

Civil Protection of the Human Body from Medical Experiments

Amel BENZAZZA

Belhadj BOUCHAIB University, Ain Temouchent, Algeria

Amal.benazza@univ-temouchent.edu.dz

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Abstract: Medical experiments on the human body raise two main problems, one of which is related to the freedom to practice scientific research to reach the progress of medical science, and the second is the sanctity of prejudice to the human body due to the methods and methods raised by the medical experiment in this field. Therefore, it was necessary to provide civil protection for the human body from these experiences, whatever their nature, whether it is related to civil liability in its contractual or tort part, as compensation must be ensured for the injured as a result of these errors.

Keywords: civil protection- medical experiments- human body- health law

*Corresponding author: Amel BENZAZZA

Introduction:

Scientific developments in the biological and medical field have become growing and increasing, so that the concepts and principles agreed upon have changed with them..

Medical experiments have become a revolution in legal concepts in an attempt to adapt to scientific medical discoveries in a direct relationship between them.

Medical sciences are not limited to a certain time, they bring new things every day in all disciplines. Medical science has gone beyond its original mission of prevention and treatment to include even non-therapeutic methods to meet human needs. But the matter is not limited to this point, as a great jurisprudential controversy has arisen due to the difficulty of distinguishing between medical experiments whose goal is to treat the sick person, and those experiments that aim to satisfy the doctor's desire, as the world has recently witnessed several diseases and viruses, and the best Evidence of this is the virologist and what he came up with in the field of covid19, after conducting many studies and examining theories, the drug or vaccine was tried on animals, but the need always remains urgent for the need to try it on the human body to ensure its safety.

In view of the seriousness of these treatment methods, most constitutions have been keen to enshrine the principle of the inviolability of the human body, including the Algerian Constitution through Article 39 thereof, which states: "The State guarantees the inviolability of the human person.

and prohibits any physical or moral violence or violation of dignity...".

But medical experiments on the human body have become a necessity that has dominated the minds of specialists, making them a danger to the human body, because they often do not succeed, as not all experiments are one hundred percent successful.

In order to protect the person's right to physical integrity, and to regulate the practice of these experiments in order to ensure medical stability and scientific progress, the legislator sought to enact a number of legal texts¹, through which he reshaped the legal framework of medical rules, thus starting the first steps of medical law.

Medical experiments have sparked wide controversy because of their special nature in the legal and medical circles on the one hand, and because of the problems they can raise on the other hand, as it is no longer limited to traditional therapeutic methods on the patient's body, but there can be non-therapeutic experiments and on the bodies of healthy people, so that the human body in this case becomes the weakest link in this experience, which requires intervention to raise the rules of civil liability in this regard.

Hence, we wonder about: What are the legal guarantees guaranteed to the injured as a result of these experiments? How can they respect human rights over his physical and moral body?

To answer this problem, we divided this study into two main points, the first dealt with the legal controls for conducting medical experiments on the human body, and the second the effects of the doctor's error in the field of medical experiment.

¹Law No. 18-11 of 02 July 2018 on Health, G.R., n° 46, of 29 July 2018.

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I. Legal controls for conducting medical experiments on the human body:

In recent years, doctors have come up with many drugs and medical theories, which were the inevitable result of a series of successful medical experiments, in which doctors and scientists used innovative methods in this field.

However, given the vastness of the field of medical experiments, it is necessary to identify their concept in order to be able to distinguish them from the circle of questionable medical experiments, which violate the general Sharia, the latter of which necessitated the establishment of rules and conditions for the practice of medical experiments in order to become permissible and perform the desired goal, which is to preserve human life and health.

1- The concept of medical experiments:

Medical experience is considered one of the important topics due to the scientific benefit it provides, not to mention that it is credited with the expansion of the field of various sciences, including medical law².

Experiment is a language that is from the source "try" and means "test", so the man tried an experiment, that is, he tested it, and he tried it experimentally, and he tried it again³.

Idiomatically, experiment is "a deviation from conventional medical principles for the purpose of collecting scientific or technical data or acquiring new medical knowledge with a view to developing medical, biological and biological sciences"⁴.

A medical experiment is with this intention the collection of scientific data to detect or verify hypotheses for scientific purposes, and it is part of the experimental research method on humans, which varies according to the purpose and general purpose of conducting it...⁵.

It has also been defined: "Any research that would achieve progress or lead to scientific innovation with regard to the functions of human organs, whether in health or in the state of disease, and be applicable to it"⁶.

It is also defined as: "deviation from medical assets for the purpose of acquiring new knowledge"⁷.

In legislative terms, French Law No. 1138/88 of 20/12/1988, as amended and supplemented by Law No. 86/90 of 23/01/1990 on the method of conducting medical experiments, defines a medical experiment as: "the collection of scientific research and studies carried out on the human being with the aim of developing the biological and medical sciences"⁸. (as amended by the named Jarre law of 2012), on the protection of persons subject to biomedical research.

²MawasiAlja, Dealing with Human Organs from a Legal Point of View, PhD Thesis, Faculty of Law and Political Science, Mouloud Mammeri University, TiziOuzou, 2016, p. 95.

³IbnManzur Jamal al-Din Muhammad bin Makram al-Ansari, Lisan al-Arab, Dar Sader, Beirut, 1994, p.262.

⁴Belhaj Al-Arabi, The Legal and Ethical Limits of Medical Experiments on Humans, University Press Office, 2011, p. 16.

⁵Belhaj Al-Arabi, Rulings on Medical Experiments on Man in the Light of Sharia and Contemporary Medical Laws - A Comparative Study - 1st Edition, Dar Al-Thaqafa for Publishing and Distribution, 2012, p. 25.

⁶Ashraf Gaber, Insurance from Civil Liability for Doctors, Dar Al-Nahda Al-Arabiya, Cairo, 1999, p. 294.

⁷Al-Nawawi Khaled, Principles for the Protection of the Human Body, Controls of the Legality of Medical Experiments and their Impact on Civil Liability, Dar Al-Fikrwal-Qanoon, Mansoura, 2010, p. 50.

⁸<http://www.legifrance.gouv.fr>

As for the Arab laws, most of them do not deal with the definition of medical experience, unlike the Health Law No. 18-11 through Article 337 thereof, which states: "Research in the field of biomedicine consists of conducting studies on the human organism for the purpose of developing epidemiological, diagnostic, biological and therapeutic knowledge and improving medical practices.

Clinical studies can be observational or interventional in particular:

- Therapeutic or diagnostic and preventive studies.
- Bioequivalence and bioavailability studies.
- Epidemiological and pharmaceutical-epidemiological studies."

It should be noted from the text of this article that the Algerian legislature has adopted the term clinical studies as an alternative to medical experiments. In addition to its definition, it has defined its scopes in the three cases mentioned in paragraph 2 of the above-mentioned article.

Moroccan legislation, which calls medical experiments biomedical research, defines them as: "Any research or experiment organized and conducted on a human being for the purpose of collecting information, developing biological or medical knowledge, or in order to respond to public health requirements"⁹.

By the above definitions, medical experimentation can be defined as: "the sum of biological processes organized and scientifically developed for application to human beings for the purpose of eradicating diseases and epidemics and discovering new treatments..."

2- Legal conditions for conducting medical experiments:

In order to authorize medical experiments, a set of legal conditions must be met in light of the reality that imposes itself, which has contributed to many developments in all fields, as the patient is considered a weak party in this relationship, which must be protected because the right to physical integrity is guaranteed to all.

2-1. Satisfaction of the patient undergoing medical experience:

Based on the principle of the inviolability of the human being in his body, the satisfaction of the patient subject to medical experience is important, because there is no doubt that the patient is free to undergo or not to undergo the medical experiment, he has the right to self-determination.

The doctor's access to the patient's consent is a reverse protection that protects him from any future judicial follow-up¹⁰.

Patient consent means his express or implicit expression to the effect that he agrees to the conduct of the medical experiment or refuses it, provided that the patient's consent is free and not subject to coercion, deception or error.

⁹Law No. 110-15 August 04, 2015 implementing Law 13-28 on the protection of persons involved in biomedical research.

¹⁰BarakatEmad El-Din, Scientific and medical experiments on the human body in the light of the rules of civil responsibility - a comparative study -, PhD thesis, Faculty of Law and Political Science, Ahmed Derayah University, Adrar, 2018-2019, p. 119.

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The patient must be fully competent and of legal age in accordance with Article 40 of the Civil Code and not suffer from any of the symptoms of incapacity, but this does not prevent him from obtaining the consent of his legal representative in the event of experiments involving minors.

Therefore, the patient's consent must be obtained in all medical interventions while respecting his choice, and this is according to the text of Article 42 of the Code of Medical Ethics¹¹: "The patient is free to choose his doctor or dental surgeon or to leave them, and the doctor or dental surgeon should respect the patient's right..."

Therefore, consent must be: free - insightful.

2-2. License to practice medicine:

This means that a physician has obtained an administrative license to practice medicine in accordance with the laws regulating this profession, as this is a necessary condition for the permissibility of medical interventions.

This was addressed by the Algerian legislator in Law No. 05-85¹², chapter II, section I, entitled "Conditions and regulations of health professions", in articles 197 to 227 thereof, and amended by Law No. 98-09¹³.

He then added Executive Decree No. 92-276 of 06/07/1992 containing the Code of Medical Ethics.

In order for a doctor to obtain this license, he must obtain the required scientific qualification in accordance with the specialization granted to practice medical work and registered in a special register with the Ministry of Health, and if he violates this, he shall be responsible in accordance with the general rules with a penalty for practicing the profession of medicine and surgery in violation of the law¹⁴.

Under article 166 of the Health Act, a licence is required to:

- Algerian nationality.
- Possession of the required Algerian diploma or equivalent certificate.
- Enjoyment of civil rights.
- Not to be subjected to any penal provision incompatible with the practice of the health profession.
- Enjoy physical and mental abilities that are not incompatible with the practice of the medical profession.
- Registration in the list of doctors.

¹¹Executive Decree No. 92-276 of July 6, 1992, G.R. No. 52, issued on July 8, 1992.

¹²Law No. 85-08 of February 16, 1985, on the Protection and Promotion of Health, G.R., No. 61, amended and supplemented.

¹³Law No. 98-09 of 19/09/1998.

¹⁴Mohamed Abdel Wahab Abdel Meguid, The Criminal Responsibility of Doctors Arising from the Use of Modern Scientific Methods in Medicine (A Comparative Study of Islamic Law), PhD Thesis, Cairo University, Egypt, 1997, p. 11.

Article 204 of the Code of Medical Ethics also stipulates that registration in the accreditation list must be made for anyone applying for a license to practice medicine¹⁵.

2-3. Authorization to conduct a medical and surgical experiment:

Health Law No. 11-18 stipulates that a license to conduct a medical experiment, whether therapeutic, non-therapeutic or surgical, must be obtained by the Minister in charge of Health, after submitting an application attached to the research protocol¹⁶.

The Minister must decide on the application submitted to him within 3 months of acceptance or rejection, although the article does not refer to any other procedures followed in the event of rejection in relation to appealing the Minister's decision.

The Algerian legislator has also confirmed that in the event of a change in the search protocol, after obtaining the license, the Minister must be notified of this amendment in order to obtain a new approval.

Most medical projects of this type are subject to the approval of the Medical Ethics Committee for Clinical Studies, which gives its opinion on each project for a medical experiment on humans¹⁷.

Article 53 of the Code of Medical Ethics also stipulates: "The doctor shall be prepared to conduct trials of medicines and techniques before they are approved by the competent authority."

In the event that the medical experiment is initiated without a license from the competent authorities, the penalty shall be imprisonment from two (02) to five (05) years and a fine of 5,000,000 -10,000,000 DA¹⁸.

2-4. Conducting the medical trial in qualified hospitals:

Article 379 of the Algerian legislature stipulates that: "Clinical studies must be carried out in conformity with the rules of good practice in this field in the structures approved and authorized for this purpose, according to the modalities specified by the Minister in charge of Health."

With this article, the Algerian legislator has stipulated that the medical experiment be carried out in qualified places so that it is equipped with medical equipment in anticipation of any emergency, in order to ensure the success of the medical experiment, provided that the following conditions are respected¹⁹:

- Ensure that people are monitored.
- Securing a number of beds commensurate with the planned activities.

¹⁵Doctors and surgeons working in the military health sector and doctors who do not actually practice the profession are excluded.

¹⁶Article 381 of the Code states: "Clinical studies shall be subject to the authorization of the Minister in charge of Health, which shall be broadcast within 3 months, on the basis of a medical and technical file, and a declaration on clinical studies on human beings submitted by the promoter."

¹⁷See Article 383 of the Code of Criminal Procedure.

¹⁸See article 438 of Law 11-18.

¹⁹AshrafRimmel, Medical Experiments on the PSHR, Journal of Law and Political Science, No. 15, Modern Book Foundation, Lebanon, 2017, p. 75.

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- Good organization while ensuring the confidentiality of information.
- Availability of conditions for cleanliness, maintenance and efficiency to ensure the safety of people.
- Establish a quality assurance system.

II. **Consequences of a doctor's error in the field of medical experimentation:**

Medical experiments have imposed themselves in practice and have assumed great and indispensable importance in the medical field. However, due to the seriousness that characterizes it, the doctor may fall into a mistake within the field of his experience that entails liability in the civil part, whether contractual or tort, and therefore the damage caused to the patient as a result of this error must be compensated.

1- The doctor's contractual responsibility for medical experiments:

Obligations often arise between the patient and the doctor between both parties, the breach of which entails contractual liability. Whenever a contract is required between the doctor that is valid and arranges for its legal effects and the injured person who is subject to medical probation and results in damage as a result of the doctor's breach of his obligation, liability arises²⁰.

Contractual liability for medical experiments in general is compensation for damage resulting from the breach of the obligation established by the doctor, the source of which is the contract that binds him to the injured party, which determines its judgment and extent²¹.

In this case, the doctor is responsible for the medical experiment he performs if the patient proves that the damage he suffered was due to the doctor's breach of one of the existing contractual obligations mentioned in the medical contract, whether the experiment was paid or free of charge²².

In order for the contract to result in contractual liability, the contract must be in writing as referred to in article 04 of the Declaration of Helsinki (Part 2) and article L1-1122 of the French Public Health Code.

The medical experience carried out by the doctor in charge is completely different from the treatment provided by the average doctor, as the latter can do his work in case of necessity and urgency, while the medical experience is not, but the same in both cases does not negate the fact that the responsibility is nodal in them. In order for liability to be contractual, the following conditions must be met:

- The existence of a contract between the doctor and the subject of the medical experiment:

The Algerian legislator defined a contract in article 54 of the Civil Code²³ as: an agreement whereby one or several persons commit to one or several other persons to grant, do

²⁰Ibn al-NawaKhaled, officer of the legality of medical experiments and their impact on civil liability, Dar al-Fikrwal-Qanoun, Mansoura, Egypt, 2010, p. 182.

²¹Sherif Al-Tabakh, Medical Error Crimes and Compensation, Dar Al-Fikr Al-Jamia, Alexandria, 2005, p.219.

²²Ibn al-Nawawi Khalid, op. cit., p. 184.

²³Order No. 75-58 of September 26, 1975, G.R. No. 78 of 1975.

or not do something, and therefore any act of a doctor outside this framework entails his contractual liability.

The prior agreement between the probation patient and the doctor defines the obligations of both parties, and any departure from the norm entails the responsibility of the treating physician, but outside this framework the liability is considered tort rather than contractual.

- **The contract must be valid:**

This means that the contract concluded between the treating doctor and the patient fulfills the legally imposed conditions of consent, place and reason, and the will of the parties is free of defects, in addition to the obligation to write the contract²⁴, as the failure of one of these conditions makes the contract null and void and thus the liability becomes tort.

- **Doctor's breach of contractual obligation:**

Contractual liability must relate to the fault of the experimenter resulting from the failure to perform an obligation linked to the medical probationary contract, but if the fault has nothing to do with the nodal bond, the liability is in tort.

- **The plaintiff must be the owner of a right in the lawsuit:**

Once a contract is concluded between the doctor and the patient or his legal representative, only the doctor has the right to sue and the successor general also has the right to do so when the patient on medical probation dies²⁵, but what if the person entitled to the lawsuit is a minor?

The minor is that person who does not enjoy full awareness and discrimination, which means that it is not possible to express his positive or negative opinion and express his will, especially in the case of medical intervention, and this is due to their young age, which requires highlighting the role of their legal representative in this imposition as stipulated by law²⁶.

With reference to the general provisions²⁷, only the father, mother or legal representative shall have the right to consent to the medical work to be performed on the minor, and they shall be informed of all information by the doctor²⁸.

Article 386-1 of the Health Code states: "Clinical studies may only be carried out if persons who are willing to undergo clinical studies express themselves or when their legal representatives are unable to do..."

From this text, it is clear that the legislator did not object to conducting medical experiments on minors, but rather linked this to obtaining the consent of the legal representative, and did not distinguish between therapeutic or scientific experiment, while the

²⁴Ibn al-Nawawi Khalid, op. cit., p. 175.

²⁵Ibid., p.p. 176-177.

²⁶Barakat Muhammad, previous reference, p. 158.

²⁷Article 83 of Law No. 84-11, as amended and supplemented by the Family Code, stipulates: "Whoever has reached the age of discrimination and has not reached the age of majority in accordance with article 42 of the Civil Code, his actions shall be effective if they are beneficial to him, null and void if they are harmful to him and depend on the authorization of the guardian or guardian if they are hesitant between benefit and harm.

²⁸Ali Filali, Patient Satisfaction with Medical Work, Algerian Journal of Legal, Economic and Political Sciences, vol. 36, No. 03, Algeria, 1990, p. 54.

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difference between them is clear and clear, as the first represents an experiment in favor of the disease and originally aims to provide treatment for it, while the second is likely to be very dangerous for this minor and may harm his safety.

This was supposed to be the need for the legislator to intervene to develop guarantees to protect this category from the dangers of medical experimentation, especially since this law was newly established.

2- The doctor's tort liability for medical experiments:

Tort liability is the result of the fault of a person who causes harm to others, but with whom he has no contractual relationship, the source of such liability being the law.

Tort liability is one that arises as a result of the fault of a person who causes harm to others, but with whom he does not have a contractual relationship. A fault or breach of a legal obligation entails liability.

The doctor's failure to observe vigilance and his deviation from the duty not to harm others, such as his error in diagnosing the disease or not doing so in the first place, or his error in reading the results of analyses and radiological images, is subject to tort liability²⁹.

The trial judge can extract and prove the elements of the case without the doctor's supervision, provided that the compensation for the doctor includes the damage caused by his mistreatment. The liability here is in tort and far removed from contractual liability for lack of contract³⁰. The same was ruled by the French Court of Cassation, basing it on the text of articles 1382 and 1383 of the French Civil Code³¹. As for the Algerian legislator, he did not specify the nature of the responsibility for the doctor, and based on custom, whenever there is a contract between the patient and the doctor, the liability is contractual, but if the contractual relationship is absent, the liability is in tort based on the text of Article 124 BC, which states: «Every act, whatever committed by a person by his fault and causing harm to others, obliges those who caused its occurrence to compensate». The obligation here is to pay attention by the doctor responsible for the medical experiment. There are a series of confirmed cases in which the tort of the doctor responsible for the experiment is in tort³²:

- In the absence of a contract between the experimental patient and the attending physician, especially if the patient is at great risk such as using new means to save the patient.
- The harmful act of the experimenter is in itself a crime.
- The case of a doctor working in the public sector or research centers affiliated with the latter, in which the patient is unable to choose the doctor conducting the experiment and therefore there is no contract between them.

Conclusion:

The progress of medical science has become indispensable for carrying out a set of medical experiments conducted on the human body, but the latter has raised many problems,

²⁹Anas Mohamed Abdel Ghaffar, *Civil Responsibility in the Medical Field (A Comparative Study between Law and Islamic Sharia)*, Dar Al-Kutub Al-Qanoon, Egypt, 2010, p. 103, quoted in, Barakat Mohamed, previous reference, p. 254.

³⁰Egyptian Civil Cassation (June 22, 1936), quoted by, Sherif Al-Tabakh, previous reference, p. 165.

³¹For more information, see: Ibn al-Nawawi Khalid, *op. cit.*, p. 182.

³²Barakat Muhammad, *op. cit.*, pp. 255-257.

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especially those related to civil protection and the extent of its necessity, especially if it comes to damage to the patient.

When medical errors occur during the intervention in the field of medical experiments, the civil liability of the doctor is established, and even if the error is absent, this does not exempt the doctor from responsibility, so whenever the damage occurs, his civil liability is required.

Care must also be taken to obtain the consent of the person subject to the medical experiment and the availability of the rest of the other conditions, and this is so that we are in front of a medical experiment that meets the legal conditions, in case of violating it, it is possible to impose a penalty, as the doctor's obligation in the field of therapeutic medical experiments is to exert care. If the experiment is scientific, his commitment to achieving a result is what makes him different from the average doctor.

Based on these findings, we recommend the following:

- The Algerian legislator must take care of the subject of medical experiments by issuing a set of legal articles regulated.
- The need to establish specialized centers equipped with all medical tools to conduct such experiments, whether therapeutic or scientific, as the human right to physical integrity is one of the rights guaranteed by law, which must put the relationship between the doctor and the patient in a legal framework.
- The need to respect medical ethics.
- The necessity of protecting minors and all special groups during the conduct of the medical experiment.
- Civil liability can be in accordance with the rules of strict liability based on the element of damage only, for several reasons, including, for example, the absence of legislative provisions on medical experiments on humans in Algerian law.
- Subjecting these experiments to Health Law No. 18-11.
- The necessity of enacting a special law on the ethics of medical scientific research.