

## REVIEW ARTICLE

## LEGAL OBLIGATIONS IN THE CONTEXT OF HUMAN ORGANS AND TISSUES TRANSPLANTATION

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### ABSTRACT

**The aim:** To highlight and analyze the nature of certain legal obligations occurring in the process of human organs and tissues transplantation, in particular, the following obligations: compliance with regulatory and medical requirements for organ and human tissues transplantation, obtaining the donor's consent for organs and tissues transplantation, organs or tissues transplantation on a non-commercial basis.

**Materials and methods:** Methodologically, this work is based on the system of methods, scientific approaches, techniques and principles with the help of which the realization of the research aim is carried out. There have been applied universal, general scientific and special legal methods.

**Conclusions:** Analyzed regulatory and medical requirements, indicate the complexity of the transplant process, as well as the need for strict compliance with established regulations and rules. For the whole complex transplant procedure, one of the key points is the donor's consent (disagreement) to remove anatomical materials from him. The obligation to perform organ or tissue transplantation on a non-commercial basis has a dual purpose: first, to prevent offenses and legal violations in this area; secondly, to determine as transparently and clearly as possible the list of costs incurred by the donor in connection with the organs and tissues removal and subject to reimbursement, the procedure for such reimbursement and its reasonable, acceptable and sufficient amount.

**KEY WORDS:** obligations, law, transplant, donor, recipient, donation

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### INTRODUCTION

Several years of experience in transplantation have demonstrated the importance of this institute in medicine, as well as the need for its proper regulation at the level of international and national legislation [1]. At the present stage, transplantation of human organs and tissues should be an effective means of saving lives, restoring health and having a significant effect on the duration and quality of population life. As the medical procedure itself is complex in nature, the need to identify and further study the legal responsibilities of the transplant procedure is of particular importance. After all, they show the need for participants' increased responsibility and strict compliance with legal requirements in the relevant activities. Responsibilities allow us to emphasize the importance of acting in accordance with the existing legislation considering medical intervention. In this study, we will focus on the justification of certain legal obligations arising from the connections in the field of human organs and tissues transplantation.

### THE AIM

The aim of the work is, therefore, to study and analyze the nature of certain legal obligations occurring in the process of human organs and tissues transplantation, in particular, the following obligations: compliance with regulatory and medical requirements for organ and human tissues trans-

plantation, obtaining the donor's consent for organs and tissues transplantation, organs or tissues transplantation on a non-commercial basis.

### MATERIALS AND METHODS

Methodologically, this work is based on the system of methods, scientific approaches, techniques and principles with the help of which the realization of the research aim is carried out. There have been applied universal, general scientific and special legal methods. In particular, the formal-legal method, which is used to study the internal form of legal phenomena and processes, allowed to formulate the concept of relevant legal obligations in the field of transplantation on the basis of generalization and identification of features. The object of the formal legal method is the sources of law at all levels, the law and the legal systems. In turn, the comparative law method, which involves comparing legal phenomena having similar properties, allowed us to identify common and different aspects that reveal the nature of our legal obligations within different national legal orders (based on a comparison of legal regulations of some foreign states, including Ukraine).

### REVIEW AND DISCUSSION

Obligation to comply with regulatory and medical requirements for human organs and tissues transplantation. We

consider this responsibility to be one of the most important and fundamental, as it emphasizes the complexity of the transplant process, as well as the need to take into account legal requirements and medical indications for its proper implementation.

According to the Convention on Human Rights and Biomedicine, removal of organs or tissues from a living donor for transplantation is possible only for the recipient treatment, as well as in the absence of the required organ or tissue of the deceased and other (alternative) treatment [2]. In turn, based on the Additional Protocol regulations of the Convention on Human Rights and Biomedicine on human organs and tissues transplantation, as well as the content of other international instruments, it is possible to identify the following requirements without which transplantation is impossible, namely:

1) removal of organs and tissues from a living donor is allowed only for the recipient therapeutic purposes, provided that the deceased does not have the required organ or tissue, as well as if there is no alternative method of treatment [3]; such a procedure can be used only after a careful assessment of the feasibility and effectiveness of other therapies [4];

2) transplantation intervention is possible only if professional duties are performed and professional standards are observed [3]; removal of organs and tissues should be carried out in appropriate places, in particular, in public or private medical institutions that are provided with the necessary personnel and equipment [5]; the doctor performing the transplant must have special medical knowledge and techniques through special training, education and practice [4]; relevant professionals should take all reasonable steps to minimize the health risks of transplant participants.

3) removal of organs and tissues is possible only in the absence of a serious risk to the life and health of the donor [3]; in case that such a risk still exists, removal may be carried out only when it is justified by the donor's motivation, family ties to the recipient and medical indications; at the same time, the state is allowed to prohibit such seizures [5];

4) the donor is provided with information about the purposes, nature, consequences and risks of organs and tissues removal, as well as his rights and guarantees provided by law;

5) for the organs and tissues removal from a deceased person it is necessary, first of all, to certify his death, as well as to obtain consent due to the prescribed by law [3]; organs and tissues removal from a deceased person is not allowed if there were obvious or previous objections, including taking into account the religious or philosophical beliefs of such person [5].

With regard to the death certificate of the deceased, whose organs and tissues will be removed for transplantation to the recipient, the Declaration of the World Medical Assembly on human organ transplantation requires the statement of two or more independent doctors (each of them) who do not participate in the transplantation procedure. At the same time, physicians should be guided by the scientific methods and criteria known at the time, as

well as ethical requirements and professional standards [4]. According to the WHO Guidelines for Transplantation of Human Cells, Tissues and Organs, such rules, as well as the fact that doctors establishing the death of a person, should not be physicians of potential organs and tissues recipients, are aimed at preventing conflicts of interest between health professionals [6].

The above requirements that must be met during transplantation can be also found in national legislation. Thus, the Federal Law of Germany «On Donation, Collection and Transplantation of Organs and Tissues» establishes the following conditions under which it is possible to take organs and tissues from a living donor for transplantation to another person: first, the donor has reached adulthood and has legal capacity; secondly, the transplantation, according to the doctor, is able to support the recipient and cure him of a serious illness, prevent exasperations or alleviate symptoms; thirdly, the intervention must be performed by a physician [7].

Under Argentine federal law on transplantation, it can only be performed by a doctor or a team of doctors who are registered and authorized by the judicial authorities. For such doctors, their accreditation, training and experience in this field are examined. Organs and tissues removal from a living donor is possible only if he is 18 years old, and if the recipient is his blood relative or was adopted to the 4th generation, or a wife (husband), or a person who, without being a wife (husband), is in relationship with the donor for at least 3 years on an ongoing basis. In the case of underage donors, they may donate their organs and tissues with the prior consent of their legal representative and are recipients relatives. A doctor's opinion on such a possibility is also required for a transplant [8].

Therefore, the Tajikistan Republic legislation of presupposes the following: first, the transplant can be performed only for the recipient's health reasons and in case of the alternative treatment method absence, that is comparable in degree of effectiveness; secondly, the donor voluntarily and consciously agreed to donate organs and tissues; thirdly, the donor is warned about possible complications for his health after his organs and tissues removal; fourth, the donor has undergone a full medical examination and there is the medical council conclusion on the possibility of organs and tissues removal; fifth, the donor is warned about the consequences of his disagreement during the final period of organs and tissues preparation for transplantation. In the case of a living donor, the transplant must be genetically related to the recipient, except in the case of a bone marrow transplant [9].

As for Ukrainian legislation, transplantation is possible only if the necessary medical indications are provided, as well as the voluntary consent of an informed person with legal capacity is given: at the same time, medical evidences are established by the doctors council of that health care institution where the patient is being treated or being in dispensary. Withdrawal of anatomical materials from the donor is carried out only with the appropriate conclusion of the medical council, provided after a complete medical

examination of the donor, and if the damage to his health is less than the danger to the recipient life [10].

### OBLIGATION TO OBTAIN THE DONOR'S CONSENT FOR ORGANS AND TISSUES TRANSPLANTATION

To a greater extent, we will pay attention to the cases of obtaining consent for a posthumous transplant. Foreign practice in this regard has developed two main models (approaches) to the formation of the preconditions for its implementation:

1) «presumption of consent» (opt-out) (objection model) – according to which the removal and further organs and tissues use of the deceased is carried out provided that he has not objected to it during his life, or if such objections are not expressed by his relatives or legal representatives; this model is provided by the laws of Belarus, Israel, Spain, Austria, Great Britain and others;

2) «presumption of dissent» (opt-in) (informed consent model) – according to which the removal and further organs and tissues use of the deceased is carried out provided that he clearly expressed his informed consent to such actions after death, or if members of his family agree; thus, the lack of the donor or his relatives consent means the refusal of the transplant; this model is used, in particular, in the United States, Denmark, Ukraine, Portugal, Australia, Canada and other countries [11].

Under the opt-out model, states apply either «soft» or «hard» law. In the case of «soft» one – family members of the deceased may refuse to transplant his anatomical materials. In case of hard – organ transplantation is allowed for everyone who has not given up on it for life [12].

At the same time, the approaches we have given concerning giving consent are quite debatable. On the one hand, the presumption of consent approach can be justified by the fact that it helps to improve the coverage of needs for donor organs and tissues among the population of a country. On the other hand, let us agree with M. Laszewska-Helrigel that such a commitment cannot be justified by the public interest. The obligation of the state to protect the lives of recipients cannot be used as an excuse. The opt-in model better meets the needs of society. It does not impose any additional obligations on citizens. Moreover, the researcher adds, the experience of countries around the world does not prove a significant increase in the number of donors on the opt-out model. Other methods can be implied for this [13].

It should be added that for several decades, informed consent to medical intervention has been considered an international standard, enshrined in the Convention on Human Rights and Biomedicine, the European Charter of Patients «Rights, the World Medical Assembly's Declaration on Patients» Rights and a number of other international instruments. Yes, Art. 5 of the Convention on Human Rights and Biomedicine regulates the legality of any medical intervention only after voluntary and informed consent. The relevant consent may be revoked at any time by the person. Giving consent is preceded by the person

receiving information about the purpose, nature, risks and consequences of the intervention. However, the Convention prohibits the organ or tissue removal from a person who is unable to consent. In this case, as an exception, prescribed by law, a regenerative tissue can be removed from such a person, if: first, the recipient of the donor is a brother or sister; second, there is no compatible donor who is able to give consent; third, transplantation aims to save the patient's life; fourth, there are no objections from a potential donor [2].

Therefore, the issue of consent (disagreement) for the transplantation of anatomical materials is stipulated in the national legislation on transplantation. After all, this is a key prerequisite for «starting» the process.

Swiss federal transplant law requires a lifelong donor to transplant after his or her death. If there is no such consent or disagreement, the medical institution must first ask the immediate relatives of the deceased whether they were aware of their consent for life. If such information is not known, the transplant may be performed with the consent of the deceased donor's close relatives. If there are no such relatives or they cannot be contacted, the transplant cannot be performed. Provided that the deceased left the decision to transplant his organs and tissues to a trustee, it is his will that must be accepted by the medical institution, and it has priority over the decision of close relatives [14].

Under German federal transplant law, a person has the right to consent to a transplant of his or her organs and tissues, to refuse to do so, and to transfer the right to make a decision in this regard to a trustee. Such consent may include the specification about certain organs and tissues. At the same time, consent to transplantation can be given to people who turned 16, and refusal – to those who turned 14 [7]. Interestingly, a person who turned 16 must indicate in his medical policy his readiness to become organs and tissues donor after death. Upon agreement, the potential donor receives a special certificate, which he undertakes to carry. If such a certificate is found in the documents of the deceased, it is possible to take organs and tissues without asking relatives [15]. At the same time, consent for organs and tissues transplant from a deceased donor may be given by his close relatives if they have had personal contact with the deceased during the last two years before death. This information is obtained by a doctor. Close relatives must still adhere to the deceased's will regarding his or her intended intention to become an organ and tissue donor. The doctor is obliged to inform the close relatives about this. In the event of a dispute between close relatives over a donation decision, they may be given a reasonable period of time to reconcile their positions. If they have not agreed on one decision, the differences can be considered by the court [16].

According to the law on transplantation in Belarus, a person who does not want to become a donor of his organs and tissues after death submits an application to the state health care organization. In the case of underage people, such a statement is submitted by their legal representatives. If the person is not able to make an informed decision due

to health reasons, the statement of disagreement is submitted to the other spouse or close relative (parents, adoptive parents, children, siblings, grandparents, grandchildren). Moreover, public health organizations have the right to dispose deceased organs without his will or without his close relatives or legal representatives decision, if they have not shown in the manner, prescribed by law, their negative attitude to organ and tissue transplantation. Statements of refusal to be a donor are entered in a special Unified Register [17]. At the same time, before the organs and tissues collection from the donor, the employees of the state health care organization should check the information whether the authorized persons did not receive a statement of disagreement to participate in the transplant before death and whether they came from another spouse, close relatives or legal representatives of the statement of disagreement with organs and tissues donation of the deceased, addressed to the state health care organization or the State Committee of Forensic Science, after the death of the donor [18].

South African health law provides for the right of a person over the age of 16 to donate his or her organ or tissue in a will or in a document signed by him or her and at least two witnesses, or in an oral statement in the presence of at least two witnesses. Such a will or document should specify the institution or person of the recipient, as well as which organ or tissue can be used after death. Provided that no specific gifted person is identified, the donation will be considered invalid [19].

Ukrainian legislation establishes the possibility of seizing anatomical materials from an adult individual only in the presence of his voluntary and conscious consent to donate. Such consent shall be given in a written form. It should be noted that consent is given after the doctor has provided objective and accessible information to the potential donor about the possibility of complications for his health, as well as about his rights as a donor. With regard to posthumous donation, a note on the consent or disagreement of a person may, if he wishes, be included in the passport of a citizen of Ukraine and (or) a driver's license. An adult has the right to appoint an authorized representative, who after his death will agree to the removal of anatomical materials from his body. Such a representative must also give his or her voluntary consent to such authorization. If during his lifetime the person did not consent or disagree with the posthumous donation, did not appoint an authorized representative, consent to remove from his body anatomical materials for transplantation after determining his condition as irreversible, death is requested by the transplant coordinator from the other spouse or close relatives of the deceased. In the absence of the latter, consent to the seizure is requested from the person who undertook to bury the deceased [10].

#### OBLIGATION TO PERFORM ORGAN OR TISSUE TRANSPLANTATION ON A NON-COMMERCIAL BASIS

Adherence to the principle of de-commercialization in the process of transplantation is of paramount importance, es-

pecially in view of a number of international organizations that regularly record and publish reports and other news of human rights violations whose anatomical material has been the subject of commercial agreements. One of the means of counteracting such illegal actions should be the proper consolidation at the international and domestic levels of the obligation to perform transplantation on a non-commercial basis, ie without the purpose of obtaining financial or other benefits.

Thus, the Convention on Human Rights and Biomedicine clearly sets out the rule prohibiting financial gain from the human body or its parts (Article 21) [2]. The Additional Protocol to this Convention supplements this prohibition with possible exceptions. The point is that various payments are allowed that do not represent a financial benefit, in particular: compensation for loss of earnings and other costs of a living donor incurred through participation in the transplant procedure; compensation in case of unforeseen damage due to removal of organs and tissues from a living donor; payments for legitimate medical or related technical services provided in connection with transplantation [3].

Thus, today the problem of trade in human organs and tissues for transplantation is one of the leading and is the subject of attention and solution of the World Medical Assembly. In particular, in one of its resolutions WHA63.22, the international organization recommended that the following: to promote the system of altruistic donation of human organs and tissues and raise public awareness in this regard; to encourage health professionals to report on the practice of receiving financial benefits from transplantation; to ensure transparent and fair distribution of organs and tissues, as well as free access to transplantation; to promote the application of international best practices in transplantation to ensure the safety and effectiveness of donation; to conduct international cooperation in the collection of data on transplantation practice, etc [20].

The Istanbul Declaration on Transplant Tourism and Organ Trade is also dedicated to this issue. The primary purpose of transplantation should be to provide medical care to ensure the health of both the donor and the recipient, while financial gain or other material factors should not influence the decision to perform the procedure. In general, transplant tourism is the movement of organs, donors, recipients or transplant professionals across jurisdictional boundaries for the purpose of transplantation. It should be distinguished from medical tourism, which implies the importance of ensuring the interests and well-being of both the living donor and the recipient. While the medical «resource» used by transplant tourism is the exploited living donor [21].

Organ trafficking and transplant tourism, according to the Istanbul Declaration, must be banned because they do not respect the principles of justice, equality and respect for human dignity. The prohibition of such forms of activity should include, in particular: all forms of advertising, all forms of mediation, purchase and sale of organs, transplant tourism. It should also provide for penalties for such activities [22].

The WHO Guidelines for the Transplantation of Human Cells, Tissues and Organs (Principles 5, 7, 8) contain requirements for the non-financial benefit of transplantation. Particular attention should be paid to principle № 8, according to which all medical institutions and specialists should be prohibited from receiving any payment in excess of the reasonable amount of remuneration for services for transplantation and supply of human organs and tissues. To obtain this, health authorities should control the amount of fees for these services to prevent situations where such fees are a veiled form of organs and tissues remuneration. In addition, all institutions and individuals involved in the transplant process should be accountable for all payments associated with the provision of such services [6].

In addition, some researchers rightly emphasize the need to adopt at the UN level a single mandatory convention act that would prohibit commercial relations in the field of transplantation, as well as streamline the transplantation procedure [23].

For now, let's turn to the analysis of the relevant legal provisions of foreign countries, which establish the principle of de-commercialization in the implementation of transplantation. Thus, the Indian Law on Human Organ Transplantation of 1994 prohibits the human organs removal for commercial purposes; contains norms aimed at preventing the realization of such a goal; regulates the issue of brain death, after which it is possible to remove organs and tissues; establishes liability for violation of its requirements [24]. Article 143 of the Health Code of the Republic of Tajikistan [9] prohibits the human organs and tissues sale. Article 17 of the Federal Law of Germany on Transplantation explicitly prohibits trade in organs or tissues intended for therapeutic treatment. It is possible to obtain a reasonable reward for the measures necessary for the purpose of therapeutic treatment, in particular, for the removal, preservation, further processing, protection against infections, storage and transportation of organs or tissues [7]. By enshrining the obligation to de-commercialize transplantation, Swiss law allows for a symbolic gesture of gratitude that is not seen as a financial benefit or advantage [14].

Polish transplantation legislation stipulates that no payment, other material or personal benefits may be claimed or accepted for organs or tissues taken from a donor. Reimbursement of expenses incurred in connection with the transplant procedure is not a fee and does not constitute property or personal gain. In addition, the list of costs to be reimbursed and the procedure for such reimbursement are clearly defined. Article 20 of the Law of Ukraine «On the Application of Transplantation of Human Anatomical Materials» prohibits the conclusion or offer of contracts involving the purchase and sale of human anatomical materials. Advertising of human anatomical materials, except for social ones, aimed at promoting transplantation is also prohibited [25].

## CONCLUSIONS

Thus, we have identified and researched the following legal obligations in the light human organs and tissues transplantation: compliance with regulatory and medi-

cal requirements for organs and tissues transplantation; obtaining the donor's consent for organs and tissues transplantation; organ or tissue transplantation on a non-commercial basis.

1. Analyzed regulatory and medical requirements, indicate the complexity of the transplant process, as well as the need for strict compliance with established regulations and rules. The legislator (at the international and national levels), setting mandatory requirements for transplantation, must first and foremost be guided by the principles of expediency and justification of their implementation in order to balance the rights of donors and recipients, maximize preservation and improve their quality of life.
2. For the whole complex transplant procedure, one of the key points is the donor's consent (disagreement) to remove anatomical materials from him. Each state chooses its own method (opt-in or opt-out model) and mechanisms for obtaining the necessary will of the person – the predominant is either individual or public interest.
3. The obligation to perform organ or tissue transplantation on a non-commercial basis has a dual purpose: first, to prevent offenses and legal violations in this area, as anatomical materials cannot be traded or enriched; secondly, to determine as transparently and clearly as possible the list of costs incurred by the donor in connection with the organs and tissues removal and subject to reimbursement, the procedure for such reimbursement and its reasonable, acceptable and sufficient amount. In the sense of the second mentioned goals, of course, it is also a necessary practice on the part of states to promote the development of human organs and tissues altruistic donation system and to raise public awareness in this regard.

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#### Conflict of interest:

The Authors declare no conflict of interest.

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