

# THE RIGHT OF THE DONOR/RECIPIENT TO INFORMATION IN THE CASE OF TRANSFER AND TRANSPLANT OF ORGANS, TISSUES AND HUMAN CELLS FOR THERAPEUTIC PURPOSES

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## Abstract

*The current study starts from the fact that, in the contemporary society, the patient can no longer be considered a simple consumer of services totally subordinated to the doctor, but he is an active participant in the performance of the medical act, having a series of rights, among which his right to information. This right completes the right to life and to health, his right to physical and psychological integrity, the right to dispose of oneself and the right over his own body. Knowing, accepting and bearing the consequences of his own (in) actions are important aspects for each individual, more valuable for the person subjected as donor or recipient of a transplant of organs, tissues or human cells for therapeutic purposes, given the implications of such a procedure. This is why a decision concerning the human body and health of an individual can be taken only after serious, real and intelligible information regarding the risks and benefits of the intervention to which that individual shall be subjected to.*

**Keywords:** *right to information, donor, recipient, doctor's obligation to inform, organ transplant, human tissues and cells for therapeutic purposes.*

## 1. Introduction

Starting from the fact that in many cases the conflict between the doctor and the patient occurs because the patient has not been informed about the specificity of the illness, the difficulties of the medical profession and the sometimes limited possibilities of medical science<sup>1</sup>, was adopted the European Charter of patients' rights that expressly entitle the patient to be informed. In the same meaning, the Convention on Human Rights and Biomedicine ratified by Romania by Law No 17/2001, states in Art 10 Para 2 that "Everyone is entitled to know any information collected about his or her health. However, the wishes of individuals not to be so informed shall be observed".

In the same spirit, the Romanian legislator expressly stated the right of the patient to be informed, by Law No 46/2003 on the patient's rights<sup>2</sup>.

By "patient", according to Art 1 Let a) of the above mentioned law, it is defined the healthy or ill person benefiting from a health insurance. In the virtue of the legal provisions, the person shall have the right to be informed regarding: the available medical services, their means of use, the identity and professional status of the health services providers, his own health condition, the proposed medical services, the potential risks of each procedure, the existing alternatives for each proposed procedure, including about risks of non-complying with the treatment or with the medical recommendations, as well as information

regarding the diagnosis and prognostics. Also, the hospitalized patient has the right to be informed regarding the rules and customs to be complied with during his hospitalization.

In the same time, the Law No 46/2003 acknowledges for the patient the possibility to decide if he wants to be informed if the medical data presented to him would cause sufferance, having the right to expressly ask for him not to be informed and to appoint another person to receive the information.

Correlative with the patient's right to information, the Deontological Code of the Romanian College of Physicians<sup>3</sup> states the doctor's obligation to inform. Thus, Art 14 states that no intervention in the health condition shall be performed without the consent of the person to be subjected to it. The consent shall be asked for only after the doctor has given appropriate information regarding the purpose and nature of the intervention, regarding the consequences and risks of the intervention. As far as possible, the language shall be appropriate for each patient, clear and respectful, minimizing as possible the specialist terminology, and if the patient is not familiar with the language, the information shall be brought to them knowledge in the native language or in the language they know or, where appropriate, another form of communication will be sought.

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<sup>1</sup> Liviu Oprea, "Un studiu analitic asupra relației medic-pacient" (Part 1), in *Romanian Magazine of Bio-ethics*, 7<sup>th</sup> Volume, No 2 (2009): 57-70; G. C. Curcă, "Aspecte conceptuale privind răspunderea deontologică și malpractica medicală", *Romanian Magazine of Bio-ethics*, 8<sup>th</sup> Volume, No 1(2010): 51-59.

<sup>2</sup> Official Gazette of Romania, No 51/20 January 2003.

<sup>3</sup> Official Gazette of Romania, No 981/7 December 2016.

## 2. The donor/recipient's right to information in the case of organs, tissues and human cells harvesting and transplant for therapeutic purposes

The Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin, signed in Strasbourg on 20 February 2015 and ratified by Romania in 2016 by the Law No 9/2016<sup>4</sup> guarantees, without discrimination, the compliance with the human integrity and with the other types of rights and fundamental freedoms in the field of transplantation of organs and tissues of human origin.

For the purposes of the Protocol, the term "transplantation" covers the complete process of removal of an organ or tissue from one person and implantation of that organ or tissue into another person, including all procedures for preparation, preservation and storage; and the term "removal" refers to removal for the purposes of implantation.

Similarly, Law No 95/2006 on healthcare reform<sup>5</sup> defines the transplant as being that medical activity which, for therapeutic purposes, within the body of a patient, named recipient, is transplanted or grafted an organ, tissue or cells harvested from another person, named donor", and the harvesting as being "the removal of healthy organs and/or tissues and/or human cells for the purpose of a transplant".

Currently, in Romania, the harvesting and transplant of organs, tissues or human cells from a living patient are being performed in accordance to Art 68 of the Civil Code and the Law No 95/200 on health care reform, republished.

The legislator also states that the harvesting and transplant of organs, tissues or human cells from living donors shall be made exclusively for the cases and conditions states by the law, based on the written, free expressed and prior agreement and only after they have been informed upon the risks of the procedures. For all cases, it is forbidden the harvesting of organs, tissues or human cells from minor persons, as well as from living persons without discernment due to a mental handicap, a serious mental disorder or from another similar reason, except the cases mentioned by the law. As exceptions, the republished Law No 95/2006 states in Art 145 Para 2 that the harvesting of bone marrow (hematopoietic stem cells) can also be performed from a minor person relative up to the 4<sup>th</sup> degree with the recipient, in compliance with the following conditions: the harvesting shall be performed only with the consent of the minor who has turned the age of 10 and the written agreement of his legal representative (parents, guardian or curator), according to the form approved by a Minister's order. If the minor is under the age of 10,

the harvesting can be performed with the legal representative's consent. The written or verbal consent of the minor aged at least 10 years old shall be expressed in front of the president of the court, after a mandatory psycho-social investigation of the General Directorate of Social Assistance and Child Protection.

Therefore, from the above-mentioned legal provisions result the following conditions to be fulfilled by the consent given for the harvesting and transplant of organs, tissues and human cells<sup>6</sup>:

- The consent shall be free, namely not altered by any vice of consent, being forbidden the harvesting of organs and/or tissues and/or human cells if the procedure is performed due to the physical or moral constraint of a natural person, this being the case of the violence as vice of consent;
- The consent must be prior, its subsequent expression not being allowed;
- The consent must be expressed, not deduced from the concerned person's behavior nor determined under certain aspects by a third party, as for the common law;
- The consent must be informed regarding the possible physical, psychical, family and professional risks and consequences resulting from the harvesting.

The harvesting of organs, tissues or human cells from a living donor shall be performed with the approval of the commission for approvals of transplants from living donors, established in the hospital in which the transplant is being performed, thus guaranteeing the free, informed and altruistic features of the consent. The members of the commission shall also sign the document expressing the consent for harvesting, thus certifying that all legal conditions have been fulfilled. In his position, the recipient shall sign this document after being informed about the risks and benefices of the procedure, as stated by Art 150 of the Law No 95/2006. By signing the document by the recipient, he is confirming that the harvesting is not the object of legal acts or facts, for the purpose of receiving a material benefit or of other nature. This is the proof of complying with another legal condition: the harvesting must be performed only for a transplant whose beneficiary shall be a certain person. Signing that document also by the recipient does not turn the donation of cells, tissues or human organs into a contract, the human body not being tradable<sup>7</sup>.

For the case in which the recipient is not able to express his consent, it can be given in written by one of the family members or by his legal representatives. The transplant can be performed even without the prior consent if, due to objective circumstances, cannot contact as soon as possible the family or the legal representative, and the delay would inevitably result in the death of the patient, this situation being reported by the chief doctor and the patient's doctor, using the form

<sup>4</sup> Official Gazette of Romania, No 62/28 January 2016.

<sup>5</sup> Republished in the Official Gazette of Romania, Part I, No 652/28 August 2015.

<sup>6</sup> See also Eugen Chelaru, *Drept civil. Persoanele, în reglementarea NCC*, 4th Edition (Bucharest: C.H. Beck, 2016), 31-32.

<sup>7</sup> Chelaru, *Drept civil. Persoanele, în reglementarea NCC*, 30-31; Eugen Chelaru and Ramona Duminićă, „Brief considerations about the informed consent of the patient”, in *Legal and administrative studies*, No 2 (2017): 7-27.

approved by Minister's order. As exception, for the minors or persons without capacity of exercise, the consent shall be given by the parents or other persons legally representing the minor.

For the purposes of harvesting and transplant of organs, tissues or human cells it is mandatory the information both of the donor, as well as of the recipient<sup>8</sup> by the doctor, social assistant or other medically trained persons on the possible risks and consequences for the physic, psychic, family and professional, resulted from the procedure.

In this meaning, Art 5 of the Strasbourg Protocol states that "the recipient and, where appropriate, the person or body providing authorisation for the implantation shall beforehand be given appropriate information as to the purpose and nature of the implantation, its consequences and risks, as well as on the alternatives to the intervention", while Art 12 states that "the donor and, where appropriate, the person or body providing authorisation [...] shall beforehand be given appropriate information as to the purpose and nature of the removal as well as on its consequences and risks. They shall also be informed of the rights and the safeguards prescribed by law for the protection of the donor. In particular, they shall be informed of the right to have access to independent advice about such risks by a health professional having appropriate experience and who is not involved in the organ or tissue removal or subsequent transplantation procedures".

The condition for the information of the donor about the risks deriving from the procedure has been stated in order to insure the informed consent of the donor, who has the possibility of rejecting, at any moment, the offer of harvesting the tissue should they consider that they would suffer unacceptable damage<sup>9</sup>.

After harvesting, the physical perfection of the donor's body, as well as the physic and psychical potential shall be reduced or even disappear, there may be possible professional damaging risks or consequences, as well as a new attitude of the family members regarding the harvesting and the subsequent physical and psychical state of the donor, aspects to be known and accepted before the medical intervention.

From this perspective, the draft-project of the Law for human transplantation, in public debate, represent a step forward from our perspective, maintaining the direction established by the Law No 95/2006 and bringing a series of novelties and clarifications in the shape of certain guarantees for the donor/recipient's right to be informed about the procedure to which he shall be subjected to. Thus, Art 46 of the draft-project details the conditions in which the harvesting of organs, tissues or human cells from a living donor shall be performed:

a) The harvesting of human organs, tissues or cells

for the purpose of a human transplantation, shall be performed from living major persons, with full capacity of exercise, after receiving their informed, written, free, prior and express consent, according to the form approved by a Minister's order. Thus, it is forbidden the harvesting of organs, tissues and/or human cells from persons without capacity of exercise;

- b) The consent shall be signed only after the donor has been informed by the doctor, social assistant or other persons with specialized training about the possible physical, psychical, family, professional and social risks and consequences resulting from the harvesting;
- c) The donor can reconsider his given consent, until the moment of harvesting;
- d) The harvesting and transplantation of organs, tissues and/or human cells as result of a physical or psychical constraint against a person are strictly forbidden;
- e) The harvesting and transplantation of organs, tissues and/or human cells cannot represent the object of legal actions or facts for material purposes for themselves and/or third parties;
- f) The donor and the recipient shall sign an authenticated document declaring that the harvesting of human organs, tissues and/or cells shall have a humanitarian purpose, altruistic and shall not represent the object of legal actions or facts for the purpose of receiving material benefits or of other nature, according to the form approved by Minister's order;
- g) The donor of hematopoietic stem cells shall sign an authenticated document stating that the donation shall have a humanitarian purpose, an altruistic feature and shall not represent the object of legal actions or acts for the purpose of receiving material benefits or of other nature, according to the form approved by a Minister's order;
- h) As exception from Let f) and g) if the donor does not wish to reveal his identity, the confidentiality shall be preserved;
- i) The donor shall be exempted from the payment of hospitalization resulted from the harvesting, as well as from the costs of the periodical medical controls post-harvesting.

### 3. The obligation for information of the doctor

Correlative to the right of the patients to medical information, Art 649 of the Law No 95/2006<sup>10</sup> and the Code of Deontology of the Romanian College of

<sup>8</sup> Ovidiu Ungureanu, "Noile dispoziții legale privind prelevarea și transplantul de organe, țesuturi și celule de origine umană în scop terapeutic", *Dreptul Magazine*, No 5(2007): 19.

<sup>9</sup> In the same meaning, see also Chelaru, *Drept civil. Persoanele, în reglementarea NCC*, 30-31.

<sup>10</sup> Official Gazette of Romania, Part I, No 372/28 April 2006.

Physicians<sup>11</sup> states the obligation of the medic to correct, complete and understandable information given to the patient or other designated persons to approve the medical intervention.

For the harvesting and transplant of organs, tissues or human cells, the doctor has the obligation to really inform the donor, without minimizing or exaggerating the damaging consequences<sup>12</sup>. Also, he has the obligation to specifically, really and intelligibly inform the recipient regarding the risks and benefits of the procedure and, when appropriate, his family members, his legal representative, aiming the legitimate purpose of protecting the persons involved and thus excluding the possibility of distorting the intention to carry out the transplant.

Guaranteeing an informed consent of the donor/recipient assumes the provision of all the relevant information by the doctor using an easily understandable for the patient to be able to decide fully aware of the situation. Also, it refers to the evaluation of the patient on the understanding of the information and the insurance that, as it is possible, the patient has the freedom to choose between medical alternatives without coercion or manipulation<sup>13</sup>.

The obligation to information for the donor/recipient and/or legal representative has the nature to remove the possibility of any vice of consent, such as the error or the dolus. This does not mean that, practically, they cannot exist, being situations in which there is the complicity or unprofessionalism of the one compelled to inform the donor/recipient. For example, the literature<sup>14</sup> has showed that any form of reluctance of the donor in expressing his approval must be seen as vice of consent.

This is why the professional obligations of the doctor<sup>15</sup> towards its patients are the base of the legal construction of the medical malpractice, representing a starting point in the evaluation of the behaviour of the responsible. According to Art 653 Para 1 Let b) of the Law No 95/2006, malpractice represents the “professional error committed in the performance of

the medical or medical-pharmaceutical act causing prejudices for the patient, by implying the civil liability of the medical personnel and of the supplier of medical, sanitary or pharmaceutical services and products”.

Regarding the obligation for information, it is considered<sup>16</sup> that it is an obligation of result, whose violation may entail the liability of the doctor on objective grounds, namely that of the risk of his profession, Art 653 Para 3 of the Law No 95/2006 establishing that the medical personnel is civil liable also for the prejudices resulted from the non-compliance with the regulations regarding the informed consent of the patient.

By entailing the civil liability does not exclude the criminal liability, if the action which generated the prejudice represents an offence according to the law and/or of the disciplinary liability of the doctor. According to Art 155 of the Law No 95/2006 it represents an offence the harvesting or transplant of organs and/or tissues and/or human cells without the consent given as stated by the law.

Also, the violation of the patient’s right to medical information may entail the disciplinary liability of the doctor<sup>17</sup>, as mentioned by Art 37 of the Law No 46/2003 and the Code of Ethics. Non-compliance of the rules of medical ethics, including of those regarding the obligations correlative with the patient’s rights, shall entail such liability.

#### 4. Conclusions

Given the importance of the rights endangered in case of a transplant of organs, tissues or human cells of therapeutic purposes, the statement of the right to information of the patient has represented a necessity for the performance of the medical act.

The patient’s consent represents an important decision regarding his life, health and body integrity, this is why he shall base the decision on correct information provided by his doctor.

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<sup>11</sup> Official Gazette of Romania, Part I, No 981/7 December 2016.

<sup>12</sup> Iancu Tănăsescu, Gabriel Tănăsescu and Camil Tănăsescu, *Transplantul și prelevarea* (Bucharest: C.H. Beck Publ.-house, 2008), 48-52.

<sup>13</sup> Angela Butnariu, Iustin Lupu and Mircea Buta, “Consimțământul informat în practica pediatrică și în cercetarea vizând copilul”, *Romanian Magazine of Bio-ethics*, 7<sup>th</sup> Volume, No 1(2009): 40-41.

<sup>14</sup> Ungureanu, “Noile dispoziții legale privind prelevarea și transplantul de organe, țesuturi și celule de origine umană în scop terapeutic”, 19; Chelaru, *Drept civil. Persoanele, în reglementarea NCC*, 32.

<sup>15</sup> For an analysis of these obligations, see also Lacrima-Rodica Boilă, “Malpraxis. Propuneri legislative privind despăgubirea victimelor accidentelor medicale”, in *Romanian Magazine of Private Law*, no. 5 (2012): 52.

<sup>16</sup> Lacrima-Rodica Boilă, *Răspunderea civilă delictuală subiectivă*, 2<sup>nd</sup> Edition (Bucharest: C.H. Beck, 2009), 392-393; Chelaru and Duminiță, „Brief considerations about the informed consent of the patient”, 7-27.

<sup>17</sup> Silviu Morar, Horatiu Dura, Mihaela Cerunșcă-Mițariu and Adrian Cristian, “Reflectarea drepturilor pacienților în noile coduri deontologice din domeniul medical”, in *Acta Universitatis Lucian Blaga*, No 1(2013): 34.

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