

LEGAL REGIME APPLICABLE TO THE REMOVAL AND TRANSPLANTATION OF ORGANS, TISSUES AND CELLS OF HUMAN ORIGIN FOR THERAPEUTIC PURPOSES FROM THE LIVING DONOR

*“What we have done for ourselves alone dies with us;
what we have done for others and the world remains and is immortal”.*
(Albert Pike, American lawyer, journalist, and soldier, 1809-1891)

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Abstract: *Transplantation of organs, tissues and cells of human origin is considered to be the best and often the only form of treatment for patients with organ failure.*

Although the contribution of this medical intervention to saving human lives or to increasing the quality of life of sick people is undeniable, it also involves a number of dangers.

Improper use of organs or tissues could prejudice fundamental human rights, such as the right to life, the right to physical and mental integrity or the right to dignity. Also, the insufficiency of available organs and the pressure to increase their number can favour the emergence and development of practices that go beyond ethical and legal limits. Beyond these possible dangers, the psychological and sociocultural implications

inherent in carrying out such medical intervention that significantly and irreversibly affect the lives of the persons involved must be considered.

Based on these considerations, this article examines the strengths and weaknesses of the legislation governing the transplantation of organs, tissues and cells of human origin in Romania. Finally, it advocates the existence of a firm and balanced legal framework through which to maximize the quality, safety of interventions, to guarantee the rights and freedoms of donors and recipients, without, however, representing an obstacle to medical progress.

Keywords: *transplant; organs; donor; recipient; consent.*

Introduction

The idea of transferring an organ from man to man or from animal to man is very ancient, existing since prehistory. In the period of myths and miracles, transplants performed by gods, saints and healers are mentioned.

There is the myth that in the 3rd century the surgeon saints Cosmas and Damian performed the “successful transplantation” of an entire leg, a procedure depicted in several famous paintings (Barker & Markmann, 2013). The miracle of saints Cosmas and Damian concerned the transplantation of the leg from a black man to a white man that would have taken place in medieval Rome (van Gulik, 2024). Although technically this event is considered a miracle or a dream, the choice of a leg graft from a black deceased donor onto a white recipient is remarkable in its symbolism for the further development of the field of transplantation both from the perspective of medical technique, but also from an ethical and legal perspective.

This choice demonstrates that even in times when surgeons could only dream of transplantation, altruism prevailed without racial problems. Altruism is the fundamental principle that must govern organ donation. According to this principle every available organ should go to anyone who needs the organ, regardless of race, religion or any other criteria (van Gulik, 2024).

References to a form of transplantation we also find in the Bible where it can be concluded that Eve owes its existence to a rib “transplanted” from Adam: *“And the Lord God caused a deep sleep to fall upon Adam, and he slept: and he took one of his ribs, and closed up the flesh instead thereof; And the rib, which the Lord God had taken from man, made he a woman, and brought her unto the man”* (The Old Testament, 21:22).

Although the history of transplants is not of divine origin, yet the role of various religions in the development of this medical technique cannot be disputed.

For example, the Orthodox Christian Church is favourable to this form of intervention on the human body, showing that it blesses any medical practice in order to reduce the suffering in the world, and sees in the organ donor a man capable of self-healing and fulfilling his gesture out of love for his neighbour (Romanian Orthodox Church). In turn, the Islamic religion also supports organ transplantation, blood transfusion and scientific research in the field provided that the freedom, dignity and responsibility of donors, recipients and health operators are respected (Ionașcu, 2005).

1. Brief historical considerations on organ transplantation

The first medical scientific achievements in the field of organ transplantation barely appear in the late 19th and early 20th centuries and are connected with the name of the great French surgeon Alexis Carrel. His research is the cornerstone of organ transplantation by perfecting the technique of blood vessel ligation (Mustață, 2019).

In 1954, the first successful kidney transplantation between identical twins was performed by dr. Joseph Murray of Harvard University, and in 1967 the first liver transplantation with receptor survival performed by dr. Thomas Starzl. An important moment in the history of world transplantation is the first heart transplant, performed in 1967 by the surgeon of Romanian origin Christiaan Barnard (Deac, 2010).

Regarding the history of Romanian transplantation, data attest that it begins in 1980, with the first kidney transplantation performed by Prof. dr. Eugeniu Proca, followed shortly by the first kidney transplantation from a deceased donor, performed by Prof. dr. Petru Drăgan. However, the modern stage in transplantation will start in our country only after December 1989 (National Transplant Agency, 2025; Deac, 2010).

Regarding the legal regulation of organ transplantation in Romania, the first rules in this matter are found in Law no. 3/1978 on ensuring the health of the population. A distinct regulation of this medical field is identified quite late by the Law no. 2/1998 on the procurement and transplantation of human tissues and organs and Law no. 104/2003 on the handling of human cadavers and the procurement of organs and tissues from cadavers for transplantation purposes.

Currently, the removal and transplantation of organs, cells, tissues and organs from the living donor for therapeutic purposes is regulated by the provisions of art. 68 Civil Code which is supplemented by the provisions of Title VI called “Performing the removal and transplantation of organs, tissues and cells of human origin for therapeutic purposes” (art. 141-art.162) Law 95/2006 on health care reform. The national provisions are in agreement with the European Union legislation, with the European and international legislation in the matter.

2. Principles and conditions for the removal and transplantation of organs, cells, tissues and organs from the living donor for therapeutic purposes in Romania

From the set of legal provisions listed above, a number of principles are derived that govern the removal and transplantation of organs, cells, tissues and organs from the living donor for therapeutic purposes, namely: the principle of legality of intervention, the principle of non-patrimoniaity and altruism, the principle of confidentiality of the procedure and respect for personal data and the principle of freely consented donation.

The *principle of legality* emerges from Thesis 1 of art. 68 Civil Code according to which the removal and transplantation of organs, cells, tissues and organs can be carried out only in the cases and conditions prescribed by law. Also, the procedure is carried out under state control. In this regard, art. 143 para. 2 and para. 3 of Law 95/2006 stipulate that the coordination, supervision, approval and implementation of any provisions regarding the transplantation activity are the responsibility of the National Transplant Agency. The inspection and control measures regarding the transplant activity are the responsibility of the Ministry of Health, through the control structure in the field of health.

The *principle of non-patrimoniaity and altruism* refers to the fact that the donation and transplantation of organs, tissues and cells of human origin cannot be the subject of legal acts and facts for the purpose of obtaining material or other use, are made only for humanitarian purposes and are altruistic in nature, as emerges from art. 144 para. 1 letter e) and f) of Law 95/2006 on health reform. We are thus in the presence of an application of the principle of non-patrimoniaity of the human body, enshrined in art. 66 Civil Code. According to it, it is forbidden to evaluate the human body in money and to conclude patrimonial legal acts having as object the body in its whole or its component parts. The foundation of this principle lies in the fact that this body is the physical person themselves, the biological support of their existence. The non-patrimoniaity also extends to the constituent elements of the body (organs, tissues, cells), as well as to its biological products (blood, breast milk, sperm).

Donation in order to obtain material benefits for oneself or for another is an offence according to art. 156 para. 1 of Law no. 95/2006. According to par. 3 of the same article constitutes an offence also the publication or media coverage of announcements regarding the donation of organs, tissues or cells of human origin, donation that would be carried out in order to obtain material benefits for oneself or for others. The law also qualifies as an offence the organization or carrying out of the removal of organs, tissues or cells of human origin for transplantation, in order to obtain a material benefit for the donor or organizer, as well as

the purchase of organs, tissues or cells of human origin, for the purpose of resale (art. 157 para. 1 and para. 2 of Law no. 95/2006) (Diaconescu et al., 2009).

The *principle of confidentiality and respect for personal data* is another principle that underlies the performance of these types of medical interventions. Art. 144 para. 2 of Law 95/2006 establishes that “removal and transplantation centres will keep a record of living donors who have donated to the centre in accordance with national provisions on personal data protection and statistical confidentiality”. At the same time, according to art. 146 para. 8 and par. 9 of the same law “data on the donor and receiver, including genetic information, to which third parties may have access, will be disclosed anonymously so that neither the donor nor the receiver can be identified. If the donor does not wish to disclose their identity, the confidentiality of the donation will be respected, except in cases where the declaration of identity is mandatory by law”.

The *principle of freely consented donation* is the rule that the removal and transplantation of organs, cells, tissues and organs can only be carried out after obtaining the informed, written, free, prior and express consent of the donor and recipient.

The terms of the consent of the donor/recipient are established by art. 68 para. 1 Civil Code and art. 144 letter a) of Law no. 95/2006. No removal may be made without the consent of the person concerned and the donor may revoke such consent at any time prior to removal. The legislation in force prohibits by removal and transplanting human organs, tissues and cells from potential minor donors, as well as from people without discernment. It is thus established the rule according to which removal can be carried out only from persons who have full capacity for exercise (Chelaru & Duminiță, 2017).

By exception, according to art. 145 para. 2 of Law no. 95/2006, the removal of medullary or peripheral hematopoietic stem cells may also be performed from a minor who is related to the recipient up to the fourth degree, subject to the following requirements: the salvation of the minor who has reached the age of 10 years and the written consent of the legal protector (parents, guardian or curator) according to the model form

approved by order of the minister. If the minor has not reached the age of 10, the removal can be done with the consent of the legal guardian. The written or verbal consent of the minor who is at least 10 years old is expressed before the president of the court, after the mandatory carrying out of a psychosocial investigation by the General Directorate of Social Assistance and Child Protection. The written or verbal refusal of the minor prevents any removal.

Concluding, from the legal provisions mentioned above, it results that the following *conditions have to be met by the consent given* in the case of removal and transplantation of human organs, tissues and cells from the living donor (Chelaru & Duminică, 2017; Chelaru & Chelaru, 2023):

- consent must be free, that is, it must not be altered by any vice of consent, being forbidden to remove organs and/or tissues and/or cells if it is carried out following the exercise of a physical or moral constraint on a natural person, being in this case in the presence of violence as a vice of consent;
- consent must be prior, and it is not allowed to express it later;
- consent must be express, which cannot be deduced from the conduct of the person concerned, nor determined in certain aspects by a third person as in common law;
- consent must be informed of the possible risks and consequences on the physical, mental, family and professional level resulting from the act of removal. The doctor's obligation to inform the donor/recipient and/or the legal protector is such as to eliminate the possibility of error or mourning.

The externalization of the consent is made by written deed, concluded in authentic form and having a predetermined content by order of the minister of health. Specific to the removal of organs, tissues or cells is the revocable nature of the consent without the need to comply with any form, which constitutes an exception to the irrevocable character of the unilateral legal deeds.

The removal of organs, tissues or cells from the living donor shall be carried out with the consent of the Commission for the approval of donation from the living donor, set up within the hospital where the

transplant is performed. This Commission will assess the motivation of the donation and guarantee the observance of the rights of patients, according to the model of the form approved by order of the minister of health, as follows from art. 146 of the Law on health care reform. The Commission will assess both the donor and the recipient who will undergo a psychological and/or psychiatric examination, with the aim of testing the capacity for exercise, as well as determining the motivation for the donation. The psychological/psychiatric examination will be carried out by a specialist, psychologist or psychiatrist, independent of both the team performing the transplant and the families of the donor and recipient.

The members of the Commission will also sign the document expressing their consent to the removal, thus certifying that all the conditions provided by law have been respected. In turn, the recipient will sign this document. The signature of the document by the recipient confirms that the removal is not the subject of legal acts and facts for the purpose of obtaining material or other use. In this way, proof is provided of compliance with another condition provided by law: the removal must be carried out only for the purpose of carrying out a transplant whose beneficiary will be a determined person. The signing of that document by the recipient does not, however, transform the donation of human cells, tissues or organs into a contract, the human body being out of trade. Therefore, consent to removal is a unilateral, essentially free and solemn legal act (Chelaru & Chelaru, 2023).

Removal or transplantation of organs, cells, tissues and organs from living donors without consent given under the law constitutes an offence (art. 154 para. 1 of Law no. 95/2006). It is an offence and coercion of a person to donate organs, tissues or cells of human origin (art. 156 para. 2 of Law no. 95/2006).

All these principles are strengths of the relevant legislation guaranteeing respect for human dignity, as well as for other rights such as the right to life, the right to physical and mental integrity, the right to health, the right to privacy and the right to the protection of personal data.

However, there is a lack of accessible and unitary regulations that include in a separate normative act all the norms in the matter. Unlike other European states, Romania does not have a special law dedicated exclusively to organ transplantation although there have been attempts to do so over time. Unfortunately, no consensus has yet been reached for its adoption. The lack of a special law, as well as the poor financing of the medical system, the low number of transplant coordinators, the small number of donors, the excessive bureaucracy, as well as the poor cooperation between hospitals are just some of the causes of a low rate of organ donations in our country (National Transplant Agency, 2025).

Conclusions

Organ transplantation is one of the greatest medical performances of the 20th century. Currently, it constitutes a routine therapeutic method capable of saving the lives of people with serious health problems around the world. Since the first human-to-human organ transplant performed in 1954, when a kidney was successfully transplanted between identical twin brothers, and to this day, medical science in this area has evolved substantially. In 2024, surgeons at a hospital in Massachusetts, United States, transplanted the kidney of a genetically modified pig into a human receptor, and in March 2025, in a world premiere, surgeons in China reported that they transplanted the first genetically modified pig liver to a patient (Tao et al., 2025). The progress in the field of medical sciences, with all the benefits that it brings to man and society, is also accompanied by a series of ethical and legal dilemmas, as is the case with this new revolutionary medical procedure, called xenotransplantation. It consists in transplanting to humans tissues, cells, organs, coming from animals subjected to genetic modification. Recent achievements in this field raise a number of bioethical problems, such as limiting genetic diseases transmissible from animals to humans, respect for animal welfare, crossing the inter-species barrier and social acceptance of the practice, as well as a number of legal issues relating to the regulation of research in the field or access to this form of organ transplantation.

In this context, the intervention of the legislator becomes essential for guaranteeing human rights, for the safety and quality of research and medical interventions carried out, but especially for guaranteeing human dignity, understood as the foundation of all human rights and as a guarantee of the genetic specificity of man.

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