit suicide, and experimented with them while under narcotics to discover what would discourage them from committing suicide –

- Dr. - Shawki Zakaria Al-Salhi, IVF between Sharia and Law, Comparative Study, PhD thesis, Faculty of Law, Cairo University, 2001, p. 64.

the experiment for fear of neglect in care,[1]and we will review three examples of such cases below:

A- For prisoners:

It is required that the prisoner has seen in advance all the possible results that may arise from the experiment, provided that those results do not have serious damages, and that the prisoner's consent to conduct the experiment on his person is not flawed by what invalidates it, such as that the pressure exerted on his will by the prison authorities arises from visions that these experiments are not announced orally in prison, but are done in writing to the prisoners themselves, so that only those who apply on their own initiative to obtain the experiments are accepted by them. A printed application specially prepared for this, so that it fills out and signs these statements.[2]

The problem has been the subject of many studies in the United States of America,[3] where people's consciences arose when they learned that medical experiments were being conducted on prisoners in that country. This raised the question: Should such experiments be banned or confined to the strictest limits?

Many U.S. states have taken this trend, especially in New York State, as well as the Nuremberg Court Act, which prohibited experimenting with prisoners of war. Canada has also taken this direction; in light of Article 24 of the Federal Directive on Professional Conduct in Penal Institutions, it prohibits all non-therapeutic trials of prisoners.

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(1) : Dr. Muhammad Eid Al-Gharib, Medical and Scientific Experiments and the Sanctity of the Bodily Entity of Man (A Comparative Study), First Edition, Without Publisher, 1989. p 78.

(2) Shawky Zakaria Al-Salihi, Implications for the process of artificial insemination, Science and Faith for Publishing and Distribution, 2007p.

(3) In 1942, a malaria parasite was injected to eight hundred volunteer prisoners in order to show the extent of the body's resistance to it by forming antibodies to the disease. In the same year, the hepatitis B virus petite hé l' was injected to some opponents of the war. In May 1956, 96 prisoners in Ohio volunteered to accept injections of cancer cells to study the impact on them

-D Jaber Mahjoub Ali, The Role of the Will in Medical Work (Part Two), Journal of Law and Economics, Issue 69, 1999 pp. 773 .

Article (380/3-d) of the French Code of Criminal Procedure, as amended by Decree No. 852-72 of September 12, 1972, states: "Prisoners shall not be subjected to medical or scientific experiments that may involve prejudice or assault on the physical and meaningful integrity of the person."

Article 1121-6 of the Public Health Act also stipulates that "medical experiments may be carried out on prisoners only if the expected benefit of the experiment for the prisoner justifies subjecting him to the foreseeable danger, or if such experiments benefit persons in the same situation and cannot be carried out in an effective manner for other groups of society, in the latter case it is required that the risks expected from the experiment to which the prisoner will be subjected constitute a minimum of risk".(1)

The Belgian Code of Medical Ethics also explicitly excluded prisoners from the field of non-therapeutic experimentation, with Article 90 stipulating: "The experiment may not be conducted on a healthy human being unless the experimenter is an adult, in a situation that allows him to express his free consent, and this is not the case of the prisoner, and that the experiment is accompanied by medical supervision that will face all difficulties."

It can also be said that the Egyptian Constitution of 2014 prohibited the conduct of medical experiments on detained prisoners, which is derived from Article (52), which stipulates the following: "Torture in all its forms and forms is a crime that does not fall within the statute of limitations", and the same meaning is stipulated in Article

(1) Art L.1121-6 C.S.P.F: "Les personnes privées de liberté par une décision judiciaire ou administrative, les personnes faisant l'objet de soins psychiatriques en vertu des articles L.3212-1 et L.3213-1 qui ne relèvent pas des dispositions de l'article 1121-8 et les personnes admises dans un établissement sanitaire ou social à d'autre fins que celle de la recherche ne peuvent être sollicitées pour se prêter a des recherches biomédicales que dans les conditions suivantes: - soit l'importance du bénéfice escompté pour ces personnes est de nature à justifier le risque prévisible encouru ; - soit ces recherches se justifient au regard du bénéfice escompté pour d'autre personne se trouvant dans la même situation juridique ou administrative à la condition que des recherches d'une efficacité comparable ne puissent être effectuées sur une autre catégorie de la population. Dans ce cas, les risques prévisible et les contraintes que comporte la recherche doivent présenter un caractère minimal"..

(31/2) of the Kuwaiti Constitution, which prohibits subjecting any human being to torture or degrading treatment.[1]

The researcher believes that the reality is that experiments in such cases can be allowed, but on very narrow terms that allow to confirm that science does not exploit the special situation in which the prisoner is located.

B- For prisoners of war:

During the Second World War, flagrant violations of human rights were committed, and the Nazis conducted many medical and scientific experiments on prisoners of war by coercion and coercion without regard to any amount of principles and principles governing the conduct of such experiments, so the Nuremberg Tribunal was established in 1947 to try the major war criminals from the Axis countries for the atrocities they committed with prisoners of war while conducting non-therapeutic experiments on them to know some scientific results, such as knowing the effect of chemicals, toxins and anti-serum For gangrene and artificial hormones. Salvamide affected contaminated wounds and typhoid, surgeries on nerves, muscles and bones and sterilization, knowledge of the effects of high altitudes and cold freezing, and the number of these accused was (23) including directors of major health institutions in the administration and army, university professors and doctors in Nazi concentration camps.[2]

The Human Rights Committee, which was formed to finalize the provisions of the Universal Declaration of Human Rights, considered that article 5 of the Human Rights applies to cases of medical experimentation on human beings, and it states that "no one shall be subjected to torture or to cruel, brutal or degrading punishments or treatments".

The four Geneva Conventions on the Protection of Civilian Persons in Time of War, held on August 12, 1949 to ensure human rights in periods of war, prohibited biological testing of citizens of occupied countries,[3]enemies or prisoners of war to

[1] Dr. Jaber Mahjoub Ali, The Role of Will in Medical Work (Part II), op. cit., p. 743.
[2] Mohamed Eid al-Gharib, Medical and Scientific Experiments and the Inviolability of the Physical Entity of Man, op. cit., p. 17,.
[3] They are four agreements to guarantee human rights in times of war, as those agreements included the prohibition of conducting biological experiments that are conducted to find out the effects of a new drug on the sons of the occupied or

find out the effects of new medicines, in order to guarantee human rights only in periods of war, and the prohibition does not extend beyond that period.

It also obliges the signatory States to intervene in order to enact criminal penalties for those who conduct such experiments or order them to be conducted, as Article 147 prohibits the following acts:

1 – Murder.

2. Torture or inhumane treatment, including life science experiments.

3. Acts that intentionally cause severe pain or serious injury to the body or health."[(1)]

The protocols added to these conventions also contain the same prohibition as those contained therein, where the first protocol in article (11/2) thereof states that it is forbidden to conduct medical or scientific experiments on the children of the occupied countries, the enemy or prisoners of war, even with their consent.

Article 7 of the International Convention on Civil and Political Rights of December 16, 1966." [(2)]

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enemy countries or prisoners of war, and the four conventions considered conducting such experiments among the serious crimes. which obliged signatory states to enact legislation to punish them; This is because these agreements did not include specific criminal penalties for those who conduct such experiments. Therefore, Article 49 of the First Agreement, Article 50 of the Second Agreement, Article 129 of the Third Agreement, and Article 146 of the Fourth Agreement = = stipulated that The contracting parties undertake to enact binding legislation to impose effective penalties on persons who commit or order serious breaches of these conventions, and the protocols added to these conventions in 1977 stipulated the prohibition of medical or scientific experiments on the aforementioned persons even with their consent in Article (11 / 2) From the first protocol, and article (10/2) of the second protocol, and article (5/2) of the same protocol.

(1) Dr.. Alaa Ali Hussein Nasr, The process of human cloning and genetic engineering from a legal point of view, Ph.D. thesis, Cairo University, 2006 P. 432 ff.

(2)Article 7. stipulates that: "No one shall be subjected to torture or to cruel, inhuman or degrading punishment or treatment, and in particular no individual may be subjected without his free consent to medical or scientific experiments. It was put into effect on March 3, 1976 after being signed by the required majority of the

C- For patients:

It seems logical to exclude a non-therapeutic experiment conducted on a sick person by the attending physician, given the dependency of the patients vis-à-vis his doctor. However, such experiments, especially in the context of pharmacologique d'essays, may find justification in that the physician is free to experiment with modern drugs on his patient. With the obligation of the doctor to take care and vigilance in the use of these drugs [(1)]).

(4) Exploitation of character or trust

The doctor's character in his patient has sacredness, respect and trust that may push him to accept any medical work on him because of his trust in his doctor, and this is a kind of medical pressure, where the patient generates a negative situation in the face of his doctor for his trust in this doctor, and looks forward to healing with a measure of unlimited hope and clinging, and in most cases he holds himself to trust the specialist whatever the circumstances, what if the doctor exploits his character, and that trust granted to him in conducting scientific experiments on patients?

We find that the legislator has tightened the punishment in some crimes depending on that characteristic, and even the trust granted to him, including the crime of abortion, and since these experiments, whether therapeutic or scientific (non-therapeutic), are expected only from a doctor, and since therapeutic experiments are carried out with the aim of benefiting the patient by finding new ways to treat him, as for scientific experiments that do not benefit the patient but may result in harm to the patient, the doctor's exploitation of his character and the trust granted to him by deluding the patient of the usefulness of that experiment for him; It is merely a scientific experiment that has violated the license granted to him, which necessitates his criminal responsibility for a deliberate crime.

Section III : Tightening the commitment to disclosures in clinical trials

In the field of medical and scientific experiments, the freedom and frankness of consent emanating from the person subject to the experiment is not enough, but it

countries of the world, Khalid Jamal Ahmed Hassan, The Patient's Will in Medical Work Between Release and Restriction, op. cit., pp. 243 et seq.

(1) D .Mamoon Abdel Karim. Patient Satisfaction with Medical and Surgical Work, a thesis for obtaining a doctorate degree, Faculty of Law, Aib Bakr Belkaid University, Tlemcen, year. 2004-2005,., p. 433

must be an informed consent. This requirement imposes an obligation on the experimenter to inform the person of the nature and objectives of the experiment, and of the effects and consequences arising from it.

The legislator has also intervened to tighten the obligation of foresight for medical experiments, both at the level of international norms and at the level of legislation, and we review this briefly within the limits of what serves the research, as follows:

(a) The obligation of the experimenter to inform the person being experiment.

(b) The method of informing the person on whom the experiment is being conducted.

(c) Cases in which the person subject to the experiment may not be informed.

(d) Rules relating to the tightening of the content of the obligation to disclose.

(1) The obligation of the experimenter to inform the person being experiment

For the validity of the consent the person being experiment, the person conducting the experiment must inform him of the nature, objectives and duration of the experiment, so that he is aware of his or her own and can determine a position by initiating or abstaining from that experiment.[(1)] However, the content of the commitment to the media is controversial, as it varies from person to person, according to the psychological and physical condition of each person and the extent of the expected reactions to the person's body. Therefore, the experimenter should commit to disclosing all the possible and harmful consequences that can result from or provoke

(1) Muhammad Eid al-Gharib, Medical and Scientific Experiments and the Inviolability of the Physical Entity of Man, op. cit., p. 82 et seq., Alaa Ali Hussein Nasr, The Process of Human Reproduction and Genetic Engineering from a Legal Point of View, op. cit., p. 87.

- See, Oonagh Corrigan , Kathleen Liddell , John Mcmillan , Alison Stewart , susan Wallaca: Ethical legal and social issues in stem cell research and therapy , Cambridge Genetics Knowledge Park , 2 nd Edition , March 2006 م, page 9 .
- See, Ching – Pou Shih: Moral and legal Issues concerning contemporary human cloning technology: Quest for regulatory consensus in the international community to the future in the international community to the future of humanity, sanfrancisco, California, without the publisher, 12 March 2010 م, page160.
- A Report by the bioethics advisory committee Singapore, Donation of human eggs for research, November 2008 م, page 11

the body's reactions. This does not mean that full knowledge of all possible results has been achieved, as medical experiments may produce unexpected results that the doctor does not know before the experiment, which makes it impossible to oblige him to disclose it.

If the principle is that the experimenter may not conceal the dangers and harms of the experiment to the person being experiment, on the contrary, he is obliged to disclose in an explicit and clear way the possibilities of danger that could affect his life or health, or even just the transient damage or discomfort that could affect him(1). However, this obligation must be assessed in the light of the specific circumstances of each individual according to his psychological condition and the extent of his response, as full information of the person, although it alleviates the responsibility of the experimenter, but it may affect the morale of the person, resulting in psychological trauma that is sometimes difficult to bear. In addition, it may have a bad impact on the course of the experiment.(2)

This does not mean that the experimenter is obliged to inform the person in question of all the technical details related to the experiment, which he cannot understand scientifically. The doctor cannot explain to him everything that can be scientifically provoked by the conduct of the experiment, but he must make sure that he has a real understanding of the person on whom the experiment is being conducted.(3)

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(1) The Seoul National University Committee issued a report on the research cloning experiments, carried out by Dr. Hwang and his team, in which he used more than 2,000 m of eggs for his experiments, not 427 eggs as claimed, in addition to the fact that the donors of those eggs were only some of them aware of the health risks that may result from these donations, and == 66 of them= = received financial compensation following the findings of the Seoul National University Committee, and the Hwang scandal prompted the National Bioethics Commission. Korean to reconsider whether or not to allow more cloning research, returns:

See, Rosario M. Isasi, Bartha M. Knoppers: Mind the Gap: Policy approa ches to embryonic stem cell and cbning research in 50 countries, European Journal of Health Law, Printed in the Nether lands, 9 – 26 – 2006 م, page 11.

(2) Alaa Ali Hussein Nasr, op. cit., pp. 88 ff.

(3) Muhammad Eid al-Gharib, op. cit., pp. 82 ff.

Certain points can be identified that the researcher should take into account to enlighten the person subject to the experiment, whether he is just a donor or the situation in which the experiment will be carried out, and whether it is a scientific or therapeutic experiment out of respect for the right and autonomy of individuals in decision-making. These points are as follows:(1)

- Inform him of the nature and purpose of the research.
- Inform him of the procedures and potential health risks, and the procedures are not concerned with the precise technical details that the average person does not understand, but is limited to understanding the content of the experience and the return from it on him.
- Identify confidential information that may not be disclosed, permissible information that relates to scientific matters while concealing the personality of the person subject to the experiment out of respect for the desire of the person subject to the experiment.
- Inform the person subject to the experiment of his or her right to withdraw his consent at any time, provided that he or she has not commenced the experiment.

(2) How to inform the person being experiment

The method of notification is often based on the therapist or volunteer sharing a document to inform him of everything related to the treatment he should undergo, or the experience he is applying for as a volunteer. Such documents usually actually appear to be a doctor's protection editor to avoid disputes that may arise later, and do not then correspond to the meaningful role that such information should have from the point of view of morality.

(3)Cases in which the person subject to the experiment may not be informed

- The first case: - Experiments conducted in the manner of double ignorance or double blindness:

The doctor may conduct experiments on an alternative drug or drug that makes it impossible for the experimenter to fully inform the subject of the possible results of the experiment, since he himself does not know the result to which the experimenter will be exposed, even if it is a real experiment in which the information given is very

(1) A Report by the bioethics advisory committee Singapore, Donation of human eggs for research, November 2008م , page12 and beyond.

brief, because the doctor does not know all the possible results, otherwise he would not have conducted the experiment [1].

- **The second case**: - Simple encryption of the technical details related to the experiment that he cannot understand scientifically:

The doctor cannot explain all the scientific details of the experiment. Especially if the experiment on the therapeutic effect of the tried drug is not known in advance[2].

- **The third case:** - Respect the trust of the doctor based on the experiment:

It is stipulated in Article 209-9, fourth paragraph of the French Law of December 20, 1988 (and the explanations made thereto), which states that, "If the patient's interest has necessitated that he not be allowed to diagnose the disease he suffers from, the researcher may, as an exception, out of respect for trust, withhold from him certain information relating to this diagnosis, provided that the research protocol has included a reference to this possibility."

It is clear through him that it relates to therapeutic experiments, and he assumes that the attending physician has discovered that the disease suffered by the patient is of a degree of seriousness, and that the interest requires not to intimidate and disclose his diagnosis, and then if he sees a new treatment experience on this patient, then the doctor who conducts the experiment may hide this diagnosis from the patient, except for the text of Article (35/2) of the Code of Professional Ethics, in order to ensure the success of the experiment, but the concealment here Complies with the provisions of Article (35), so that the diagnosis may not be concealed when the patient has a disease that threatens others with the risk of transmission of infection to him. The doctor should also inform the patient's relatives of the reality of his illness, unless the patient has prevented it in advance, and finally, when the experiment ends - with success or failure - it is necessary after taking appropriate precautions, to inform the patient of the reality of what he suffers from the disease.

(4) Rules on the Tightening of the Content of the Obligation to Discharge And the right of the person subject to experimentation to deny his previous satisfaction

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[1] Jaber Mahjoub Ali, The Role of Will in Medical Work (Part II), op. cit., p. 740, Muhammad Eid al-Gharib, op. cit., p. 85.

[2] Muhammad Eid al-Gharib, op. cit., p. 85, and Walid Rashad Judah Yusuf, op. cit., pp. 438 ff.

(a) At the level of international rules:

The first article of the Nuremberg Codification stipulates that "the patient's consent must be obtained." Article IX of the same codification stipulates that "the patient has the right to revoke his consent to participate in the experiment at any time he wishes, whenever the continuation of the experiment causes him mental or physical discomfort or when he began it, for any other reason that the continuation of the experiment has become impossible."

Helsinki's announcement came to emphasize the principle that a physician should obtain the free and informed consent of the person subject to the experiment, and his right to stop participating in it at any time. The Declaration also included a stipulation of the need to enlighten the person in question, explicitly stating that "every clinical research project must be preceded by a detailed and comprehensive list of the risks it causes and the benefits expected of it." It also states elsewhere that "the nature, purpose, and risks of the experiment must be explained to those who undergo it."

The Tokyo Declaration states that "when conducting any research on a human being, the person to whom he is subjected must be properly informed of the objectives, methods, benefits expected of him and the potential risks, and inconveniences that it can cause him. He should also be informed that he has the right to retract his consent to participate in the research at any time he wishes."

As stated in the Directions for Experimental Research on Humans, issued by the World Medical Association, "When the subject of the research is able to discern, the physician must provide him with all necessary clarifications about the nature and meaning of the research to be carried out, and about the potential risks of such research to his life or health."

It is clear from the above that the person subject to medical experimentation should be cared for by enlightening his satisfaction in particular, by tightening the obligation to discredit the doctor conducting the medical experiment.[(1)]

(b) At the level of various legislations:

[(1)] Jaber Mahjoub Ali, The Role of the Will in Medical Work (Part II), op. cit., pp. 733 ff., Walid Rashad Judah Youssef, op. cit., pp. 440-441.

1- Modern French legislation:

The French legislator specified in the Law of December 20, 1988 (and the amendments thereto), in Article (209-9) the content of the obligation to discharge in relation to any experimental research, by stipulating that before conducting any medical research a person must obtain the free and informed and explicit consent of this person, after the researcher or doctor representing him has defined the following elements:

– The objective, method and duration of the research.

– Expected benefits, limitations and anticipated risks, including risks arising from the cessation of research before the term assigned to it.

– Opinion of the Advisory Committee for the Protection of Persons Involved in Biomedical Research.

The French Public Health Code obliges the physician, in article 1122-1, paragraphs 1 and 3, of the procedure to inform the volunteer about the purpose of the experimentThe methodology of action, the duration of the trial, the expected benefits and risks, the expected risks, the alternative medical possibilities when stopping before the trial ends, and the methods of medical care expected at the end of the trial.

Article (1131-2) of Law No. 2011-814 of July 7, 2011 stipulates that: "The doctor has the obligation, during the examination of a person's genetic characteristics, to inform him of the risks to which his family members may be exposed as a result of his silence on the disclosure of the existence of serious genetic defects in him as a result of the diagnosis, and the consequent need to take care and prevention measures."[(1)]

In addition, the researcher or clinician must notify the person whose consent is sought (who is participating in the experiment or acting on his behalf if he himself is not qualified to issue consent), and that he has the right to refuse to participate in the research, or to withdraw his consent at any moment without incurring No responsibility for it [(2)].

[(1)] Beringer LaSalle, Michel Boudotte Rabkour, Jean-Marc Rocks, Marc Broche, Dr. Anne Tessier, Christian Giovanangel, translated by Ahmed Mohamed Eid: The Law of Human Biology, op. cit., p. 263, Ben Odeh Snoussi, op. cit., pp. 160 ff.

[(2)] Jaber Mahjoub Ali, The Role of Will in Medical Work (Part II), op. cit., pp. 735, 736 ff., Walid Rashad Judah Youssef, op. cit., pp. 443 ff.

It is clear from this that the doctor is obliged to disclose the expected risks in all cases to the person subject to the experiment; however, in the absence of a therapeutic purpose, for scientific experiments, it is necessary to apply the rule of extended disclosure in the first place, and he has an obligation to disclose all serious risks, even if their realization is rare.

The French legislator wanted by the term "foreseeable risks" all the risks that could be foreseen, including rare risks, if, although rare, they were of some gravity, they would have consequences if they occurred.

It is noted, however, that the legislator does not allow research to be conducted that has no direct benefit to those who undergo it (scientific experiments) when they involve foreseeable and significant risks to the health of those who undergo them. It is therefore the responsibility of the Advisory Committee to Protect Medical Research to assess the risks to volunteers of participating in non-therapeutic trials. The Commission is expected to base its assessment not only on the frequency of the risks, but also on the degree of their severity, which means that non-therapeutic trials are not qualified as legal under French legislation, unless they include a certain degree of risk in terms of number and attractiveness.

Article 226-25 of the new French Penal Code stipulates that: "Carrying out the study of the genetic characteristics of a person for purposes other than medical or scientific research, or for medical or scientific research, without obtaining his prior consent in accordance with article 16-10 of the Civil Code, punishable by imprisonment for one year and a fine of 15,000 euros."

Article 16-10 of the French Civil Code states: " It is not permissible to study the genetic characteristics of a person on the occasion of conducting medical or scientific research except after obtaining the express and written consent of the person before completing the experiment, in accordance with the nature and purpose of the experiment. This consent shall remain in effect, but this consent can be withdrawn at any time."

Law No. 2011-814 of July 7, 2011 defines the obligations of the doctor in Article (1122-1), which stipulates that: "Before conducting biological research on the human body, the doctor must see it with the following information:

1 – Objective, methodology and time of research.

2 – The expected benefits of this biological research on the person himself, At the same time, the expected risks, as well as the risks that arise from stopping the research before the expiry of its term.

3- Possible medical alternatives.

4- The methods of medical care prescribed for research, whenever such care is necessary in the case of the time associated with the research, and in the event that the research is excluded.

5- The opinion of the committee referred to in Article 1123-1, and the license issued by the competent authority stipulated in Article 1123-12, and informing him of his right to be informed during the research process, or at the end of it, of all information related to his health.

6. Prohibition of participation in another research at the same time, or during the period of exclusion provided for in the Protocol and its registration in the national card established in accordance with Article 1121-16.

He must also inform the person whose consent is required of his right to refuse to participate in the research, or to withdraw his consent at any time, without being prosecuted before the judiciary and without causing any harm to them as a result of the withdrawal of their consent...".[(1)]

A– Jordanian legislation:

Article (8) of the Jordanian Medical and Health Liability Law No. 25 of 2018 also stipulates the following: "The service provider is prohibited from the following:22[(2)]

(a) Treatment of the recipient of the service without his consent, except in cases where emergency medical intervention is required and where consent cannot be obtained for any reason, or where the disease is contagious or threatens public health or safety, as stated in the governing legislation."

Article (7) of the same law also stipulates the following: "The service provider shall abide by the rules, standards and procedures for the practice of the

[(1)] Beringer LaSalle, Michel Bodot Ricoeur, Jean-Marc Rocks, McBroach, Anne Tessier, Christian Giovanangel, Human Biological Law / Translated and revised by Ahmed Mohamed Eid,.,Op.cit pp. 267 ff.

[(2)]) Published on page 3420 of the Official Gazette No. 5517 dated 31/5/2018.

profession according to his degree and field of specialization, and document this in the file of the recipient of the service, and the doctor in particular shall comply with the following:

- Published on page 3420 of the Official Gazette No. 5517 dated 31/5/2018. ...

B- Egyptian legislation:

Article 43 of the Egyptian Constitution stipulates that: "No medical or scientific experiment may be conducted on any human being without his free consent," as the constitutional legislator legitimized medical experiments of both types (therapeutic or scientific). He stipulated that the consent of the person subject to the experiment must be obtained;

However, Professional Ethics Regulation No. 238 of 2003 A.D. stipulated in Article (21): “The doctor must provide his patient with information related to his. condition in a simple and understandable manner. The patient, in a decent humane manner, is concerned with the seriousness of the disease and its serious consequences, unless the patient expresses his desire that no one be informed of his condition, or he selects specific people to inform them of it, and there is no danger to those around him.” As stipulated in Article (55): "The researcher is obligated to acquaint the volunteers fully and in a clear manner with the objectives of the research, the research methods that will be used in the research and the expected benefits from it, the potential risks, and the extent of their impact on the volunteers. It is also necessary to inform the volunteers of the sources of research funding, and the identity of the researcher. The official and his institutional affiliation, and confirming the volunteer’s right to stop volunteering to conduct experiments and tests or completely withdraw from the research without incurring any negative consequences as a result of his approval or withdrawal,” as stipulated in Article (56): “The research doctor is obligated to obtain written consent from the volunteer. To conduct research on him, and to obtain this approval in an official manner, in the presence of witnesses, and in the event that the volunteer is a minor, disabled, or incompetent, the approval must be obtained from the official guardian or curator, and it is required that the research be specific to his case pathological.”

The Egyptian Clinical Medical Research Organization Law No. 214 of 2020 stipulates in Article (12) the following:

"The researcher shall have the following rights:

1. The right to withdraw from medical research at any time and without obliging him to give any reasons for this, provided that the principal investigator is informed of the medical damage caused by his withdrawal.

2- Not to disclose his identity or any of his statements, except after the conditions of scientific justification approved by the competent institutional committee and approved by the Supreme Council are met, and with the written approval of the researcher or his legal representative.

3. Obtain a copy of the informed consent.

The request for the consent of the researcher in this case excludes the cases required by the proper application of medical research and described in the Egyptian laws and regulations governing the circulation and confidentiality of data, without prejudice to the authority of the investigating authorities or the competent court to request the disclosure of these data because of the necessity required by the investigation or trial procedures.

And all this as detailed in the executive regulations of this law."

C: - Form and time of satisfaction:

(1) The form in which consent is required to be emptied:

Consent does not require a particular form; it may be issued orally, and it may be written [(1)], but it is preferable that the consent be written and stamped with the signature of the person subject to the experiment, especially if the experiment to be carried out is scientific, because such kind of consent is a fundamental guarantee for the doctor to prevent attempts to deny the person subject to the experiment the issuance of consent from him, and also constitutes an effective protection for the person subject to the experiment itself, as this written consent usually reveals accurately the limits of his consent in a way that cuts off the The doctor shall override or overdo the conduct of the experiment, or prevent him from conducting the experiment without the knowledge of his patient, or without obtaining his consent to it.

Therefore, before the experiment, doctors are usually keen to obtain a written acknowledgement by the person subject to the experiment, the content of which is

[(1)] Ibn Odeh Snoussi, op. cit., pp. 164 ff.

formulated in a printed form prepared in advance by this doctor, including all the data related to the experiment in terms of its nature and means of conduct, its negative and positive effects, and other material information that facilitates the patient's way of knowing and knowing all the essential matters related to this experiment and through which he can build his satisfaction with it consciously and informed, and this requires the doctor to carry out his commitment to the good performance of the doctor's commitment. By informing his patient to enlighten and enlighten him with everything that he is interested in knowing about the experience to which he will be subjected with all honesty and honesty [(1)]).

This is what the French legislator adopted in the Law of December 20, 1988 in Article (209-5) of the Public Health Regulation of "the delivery of a written document to the person whose consent is to be obtained, containing a summary of the information to be disclosed. Among these information is his right to refuse to participate in the research, or to withdraw his consent at any time without liability."[(2)]

Article 1122-1, paragraph 6, of the French Public Health Code also requires that consent be issued in written form, and in the event that this is not possible, consent shall be made by acknowledgment by a third party, provided that the latter is not related to the procurator or supervisor of the experiment.

As for the Egyptian legislation, article 56 of the Medical Ethics Regulation of 2003 stipulates that: "The research doctor is obliged to obtain written consent (based on knowledge) from the volunteer to conduct the research on him, and to obtain this consent in an official manner, and in the presence of prosecution witnesses.[(3)]

The question is: how independent is a person in deciding whether or not to participate in a scientific experiment, on the basis of which a sample is obtained from him to be

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[(1)] Khalid Jamal Ahmed Hassan, The Patient's Will in Medical Work Between Release and Restriction, op. cit., p. 247, Alaa Ali Hussein Nasr, op. cit., p. 89, Ihab Yusr Anwar Ali, op. cit., p. 145, Habiba Saif Salem Rashid al-Shamsi, op. cit., = p. 313, Babaker al-Sheikh, op. cit., p. 312, Shawki Zakaria al-Salhi, Implications of IVF, op. cit., p. 41, Beringer LaSalle, Michel Boudot Rabkour, Jean-Marc Rox, Marc Broach, Dr. Anne Tessier, Christian Giovanangel, translated by Ahmed Muhammad Eid, The Law of Human Biology, op. cit., pp. 162 et seq.

[(2)] Jaber Mahjoub Ali, The Role of the Will in Medical Work (Part II), op. cit., pp. 785 ff.

[(3)] Ibn Odeh Sanussi, op. cit., pp. 165 ff.

the material for that experiment, taking into account the possibility that he will be exposed to some risk while undergoing a scientific experiment?

This question can be answered in the light of the basic principles; the Nuremberg Regulation affirmed in the first of the ten principles contained in the Regulation "the importance and necessity of the consent of the volunteer person to conduct laboratory studies", and the Declaration of Helsinki affirmed the principle of "respect for the right of the volunteer person to maintain his safety", as stated in the Belmont report to emphasize several basic principles represented in the following:

1 – Respect the humanity of the volunteer person.

2 – The right to obtain sufficient information about the studies or experiments in which he will participate.

3 – The right to participate in such research voluntarily.

There are also three principles advocated by biomedical research ethics: independence, interest, and justice.

Respect for the independence of the volunteer person and the primacy of his interest are undoubtedly expressed by his written consent to conduct an experiment on him, whether that experiment will be carried out directly on him or through the taking of a sample of his body, and this already reflects the growing interest in the need to obtain the explicit consent of the person, out of free and informed will regarding the conduct of experiments on him, and this interest came as a result of the objections raised about the radiation experiments conducted during the period of the cold war between the western and eastern camps.

(2) The time at which satisfaction is significant:

It requires the availability of the consent of the person subject to the experiment before the experiment is conducted on him, and that this consent continues until the end of the completion of the experiment, while the subsequent consent to the conduct of the experiment is not considered to be a matter of tolerance and forgiveness, and the waiver of the person subject to the experiment from his civil claim, and this does not prevent the initiation of criminal proceedings before the doctor, as this is the authority of the Public Prosecution with the inherent competence in this regard.

The law allows for the reversal of consent in the field of medical experiments and gives the person complete freedom to refrain from undergoing such acts, and the determination of this exception is the result of many privileges, the most important of

which is the seriousness of these medical acts and their harm to the integrity of the human body, which is already outside the circle of dealing.22[1]

International declarations and comparative legislation have agreed on the right of the probationary person to withdraw his consent at any time under special provisions, with article 9 of the Nuremberg Codification stating: "For the duration of the experiment, the volunteer person shall have the right to decide to discontinue the experiment, if the continuation of the experiment causes him moral or physical discomfort or, for any reason whatsoever, it appears to him that the continuation of the experiment is impossible."

Article 124 of the Helsinki Declaration stipulates that the subject of the experiment has the right to withdraw his consent at any time, that withdrawal from the experiment does not entail any penalties or deprivation of certain rights or benefit, and that it is his fundamental right to request that the experiment be stopped at any moment and whenever he wishes.

Article 306, paragraph (2), of the Universal Declaration of Biomedicine issued by UNESCO on 19 O ctober 2005 also affirmed this right, stating that when conducting therapeutic or scientific experiments on a human being, the explicit consent of the volunteer must be obtained, with the latter having the possibility of withdrawing his consent at any moment, for any reason, without causing him any harm.[2]

Article (55) of the Regulation on Medical Ethics in Egypt for the year 2003 stipulates that the person subject to the experiment may retract his prior consent to conduct a medical experiment on him.

CONCLUSION

After we have concluded the study of clinical trials, which consisted of criminalizing the conduct of clinical trials without the consent of the person subject to the trial, through the statement of the international position, and the study of these crimes by comparative laws.

Through this research, we wanted to state the positions of legislators on those trials, applying this to clinical trials .

[1] Jaber Mahjoub Ali, op. cit., p. 360.
[2] Ibn Odeh Sanussi, op. cit., p. 168.

The study showed several results that could be summarized as follows:

RESULTS

1. Some clinical trials are a deviation from the customary technical medical assets, for the purpose of collecting scientific or technical data, or acquiring new knowledge, with the aim of developing the medical sciences conducted by the doctor who is a researcher on the patient or the volunteer person, with the aim of experimenting with the effect of a particular drug.
2. Medical experiments on the human body are an indispensable imperative in order to verify the effectiveness of new drugs being tested on the human body, as this intervention is dictated by social necessity. It has been practiced by human beings since ancient times in different ways and in all fields.
3. The emergence of some untreated diseases in the medical arena, particularly the emerging COVID-19 virus, has prompted the whole world to pay attention to scientific and clinical experiments to find an effective treatment or vaccine for the emerging CORONA virus, which has infected and killed millions around the world.

Recommendations

We propose some recommendations that we hope will be taken into account in the future:

1. Volunteer people should be informed of the trial mechanism, the side effects of the drugs by the researcher doctor, and make the trial prohibited in the absence of such insight.
3. Amending the Law regulating clinical medical research No. 214 of 2020 in the Egyptian legislature by establishing special provisions protecting vulnerable groups undergoing medical trials, such as minors and prisoners

References

Abdel Rashid Maamoun, The Contract of Medical Treatment between Theory and Practice, Dar al-Nahda al-Arabiya, Cairo, 1986, .

Mohammed Al-Ammari, Second Report Joint Committee of the Health Affairs Committee and the Offices of the Education and Scientific Research Committees, and Constitutional and Legislative Affairs, on a draft law submitted by the government on "Issuing the Law on the Organization of Clinical Medical Research", 20/4/2018, .

Beringer LaSalle, Michel Bodot Ricoeur, Jean-Marc Rocks, McBroach, Anne Tessier, Christian Giovanangel, Human Biological Law / Translated and revised by Ahmed Mohamed Eid, Dar al-Thaqafa for Publishing and Distribution, 1435 AH – 2014

Khaled Gamal Ahmed Hassan: The will of the patient in medical work between divorce and restriction, Journal of Rights, Volume Five - Number Two - July 2008..

Shawqi Zakaria Al-Salhi, Implications of IVF, Science and Faith for Publication and Distribution, 2007.

Oonagh Corrigan , Kathleen Liddell , John Mcmillan , Alison Stewart , susan Wallaca: Ethical legal and social issues in stem cell research and therapy , Cambridge Genetics Knowledge Park , 2 nd Edition , March 2006م,

Alaa Ali Hussein Nasr, The process of human cloning and genetic engineering from a legal point of view, Ph.D. thesis, Cairo University, 2006,.

Shawki Zakaria Al-Salhi, IVF between Sharia and Law, Comparative Study, PhD thesis, Faculty of Law, Cairo University, 2001.

Muhammad Eid Al-Gharib, Medical and Scientific Experiments and the Sanctity of the Bodily Entity of Man (A Comparative Study), First Edition, Without Publisher, 1989.

Shawky Zakaria Al-Salihi, Implications for the process of artificial insemination, Science and Faith for Publishing and Distribution, 2007p.

Jaber Mahjoub Ali, The Role of the Will in Medical Work (Part Two), Journal of Law and Economics, Issue 69, 1999 pp. 773 .

Mohamed Eid al-Gharib, Medical and Scientific Experiments and the Inviolability of the Physical Entity of Man, op. cit., .

Mamoon Abdel Karim. Patient Satisfaction with Medical and Surgical Work, a thesis for obtaining a doctorate degree, Faculty of Law, Aib Bakr Belkaid University, Tlemcen, year. 2004-2005,., .

Ching – Pou Shih: Moral and legal Issues concerning contemporary human cloning technology: Quest for regulatory consensus in the international community to the future in the international community to the future of humanity, sanfrancisco, California, without the publisher, 12 March 2010م .

Rosario M. Isasi, Bartha M. Knoppers: Mind the Gap: Policy approa ches to embryonic stem cell and cbning research in 50 countries, European Journal of Health Law, Printed in the Nether lands, 9 – 26 – 2006م. –

Ahmed Shawki Abu Khatwa, Criminal Law and Modern Medicine, Arab Renaissance House, 2007, p. 70.

Reports

1- A Report by the bioethics advisory committee Singapore, Donation of human eggs for research, November 2008م , .

French references

1- conseil de l'Europe: La protection de l'embryon humain in vitro, rapport du groupe de travail sur la protection de l'embryon et du fœtus humains, comite directeur pour la bioéthique(CDBI), Strasbourg le 19 Juin 2003م page 20 et au – delà.

2- Garcia Victor, Mailland Quentin, Robert Antoine, Thiery Florian, François Régis Mahieu: Le clonage thérapeutique, sans l'éditeur, 2009 – م2010, ..

3- , Garcia Victor, Mailland Quentin, Robert Antoine, Thiery Florian, François Régis Mahieu: Le clonage thérapeutique, sans l'éditeur, 2009 – م2010 .